REDICA Systems

Redica Systems 510(k) Sample

REPORT

IN THIS SAMPLE 510(K) SUBMISSION:

- See how a 510(k) submission is structured
- Find out what information to include
- Review correspondence between sponsor and FDA

PUBLISHED BY

REDICA SYSTEMS
6800 KOLL CENTER PARKWAY
SUITE 120
PLEASANTON, CA 94566

SALES@REDICA.COM
844-332-3320

Table of Contents

510K SUMMARY - 5 pages	1
AMENDMENT - 181 pages	6
CORRESPONDENCE - 7 pages	187
ORIGINAL - 33 pages	194
REVIEWER INFORMATION - 11 pages	227

K061088

510(k) Summary

Honeywell HomMed Sentry OTC Monitor

Date: April 11, 2006

JUN - 9 2006

Consultant Contact: Tommie J. Morgan, Ph.D., President
Morgan Consultants Inc.
2018 North Durham Drive
Houston, TX 77008
713.880.5111 Voice or 713.880.3494 Fax

Company: Michael Leigh, Director Regulatory/Quality
Honeywell HomMed, LLC
3400 Intertech Drive, Suite 200
Brookfield, WI 53045
262.252.5794 Voice or 262.252.6119 Fax

Trade Name: Honeywell HomMed Sentry OTC Monitor

Common Name: Vital Signs Monitor

Classification Name: Cardiovascular and Respiratory Devices, Class II

Product Code: NIBP Measurement System, DXN

Predicate Device: HomMed Sentry IIIB Patient Monitor System K040651

Device Description: The Honeywell HomMed Sentry OTC Monitor is a vital signs monitoring system. The system measures noninvasive blood pressure, pulse rate, oral temperature and weight. The Sentry OTC Monitor has six serial ports available for external options. The Sentry OTC Monitor acquires the vital signs data and displays it. The data can be transmitted via the communication module to a central viewing station.

Indications for Use: *The Honeywell HomMed Sentry OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Sentry OTC Monitor's measurement capabilities. Data from the Sentry OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Sentry OTC Monitor is not intended for emergency use or real-time monitoring.*

Intended Use: The Honeywell HomMed Sentry OTC is the remarketing of a previously approved product for OTC use. It is intended for personal use and use of the system allows retrospective review of certain physiological functions. The Sentry OTC collects vital signs data (including noninvasive blood pressure, pulse rate, oral temperature, and weight) then can transmit the data to a central review station via a communication network. The Sentry OTC is intended for use with adult and pediatric patients over twelve years of age.

Technology: The Honeywell HomMed Sentry OTC Monitor employs the same technologies of the predicate device, HomMed Sentry IIIB Patient Monitor System, K040651.

The Honeywell HomMed Sentry Monitor(s) complies with the following voluntary standards:

- EN 60601-1 Medical Electrical Safety
- IEC 601-1-2 EMC Compliance
- ISO 10993-5,10-11 Biocompatibility

Test Summary: The Honeywell HomMed Sentry System (Sentry OTC and its predicate Sentry IIIB) utilized within the environments for which it is marketed performs consistent with guidelines and standards found in the FDA reviewer's guides for respiratory devices and electronic thermometers. Completed EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing demonstrate compliance with applicable standards. The test results demonstrated that the Sentry is in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements.

Conclusion: It is the Honeywell HomMed position that the results of these evaluations demonstrate the Sentry OTC Monitor is as safe, as effective and performs as well as the legally marketed predicate device, HomMed Sentry IIIB Patient Monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2006

Honeywell HomMed, LLC
c/o Tommie J. Morgan, Ph.D.
President
Morgan Consultants Inc.
2018 North Durham Drive
Houston, TX 77008

Re: K061088
Trade Name: Honeywell HomMed Sentry OTC Monitor
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: II (two)
Product Code: DRG
Dated: April 12, 2006
Received: April 18, 2006

Dear Dr. Morgan:

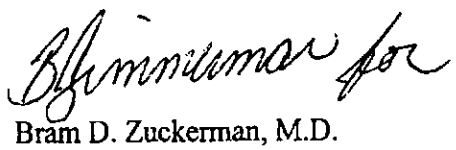
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061088

Device Name: Honeywell HomMed Sentry OTC Monitor

Indications For Use:

The Honeywell HomMed Sentry OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Sentry OTC Monitor's measurement capabilities. Data from the Sentry OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Sentry OTC Monitor is not intended for emergency use or real-time monitoring.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061088

K061088/A1

Morgan Consultants, Inc.

2018 North Durham Houston, TX 77008
Ph: 713/880-5111 FAX: 713/880-3494
email: MCI2000@swbell.net

May 22, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) Application for Honeywell HomMed Sentry OTC Monitor, K061088

Dear Sir or Madam:

Morgan Consultants Inc. hereby submits additional information for Honeywell HomMed, LLC submission of Sentry OTC Monitor, 510(k) Application K061088 for your review.

This request represents a supplement to the information already submitted in April 2006 regarding the Sentry OTC Monitor.

Attached is an original and copy of the Honeywell HomMed Genesis OTC Monitor manual(s) referenced in the 510(K) submission, *Section III: Proposed Labeling.* This addendum replaces *Section III: Proposed Labeling,* pages 0007 to 0008 with replacement pages in the addendum at the end of the submission titled ***Addendum: Draft Labeling***. The Addendum includes the replacement pages and four (4) manuals instead of the five (5) listed in the original *Section III* of the submission.

Your consideration of this Honeywell HomMed addendum to the 510(k) application is appreciated. If there are any questions please contact my office.

Sincerely,

Tommie J. Morgan, Ph.D.
President

TJM/mm
Attachment

Cc: Michael Leigh, Director of Regulatory/QA, Honeywell HomMed LLC

1 of 29

Honeywell HomMed
Sentry OTC Monitor, K061088

Addendum: Draft Labeling

ORIGINAL

16

ADDENDUM: DRAFT LABELING

There follows a list of documents for the Honeywell HomMed Sentry OTC Monitor:

- Sentry Monitor Operator's Guide
- Sentry Monitor Quick Reference Guide
- Sentry Monitor Support Guide
- Sentry Monitor Getting Started – Setup Instruction Sheet

Sentry Monitor Operator's Guide

The Operator's Guide includes: safety, programming, health monitoring sessions, taking vital signs with the Honeywell HomMed Sentry Monitor; and troubleshooting information

General Information:	This section contains the indications of use, special conventions, additional references and additional information.
Safety Information:	This section contains the pertinent safety information, safety conventions and safety notes.
Programming Your Monitor	This section contains an explanation of the function keys, set-up mode, scheduling options, and a programming menu list.
Monitoring Sessions:	This section contains: an explanation of monitoring sessions, monitor prompts, a menu data list, text displays, and prompts for accessory devices (compatible peripheral devices).
Taking Your Vitals:	This section contains the information how to take their vital signs: blood pressure, weight, temperature, and blood-oxygen levels. It also contains information on collecting data from accessory devices.
Programming for Transmission:	This section contains information on transmission requirements: password, PIN information, transmit menu, transmit protocols, ISP settings, options menu (including options for accessory devices), and information on how to send a test message.
Troubleshooting:	This section provides summary of the most commonly encountered problems/situations, probable causes, and resolutions. Included are a list of error codes, their meanings, and a list of additional references.
Appendices:	This section provides additional relevant information: text list of programmable subjective questions; text list of sleep apnea questions; the Honeywell HomMed warranty information; list of compatible peripheral and accessory devices
Glossary and Index:	*Glossary:* List of definitions for the most commonly used terms, expressions, and devices used in this document. *Index:* List of sections, chapters, subjects, and specific items mentioned in this document.

17

Sentry Monitor Quick Reference Guide

This Quick Reference Guide is intended as a daily use reference document for the customer with their Honeywell HomMed Sentry Monitor.
This document includes: safety information; an overview of the Sentry Monitor, explanation of monitor keys, monitor prompts, a list of general prompts, and text displays. Included in this document is information on what to do if accidental spills occur, and how to take vital signs: blood pressure, scale, oximeter (optional prescription device), temperature. Further information is provided on collecting data from other accessory devices, customer service contact information, and safety information. A blank chart is provided in the back of the document for customers to record their vital signs.

This document is intended to assist customers in the proper setup and installation of the Honeywell HomMed Sentry Monitor. This document includes: customer service contact and safety information, an installation overview, and an itemized list of installation "do and don'ts." Specific installation information is provided for each component of the Honeywell HomMed Sentry Monitor. This includes: the HomMed and Fairbanks scales, blood pressure cuff, oximeter, and temperature probe. Other information included: connecting the pass-through phone and modem, powering up, and how to send a test message.

Sentry Monitor Support Guide

The Support Guide is intended to give customers information on the proper maintenance, cleaning and calibration of their Honeywell HomMed Sentry Monitor. This document includes: safety information and warnings, hazard conventions, CE Marking information, electromagnetic guideline information, product information, including specifications for monitor, pager, modem, and non-invasive blood pressure cuff, customer service contact information, repairing equipment, and how to ship the monitor/equipment to Honeywell HomMed are included in the Support Guide. Other sections cover the cleaning, inspection, and calibration of the monitor, NIBP cuff and other accessories. Appendices include a text list of prompts, and a supply list of available parts.

Sentry Monitor: Getting Started – Setup Instruction Sheet

The Setup Instruction Sheet is a visual aid intended to assist customers in the proper setup and installation of the Honeywell HomMed Sentry Monitor. As such, it is meant to be an adjunct to the Quick Reference Guide. Graphics and text are used to show the proper placement and port attachment for each component or accessory. Included is a packing list of items that come with the Sentry Monitor.

Honeywell
HomMed OTC Sentry Monitor

Operator's Guide

Honeywell
HomMed

P44XX.XX
May, 2006

19

Notices

Customer Service	*Honeywell HomMed®, LLC* 3400 Intertech Drive, Suite 200 Brookfield, Wisconsin 53045 *Toll-free:* (888) 353-5404 *Phone:* (262) 783-5840 *Fax:* (262) 252-5795 *Web:* http://www.hommed.com/
Copyright	
Trademarks	HomMed® is a registered trademark of Honeywell HomMed, LLC.
Intended Use	The Honeywell HomMed OTC Sentry Monitor designed to retrospectively measure vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Honeywell HomMed Sentry Monitors measurement capabilities. Data from the Sentry Monitor can be transmitted via a communication module to a central viewing station for display. The Honeywell HomMed OTC Sentry Monitor is not intended for emergency use or real-time monitoring. Healthcare professionals are responsible for the interpretation of all monitored data. Sentry Monitor is not intended for emergency use or real-time monitoring.
Device Information	Serial Number: _____
	Part Number :_____

Numbers Required For Transmission of Data Packets Only.

Pass Word	Pass Word: _____
Account Number	PIN Number: _____
Transmission Numbers	Transmit Phone Num.: _____
	ISP1 Phone Number: _____
	ISP2 Phone Number: _____
	ISP3 Phone Number: _____
	ISP4 Phone Number: _____
Modem Settings	Modem Number: _____

20

Table of Contents

Notices 2
Table of Contents 3
General Information 6
Content overview 6
Special conventions 7
Safety information 7
Hazard Conventions 7
Notes 13
Programming Your Sentry Monitor 14
PIN and phone numbers 14
Sentry menus 14
Setup mode 15
Function keys 15
Exiting menus and Setup Mode 16
Scheduling frequency options 16
Programming menu chart 17
Chart key 17
Menu Chart 18
Time Menu 19
Time 19
Date 19
Time Format 20
Date Format 20
Daylight Savings 21
Report Time (1 – 4) 21
Exit Time Menu 22
System Settings 23
Volume 23
Temperature Prompt 23
Temperature Time 24
Scale Prompt 25
Language 25
Units 26
Inflation Settings 26
Display Brightness 27

Exit System Settings 27
Questions Menu (1 – 10) 28
Questions 28
Question Time 29
Sleep Apnea mode 30
Exit Question Prompt 30
Monitoring Sessions **31**
What is a Monitoring Session? 31
Sentry monitor voice and text prompts 31
Prompt timing 31
General prompts and text displays 32
Taking Your Vitals Signs **34**
Before you take your vitals 34
Monitor keys 34
Taking Your Blood Pressure (NIBP) 35
Using the blood pressure (NIBP) cuff 36
Taking Your Temperature (Temperature Probe) 38
Using the temperature probe 38
Taking Your Weight (Honeywell HomMed Scale) 39
Using the scale 39
Taking Your Blood-Oxygen Saturation (SpO2) 40
Using the Oximeter Finger Sensor 40
Programming for Transmission **41**
Transmission Requirements 41
Password 41
Exit Password Menu 42
Transmit Menu 42
PIN Number (P) 42
Dial Type 43
Transmit Mode 43
Test Message 44
Send a Test Message 44
ISP1 Phone # (P) 45
ISP2 Phone # (P) 45
Transmit Phone # (P) 45
Serial Mode 46
Modem Settings (P) 46
ISP Settings Menu (P) (Internal Settings Menu) 46
Exit Transmit Menu 47
Option Menu 48
Prompts for accessory devices 48

Transmitting test results from accessory devices 49
Exit Options Menu 49
Service Menu 50
Service Call 50
Service Call Phone # (P) 50
Calibration Verify (P) 50
Report Menu (P) 50
Exit Service Menu 51
Troubleshooting 52
Monitor installation 52
Equipment Problems 53
Transmission 59
Additional References 66
Appendix A: Questions Text 67
Appendix B: Sleep Apnea Questions 69
Appendix C: Honeywell HomMed Warranty Information 70
Appendix D: Peripheral Devices 72
Glossary 73
Index 83

General Information

This booklet is an Operator's Guide and includes, the safety, programming and troubleshooting information for the Honeywell HomMed OTC Sentry Monitor model number **6010000A1.**

When you encounter a difficulty, please use this booklet first to answer your questions and resolve the issue.

If you have any difficulties that you cannot resolve, call Honeywell HomMed Customer Service at **1-888-353-5404**. Customer Service will make every attempt to resolve the issue over the phone; or if not, Honeywell HomMed may repair.

Content overview

The following chart provides a brief overview of the sections in the manual.

Section	Overview
General Information	Describes the pertinent safety conventions, information, safety notes, and customer support information
Programming Your Sentry Monitor	Provides an explanation of the function keys, set-up mode, scheduling options, a chart of Sentry programming menus explains programming concepts, and provides step-by-step programming instructions
Monitoring Sessions	Provides an explanation of monitoring sessions, monitor prompts, a menu data list, text displays, and prompts for peripheral devices.
Taking Your Vitals	Provides important information about how the monitor works; and explains how to take your vital signs, including: blood pressure, weight; temperature, and blood-oxygen levels. Also contains information on taking vitals from peripheral devices.
Programming For Transmission	Provides information on transmission requirements, Password, PIN information, Transmit menu, Transmit Protocols, ISP Settings, Options Menu (including options for accessory devices), and how to send a Test Message.
Troubleshooting	Provides a summary of the most commonly encountered problems/situations, their probable causes, and resolutions. Included are a list of error codes, their meanings, and a list of additional references.
Appendices	Provides additional reference information
Glossary	Provides a list of definitions of the commonly used words and terms, used in this manual.
Index	Allows you to locate information using key words

Special conventions

The following table lists the conventions used in this manual.

This Convention	Identifies
Function font	Keys that you press on the keypad
+ sign between key names	Keys that you press simultaneously **STOP BP + YES**
Courier font	Text that displays in the front panel display
Italics font	Menu names, publication titles, or references to sections of this binder
!	Critical information
	A note that provides an important piece of information
	A tip that help to ensure good results.

Safety information

To prevent injury to yourself or damage to any equipment, please read and observe all the safety information in this section **before** you install the Honeywell HomMed OTC Sentry Monitor.

Hazard Conventions

The following chart explains the hazard conventions used in this manual. Serious personal injury implies permanent impairment or any injury that requires medical or surgical intervention to preclude permanent impairment.

Term	Level of risk	Definition
 **WARNING**	Moderate	Could cause death or serious personal injury
 **CAUTION**	Moderate	May result in minor or moderate personal injury
CAUTION	Minor	May result in equipment damage
NOTE	None	Important information

WARNING

NOT AN EMERGENCY RESPONSE DEVICE

The monitor is **NOT** an emergency device.

If you have a medical emergency, call your local Emergency Medical Service and your health care provider.

WARNING

ELECTRIC SHOCK

Some of the parts inside the monitor could shock you. The shock could be severe enough to cause death or serious injury.

DO NOT take the monitor apart.
DO NOT put the monitor in water or any other liquid.
ALWAYS UNPLUG the monitor before you clean it.
DO NOT try to fix the monitor.

If you have a problem with your monitor, call Honeywell HomMed Customer Service

WARNING

NOT TO BE USED ON INFANTS

The monitoring equipment could cause serious injury if used on infants or small children.

DO NOT use any equipment on infants or small children.

WARNING

EXPLOSION HAZARD

This unit is powered with electricity and could ignite highly flammable gases (for example: Anesthetic, fuels etc.).

DO NOT use this device in the presence of explosive or flammable agents.

CAUTION

THE TEMPERATURE PROBE IS FOR ADULT, ORAL USE ONLY

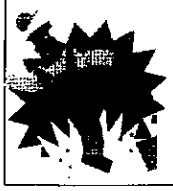
Only adults (age 12 years and older) should use the temperature probe. Use the temperature probe only in your mouth.

DO NOT use the temperature probe on children.

DO NOT use the temperature probe to take rectal or axillary temperatures.

CAUTION

PERSONAL INJURY HAZARD: SCALE TIPS



Weight placed on the edge of the scale will cause the scale to tip and can cause you to fall.

DO NOT step onto the edge of the scale.

DO NOT stand on the edge of the scale.

CAUTION

PERSONAL INJURY HAZARD: NIBP Cuff

Verifying the calibration while the cuff is attached to you, (while wearing the cuff) could cause bruising or other injury.

DO NOT verify NIBP calibration while the cuff is attached to you.

CAUTION

NON-RECHARGABLE BATTERIES

Attempting to recharge the batteries could cause batteries to leak battery acid or over heat resulting in potential hazard to the user. It could also cause permanent damage to the unit.

DO NOT charge the batteries.

CAUTION

ELECTRICAL SHOCK

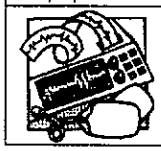
Using a spirometer while attached to the Sentry Monitor could possibly result in receiving an electrical shock.

- **DO NOT attempt to take readings with a spirometer when it is connected to the Sentry Monitor.**
- **Disconnect the spirometer before use.**
- **Always follow the manufacturer's instructions for proper use.**

CAUTION

NOT EXTERNAL DEFIBRILLATOR PROOF

Using the Sentry monitoring system while undergoing **external defibrillation** may damage the monitor or peripheral equipment.

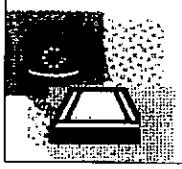


DO NOT use the monitor if undergoing defibrillation with an external defibrillator.

CAUTION

REQUIRES ANALOG PHONE LINE

The modem requires an analog phone line. A digital phone line will destroy the modem.

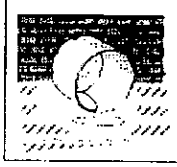


DO NOT connect the monitor to a digital phone line. If you want to move your monitor after setup, contact your health care provider.

CAUTION

SPILLAGE

Liquid spilled onto the monitor may cause damage to the monitor and may present a safety hazard to the user.



Should this monitor become wet, wipe off all moisture and allow sufficient time for drying before operating.

CAUTION

BLOOD PRESSURE HOSE DAMAGE

Bending, kinking, or otherwise restricting the blood pressure hose can damage the hose or interfere with readings.

DO NOT bend or crimp the blood pressure hose. Keep the hose free from furniture or other objects that could bend or crush it.

CAUTION

SENSITIVE EQUIPMENT

Your monitor and the accessories that come with it are sensitive equipment.

DO NOT put the scale, temperature probe, blood pressure cuff, or any other accessory in water or other liquid.

DO NOT drop the monitor.

Call your Honeywell HomMed Customer Service if. . .

- Any liquid is spilled onto the monitor
- The monitor is dropped or damaged

CAUTION

SENSITIVE KEYPAD

Sharp or pointed objects may permanently damage the keypad.

DO NOT press keys with any object.

Use your fingers to press the monitor keys.

CAUTION
EQUIPMENT DAMAGE Connecting the Honeywell HomMed scale to any device not mentioned in this manual could severely damage the scale or the connected equipment.  Connect your Honeywell HomMed scale **ONLY** to your Sentry 6-port monitor (6010000A1) **DO NOT** connect the Honeywell HomMed scale to a Sentry 4-port (5020000A1) or any other device other than the ones specified in this manual.

CAUTION
ELECTROMAGNETIC COMPATABILITY Electromagnetic compatibility of electrical equipment at very close distances to the Sentry has not been evaluated.  **DO NOT use the Sentry adjacent to or stacked with other equipment. If it is necessary to do so, observe the monitor and verify normal operation prior to use.**

CAUTION
INCORRECT AC POWER RATINGS CAN DAMAGE MONITOR Incorrect AC power ratings could damage the Sentry monitor.  **Ensure that the AC rating is correct for the AC voltage at your installation site before using the monitor. The AC rating is located on the AC power supply label. If the rating is not correct, do not use the monitor and Contact Honeywell HomMed Customer Service.**

CAUTION
USE ONLY HOMMED AUTHORIZED MEDICAL EQUIPMENT Attaching unauthorized equipment to the Honeywell HomMed Sentry monitor may cause damage or equipment failure, including increased emissions or decreased immunity of the Sentry monitor. Vital sign measurements may be inaccurate if unauthorized equipment is used with the Sentry monitor. **DO NOT attach unauthorized medical equipment to the Sentry monitor. When connecting this device to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions.** Any peripheral devices connected to the data interface must be certified according to the respective IEC standards. All combinations of equipment must comply with IEC 601-1-1 systems requirements. For a list of Honeywell HomMed equipment and compatible peripheral devices, see the Honeywell HomMed OTC Sentry Monitor Service and Support Guide.

Notes

- Blood pressure measurements may not be accurate for those people experiencing moderate to severe **arrhythmias**, or who suffer from with **tremors**.
- Any condition that restricts blood flow, such as use of a blood pressure cuff, extremes in systemic vascular resistance (blood flow), or low perfusion (blood saturation) may cause difficulties in obtaining an accurate pulse reading.
- Dashes displayed in any parameter indicate the measurement is invalid or unavailable.
- The Oximeter (SpO2 sensor) is a **prescription only device**. You may use only the Oximeter as part of Physician prescribed care plan.
- The Honeywell HomMed scale is not a stand-alone device. The scale must be connected to a Sentry monitor (6010000A1) for proper operation.

Programming Your Sentry Monitor

This section provides programming concepts and instructions that will enable you to correctly program your Sentry Monitor.

PIN and phone numbers

The following on PIN and Phone numbers **only applies if you will be transmitting** the data collected by your Sentry monitor.

If you are under a Physician's Plan-of-Care, the Clinical Consultant will explain the best transmit mode for your area and give you the required PIN and phone numbers for primary and secondary ISP accounts. When you program a monitor you should go through each menu to verify that the entered numbers match the numbers given to you by the person to whom you will be transmitting or Plan-of-Care provider.

Sentry menus

The Sentry monitor displays menu names and options in the display face. Because of the limited space, you can only see one menu or menu option at a time as you scroll through available choices. Entering Setup Mode opens the Main menu which offers seven menu options:

- Time Menu
- System Settings
- Questions Menu
- Password Menu
- Transmit Menu
- Option Menu
- Service Menu, and the
- Exit Setup Menu

Each menu, with the exceptions of *Exit* and *Password*, has **sub-menus** with additional options. Each menu has a **default setting**. However, default settings may have been changed if your monitor was recently repaired or serviced, verify the settings after service.

Some menu options are password protected. **If you do not enter your password, you will not see password-protected sub-menus.** The *Programming Menu Chart* on page 17 shows the menu and sub-menu layout for your Sentry Monitor. Password-protected options are noted with (P).

Setup mode

You can enter Setup Mode anytime the Sentry Monitor is idle. However, if you are in Setup Mode during a scheduled report time, the monitor will skip the monitoring session and will not transmit any information. Your Central Station will post a **No Data Received** (NDR; orange alert) for the missed reading.

To enter Setup Mode, quickly press and release the **STOP BP** and **YES** keys simultaneously. **Do not hold the keys.** Setup Mode normally opens to the *Time Menu*. However, if you press and hold instead of press and release, you may scroll to a different menu.

To press keys correctly, press them firmly in the middle. When you press keys correctly, you will hear a beep.

Function keys

Once in Setup Mode, you can use the keys on the front panel to enter or exit menus, scroll up or down, and select menu options. The following table summarizes the functions for each key or key combination.

Key(s)	Action	Use to...
STOP BP + YES =		Enter/exit Setup Mode
RETEST =	← Back	Exit current menu or menu option
YES =	↑	Scroll forward/up through numbers, menu options, or menus
NO =	↓	Scroll backward/down through numbers, menu options, or menus
MANUAL =	**Enter**	Enter a menu: Accept a displayed value

Retest button

The Retest allows you to **back out one level** from your current location. It is handy when you want to quickly back out of a menu without scrolling to an exit option.

For example, if you enter a menu option and then realize that you are in the wrong menu, you can press **RETEST** to back out. Keep in mind however, that pressing **RETEST** just backs up one level. So if you are in Report Time #1 setting a value (a value is blinking) and press **RETEST**, the displayed values are accepted and you back up or return to Report Time #1. If you press **RETEST** a second time, and you return to the Main menu.

Exiting menus and Setup Mode

If you look at the *Programming Menu Chart* layout on page 17, you can see that the *Main* menu as well as every sub-menu has an *Exit* option. The *Exit* option takes you out of the current menu and returns you to the Main menu. The *Exit Setup Menu* in the *Main* menu takes you out of Setup Mode and returns the monitor to idle mode.

To immediately exit Setup Mode at any time, press **STOP BP + YES**.

Scheduling frequency options

You may schedule how often Sentry collects temperature, weight, questions, and optional device data. Scheduling options include **every time**, **one time per day**, or **not at all** (off).

- OFF
- Every day (Su Mo Tu We Th Fr Sa)
- Any combination of days (_ _ Mo _ _ We _ _ Fr _ _)
- Every time (Su)
- Only once per day (S*) (example: **M*** for Monday)

Once-a-day collection

If you choose one time per day (a day marked with an asterisk, example: **M*** for Monday), the Sentry Monitor collects the scheduled data during the first monitoring session initiated by a scheduled Report Time or by pressing **RETEST**. Once the scheduled data is collected, the monitor will not collect it again until the next day. The Sentry Monitor resets to a new day at midnight.

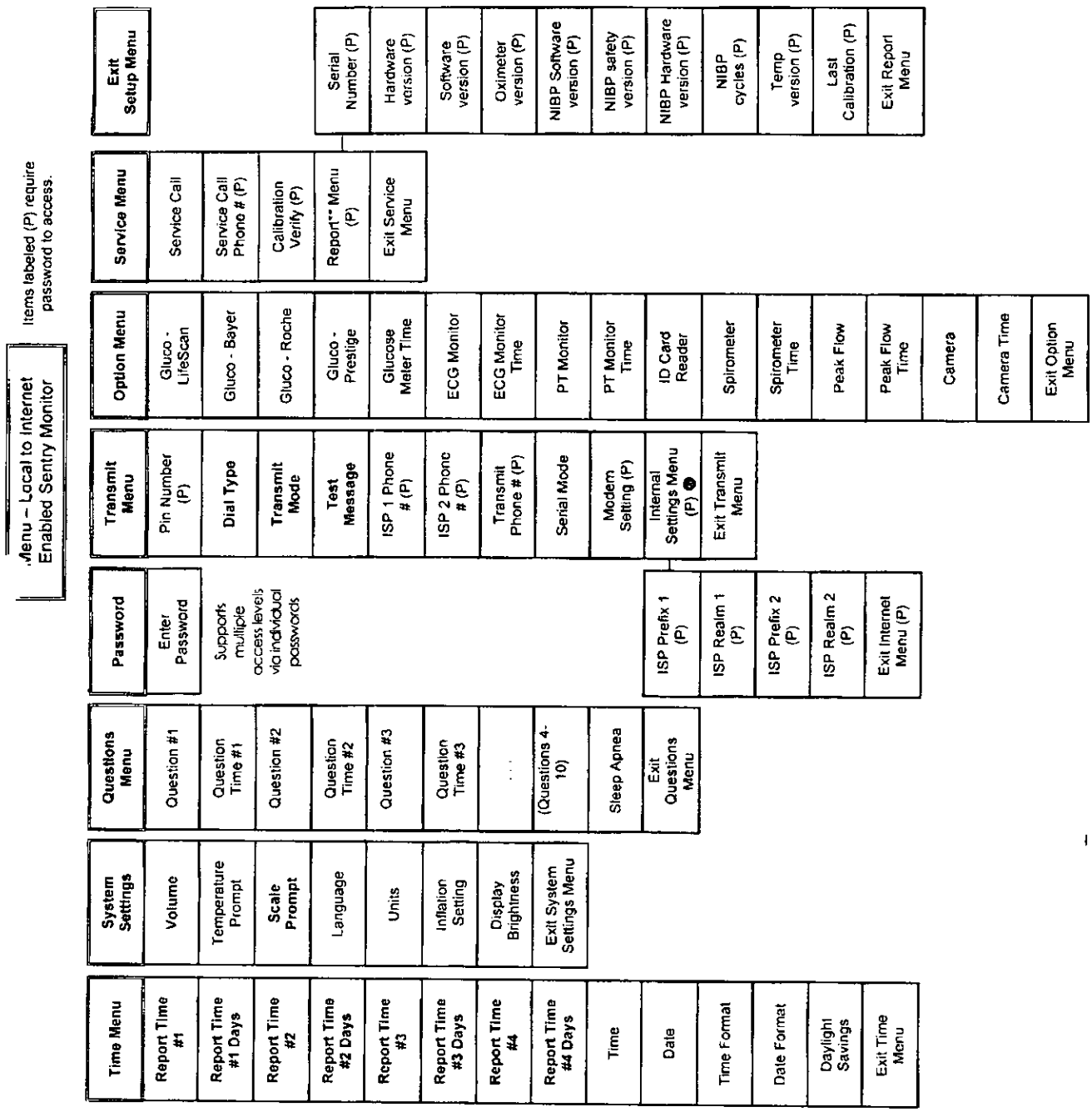
If the monitor times out without a response, (not taking a reading or pressing **NO**), it will attempt to collect the scheduled data the next monitoring session. Timing out, or powering down, **will not affect** the once-a-day schedule.

Programming menu chart

The programming menu chart on the following page shows you the location of each menu in the monitor.

Chart key

Symbol	Means
(P)	Password-protected menu You **must enter your password** in order to view this menu Your password is: _____
Bold text	Frequently used option


Menu – Local to Internet Enabled Sentry Monitor
Items labeled (P) require password to access.
Time Menu
Report Time #1
Report Time #1 Days
Report Time #2
Report Time #2 Days
Report Time #3
Report Time #3 Days
Report Time #4
Report Time #4 Days
Time
Date
Time Format
Date Format
Daylight Savings
Exit Time Menu
System Settings
Volume
Temperature Prompt
Scale Prompt
Language
Units
Inflation Setting
Display Brightness
Exit System Settings Menu
Questions Menu
Question #1
Question Time #1
Question #2
Question Time #2
Question #3
Question Time #3
(Questions 4-10)
Sleep Apnea
Exit Questions Menu
Password
Enter Password
Supports multiple access levels via individual passwords
Transmit Menu
Pin Number (P)
Dial Type
Transmit Mode
Test Message
ISP 1 Phone # (P)
ISP 2 Phone # (P)
Transmit Phone # (P)
Serial Mode
Modem Setting (P)
Internal Settings Menu (P)
Exit Transmit Menu
ISP Prefix 1 (P)
ISP Realm 1 (P)
ISP Prefix 2 (P)
ISP Realm 2 (P)
Exit Internet Menu (P)
Option Menu
Gluco - LifeScan
Gluco - Bayer
Gluco - Roche
Gluco - Prestige
Glucose Meter Time
ECG Monitor
ECG Monitor Time
PT Monitor
PT Monitor Time
ID Card Reader
Spirometer
Spirometer Time
Peak Flow
Peak Flow Time
Camera
Camera Time
Exit Option Menu
Service Menu
Service Call
Service Call Phone # (P)
Calibration Verify (P)
Report** Menu (P)
Exit Service Menu
Exit Setup Menu
Serial Number (P)
Hardware version (P)
Software version (P)
Oximeter version (P)
NIBP Software version (P)
NIBP safety version (P)
NIBP Hardware version (P)
NIBP cycles (P)
Temp version (P)
Last Calibration (P)
Exit Report Menu

Time Menu

Time Menu	System Settings	Questions Menu	Password	Transmit Menu	Option Menu	Service Menu

Enter setup mode and, if necessary, scroll until **Time Menu** displays on the monitor. Press **MANUAL** to enter the Time menu. Use **YES** or **NO** to scroll to the Time Menu option you wish to enter.

Time

Options: Time in the format set in *Time Format* menu
Default: Present time for your time zone
Access Level: General

The *Time* menu allows you to set the correct time. If you need to reset the time, follow the steps below.

1. In the *Time* menu, scroll to the *Time:* option and press **MANUAL**. The hour blinks.
2. Scroll to the correct hour. Press **MANUAL** to accept the hour setting and move to minutes.
3. Scroll to the correct minutes. Press **MANUAL** to accept the minute setting.

You can scroll to the next *Time Menu* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit Setup Mode.

Date

Options: Day of the week, month, day, and year (displays according to selected date format)
Default: Today's day and date
Access Level: General

The *Date* menu allows you to set the correct date. If you need to change the date, follow the steps below.

1. In the *Time* Menu, scroll to the *Date* option and press **MANUAL** to enter the menu. The day of the week blinks.
2. Scroll to the correct day of the week. Press **MANUAL** to accept the day. The numeric month blinks.
3. Scroll to the correct month. Press **MANUAL** to accept the setting and move to the numeric day.
4. Scroll to the correct day. Press **MANUAL** to accept the setting and move to the year.
5. Scroll to the correct year. Press **MANUAL** to accept the setting.

You can scroll to the next *Time Menu* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit Setup Mode.

Time Format

Options: A.M./P.M. or 24-hour format
Default: A.M./P.M.
Access Level: General

You can set the monitor to display either 24-hour or A.M./P.M. time. To change the format, follow the steps below.

1. In the *Time Menu*, scroll to *Time Format*, and press **MANUAL** to enter. The currently programmed format blinks.
2. Press either **YES** or **NO** to change the format, and press **MANUAL** to accept the setting.

You can scroll to the next *Time Menu* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** until you exit Setup Mode.

Date Format

Options: MMDDYY or DDMMYY
Default: MMDDYY
Access Level: General

The *Date Format* allows you to set the Sentry monitor to a United States format of month/day/year, or to a European format of day/month/year.

1. In the *Time Menu*, scroll to *Date Format*, and press **MANUAL** to enter. The currently programmed format blinks.
2. Press either **YES** or **NO** to change the format, and press **MANUAL** to accept the new setting.

You can scroll to the next *Time Menu* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** until you exit Setup Mode.

If there are any once-a-day frequency settings set, resetting the date **will** clear the memory of any collected once-a-day readings. The monitor will recollect these readings at the next monitoring session.

Daylight Savings

Options: USA, EEC, OFF
Default: Set to locale
Access Level: General

If the monitor is powered on, Daylight Savings automatically adjusts the clock to accommodate the time change. The USA default setting moves the clock forward one hour at 2:00 A.M. on the first Sunday in April and back one hour at 2:00 A.M. on the last Sunday of October. The European setting (EEC) moves the clock forward one hour at 1:00 A.M. on the last Sunday in March and back one hour at 1:00 A.M. on the last Sunday of October. If your location does not have Daylight Savings, turn this setting to OFF.

1. In the *Time Menu*, scroll to *Daylight Savings*, and press **MANUAL** to enter. The currently programmed format time blinks.
2. Press either **YES** or **NO** to change the format, and press **MANUAL** to accept the setting.

You can scroll to the next *Time Menu* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** until you exit Setup Mode.

Report Time (1 – 4)

Options: Time (in selected format), and Off
Default: Time 1 defaults to 08:00; all other times are set to Off
Access Level: General

The Report Time is the scheduled time for your Sentry Monitor to collect and transmit your vitals. You can have up to four report times in one 24-hour period.

If you set more than one report time, and are transmitting your readings for review, make sure that you schedule the report times at least one hour apart. This is to accommodate the *Scheduled Reading* window in Central Station.

The Report Time displays in the format programmed in the *Time Format* menu (A.M./P.M. or 24-hour format).

1. In the *Time Menu*, scroll to the *Report Time* option that you wish to set (1, 2, 3, or 4).
2. Press **MANUAL** to enter. Depending on the current setting, either On or Off blinks.

3. To change the setting, press either **YES** or **NO**, and then press **MANUAL**. The hour blinks.

OR

1. Press **MANUAL** to accept the setting. The hour blinks.
2. Scroll to the correct hour. Press **MANUAL** to accept the hour setting. The minutes blink.
3. Scroll to the correct minutes. Press **MANUAL** to accept the minute setting.

Exit Time Menu

Press **STOP + BP** to exit the Time Menu.

System Settings

Time Menu	System Settings	Questions Menu	Password	Transmit Menu	Option Menu	Service Menu

After entering setup mode, press **YES** to scroll to *System Settings*, and then press **MANUAL** to enter the *System Settings* menu.

Volume

Options: Lowest, Low, Med, High, and Highest
Default: Med
Access Level: General

The volume setting controls both the key beep and the voice prompt volumes. To change the volume, follow the steps below.

1. Press **MANUAL** to enter the *Volume* option. The current setting blinks.
2. Press either **YES** or **NO** to scroll to a new setting, and press **MANUAL** to accept the setting. A sample sound clip plays. If the volume level is not satisfactory, press **MANUAL** to reenter Volume and change the setting.

You can scroll to the next *System Settings* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit setup mode.

Temperature Prompt

If your Sentry Monitor is programmed to your collect temperature, temperature prompts begin after the prompt instructing you to sit in a chair. The monitor displays the temperature prompt text at the same time as it plays the audio prompt.

When the audio completes, the text prompt is replaced with the following text: "`Temperature _ _ _ . _ F.`"

When the temperature probe is removed, the `_ _ _ . _ F` portion of the text flashes.

1. The monitor will instruct you to remove the probe and attach a probe cover. Cue text: **`Remove probe from holder`** and then returns to the indicator text.
2. The monitor will prompt you to put a cover on the temperature probe and place probe under your tongue.
3. The final temperature prompt instructs you to discard the probe cover and replace the probe in its holder, and the temperature indicator will display the collected temperature.

Taking a temperature reading if the temperature prompt is turned off

If the temperature prompt is set to OFF, you can still collect a temperature reading as long as you do so after collecting your weight, and before the conclusion of vital collection. Do the following:

1. When prompted, step off the scale and sit down in the chair.
2. Ignore the prompt to put on the blood pressure cuff. Instead, remove the temperature probe from the channel holder.
3. Follow the temperature prompts. Once your temperature is collected, the monitor begins the prompts for blood pressure.
4. Complete the normal monitoring session.

Temperature Time

Options:	OFF, every time for all or any combination of days (_ _ Mo _ _ We _ _ Fr _ _), or only one time each day (_ _ M* _ _ W* _ _ F* _ _)
Default:	OFF (_ _ _ _ _ _ _ _ _ _ _ _ _ _)
Access Level:	General

1. In the *System Settings* menu, scroll to *Temperature Time*, and press **MANUAL** to enter. The first selection blinks. If the prompt is off, only underscores display.
2. Press either **YES** or **NO** to change the setting, and press **MANUAL** to accept the new setting.
3. Continue through the seven settings until all are set correctly.

You can scroll to next *System Settings* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit setup mode.

Scale Prompt

Options:	OFF, every time for all or any combination of days (_ Mo _ _ We _ _ Fr _ _), or only one time each day (_ _ M* _ _ W* _ _ F* _ _)
Default:	Every day (Su Mo Tu We Th Fr Sa)
Access Level:	General

Scale Prompt allows you to turn the audio and text scale prompts off or turn the prompts on for all or any combination of days. The factory default is on for every day, but if the prompt is turned on, the monitor prompts for (and collects), your weight at the beginning of each monitoring session.

1. In the *System Settings* menu, scroll to *Scale Prompt*, and press **MANUAL** to enter. The first selection blinks. If the prompt is off, only underscores display.
2. Press either **YES** or **NO** to change the setting, and press **MANUAL** to accept the new setting.
3. Continue through the seven settings until all are set correctly.

You can scroll to next *System Settings* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit setup mode.

Language

Options:	SBVOX:	English, French, Spanish, Hindi, German, Italian, French Canadian, or Portuguese
	SBVOXB:	English, Spanish, Armenian, Polish, or Russian
Default:	English	
Access Level:	General	

The Language menu allows you to change the language of the audio and text prompts.

To change the language setting, follow the steps below.

1. In the *System Settings* menu, scroll to *Language*, and press **MANUAL** to enter. The current setting blinks.
2. Press either **YES** or **NO** to scroll to the desired language, and press **MANUAL** to enter the setting.

You can scroll to the next *System Settings* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit setup mode.

Units

Options: English (Lbs and °F) or Metric (Kg and °C)
Default: English
Access Level: General

You can set the Sentry to display either English or metric units. Sentry monitors should default to what is customary in your locale. However, if you need to change the units, follow the steps below.

1. In the *System Settings* menu, scroll to *Units*, and press **MANUAL**. The current selection blinks.
2. Press either **YES** or **NO** to change the setting, and press **MANUAL** to accept the new setting.

You can scroll to the next *System Settings* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit setup mode.

Inflation Settings

Options: 125 – 250 mmHg
Default: 175 mmHg
Access Level: General

You can use this menu to set the **initial** NIBP cuff inflation setting on a single-person monitor.

If used for a **multi-person system** (example: worksite kiosk) the NIBP settings are established when I.D. cards are assigned.

The Sentry Monitor uses initial setting is only used for the **first** blood pressure collection, because the latest BP reading is stored in the memory to use as a setting for the next blood pressure. The monitor inflates the cuff to 35 mmHg higher than the last systolic reading.

1. In the *System Settings* menu, scroll to *Inflation Settings*, and press **MANUAL** to enter. The current setting blinks.
2. Press either **YES** or **NO** to scroll to the desired inflation setting, and press **MANUAL** to accept the new setting.

You can scroll to the next *System Settings* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit setup mode.

Display Brightness

Options: Low, Med, High
Default: High
Access Level: General

This menu allows you to adjust the brightness level of the VFD display. To adjust the brightness level, follow the steps below.

1. In *System Settings*, scroll to *Display Brightness*, and press **MANUAL** to enter. The current selection blinks.
2. Press either **YES** or **NO** to scroll to the desired brightness, and press **MANUAL** to accept the new setting.

You can scroll to the next *System Settings* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit setup mode.

Exit System Settings

Press **STOP BP + YES** to exit System Settings Menu.

Questions Menu (1 – 10)

Time Menu	System Settings	Questions Menu	Password	Transmit Menu	Option Menu	Service Menu

The *Questions Menu* allows you to program the Sentry Monitor to ask subjective disease-state questions similar to the questions you might be asked during a visit to your physician. There is a block of fifty-one questions, out of which you may **select up to ten** to include in the monitoring session. For a list of all of the questions, refer to Appendix *A: Subjective Questions* in this manual, or to the *Honeywell HomMed OTC Sentry Service and Support Guide.*

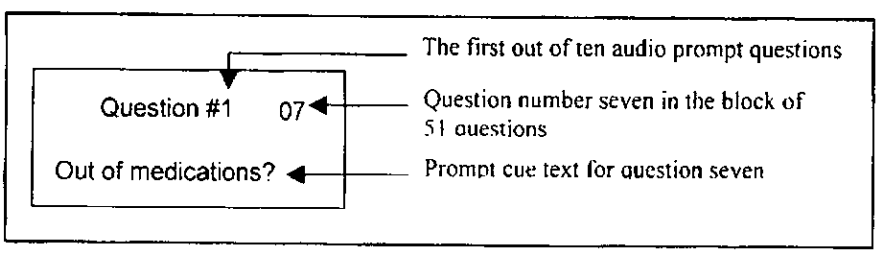
The menu also offers a block of questions for Sleep Apnea. It is an **on/off option only**. If you turn the option on, the monitor asks all twelve questions in the block. Please refer to Appendix *B: Sleep Apnea Question* in this manual.

Questions

Options: Off or Question 1 - 51
Default: Off
Access Level: General

As you scroll through the block of questions, you see blinking cue text and the question ID number. The ID number is located in the upper right-hand corner of the display. Each question has its own unique ID number that separates it from the other questions in the list.

Do not confuse the question *ID number* with the number that identifies the *prompt order.* In the following illustration, the number "07" and the prompt cue text, "Out of medications?" identifies the question, "Are you out of any of your medications?" which is the seventh question in the block of fifty-one. The text "Question #1", tells you that this is the first question that the monitor will ask you during the monitoring session.



For the list of all fifty-one questions, refer to the *Honeywell HomMed OTC Sentry Service and Support Guide*, Appendix *A: Prompt Text.*

Question Time

Options:	OFF, every time for or any combination of days (_ _ Mo _ _ We _ _ Fr _ _), or only one time each day (_ _ Mo* _ _ We* _ _ Fr* _ _)
Default:	All days
Access Level:	General

Each question is followed by an option that allows you to set a question frequency. **The default is daily**. However, you can program any combination of days. You must have at least one day selected or the monitor will not ask the question.

To program a question and question time

1. In *Questions Menu*, scroll to the desired question, and press **MANUAL**. The Off text (or cue text) blinks.
2. Press either **YES** or **NO** to change the setting, and press **MANUAL** to accept the new setting.
3. Press **YES** to scroll to the question time, and press **MANUAL** to enter. The first selection blinks.
4. Press either **YES** or **NO** to change the setting, and press **MANUAL** to accept the new setting.
5. Continue through the seven days until all are set correctly.
6. Scroll to the next question you want to program and repeat steps 1 – 5.
7. When finished, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit Setup Mode.

Sleep Apnea mode

Sleep apnea questions are a single block of twelve questions that are either on or off. The default is *Off*. When turned on, the Sentry monitor will go through **all** of the questions. For a list of all possible questions, refer to Appendix *A: Questions Text*.

1. In the *Questions* menu, scroll to *Sleep Apnea*, and press **MANUAL**. The first selection blinks. If the prompt is off, only underscores display.
2. Press either **YES** or **NO** to change the setting, and press **MANUAL** to accept the new setting.
3. Continue through the seven settings until all are set correctly.
4. When finished, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit Setup Mode.

Exit Question Prompt

Press **STOP BP + YES** to exit Questions menu.

Monitoring Sessions.....

What is a Monitoring Session?

A monitoring session will always includes collecting your blood pressure, and heart rate readings. Depending on your monitor's settings, or if have any of the compatible peripheral devices, then the session may also include weight, temperature, and giving answers to your customized questions.

Sentry monitor voice and text prompts

The monitor uses friendly voice prompts and easy-to-read text prompts to guide you through each step of the monitoring session. Text cue prompts display in the monitor's display panel at the same time that the audio prompt plays.

Prompt timing

A monitoring session generally includes collecting weight, blood pressure, heart rate, and answers to customized questions. You may also use the optional temporal temperature, oximeter or peripheral devices.

Audio and text prompts are spaced far enough apart to allow you ample time to perform the **requested tasks**. If, after the first prompt, you do not complete the requested task within the time allowed, **the monitor repeats the prompt**.

At the beginning of a session, you will have thirty minutes to comply with the initial prompt. During the thirty minutes, the prompt is **repeated** at the **rate of once every five minutes** until you complete the reading or the thirty-minute time frame ends. If the monitor times out, it sends a null (empty) packet of data.

Once the session is started, the monitor allows time for each task as follows:

- **Five minutes** to collect blood pressure and heart rate.
- **One minute** to collect temperature (starting from the removal of the probe from its storage channel)
- **Thirty seconds** to answer each question
- **Three minutes** to attach any peripheral device

The Sentry monitor repeats prompts for each step until you comply with the instruction, and the unit gets a valid reading; or until time allowed for the task runs out. If the monitor **does not get a reading** for an enabled vital or peripheral device, it inserts a null value in the data packet for that vital or device.

General prompts and text displays

The monitor goes through the following procedure:

- Says a greeting
- Prompts for weight and then blood pressure
- Asks programmed questions
- Prompts for programmed peripheral devices
- Reminds you to take your medications
- Thanks you for completing your vital signs

If the monitor is programmed to collect temperature and/or oxygen saturation (SpO2) reading, the prompts are incorporated into the session.

The following list describes the **basic** prompts and text displays, for a typical monitoring session. For a list of all possible prompts, refer to *Appendix C: Prompt Text*.

1. The monitor says a greeting and announces that it is time to take your viral signs.

   Cue text: `Good Morning` (Afternoon, Evening).

2. The monitor will instruct you to stand on the scale. (If the scale is not attached, the monitor skips this prompt.).

   Cue text: `Step on the scale`

3. After your weight is recorded, the monitor prompts you step off the scale and sit down on a chair in front of the monitor. **Wait for the prompt to ensure that weight is collected!**

   Cue text: `Step off the scale` Weight results display by the scale symbol.

4. A voice prompt will instruct you to place the blood pressure cuff on your right arm above the elbow and tighten it securely.

   Cue text: `Put cuff on arm`

5. An additional blood pressure prompt will instruct you to rest their arm as instructed.

   Cue text: `Rest arm as instructed`

6. The unit will instruct you to place the finger probe (sensor) on the middle finger of your left hand with the finger design facing up.

   Cue text: `Put sensor on finger` (pulsing bar graph also displays)

7. You will be prompted to press the **START BP** key.

   Cue text: `Press Start`

   Real-time inflation and deflation pressures display while the monitor measures blood pressure. When done, the monitor displays the blood pressure readings, heart rate, and oxygen saturation (SpO2) readings.

8. The monitor will instruct you to remove the sensor and blood pressure cuff.

   Cue text: `Remove sensor and cuff`

9. The monitor then asks your selected questions, requesting that you press either the **YES** or **NO** key in response.

   Cue text: cue text for each question

10. The Sentry monitor will then remind you to continue with prescribed medications and diet, and then thanks you for completing your vital signs.

    Cue text: `Thank you` and then `Transmitting`

11. Your data is then transmitted automatically. If the transmission is successful, the display reads, "`Transmission success.`"

12. The Sentry monitor continues to display your weight, blood pressure, oxygen saturation (SpO2), and if collected, temperature for five minutes to allow you to record your vitals if you wish. To clear the display and return to idle mode right away, press the **START BP key**, the **STOP BP key**, the **YES key**, or the **NO** key once.

Taking Your Vitals Signs

WARNING

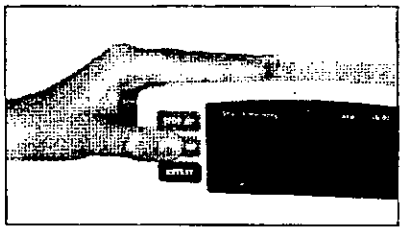
NOT AN EMERGENCY RESPONSE DEVICE

The monitor is **NOT** an emergency device.

If you have a medical emergency, call your local Emergency Medical Service and your health care provider.

Before you take your vitals

When you press the monitor keys, hold the top of the monitor with your fingers and use your thumb to press the keys. The picture below shows you the correct way to press the keys.



Before taking your vitals, make sure that you can reach each piece of the equipment and the monitor keys from your chair (or bed) without stretching. For stability, sit completely on the chair seat or fully on the bed. **Do not sit** on the edge.

Monitor keys

There are six keys on the front of the monitor. To learn what each key does when you press it, look at the following table.

Press this key	To
STOP BP	**STOP** the blood pressure cuff inflation.
START BP	**START** the blood pressure cuff inflation.
SEND	Take your vitals and **SEND** them to your health care provider.
YES	Answer "**YES**" to a question.
NO	Answer "**NO**" to a question.
MANUAL	Take your vitals **without sending** them to your health care provider. **NO VOICE PROMPTS**

Taking Your Blood Pressure (NIBP)

Proper cuff size and placement are essential to the accuracy of the blood pressure reading. Every cuff has an arm size range (in centimeters) printed on the outside label. The smallest and largest points in the range are determined as follows:

- The **smallest size** in the range is the point where the tab can no longer be pulled through the ring. If the cuff is still loose, use the next smaller size cuff.
- For the **largest size** in the range, the ring should fall in the natural break of the cuff. The natural break is the seam where the two Velcro patches meet. If the arm is larger than this, use the next larger cuff size.

While taking blood pressure, the monitor displays the real-time cuff inflation pressure in the Systolic display. When the reading is complete, the monitor displays systolic, diastolic, and mean arterial results.

Before you start, make sure that...

- The blood pressure hose is not kinked, compressed, or restricted in any way.
- You are using the proper cuff size and are placing the cuff correctly on your arm.
- The arm you use is bare or only has light clothing covering it. **Do not** wear a heavy sweater or coat.
- That you rest your arm on a level surface; and **do not move** or **talk** until the monitor completes your reading.

Inflation pressure

The Sentry Monitor has a preset default inflation pressure of **175 mmHg**. However, it only uses this setting once, because the Sentry monitor saves the last BP reading in memory. The next inflation pressure is **35 mmHg** above the last saved systolic.

If your blood pressure is higher than the inflation pressure, the Sentry Monitor increases the pressure by 35 mmHg, re-inflates, and takes a new blood pressure reading. If the monitor can not obtain a blood pressure after a total of three (3) attempts, the monitor displays an error.

Using the blood pressure (NIBP) cuff

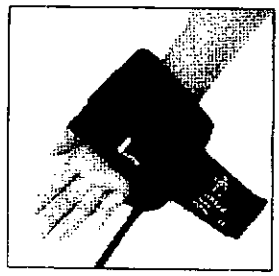
For stability, sit completely on the chair seat or fully on the bed. **Do not** sit on the edge. Rest your arm so that it is at **heart level** (on a level surface), in order to obtain the most accurate reading.

! The blood pressure cuff maybe placed on either on the right, or left arm. It is important for accurate readings that you use the **same arm,** each time you take a blood pressure reading; however if you cannot use the usual arm, **you may use the other arm**.

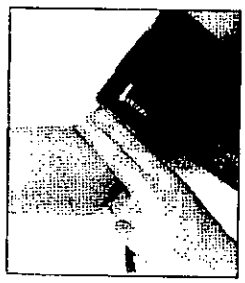
---

1. Hold the cuff so that the artery marker (white arrow) points away from you.

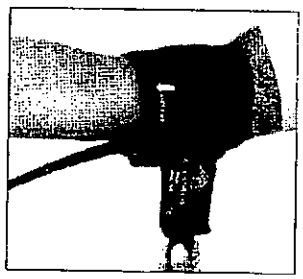
2. With our palm facing upwards, slip your hand through the cuff.



3. Position the cuff so that the artery marker arrows point to your ring finger and slide the cuff up your arm over your elbow. There should be about a two-finger space between the crease in your elbow and the cuff.



4. Grasp the tab and pull down to tighten the cuff. **Do not** make the cuff too tight. You should be able to slide your finger between your cuff and your arm.



5. Wrap the cuff end under and around your arm and fasten it to the Velcro.

6. Rest your arm at heart level. **Do not move** or **talk** until the monitor completes your reading.

REMEMBER: You can stop the inflation at any time by pressing the red **STOP BP** key. To restart inflation, press the green **START BP** key.

If the monitor cannot obtain a blood pressure after **two attempts**, the monitor displays an error.

Taking Your Temperature (Temperature Probe)

Attach the temperature probe to your monitor if you need to take your temperature.

CAUTION

THE TEMPERATURE PROBE IS FOR ADULT, ORAL USE ONLY

Only adults (age 12 years and older) should use the temperature probe. Use the temperature probe only in your mouth.

DO NOT use the temperature probe on children.

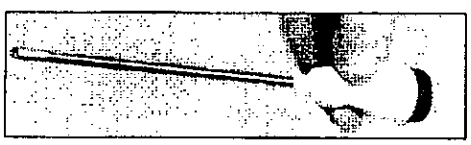
DO NOT use the temperature probe to take rectal or axillary temperatures.

Be sure to...

- Always use a temperature probe cover.
- Hold the probe in place by hand and not with the mouth
- Wait until ready to take your temperature before removing the probe from the holder.

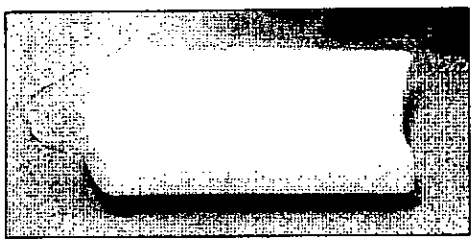
Using the temperature probe

1. Remove the temperature probe from its holder.
2. Hold the probe in the indent as shown in the figure below, and push the probe firmly into a probe cover. The **blue** end separates as the probe cover slides into place.



3. Place the probe under your tongue and close your mouth. Hold the probe still with your hand. **DO NOT bite the probe**.
4. When the monitor prompts you, remove the probe from your mouth.
5. Push the **blue** end of the temperature probe to release the probe cover, and throw the cover away.
6. Replace the temperature probe **firmly** into the storage channel.

Taking Your Weight (Honeywell HomMed Scale)



When you step onto the scale, place your feet towards the center of the scale, not on or near the edge. **Do not** move while the scale collects your weight.

CAUTION

PERSONAL INJURY HAZARD: SCALE TIPS

Weight placed on the edge of the scale will cause the scale to tip and can cause you to fall.

DO NOT step onto the edge of the scale.

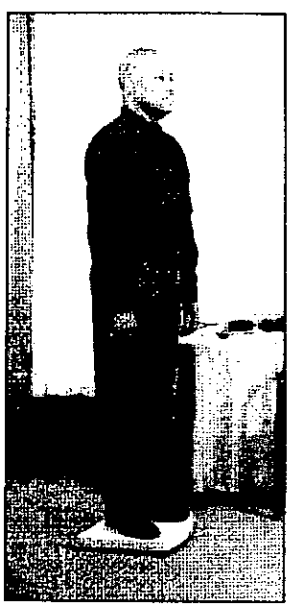
DO NOT stand on the edge of the scale.

You must be able to stand on a scale **without support** for the time that it takes the monitor to collect a weight.

Always step or stand in the **middle of the scale**, and **DO NOT** step or stand on the edge, which will cause the scale to tip and possibly cause you to fall.

Be sure to...

If you are not able to stand on the scale without support, disconnect the scale and turn the scale prompt off.



Using the scale

1. When the voice prompts instructs you, step onto the scale.
2. Stand still until the monitor prompts you to step off the scale.

Taking Your Blood-Oxygen Saturation (SpO2)

The Oximeter Finger Sensor collects an oxygen saturation, (SpO2) reading. If you need to collect SpO2 reading, attach the finger sensor to your monitor. You'll know if the oximeter is properly placed, when the pulse bar on the monitor display shows a **strong pulse** while collecting the SpO_2 reading.

The Oximeter is a prescription only device! You may only use the Oximeter as part of **Physician prescribed care plan.**

The Oximeter sensor, or Finger Sensor, is not meant for continuous monitoring of SpO_2 levels (blood saturation); no alarms are provided.

Dark finger nail polish or false nails may interfere with the reading. If you cannot get a reading, remove finger nail polish, and try again.

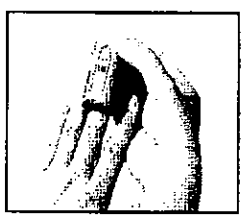
Be sure to…

- Always place the sensor on the hand opposite the arm you use for your blood pressure measurement.
- Remain still, this ensures an accurate reading, once the monitor starts take your SPO_2 reading.

Using the Oximeter Finger Sensor

Hold the finger sensor so that the raised design is on top.

1. Gently insert your finger into the sensor. If necessary, open the sensor by squeezing it similar to opening a clothespin.



2. Follow the monitor voice prompts

Programming for Transmission

Transmission Requirements

This section provides programming concepts and instructions that will enable you to correctly program your Sentry monitor for transmission of data packets to a Honeywell HomMed Central Station.

Always **test transmission** after you complete programming and setup for a new monitor (or a reassigned one), to make sure Central Station can receive data from the monitor.

Password

Time Menu	System Settings	Questions Menu	**Password**	Transmit Menu	Option Menu	Service Menu

Without entering a password, you will not be able to see or enter password-protected menus or menu options. The password protected menu options are found in the *Service* and *Transmit* menus.

Your Password: _____

All Sentry Monitors use the same password. If you do not know the password, contact *Honeywell HomMed Customer Service*. Follow the steps below to enter the password.

1. In Setup Mode, scroll to the *Password* menu.
2. Press **MANUAL** to enter the menu. The first underscore blinks.
3. Use either the **YES** or **NO** key to scroll to the first number of the password.
4. Press **MANUAL** to enter the number and move to the next underscore.
5. Repeat steps 4 and 5 until all four numbers are entered. Once you have pressed **MANUAL** to enter the fourth number, all menu options become available.

Exit Password Menu

Press **STOP BP + YES** to exit Password Menu.

Transmit Menu

Time Menu	System Settings	Questions Menu	Password	**Transmit Menu**	Option Menu	Service Menu

In Setup Mode, use **YES** or **NO** to scroll to the *Transmit Menu*, and press **MANUAL** to enter. The first option, PIN, displays.

PIN Number (P)

Options: 7-digit number
Default: ISP or email PIN number
Access Level: Password protected

The PIN number identifies the destination mailbox provided by your communications service. The Sentry Monitor sends its data to this mailbox address and the Central Station checks this same address to retrieve the data.

You must **make sure that this number is correct.** Check the number against the one you received from the person or party to whom you will be transmitting. For your reference, copy the correct mailbox PIN number on the line below.

Your PIN number: _____
____

The PIN Number should always be followed by four dashes (hyphens). See above.

1. In the *Transmit Menu*, scroll to the *PIN Number* option. If the number is correct, you can move to your next task. However, if it is incorrect, press **MANUAL** to enter the option. The first digit blinks.
2. Use **YES** or **NO** to scroll to the correct number, and press **MANUAL** to accept the value and move to the next digit.
3. Repeat steps 2 and 3 until you enter or correct the entire PIN number.

You can scroll to the next *Transmit Menu* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit Setup Mode.

If you just need to correct one digit, use the **RETEST** key instead of the **MANUAL** key. The **RETEST** key will enter the new digit and also back you out of the menu.

Dial Type

Options: Tone or pulse (rotary)
Default: Tone
Access Level: General

If tone dialing is unavailable and there is a rotary phone, change the dial type to pulse.

1. In the *Transmit Menu*, scroll to the Dial Type option and press **MANUAL** to enter.
2. Press either **YES** or **NO** to change tone to pulse, and press **MANUAL**.

You can scroll to the next *Transmit Menu* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit Setup Mode.

Transmit Mode

Options: ISP, Local Gateway, Remote Gateway, Automatic or Pager
Default: ISP
Access Level: General

The transmit mode determines how your Sentry Monitor transmits data. When set to ISP, the monitor sends data over a phone line to your mailbox.

If the monitor is going to transfer your data to a local server, set the transmit mode to *Local Gateway*. For example, use *Local Gateway* when you demonstrate the Genesis monitor.

Set the transmit mode to *Remote Gateway* if you want the monitor to transmit data to a remote site other than an ISP mailbox.

1. In the *Transmit* menu, scroll to the *Transmit Mode* option, and press **MANUAL**. The current setting blinks.
2. Press either **YES** or **NO** to scroll to the correct transmit mode, and press **MANUAL** to accept it.

You can scroll to the next *Transmit Menu* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit Setup Mode.

Test Message

Access Level: General

Test Message allows you to verify or test transmission by sending an empty (null) test data packet to Central Station. Although you can send a test message at any time to verify transmission, **always** test transmission after you complete both programming and setup, to make sure Central Station can receive data from the monitor.

DO NOT take any vitals until you have sent a test message and verified the transmission. Verify transmission after you complete the programming and setup for **any new monitor.**

If you've made any changes to the configuration since the last time a configuration packet was sent to the Central Station, the monitor asks if you'd like **to send a test message to the Central Station** when you exit *Setup Mode.* Central Station must have received at least one test message or regular transmission of reading data in order to add the monitor to its list of available monitors.

Be sure to...

- Send a **test message** from the location that the monitor will be used, (bedroom, living room, etc.).

Send a Test Message

To send a test message do the following:

1. Scroll to the *Transmit* Menu, and press **MANUAL** to enter.
2. Scroll to *Test Message*, and press **MANUAL** to enter.
3. Press **YES** to transmit a test packet. The monitor will transmit an empty or null data packet. If the transmission is successful if the monitor displays the message, "Transmit successful." This **only** confirms that the packet successfully left the monitor.
4. To complete the test, **call and verify** that Central Station received the null transmission. This step verifies that the monitor is properly assigned, and in the Central Station, and the null posts to the correctly to your account.

ISP1 Phone # (P)

Options: Numeric characters 0 – 9; hyphen (-); underscore (_); comma (,)
Default: Set to locale
Access Level: Password protected

This is the phone number to be dialed to connect to the primary ISP account for transmission of information to the Central Station. The ISP number is already entered, but verify it against the one you received from the person to whom you will be transmitting.

If the monitor must dial 9 (and/or another character or digit) for an outside line, you will need to go into this menu and add the dial-out digit(s) in front of the phone number.

1. In the *Transmit Menu*, scroll to the *Transmit Phone Number* option, and press **MANUAL** to enter the option. The first digit (or underscore) blinks.
2. Use **YES** or **NO** to scroll to the correct number, and press **MANUAL** to accept the value and move to the next digit.
3. Repeat step two until you enter the entire phone number.

You can scroll to the next *Transmit Menu* option, press **RETEST** to return to the *Main* menu, or press **STOP BP + YES** to exit setup mode.

ISP2 Phone # (P)

Options, Default, and Access Level same as ISP1 Phone #

Verification is the same as ISP1 Phone #.

Programming information same as ISP1 Phone #

Transmit Phone # (P)

Options, Default, and Access Level same as ISP1 Phone #

Verification is the same as ISP1 Phone #.

Programming information same as ISP1 Phone #

Serial Mode

Options: ON, OFF, Kiosk

Default: OFF
Access Level: Password protected

Serial Mode programs the monitor to download a copy of the data packet to a local personal computer (PC) before it transmits the packet to your assigned *ISP address* or to a *remote gateway*. If you are placing the monitor in a kiosk, the *Kiosk* setting automatically transmits data to the kiosk PC. The data packet in Kiosk mode has additional data-protection features.

1. In the *Transmit Menu*, scroll to *Serial Mode*, and press **MANUAL**.
2. Press either **YES** or **NO** to change the Serial Mode to ON, and press **MANUAL**.

You can scroll to the next *Transmit Menu* option, press **RETEST** to return to the Main menu, or press **STOP BP + YES** to exit Setup Mode.

Modem Settings (P)

Options: 20 AT characters
Default: OFF
Access Level: Password protected

Modem Setting allows technicians to enter AT prefix characters for transmitting and service phone numbers. You do not need to enter this menu.

ISP Settings Menu (P) (Internal Settings Menu)

Choose the *ISP Settings* menu to access the following settings:

- ISP1 Prefix (P)
- ISP1 Realm (P)
- ISP2 Prefix (P)
- ISP2 Realm (P)

ISP1 Prefix (P)

The text string in the ISP1 Prefix field is appended to the username for authentication purposes when connecting to the primary ISP account for transmission of information to the Central Station.

ISP1 Realm (P)

The text string in the ISP1 Realm field is appended to the username for authentication purposes when connecting to the primary ISP account for transmission of information to the Central Station.

ISP2 Prefix (P)

The text string in the ISP2 Prefix field is appended to the username for authentication purposes when connecting to the secondary ISP account for transmission of information to the Central Station.

ISP2 Realm (P)

The text string in the ISP2 Realm field is appended to the username for authentication purposes when connecting to the secondary ISP account for transmission of information to the Central Station.

Exit ISP Settings

Exit the ISP Settings menu and return to the previous menu.

Exit Transmit Menu

Press **STOP BP + YES** to exit Transmit Menu.

Option Menu

Time Menu	System Settings	Questions Menu	Password	Transmit Menu	Option Menu	Service Menu

The *Options Menu* allows you to assign communication ports to compatible peripheral devices. You must assign a com port to each device, or the monitor **will not prompt** for the device. The monitor **will not collect data** from that device, even if the device is connected to the com port.

After assigning a com port, you can then program how often the Sentry Monitor collects test results from the device. The default is daily. However, you can program any combination of days.

You must have at least one day selected for an accessory device, or the monitor **will not prompt** for the device.

Prompts for accessory devices

Prompts for accessory devices vary depending on the device. If the monitor is only uploading collected test results from a device, it only prompts you to attach the device to the monitor. However, if you must use the device or perform more than one task, the monitor will prompt you through the required steps.

The monitor uploads data from each programmed device and displays the following messages:

- If this is the first time this monitor has collected readings from this device, "`new <device name> detected.`"
- If there is new data: "`Receiving Data`" followed by "`Data upload finished.`"
- If there is no new data: "`No new data.`"

The monitor **does not display test results** collected from accessory devices, only the **text prompts** related to the device. Once it has collected data, it repeats the process with the next scheduled device.

For programming instructions for accessory devices, refer to the **instruction sheet** which came with the device. For any on information on accessory devices, refer to Appendix *D: Accessory Devices*, of this manual.

Transmitting test results from accessory devices

If you are transmitting test results from am accessory device (example: a glucose meter), wait for the prompt and then attach your device.

For more information, refer to the **instruction sheet** provided with the specific accessory device.

Exit Options Menu

Press **STOP BP + YES** to exit Option Menu.

Service Menu

Time Menu	System Settings	Questions Menu	Password	Transmit Menu	Option Menu	Service Menu

These menus allow Honeywell HomMed technicians to access the Sentry Monitor to obtain specific diagnostic data and perform calibration tasks. If you are asked to perform any tasks that require you to enter this menu, Customer Service will walk you through the steps.

Service Call

Choose this item to initiate a connection between the monitor and the Honeywell HomMed service department computer.

Service Call Phone # (P)

This item contains the number the monitor uses to connect to the Honeywell HomMed service department computer.

Calibration Verify (P)

This item is used to perform a calibration test on the NIBP measurement. For more information, see page 40, in the *OTC Sentry Monitor Service and Support Guide.*

CAUTION

PERSONAL INJURY HAZARD: NIBP Cuff

Verifying the calibration while the cuff is attached to you, (while wearing the cuff) could cause bruising or other injury.

DO NOT verify NIBP calibration while the cuff is attached to a patient.

Report Menu (P)

Choose the Report Menu (P) to access the following information:

- Serial Number (P)
- Hardware Version (P)
- Software Version (P)
- Oximeter Version (P)
- NIBP Version (P)
- BP Safety Version (P)

- BP Hardware Version (P)
- NIBP Cycles (P)
- Last Calibration (P)

Serial Number (P)

This item reports the serial number assigned to the monitor.

Hardware Version (P)

This item reports the hardware version of the monitor.

Software Version (P)

This item reports the software version of the software currently installed on the monitor.

Oximeter Version (P)

Reports the hardware version of the oximeter board installed in the monitor.

NIBP Version (P)

Reports the NIBP version of the monitor.

BP Safety Version (P)

Reports the BP Safety version of the monitor.

BP Hardware Version (P)

Reports the BP Hardware version of the monitor.

NIBP Cycles (P)

Reports the number of NIBP cycles.

Last Calibration (P)

Reports the date of the last calibration of the monitor.

Exit Service Menu

Exit the Service menu and return to the previous menu.

Troubleshooting

This section provides resolutions to the most common situations you may encounter in the field when installing or operating Honeywell HomMed Sentry 6 monitors. A table of error codes starts on page 62 of this manual. If you experience a problem operating a peripheral device, refer to the manufacturer's product information.

Monitor installation

Monitor installation problem – Caller ID / TDD
You have a caller ID box attached to the phone, or You have a Telecommunication Device for the deaf (TDD) on the phone line.
Resolution
Use the **pass-through connection** that comes with your Sentry Monitor.
Steps
1. Unplug caller ID box phone cord from the wall jack. 2. Insert duplex jack. 3. Plug caller ID box phone cord into duplex jack. 4. Plug the monitor phone cord into duplex jack.

Monitor installation problem – Duplex jack
You already have a duplex jack in the jack outlet.
Resolution
Use the **pass-through connection** that comes with your Sentry Monitor.
Steps
1. Unplug the phone line from the duplex jack. 2. Plug the phone line in to the PHONE port on the rear of the monitor. 3. Plug one end of a phone cord into the MODEM port on the rear of the monitor. 4. Plug the other end of the phone cord into the duplex jack.

Monitor installation – Phone cords
Have two short phone cords but need a longer cord.
Resolution
Use a phone coupler.
Steps
Connect phone cords using coupler to create a single cord.

Equipment Problems

Equipment Problems – Monitor (problem #1)	
Monitor does not power up	
Possible Cause	**Resolution**
Unit is not plugged in.	Make sure plug is firmly into the power strip.
Wall outlet is not working.	Test wall outlet with another electrical appliance.
Wall outlet is controlled by a light switch and switch is off.	Plug unit into a wall outlet that is not controlled by a switch.
Power strip is not on.	Turn power strip on.
Power strip has bad outlet.	Try other outlets, if none work, replace the power strip.

NOTE: If unit still does not power up, call Honeywell HomMed Customer Service.

Equipment Problems – Monitor (problem #2)	
The monitor's green light comes on indicating power to the unit, but the display does not light up.	
Possible Cause	**Resolution**
The power cord is not completely inserted into the monitor	Unplug the power cord, and then plug it in again making sure to push it firmly into place.

NOTE: If unit still does not power up, call Honeywell HomMed Customer Service.

Equipment Problems – Scale (problem #1)	
Weight does not register.	
Possible Cause	**Resolution**
You moved or stepped off scale during measurement.	Stand still on scale and to wait for prompt before stepping off.
Scale not connected or connection loose.	Make sure scale cable is connected to the scale and to the monitor. Reboot the monitor.

NOTE: If the weight still does not register, call Honeywell HomMed Customer Service.

Equipment Problems – Scale (problem #2)	
Scale does not zero properly; monitor displays dashes instead of 0.0.	
Possible Cause	**Resolution**
Scale cable attached to the monitor **after** the monitor was powered up.	1. Power-down the monitor. 2. Disconnect the scale cable from the scale. 3. Place scale on a flat surface and that it is level (bubble should be in the circle). 4. Be sure scale is not a thick carpet. 5. Reattach the scale cable to the scale. 6. Reboot the monitor.
Scale is not on a flat surface.	
Scale is not level.	
Scale is on a thick carpet.	
The scale was moved.	
Weight is > than 500lb / 227kg.	

NOTE: If scale still does not zero it must be recalibrated. Call Honeywell HomMed Customer Service.

Equipment Problems – Scale (problem #3)	
Your pulse-rate drops easily after obtaining weight.	
Possible Cause	**Resolution**
The oximeter obtains an oxygen saturation (SpO2) reading in either: • 8 beats or • 8 seconds	Do the following: 1. After taking your weight, sit down and follow BP prompts, but **IGNORE** the SpO2 prompt. Once your BP is collected, the monitor will know to collect a oxygen saturation (SpO2) reading, 2. Then, when prompted, place the oximeter on a finger and take a resting SpO2.

Equipment Problems – Scale (problem #4)	
Monitor displays varying weights.	
Possible Cause	**Resolution**
You maybe dressed differently. You are possibly unsteady, and holding on to support.	Review the steps in *Taking Your Weight*. Be sure you are standing in the middle of scale.
Scale does not clear the carpet. Scale is not level.	1. Power-down the monitor. 2. Disconnect the scale cable from the scale. 3. Adjust the feet until the scale clears the carpet and is level (bubble should be in the circle). 4. Reattach the scale cable to the scale. 5. Reboot the monitor.

Equipment Problems – Blood Pressure Cuff (problem #1)	
Blood pressure cuff leaks.	
Possible Cause	**Resolution**
Loose connection	Tighten all tubing and cuff connections.
Defective cuff or hose	Replace cuff or hose.

Equipment Problems – Blood Pressure Cuff (problem #2)	
Blood pressure does not register.	
Possible Cause	**Resolution**
Loose connection	Check and tighten all connections.
BP hose is kinked, compressed, or leaks	Straighten hose, remove source of compression, or replace leaky hose.
Defective cuff or hose	Replace cuff/hose.
Incorrect cuff placement	Review the steps on how to put on the cuff, in *Taking Your Blood Pressure.*
Movement	Remember to **remain still.** (If needed, place your arm on a pillow for support.)

Equipment Problems – Blood Pressure Cuff (problem #3)	
Blood pressure readings vary.	
Possible Cause	**Resolution**
Incorrect technique	Review the section, *Taking Your Blood Pressure* and retake your blood pressure reading. Be sure you have the following: • The right cuff size • The correct cuff placement • Good posture • That you are not talking or moving. • That your arm is at heart level

Equipment Problems – Temperature Probe	
Monitor prompts for temperature, when temperature was not programmed for collection.	
Possible Cause	**Resolution**
Temperature probe is not fully inserted into the channel.	Push probe fully into channel.

Equipment Problems – Oximeter (problem #1)	
Heart rate is very low or does not register.	
Possible Cause	**Resolution**
Oximeter is not connected to monitor or to you.	Plug the oximeter into the correct outlet, making sure it firmly latches into place.
Oximeter incorrectly positioned on your hand.	Review the steps on the proper placement of the oximeter, in *Taking Your Blood Oxygen Saturation*
Poor perfusion (blood flow to the hands).	Reposition the oximeter on hand.
Fingernail polish or false nails are interfering with sensor light.	Remove your finger nail polish or your false nails.
Defective sensor or cable.	Replace finger sensor.

NOTE: If the heart rate still does not register, call Honeywell HomMed Customer Service.

Equipment Problems – Oximeter (problem #2)	
Pulse rate erratic, intermittent, or incorrect.	
Possible Cause	**Resolution**
Oximeter is incorrectly positioned	Be sure to place oximeter on the finger, with **the finger design facing up**.
Poor perfusion (blood flow) to your hands.	Reposition the oximeter
	Be sure to move your hands prior to taking the reading.
	Apply a warm washcloth to hand(s).
	Lie down (if able) when taking reading.
Moved while reading was being taking.	Remember to **remain still.** (If needed, place your arm on a pillow for support.)
Ambient light (i.e. Sunlight, or bright room lights)	Shield the oximeter from the ambient light.

NOTE: If the SENSOR light remains on and monitor does not collect a reading, call Honeywell HomMed Customer Service.

FINAL:

Transmission

If you get a transmission error code, write down the error code. Refer to the following Transmission Error table, or proceed to the *Error Code Table* section that immediately follows (See page 62). If you can not resolve the error, contact the person to whom who will be transmitting, or contact Honeywell HomMed Customer Service.

Transmission Problem	
Monitor collected the vitals but did not transmit.	
Possible Cause	**Resolution**
Modem line is not connected to unit or wall.	Connect modem line to the unit and the wall jack.
Transmission mode is incorrect.	Set monitor to correct transmission mode. (Refer to the *Programming Your Monitor* section of this manual).
PIN or phone number is incorrect.	Verify that the PIN is correct; verify that the modem phone number is correct. (Refer to the *Programming Your Monitor* section of this manual).
The pager is out of range or failed transmission.	Relocate monitor. If pager is out of range, switch to modem.
Monitor serial number and the serial number assigned in Central Station do not match.	Call Central Station and verify serial numbers.
Transmit Mode programmed incorrectly.	Verify that *Transmit Mode* is programmed correctly for your area. If you do not know the correct mode, contact Customer Service.
Wall jack does not work.	Test wall jack with a phone.
Faulty duplex jack.	Use a new duplex jack.

Transmission Problem (continued)	
Monitor collected the vitals but did not transmit.	
Possible Cause	**Resolution**
Monitor serial number does not match unit label.	Go to Report in the Service Menu. Compare the serial number that displays in Report to the serial number recorded on the monitor's label (located on the bottom of the unit.). If they do not match, call the Honeywell HomMed Customer Service.
Monitor must dial a prefix for an outside line.	Add the prefix number to the transmit phone number.
You have a digital phone line.	If the monitor tried to transmit data via modem over a digital line, the **modem is damaged**. Call Customer Service to make arrangements for returning the monitor to Honeywell HomMed.

NOTE: If you still experience transmission difficulties, call Honeywell HomMed Customer Service.

Error codes table.

If there is a problem the Sentry problem the Sentry Monitor displays error codes, to explain what is wrong. Note this is as long as the Sentry Monitor has power. By learning the codes, you can quickly identify and correct most difficulties yourself. If you cannot solve the problem yourself, make a note of the error code and call Honeywell HomMed Customer Service.

#	VFD Display	Meaning	Possible Cause	Resolution/Action
100	NVRAM	Non-volatile memory checksum error		Call Honeywell HomMed.
200	SCALE_TIMEOUT	User timeout - scale	Did not stand on scale in time. Did not attach in time.	Review the *Taking Your Vitals* section of this manual.
201	SCALE_COMM	Disconnected scale	Scale not connected to the monitor Bad cable Scale not working properly	Connect the scale. Replace the cable. Replace the scale; call Honeywell HomMed.
210	NIBP_TIMEOUT	User timeout - NIBP	Did not attach cuff to arm in time.	Review the *Taking Your Vitals* section of this manual.
211	NIPB_COMM	Lost communication with NIBP		Call Honeywell HomMed.
212	NIBP_VERS	NIBP processor failed to send version information		Call Honeywell HomMed.
215	NIBP_TIME_OUT	NIBP cuff timeout	Moved while cuff was attached.	Review the *Taking Your Vitals* section of this manual.
216	NIBP_CUFF_LEAK	NIBP cuff leak	Loose connection Defective cuff or hose	Tighten all tubing and cuff connections. Replace cuff or hose.
217	NIBP_CANCEL	NIBP cancelled by user		No action
218	NIBP_NOISE	NIBP Too much noise	Moved while cuff was attached.	Review the *Taking Your Vitals* section of this manual.
219	NIBP_WEAK_SIGNAL	NIBP Weak signal	Cuff not tight enough Improper cuff size	Review how to put on your cuff in the *Taking Your Vitals* section of this manual. Replace with correct cuff size.
220	NIBP_SYS	NIBP System error		Call Honeywell HomMed.
221	NIBP_OVER_PRESSURE	NIBP Cuff pressure > 315mmHg		Call Honeywell HomMed.
222	NIBP_TIMER	NIBP Timers out of range		Call Honeywell HomMed.
223	NIBP_CAL	NIBP Calibration error		Call Honeywell HomMed.
224	NIBP_VALVE	NIBP Valve failure		Call Honeywell HomMed.
230	SPO2_TIMEOUT	User timeout - SpO2	Did not attach oximeter to finger in time.	Review the *Taking Your Vitals* section of this manual.
231	SPO2_COMM	Lost communication with SpO2 board	Loose connection	Verify cable connections are secure. Call Honeywell HomMed.
232	SPO2_VERS	SpO2 board failed to send version information		Call Honeywell HomMed.

#	VFD Display	Meaning	Possible Cause	Resolution/Action
233	SPO2_LOST	Sp02 signal lost	Oximeter (finger sensor) not properly placed on finger Moved during reading.	Review the placement of oximeter *Taking Your Vitals* section of this manual.
234	SPO2_SENSOR	Sp02 off finger or disconnected		Review the *Taking Your Vitals* section of this manual. Connect the sensor. Verify cable connections.
240	TEMP_TIMEOUT	User timeout – temperature	Did not place temperature probe in mouth in time.	Review the *Taking Your Vitals* section of this manual.
241	TEMP_COMM	Lost communication with temperature processor		Call Honeywell HomMed.
242	TEMP_VERS	Temp processor failed to send version information		Call Honeywell HomMed.
243	TEMP_UNRECOVERABLE	Temperature error		Call Honeywell HomMed.
244	TEMP_RECOVERABLE	Temperature error	Probe not positioned properly.	Review the placement of the temperature probe in the *Taking Your Vitals* section of this manual.
245	TEMP_NO_PROBE	Temperature probe disconnected		Connect the probe. Verify all connections secure.
246	TEMP_HI_AMBIENT	Temperature probe too warm		Operating range: 84° to 108°F (28.9° to 42.2 °C)
247	TEMP_LO_AMBIENT	Temperature probe too cold		Operating range: 84° to 108°F (28.9° to 42.2 °C)
250	IDCARD_TIMEOUT	User timeout – ID Card		Review the *Taking Your Vitals* section of this manual.
251	IDCARD_COMM	Lost communication with ID card reader	Not properly setup or connected Not assigned to com port Bad card reader	Reconnect the card reader. Assign a com port. Attach a new card reader.
252	IDCARD_ID_CRC	ID number CRC error	Card not swiped correctly Bad card	Swipe the card again. Create a new card.
253	IDCARD_DATA_FORMAT	Data format is bad on ID Card		Rewrite the card. Create a new card.
254	IDCARD_DATA_CRC	Data track CRC error		Rewrite the card. Create a new card.
255	IDCARD_LANGUAGE	Language on card is not available		Make sure that the monitor supports the language written on the card.
300	MODEM_COMM	Modem failed self test		Call Honeywell HomMed.
301	MODEM_HARDWARE	Modem failure		Call Honeywell HomMed.
302	MODEM_TIMEOUT	No answer after successful dial	Modem dialing wrong number	Program correct phone number.

#	VFD Display	Meaning	Possible Cause	Resolution/Action
303	MODEM_DIAL_TONE	No dial tone	Modem not connected Line is in use	Connect monitor modem to analog phone line Do not use phone during monitoring sessions.
304	MODEM_CONNECT	Modem failed to connect (no modem on other end)	Modem dialing wrong number Phone has 800/900 block	Program correct phone number. (Refer *Programming Your Monitor* section in this manual.) Check for block by dialing 1-800-679-2778. If you do not hear a sound similar to a fax, you may have an 800/900 block on the phone line. Either remove the block to allow the monitor to send data by modem; or set the monitor to *Page Only*.
305	MODEM_BAUD_RATE	Skytel baud rate lock failed		If problem persists, call Honeywell HomMed.
311	MODEM_LOGON	Skytel logon not accepted		If problem persists, call Honeywell HomMed.
312	MODEM_DISCONNECT	Skytel forced disconnect		If problem persists, call Honeywell HomMed.
313	MODEM_GO_AHEAD	Skytel go ahead not received		If problem persists, call Honeywell HomMed.
314	MODEM_ACKNOWLEDGE	Skytel packet reception not acknowledged		If problem persists, call Honeywell HomMed.
315	MODEM_RULE_VIOLATION	Skytel system rule violation		If problem persists, call Honeywell HomMed.
316	MODEM_LOGOFF	Skytel premature logoff initiated		If problem persists, call Honeywell HomMed.
320	PAGER_COMM	Pager self test failure		Call Honeywell HomMed.
321	PAGER_OUT_OF_RANGE	Pager is out of range		Set *Transmit Mode* to *Modem*.
322	PAGER_ERR_HARDWARE	Pager failure		Call Honeywell HomMed.
323	PAGER_ERR_TIMEOUT	TX took too long (>15 minutes)		Set *Transmit Mode* to *Modem*, and retake vitals. If problem persists, call Honeywell HomMed.
324	PAGER_MSG_FAIL	Message failed		If problem persists, call Honeywell HomMed.
410	GLUCO_TIMEOUT	User timeout -- glucose meter	Did not attach glucose meter to monitor in time.	Review the *Product Insert* that came with your glucose meter.
411	GLUCO_COMM	Glucose meter disconnected	Glucose meter cable not connected. Loose Connection.	Connect the cable. Make sure all connections are secure.

#	VFD Display	Meaning	Possible Cause	Resolution/Action
412	GLUCO_OFF	Glucose meter not enabled		In Options menu, set appropriate glucose meter to *On*.
413	WRONG_GLUCO	ID Card and monitor setup gluco-type mismatch		Program the card or the monitor for the correct glucose meter.
420	SPIRO_TIMEOUT	User timeout - spirometer	Did not attach the spirometer in time.	Review the *Product Insert* that came with your spirometer.
421	SPIRO_COMM	Spirometer disconnected	Spirometer cable not connected Loose connection	Connect the cable. Make sure all connections are secure.
412	SPIRO_OFF	Spirometer not enabled (no assigned COM port)	Prothrombin Meter	In Options menu, set appropriate spirometer to *On*.
430	PT_TIMEOUT	User timeout – PT/INR	Did not attach in Prothrombin (PT) device in time.	Review the *Product Insert* that came with your prothrombin meter.
431	PT_COMM	PT/INR disconnected	PT/INR cable not connected Loose connection	Connect the cable Make sure all connections are secure
412	PT_OFF	PT/INR not enabled (no assigned COM port)		In Options menu, set appropriate PT/INR to *On*.
440	ERROR_ECG_TIMEOUT	User timeout – ECG	Did not take an ECG reading in time. Did not attach in time.	Review the *Product Insert* that came with your ECG device.
441	ERROR_ECG_COMM	ECG disconnected	ECG cable not connected Loose connection	Connect cable. Make sure all connections are secure.
442	ERROR_ECG_OFF	ECG not assigned a COM port		In Options menu, set ECG to *On*
450	PEAKFLOW_TIMEOUT	User timeout – peak flow	Did not attach peak flow device in time.	Review the *Product Insert* that came with your peak flow meter.
451	PEAKFLOW_COMM	Peak flow discontinued	Peak flow cable not connected Loose connection	Connect the cable. Make sure all connections are secure
452	PEAKFLOW_OFF	Peak flow not assigned a COM port		In Options menu, set peak flow to *On*.
500	ERROR_ETHERNET			
600	ERROR_UNKNOWN_ CONNECT_ERROR	Unknown ISP connection error		
601	ERROR_TCP_ CONNECTION _REFUSED	Remote TCP Server refused connection		
602	ERROR_TCP_CONNECTION FUNKNOWN	Connection failed for unknown reason		
603	ERROR_PPP_LOGIN	User name or password was incorrect		

#	VFD Display	Meaning	Possible Cause	Resolution/Action
604	ERROR_MODEM_COM	Failed communications with modem		
605	ERROR_TCP_SERVER_COMS	Communications with server failed after connection established		
606	ERROR_TCP_CLOSED	Socket was closed by remote host		
607	ERROR_BAD_PIN	Pin number not recognized by server		
608	ERROR_BUSY_SIGNAL	Modem received a busy signal		
901	RAM_ERROR	RAM self test failed		Call Honeywell HomMed.
902	ROM_ERROR	ROM Checksum error		Call Honeywell HomMed.
903	UART_ERROR	Hardware error		Call Honeywell HomMed.
904	RTCC_ERROR	Real time clock failure		Call Honeywell HomMed.
910	ERROR_FILE_SYSTEM	Language text files missing or corrupt		Replace the SmartMedia card.
911	DISK_ERROR	SmartMedia failure		Replace the SmartMedia card.
912	DISK_ERROR_BAD_FORMAT	SmartMedia failure – bad format		Replace the SmartMedia card.
913	DISK_ERROR_NO_CARD	SmartMedia failure – card removed		Insert the correct SmartMedia card.
914	DISK_ERROR_BAD_CARD	SmartMedia failure – bad card		Replace the SmartMedia card.
915	DISK_ERROR_CHANGED_CARD	SmartMedia failure – card swapped		Reboot the unit; if problem persists, call Honeywell HomMed.
916	DISK_ERROR_CARD_FAILURE	SmartMedia failure – card failure		Replace SmartMedia card; if problem persists, call Honeywell HomMed.
930	PHOTOCARD TIMEOUT	No response – card removed or defective	Card removed before monitor could download images. Defective card	Review the Product Insert that came with device. Use new card, retake photo, resend.
931	PHOTOCARD FAILURE	Card not readable: damaged, wrong type		Use only SmartMedia cards for digital images. Use new card, retake photo, resend.
932	PHOTOCARD READ ERROR	Invalid CRC, parity error, etc.		Take another picture and resend. Use new card, retake photo, resend.
933	PHOTOCARD CONFIG BAD	Config. file (*.CFG) missing or contains invalid info		Use only appropriate SmartMedia cards for digital images. Use new card, retake photo, and resend.
934	PHOTOCARD PAT. ID BAD	Pt. ID file (*.PAT) missing or contains invalid info		Use new card, retake photo, and resend.
935	PHOTO NOT FOUND	No photos in photo directory		Take pictures and resend.

Additional References

Honeywell HomMed OTC Sentry Monitor Quick Reference Guide.
PXXXX Honeywell HomMed, 2006

Honeywell HomMed OTC Sentry Monitor Installation Sheet.
PXXXX Honeywell HomMed, 2006

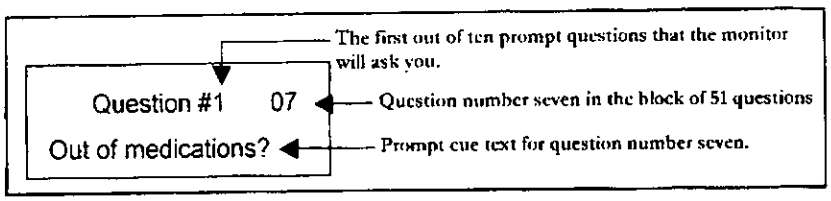
Honeywell HomMed OTC Sentry Monitor Service and Support Guide.
PXXXX. Honeywell HomMed, 2006

Honeywell HomMed OTC Central Station User Guide.
PXXXX Honeywell HomMed, 2006

For more information about authorized peripheral devices, refer to the individual manufacturer's **instruction sheet**, which came with the device.

Appendix A: Questions Text .....

The following fifty-one (51) questions are available for programming. Up to ten (10) may be programmed for a monitoring session.



Number	Questions
00	Off
01	Are you experiencing more difficulty breathing today compared to a normal day?
02	Are you more tired today compared to a normal day?
03	Have you been using your inhalers more than usual?
04	Did you need extra pillows to sleep comfortably last night?
05	Have you had to limit your activities more than usual?
06	Do you need your clinician to contact you today?
07	Are you out of any of your medications?
08	Are you having difficulty taking any of your medications?
09	Are you having difficulty following your diet?
10	Are you having any nausea today?
11	Are you having trouble controlling your blood sugar?
12	Are you having any pain?
13	Have you been having any chest pain?
14	Are you having any headaches?
15	Have your ankles been swollen more than usual?
16	Are you having any difficulty standing or walking?
17	Have you been having any new numbness or tingling?
18	Are you having any dizziness?
19	Have you noticed any bleeding today?
20	Have you noticed any new bruising today?
21	Are you having any trouble with urination?

Number	Questions
22	Are you having any trouble with your bowel movements?
23	Has your wound changed in size or color?
24	Have you noticed a change in odor from your wound?
25	Have you noticed a change in the drainage from your wound?
26	Have you had to use your nitroglycerin in the last day?
27	Have you had to use your oxygen in the last day?
28	Have you developed a cough?
29	Have you noticed a decrease in your appetite?
30	Are you having difficulty swallowing?
31	Have you had a fall in the last day?
32	Are you having difficulty taking care of your wound?
33	Have your hands or face been more swollen in the last day?
34	Has there been any protein in your urine in the last day?
35	Do you have severe heartburn today?
36	Have you noticed a decrease in your baby's movement today?
37	Have you had any blurred vision today?
38	Have there been any changes in the medication you are taking?
39	Are you having difficulty following your weight-loss plan?
40	Are you having difficulty following your exercise plan?
41	Do you feel more anxious or upset today?
42	Has your mood been more depressed this week compared to a normal week?
43	Are you having difficulty managing stress this week compared to a normal week?
44	Are you having difficulty following your smoking cessation plan?
45	Are you having difficulty following your alcohol reduction plan?
46	Are you having difficulty understanding your diagnosis?
47	Have you had 2 plus or greater protein in your urine today?
48	Have you been to the emergency room this week?
49	Were you admitted to the hospital any time this week?
50	Has your doctor added, deleted, or changed any of your medications this week?
51	Did you have an unexpected visit to your physician this week?

Appendix B: Sleep Apnea Questions.....

Sleep apnea questions are a single block of twelve questions that are either on or off. When turned on, the Sentry Monitor will go through **all** of the questions. The questions are listed below.

Number	Questions
1	Do you snore nearly every day?
2	Do you snore 3-4 times a week?
3	Have you been told that your snoring is louder than talking?
4	Can others hear your snoring in another room?
5	Has your snoring ever bothered other people?
6	Has anyone noticed that you quit breathing nearly every day during your sleep?
7	Has anyone noticed that you quit breathing during sleep 3-4 times a week?
8	Do you feel tired or fatigued today after your sleep?
9	Do you feel tired, fatigued, or not up to par during your wake time nearly every day?
10	Do you feel tired, fatigued, or not up to par during your wake time 3-4 times a week?
11	Do you nod off or fall asleep while driving a car nearly every day?
12	Do you nod off or fall asleep while driving a car 3-4 times a week?

Appendix C:
Honeywell HomMed Warranty Information

System Limited Warranty

For a period of five (5) years commencing with the receipt of the System Monitor and/or Supplier's standard System Receiver and for a period of one (1) year commencing with the receipt of the System MedPartner, Supplier warrants the Monitor, Supplier's standard System Receiver, the MedPartner and the Licensed Software, under normal use and service, to be free from defects in material and workmanship and to operate in accordance with the product specifications in the environment specified. If Customer elects to utilize Supplier's standard rack mount Receiver, the Receiver is warranted for three (3) years, from the date of receipt. If Customer elects to utilize a non-standard rack mount Receiver, the Receiver is only warranted for the period provided by manufacturer of the non-standard rack mount Receiver (herein "Warranty Period").

SUPPLIER DOES NOT WARRANT PRODUCTS NOT MANUFACTURED BY IT BUT ASSIGNS TO CUSTOMER, TO THE EXTENT POSSIBLE, ANY WARRANTY EXTENDED BY THE MANUFACTURER OF SUCH PRODUCTS TO SUPPLIER. THIS WARRANTY IS VOID IN CASES WHERE THE PRODUCT IS ALTERED, SERVICED OR REPAIRED BY ANYONE OTHER THAN SUPPLIER; NOT USED IN ACCORDANCE WITH THE OPERATING MANUAL; EXPOSED TO ENVIRONMENTS OUTSIDE OF ITS INTENDED USE; OR DAMAGED THROUGH NEGLIGENCE OR INTENTIONAL ACTS OF ANY PARTY OTHER THAN SUPPLIER.

Exclusion of Warranties

THE WARRANTY SET FORTH HEREIN IS IN LIEU OF ALL OTHER WARRANTIES WHETHER WRITTEN, ORAL, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Exclusive Remedies

In the event of a valid warranty claim, Supplier's entire liability, and Customer's exclusive remedy, shall be, at Supplier's option, either (i) to return the purchase price paid for the System, or (ii) to replace the defective component of the System. Customer must return the defective component to Supplier in accordance with the warranty claim procedure set forth below. Any replacement component provided by Supplier will be warranted for the remainder of the original Warranty Period. Outside the United States, this remedy is not available to the extent that Supplier is subject to restrictions under United States export control laws and regulations.

Warranty Claim Procedure

If Customer believes one or more components of the System is defective or working improperly ("Putative Defective Component"), Customer shall contact Supplier for technical support pursuant to the provisions of Paragraph 11 of the System Supply Agreement. Customer shall follow the instructions and exhaust the recommendations of Supplier's technical support team prior to making a warranty claim. In response to a warranty claim, Supplier shall deliver a replacement component in exchange for the Putative Defective Component which shall be returned to Supplier at Supplier's expense. If Supplier determines that the Customer's warranty claim with respect to the Putative Defective Component was valid, the warranty claim procedure ends; if Supplier determines that the Customer's Putative Defective Component was either (i) not defective or (ii) the defect was the result of an event which voided the Warranty, Customer shall be entitled to retain the replacement component, but shall be responsible to pay to the Supplier the shipping costs for the delivery of the replacement component and the return of the Putative Defective Component, plus the cost of repairs and a handling charge of $150.00, all of which will be separately invoiced to Customer by Supplier. **THE FOREGOING IS CUSTOMER'S SOLE AND EXCLUSIVE REMEDY IN THE EVENT OF A WARRANTY CLAIM.**

Appendix D: Peripheral Devices .....

The following is a list of peripheral devices, compatible with your Honeywell HomMed Sentry Monitor.

Peripheral Device	Manufacturers	Purpose
Weight Scale	Honeywell HomMed	Measures body weight
Finger Sensor	BCI/Smith	Measures oxygen saturation (SpO_2) and heart pulse rate
Temporal Scanner™	Exergen	Measures body temperature
Electrocardiogram Recorder (ECG)	HealthFrontier	The ECG, measures the electrical activity of the heart, and can detect normal or irregular heart rhythm.
Glucose Meter	LifeScan™ ▪ One Touch Basic ▪ One Touch Ultra ▪ One Touch Profile Bayer ▪ Ascensia Elite XL Roche ▪ Accu-Chek Advantage Home Diagnostics ▪ Prestige IQ	Measures blood-sugar levels of diabetic patients.
PiKo-1 Peak Flow Meter	Pulmonary Data Services (PDS)	Measures air flow, or peak expiratory flow rate (PEFR), of asthma patients.
Prothrombin Meter	International Technidyne Corporation (ITC)	Measures the Prothrombin Time (PT) or the clotting time of blood, for patients with prothrombin diseases
MicroDL Spirometer	Mirco Direct	Pulmonary Function Testing (PFT), screens for obstructive and restrictive lung diseases, and the effectiveness of therapeutic intervention
Digital Camera SmartMedia card	Various	Uploads digital images and transmits them to the Honeywell HomMed Central Station unit.

Glossary

A

AC Power Adapter: AC: Alternating Current, adapter that allows you to power your monitor or accessory device from a standard wall outlet.

AT Prefix Characters: Allows the of transmitting and service phone numbers.

Accessories, or Accessory devices Medical devices which came with your Honeywell HomMed OTC Sentry Monitor. These may include: Scale, Temperature Probe and Oximeter.

Account Numbers Your PIN number and Password (See *PIN number* and *Password*).

Ambient Light The surrounding light in a room or area, such as strong light coming through a window from the outside, or from a high-watt lamp.

Analog Phone Line A non-digital, traditional phone line.

Atrial Fibrillation Atrial fibrillation (See Defibrillation)

Automatic Self-running, self-operating function.

B

BCI/Smith BCI/Smith is the manufacturer of the *Ascensia Elite XL* Glucose Meter.

Bayer Bayer is the manufacturer of the *Oximeter* (SpO2) finger sensor.

BP Blood Pressure (See blood pressure).

Battery, Lithium If your monitor looses power accidentally, the Lithium battery allows the monitor to maintain, your settings, as well a time and date functions.

Blood Pressure The pressure of blood against your artery walls created by the pumping of a person's heart. Blood pressure is measured in *Systolic* and *Diastolic* measures usually written with the Systolic number over the Diastolic number, e.g.: 110/80 mm Hg.

Blood Pressure – Systolic The Systolic pressure is when the heart has just finished contracting (pumping). It is the first or top number of a blood pressure reading, e.g.: 110/80 mm Hg.

Blood Pressure – Diastolic	The Diastolic is pressure, is the pressure of the blood between heartbeats, when the heart is relaxed and filling with blood. It is the second or bottom number in a blood pressure reading, e.g.: 110/**80** mm Hg.
Blood Pressure Cuff	The blood pressure cuff is used take a blood pressure reading (Same as NIBP cuff).
Blood Sugar level	Level of sugar in your blood, **Hyperglycemia** refers to elevated blood sugar, while **Hypoglycemia** refers to low blood sugar. Blood sugar levels are measured through the use of a Glucose meter (See Glucose meter).

C

CE Mark	The letters 'CE' are an abbreviation of Conformité Européenne, (French for *European Conformity*). The CE mark is a mandatory European marking for product groups to indicate conformity with the essential health and safety requirements; and without the CE marking, a product may not be placed in the market within the European Union. (See the *Honeywell HomMed OTC Sentry Monitor Service and Support Guide*).
Calibration	Calibration is the act of verifying the proper operation of a medical device or system, including the receipt of accurate and correct test results.
Caller ID box	A device attached to a phone which identifies any incoming caller by name and phone number.
Card Reader	See SmartMedia Card (same as)
CAUTION (1)	Indicates that this action *may result in minor or moderate personal injury*. Visual signage includes the text: "**CAUTION**" in bold font, on a background color of Safety Yellow, with the Safety graphic of an exclamation mark in a black triangle ⚠ (per ANSI Z535.3-2002).
Caution (2)	Indicates that *may result in equipment or device damage*. Visual signage includes the text "CAUTION" in regular font (per ANSI Z535.3-2002).
Central Station Unit.	A personal computer to which data packets can be transmitted, and which is operated by a Homecare service or other medical professional to monitor your daily vital signs. This is not pertinent unless you are transmitting data packets. (See the *Programming for Transmission* section of this manual).
Customer Service	Honeywell HomMed Customer Service is available to assist you with any questions, problems or concerns about your Sentry Monitor. (See *Honeywell HomMed Customer Service* in the *Notes* section at the beginning of this manual).

D

Data Packet:	All of the individual vital signs collected in one monitoring session and transmitted to the Central Station.
Decompensation:	Cardiac decompensation is marked by dyspnea (sweating), venous engorgement (enlargement of vein), and edema (swelling).
Default Settings	Original factory installed settings.
Destination	See Programming ISP destination (same as)

Defibrillation Defibrillation or (electrical cardioversion) is a procedure in which a brief electric shock is given to the heart to reset the heart rhythm back to its normal, regular pattern (normal sinus rhythm). Defibrillation is often used as an emergency procedure to correct a fast heart rhythm that is causing low blood pressure, chest pain, or heart failure.

Defibrillator, – External, A device which delivers an electrical shock, usually through metal paddles or patches applied to the outside of the chest wall, in order to perform an electrical cardioversion or defibrillation. **NOTE: An undergoing external defibrillation while attached to the Sentry monitor, may cause damage to the Sentry monitor!**

Defibrillator, – Internal (ICD) The implantable cardioverter-defibrillator (ICD) is a small electrical device implanted in the chest, to correct ventricular tachycardia, ventricular fibrillation, and to restore a normal heartbeat. The ICD does this by delivering precisely calibrated electrical shocks. **NOTE: An ICD may cause the Sentry monitor to give poor reading of heart rate or pulse!**

Digital Camera Any electronic device that takes and stores digital images. (See SmartMedia card port).

Digital Phone Line A line which transmits phone calls digitally. Digital phone lines are not compatible with the Sentry monitor. (See the *Programming for Transmission* section of this manual).

Duplex Jack A device which allows **two** phone lines to be attached to a single phone outlet. (See the *Troubleshooting* section of this manual; or the *Honeywell HomMed OTC Sentry Monitor Installation Instruction Sheet* for further information).

E

ECG An electrocardiogram (also EKG) measures the electrical signals that control the rhythm of your heartbeat.

ecg@home The electrocardiogram recorder manufactured by Health Frontier.

Electromagnetic compatibility *Electromagnetic Compatibility* (EMC) refers to the correct operation of electrical equipment in the presence of electromagnetic disturbances generated from other different electrical equipment in the same environment.

Electrical Cardioversion (See *Defibrillation*, same as)

Error Code Error codes are displayed when there is a problem with your Sentry monitor. The error codes inform you or an authorized Service Technician of the possible cause of the problem. (See the *Error code table* of the *Troubleshooting* section of this manual for a complete list of error messages).

Exergen Exergen is the manufacturer of the Temperature Scanner™

F

Function keys *Function keys* are on the front panel of the monitor, and allow you to enter or exit menus, scroll up or down, and select menu options. (See the *Programming Your Monitor* section of this manual).

G

Glucose meter Device which measures the blood-sugar levels (glucose levels) of diabetic patients.

Glucose levels (Same as Blood Sugar levels)

H

Hazard Conventions The visual and verbal standard of communication hazardous situations that may result it serious injury, as set forth by the ANSI Criteria for Safety Symbols (ANSI Z535.3-2002). The three conventions that apply to the Sentry monitor are as follows: ***WARNING***, ***CAUTION*** and *CAUTION*.

Heart rate The heart pulse rate is the number of heart beats as measured per minute, e.g.: **60 per minute** equals a **heart rate of 60**. The Sentry monitor can measure heart rate via the NIBP cuff or Oximeter (SpO2) finger sensor.

Health Frontier Health Frontier is the manufacturer of the ecg@home™ Electrocardiogram (ECG) Recorder.

Home Diagnostics Home Diagnostics is the manufacturer of the *Prestige IQ* Glucose Meter.

Honeywell HomMed Manufacturer of the Sentry and Genesis monitors, and the accompanying accessory Weight Scale.

Hyperglycemia Occurs when the level of sugar, or glucose, in the blood climbs too high, and can be caused by insufficient insulin as with the case of diabetes (See *Blood Sugar Levels*).

Hypoglycemia Occurs when the level of sugar, or glucose, in the blood drops too low to fuel the body. Maybe caused by excess insulin (diabetic patients) or other metabolism disorder (See *Blood Sugar Levels*).

I

ICD Implantable Cardioverter-defibrillator (See *Defibrillator, – Internal*).

ID card Identification Card, used in a multi-person or Kiosk monitor setup. Allows an individual to access the monitor and take their vital signs.

Instruction Sheet Product information provided with each accessory device by the manufacturer. The instruction sheet contains product specifications, use instructions calibration, and cleaning information; as well as service and return shipping information specific to the device.

ISP (I_S_P_) Internet Service Provider, the internet service that permits the monitor to transmit data packets.

ISP Destination The internet address to which the monitor is transmitting the data packets.

ISP Mail Server The internet email provider through which the monitor transmits the data packets is routed.

ISP Settings Menu Menu for ISP Settings

ITC International Technidyne Corporation is the manufacturer of the Prothrombin Meter.

Images Image files (JPEG, TIF, BMP etc.) taken with a digital camera, uploaded via a SmartMedia card, and transmitted to the Central Station or [other]. (See SmartMedia Card)

K

Keypad Keys at the front of the Sentry monitor that allow you to use and program your monitor. (See the *Programming Your Monitor* section of this manual or the *Honeywell HomMed OTC Sentry Installation Instruction sheet for more information*).

Kiosk mode Same as a **multi-person system** (See multi-person system).

L

Local Gateway Mode *Local Gateway* allows the monitor to transmit data to a remote site such as an ISP mailbox used by a Central Station unit. Important only if you are transmitting data packets.

LifeScan™ LifeScan it the manufacturer of the *One Touch* line of Glucose Meters.

M

Mail Server See *ISP Mail Server* (same as)

Manual The Manual key allows you to reset the menu when programming your monitor (See *Programming Your Monitor* section of this manual).

Micro Direct Micro Direct is the manufacturer of the *Micro DL* Spirometer.

Modem Setting *Modem Setting* allows technicians to enter the Service menu. You do not need to enter this menu (Contact *Honeywell HomMed Customer Service* for further information).

Multi-person system Allows for **multiple persons** to take their vital signs from a single Sentry monitor, example: worksite kiosk). Each person using the Sentry monitor has their individual settings established when I.D. cards are assigned. Same as *Kiosk mode*

N

NIBP Non-Invasive Blood Pressure cuff: (See *BP cuff*).

NSR Normal Sinus Rhythm (See *Defibrillation*)

NDR No Data Received. An NDR can indicate a breakdown in communication or a mismatch between the monitor and Central Station report times.

O

Once-a-Day-Collection Collection of vital signs on a only **once per day** option. A programming option of the Sentry monitor (see the *Programming You Monitor* section of this manual).

Option Menu The Options menu allows you to program your Sentry monitor for any peripheral devices that you may wish to add (see the *Programming You Monitor* section of this manual).

Oxygen saturation The amount of dissolved oxygen in the blood flowing through the tiny blood vessels. (See Oximetry).

Oximeter A special sensor device to measuring the amount of oxygen in the blood (oxygen saturation or SpO2 levels); and is usually placed at the end of the finger, toe, or on the earlobe. **NOTE: The Sentry Oximeter is only placed at the end of the finger.**

Oximetry Oximetry is a medical test that uses a device called an oximeter to measure the amount of oxygen in the blood (oxygen saturation or SpO2 levels).

P

PDS Pulmonary Data Services is the manufacturer of the *PiKo-1* Peak Flow Meter.

PFT Pulmonary Function Testing (See *Spirometer*).

PIN Number Personal Identification Number;, used to identify your personal account for transmission of data packets to a Central Station Unit.

Pager A peripheral device, much like a standard electronic pager, which allows the transmission of data packets to a Central Station Unit, **without** an internet connection. (Contact *Honeywell HomMed Customer Service* for further information).

Pass-through phone connection A device allows the operation of a phone while still permitting a modem internet connection. (See *Troubleshooting* section of this manual; or the *Honeywell HomMed OTC Sentry Monitor Installation Instruction Sheet* for further information).

Password The user selected word which gives access to an electronic device, or program. (Also see the *Programming Your Sentry Monitor* section of this manual).

Password Menu The menu which allows access to the password protected area of programming for the Sentry monitor. NOTE: The Password menu **should not** be utilized except to access the options menu or under supervision of Honeywell HomMed Customer Service.

Password Protected (P) Programming area with restricted access (see *Password Menu*).

Peak flow meter A device which measures the air flow, or peak expiratory flow rate (PEFR), of asthma patients. (Also see *Spirometer*).

Perfusion The injection of fluid into a blood vessel in order to reach an organ or tissues, usually to supply nutrients and oxygen. **NOTE: Poor perfusion of fluid to the tissues may cause inconsistent pulse rate and SpO2 readings with the Sentry monitor.**

Peripheral devices Any medical devices which are compatible with your Sentry Monitor and that are authorized for use with the Sentry Monitor. *Peripheral devices* are available through Honeywell HomMed (See Appendix *D: Peripheral Devices*, for a complete list of compatible devices).

Phone coupler Connects two phone cords using to create a single cord.

Photocard Same as the SmartMedia Card (See *SmartMedia Card*).

Ports Ports on the Sentry monitor are for attaching the AC power adapter, accessory devices such as the NIPB cuff, Temperature probe etc., or to connect a telephone and internet line to the monitor. (See the *Honeywell HomMed OTC Sentry Installation Instruction Sheet* for more information.)

Ports, Isolated The isolated ports are the communication ports on the Sentry monitor dedicated for the accessory devices which came with your monitor. They are **SCALE**, **COM1**, **COM2**, and **COM3** ports. (See the *Programming Your Monitor* section of this manual, or the *Honeywell HomMed OTC Sentry Installation Instruction Sheet* for more information.)

Ports, Non-isolated The non-isolated ports on the Sentry monitor are those communication ports available for any compatible peripheral devices. They are **COM A**, **COM B**, and **COM C** ports. (See the *Programming for Transmission* section of this manual, or the *OTC Sentry Installation Instruction Sheet* for more information.)

Power strip The power strip allows to your to plug in your Sentry monitor, accessories and peripheral devices to a single power source. A power strip also protects the monitor and other sensitive medical devices from power surges and electrical storms.

Power up To "power up" means to turn on your Sentry monitor, accessories and peripheral devices.

Primary IP Address The *Primary IP internet Address* is the address to o which the Sentry monitor sends your data packet, this address is holds the data until it can be accessed by the Central Station unit. (See the *Programming Your Monitor for Transmission* section of this manual).

Programming *Programming* is setting the commands the Sentry monitor follows to take your vital signs and transmit data packets. (See the *Programming Your Monitor for Transmission* section of this manual).

Prompts, general The *General prompts* are visual text displays and audio clips that accompany a typical monitoring session. (For a list of all possible prompts, refer to the *Honeywell HomMed OTC Sentry Service and Support Guide, Appendix A: Prompt Text*).

Prompts, peripheral devices The *Peripheral device prompts* are visual text displays and audio clips that accompany specific peripheral devices, when included in a typical monitoring session. (For a list of all possible prompts, refer to the *OTC Sentry Service and Support Guide, Appendix A: Prompt Text*).

Prothrombin meters A device which measures the Prothrombin Time (PT) or the blood clotting time for patients with prothrombin diseases.

Pulse rate (Same as heart rate: see *Heart rate*).

Q

Questions The Sentry monitor will asks you a series of questions each time you take vital signs. (For a list of questions refer to the *Appendix A: Question Text* and *Appendix B: Sleep Apnea Questions* of this manual for a complete list of possible questions).

Question Menu The Question menu allows you to program the daily questions you wish the Sentry monitor to ask you each time you take vital signs. (See the *Programming Your Monitor* section of this manual).

R

RMA — *Return Material Authorization* (number) – The number issue by Honeywell HomMed Customer Service that allows you to ship your monitor back. (See the *Honeywell HomMed OTC Sentry Monitor Service and Support Guide*).

Report Time — The scheduled time each day when your Sentry monitor sends your data packet to the Central Station unit. (See the *Programming Your Monitor for Transmission* section of this manual).

Remote Gateway Mode — *Remote Gateway* allows the monitor to transmit data to a remote site other than an ISP mailbox. NOTE: Used normally for demonstration purposes only.

Retest Key — Use the **RETEST** key to return to the *Main* menu when programming your monitor. (See *Programming Your Monitor for Transmission* section of this manual).

Roche — Roche is the manufacturer of the *Accu-Chek Advantage* Glucose Meter.

S

SpO2 — Blood oxygen level (See *Oxygen saturation)*

Scales — Measures personal body weight.

Scheduling frequency — The frequency with which you take vital signs with the Sentry monitor, (see the *Programming Your Monitor* section of this manual).

Serial Mode — The *Serial Mode* setting allows you to program the monitor to download a copy of the data packet to a local personal computer (PC) before it transmits the packet to your assigned *ISP address* or to a *remote gateway*.

Service Menu — The Options menu allows an authorized Honeywell HomMed Service Technician to program your Sentry monitor for any necessary service. (Contact the *Honeywell HomMed Customer Service* for information on this option).

Sessions — (See Monitoring Sessions)

Setup Menu — The Setup menu allows you to begin programming your Sentry monitor. (See the *Programming Your Monitor* section of this manual).

Sleep apnea — Interruptions in breathing during sleep caused by a blocked airway, making breathing labored, noisy (loud snoring), and may stop breathing altogether. This nighttime breathe difficulties result in low levels of oxygen, and increased levels of carbon dioxide in the blood.

SmartMedia Card — Peripheral device which uploads, and transmits digital images to the Honeywell HomMed Central Station unit. Can be used with any digital camera. (Same as Videophone card).

SmartMedia Card port — Designated port on the Sentry monitor for the SmartMedia Card. (See the *Honeywell HomMed OTC Sentry Monitor Installation Guide*)

Spirometer A medical device on which to perform Pulmonary Function Testing (PFT). PFT testing screens for obstructive lung diseases, asthma, or for the effects of exposure to hazardous materials. It also tests for the effect of therapeutic intervention, such as inhalers, or breathing treatments.

System Settings menu The System Settings menu allows you to program the individual settings for taking vital signs on your Sentry monitor. (See the *Programming Your Monitor* section of this manual).

T

TDD Telecommunication Device for the deaf. Any device which attaches to a phone to enable hard of hearing persons to receive phone calls.

Temperature probe A device to measure the core body temperature.

Test message The Test Message allows you to **verify** or **test transmission** by sending an empty (null) test data packet to Central Station.

Timeout The time when your Sentry monitor stops prompting you to take a particular vital sign and when it records that vital sign as missing. When this occurs your monitor is said have "timed out" for that task. (See the *Programming Your Monitor* section of this manual).

Time Menu The Time menu allows you to program the date, time and frequency for taking vital signs on your Sentry monitor. (See the *Programming Your Monitor* section of this manual).

Transmit Menu The Transmit menu allows you to program the transmission settings for sending data packets to the Central Station unit. (See the *Programming Your Monitor for Transmission* section of this manual).

Triplex jack A device which allows **three** phone lines to be attached to a single phone outlet. (See the *Troubleshooting* section of this manual; or the *Honeywell HomMed OTC Sentry Monitor Installation Instruction Sheet* for further information).

V

Ventricular tachycardia Fast heart rhythm that starts in the lower part of the heart (ventricles). **NOTE: If left untreated may lead to ventricular fibrillation, which can be life-threatening!**

Ventricular fibrillation Irregular and rapid heart rhythm, causing uncoordinated contractions (squeezing) of the heart muscle. **NOTE: Can be life-threatening!**

Videophone Same as SmartMedia Card.

Vital Signs All of the individual vital signs collected in one monitoring session (including any peripheral devices). Same as *Data Packet*.

W

Wall outlet Any electrical wall outlet to which standard electrical appliances maybe plugged in.

WARNING ANZI Hazard convention: Indicates that this action *could result in death or serious personal injury*. Visual signage includes: the text "**WARNING**" in bold font, on a background color of Safety Orange, with the graphic of an exclamation mark on a black triangle ⚠ (per ANSI Z535.3-2002).

Warranty The guarantee given to the purchaser by a company stating that a product is reliable and free from known defects and that the seller will, without charge, repair or replace defective parts within a given time limit and under certain conditions. (See *Appendix C: Honeywell HomMed Warranty Information*).

Index

B

Blood pressure
inflation pressure 38

C

Central Station 2
Content overview 7
Copyright 2
Customer Service 2

E

Exiting menus and Setup Mode 19

G

General Information 7

H

Hazard Conventions 8

I

Intended Use 2

M

Manual
hazard conventions 8
information 8
Information 7
notices 2
overview 7
special conventions 8
Menus
Questions 31
Service 54
Transmit 45
Monitor
prompts 34

N

Notices 2

P

Password
entering 44
PIN and phone numbers 16
Programming
BP inflation settings 29
brightness 30
chart key 20
date format 23
Daylight Savings 24
dial type 46
entering a password 44
frequency options 19
keys 18
lanquage 28
menu chart 20
menu chart 21
menus 16
mode 18
monitor 16
phone numbers 16
PIN number 45
question time 32
Questions 47
Report Time (1-4) 24
serial mode 49
settings 26
Setup Mode 19
sleep apnea 33
subjective questions 31
temperature 26
the current date 22
the current time 22
the scale prompt 28
time format 23
Time menu 22
transmit mode 46
units 29
volume 26

Programming menu chart 20
Programming Your Sentry Monitor 16
Prompts 34
general 35
timing 34

R

Retest button 19

S

Safety information 8
Scheduling frequency options 19
Sentry menus 16
Setup mode 18
Special conventions 8
System Settings 26

T

Time Menu 22

V

Vitals
Blood Pressure 38
Voice prompts 34

Honeywell HomMed
OTC Sentry Monitor

Quick Reference Guide

P4XX.XX
May, 2006

103

Contacts for questions or problems

Problem	Contact
Medical emergency	**Your local Emergency Service:** _____
All other health related questions or problems	Your health care provider: _____
Equipment problems or related questions	Honeywell HomMed: (888) 353-5440

Name _____

Phone _____

Honeywell HomMed, LLC
3400 Intertech Dr., Suite 200
Brookfield, WI 53045
Phone: (262) 783-5840
Fax: (262) 252-5795
Toll Free: (888) 353-5404

Table of Contents

Table of Contents iii
Hazard conventions iv
Notes xii
Overview **13**
Physician-prescribed Plan of Care 13
At home health-monitoring system 13
Once your Sentry Monitor is programmed 14
Monitor keys **15**
Monitor Prompts **16**
General Prompts and Text Displays 16
Taking your vitals **19**
Using the blood pressure cuff 20
Using the scale 23
Using the SpO2 finger sensor (Oximeter) 25
Using the temperature probe 27
Other peripheral devices 28
Accidental spills **28**
Honeywell HomMed Customer Service 29
Vital signs chart **30**

Safety information

To prevent injury to yourself or damage to any equipment, please read and observe all the safety information in this section **before** you use the Sentry monitor.

The following chart explains the hazard conventions used in this manual.

Hazard conventions

Term	Level of risk	Definition
WARNING	Moderate	Could cause death or serious personal injury
CAUTION	Moderate	May result in minor or moderate personal injury
CAUTION	Minor	May result in equipment damage
NOTE	None	Important information

WARNING

NOT AN EMERGENCY RESPONSE DEVICE

The monitor is **NOT** an emergency device.

If you have a medical emergency, call your local Emergency Medical Service and your health care provider.

WARNING

ELECTRIC SHOCK

Some of the parts inside the monitor could shock you. The shock could be severe enough to cause death or serious injury.

DO NOT take the monitor apart.
DO NOT put the monitor in water or any other liquid.
ALWAYS UNPLUG the monitor before you clean it.
DO NOT try to fix the monitor.

If you have a problem with your Sentry monitor, call Honeywell HomMed Customer Service.

WARNING

NOT TO BE USED ON INFANTS

The monitoring equipment could cause serious injury if used on infants or small children.

DO NOT use any equipment on infants or small children.

WARNING

EXPLOSION HAZARD

This unit is powered with electricity and could ignite highly flammable gases (for example: Anesthetic, fuels etc.).

DO NOT use this device in the presence of explosive or flammable agents.

CAUTION

THE TEMPERATURE PROBE IS FOR ADULT, ORAL USE ONLY

Only adults (age 12 years and older) should use the temperature probe. Use the temperature probe only in your mouth.

DO NOT use the temperature probe on children.

DO NOT use the temperature probe to take rectal or axillary temperatures.

CAUTION

PERSONAL INJURY HAZARD: SCALE TIPS

Weight placed on the edge of the scale will cause the scale to tip and can cause you to fall.

DO NOT step onto the edge of the scale.

DO NOT stand on the edge of the scale.

CAUTION

PERSONAL INJURY HAZARD: NIBP Cuff

Verifying the calibration while the cuff is attached to you, (while wearing the cuff) could cause bruising or other injury.

DO NOT verify NIBP calibration while the cuff is attached to you.

CAUTION

NON-RECHARGABLE BATTERIES

Attempting to recharge the batteries could cause batteries to leak battery acid or over heat resulting in potential hazard to the user. It could also cause permanent damage to the unit.

DO NOT charge the batteries.

CAUTION

ELECTRICAL SHOCK

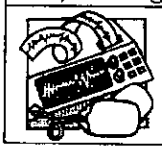
Using a spirometer while attached to the Sentry monitor could possibly result in receiving an electrical shock.

- **DO NOT attempt to take readings with a spirometer when it is connected to the Sentry monitor.**
- **Disconnect the spirometer before use.**
- **Always follow the manufacturer's instructions for proper use.**

CAUTION

NOT EXTERNAL DEFIBRILLATOR PROOF

Using the Sentry monitor while undergoing **external defibrillation** may damage the monitor or peripheral equipment.

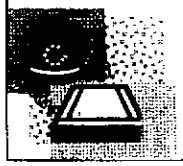


DO NOT use the monitor if undergoing defibrillation with an external defibrillator.

CAUTION

REQUIRES ANALOG PHONE LINE

The modem requires an analog phone line. A digital phone line will destroy the modem.



DO NOT connect the monitor to a digital phone line. If you want to move your monitor after setup, contact your health care provider.

CAUTION

SPILLAGE

Liquid spilled onto the monitor may cause damage to the monitor and may present a safety hazard to the user.

Should this monitor become wet, wipe off all moisture and allow sufficient time for drying before operating.

11C

CAUTION
BLOOD PRESSURE HOSE DAMAGE  Bending, kinking, or otherwise restricting the blood pressure hose can damage the hose or interfere with readings. **DO NOT bend or crimp the blood pressure hose. Keep the hose free from furniture or other objects that could bend or crush it.**

CAUTION
SENSITIVE EQUIPMENT Your monitor and the accessories that come with it are sensitive equipment. **DO NOT put the scale, temperature probe, blood pressure cuff, or any other accessory in water or other liquid.** **DO NOT drop the monitor.**  Call your Honeywell HomMed Customer Service if. . . ▪ Any liquid is spilled onto the monitor ▪ The monitor is dropped or damaged

CAUTION

SENSITIVE KEYPAD

Sharp or pointed objects may permanently damage the keypad.

DO NOT press keys with any object.

Use your fingers to press the monitor keys.

CAUTION

EQUIPMENT DAMAGE

Connecting the Honeywell HomMed scale to any device not mentioned in this manual could severely damage the scale or the connected equipment.

Connect your Honeywell HomMed scale **ONLY** to your Sentry 6-port monitor (6010000A1)

DO NOT connect the Honeywell HomMed scale to a Sentry 4-port (5020000A1) or any other device other than the ones specified in this manual.

CAUTION

ELECTROMAGNETIC COMPATABILITY

Electromagnetic compatibility of electrical equipment at very close distances to the Sentry has not been evaluated.

DO NOT use the Sentry adjacent to or stacked with other equipment. If it is necessary to do so, observe the monitor and verify normal operation prior to use.

CAUTION
INCORRECT AC POWER RATINGS CAN DAMAGE MONITOR Incorrect AC power ratings could damage the Sentry monitor.  **Ensure that the AC rating is correct for the AC voltage at your installation site before using the monitor. The AC rating is located on the AC power supply label. If the rating is not correct, do not use the monitor and Contact Honeywell HomMed Customer Service.**

CAUTION
USE ONLY HOMMED AUTHORIZED MEDICAL EQUIPMENT Attaching unauthorized equipment to the Honeywell HomMed Sentry monitor may cause damage or equipment failure, including increased emissions or decreased immunity of the Sentry monitor. Vital sign measurements may be inaccurate if unauthorized equipment is used with the Sentry monitor. **DO NOT attach unauthorized medical equipment to the Sentry monitor. When connecting this device to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions.** Any peripheral devices connected to the data interface must be certified according to the respective IEC standards. All combinations of equipment must comply with IEC 601-1-1 systems requirements. For a list of Honeywell HomMed equipment and compatible peripheral devices, see the Honeywell HomMed OTC Sentry Monitor Service and Support Guide.

Notes

Note the Oximeter (SpO_2) or Finger Sensor is a prescription only device! You may use only the Oximeter as part of Physician prescribed care plan.

The Oximeter sensor is **not meant for continuous monitoring** of SpO_2 levels (blood saturation); no alarms are provided.

Overview

The Honeywell HomMed Sentry monitor includes the monitor, blood pressure cuff, temperature probe and scale. You may also have the following accessory device: SpO_2 Finger Sensor (Oxygen saturation sensor).

The Sentry monitor either can be, a stand-alone home health monitoring system; or incorporated into part of a physician-prescribed Plan of Care.

Physician-prescribed Plan of Care

If you are under a physician-prescribed Plan-of-Care, your clinician sets up the Sentry monitor so that you can easily use it every day.

After the Sentry monitor collects your information, it sends it to your health care provider. The entire process takes only a few minutes, and all of your information is confidential.

At home health-monitoring system

If you purchased the Sentry Monitor, you will be able to setup your own at home health-monitoring system. To program your Sentry Monitor, please refer to your *Honeywell HomMed OTC Sentry Monitor Operator's Guide.*

Once your Sentry Monitor is programmed

- Your Sentry monitor will start monitoring sessions at the same time(s) every day.
- Your Sentry monitor will let you know when it is time to collect your vital signs.
- Voice prompts and text on the monitor face guide you through each step.
- The volume of the voice prompts is adjustable, so if you have difficulty hearing the prompts.

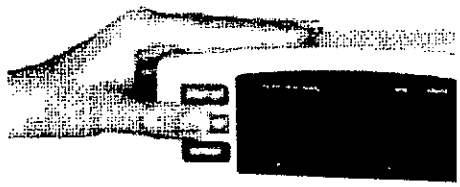
When the Sentry monitor is part of your overall health plan, whether as a personal home health monitoring system; or as part of a physician-prescribed Plan of Care; the Sentry monitor may help you live a more active lifestyle and reduce Emergency Department visits and unnecessary hospital stays.

Monitor keys

There are six keys on the front of the monitor. To learn what each key does when you press it, look at the following table.

Press this key	To
STOP BP	**Stop** the blood pressure cuff inflation.
START BP	**Start** the blood pressure cuff inflation.
RETEST	Take your vitals and **send** them to your health care provider.
YES	Answer "yes" to a question.
NO	Answer "no" to a question.
MANUAL	Take your vitals **without sending** them to your health care provider. **NO VOICE PROMPTS**

When you press the monitor keys, hold the top of the monitor with your fingers and use your thumb to press the keys. The picture below shows you the correct way to press the keys.



Monitor Prompts

The monitor uses friendly voice prompts and easy-to-read text prompts to guide you through each step of the monitoring session. Text cue prompts display in the monitor's display panel at the same time that the audio prompt plays.

General Prompts and Text Displays

The following list describes the basic prompts and text displays, for a typical monitoring session. For a list of all possible prompts, refer to Appendix *A: Prompt Text*, of the *Sentry OTC Service and Support Guide*.

1. The monitor says a greeting and announces that it is time to take your vital signs.

   Cue text: `Good Morning` (Afternoon, Evening).

2. The monitor will instruct you to stand on the scale. (If the scale is not attached, the monitor skips this prompt.).

   Cue text: **Step on the scale**

3. After your weight has been recorded the monitor prompts you step off the scale and sit down on a chair in front of the monitor. **Wait for the prompt to ensure that weight is collected!**

   Cue text: Step off the scale Weight results display by the scale symbol.

4. A voice prompt will instruct you to place the blood pressure cuff on your right arm above the elbow and tighten it securely.

   Cue text: Put cuff on arm

5. An additional blood pressure prompt will instruct you to rest their arm as instructed.

   Cue text: Rest arm as instructed

6. The unit will instruct you to place the finger probe (sensor) on the middle finger of your left hand with the finger design facing up.

   Cue text: Put sensor on finger **(pulsing bar graph also displays)**

7. The unit will then prompt you to press the **START BP** key.

   Cue text: Press Start

   Real-time inflation and deflation pressures display while the monitor measures blood

pressure. When done, the monitor displays the blood pressure readings, heart rate, and oxygen saturation (SpO2) readings.

8. The monitor will instruct you to remove the sensor and blood pressure cuff.

   Cue text: `Remove sensor and cuff`

9. The monitor then asks your selected questions, requesting that you press either the **YES** or **NO** key in response.

   Cue text: [Cue text for each question]

10. The Sentry monitor will then remind you to continue with prescribed medications and diet, and then thanks you for completing your vital signs.

    Cue text:
    `Thank you` **`and then`** `Transmitting`

11. Your data is then transmitted automatically. If the transmission is successful, the display reads, "`Transmission success.`"

12. The Sentry monitor continues to display your weight, blood pressure, oxygen saturation (SpO2), and if collected, temperature for five minutes to allow you to record your vitals if you wish. To clear the display and return to idle mode right away, press the **START BP** key, the **STOP BP** key, the **YES** key, or the **NO** key once.

Taking your vitals

Before taking your vitals, make sure that you can reach each piece of the equipment and the monitor keys from your chair (or bed) without stretching.

For stability, sit completely on the chair seat or fully on the bed. **Do not** sit on the edge.

Using the blood pressure cuff

Before you start, make sure that…

- The blood pressure hose: is not kinked, compressed, or in any way restricted.
- That you are using the proper cuff size and are placing the cuff correctly on your arm.
- That the arm you use is bare or only has light clothing covering it. **Do not** wear a heavy sweater or coat.
- That you rest your arm on a level surface; and **do not move** or **talk** until the monitor completes your reading.

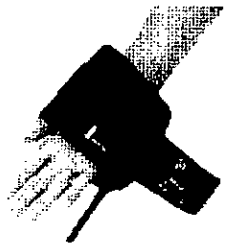
! The blood pressure cuff maybe used either, on the right, or left arm. However, it is important that you **use the same arm,** each time you take a blood pressure reading; however if you cannot use the usual arm, **you may use the other arm**.

If you cannot use the usual arm for some reason, you may use **the other arm**.

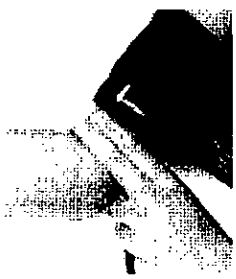
Be sure you are using the proper cuff size and are placing the cuff correctly on your arm.

Placing the blood-pressure cuff

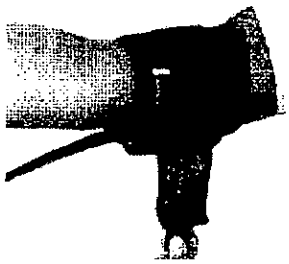
1. Hold the cuff so that the artery marker (white arrow) points away from you.
2. With our palm facing upwards, slip your hand through the cuff.



3. Position the cuff so that the artery marker arrows point to your ring finger and slide the cuff up your arm over your elbow. There should be about a two-finger space between the crease in your elbow and the cuff.



4. Grasp the tab and pull down to tighten the cuff. **Do not** make the cuff too tight. You should be able to slide your finger between your cuff and your arm.



5. Wrap the cuff end under and around your arm and fasten it to the Velcro.
6. Rest your arm on a level surface. **Do not** move or talk until the monitor completes your reading.

! You can stop the inflation of the blood pressure cuff **at any time** by pressing the red **STOP BP** key. To restart inflation, press the green **START BP** key.

If the monitor cannot obtain a blood pressure after **two attempts**, the monitor displays an error.

Using the scale

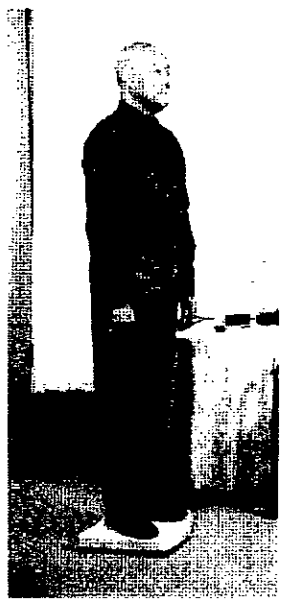
When you step onto the scale, place your feet towards the center of the scale, not on or near the edge. **Do not** move while the scale collects your weight.

Standing on the scale

1. When the voice prompts instructs you, step onto the scale.
2. Stand still until the monitor prompts you to step off the scale.

You must be able to stand on a scale **without support** for the time that it takes the monitor to collect a weight.

Always step or stand in the **middle of the scale**, and **DO NOT** step or stand on the edge, which will cause the scale to tip and possibly cause you to fall.



Be sure to…

You must be able to stand on a scale without support for the time that it takes the monitor to collect a weight. If you are not able to stand on a scale **without support**, disconnect the scale and turn the scale prompt off.

Using the SpO2 finger sensor (Oximeter)

Attach a finger sensor to your monitor if you need to collect SpO_2 (Oxygen saturation) readings. You'll know if the oximeter is properly placed, when the pulse bar on the monitor display shows a **strong pulse** while collecting the SpO_2 reading.

The Oximeter is a prescription only device! You may only use the Oximeter as part of **Physician prescribed care plan.**

The Oximeter sensor, or Finger Sensor, is not meant for continuous monitoring of SpO_2 levels (blood saturation); no alarms are provided.

Dark finger nail polish or false nails may interfere with the reading. If you cannot get a reading, remove finger nail polish, and try again.

Be sure to…

- Always place the sensor on the hand opposite the arm you use for your blood pressure measurement.
- Remain still, this ensures an accurate reading, once the monitor starts take your SPO_2 reading.

Placing the finger sensor

1. Hold the finger sensor so that the raised design is on top

2. Gently insert your finger into the sensor. If necessary, open the sensor by squeezing it similar to opening a clothespin.
3. Follow the monitor voice prompts.

Using the temperature probe

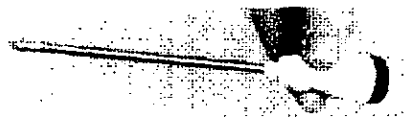
Attach a temperature probe to your monitor if you need to take your temperature.

Be sure to...

- Always use a temperature probe cover.
- Hold the probe in place by hand and not with the mouth.
- Wait until ready to take your temperature before removing the probe from the holder.

Placing the temperature probe

1. Remove the temperature probe from its holder.
2. Hold the probe in the indent as shown in the figure below, and push the probe firmly into a probe cover. The **blue** end separates as the probe cover slides into place.



3. Place the probe under your tongue and close your mouth. Hold the probe still with your hand. **DO NOT bite the probe.**
4. When the monitor prompts you, remove the probe from your mouth.

5. Push the **blue** end of the temperature probe to release the probe cover, and throw the cover away.
6. Replace the temperature probe **firmly** into the storage channel.

Other peripheral devices

For more information on other peripheral devices, refer to your *Honeywell HomMed OTC Sentry Monitor Operator's Guide*, or the **instruction sheet** for your specific device.

If you are transmitting, test results from other peripheral medical devices (e.g. a glucose meter), wait for the prompt and then attach your device.

Accidental spills

If you spill liquid on the monitor or scale:

1. Unplug the monitor from your wall outlet.
2. Wipe up the spill with a clean, soft cloth. Let the monitor dry completely.
3. Once completely dry, plug the monitor back into your wall outlet.

Honeywell HomMed Customer Service

Call Honeywell HomMed Customer Service right away if...

- The spill was more than a few drops.
- Liquid seeped inside the unit.

For routine maintenance such as cleaning and inspection of your Sentry monitor and accessory equipment, please refer to your *Honeywell HomMed OTC Sentry Monitor Operator's Guide.*

Vital signs chart

Use the following chart to record your vital signs.

Date	Weight	Blood pressure	Heart rate	SpO_2	Temp.[1]

[1] This feature optional for Sentry model monitor.

Date	Weight	Blood pressure	Heart rate	SpO_2	Temp.

Date	Weight	Blood pressure	Heart rate	SpO_2	Temp.

Date	Weight	Blood pressure	Heart rate	SpO_2	Temp.

Date	Weight	Blood pressure	Heart rate	SpO_2	Temp.

Honeywell HomMed
OTC Sentry Monitor

Service and Support Guide

Honeywell HomMed

Notices

Customer Service	*Honeywell HomMed®, LLC* 3400 Intertech Drive, Suite 200 Brookfield, Wisconsin 53045 *Toll-free:* (888) 353-5404 *Phone:* (262) 783-5840 *Fax:* (262) 252-5795 *Web:* http://www.hommed.com/
Copyright	
Trademarks	HomMed® is a registered trademark of Honeywell HomMed, LLC.
Intended Use	The Honeywell HomMed OTC Sentry Monitor designed to retrospectively measure vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Honeywell HomMed Sentry 6 Port Health Monitoring System's measurement capabilities. Data from the Sentry Monitor can be transmitted via a communication module to a central viewing station for display. The Honeywell HomMed OTC Sentry Monitor is not intended for emergency use or real-time monitoring. Healthcare professionals are responsible for the interpretation of all monitored data. Sentry Monitor is not intended for emergency use or real-time monitoring.
Device Information	Serial Number: _____ Part Number :_____

Numbers Required For Transmission of Data Packets Only.

Account Numbers	Pass Word: _____ PIN Number: _____
Transmission Numbers	Transmit Phone Num.: _____ ISP1 Phone Number: _____ ISP2 Phone Number: _____ ISP3 Phone Number: _____ ISP4 Phone Number: _____
Modem Settings	Modem Number: _____

Table of Contents

Notices 2
Table of Contents 3
General Information 6
Content overview 6
Safety Information 6
Special Conventions 7
Honeywell HomMed Customer Service 8
Repairing equipment 8
Shipping equipment back to Honeywell HomMed 9
Hazard Conventions 9
Notes 15
CE Mark 15
Additional References 15
Equipment Overview 16
The Sentry Monitor 16
Monitor ports 18
Side ports 19
Lithium battery 20
Other system equipment 21
Scales 21
NIBP 21
Oximeter 22
Power supply and strip 22
Peripheral Devices 23
ecg@home 23
Overview 24
Safety information 24
Assigning a com port 25
The ecg@home device 25
Attaching the ecg@home cable 26
Replacing the batteries 26
Cleaning the ecg@home 27
Specifications 27
Glucose Meters 28
Overview 28

Safety information 29
Assigning a com port 29
Attaching the glucose connector cable 29
Peak Flow Meters 32
Overview 32
Safety information 32
Assigning a com port 32
Attaching the peak flow meter cradle to the Sentry Monitor 33
Prothrombin Meters 33
Overview 34
Safety information 34
Assigning a com port 34
Attaching the prothrombin meter connector cable 35
Spirometers 35
Overview 35
Safety information 36
Assigning a com port 36
Attaching the spirometer connector cable 36
Routine Maintenance **37**
Cleaning 37
Cleaning the Sentry Monitor and peripheral devices 37
Cleaning the NIBP cuffs 37
Inspection 38
Calibration verification 38
Scale calibration verification 39
NIBP cuff calibration verification 39
Optional finger sensor calibration verification 40
Honeywell HomMed Customer Service 40
Repairing equipment 40
Shipping equipment back to Honeywell HomMed 41
Peripheral Devices 42
Additional Information 42
Appendix A: Prompt Text **43**
Appendix B: Sentry System Supplies **45**
Appendix C: Specifications **47**
Sentry Monitor specifications 47
Physical 47
Power 47
Environment 47
Languages 47
Pager 48

Modem 48
Non-Invasive Blood Pressure (NIBP) Cuff 48
Oximeter module 49
Heart rate (oximeter) 49
Heart rate (via NIBP Cuff) 49
Pulse Strength (via Oximeter) 50
Scale 50
Appendix D: Electromagnetic Guidances 51
Guidance and Manufacturer's Declaration – Electromagnetic Emissions 51
Guidance and Manufacturer's Declaration – Electromagnetic Immunity 52
Guidance and Manufacturer's Declaration – Electromagnetic Immunity 53
Separation Distances Between Portable and Mobile RF Communications Equipment and the Sentry Monitor 54
Index 55

General Information

Content overview

The following chart provides a brief overview of the sections in the manual.

Section	Overview
General Information	Describes the content overview, safety conventions, special conventions, safety notes, hazard conventions, customer support information, and additional references.
Equipment Overview	Provides an explanation of each component of the Sentry Monitor. Also included is information on accessory devices: scale, NIBP cuff, and temporal probe.
Peripheral Medical Devices	Provides an overview of each comparible accessory device (peripheral devices or PMD), available for the Sentry Monitor. Included are the ecg@home device, all compatible Glucose meters, Oximeter, Peak Flow meter, Prothormbin meter, and Spirometer.
Taking Your Vitals	Provides important information about how the monitor works; and explains how to take your vital signs, including: blood pressure, weight; temperature, and blood-oxygen levels. Also contains information on taking vitals from Peripheral Devices .
Routine Manitance	Provides information on cleaning, calibration and routine maintenance for the Sentry Monitor and accessory devices.
Appendixes	Provides additional reference information: Prompt text list, Sentry Supplies, Specifications, and Electromagnetic Guidances.
Glossary	Provides a list of definitions of the commonly used words and terms, used in this manual.
Index	Allows you to locate information using key words

Safety Information

To prevent injury to yourself or damage to any equipment, please read and observe all the safety information in this section **before** you install the Sentry Monitoring System.

The following chart explains the hazard conventions used in this manual. Serious personal injury implies permanent impairment or any injury that requires medical or surgical intervention to preclude permanent impairment.

Special Conventions

The following table lists the conventions used in this manual.

This Convention	Identifies
Function font	Keys that you press on the keypad
+ sign between key names	Keys that you press simultaneously **STOP BP + YES**
Courier font	Text that displays in the front panel display
Italics	Menu names, publication titles, or references to sections of this binder
!	Critical information
	A note that provides an important piece of information
	A tip that will help you work faster or more efficiently

Honeywell HomMed Customer Service

The goal of Customer Service is to do everything possible to support you in meeting the needs of your clients. We are available 24/7, and we will work quickly to resolve issues.

When you call, please have this manual and a copy of the *Honeywell HomMed Monitor Field Reference* handy. We will walk you through various troubleshooting techniques to assist you in identifying causes and resolutions.

A Customer Service Representative will make every attempt to resolve the issue over the phone. However, if equipment must be sent back, we will issue a Return Material Authorization (RMA) number. For shipping instructions, please refer to Shipping equipment back to Honeywell HomMed.

Toll-free: 888-353-5404
Phone: 262-252-5840
Fax: 262-252-5795
Web: www.honeywell.com

Repairing equipment

Honeywell HomMed recommends that authorized repair centers make all repairs for the monitor and all of its accessories. Repairs made by unauthorized personnel will invalidate your warranty. For product warranty information, please refer to your Honeywell HomMed contact.

If any equipment needs repair, contact Customer Service and explain which piece of equipment needs repair (monitor, scale, or accessory) and what the problem is. If the damaged item is a monitor or a scale, have the **model and serial number** ready to give the Customer Service Representative when you call.

- Monitor model and serial numbers are located on the bottom of the monitor.
- Scale model and serial numbers are located on the side of the scale.

For repair of peripheral devices, contact the manufacturer of the device.

Shipping equipment back to Honeywell HomMed

If Customer Service requests that you ship equipment back to Honeywell HomMed, please follow the directions below.

1. Carefully pack the equipment in the original box. If you do not have the original box, you may use any sturdy box that allows at least a one-inch clearance around the equipment for packing materials.
2. When Customer Service gives you an RMA number, include it on the outside of the shipping container.
3. Ship to the following address:

   RMA #
   Customer Service Department, Repairs
   Honeywell HomMed
   3825 Ohio Ave.
   St. Charles, IL 60174

Hazard Conventions

Term	Level of risk	Definition
WARNING	Moderate	Could cause death or serious personal injury
CAUTION	Moderate	May result in minor or moderate personal injury
CAUTION	Minor	May result in equipment damage
NOTE	None	Important information

WARNING

NOT AN EMERGENCY RESPONSE DEVICE

The monitor is NOT an emergency device.

If you have a medical emergency, call your local Emergency Medical Service and your health care provider.

1ST DRAFT:

WARNING

ELECTRIC SHOCK

Some of the parts inside the monitor could shock you. The shock could be severe enough to cause death or serious injury.

DO NOT take the monitor apart.

DO NOT put the monitor in water or any other liquid.

ALWAYS UNPLUG the monitor before you clean it.

DO NOT try to fix the monitor.

If you have a problem with your monitor, call Honeywell HomMed Customer Service

WARNING

NOT TO BE USED ON INFANTS

The monitoring equipment could cause serious injury if used on infants or small children.

DO NOT use any equipment on infants or small children.

WARNING

EXPLOSION HAZARD

This unit is powered with electricity and could ignite highly flammable gases (for example: Anesthetic, fuels etc.).

DO NOT use this device in the presence of explosive or flammable agents.

CAUTION

THE TEMPERATURE PROBE IS FOR ADULT, ORAL USE ONLY

Only adults (age 12 years and older) should use the temperature probe. Use the temperature probe only in your mouth.

DO NOT use the temperature probe on children.

DO NOT use the temperature probe to take rectal or axillary temperatures.

CAUTION

PERSONAL INJURY HAZARD: SCALE TIPS

Weight placed on the edge of the scale will cause the scale to tip and can cause you to fall.

DO NOT step onto the edge of the scale.

DO NOT stand on the edge of the scale.

CAUTION

PERSONAL INJURY HAZARD: NIBP Cuff

Verifying the calibration while the cuff is attached to you, (while wearing the cuff) could cause bruising or other injury.

DO NOT verify NIBP calibration while the cuff is attached to a patient.

CAUTION

NON-RECHARGABLE BATTERIES

Attempting to recharge the batteries could cause batteries to leak battery acid or over heat resulting in potential hazard to the user. It could also cause permanent damage to the unit.

DO NOT charge the batteries.

CAUTION

ELECTRICAL SHOCK

Using a spirometer while attached to the Sentry Monitor could possibly result in receiving an electrical shock.

- **DO NOT attempt to take readings with a spirometer when it is connected to the Sentry Monitor.**
- **Disconnect the spirometer before use.**
- **Always follow the manufacturer's instructions for proper use.**

1ST DRAFT:

CAUTION

NOT EXTERNAL DEFIBRILLATOR PROOF

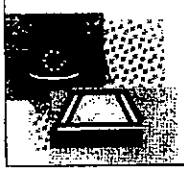
Using the Sentry monitoring system while undergoing **external defibrillation** may damage the monitor or peripheral equipment.

DO NOT use the monitor if undergoing defibrillation with an external defibrillator.

CAUTION

REQUIRES ANALOG PHONE LINE

The modem requires an analog phone line. A digital phone line will destroy the modem.



DO NOT connect the monitor to a digital phone line. If you want to move your monitor after setup, contact your health care provider.

CAUTION

SPILLAGE

Liquid spilled onto the monitor may cause damage to the monitor and may present a safety hazard to the user.

Should this monitor become wet, wipe off all moisture and allow sufficient time for drying before operating.

CAUTION

BLOOD PRESSURE HOSE DAMAGE

Bending, kinking, or otherwise restricting the blood pressure hose can damage the hose or interfere with readings.

DO NOT bend or crimp the blood pressure hose. Keep the hose free from furniture or other objects that could bend or crush it.

CAUTION
SENSITIVE EQUIPMENT Your monitor and the accessories that come with it are sensitive equipment. **DO NOT put the scale, temperature probe, blood pressure cuff, or any other accessory in water or other liquid.** **DO NOT drop the monitor.**  Call your Honeywell HomMed Customer Service if. . . ▪ Any liquid is spilled onto the monitor ▪ The monitor is dropped or damaged

CAUTION
SENSITIVE KEYPAD  Sharp or pointed objects may permanently damage the keypad. **DO NOT press keys with any object.** Use your fingers to press the monitor keys.

CAUTION
EQUIPMENT DAMAGE Connecting the Honeywell HomMed scale to any device not mentioned in this manual could severely damage the scale or the connected equipment.  Connect your Honeywell HomMed scale **ONLY** to your Sentry 6-port monitor (6010000A1) **DO NOT** connect the Honeywell HomMed scale to a Sentry 4-port (5020000A1) or any other device other than the ones specified in this manual.

1ST DRAFT:

CAUTION

ELECTROMAGNETIC COMPATABILITY

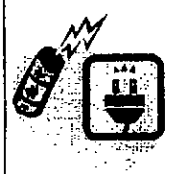
Electromagnetic compatibility of electrical equipment at very close distances to the Sentry has not been evaluated.

DO NOT use the Sentry adjacent to or stacked with other equipment. If it is necessary to do so, observe the monitor and verify normal operation prior to use.

CAUTION

INCORRECT AC POWER RATINGS CAN DAMAGE MONITOR

Incorrect AC power ratings could damage the Sentry monitor.



Ensure that the AC rating is correct for the AC voltage at your installation site before using the monitor. The AC rating is located on the AC power supply label. If the rating is not correct, do not use the monitor and Contact Honeywell HomMed Customer Service.

CAUTION

USE ONLY HOMMED AUTHORIZED MEDICAL EQUIPMENT

Attaching unauthorized equipment to the Honeywell HomMed Sentry monitor may cause damage or equipment failure, including increased emissions or decreased immunity of the Sentry monitor.

Vital sign measurements may be inaccurate if unauthorized equipment is used with the Sentry monitor.

DO NOT attach unauthorized medical equipment to the Sentry monitor. When connecting this device to any instrument, verify proper operation before clinical use. Refer to the instrument's user manual for full instructions.

Any peripheral devices connected to the data interface must be certified according to the respective IEC standards.

All combinations of equipment must comply with IEC 601-1-1 systems requirements.

For a list of Honeywell HomMed equipment and compatible peripheral devices, see the Honeywell HomMed OTC Sentry Monitor Service and Support Guide.

ISO

Notes

- Blood pressure measurements may not be accurate for those people experiencing moderate to severe **arrhythmias**, or who suffer from with **tremors**.
- Any condition that restricts blood flow, such as use of a blood pressure cuff, extremes in systemic vascular resistance (blood flow), or low perfusion (blood saturation) may cause difficulties in obtaining an accurate pulse reading.
- Dashes displayed in any parameter indicate the measurement is invalid or unavailable.
- The Oximeter (SpO2 senosor) is a **prescription only device**. You may use only the Oximeter as part of Physician prescribed care plan.
- The Honeywell HomMed scale is not a stand-alone device. The scale must be connected to a Sentry 6-port (6010000A1).

CE Mark

Marking by the symbol CE 0 indicates compliance of this device to the Medical Device Directive 93/42/EEC.

Authorized Representative:

MDSS
Burckhardtstr. 1
30163 Hannover
Germany

Additional References

Honeywell HomMed OTC Sentry Monitor Operator's Manual.
PXXXX Honeywell HomMed, 2006
Honeywell HomMed OTC Sentry Monitor Quick Reference Guide.
PXXXX Honeywell HomMed, 2006
Honeywell HomMed OTC Sentry Monitor Installation Guide.
PXXXX Honeywell HomMed, 2006
Honeywell HomMed OTC Sentry Monitor Central Station User Guide.
PXXXX Honeywell HomMed, 2006

For more information about authorized peripheral devices, refer to the individual manufacturer's **instruction sheet**, which came with the device.

Equipment Overview

When you receive your shipment from Honeywell HomMed, carefully remove each piece of equipment from the box. Save the carton and packing materials in case you need to return any of the contents. As you inventory the contents of the box, check each piece of equipment for damage. If anything is damaged or missing, contact Customer Service. Your package should include the following items:

- Sentry Monitor
- Scale and scale cable
- Blood pressure cuff
- Blood pressure hose
- Temporal Probe
- Oximeter (SpO2) Finger Sensor
- Phone cord and duplex jack
- AC adapter (power supply)
- Power strip

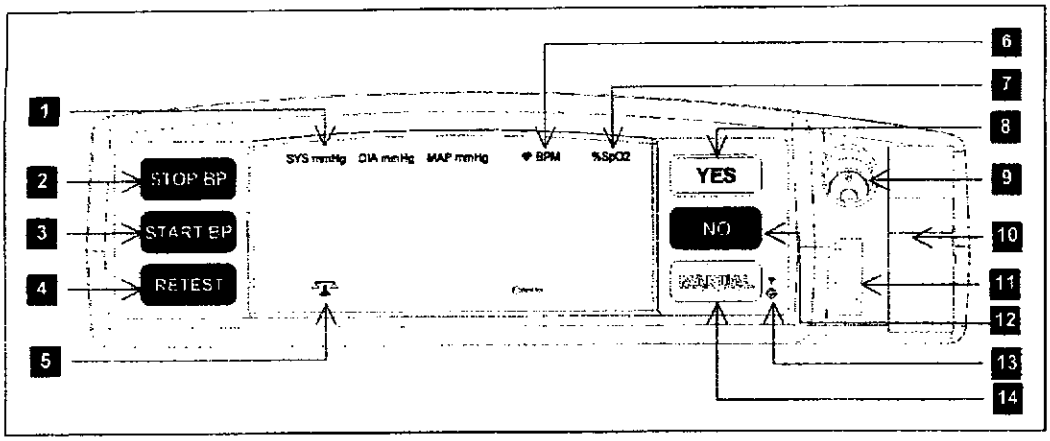
The Sentry Monitor

The front of the monitor has a vacuum fluorescent display (VFD) surrounded by six function keys. Each key is labeled and color-coded for easy visual identification. When you press the keys correctly, the monitor beeps. The volume of the beep matches the volume of the voice prompts.

The panel displays messages, bar graphs, and menus in a light font against a dark background for easy reading.

If the monitor has programmed report times, the current day, date, and time display randomly over the display face when the monitor is idle. If the monitor is programmed for multi-person use, then a prompt to swipe an ID card displays instead of the current time.

The figure below and the following chart explain the monitor features and key functions.



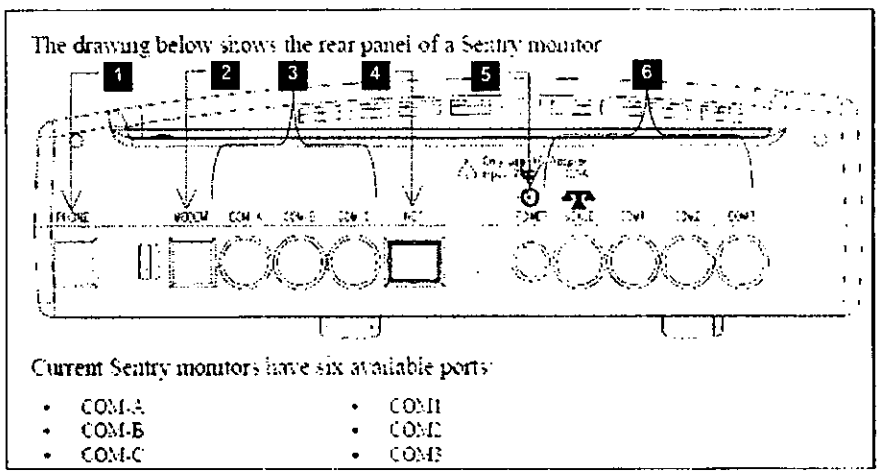
#	Feature	Function
1	SYS/DIA/MAP	Displays the systolic, diastolic, and mean arterial pressure in mmHg
2	Red STOP BP key	Stops BP reading and deflates the cuff; enters/exits Setup Mode (with **YES** key)
3	Green START BP key	Starts a BP reading
4	Blue RETEST key	Starts an unscheduled monitoring session; exits a menu in Setup Mode
5	Scale	Displays weight
6	BPM (with heart)	Displays the pulse rate. If optional Sp02 is attached, a pulse strength bar appears next to the pulse rate number during Sp02 collection. There is no auditory pulse beep.
7	%SpO2	Displays oxygen saturation measurement (for optional device)
8	White YES key	Records a "yes" answer; enters/exits Setup Mode (with **STOP BP** key); scroll key in Setup Mode
9	Storage Channel	Temporal Probe storage channel.
10	Cover Storage Channel	Temporal Probe cover storage channel. Holds one (1) box of Temporal Probe covers.
11	Probe Port	Temporal Probe attachment port.
12	Black NO key	Records a "no" answer; scroll key in Setup Mode
13	Green light in MANUAL key	Power indicator. This is a steady green light as long as the monitor has DC power.
14	Gray MANUAL key	Enters Manual Mode; selects a menu option in Setup Mode

After transmitting vitals, pressing **MANUAL** twice clears vitals and returns the display to idle mode.

1ST DRAFT:

Monitor ports

There are numerous ports located on the rear and left side of the Monitor that connect to devices including the scale, modem, NIBP, optional accessories, and peripheral medical devices. The following figure shows the ports located on the rear of the monitor.



(1) Phone line

The phone line is the jack for the connecting your phone to the Sentry Monitor.

(2) Modem connection

The modem connection is for a standard phone cord that runs from the monitor to a duplex phone jack and allows the modem to dial and transmit data using a phone line.

Be sure the line is a traditional analog phone (non-digital) line.

(3) Non-isolated communication port (COMA, COMB, COMC)

These non-isolated ports, each with a Mini-DIN 6-pin connector, can supply up to +5VDC @ 250mA to as many as 3 external devices. These three ports are for external devices that **only transmit data**. You should **never** attempt to use a device connected to the monitor via a non-isolated port.

(5) Net

The Net jack is not used on the Sentry Monitor.

(5) Power Jack

The power jack is the jack for the AC adapter which powers the monitor.

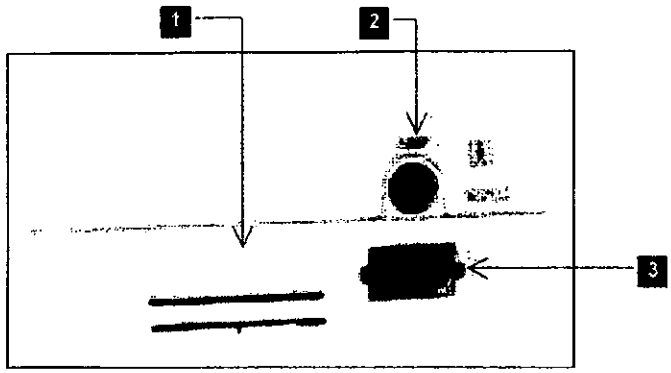
(6) Isolated serial I/O ports (SCALE, COM1, COM2, COM3)

The three **isolated** ports with Mini-DIN 4 connectors supply up to +5VDC @ 250mA. The first isolated port is a dedicated scale com port. COM1, COM2, and COM3, which allows you to use an external device connected to the monitor. Isolation protects you from any potential of shock.

Connector cables for external devices only fit the port appropriate for the device.

Side ports

The following figure shows the ports located on the left side of the Sentry Monitor.



(1) Sentry SmartMedia Card slot

The card slot holds a SmartMedia Flash Memory card that stores voice and text prompts and customizable questions. Cards contain eight language options: English, Spanish, French, German, Italian, Portuguese, French Canadian, and Hindi.

(2) Non-invasive blood pressure (NIBP) pneumatic port

The NIBP pneumatic port with its quick-release connector is the attachment site for the blood pressure hose.

1ST DRAFT:

(3) Oximeter port

The Oximeter port with its easy-release attachment site is for the SpO2 finger sensor (oximeter).

Lithium battery

The lithium battery maintains the memory for a minimum of five years. **You cannot replace the lithium battery.** If the battery fails, contact Customer Service to have it replaced.

Other system equipment

In addition to the monitor, the monitoring system includes a scale with a scale cord, blood pressure cuff and hose, power supply, and a power strip. The Oximeter (SpO_2 finger sensor) with external module cable is an optional accessory (requires Physician prescription). This section provides a general overview of each piece of equipment. For detailed specifications, refer to *Appendix D, Equipment Specifications.*

Scales

The Honeywell HomMed scale, has a capacity of 500 lb (227 kg) and collect weight using four load cells, one in each corner of the scale. The accuracy of the weight is to 0.5 lb (0.2kg) or 0.5%. The Sentry supplies power and communication to the scale through the scale cord. The following table identifies distinguishing features of each scale.

NIBP

The NIBP module inside the monitor measures systolic pressure, diastolic pressure, and mean arterial pressure (MAP) values. Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method. Pressures are calculated as follows:

Systolic: The cuff pressure when an increase in oscillations is perceived

Diastolic: The cuff pressure when oscillations are no longer decreasing as pressure is released from the cuff

MAP: The lowest cuff pressure that provides the maximum cuff oscillations. MAP is the largest signal received and is the most accurate reading.

Heart pulse rate is also collected with the blood pressure and that value is transmitted. However, it is only posted in Central Station if an oximeter heart pulse rate reading is not present.

The blood pressure cuff is a D-ring style cuff that complies with SP10 specifications for cuff length and width. The cuff is available in the following sizes:

Size	Fits limb size
Adult I	16 - 22 cm (6 - 8.5 inches)
Adult II	21 - 29 cm (8 - 11 inches)
Adult III	28 - 37 cm (11 - 4.5 inches)
Adult IV	36 - 46 cm (14 - 18 inches)

To order cuffs, refer to Appendix *B: Sentry System Supplies* on page **Error! Bookmark not defined.**.

Oximeter

A BCI/Smith finger sensor attaches to an external oximeter module cable which measures oxygen saturation (SpO_2) and heart rate with the averaging time fixed at 8 beats and 8 seconds. During the heart rate measurement, the monitor displays a small pulse bar under the Beats Per Minute (BPM) label. If you use the optional oximeter, the oximeter heart rate over-rides the NIBP heart rate in the monitor display. Sentry monitor transmits both the NIBP and oximeter heart rate values. Central Station stores both values in the database but only displays the oximeter heart rate.

Power supply and strip

The AC adapter converts alternating current to direct current to power the monitor. The adapter is medical grade and UL and IEC compliant. The power strip is 4-outlet surge protector, model 99038, manufactured by Fellowes.

A small Lithium battery maintains power for volatile memory (RAM) and the real-time clock, but does not provide any power to the monitor.

Peripheral Devices

This section discusses each of the peripheral devices that are compatible with the Sentry Monitor.

The programming instructions in this section assume that you understand basic programming concepts such as how to enter Setup Mode, use the monitor keys for programming, and navigate through the menu options. If you do not know how to perform these tasks, please review the information in the *Programming the Sentry Monitor* section of this manual.

ecg@home	**23**
Glucose Meters	**28**
Peak Flow Meters	**32**
Prothrombin Meters	**33**
Spirometers	**35**

Be sure to...

- Make sure that the Sentry Monitor's date and time are correct before transmitting any test results. This will ensure accurate recording of your transmission data. To set the date and time, refer to the Sentry Monitor Operator's Guide.

ecg@home

This section explains how to program the Sentry Monitor to prompt for an ECG recording, setup the ecg@home device, and instructions on obtaining an ECG recording. For information about viewing ECG recordings in Central Station, refer to your *Honeywell HomMed Central Station User Guide.*

The ecg@home package contains the following items:

- ecg@home device
- 2 1.5V AAA batteries
- RS 232 connection cable
- 1 bottle (15 ml) K2 solution
- 1 external auxiliary electrode

1ST DRAFT:

Overview

The ecg@home is a personal electrocardiogram recorder manufactured by HealthFrontier for Honeywell HomMed (available in the U.S. and Canada only). During the monitoring session, you can use the ecg@home to obtain a six-second rhythm strip which the device then transmits to the Sentry Monitor. The rhythm strip is included in the data packet that the Sentry Monitor transmits to the Central Station.

Safety information

CAUTION

NON-RECHARGABLE BATTERIES

Attempting to recharge the batteries could cause batteries to leak battery acid or over heat resulting in potential hazard to the user. It could also cause permanent damage to the unit.

DO NOT charge the batteries.

To prevent damage to the unit:

- **DO NOT** immerse the device in water or in any other type of liquid.
- **DO NOT** open the equipment or try to repair it. If the device is not working properly, contact Customer Service.
- **DO NOT** clean the **ecg@home** device or the cables with detergent or other cleaning solution.
- **DO NOT** use any other cables than the ones provided by Honeywell HomMed to connect the **ecg@home** to the Sentry Monitor.
- **DO NOT** use any other solution or liquid on the electrodes other than the K2 solution **or** an isopropyl alcohol (60-70%) and water (40-30%) solution.
- **DO NOT** rest arms on the monitor when taking a reading. Electrical interference from the Sentry Monitor could prevent the ecg@home from obtaining a reading.

If you have any questions or concerns, call Customer Service. For repair or shipping information, refer to the *Getting Started* section of this manual.

Assigning a com port

To enable the monitor to prompt for and collect ECG data, you must assign a com port. If you do not assign a com port, the monitor **will not prompt** for the device and it **will not collect data** from that device even if the device is connected to the com port.

It is also important to use an *isolated* port. Isolated ports protect you from any potential of shock when they use a device that is connected to the monitor.

1. Enter Setup Mode.
2. Scroll to and enter the *Option* Menu.
3. In the *ECG Monitor* menu, assign either COM1 or COM 2.
4. In the *ECG Time* menu, set the collection frequency.
5. Exit Setup Mode.

The ecg@home device

The ecg@home displays various symbols and information in the LCD display as it takes a reading.

This ...	Indicates...
BATTERY	Losing power; change batteries
	Pre-acquisition phase
	Recording phase
*	No recording stored in memory
**	Recording stored
32	Open RS232 port
PULS	**Flashing during recording:** instantaneous heart rate
	Static at end of recording: mean heart rate

When the ecg@home device is first turned on, it erases the last recording, if any, and displays the single asterisk. The heart symbol continues to flash until you place both thumbs on the electrodes and the device determines that it can obtain a reading.

As the ecg@home records, the unit beeps and the wave symbol moves from left to right across the display. The wave is merely an indicator; it is **NOT** your actual wave rhythm. During collection, the instantaneous heart rate value flashes next to **PULS**.

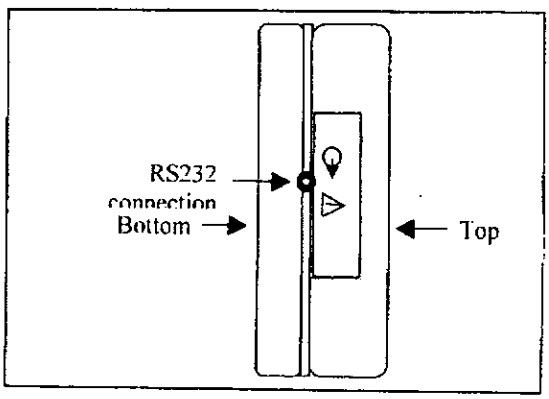
When the recording is completed, the wave symbol stops flashing, the mean heart rate displays briefly next to PULS, and there are two beeps. A second asterisk also displays on the screen to indicate that the recording is stored in memory.

The unit displays **32** to indicate that the communication port is open and the device is transmitting.

Attaching the ecg@home cable

The cable that connects the ecg@home to the Sentry Monitor has a 4-pin connector on one end and a jack on the other. The pin connector plugs into a com port on the Sentry monitor, and the jack plugs into the RS232 connection on the ecg@home. To attach the ecg@home to the Sentry Monitor, follow the steps below.

1. Locate the RS232 connection on the side of the ecg@home device.



2. Plug cable jack into the ecg@home RS232 connection.
3. Plug the 4-pin connector into the **assigned** com port of the Sentry Monitor.

Replacing the batteries

The ecg@home uses non-rechargeable, **1.5 V AAA** size batteries. Each set of fresh batteries provides approximately 2200 recordings. When you need to replace the batteries, the message **BATTERY** displays.

The battery case is on the back of the device. To replace the batteries, open the battery case, remove the old batteries, and

insert two new ones according to the polarity as indicated on the label in the battery case. Close the battery case.

Cleaning the ecg@home

Always disconnect the device from the Sentry Monitor prior to cleaning. Clean the device with a soft cloth moistened with the K2 solution. Do not use water, detergent or any other cleaning product. To clean the electrodes, moisten a cotton swab with the K2 solution and gently swab clean. To **disinfect** the unit, use a solution of isopropyl alcohol (60-70%) and water (30-40%).

Specifications

Input impedance:	>10 Mohm
Input dynamic range:	+/- 5 mV within bandpass
	+/- 300 mV @DC
Bandwidth:	0.5 – 30 Hz linear phase
Common mode rejection ratio:	>100dB
AD conversion:	11 bits
Sampling frequency:	250 samples/s
Recorded lead:	Standard leads I and II
Memory:	6 seconds of recording typical
Display:	Custom LCD display panel
Input:	External auxiliary electrode
Output:	RS 232 digital port
Power supply:	2 x 1.5V AAA size batteries
Size:	4.13 x 3.15 x 0.59 inch
Weight:	100 gr.
Environmental conditions	
Storage temperature:	32° F - 122° F (0° C – 45° C)
Operating temperature:	50° F - 113° F (10° C – 45 ° C)
K2 solution ingredients	De-ionized water Biocide agent Wetting agent Chlorhexidine 0.1% Electrolyte (sodium chloride based) Isopropyl alcohol IP97 2.6% Propylene Glycol

1ST DRAFT:

Glucose Meters

This section provides information and instructions for programming the Sentry Monitor to upload test results, attaching glucose meter cables and devices, and instructs you how to upload test results. For information about glucose meter specifications and capabilities or for instructions on how to use, test, or maintain glucose meters, refer to the appropriate manufacturer material.

Overview

The Sentry Monitor is compatible with the following glucose meters:

- LifeScan One Touch Basic
- LifeScan One Touch Ultra
- LifeScan One Touch Profile
- Bayer Ascensia Elite XL
- Roche Accu-Chek Advantage
- Home Diagnostics Prestige IQ

The Sentry Monitor uploads up to twelve of the most recent, **valid** glucose test results from a glucose meter. A valid reading has the test time and date. If any reading is missing a time and date stamp, the monitor will not collect it.

The monitor does not erase any data from the glucose meter and does not collect or transmit control-solution test results obtained in test mode or designated as control results.

If you want to erase data from the LifeScan or Roche Accu-Chek models, you can purchase software and a customized cable from LifeScan or Roche. For further information, contact:

LifeScan at 800-227-8862.

Roche Diagnostics Corporation at 800-428-5076

Be sure to...

- Make sure that the Sentry Monitor's date and time are correct before transmitting any test results. This will ensure accurate recording of your transmission data. To set the date and time, refer to the Sentry Monitor Operator's Guide.

Safety information

Remember to thoroughly read the user documentation provided by the manufacturer and to pay close attention to any cautions or warnings.

Assigning a com port

You must **assign** a com port to the glucose meter or the monitor will not prompt you for data or communicate with the device to collect data (even if the device is connected to the com port). Assigning a com port triggers the monitor to include glucose meter prompts during the monitoring session, to communicate with the glucose meter, and to upload test results.

1. Enter Setup Mode.
2. Scroll to and enter the *Option* Menu.
3. In the *Glucometer Type* menu, select the appropriate glucose meter.
4. In the *Glucometer* menu, assign either COM1 or COM 2.
5. In the *Glucometer Time* menu, set the collection frequency.
6. Exit Setup Mode.

If you are programming a com port for the Prestige glucose meter, the only option is COM A.

Attaching the glucose connector cable

One end of the connector cable has a 4 or 6-PIN-connector that plugs into the com port on the rear of the monitor. The other end of the cable either has a jack connector that plugs into the communication port on the glucose meter, or a DB-9 connector that plugs into another cable. The second cable then plugs into the glucose meter.

The pins in the connector cables can be damaged if you attempt to plug the cable into a receptor that doesn't match the pin configuration of the cable. To prevent damage to the pins in the connector cables, always program the monitor first and then make sure you plug the cable into the port you programmed for glucose.

Connecting single cable models

The following glucose meters have single connector cables:

- LifeScan (all models)
- Bayer Ascensia Elite XL

1. Plug the 4-PIN (for Prestige, the 6-PIN) connector into the port that you assigned to the glucose meter when you programmed the Sentry monitor.
2. Place the cable so that you can easily attach the glucose meter.

Connecting the cables for the Roche Accu-Chek Advantage

The Roche Accu-Chek Advantage comes in two styles. The earlier style is silver and black, the newer style is white and blue. Both meter types use the same Honeywell HomMed glucose meter cable. The cable has a 4-pin connector that connects to the monitor and a DB 9 male connector that connects to a Roche cable. However, the two Accu-Chek styles use different Roche cables to connect to the meter.

- The older, **silver and black glucose meter**: Use the cable that has the large DB-9 female connector on one end and a **long flat** connector on the other end.
- The newer, **white and blue glucose meter with serial number starting with 850 or higher**: Use the cable that has the smaller DB-9 female connector on one end and a **jack** connector on the other end.

Attaching the cables

1. Attach the *Honeywell HomMed* glucose meter cable to the monitor by inserting the round, 4-pin connector into the com port programmed for the glucose meter.
2. Insert the *Honeywell HomMed* DB-9 connector into the appropriate *Roche* DB-9 connector matching the pin configurations. (The screws do not connect.)
3. Place the cable so that you can easily insert the cable into the glucose meter communication port.

Attaching the silver and black glucose meter to the cable

1. Holding the glucose meter so that you are looking at the back of the meter, locate the Code Key slot near the top of the meter. (See Accu-Chek *Owners Booklet*)
2. Slide the flat connector (green side of the connector should face the same direction as the front of the monitor) into the slot.

Attaching the blue and white glucose meter to the cable

1. Locate the computer port on the top of the glucose meter next to the blue power button. (See Accu-Chek *Owners Booklet*)
2. Insert the jack into the computer port.

Connecting the cables for the Home Diagnostics, Inc. Prestige

To attach a Prestige glucose meter to the monitor requires the following two cables:

- Honeywell HomMed adapter cable that attaches to the monitor
- Prestige glucose meter cable that plugs into the glucose meter

The Honeywell HomMed adapter cable has a 4-pin connector that matches the com-port configuration on the monitor and a DB-9 connector that matches the Prestige cable. The Prestige cable has a jack that plugs into a data port on the glucose meter.

1. Attach the ***Honeywell HomMed*** glucose meter cable to the monitor by inserting the round, 4-pin connector into the com port programmed for the glucose meter.
2. Insert the ***Honeywell HomMed*** DB-9 connector into the ***Prestige*** **DB-9** connector matching the pin configurations. (The screws do not connect.)
3. Place the cable so that you can easily insert the cable into the glucose meter communication port.

Peak Flow Meters

This section provides information and instructions for programming the Sentry Monitor, attaching the peak flow cable and meter, and teaches you how to upload test results. For information about peak flow meter specifications and capabilities, or for instructions on how to use, test, or maintain meters, refer to the **instruction sheet** that came with the device.

Overview

The Sentry Monitor is compatible with the PiKo-1 manufactured by Pulmonary Data Services (PDS). The PiKo-1 can store up to 96 tests with the warning indicators and time and date stamp. However, the Sentry Monitor only downloads the 12 most recent readings.

Safety information

- The PiKo-1 is intended for use as a single-user device. Remember that no one else is to use their peak flow meter but yourself.
- Remember to thoroughly read the user documentation provided by the manufacturer and to pay close attention to any cautions or warnings.
- The *PiKo-1 Peak Flow Meter User's Manual* contains the following warning: "If you use the PiKo-1 above 1000 feet elevation, (300m), adjust your values by adding 1.5%. To do this, multiply the PEF & FEV1 by 1.015.

Assigning a com port

You must **assign** a com port to the peak flow meter or the monitor will not prompt you for data or communicate with the device to collect data (even if the device is connected to the com port). Assigning a com port triggers the monitor to do the following:

- Include peak flow meter prompts during the monitoring session
- Communicate with the peak flow meter
- Upload test results

The following instructions assume you know how to navigate in Setup Mode. If you have not programmed a monitor, refer to section *3 Programming the Sentry Monitor* for complete programming instructions.

1. Enter Setup Mode, and enter your password.
2. Scroll to and enter the *Option* Menu.
3. In the *Peak Flow* menu, assign COM A.
4. In the *Peak Flow Time* menu, set the collection frequency.
5. Exit Setup Mode.

Attaching the peak flow meter cradle to the Sentry Monitor

The peak flow meter transmits data to the Sentry Monitor via its cradle and a Honeywell HomMed connector cable. The Honeywell HomMed cable has a black, 9-pin connector that matches the cradle cable connector, and a round, 6-pin connector that matches COM-A on the rear of the Sentry Monitor. To attach the peak flow cradle to the monitor, follow the steps below.

1. Plug the Honeywell HomMed cable 6-PIN connector into COM-A.
2. Plug the Honeywell HomMed 9-pin male connector into the cradle cable connector. If you have difficulty, make sure that the pins in the Honeywell HomMed connector properly align with the holes in the cradle connector.
3. Tighten the screws on the cradle connector until snug.
4. Arrange the equipment so you can easily place their peak flow into the cradle and the cables are out of the way.
5. Place the peak flow meter into the cradle.

Prothrombin Meters

This section provides information and instructions for programming the Sentry Monitor, attaching the prothrombin cable and meter, and teaches you how to upload test results. For information about prothrombin meter specifications and capabilities or for instructions on how to use, test, or maintain meters, refer to the **instruction sheet** that came with the device.

Overview

The Sentry Monitor is compatible with the ProTime prothrombin meter manufactured by International Technidyne Corporation (ITC). The prothrombin meter transmits only the latest reading to the Sentry Monitor. The monitor does not erase any data from the prothrombin meter. Prothrombin meters automatically synchronize their date and time to the monitor. If you need to change meter dates or times, refer to the manufacturer's instructions.

Safety information

WARNING

ELECTRICAL SHOCK

Using a spirometer while attached to the Sentry Monitor could possibly result in receiving an electrical shock.

- **DO NOT** attempt to take readings with a spirometer when it is connected to the Sentry Monitor.
- Disconnect the spirometer before use.
- Always follow the manufacturer's **instruction sheet** that came with the device for proper use.

- **Never** use their prothrombin meter when it is attached to the Sentry Monitor.
- Remember to thoroughly read the user documentation provided by the manufacturer and to pay close attention to any cautions or warnings.

Assigning a com port

You must **assign** a com port to the prothrombin meter or the monitor will not prompt you for data or communicate with the device to collect data (even if the device is connected to the com port). Assigning a com port triggers the monitor to include prothrombin prompts during the monitoring session, to communicate with the prothrombin meter, and to upload test results.

1. Enter Setup Mode.
2. Scroll to and enter the *Option* Menu.
3. In the *PT Monitor* menu, assign COM-A.
4. In the *PT Monitor* Time menu, set the collection frequency.
5. Exit Setup Mode.

Attaching the prothrombin meter connector cable

Prothrombin meter cables are white with a green color band. One end of the cable has a 6-PIN connector that plugs into the non-isolated ports on the rear of the Sentry Monitor. The other end of the cable has a 9-PIN connector that plugs into the prothrombin data port located on the back of the device.

1. Plug the 6-PIN connector into COM-A.
2. Place the cable so that you can easily attach the prothrombin meter.

Spirometers

This section provides information and step-by-step instructions for programming the Sentry Monitor, attaching the spirometer cable and meter, and teaches you how to upload test results.

For information about spirometer specifications and capabilities or for instructions on how to use, test, or maintain meters, refer to the **instruction sheet** that came with the device.

Overview

The Sentry Monitor is compatible with the MicroDL spirometer manufactured by Mirco Direct.

The Sentry Monitor collects up to twelve of the most recent readings and then clears the spirometer memory. Deleting data allows more than one you to use a spirometer.

Spirometers automatically synchronize their date and time to the monitor. If you need to change meter dates or times, refer to the manufacturer's instructions.

Safety information

CAUTION

ELECTRICAL SHOCK

Using a spirometer while attached to the Sentry Monitor could possibly result in receiving an electrical shock.

- **DO NOT attempt to take readings with a spirometer when it is connected to the Sentry Monitor.**
- **Disconnect the spirometer before use.**
- **Always follow the manufacturer's instructions for proper use.**

- Remember to **never** use their spirometer when it is attached to the Sentry Monitor.

- Remember to thoroughly read the user documentation provided by the manufacturer and to pay close attention to any cautions or warnings.

Assigning a com port

You must **assign** a com port to the spirometer or the monitor will not prompt you for data or communicate with the device to collect data (even if the device is connected to the com port). Assigning a com port triggers the monitor to include spirometer prompts during the monitoring session, to communicate with the spirometer, and to upload test results.

1. Enter Setup Mode.
2. Scroll to and enter the *Option* Menu.
3. In the *Spirometer* menu, assign COM-A.
4. In the *Spirometer Time* menu, set the collection frequency.
5. Exit Setup Mode.

Attaching the spirometer connector cable

Spirometer connector cables are white with a yellow color band. One end of the cable has a 6-PIN connector that plugs into COM-A. The other end has a jack connector that plugs into the data port on the side of the spirometer.

1. Plug the 6-PIN connector into the port that you assigned to the spirometer when you programmed the Sentry monitor.
2. Place the cable so that you can easily attach the spirometer.

Routine Maintenance

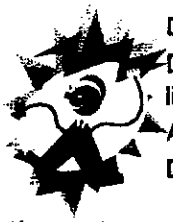
This section provides instructions for routine maintenance. Follow the instructions and safety information carefully. Failure to do so may void your warranty. Honeywell HomMed offers preventative maintenance services at the fees and terms stipulated in your contract. If you wish Honeywell HomMed to perform any services, contact Customer Service.

Cleaning

WARNING

ELECTRIC SHOCK

Some of the parts inside the monitor could shock you. The shock could be severe enough to cause death or serious injury.



DO NOT take the monitor apart.
DO NOT put the monitor in water or any other liquid.
ALWAYS UNPLUG the monitor before you clean it.
DO NOT try to fix the monitor.

If you have a problem with your monitor, call Honeywell HomMed Customer Service

Clean only the surfaces of the monitor and the peripheral devices. Qualified service technicians must perform any cleaning, servicing, or repairs that require disassembly.

Cleaning the Sentry Monitor and peripheral devices

1. Unplug the Sentry Monitor. The monitor's memory retains all programmed settings even when powered down.
2. Detach all accessories and peripheral devices.
3. To clean and disinfect, wipe the surfaces with isopropyl alcohol, and then wipe with a lint-free cloth moistened in water.

Cleaning the NIBP cuffs

1. Remove bladders from each cuff.
2. Using a mild disinfectant/detergent and warm water, wash cuffs by hand or in a washing machine.
3. Hang cuffs to dry. **DO NOT** dry cuffs in a dryer.
4. When cuffs are dry, replace the bladders. Be sure to insert the correct bladder into the right cuff.

1ST DRAFT:

Inspection

From time to time, it is a good idea to inspect your Sentry Monitor and accessories. You should check the following:

- Power cord is not frayed or connected to unauthorized equipment.
- Cables are properly attached and in good condition.
- All accessories are securely attached.
- Monitor is not standing in or near water.
- Monitor has not been moved to an unsuitable location.

If there is a frayed power cord or if the unit is attached to unauthorized equipment, unplug the unit and notify Customer Service.

If a monitor has been dropped or damaged, call Customer Service. Qualified service personnel **must** inspect any dropped or damaged units before they are assigned for use.

Calibration verification

This section provides instructions for calibration verification for Honeywell HomMed equipment. Honeywell HomMed recommends **calibration verification at least once a year**. If between calibration verifications, you have doubt about the accuracy of the measured values for the scale or oximeter; or if equipment appears to be out of calibration, you may choose one of the following:

1. Verify calibration using the instructions in this section, or
2. Send your device to Contact Honeywell HomMed for calibration.

Honeywell HomMed's repair policy

- If the item is under warranty **and** the repair is covered under the warranty, there is no charge for the repair service.
- If the item is no longer under warranty, **or** if the repair is not covered in the warranty, we will charge a fee for the repair.

For additional warranty information, please refer to your *Sentry Monitor OTC Sentry Monitor Operator's Manual.* , or contact Honeywell HomMed Customer Service.

Scale calibration verification

This procedure requires the use of a calibrated weight greater than 30 pounds (14kg) and less than 500 pounds (227kg). To verify the scale's calibration:

1. Make sure that there is no weight on the scale.
2. With the scale attached to the Sentry Monitor, power up the monitor.
3. From idle mode, press **MANUAL** to enter Manual Mode.
4. Place a calibrated weight on the scale.
5. Verify that the weight displayed is equal to the calibrated weight ± 0.5 pounds.

NIBP cuff calibration verification

CAUTION

PERSONAL INJURY HAZARD: NIBP Cuff

Verifying the calibration while the cuff is attached to you, (while wearing the cuff) could cause bruising or other injury.

DO NOT verify NIBP calibration while the cuff is attached to a patient.

To verify the NIBP cuff's calibration:

1. Secure the blood pressure cuff to a rigid fixture about the size of an arm.
2. Tee-in a standard mercury or digital manometer with the NIBP cuff.
3. Press **YES + STOP BP** to enter the monitor's Setup Mode.
4. Scroll to *Password* menu and enter your password.
5. Scroll to the *Service Menu* and press **Manual** to enter the menu.
6. Scroll to *Calibration Verify*, and press **Manual** to enter the option.
7. Press **START BP** to begin the calibration verification. The NIBP pumps the pressure to 260 mmHg (± 10 mmHg). Verify the monitor's displayed blood pressure numbers to the manometer reading. The manometer reading should agree to within ± 3 mmHg or ± 2%, whichever is greater.
8. Press **STOP BP** to cancel the reading and release the pressure.
9. Press **YES + STOP BP** to exit Setup Mode.

Optional finger sensor calibration verification

To verify oximeter calibration requires a pulse oximeter tester. Refer to the manufacturer's manual for testing procedures. For information about ordering testers, contact *Honeywell HomMed Customer Service.*

Honeywell HomMed Customer Service

The goal of Customer Service is to do everything possible to support you in meeting the needs of your clients. We are available 24/7, and we will work quickly to resolve issues.

When you call, please have this manual and a copy of the *Honeywell HomMed OTC Sentry Monitor Service and Support Guide* handy. We will walk you through various troubleshooting techniques to assist you in identifying causes and resolutions.

A Customer Service Representative will make every attempt to resolve the issue over the phone. However, if equipment must be sent back, we will issue a Return Material Authorization (RMA) number. For shipping instructions, please refer to the section: Shipping equipment back to Honeywell HomMed.

Toll-free:	**888-353-5404**
Phone:	**262-252-5840**
Fax:	**262-252-5795**
Email:	**hommedcustomerservice@honeywell.com**

Repairing equipment

Honeywell HomMed recommends that authorized repair centers make all repairs for the monitor and all of its accessories. Repairs made by unauthorized personnel will invalidate your warranty. For product warranty information, please refer to the *Honeywell HomMed OTC Operator's Manual,. Appendix: X Honeywell HomMed Warranty Information.*

- If your monitor is under warranty **and** the repair is covered under the warranty, there is no charge for the repair service.
- If your monitor is no longer under warranty, **or** if the repair is not covered in the warranty, Honeywell HomMed will charge a fee for the repair.

If equipment needs repair

If any equipment needs repair, contact Customer Service and explain which piece of equipment needs repair (monitor, scale, or accessory) and what the problem is. If the damaged item is a monitor or a scale, have the **model** and **serial number** ready to give the Customer Service Representative when you call.

- Monitor model and serial numbers are located on the bottom of the monitor.
- Scale model and serial numbers are located on the side of the scale.
- For accessory peripheral medical devices, please refer to the **instruction sheet** that came with your device, to locate the model and serial numbers.

Shipping equipment back to Honeywell HomMed

If Customer Service requests that you ship equipment back to Honeywell HomMed, please follow the directions below.

1. Carefully pack the equipment in the original box. If you do not have the original box, you may use any sturdy box that allows at least a one-inch clearance around the equipment for packing materials.
2. When Customer Service gives you an RMA number, include it on the outside of the shipping container.
3. Ship to the following address:

RMA #
Customer Service Department, Repairs
Honeywell HomMed
3825 Ohio Ave.
St. Charles, IL 60174

Peripheral Devices

The following is a list of peripheral devices that are compatible with your Sentry III monitor.

PMD Device	Manufacturers	
Weight Scale	Honeywell HomMed	
Finger Sensor	BCI/Smith	
Temperature Probe	Welch-Allyn	
Electrocardiogram Recorder (ECG)	HealthFrontier	
Glucose Meter	LifeScan™ ▪ One Touch Basic ▪ One Touch Ultra ▪ One Touch Profile Bayer ▪ Ascensia Elite XL	Roche ▪ Accu-Chek Advantage Home Diagnostics ▪ Prestige IQ
PiKo-1 Peak Flow Meter	Pulmonary Data Services (PDS)	
Prothrombin Meter	International Technidyne Corporation (ITC)	
MicroDL Spirometer	Mirco Direct	
Digital Camera SmartMedia card	Various	

Additional Information

CE Mark information

Marking by the symbol CE indicates compliance of this device to the Medical Device Directive 93/42/EEC.

Authorized Representative:

MDSS
Burckhardtstr. 1
30163 Hannover
Germany

Appendix A: Prompt Text

The following list is a compilation of Sentry Monitor audio prompts. This list does not contain questions. For a list of all possible questions, refer to *Appendix A: Question Text* of the *Sentry OTC Monitor Operator's Manual*

Good Morning (Afternoon, Evening), it is now time to record your vital signs.

Please swipe your card.

Please verify that this is your card using the yes and no keys.

Please swipe your card again.

Please step on the scale.

Please step off the scale and sit down on a chair in front of the monitor.

Please sit down on a chair in front of the monitor.

Place the blood pressure cuff on your right arm above the elbow. Tighten it securely.

Place the finger sensor on the middle finger of your left hand with the finger design facing up.

Rest your arm as instructed by your clinician.

Press the green start BP key.

Please remove the finger sensor and the blood pressure cuff.

Please remove the temperature probe from its holder.

Put a cover on the temperature probe

Place the probe under your tongue.

Discard the probe cover and replace the temperature probe in its holder.

Please answer the following questions using the yes and no keys.

Please attach the glucose meter to the monitor.

No glucose meter detected.

New glucose meter detected.

Please attach the spirometer to the monitor.

No spirometer detected.

1ST DRAFT:

Detach the spirometer from the monitor.

Please attach the prothrombin time meter to the monitor.

No prothrombin time meter detected.

Please activate your peak flow meter and place it in the cradle.

No peak flow detected.

It is now time to take your ECG reading.

Apply two to three drops of the electrode solution on both electrodes of the ECG

Press the start key on the ECG device.

Place your thumbs gently on the two electrodes to take an ECG reading.

Press the yes key when you are finished.

Please attach the ECG device to the monitor.

No ECG device detected.

Insert photo card.

No photo card detected.

Do not remove photo card until notified.

Remove photo card.

Please make sure the cable is attached to the port marked COM (A, B, C, 1, 2, 3) on back of the monitor.

Receiving data, please wait.

No new data.

Data upload is finished.

Please remember to take your medications as prescribed by your physician and ma the proper diet.

Thank you for completing your vital signs measurement.

No vital signs, your clinic will be notified.

Appendix B: Sentry System Supplies .....

Use only supplies authorized by Honeywell HomMed, as other equipment may result in poor operation of the Sentry Monitor; or in increased electronic emissions and decreased equipment immunity of the Sentry monitor. To order supplies, contact Customer Service and include the part number and name.

Part #	Part Name
3000012B1	BP Cuff, Adult I 16 - 22 cm (6 8.5 inches)
3000013B1	BP Cuff, Adult II 21 - 29 cm (8 - 11 inches)
3000014B1	BP Cuff, Adult III 28 - 37 cm (11 - 4.5 inches)
3000015B1	BP Cuff, Adult IV 36 - 46 cm (14 - 18 inches)
3200004B1	Card Reader
3200005B1	Card Writer
3002004B1	Carrying Case, Scale
3001004B1	Duplex Jack
3005001B1	Ear Sensor
3001104B1	ecg@home cable (miniDIN4)
3004001B1	ecg@home K2 solution
3200001B1	ecg@home monitor
6030002B1	Finger Sensor
3005000B1	Finger Sensor Extension
3001106B1	Glucose meter cable, Bayer
3001100B1	Glucose meter cable, LifeScan
3001107B1	Glucose meter cable, Roche
5100003B1	Hewlett Packard Printer Cable
3004005B1	Screwdriver
3004004B1	ID card
3001006B1	Inline Coupler
3001007B1	Modular Adapter
3000010B1	NIBP supply line
3001103B1	PC Cable
3001110B1	Peak flow meter cable

1ST DRAFT:

Part #	Part Name
300101B1	Phone Cord, 15'
300103B1	Phone Cord, 25'
300102B1	Phone Cord, 7'
3003000B1	Power Strip
6010048B1	Power supply, 115V
3003001B1	Power supply, 230V
3003005B1	Power Supply Detachable Cordset, UK
3001102B1	PT Cable
3200002B1	PT Monitor
3004002B1	Scale Foot
3200003B1	Spirometer
3001101B1	Spirometer Cable
3004000B1	Spirometer Mouthpiece
3001005B1	Triplex Jack
3200007B1	Two-foot cable, Card Reader
3200006B1	Videophone
6010062A1	SBVOX with English, French, French Canadian, German, Spanish, Italian, Portuguese, and Hindi
6010062A2	SBVOX with English, Armenian, Polish, Russian, and Spanish
NOTE: All of these parts could also be used with the Sentry Monitor.	

Appendix C: Specifications

Sentry Monitor specifications

Physical

Dimensions:

Width:	10.3 inches (26.2 cm)
Height:	3.0 inches (7.6 cm)
Depth:	7.0 inches (17.8 cm)
Weight:	2.5 lbs. approx. (1.1 kg)

Power

AC Power: Wall-mount style medical grade power supply
Input of 105-125VAC, 60 Hz
Input of 230VAC, 50/60 Hz
Output of 24VDC @ 500mA with 4kV isolation

Battery: LI+ (lithium-Ion), 3.0DC non-rechargeable for memory backup and real-time clock power, does not supply backup primary power.

Environment

The monitor may not meet its performance specifications if stored or used outside the temperature and humidity ranges listed above.

Temperature:	**Operation:**	0 - 50° C (32 - 122° F)
	Storage:	- 40 - 75° C (-40 - 167° F)

Relative humidity:

Operation:	15 - 95% (non-condensing)
Storage:	10 – 95% (non-condensing)
EMC:	EN 60601-1-2 with scale cables lot code 1103-01 or higher

Languages

Setup (Programming): English, French Canadian

Usage (Display & Audio Prompts): Armenian, English, French, French Canadian, German, Hindi, Italian, Polish, Portuguese, Russian, and Spanish.

1ST DRAFT:

Pager

Type:	Advantra Barran™
Compliance approvals:	FCC Part 90 – Radio Performance
	FCC 15 – Conducted and Emitted Radiation Class B
	FCC Part 24 – NBPCS Narrow Band PCS Transceivers
Antenna:	Fold-down whip style, ½ wave dipole or ¼ wave monopole vertical

Modem

Type:	56K baud
Compliance approvals:	FCC Part 15B, FCC Part 68
Connection:	RJ-11

Non-Invasive Blood Pressure (NIBP) Cuff

Manufacturer: SunTech

Method of measurement: Oscillometric — Diastolic values correspond to Phase 5 Korotkoff sounds

Blood pressure	Range:	20 to 260 mmHg
	Systolic	40 – 260 mmHg
	Diastolic	20 – 200 mmHg
	Heart Rate:	40 – 200 bpm

Accuracy: ±3 mmHg between 0 mmHg and 300 mmHg, for operating conditions between 0° C and 50° C and less than 95% relative humidity

Personal safety: Maximum cuff inflation time is limited to **50 seconds**

Duration of blood pressure reading is limited to **130 seconds**

Redundant safety circuitry aborts reading if cuff pressure exceeds 300 mmHg, or if cuff has been inflated for **180 seconds**

Calibration: Verify yearly

Safety standards:	Meets all relevant parts of AAMI SP-10-1992, IEC-60601-1, IEC-60601-2-30, EN1060-1, EN1060-3 Test data available upon request.
Initial inflation pressure:	120 - 250 mmHg adult mode
Default inflation pressure:	175 mmHg (120 – 280 mmHg)

Oximeter module

Range:	0 - 99% Functional SpO_2 (1% increments)
Accuracy:	±2 at 70 - 99% less than 70% is unspecified
Alarms:	None
Averaging:	8 pulse beat average
Calibration:	Factory calibrated over the range of 70% to 99% SpO_2 using human blood samples to functional saturation. Test methods available upon request. No in-service calibration is required.
Sensor:	Display Update Rate: Red - 660nm, 2mW (typical)
	Infrared - 905nm, 2-2.4mW (typical)
	1Hz (Maximum age of SpO_2 data is 20 sec.)

Heart rate (oximeter)

Range:	30-254 BPM (1 BPM increments)
Accuracy:	±2% or 2 BPM, which ever is greater
Alarms:	None. Not for continuous monitoring.
Averaging:	8 second average
Display Updare Rate:	1 Hz (Maximum age of SpO_2 data is 20 sec.)

Heart rate (via NIBP Cuff)

Range:	40 - 200 BPM (adult mode)
Accuracy:	± 5 BPM or 5%, whichever is greater

1ST DRAFT:

Pulse Strength (via Oximeter)

Range:	0-6 segment bar graph, indicates logarithmic strength of your pulse
Display Update Rate:	60Hz

Scale

Manufacturer:	Honeywell HomMed
Range:	0 to 500 lbs. (0 to 227 kg)
Accuracy:	± 0.5 lbs. (± 0.2 kg) or ± 0.5%, whichever is greater
Update Rate:	< 0.5 seconds
Stability of Calibration:	Zero cal is performed at power-up Multipoint span factory cal is preserved through power cycles Factory cal is good for 5 years of normal use.

Appendix D: Electromagnetic Guidances

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Sentry monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Sentry monitor should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Sentry monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Sentry monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class B	
Voltage Fluctuations-Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Sentry monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Sentry monitor should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	0% U_T (100% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Sentry monitor requires continued operation during power mains interruptions, it is recommended that the Sentry monitor be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Sentry monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Sentry monitor should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Sentry monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended Separation Distance** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determine by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: ((•))

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Sentry monitor is used exceeds the applicable RF compliance level above, the Sentry monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Sentry monitor.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Separation Distances Between Portable and Mobile RF Communications Equipment and the Sentry Monitor

The Sentry monitor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sentry monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sentry monitor as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	13.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Index

A

Additional References 16

B

Battery, lithium 21
Blood pressure
  calibration 40
  cuff 22
  port 20

C

Calibration 39
  NIBP cuff 40
  oximeter 41
  scales 40
CE Mark 16
Central Station 2
Communication ports 19, 20
Content overview 6
Copyright 2
Customer Service 2, 8, 41

E

ecg@home 24
  assigning a com port 26
  attaching the cable 27
  cleaning 28
  device 26
  replacing batteries 27
  specifications 28
Equipment
  monitor ports 19
  NIBP 22
  oximeter 23
  scales 22

O

Oximeter
  calibration 41
  port 21
  Sentry Monitor 17

F

Function keys
  returning to idle mode 18

G

General Information 6
Glucose meters 29
  assigining a com port 30
  attaching the cable 30

H

HomMed
  Customer Service 8, 41
  repairs 8, 41, 42
  shipping 9, 42

I

Inservice inspection 39
Intended Use 2

M

Manual
  Information 6
  notices 2
  overview 6
Modem
  port 19

N

Net 19
Notices 2

P

Peak flow meters....33
assigning a com port....33
attaching the connector cable....34
Peripheral devices
ECG....24
glucose meters....29
peak flow meters....33
prothrombin meters....34
spirometers....36
Phone line....19
Ports....19
communication....19, 20
modem....19
net....19
NIBP....20
oximeter port....21
phone line....19
power jack....20
SmartMedia....20
Power jack....20
Prothrombin meters....34
assigning a com port....35
attaching the cable....36

R

Repairs....8, 41, 42

S

Scales....22
calibration....40
Shipping....9, 42
SmartMedia Card....20
Spirometers....36
assigning a com port....37
attaching the cable....37

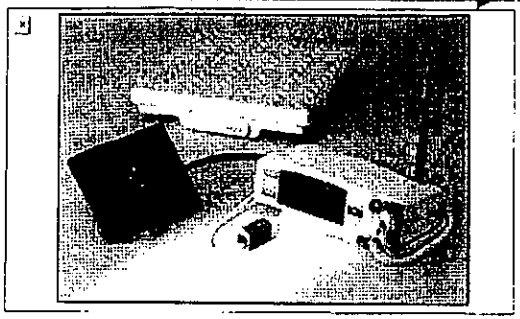
W

Warranty
product warranties....8, 41

Reprint w/ Graphic

Sentry Monitor Setup Guide

FINAL: 5/19/200



Installation Overview

When you receive your shipment from Honeywell HomMed Sentry Monitor, carefully remove each piece of equipment from the box. Save the carton and packing materials in case you need to return any of the contents. As you inventory the contents of the box, check each piece of equipment for damage.

BE SURE TO...

Read the ***Honeywell HomMed OTC Sentry Monitor Operator's Guide*** before using your monitor. The manual contains important instructions, warnings, and cautions that should be reviewed before use.

Equipment List

Your package should include the following items:

- Sentry Monitor
- Scale and scale cable
- Blood pressure cuff
- Blood pressure hose
- Temporal Probe
- Oximeter (SpO2) Finger Sensor
- Phone cord and duplex jack
- AC adapter (power supply)
- Power strip

HomMed Customer Service

Toll-free: **888-353-5404**

Phone: **262-252-5840**

Fax: **262-252-5795**

Web: **www.hommed.com**

Setting Up Your Sentry Monitor

It is important to set up the Sentry Monitor in an area where it can successfully interact with your telephone system. If you will be using any accessory devices, make sure there will be enough room for you to attach them without any difficulty. To determine a suitable location, consider the following:

Monitor

1. Choose an accessible place near an electrical outlet.
2. Locate that a bed, chair, or other support is available.
3. Place the Sentry Monitor on a flat, stable, and uncluttered surface. (Failure to do so may cause it to fall.)
4. Make sure that you can easily attach any peripheral devices.

DO NOT

- Block the vents on the Sentry Monitor. The monitor should have a two-inch rear clearance.
- Use an electrical wall outlet controlled by a light switch.
- Place near sources of water such as sinks or bathtubs.
- Place on or near a heat source (stove, fireplace, heaters, heat vents, etc.)

Scale

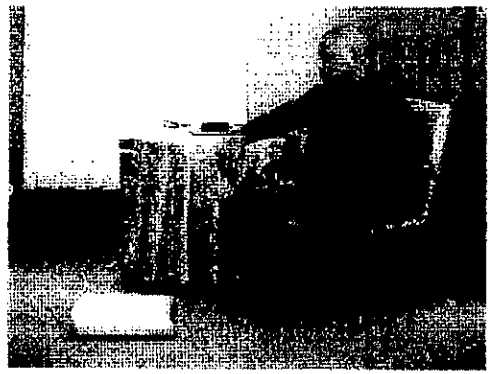
Find a permanent spot for the scale where you can easily stand on it. (Scale should not be moved).

For optimal transmission

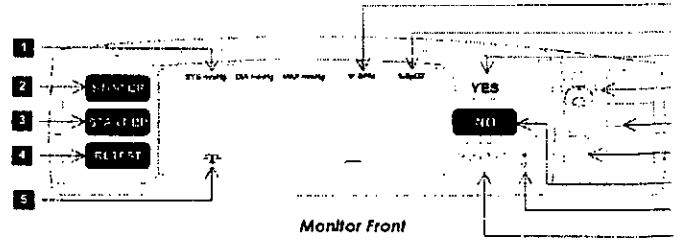
1. Place near a closed window on an outside wall.
2. Keep an open radius of one foot around the antenna.

DO NOT

- Place the Sentry Monitor on top of, or next to, electrical equipment (for example, a television or microwave). If it is absolutely necessary to place the monitor next to an electrical device, verify that the monitor works properly.
- Power up, until the monitor is setup and **all of the equipment** is properly attached.



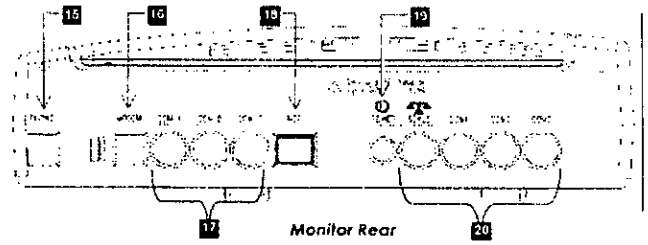
Choose a flat, stable, and uncluttered surface, near a closed window on an outside wall. Be sure the monitor is easily accessible, and you that have a place to sit. Find a permanent spot for the scale.



Monitor Front

Monitor Front

1. **SYS/DIA/MAP**
2. Red **STOP** BP key
3. Green **START** BP key
4. Blue **RETEST** key
5. Scale
6. **BPM** (with heart)
7. **%SpO2**
8. White **YES** key
9. Storage Channel
10. Cover Storage Channel
11. Probe Port
12. Black **NO** key
13. Green light in MANUAL key
14. Gray [ ] key



Monitor Rear

Monitor Rear

15. Phone line port
16. Modem connection port
17. Non-isolated communication ports (COM A, COM B, and COM C)
18. Net port
19. Power jack port
20. Isolated communication ports (SCALE, COM 1, COM 2, and COM 3)

193

Sentry Monitor Setup Guide

FINAL: 5/17/2006

Installation Overview

When you receive your shipment from Honeywell HomMed Sentry Monitor, carefully remove each piece of equipment from the box. Save the cartons and packing materials in case you need to return one of the systems. To avoid damage during transport of the box, check each piece of equipment for damage.

BE SURE TO...

Read the *Honeywell HomMed OTC Sentry Monitor Operator's Guide* before using your monitor. The manual contains important instructions, warnings, and cautions that should be reviewed before use.

Equipment List

Your package should include the following items:

- Sentry Monitor
- Scale and scale cable
- Blood pressure cuff
- Blood pressure hose
- Temporal Probe
- Oximeter (SpO2) Finger Sensor
- Phone cord and dust cap (set)
- AC adaptor (power supply)
- Power strip

HomMed Customer Service

Toll-free: **888-353-5404**

Phone: **262-252-5840**

Fax: **262-252-5795**

Web: **www.hommed.com**

Setting Up Your Sentry Monitor

It is important to set up the Sentry Monitor in an area where it can successfully measure vital signs and/or transmit results. If you will be using any accessory devices, make sure that there will be enough room to be able to attach them without any difficulty. To determine a suitable location, consider the following:

Monitor

1. Choose an accessible place to use the unit.
2. Ensure that a bed, chair, or other seating is available.
3. Place the Sentry Monitor on a flat, stable, and uncluttered surface, to allow the monitor to cool properly.
4. Make sure that you can easily attach any peripheral devices.

DO NOT

- Block the vents on the Sentry Monitor. The monitor should have a two-inch rear clearance.
- Use an electrical wall outlet controlled by a light switch.
- Place near sources of water such as sinks or bathtubs.
- Place on or near a heat source (stove, fireplace, heaters, heat vents, etc.)

Scale

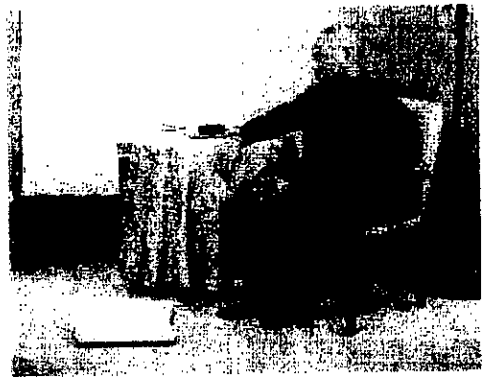
Find a **permanent spot** for the scale where you can easily stand on it. Scale should not be moved.

For optimal transmission

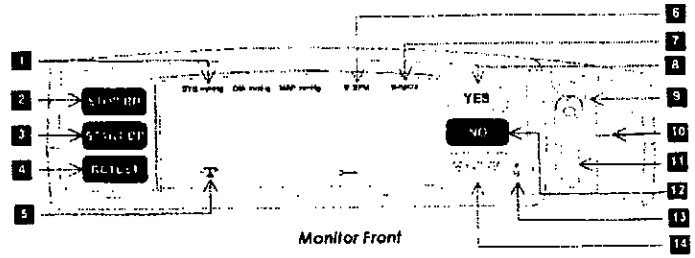
1. Place near a closed window on an outside wall.
2. Keep an open radius of **one foot** around the antenna.

DO NOT

- Place the Sentry Monitor on, top of, or next to, electrical equipment (for example, a television or microwave). If it is absolutely necessary to place the monitor next to an electrical device, verify that the monitor works properly.
- Power up, until the monitor is setup, and **all of the equipment** is properly attached.



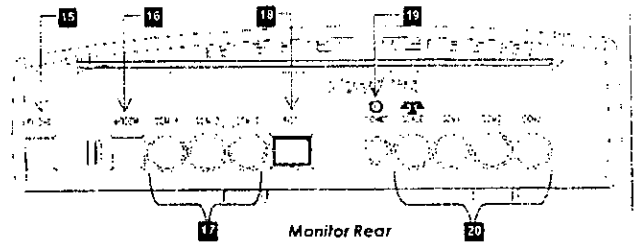
Choose a flat, stable, and uncluttered surface, near a closed window on an outside wall. Be sure the monitor is easily accessible, and you that have a place to sit. Find a permanent spot for the scale.



Monitor Front

Monitor Front

1. SYS/DIA/MAP
2. Red STOP BP key
3. Green START BP key
4. Blue RETEST key
5. Scale
6. BPM (with heart)
7. %SpO2
8. White YES key
9. Storage Channel
10. Cover Storage Channel
11. Probe Port
12. Black NO key
13. Green light in MANUAL key
14. Gray [ ] key



Monitor Rear

Monitor Rear

15. Phone line port
16. Modem connection port
17. Non-isolated communication ports (COM A, COM B, and COM C)
18. Net port
19. Power jack port
20. Isolated communication ports (SCALE, COM 1, COM 2, and COM 3)

Attaching the Honeywell HomMed scale

Make sure that you use the appropriate equipment for your monitor. Pay special attention to the scale cords.

Be sure ...

You have all the correct devices, power adapter, cords, and accompanying items **before assembling** your Sentry Monitor.

Attaching the cable to the scale

[illegible]

Plug the round MiniDIN connector into the **SCALE** connector on the port on the monitor.

Attaching the scale to the monitor

[illegible]

Finding the right location for the scale

The ideal location for the scale is on an **uncarpeted, hard surface**. [illegible]

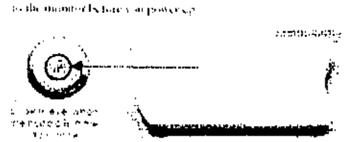
Do Not

- **Place near sources of water** such as sinks or bathtubs.
- **Move the scale** once you have set it up. This will prevent the scale from losing calibration.

Zeroing the scale

The scale **must be level** in order to zero [illegible]

[illegible]



Be sure to...

Not to move the scale [illegible]

[illegible]

Attaching the Honeywell HomMed scale (continued)

Do:

Read the label on the scale connector cord to verify that you have the correct scale cable for the scale you intend to attach to the monitor.

Do Not:

Power-down the monitor before you exchange scales. Attach and position the new scale **before** you turn the monitor back on.

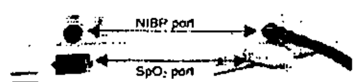
Attaching the blood pressure cuff and the oximeter

[illegible]

Attaching the oximeter

To attach the oximeter, hold the plug so that the letter **B** is on the bottom and the **BCI** label is on the top. [illegible]

1. [illegible]
2. [illegible]

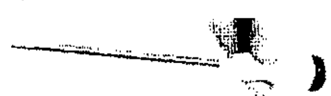


Attaching the blood pressure cuff

[illegible]

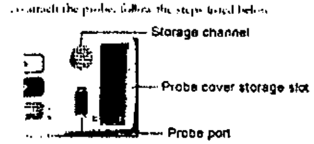
Attaching the temperature probe

[illegible]

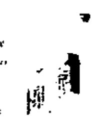


Attaching the probe (continued)

To attach the probe, follow the steps listed below.



1. With the tabbed side up, plug the temperature probe into the probe port. You should hear the tab click into place.
2. Insert the temperature probe firmly into the storage channel.
3. Remove the tab from the box of probe covers. Place the box in the rectangular storage channel with the open side down so the probe covers are easily accessible.

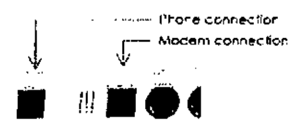


Connecting the pass-through phone and modem

CAUTION
REQUIRES ANALOG PHONE LINE
The modem requires an analog phone line. A digital phone line will damage the modem.
DO NOT use a digital phone line. Verify presence of analog phone line prior to installation.

To connect the phone and modem, follow the steps below.

1. Locate the **PHONE** and **MODEM** connectors on the back of the monitor.



2. Unplug the phone cord from the phone, and plug it into the **MODEM** port on the back of the Sentry monitor. The line is now the modem line that runs to the wall jack.
3. Plug one end of a phone cord into the phone, and plug the other end into the **PHONE** port. The phone now is connected to the pass-through.
4. The following figure shows the phone and modem cords properly connected to the Sentry monitor.

Powering up the Sentry Monitor

Before you power up:

- Check to see that you have attached all of the equipment.
- Make sure that the scale is in the proper location. You should not move the scale once you power up.
- The scale will not zero correctly if there is any weight on it when the monitor turns on.
- Check to see that the monitor's antenna is in an upright position.
- Position the monitor so that the cords are out of your way and that the back of the monitor has at least a two-inch clearance.

When you power up:

There is no on/off button on the monitor. The Sentry monitor powers up as soon as you plug it into a power source.

1. Plug the AC adapter jack into the power input on the rear of the monitor.
2. Plug the power block into an outlet or the power strip. Make sure that the back of flush with the strip.
3. Plug the power strip into a wall outlet. Turn the strip's power switch on.

[illegible]

[illegible]

[illegible]

[illegible]

ending a test message

[illegible]

[illegible]

[illegible]

195

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2006

Honeywell HomMed, LLC
c/o Tommie J. Morgan, Ph.D.
President
Morgan Consultants Inc.
2018 North Durham Drive
Houston, TX 77008

Re: K061088
Trade Name: Honeywell HomMed Sentry OTC Monitor
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: II (two)
Product Code: DRG
Dated: April 12, 2006
Received: April 18, 2006

Dear Dr. Morgan:

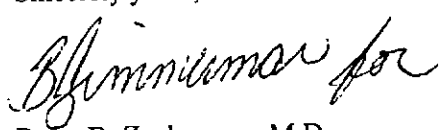
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061088

Device Name: Honeywell HomMed Sentry OTC Monitor

Indications For Use:

The Honeywell HomMed Sentry OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Sentry OTC Monitor's measurement capabilities. Data from the Sentry OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Sentry OTC Monitor is not intended for emergency use or real-time monitoring.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061088

3

~~D0003~~

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 28, 2006

HONEYWELL HOMMED, LLC
C/O MORGAN CONSULTANTS
2018 NORTH DURHAM DRIVE
HOUSTON, TX 77008
ATTN: TOMMIE J. MORGAN

510(k) Number: K061088
Received: 27-APR-2006
Product: SENTRY OTC MONITOR

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

196

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 19, 2006

HONEYWELL HOMMED, LLC
C/O MORGAN CONSULTANTS
2018 NORTH DURHAM DRIVE
HOUSTON, TX 77008
ATTN: TOMMIE J. MORGAN

510(k) Number: K061088
Received: 18-APR-2006
Product: SENTRY OTC MONITOR
User Fee ID Number: 6023713

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier (e.g., Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at http://www.fda.gov/oc/mdufma.

198

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/cdrh/dsmamain.html, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

K 06/088

Honeywell HomMed Sentry OTC
Table of Contents

Medical Device User Fee Cover Sheet

Cover Letter

Honeywell HomMed Authorization Letter

CDRH Submission Cover Sheet

Indications for Use Form

Section I: General Information

Device Modification History	1
Intended Use Defined	1
Product Compatibility	2

Section II: Summary and Certification

Summary of Safety and Effectiveness	6
Indications for Use Statement	3
510k Summary Honeywell HomMed Genesis	4

Section III: Proposed Labeling

Quick Start Guide	7

Section IV: Device Description

Device Description	9
Functional Requirement Specification	9
System Requirement Specification	9
Software Requirements and Design Summary	9

Section V: Comparison Information

Review of Substantial Equivalence	10
Risk Analysis	11
Predicate Device 510k letter	12
Predicate Device Intended Use Statement	14
Predicate Device 510k Summary	15
Comparison Matrix	17

Section VI: Product Development Activities

Product Design Summary	23
Software/Hardware Development	23
Hardware Testing	23
Software Testing	23
Validation and Verification Activities	23

K 13

II

200

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(5) Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

-->

1. COMPANY NAME AND ADDRESS (Include name, street address, city state, country, and post office code)

HOMMED LLC
19275 WEST CAPITOL DRIVE SUITE 200
BROOKFIELD WI 53045
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

(b)(5)

2. CONTACT NAME

Emily Vande Hei

2.1 E-MAIL ADDRESS

emily.vandehei@honeywell.com

2.2 TELEPHONE NUMBER (Include Area code)

262-252-6082

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

NO DATA

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column: if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms

[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)

$3,833.00

01-Dec-2005

Form FDA 3601 (08/2003)

Close Window

Morgan Consultants, Inc.

2018 North Durham Houston, TX 77008
Ph: 713/880-5111 FAX: 713/880-3494
email: MCI2000@swbell.net

April 12, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: 510(k) Application for Honeywell HomMed Sentry OTC Monitor

Dear Sir or Madam:

Morgan Consultants Inc. hereby submits for Honeywell HomMed, LLC this Sentry OTC Monitor, *Traditional 510(k) Application: Additional or Expanded Indications* for your review. This request represents a change in the intended use for the predicate device to over-the-counter (OTC) designation rather than prescription use. The predicate device is the HomMed Sentry IIIB-F Patient Monitor System 510(k) file number K040651.

The proposed intended use change to the approved Sentry Monitor does not alter the vital signs parameters being monitored or the collection of the vital signs data. The Sentry OTC monitor has the same scientific technology and intended vital sign monitoring capability as the predicate device; however, the oximetry function becomes an optional prescription offer to users of the Sentry OTC Monitor.

Attached is a copy of the Honeywell HomMed authorization letter for Dr. Tommie Morgan of Morgan Consultants Inc. to represent Honeywell HomMed LLC in correspondence with FDA. The FDA Fee Payment Identification Number for this Sentry OTC Monitor submission will be sent separately.

Thank you for your consideration of this Honeywell HomMed application.

Sincerely,

Tommie J. Morgan, Ph.D.
President

TJM/mm
Attachment

Cc: Michael Leigh, Director of Regulatory/QA, Honeywell HomMed LLC

202

Honeywell
HomMed

June 7, 2005

To Whom It May Concern:

As President of Honeywell HomMed, I hereby authorize FDA staff members to communicate directly with Tommie J. Morgan, Ph.D., President, Morgan Consultants Inc. and/or his staff regarding any and all questions, issues and requirements as may arise during the review of the attached 510(k) Medical Device Regulatory Submission for Honeywell HomMed Device(s).

Sincerely,

Herschel "Buzz" Peddicord
President/CEO

19275 West Capitol Drive, Suite 200, Brookfield, Wisconsin 53045 (262) 783-5440 Fax (262) 783-5441 www.hommed.com

203

CDRH SUBMISSION COVER SHEET

Date of Submission: **FDA Document Number:**

tion A **Type of Submission**

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	Original Submission: ■ Traditional ☐ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg. ☐ Pre-PMA mtg. ☐ Pre-PDP mtg. ☐ 180-Day mtg. ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	Describe Submission:

tion B **Applicant or Sponsor**

Company/Institution Name: Honeywell HomMed LLC		Establishment registration number: 3004183721	
Division Name (if applicable):		Phone number (include area code): 262-252-5794	
Street Address: 3400 Intertech Drive. Suite 200		Fax number (include area code): 262-252-6119	
City: Brookfield	State/Province: Wisconsin	Zip code: 53045	Country: USA

Contact Name:
Michael Leigh

Contact Title: Director Regulatory/QA	Contact e-mail address: Michael.Leigh@honeywell.com

Section C **Submission Correspondent (if different from above)**

Company/Institution Name: Morgan Consultants Inc.		Establishment registration number:	
Division name (if applicable)		Phone number (include area code): 713-880-5111	
et Address: 2018 North Durham Drive		Fax number (include area code): 713-880-3494	
City: Houston	State/Province: Texas	Zip Code: 77008	Country: USA

Contact Name: Tommie J. Morgan, Ph.D., President Email: mci2000@swbell.net

204

'ection D1 **Reason for Submission – PMA,PDP, or HDE**

☐ New Device
☐ Withdrawal
☐ Additional or Expanded Indications
☐ Licensing Agreement

☐ Change in design, component, or specification:
☐ Software
☐ Color Additive
☐ Material
☐ Specifications
☐ Other (specify below)

☐ Location Change:
☐ Manufacturer
☐ Sterilizer
☐ Packager
☐ Distributor

☐ Processing Change:
☐ Manufacturing
☐ Sterilization
☐ Packaging
☐ Other (specify below)

☐ Labeling Change:
☐ Indications
☐ Instructions
☐ Performance Characteristics
☐ Shelf Life
☐ Trade Name
☐ Other (specify below)_

☐ Report Submission:
☐ Annual or Periodic
☐ Post Approval Study
☐ Adverse Reaction
☐ Device Defect
☐ Amendment

☐ Response to FDA correspondence:
☐ Request for applicant hold
☐ Request for removal of applicant hold
☐ Request for extension
☐ Request to remove or add manufacturing site

☐ Change in Ownership
☐ Change in correspondent

☐ Other Reason (specify):

Section D2 **Reason for Submission - IDE**

☐ New device
☐ Addition of institution
☐ Expansion/extension of study
☐ IRB certification
☐ Request hearing
☐ Request waiver
☐ Termination of study
☐ Withdrawal of application
☐ Unanticipated adverse effect
☐ Notification of emergency use
☐ Compassionate use request
☐ Treatment IDE
☐ Continuing availability request

Change in:
☐ Correspondent
☐ Design
☐ Informed consent
☐ Manufacturer
☐ Manufacturing process
☐ Protocol - feasibility
☐ Protocol – other
☐ Sponsor

☐ Report Submission:
☐ Current investigator
☐ Annual progress
☐ Site waiver limit reached
☐ Final

☐ Response to FDA letter concerning:
☐ Conditional approval
☐ Deemed approval
☐ Deficient final report
☐ Deficient progress report
☐ Deficient investigator report
☐ Disapproval
☐ Request extension for time to respond to FDA
☐ Request meeting

☐ Other reason (specify):

Section D3 **Reason for Submission – 510(k)**

☐ New Device
■ Additional or expanded indications
☐ Other reason (specify):

☐ Change in technology
☐ Change in design

☐ Change in materials
☐ Change in manufacturing process

205

Section E **Additional Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety and effectiveness data: ■ 510(k) summary attached ☐ 510(k) statement
1 DXH	2	3	4	
5	6	7	8	

510(k) Number	Trade of Proprietary or model name	Manufacturer
1 K0400651	1 HomMed Sentry IIIB Patient Monitor	1 Honeywell HomMed LLC
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F **Product Information – Applicable to All Applications**

Common or usual name or classification name:
Patient Vital Signs Monitor with Options

Trade or proprietary or model name	Model Number
1 Sentry OTC	1 Sentry IIIB
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

K0400651	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

Section G **Product Classification – Applicable to All Applicants**

Product code: DXN	C.F.R. Section	Device Class: ☐ Class I ■ Class II ☐ Class III ☐ Unclassified
Classification Panel: Non-invasive Blood Pressure Measurement System		
Indications (from labeling): Patient vital signs monitor with options		206

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H **Manufacturing/Packaging/Sterilization Sites Relating to a Submission**

■ Original ☐ Add ☐ Delete	FDA establishment registration number: 3004183721	■ Manufacturer ☐Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler	
Company/Institution name: Honeywell HomMed LLC		Establishment registration number: 3004183721	
Division name (if applicable):		Phone number (include area code): 262-252-5749	
Street address: 3400 Intertech Drive, Suite 200		FAX number (include area code): 262-252-6119	
City: Brookfield	State/Province: WI	Zip code: 53045	Country: USA
Contact name: Michael Leigh			
Contact title: Director Regulatory/QA		Contact e-mail address: Michael.Leigh@honeywell.com	

☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler	
Company/Institution Name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title:		Contact e-mail address:	

☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ☐Contract sterilizer ☐ Contract Manufacturer ☐Repackager/relabeler	
Company/Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title:		Contact e-mail address:	

Indications for Use

510(k) Number (if known):

Device Name: Honeywell HomMed Sentry OTC Monitor

Indications For Use:

The Honeywell HomMed Sentry OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Sentry OTC Monitor's measurement capabilities. Data from the Sentry OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Sentry OTC Monitor is not intended for emergency use or real-time monitoring.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION I: GENERAL INFORMATION

Company	Honeywell HomMed LLC 3400 Intertech Drive, Suite 200 Brookfield, WI 53045
Establishment No.	3004183721
Manufacturing Site	Honeywell HomMed LLC
Common Name	Sentry Monitor
Trade Name	Sentry OTC Monitor
Proprietary Name	Sentry
Reason for 510(k) – Additional or Expanded Indications	Intended Use Change
Device Classification	Class II
Predicate Device(s)	HomMed Sentry IIIB Patient Monitor, K040651

*General information supplied as 510(k) summary in Section II of this document.

DEVICE MODIFICATION HISTORY

The Sentry OTC Monitor is an over-the-counter personal health monitor that provides means of easily self-monitoring physiological parameters at home. The Sentry OTC Monitor shall provide the same features and functionality as the predicate Sentry Monitor. It will continue to record vital signs measurement data with the option of further evaluation following transmission. While the focus of home health care has traditionally been on elderly and ill patients, modern trends indicate individuals want the ability to follow up and maintain their own health from the home. Offering the Sentry Monitor over-the-counter allows individuals more flexibility in monitoring choices by maintaining their own health data and making personal health monitoring convenient and cost effective for every home.

INTENDED USE

The modified intended use statement allows the Sentry OTC Monitor to be operated without prescription or healthcare provider assistance in the home. The proposed intended use change to the approved Sentry Monitor does not alter the vital signs parameters being

monitored or the collection of the vital signs data. The oximetry function becomes an optional prescription offer to users of the Sentry OTC Monitor. The Sentry OTC Monitor remains a high quality consumer medical device aimed primarily for use in the home. Data is collected, displayed and forwarded in a retrospective manner, and is not intended to provide real-time critical care monitoring, nor any local alarms or alerts.

PRODUCT COMPATIBILITY

Sentry OTC Monitor compatibility with optional external devices include:

- Glucose meters
- Spirometers
- Prothrombin Time monitors
- Magnetic card readers
- Scale
- Oximeter (w/Prescription)
- Blood Pressure Cuffs
- Temperature Probe
- ECG Monitor
- Honeywell HomMed Central Station

SECTION II: SUMMARY AND CERTIFICATION

SUMMARY OF SAFETY AND EFFECTIVENESS

The 510(k) summary contains a summary of the device characteristics compared to the predicate device. There are no different technological characteristics from the predicate device. The 510(k) summary contains a summary of how the operational characteristics of the over-the-counter device compare to the legally marketed device to which equivalence is claimed. Reason for a new 510k Submission is the additional indications in intended use from a prescription medical device to an over-the-counter designation for the Sentry OTC Monitor.

INDICATIONS FOR USE STATEMENT

The updated Honeywell HomMed Sentry OTC Monitor Indications for Use Statement follows in the required FDA format.

PREMARKET NOTIFICATION AND ACCURATE STATEMENT

An updated Premarket Notification and Accurate Statement follows in the required FDA format.

00006
21

Indications for Use

510(k) Number (if known):

Device Name: Honeywell HomMed Sentry OTC Monitor

Indications For Use:

The Honeywell HomMed Sentry OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Sentry OTC Monitor's measurement capabilities. Data from the Sentry OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Sentry OTC Monitor is not intended for emergency use or real-time monitoring.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Honeywell HomMed Sentry OTC Monitor

Date: April 11, 2006

Consultant Contact: Tommie J. Morgan, Ph.D., President
Morgan Consultants Inc.
2018 North Durham Drive
Houston, TX 77008
713.880.5111 Voice or 713.880.3494 Fax

Company: Michael Leigh, Director Regulatory/Quality
Honeywell HomMed, LLC
3400 Intertech Drive, Suite 200
Brookfield, WI 53045
262.252.5794 Voice or 262.252.6119 Fax

Trade Name: Honeywell HomMed Sentry OTC Monitor

Common Name: Vital Signs Monitor

Classification Name: Cardiovascular and Respiratory Devices, Class II

Product Code: NIBP Measurement System, DXN

Predicate Device: HomMed Sentry IIIB Patient Monitor System K040651

Device Description: The Honeywell HomMed Sentry OTC Monitor is a vital signs monitoring system. The system measures noninvasive blood pressure, pulse rate, oral temperature and weight. The Sentry OTC Monitor has six serial ports available for external options. The Sentry OTC Monitor acquires the vital signs data and displays it. The data can be transmitted via the communication module to a central viewing station.

Indications for Use: *The Honeywell HomMed Sentry OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Sentry OTC Monitor's measurement capabilities. Data from the Sentry OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Sentry OTC Monitor is not intended for emergency use or real-time monitoring.*

Intended Use: The Honeywell HomMed Sentry OTC is the remarketing of a previously approved product for OTC use. It is intended for personal use and use of the system allows retrospective review of certain physiological functions. The Sentry OTC collects vital signs data (including noninvasive blood pressure, pulse rate, oral temperature, and weight) then can transmit the data to a central review station via a communication network. The Sentry OTC is intended for use with adult and pediatric patients over twelve years of age.

Technology: The Honeywell HomMed Sentry OTC Monitor employs the same technologies of the predicate device, HomMed Sentry IIIB Patient Monitor System, K040651.

The Honeywell HomMed Sentry Monitor(s) complies with the following voluntary standards:

- EN 60601-1 Medical Electrical Safety
- IEC 601-1-2 EMC Compliance
- ISO 10993-5,10-11 Biocompatibility

Test Summary: The Honeywell HomMed Sentry System (Sentry OTC and its predicate Sentry IIIB) utilized within the environments for which it is marketed performs consistent with guidelines and standards found in the FDA reviewer's guides for respiratory devices and electronic thermometers. Completed EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing demonstrate compliance with applicable standards. The test results demonstrated that the Sentry is in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements.

Conclusion: It is the Honeywell HomMed position that the results of these evaluations demonstrate the Sentry OTC Monitor is as safe, as effective and performs as well as the legally marketed predicate device, HomMed Sentry IIIB Patient Monitor.

SECTION III: PROPOSED LABELING

There follows a list of documents for the Honeywell HomMed Sentry OTC Monitor:

- Sentry Monitor Operator's Guide
- Sentry Monitor Quick Reference Guide
- Sentry Monitor Installation Guide
- Sentry Monitor Support Guide
- Sentry Monitor Getting Started – Setup Instruction Sheet

Sentry Monitor Operator's Guide

The Operator's Guide and includes: safety, programming, health monitoring sessions, taking vital signs with the Honeywell HomMed Sentry Monitor; and troubleshooting information

General Information:	This section contains the indications of use, special conventions, additional references and additional information.
Safety Information:	This section contains the pertinent safety information, safety conventions and safety notes.
Programming Your Monitor	This section contains an explanation of the function keys, set-up mode, scheduling options, and a programming menu list.
Monitoring Sessions:	This section contains: an explanation of monitoring sessions, monitor prompts, a menu data list, text displays, and prompts for accessory devices (compatible peripheral devices).
Taking Your Vitals:	This section contains the information how to take their vital signs: blood pressure, weight, temperature, and blood-oxygen levels. It also contains information on collecting data from accessory devices.
Programming for Transmission:	This section contains information on transmission requirements: password, PIN information, transmit menu, transmit protocols, ISP settings, options menu (including options for accessory devices), and information on how to send a test message.
Troubleshooting:	This section provides summary of the most commonly encountered problems/situations, probable causes, and resolutions. Included are a list of error codes, their meanings, and a list of additional references.
Appendices:	This section provides additional relevant information: text list of programmable subjective questions; text list of sleep apnea questions; the Honeywell HomMed warranty information; list of compatible peripheral and accessory devices

00007
215

Glossary and Index: *Glossary:* List of definitions for the most commonly used terms, expressions, and devices used in this document. *Index:* List of sections, chapters, subjects, and specific items mentioned in this document.

Sentry Monitor Quick Reference Guide

This Quick Reference Guide is intended as a daily use reference document for the customer with their Honeywell HomMed Sentry Monitor.
This document includes: safety information; an overview of the Sentry Monitor, explanation of monitor keys, monitor prompts, a list of general prompts, and text displays. Included in this document is information on what to do if accidental spills occur, and how to take vital signs: blood pressure, scale, oximeter (optional prescription device), temperature. Further information is provided on collecting data from other accessory devices, customer service contact information, and safety information. A blank chart is provided in the back of the document for customers to record their vital signs.

Sentry Monitor Installation Guide

The Installation Guide is intended to assist customers in the proper setup and installation of the Honeywell HomMed Sentry Monitor. This document includes: customer service contact and safety information, an installation overview, and an itemized list of installation "do and don'ts." Specific installation information is provided for each component of the Honeywell HomMed Sentry Monitor. This includes: the HomMed and Fairbanks scales, blood pressure cuff, oximeter, and temperature probe. Other information included: connecting the pass-through phone and modem, powering up, and how to send a test message.

Sentry Monitor Support Guide

The Support Guide is intended to give customers information on the proper maintenance, cleaning and calibration of their Honeywell HomMed Sentry Monitor. This document includes: safety information and warnings, hazard conventions, CE Marking information, electromagnetic guideline information, product information, including specifications for monitor, pager, modem, and non-invasive blood pressure cuff, customer service contact information, repairing equipment, and how to ship the monitor/equipment to Honeywell HomMed are included in the Support Guide. Other sections cover the cleaning, inspection, and calibration of the monitor, NIBP cuff and other accessories. Appendices include a text list of prompts, and a supply list of available parts.

Sentry Monitor: Getting Started – Setup Instruction Sheet

The Setup Instruction Sheet is a visual aid intended to assist customers in the proper setup and installation of the Honeywell HomMed Sentry Monitor. As such, it is meant to be an adjunct to the Installation Guide. Graphics and text are used to show the proper placement and port attachment for each component or accessory. Included is a packing list of items that come with the Sentry Monitor.

00008

216

SECTION IV: DEVICE DESCRIPTION

DEVICE DESCRIPTION

The Honeywell HomMed Sentry OTC Monitor will prompt, via a digitally recorded voice, users to acquire vital signs information at programmable times. The memory storage for the voice is a removable SmartMedia card, allowing for multi-language capabilities. Once all data is collected, it may be forwarded, at user's discretion, as a packet to a central viewing station in a remote location, based on the monitor option settings and available service. The Sentry OTC Monitor is intended for use with adult and pediatric patients over twelve years of age. The card reader functionality allows multiple users of a single monitor. An external DC adapter powers the Sentry OTC Monitor. Setup modes are provided for configuration options and calibration/verification, some requiring a password. The Sentry OTC Monitor will have six serial ports available for external options, including connection to a personal computer.

FUNCTIONAL SYSTEM REQUIREMENT

For a general description of the Sentry OTC Monitor, including required features, functionality and interface, user options, and packaging, refer to the predicate device, *Honeywell HomMed Sentry IIIB Patient Monitor System,* K040651.

SYSTEM REQUIREMENT SPECIFICATIONS

For a more detailed description of the Sentry OTC Monitor, including functional description, system design and user requirements, development and operational environments, off-the-shelf software, hardware and software structural design, operating system, user interface, and hardware requirements, refer to *Honeywell HomMed Sentry IIIB Patient Monitor System,* K040651.

Refer to the predicate device, *Honeywell HomMed Sentry IIIB Patient Monitor System,* K040651 for the Risk Management Plan details.

SOFTWARE REQUIREMENTS AND DESIGN (SDD) SUMMARY

The Sentry OTC monitor is identical to the FDA cleared Sentry IIIB Monitor with no software changes made.

For software design descriptions and documentation refer to the predicate device, *Honeywell HomMed Sentry IIIB Patient Monitor System,* K040651.

00039

217

SECTION V: COMPARISON INFORMATION

REVIEW OF SUBSTANTIAL EQUIVALENCE

The following comparison information illustrates differences and similarities between the legally marketed predicate prescription device, Honeywell HomMed Sentry IIIB Patient Monitor K040651 and the Honeywell HomMed Sentry OTC Monitor, over-the-counter version including intended use and functional characteristics.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

The device to be distributed by Honeywell HomMed, LLC as the Sentry OTC Monitor is substantially equivalent to the Honeywell HomMed Sentry IIIB Patient Monitor, K040651. There are no changes in technology or functionality in the Sentry OTC Monitor when compared to the predicate device. The expanded intended use of the Sentry OTC Monitor was made to provide ease-of-use and user convenience to a more health conscious consumer market.

Like the predicate Sentry Monitor, the Sentry OTC Monitor provides an innovative solution that prompts the user with voice commands and light cues when it's time to take vital signs. The same vital signs parameters are measured and displayed.

The predicate device and the Sentry OTC provide monitoring of an individual's vital signs using programmable software. Both monitoring systems, the predicate device and Sentry OTC, offer capability to export vital signs data collected to a third party for review.

STATEMENT OF SIGNIFICANT CHANGE

The Sentry OTC Monitor is not significantly different from the predicate prescription Sentry Monitor. There is no change in technology, equipment, hardware or software. The Sentry OTC Monitor expands the intended use to allow self-monitoring of the same physiological vital sign parameters without healthcare provider involvement or a prescription. Certain compatible optional device(s), i.e. the oximetry capability, must be ordered with a physician's prescription.

This Honeywell HomMed Sentry OTC monitor does not raise new safety or effectiveness issues; a change has been made in the intended use but does not change the original specifications, and does not provide new technology.

PRODUCT EQUIVALENCE

INTENDED USE

The Intended Use contains a subtle shift to allow for self-health/wellness review:

> *The Honeywell HomMed Sentry OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Sentry OTC Monitor's measurement capabilities. Data from the Sentry OTC Monitor can be transmitted*

via a communication module to a central viewing station for display. The Sentry OTC Monitor is not intended for emergency use or real-time monitoring.

- Modifications to the Intended use include:
  - The exclusion of the professional healthcare provider review
  - Availability of use as over-the-counter
- See references to Predicate Device Intended Use, *Sentry IIIB Patient Monitor System,* K040651:
  - Predicate Device Letter
  - Predicate Device Indications for Use Statement

COMPARISON MATRIX

See Product Comparison of *Honeywell HomMed Sentry IIIB Patient Monitor K040651* vs. Honeywell HomMed Sentry OTC Monitor provided in this section.

RISK ANALYSIS

The risk assessment revealed that the same product has the same user population, which results in the same risk assessment. The Sentry products do not change nor does the user population for the products change, therefore there are no new hazards. The over-the-counter (OTC) mode means that a healthcare professional may not be directly involved in use of the product, and so updates to the manual have been made to clarify some points for the over-the-counter lay-user.

- Refer to the predicate device, *Honeywell HomMed Sentry IIIB Patient Monitor System,* K040651 for the Risk Management Plan details.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2004

HomMed, LLC
c/o Tommie J. Morgan, Ph.D.
President
Morgan Consultants Inc.
2018 North Durham Drive
Houston, TX 77008

Re: K040651
Trade Name: HomMed Sentry IIIB-F Patient Monitor System
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: II (two)
Product Code: DXH
Dated: July 29, 2004
Received: July 30, 2004

Dear Dr. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

220

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K040651

Device Name: HomMed Sentry IIIB-F Patient Monitor System

Indications for Use

The HomMed Sentry IIIB-F Patient Monitor System is designed to measure Patient Vital Signs in the home by patients or in clinical environments by health care providers. The HomMed Sentry IIIB-F Patient Monitor System is available with physicians' orders only.

The HomMed Sentry IIIB-F Patient Monitor System measures the following parameters: Non-Invasive Blood Pressures (Systolic, Diastolic and Mean Arterial Pressure), Functional Oxygen Saturation (%SpO_2), Peripheral Pulse Rate (PPR), Pulse Strength, Oral Temperature and Patient Weight via an external scale. The HomMed Sentry IIIB-F Patient Monitor System's optional, compatible devices extend those measurements to glucometer, spirometer, electrocardiogram (ECG) and prothrombin time (PT/INR) monitoring and digital image acquisition. The patient parameter data is collected and displayed by the HomMed Sentry IIIB-F Patient Monitor System. Data can be transmitted via the communication module to a central station where the patient data can be viewed and analyzed.

Prescription Use ____X____ AND/OR Over-the-Counter Use _____
(21 CFR 807 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040651

Page 1 of __

K040651

p1/2

AUG 1 0 2004

510(k) Summary

HomMed Sentry IIIB-F Patient Monitor System

Consultant Contact: Tommie J. Morgan, Ph.D., President
Morgan Consultants Inc.
2018 North Durham Drive
Houston, TX 77008
713 880-5111 Voice or 713 880-3494 Fax

Company: HomMed, LLC
19275 West Capitol Dr., Suite 200
Brookfield , WI 53045
262 783-5440 Voice or 262 783-5441 Fax

Trade Name: HomMed Sentry IIIB-F Patient Monitor System

Common Name: Patient Vital Signs Monitor with Options

Classification Name: Cardiovascular and Respiratory Devices, Class II

Substantial Equivalence Claimed to:
HomMed Sentry III Patient Monitor System with Card Reader K014025

Device Description: The HomMed Sentry IIIB-F Patient Monitor System (Sentry IIIB-F) is a portable patient vital signs monitoring system. The system measures noninvasive blood pressure, pulse rate, oral temperature, oximetry, and weight. In addition, the system has optional glucometer, spirometer, electrocardiogram (ECG) and prothrombin time (PT/INR) measuring, and digital image acquisition capabilities. The Sentry IIIB-F acquires the patient vital signs data and displays it. The data can also be transmitted via the communication system through the Skytel or PageNet Pager Network to a central station for storage with retrospective display and analysis

Indications for Use: The HomMed Sentry IIIB-F is intended for in home and/or healthcare facility applications under physician orders. The use of the system is to allow retrospective review of certain patient physiological functions. The HomMed Sentry IIIB-F can measure and display patient data including noninvasive blood pressure, pulse rate, oral temperature, oximetry, and weight. Additionally, the patient vital signs data can be communicated to a central review station via a pager network with a backup landline telephone modem for telephone communication with the central pager network if necessary.

Sentry IIIB-F provides a noninvasive blood pressure (NIBP) monitor for measurements of a patient's systolic, diastolic, and mean arterial (MAP) blood pressures; pulse oximeter, acquires a pulse rate using an oximeter; oral temperature via an electronic thermometer; weight from an electronic scale. All data collected from these functions as well as optional glucometry, spirometry, ECG devices, PT/INR monitor and acquired digital images are sent through an internal communication module.

The device will provide fast, reliable measurements on patients when using the appropriate blood pressure cuff. Sentry IIIB-F's pulse oximetry works with the

~~050512~~

00015
223

Sentry pulse oximetry probes provided by HomMed, providing Sp02 anc pulse rate on all patients. The electronic thermometry requires use of the Welch Allyn oral thermometry probe and probe covers. It provides only cral temperature information.

Comparison with Predicate Devices:

This HomMed Sentry IIIB-F allows uncomplicated measurement and remote monitoring of patient vital signs including weight utilizing the existing technologies of the predicate device, HomMed Sentry III Patient Monitor System with Card Reader.

Determination of Substantial Equivalence:

The performance of each component of the HomMed Sentry IIIB-F has been confirmed to be equivalent to the predicate device HomMed Sentry III Patient Monitor System with Card Reader.

Compliance to Standards and Regulations:

The HomMed Model Sentry IIIB-F complies with the following national and international standards:

Safety	EN 60601-1	Medical Electrical Safety
	IEC 601-1-2	EMC Compliance
	ISO 10993-5,10-11	Biocompatibility

Performance Data:

The HomMed Sentry IIIB-F is utilized within the environments for which it and Sentry III with Card Reader are marketed. The Sentry IIIB-F performs consistent with guidelines and standards found in the FDA reviewer's guides for respiratory devices and electronic thermometers. EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing has been completed demonstrating compliance with applicable standards. The test results demonstrated that the Sentry IIIB-F is in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements.

The HomMed Sentry IIIB-F performance is consistent with the HomMed Sentry III with Card Reader performance. Testing done on the Sentry III IIIB-F assures compliance with applicable electrical, safety and healthcare standards. Thus it is the HomMed position that the HomMed Sentry IIIB-F performs as well as the legally marketed predicate device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding patient monitors.

Feature / Function	Sentry IIIB 510(k) # K040651	Proposed Sentry OTC	Explanation of Differences (if any)
Indications for Use			
Intended Use	The HomMed Sentry IIIB-F Patient Monitor System is designed to measure Patient Vital Signs in the home by patients or in clinical environments by health care providers. The HomMed Sentry IIIB-F Patient Monitor System is available with physicians' orders only. The HomMed Sentry IIIB-F Patient Monitor System measures the following parameters: Non-Invasive Blood Pressures (Systolic, Diastolic and Mean Arterial Pressure), Functional Oxygen Saturation (%SpO_2), Peripheral Pulse Rate (PPR), Pulse Strength, Oral Temperature and Patient Weight via an external scale. The HomMed Sentry IIIB-F Patient Monitor System's optional, compatible devices extend those measurements to glucometer, spirometer, electrocardiogram (ECG) and prothrombin time (PT/INR) monitoring and digital image acquisition. The patient parameter data is collected and displayed by the HomMed Sentry IIIB-F Patient Monitor System. Data can be transmitted via the communication module to a central station where the patient data can be viewed and analyzed.	The Honeywell HomMed Sentry OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercial stand-alone products extend the Sentry OTC Monitor's measurement capabilities. Data from the Sentry OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Sentry OTC Monitor is not intended for emergency use or real-time monitoring.	Equivalent See Note #1
Patient Population	Pediatric to Adult	Pediatric to Adult	Identical

Feature / Function	Sentry IIIB 510(k) # K040651	Proposed Sentry OTC	Explanation of Differences (if any)
Environment of Use	Intended to be used in a clinical environment by health care providers or in the home by patients	Intended for personal use	Equivalent See Note #1
Hardware			
Hardware Platform	Main PCB w/ integrated temperature module Add-on oximeter and NIBP modules. Molded enclosure	Main PCB w/ integrated temperature module Add-on oximeter and NIBP modules. Molded enclosure	Identical
Hardware Compliance/ Conformity Standards	1) Standard for Safety for Medical Electrical Equipment, UL 2601 2) EMC, EN60601-1-2: 1998- Class B	3) Standard for Safety for Medical Electrical Equipment. UL 2601 4) EMC. EN60601-1-2: 1998- Class B	Identical
Standard Integrated Parameters			
Heart/Pulse Rate			
Range	30-254 bpm (SPO_2) 30-180(NIBP)	30-254 bpm (SPO_2) 30-180(NIBP)	Identical
Accuracy	± 2 bpm or 2% whichever is greater	± 2 bpm or 2% whichever is greater	
Temperature			
Technology	Electronic Thermometry Welch-Allyn	Electronic Thermometry Welch-Allyn	Identical
Range	84.0-108.0 F	84.0-108.0 F	Identical
Accuracy	± 0.2 F	+/-0.2 F	Identical
Weight			

Feature / Function	Sentry IIIB 510(k) # K040651	Proposed Sentry OTC	Explanation of Differences (if any)
Technology	Digital Integra	Digital Integra	Identical
Range	25 to 500 lbs. (227 kg)	25 to 500 lbs. (227 kg)	Identical
Accuracy	0.5 lbs	0.5 lbs	Identical
Non-invasive Blood Pressure (NIBP)			
Technology	Oscillometric SunTech	Oscillometric SunTech	Identical
Range	20-250 mmHg	20-260 mmHg	Identical
Accuracy	±3 mmHg (0-300mmHg)	±3 mmHg (0-300mmHg)	Identical
Default Inflation Pressure	175 mmHg	175 mmHg	Identical
Pulse Oximetry			
Technology	SIMS BCI Spectrophotometric Micro Oximeter	SIMS BCI Spectrophotometric Micro Oximeter	Identical; Optional with prescription in Sentry OTC
Range	70-100% SpO_2 (functional SpO_2)	70-100% SpO_2	Identical
Accuracy	± 2% at 70-100%	± 2% at 70-100%	Identical
Optional Stand Alone Peripherals			
Glucometry	Yes LifeScan FastTake One Touch Profile One Touch Basic One Touch Ultra Bayer Glucometer	Yes LifeScan FastTake One Touch Profile One Touch Basic One Touch Ultra Bayer Glucometer	Identical

Feature / Function	Sentry IIIB 510(k) # K040651	Proposed Sentry OTC	Explanation of Differences (if any)
Prothrombin Time/INR	ProTime Microagglutination System	ProTime Microagglutination System	Identical
Spirometer	Micro Medical Spirometer Piko-1 Peak Flow Meter	Micro Medical Spirometer Piko-1 Peak Flow Meter	Identical
ECG	Optional ECG device interface HealthFrontier ecg@home	Optional ECG device interface HealthFrontier ecg@home	Identical
Digital Camera	Optional digital camera image download via integrated digital photo adapter and transmission capability	Optional digital camera image download via integrated digital photo adapter and transmission capability	Identical
Port Powered Magnetic Card Reader	Yes	Yes	Identical
SmartMedia Cards	SmartMedia Flash Memory card used to store voice and text prompts 32 and 64 M	SmartMedia Flash Memory card used to store voice and text prompts 32 and 64 M	Identical
Power			
AC Power Input	External AC power adapter medical grade	External AC power adapter medical grade	Identical
Lithium Battery	Maintain contents of volatile RAM	Maintain contents of volatile RAM	Identical
Operator Interface			
Display	Vacuum fluorescent display	Vacuum fluorescent display	Identical
Keys	6 hard-coded	6 hard-coded	Identical
Auditory Prompts & Indicators	English, French, Spanish, German, Italian, Portuguese, French Canadian, Hindi	English, British English, Russian, Romanian, French, Spanish, German, Italian, Portuguese, French Canadian, Hindi and Armenian	Identical

Feature / Function	Sentry IIIB 510(k) # K040651	Proposed Sentry OTC	Explanation of Differences (if any)
Displayed Monitored Parameters	Systolic mmHg, Diastolic mmHg, MAP mmHg, BPM (Heart symbol), %SpO_2, Weight symbol, Temperature symbol	Systolic mmHg, Diastolic mmHg, MAP mmHg, BPM (Heart symbol), %SpO_2, Weight symbol, Temperature symbol	Identical
Communications			
Transmission	Pager Modem Local Gateway Serial mode	Pager Modem Local Gateway Serial mode	Identical
External Communication Ports	7 serial ports 3 isolated, 4 non-isolated	7 serial ports 3 isolated, 4 non-isolated	Identical
Service Features			
Flash Rom Software Update	Ability to update software via ROM file on a SmartMedia card (2 slots-removal of voice prompt card not necessary)	Ability to update software via ROM file on a SmartMedia card (2 slots-removal of voice prompt card not necessary)	Identical
SmartMedia Copy	Ability for Service/manufacturing to copy Smartmedia cards utilizing the upper and lower card slots	Ability for Service/manufacturing to copy Smartmedia cards utilizing the upper and lower card slots	Identical
Physical Specifications			
Height	4.0 in.	4.0 in.	Identical
Depth	6.5 in.	6.5 in.	
Width	10.0 in.	10.0 in.	
Weight	Approx. 2.5 lbs.	Approx. 2.5 lbs.	
Environmental Specifications			
Temperature	Storage: -40 -167 °F Operating: 32 - 122°F	Storage: -40 -167 °F Operating: 32 - 122°F	Identical

Feature / Function	Sentry IIIB 510(k) # K040651	Proposed Sentry OTC	Explanation of Differences (if any)
Relative Humidity	Storage: 10-95% (non-condensing) Operating: 15-95% (non-condensing)	Storage: 10-95% (non-condensing) Operating: 15-95% (non-condensing)	Identical

Note 1: The changes described in this analysis do not raise new safety or effectiveness issues, do not provide new features or change intended use, do not significantly affect the original specifications, and do not provide new technology.

SECTION VI: PRODUCT DEVELOPMENT ACTIVITIES

Hardware and software test plans for the predicate device, *Honeywell HomMed Sentry IIIB Patient Monitor System, K040651* adequately extend to the OTC application. No additional testing of the software or mechanics of the monitor was found to be necessary to cover the modified use at this time.

PRODUCT DESIGN

- The design concept is to provide a non-prescription multi-parameter, multi-use vital signs Sentry OTC Monitor.

- The Sentry OTC monitor displays vital signs data only, with an option to communicate data to a central viewing station.

SOFTWARE/HARDWARE DEVELOPMENT PROCESS

For Honeywell HomMed's development/planning activities, test plans and results as related to the Sentry design series, see predicate device, *Honeywell HomMed Sentry IIIB Patient Monitor, K040651.*

HARDWARE TESTING

For Hardware Validation Test Plan and Test Results, see predicate device, *Honeywell HomMed Sentry IIIB Patient Monitor, K040651.*

SOFTWARE TESTING

For Software Design Description, Software Design Requirements and Software Validation & Verification Procedures see predicate device, *Honeywell HomMed Sentry IIIB Patient Monitor, K040651.*

VALIDATION AND VERIFICATION ACTIVITES

For Hardware and Software Validation and Verification Activities refer to the predicate device, *Honeywell HomMed Sentry IIIB Patient Monitor, K040651.*

Honeywell HomMed Sentry OTC
Table of Contents

Medical Device User Fee Cover Sheet

Cover Letter

Honeywell HomMed Authorization Letter

CDRH Submission Cover Sheet

Indications for Use Form

Section I: General Information

Device Modification History	1
Intended Use Defined	1
Product Compatibility	2

Section II: Summary and Certification

Summary of Safety and Effectiveness	6
Indications for Use Statement	3
510k Summary Honeywell HomMed Genesis	4

Section III: Proposed Labeling

Quick Start Guide	7

Section IV: Device Description

Device Description	9
Functional Requirement Specification	9
System Requirement Specification	9
Software Requirements and Design Summary	9

Section V: Comparison Information

Review of Substantial Equivalence	10
Risk Analysis	11
Predicate Device 510k letter	12
Predicate Device Intended Use Statement	14
Predicate Device 510k Summary	15
Comparison Matrix	17

Section VI: Product Development Activities

Product Design Summary	23
Software/Hardware Development	23
Hardware Testing	23
Software Testing	23
Validation and Verification Activities	23

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) SKLAPPALAINEN

Subject: 510(k) Number K061088

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☑ NO
Is this device subject to the Tracking Regulation?	☐ YES	☑ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☑ NO
Is this a prescription device?	☐ YES	☑ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☑ NO
Special 510(k)?	☐ YES	☑ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☑ NO

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

☑ A 510(k) summary ~~OR ☐ A 510(k) statement~~

~~☐ The required certification and summary for class III devices~~

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ YES ☑ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

74/DRG/II/21 CFR 870.2510

Review: Sabina Reilly (Branch Chief) CEMB (Branch Code) 6/8/06 (Date)

Final Review: [signature] (Division Director) 6/9/06 (Date)

Revised:4/2/03

4

Memorandum

Date: June 7, 2006

From: Sharon K. Lappalainen, MT (ASCP), Scientific Reviewer, Cardiac Electrophysiology & Monitoring Branch, DCD (HFZ-450)

Subject: Substantial Equivalence (SE) Decision Making Documentation

To: The Record of K061088

Device: Honeywell HomMed Sentry OTC Monitor

Sponsor: Honeywell HomMed
3400 Intertech Drive, Suite 200
Brookfield, Wisconsin 53045

Contact: Tommie J. Morgan, PhD
President
Morgan Consultants, Inc.

Review History/Background
Honeywell HomMed presents the second of two **Traditional 510(k)s** for their previously cleared home use by prescription portable patient monitors. The purpose of this 510(k) is to change the prescription legend to provide the monitor available to the consumer over-the-counter (OTC). The peripheral devices used with the monitor are available OTC or by prescription (Rx). Physiological monitoring/recording systems are Class II devices, regulated under Radiofrequency Physiological Signal Transmitter and Receiver (21 CFR § 870.2910) with a product code of 74 DRG.

Intended Use
The Honeywell HomMed Sentry OTC Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, oral temperature and weight. Data from optional commercially stand-alone products extend Genesis OTC Monitor's measurement capabilities. Data from the Genesis OTC Monitor can be transmitted via a communication module to a central viewing station for display. The Genesis OTC Monitor is not intended for emergency use or real-time monitoring.

	Yes	No
• Is the device life supporting or life sustaining?		✓
• Is the device implanted (short-term or long-term)?		✓
• Does the device design use software?	✓	
• Is the device sterile?		✓
• Is the device single-use?		✓
• Is the device for home use?	✓	
• Or for prescription use?		✓

- Does the device contain drug or biological product as a component? ✓
- Is this device a kit? ✓

Device Description

(b)(5)

Performance Characteristics & Data:

(b)(5)

The sponsor provides a discussion that sufficiently documents the substantial equivalence of this device with respect to the predicate devices and with respect to its intended use, design, performance, and labeling. The predicate Rx device was designed for use in the home. The device appears to be intuitive and easy to use by the consumer and has a long history of use in the home through prescription sales. For the OTC indication, the labeling has been modified for the OTC market and consumer. Labeling provides appropriate instruction on the use of the device, as well as its appropriate troubleshooting, service and calibration requirements. Warning are in place that caution users that the device is not intended as an EMS service, nor as a substitute for regular visits to their attending physician. Therefore, the remaining concern of this reviewer, e.g., that of adequate labeling, has been provided and is satisfactory.

Substantial Equivalence (SE) Decision Making Documentation

		YES	NO	
1.	Is Product A Device	Y		If **No** = Stop
2.	Is Device Subject To 510(k)?	Y		If **NO** = Stop
3.	Same Indication Statement?	Y		If **YES** = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NE**
5.	Same Technological Characteristics?	Y		If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?		N	If **NO** = Go To 10 If **YES** = Stop **SE**
8.	New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist?			If **NO** = Stop **NE**
10.	Performance Data Available?	Y		If **NO** = Request Data
11.	Data Demonstrate Equivalence?	Y		Final Decision: SE

7. Descriptive Characteristics are not sufficient. Explain.
Performance characteristics including information about electrical safety, software, in-vitro bench testing, and standards compliance are needed to determine substantial equivalence.

10. Performance Characteristics demonstrate SE. Explain.
Data/information provided by the sponsor (e.g., conformance to electrical standards, conformance to electromagnetic compatibility standards, performance testing, material safety, etc.) indicate that the device will adequately perform to its intended use and indication for use.

Administrative Requirements
The sponsor has provided the Truthful and Accurate Statement, 510(k) Summary, and Indication for Use Statement. **Administrative requirements are met.**

Recommendation

Substantially Equivalent (SE) to devices regulated under:

CFR Section: 21 CFR § 870.2910
Panel: 74
Product Code: DRG
Class: II

Sharon K. Lappalainen, MT (ASCP)
Scientific Reviewer, Cardiac Electrophysiology & Monitoring Branch, DCD

[ ] Concur

Sabina Reilly,
Chief, Cardiac Electrophysiology & Monitoring Branch, DCD [ ] Do Not Concur

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		✓ ✓
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?	N/A CLASS II	
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?	✓ ✓	✓
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	——	✓
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	—— —— ✓	✓

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K061088

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☑ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **	—	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	—	
510(k) Kit Certification ***	—	

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

12

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.**]		

13

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:		
i) sterilization process	N/A	sterile
ii) validation method of sterilization process		
iii) SAL	Not	
iv) packaging		
v) specify pyrogen free	/	
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method	✓	
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

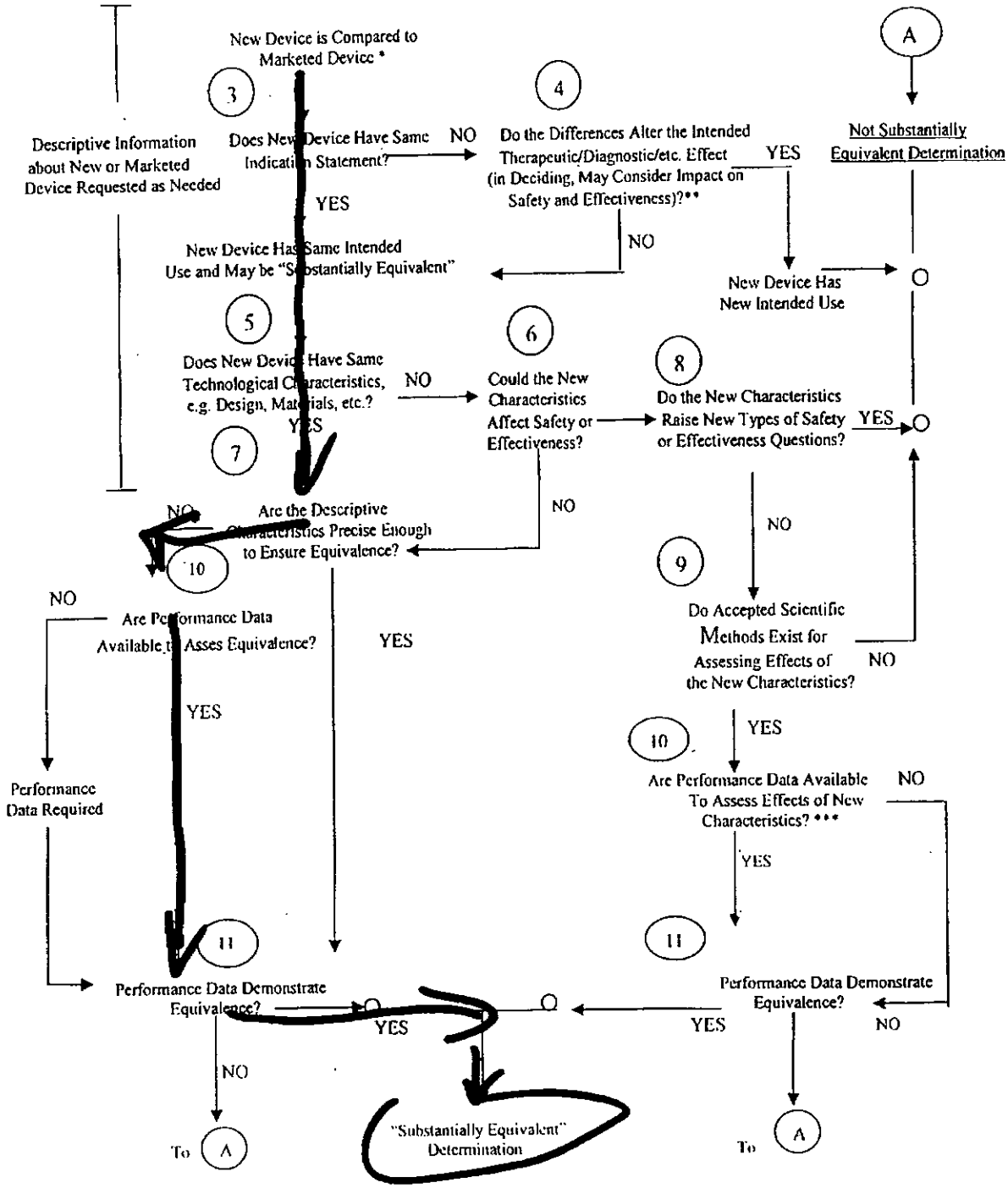
Passed Screening: ✓ Yes ___ No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

5