ATLAS MOBILITY

Bedside Mobility Monitoring System

Instructions for Use

Version: 36

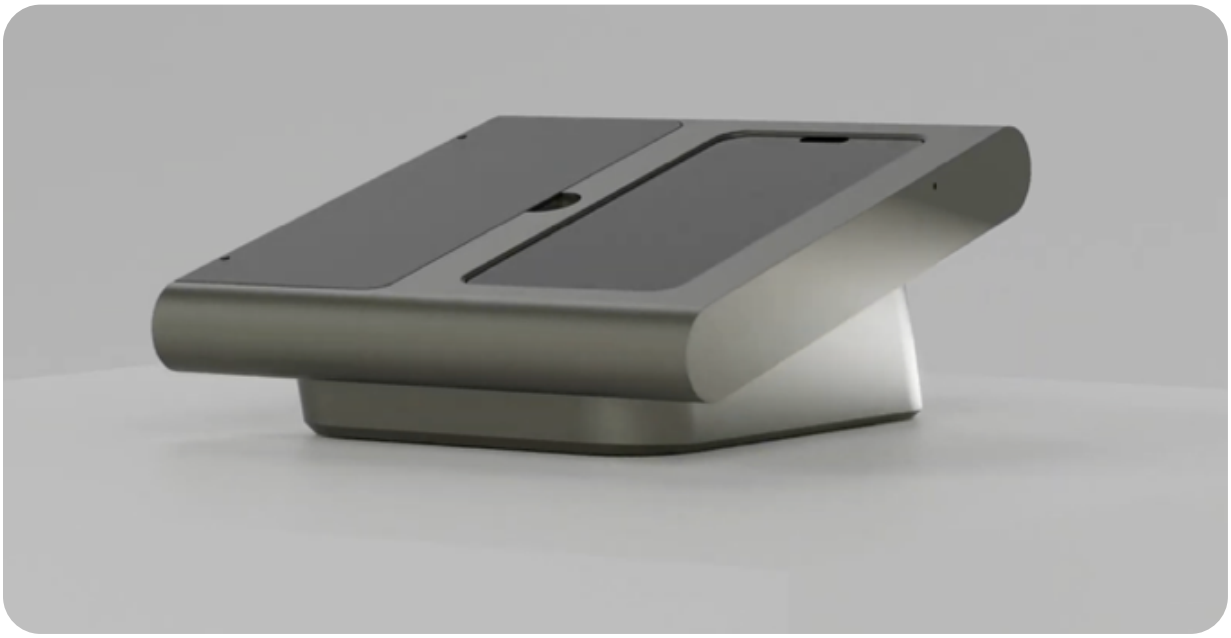


Table of Contents

Prior to using this system, the user should read and understand this *Instructions for Use* on the Bedside Mobility Monitoring System.

Caution: Federal law restricts this device to sale by or on the order of a healthcare practitioner.

Introduction

The Bedside Mobility Monitoring System delivers continuous monitoring of patient orientation and position, including for patients susceptible to pressure injury, across hospital settings. The system keeps healthcare providers informed with timely notifications whenever a patient's orientation or position deviates from their established parameters.

This Instructions for Use booklet describes the components of the Bedside Mobility Monitoring System and provides information on the system operation once the Bedside Mobility Monitoring System has been properly installed.

*Installation is required to be performed by qualified personnel from Atlas Mobility.

Description

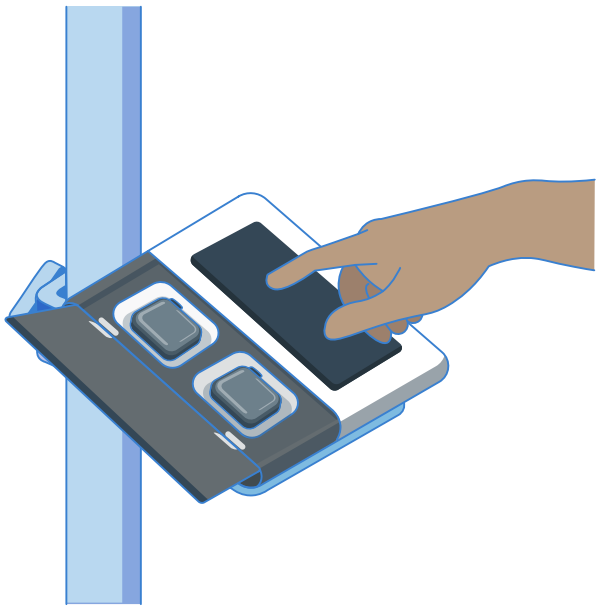
The Bedside Mobility Monitoring System is comprised of:

- Beside Mobility Monitor
- Atlas Sensors
- Atlas Wearable Patch
- SensorSuite software

The Atlas Sensor is a reusable, battery powered device that tracks a patient's orientation and position. Atlas Sensors are intended to transmit data wirelessly via Bluetooth to the Bedside Mobility Monitor.

The Atlas Wearable Patch is a single-patient-use disposable that adheres to a patient's skin and houses an Atlas Sensor.

Once the Atlas Sensor is applied to a patient and a patient monitoring session is started, the sensor continuously monitors the patient's orientation and position, communicating this data wirelessly (via Bluetooth) to the Bedside Mobility Monitor. Through the SensorSuite software, caregivers set individualized care parameters for each patient and can see the status of compliance to the set parameters.



Note: Atlas Sensors are designed to be compatible only with the Bedside Mobility Monitoring System.

Indications for Use

- The Bedside Mobility Monitoring System is intended for monitoring the orientation and position of patients.
- The Bedside Mobility Monitoring System is intended to provide notifications when the patient orientation or position deviates from the parameters set by healthcare providers.
- The Bedside Mobility Monitoring System is intended for monitoring the orientation and position of patients, including those susceptible to pressure injury.
- The Bedside Mobility Monitoring System is intended for use in healthcare environments such as hospitals, nursing homes, or other patient care facilities.

Contraindications

- The Bedside Mobility Monitoring System has no known contraindications for use, except for certain manufacturer-specific usage restrictions.
- Do **not** use an Atlas Sensor on patients with a pacemaker, implantable Cardioverter-Defibrillator (ICD), or other wearable cardioverter-defibrillator devices.

Warnings

General

WARNING: Do NOT apply the Atlas Wearable Patch to broken, irritated, or infected areas of skin.

Applying the Atlas Wearable Patch to broken or irritated areas of skin can potentially lead to infection or tissue damage. Inspect the condition of the skin around the sensor application area periodically, or as indicated by clinical judgment, to look for signs of skin irritation or signs of infection.

WARNING: Though the adhesive material used in the Atlas Wearable Patch is commonly used in other healthcare products and has a well-established safety profile, an allergic reaction to the adhesive is possible. If a patient experiences a rash, skin redness, itching, or swelling in the area where the Atlas Wearable Patch was applied, this may be a sign of an allergic reaction and should be evaluated immediately by the patient's doctor or other member of their care team. The Atlas Wearable Patch should not be used on patients who have a known tape allergy or sensitivity to commonly used medical-grade adhesives and IV film dressings.

WARNING: If signs of skin irritation or hygiene issues are caused or aggravated, REMOVE the Atlas Wearable Patch and evaluate the patient's skin.

The Atlas Wearable Patch may be reapplied on a non-irritated area. If the patient appears to have had an allergic reaction to the adhesive, do NOT re-apply another Atlas Wearable Patch. Notify the patient's doctor or other appropriate member of the patient's care team.

WARNING: Do NOT re-use the Atlas Wearable Patch on multiple patients.

Atlas Wearable Patch is for SINGLE patient use only. Infection or cross-contamination may occur if the Atlas Wearable Patch is re-used on multiple patients. If the Atlas Wearable Patch is re-applied, its adhesion performance may deteriorate, and it may not function properly.

WARNING: Do **NOT** sterilize the Atlas Sensor.
This may cause the sensor to not function properly.

WARNING: Do **NOT** use the Atlas Sensor if the sensor screen is damaged or the sensor is broken.
Handling a broken screen could injure the user. Notify Customer Support to safely remove and replace the sensor location.

WARNING: Do **NOT** use acetone, bleach, or peroxide solution or attempt to sterilize the Atlas Sensor or BMM.
This may cause the Atlas Sensor to not function properly.

WARNING: Do **NOT** use an Atlas Wearable Patch if its packaging is damaged
This may cause the Atlas Wearable Patch to not function properly.

WARNING: The Bedside Mobility Monitoring System is not to be used to alert staff of situations that would require immediate action in order to maintain patient safety.

WARNING: Remove the Atlas Sensor from the patient's body if the temperature of the sensor exceeds 41°C.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Turn off the device in an emergency. Unplug the power cable to turn off the device from supply mains.

MRI, Ionizing Radiation, and Strong Magnetic Fields

WARNING: REMOVE the Atlas Sensor prior to performing an MRI study. Strong magnetic fields can induce current within the device that could cause burns to the patient.

WARNING: Strong magnetic fields may cause the Atlas Sensor to become a projectile hazard or may cause the patient to experience tugging or skin heating where the sensor has been applied. The Atlas Sensor must be removed before these types of procedures are performed.

WARNING: High levels of ionizing radiation, strong magnetic fields, and high frequency RF may cause the Atlas Sensor to malfunction. The Atlas Sensor must be removed before these types of procedures are performed.

X-Ray and CT Imaging Procedures

WARNING: Similar to ECG leads, the Atlas Sensor is radio-opaque and therefore may block complete radiographic imaging of a body area located directly underneath the Atlas Sensor. If it is anticipated that the Atlas Sensor is going to block a critical part of the radiologic image (such as a chest X-ray or CT scan), then REMOVE the Atlas Sensor prior to performing the radiologic exam.

Electrocautery and External Defibrillation

WARNING: The Atlas Sensor must be removed if an electric current is going to be passed through the patient's skin or body, such as during external cardiac defibrillation or electrocautery. In the event that the sensor is not removed, and the patient has a medical emergency that requires external cardiac defibrillation or exposure to high frequency surgical equipment, the patient may experience a skin burn where the sensor has been applied.

WARNING: The Bedside Mobility Monitoring System needs to be installed and put into service by trained personnel in order to ensure that it functions properly.

WARNING: Do not modify the Bedside Mobility Monitoring System (or any of its components) without authorization from Atlas Mobility or the equipment may fail to operate properly. Inappropriate product modification or adulteration may void the user's authority to operate this equipment. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of the Bedside Mobility Monitoring System, including cables specified by the manufacturer. Otherwise, the performance of this equipment could degrade.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection from radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Precautions

General

CAUTION: The Bedside Mobility Monitoring System has not been tested on women who are pregnant or breastfeeding, so the risks to unborn fetuses and nursing children are unknown. Safety and effectiveness for use by pregnant women and children (persons under the age of 18) has not been established.

CAUTION: CLIP the patient's hair in the application area prior to applying the Atlas Wearable Patch to ensure good adhesion. Failure to adequately clip hair in the application area may result in sensor attachment errors.

CAUTION: Any initial settings present in the Bedside Monitoring User Interface at the time of installation must be reviewed by the user or facility for appropriateness based on their facility's procedures and protocols and updated accordingly.

CAUTION: The correct placement and orientation of the Atlas Sensor is important to ensure that the correct orientation of the patient is being reported to the Bedside Monitoring User Interface. Carefully read and review the instructions for sensor application contained in this document.

CAUTION: Do NOT use an Atlas Wearable Patch past the "Use by Date" listed on its packaging or the Atlas Wearable Patch may not operate properly or adhere to the patient skin.

CAUTION: Remove the Atlas Sensor before chest percussion therapy. Artifact from chest percussion therapy may result in inaccurate operation of the sensor.

Electrical and RF communications

CAUTION: The Bedside Mobility Monitoring System complies with Part 15 of FCC Rules and Regulations. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION: This device complies with the FCC's RF exposure limits for a portable device operated within 5 mm of a person. The output power of this device is below the level for which the FCC requires Specific Absorption Rate measurements.

Risks

A patient may experience skin irritation, redness, or itching where the Atlas Wearable Patch has been applied.

These side effects are expected to spontaneously resolve within a few minutes to hours of sensor removal without medical intervention or treatment. If side effects do not spontaneously resolve within a few hours of sensor removal, the patient's skin should be further assessed and treated accordingly.

As with other medical adhesives, skin irritation or slight skin damage, including tearing of the skin, bleeding, or bruising may be experienced when the Atlas Wearable Patch is removed. These effects may be more pronounced in patients with thin, delicate, or sensitive skin.

For patients with extremely thin, delicate or sensitive skin, an adhesive removal product may be used to assist the caregiver in removing the Atlas Sensor to reduce the risk of these possible side effects.

Other wireless communication systems may interfere with the proper functioning of the Bedside Mobility Monitoring System may interfere with the proper functioning of other wireless communication systems. However, various measures have been taken to mitigate the risk of interference. The Bedside Mobility Monitoring System is designed such that incidental interference will not put the patient at risk.

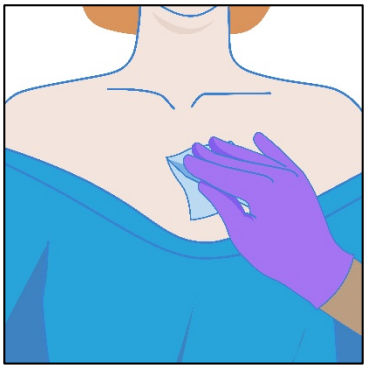
The Atlas Sensor is only intended to be used monitoring Left, Supine, and Right position; it doesn't support prone position. If the patient is put to prone position, the SensorSuite software will not give an accurate reading for the patient position and duration. Analytics will display any position other than Left, Supine, and Right as "Other."

Benefits

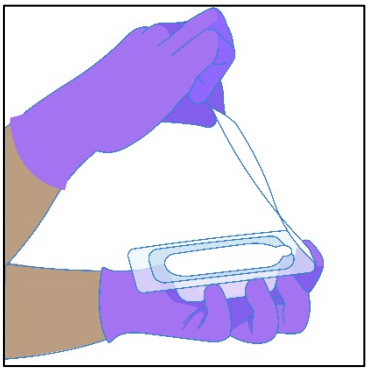
The Atlas Sensor monitors a patient's orientation and position and communicates this data wirelessly to the SensorSuite software. The Bedside Mobility Monitor will provide visual and audio notifications to help care providers ensure patients are turned according to Q2 compliance protocol. The Bedside Mobility Monitor allows caregivers to access patient analytics from the last 24 hours and gives the option to view previous days' compliance data.

How to Apply the Atlas Wearable Patch and Atlas Sensor

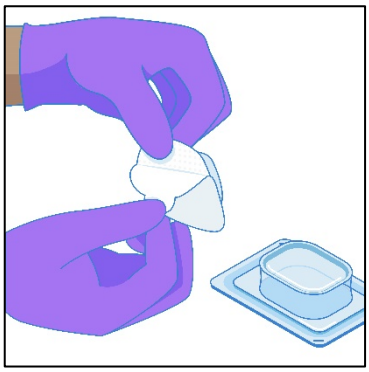
A. Ensure the patient's chest is clean and dry. Ensure the skin surface is clear of any lotion and adhesive residue.



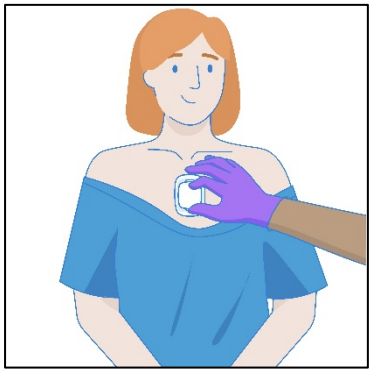
B. Open the packaging and take out the Atlas Wearable Patch.



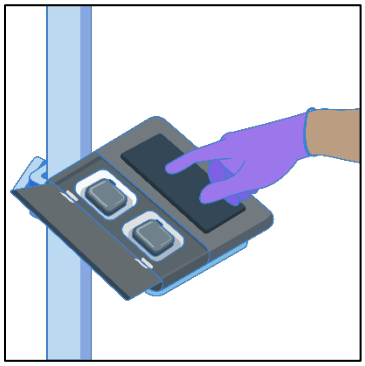
C. Remove the Atlas Wearable Patch adhesive liner by separating the helper tab from the blue line.



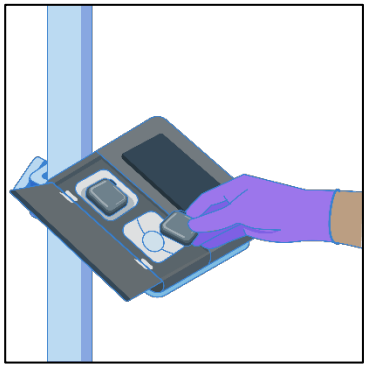
D. Carefully apply the Atlas Wearable Patch to the patient's chest and ensure the patch helper tab is facing the patient's neck.



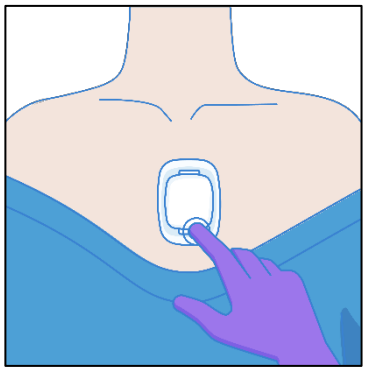
E. Begin the setup process on the Bedside Mobility Monitor by entering the patient details.



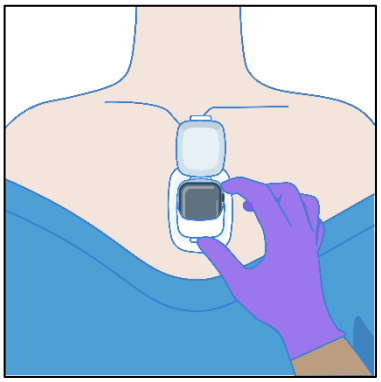
F. Remove the Atlas Sensor from the charging dock.



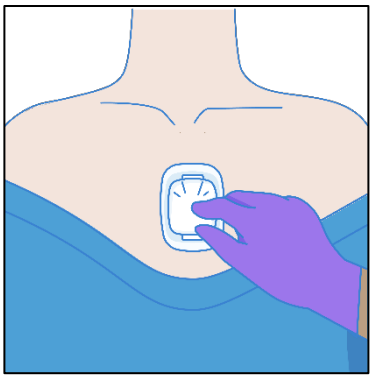
G. Open the Atlas Wearable Patch cover door by pressing the latch on the bottom of the patch.



H. Place the Atlas Sensor screen facing up inside the Atlas Wearable Patch.



I. Secure the Atlas Sensor by closing the Atlas Wearable Patch latch cover.



1. If hair is present in the application area, clip it before applying the Atlas Wearable Patch.

   If needed, clip the patient's hair in the area where you would like to apply the Atlas Sensor. Hair may prevent good adhesion of the Atlas Wearable Patch and cause discomfort upon removal.

2. For patients with sensitive skin, skin prep is recommended before applying the Atlas Wearable Patch.

   Use off-the-shelf skin prep wipes for patients with extra sensitive skin. Skin prep facilitates the easy application and removal of adhesive from the skin.

3. Examine the patient's skin in the application area to ensure the skin is clean, dry, intact, and not irritated or infected.

   If needed, cleanse and thoroughly dry the skin in the application area. The skin should be clean and dry to ensure good adhesion of the Atlas Wearable Patch.

The recommended location for the Atlas Sensor is on the sternum, just below the suprasternal notch. For patients who have a contraindication to sensor placement on the sternum (e.g. recent sternotomy), the sensor should be placed in an alternative location, either on the right or left side, at approximately the midclavicular line. The Atlas Sensor should be placed on an approximately flat surface.

The correct placement and orientation of the Atlas Sensor is extremely important to ensure that the correct orientation of the patient is being reported to the Bedside Mobility Monitor. See the "How to Set Up a Patient Session" section below for setup instructions.

Removing and Replacing the Atlas Sensor and Atlas Wearable Patch

Removing the Atlas Sensor

The Atlas Sensor should be removed prior to MRI studies, or if electric current is going to be passed through the patient's body, such as during external cardiac defibrillation or electrocautery.

The Atlas Wearable Patch should also be removed if the patient is experiencing a skin reaction, such as an allergic reaction, rash, or any compromise to the integrity of the skin under or around the Atlas Wearable Patch.
To remove the Atlas Sensor, open the Atlas Wearable Patch, remove the sensor, and place it, screen facing up, on the charging dock of the Bedside Mobility Monitor.

Removing the Atlas Wearable Patch

To remove the Atlas Wearable Patch, lift gently and slowly with continuous force on the edge of the patch adhesive. Forcefully ripping, tearing, or tugging the Atlas Wearable Patch may cause skin injury or skin irritation.

For patients with extremely thin, delicate, or sensitive skin, an adhesive removal product may be used to assist the caregiver in removing the Atlas Wearable Patch to reduce the risk of these possible side effects.

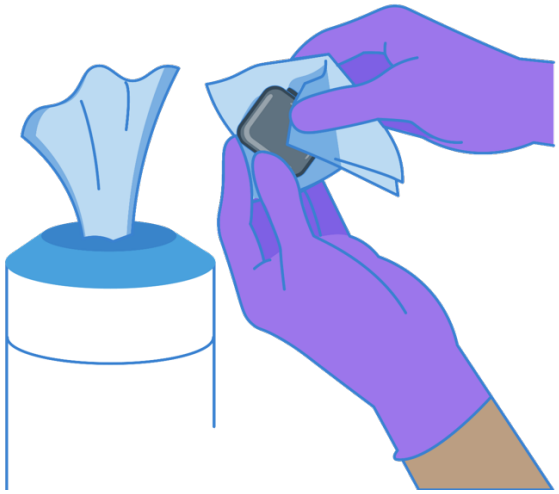
Replacing the Atlas Sensor and Atlas Wearable Patch

The Atlas Sensor should be swapped with a new sensor every 12 hours for optimal battery performance. Once a new Atlas Sensor has been applied, the patient session will be resumed by pressing "Begin Session" on the new sensor to continue monitoring.

The Atlas Wearable Patch is recommended to be replaced every 96 hours for optimal performance. Repeat the previous instructions, "How to Apply the Atlas Wearable Patch and Atlas Sensor", to apply a new Atlas Wearable Patch. If there is any indication of skin irritation, the Atlas Wearable Patch should not be applied on that location.

Cleaning the Atlas Sensor

After swapping, the sensor should be wiped clean with commonly used facility-approved alcohol wipes using the label's safety precautions and directions for use. Once cleaned, the sensor should be placed on the charging dock of the Bedside Mobility Monitor.



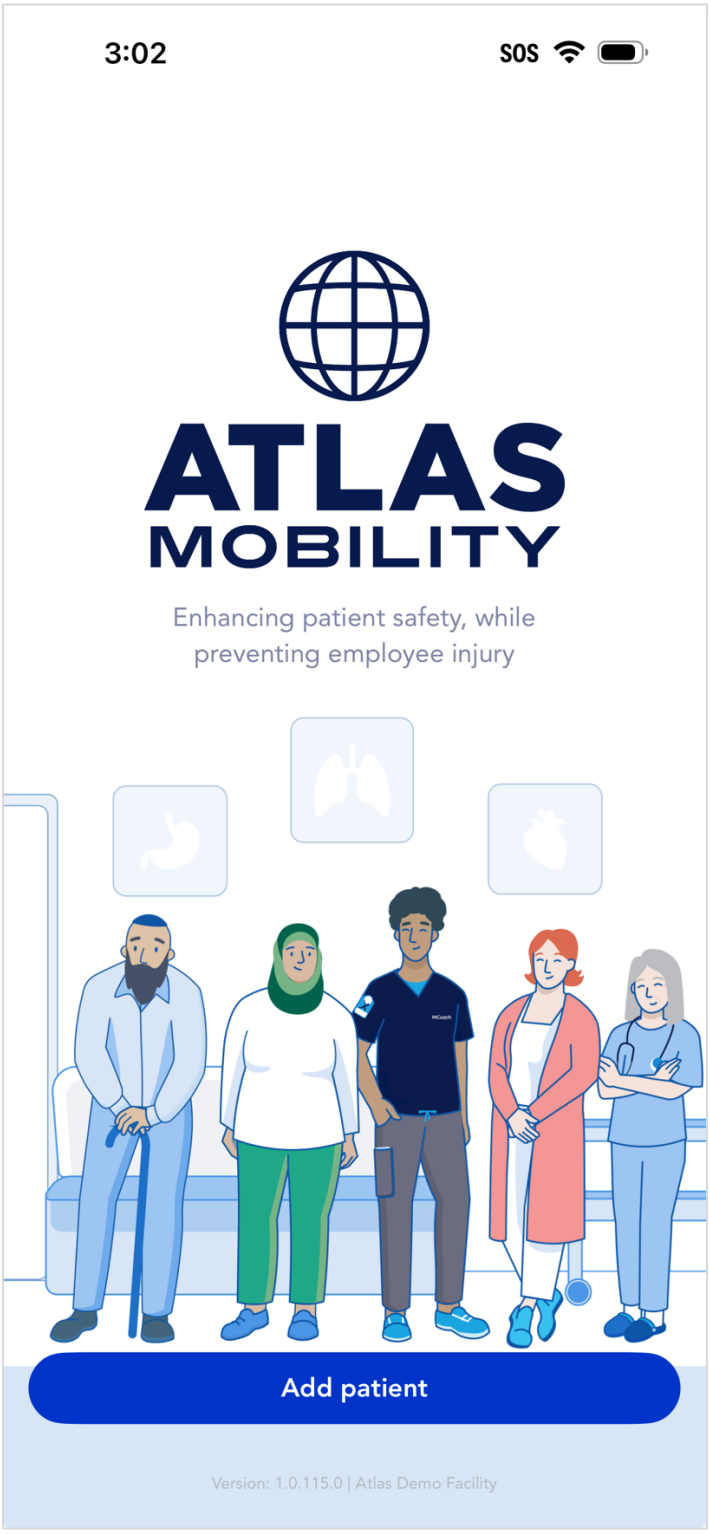
Do not use acetone on the Atlas Sensor or attempt to sterilize it. This may damage the sensor and cause it to function improperly.

How to Setup a Patient Session

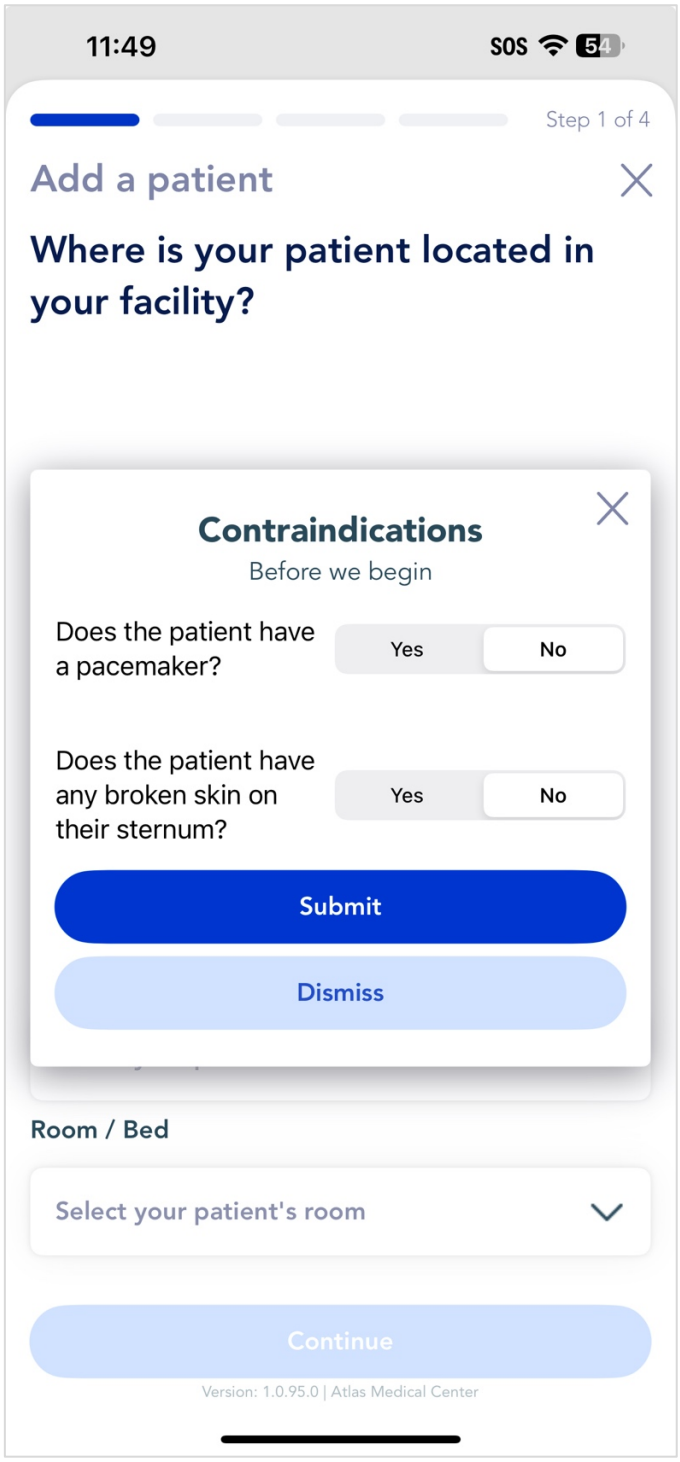
and start monitoring

Steps for adding a new patient session

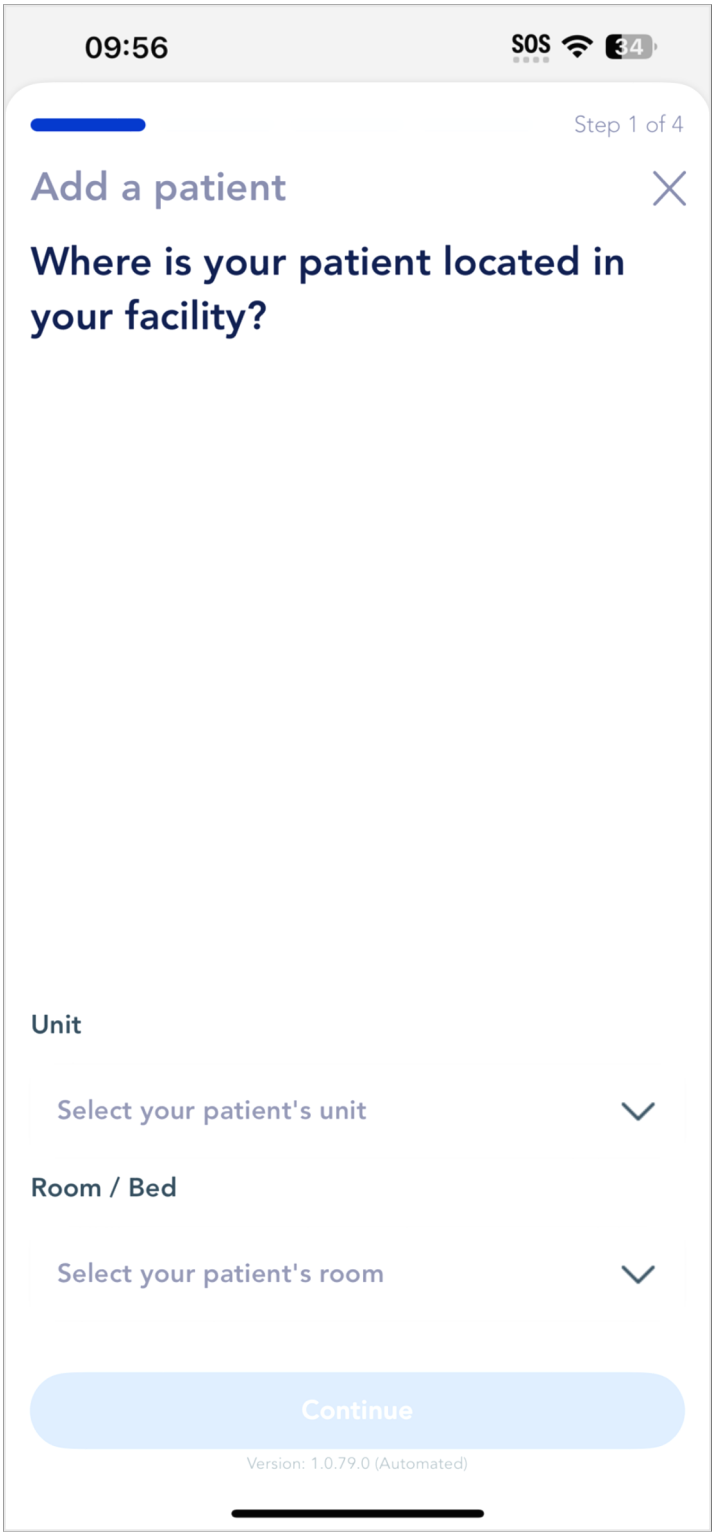
A. Select “Add patient” to enter the patient’s details and start a monitoring session.



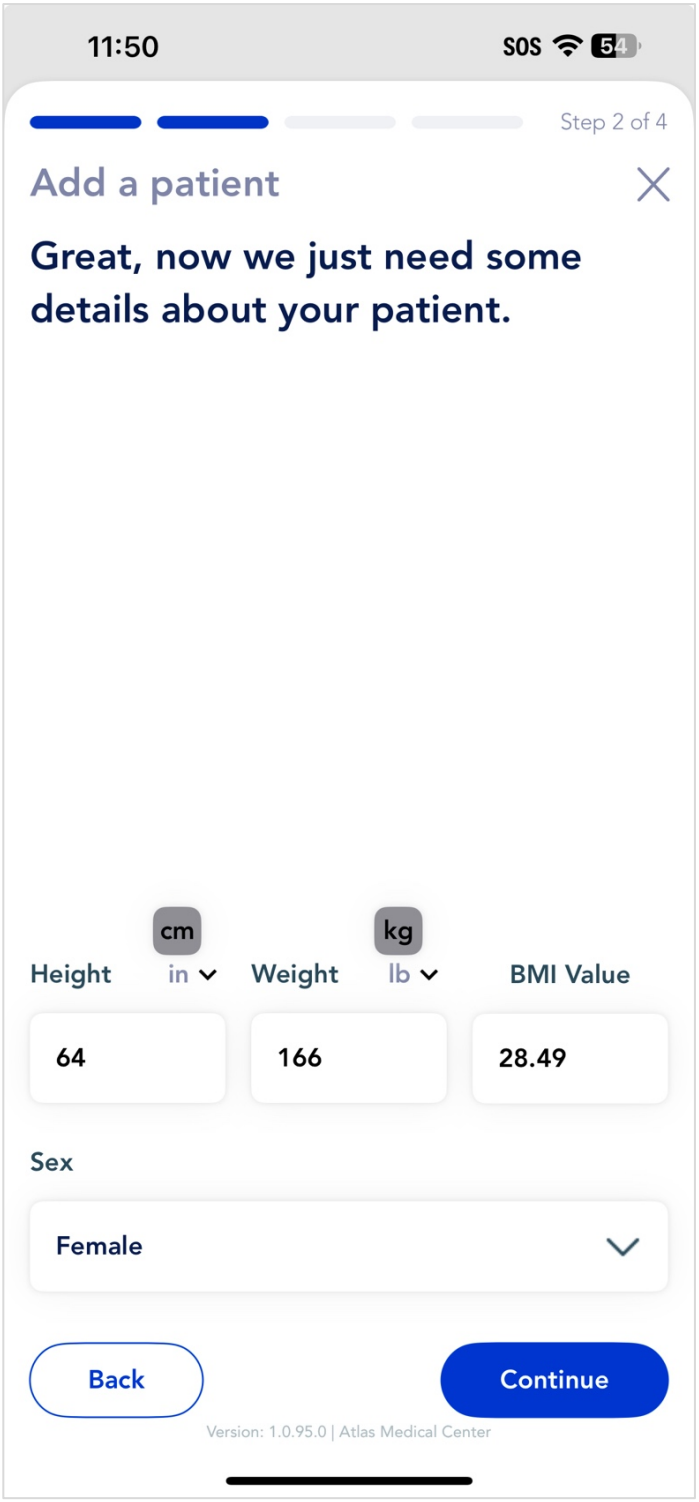
B. Confirm that there are no contraindications and select “Submit”.

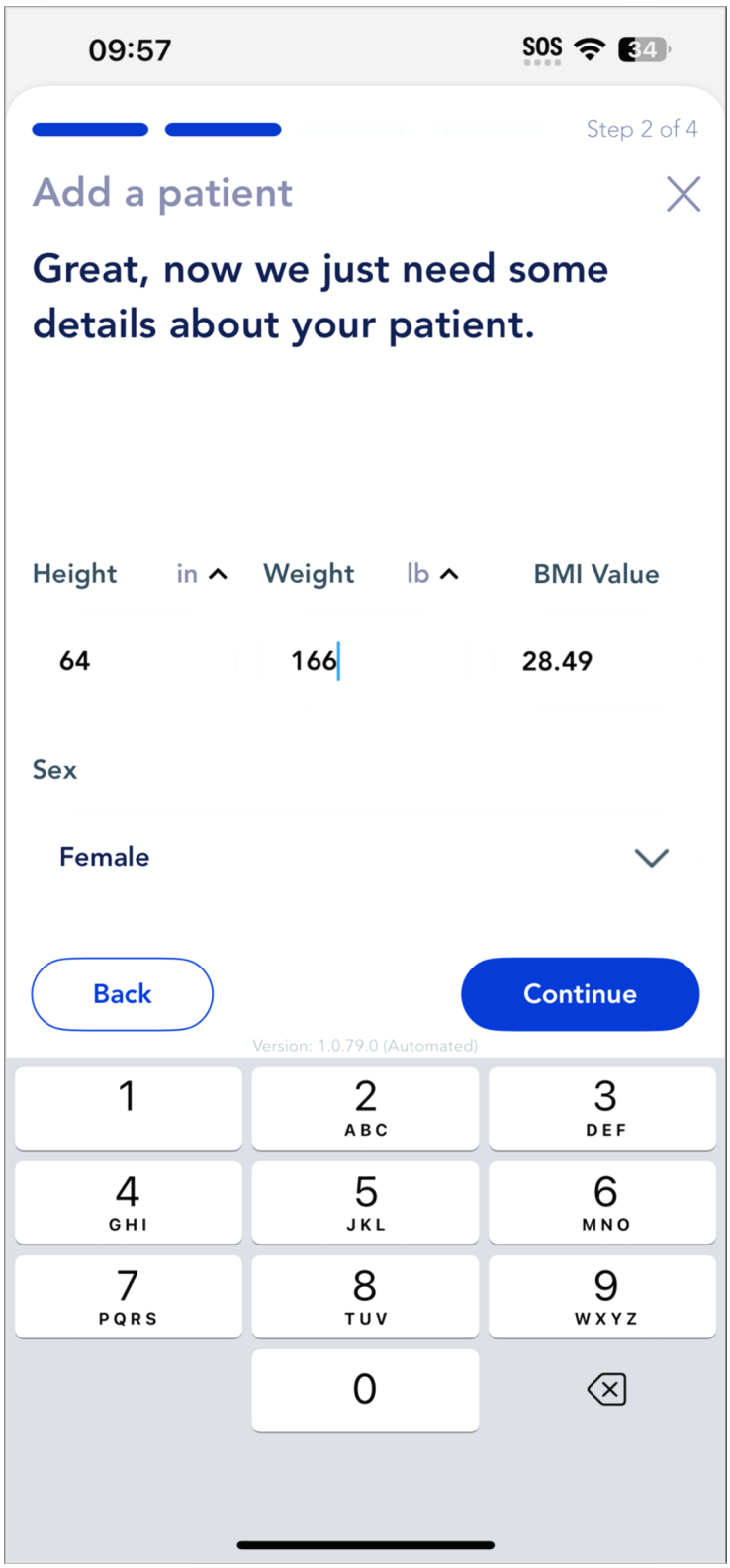


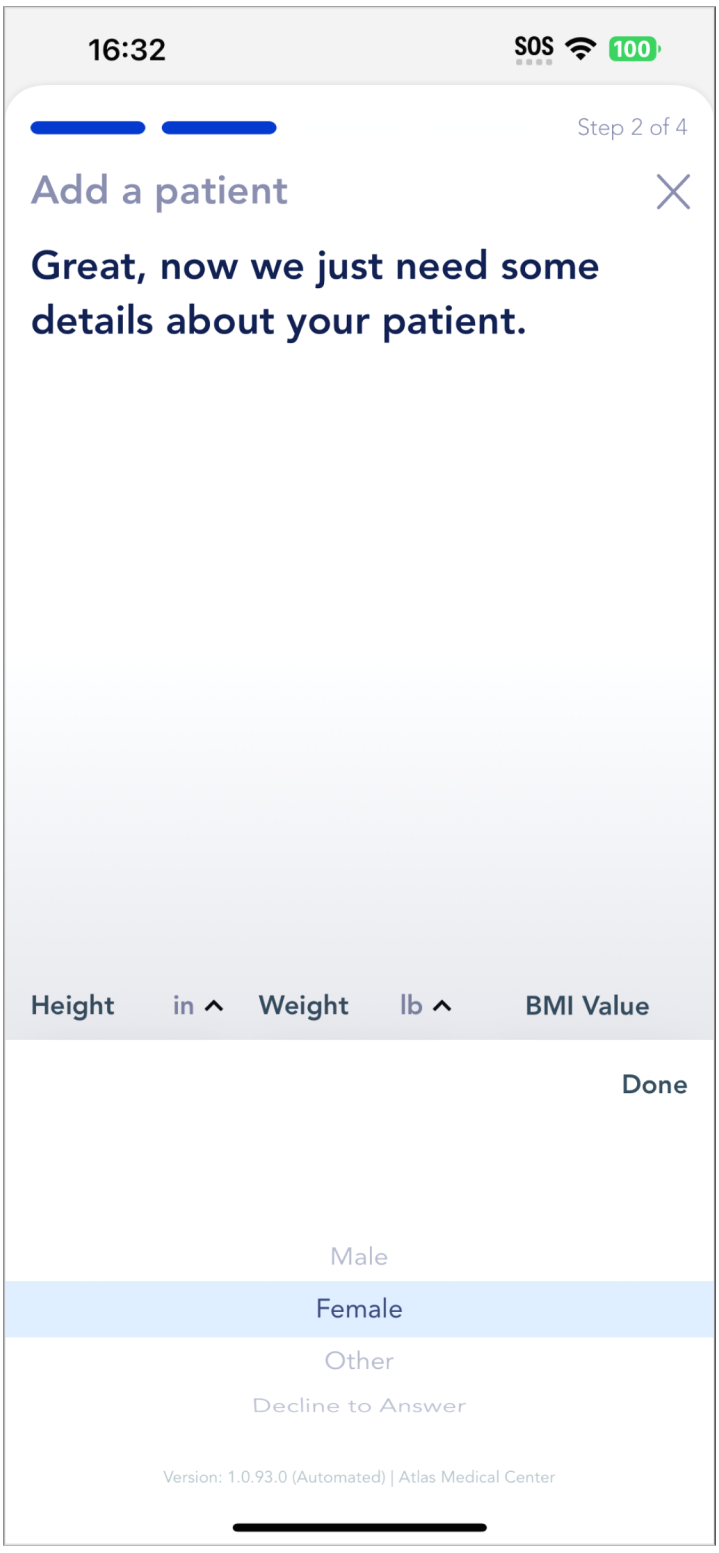
C. Select the Unit from the drop-down menu, then select the Room from the drop-down menu, then select “Continue”.



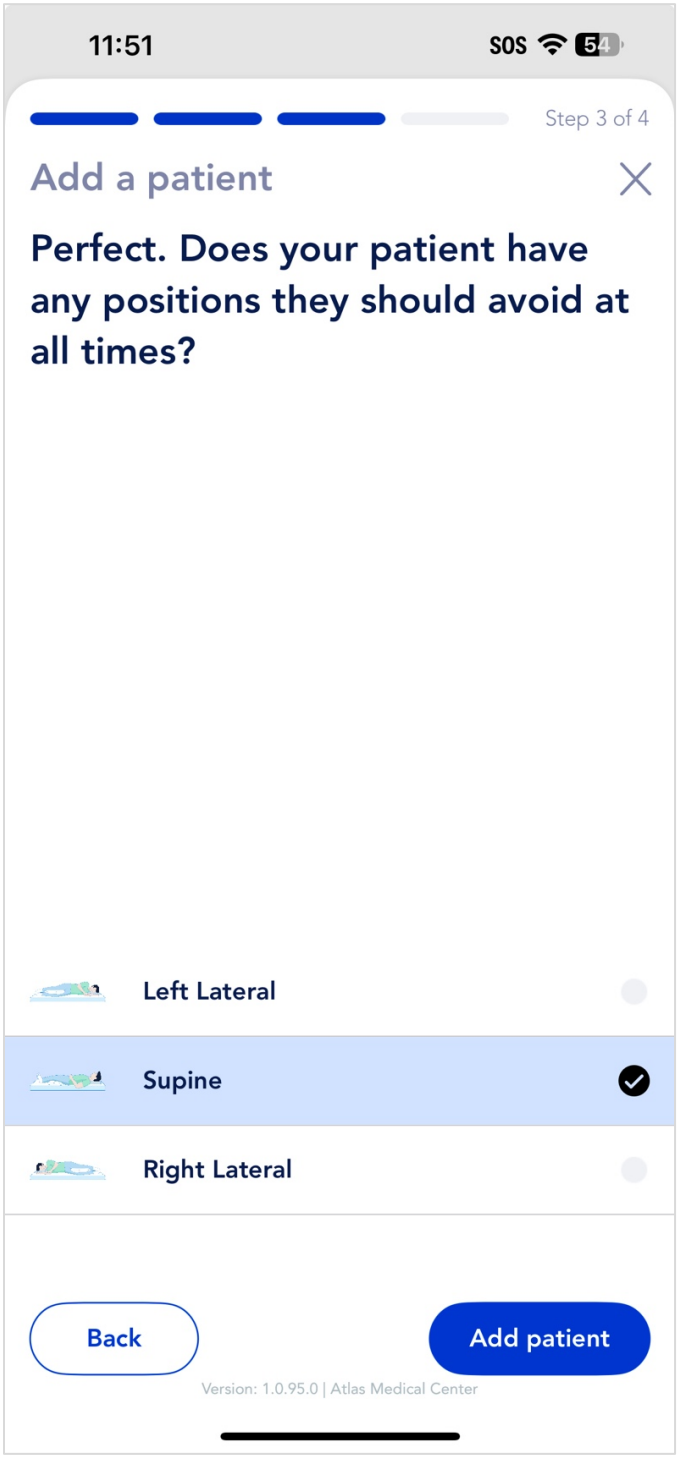
D. Complete the fields Height/Weight (optional) and Sex with the patient's information. The BMI will be calculated based on this information. The following screenshots display how to enter this information. Then select "Continue".



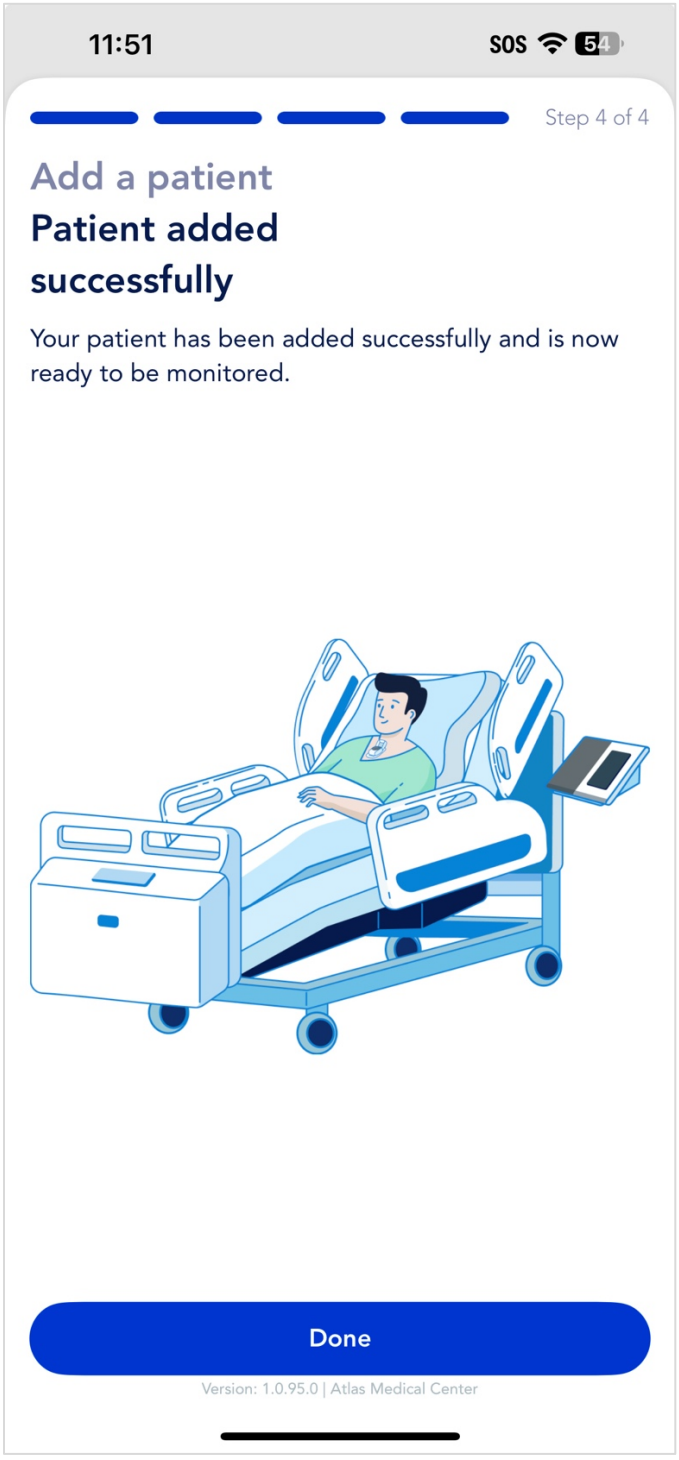

09:57
SOS
34
Step 2 of 4
Add a patient
Great, now we just need some details about your patient.
Height
in
Weight
lb
BMI Value
64
166
28.49
Sex
Female
Back
Continue
Version: 1.0.79.0 (Automated)
1
2 ABC
3 DEF
4 GHI
5 JKL
6 MNO
7 PQRS
8 TUV
9 WXYZ
0


16:32
SOS
100
Step 2 of 4
Add a patient
Great, now we just need some details about your patient.
Height
in
Weight
lb
BMI Value
Done
Male
Female
Other
Decline to Answer
Version: 1.0.93.0 (Automated) | Atlas Medical Center

E. If applicable, select a position to avoid based on the patient's medical conditions. Then select "Add patient".

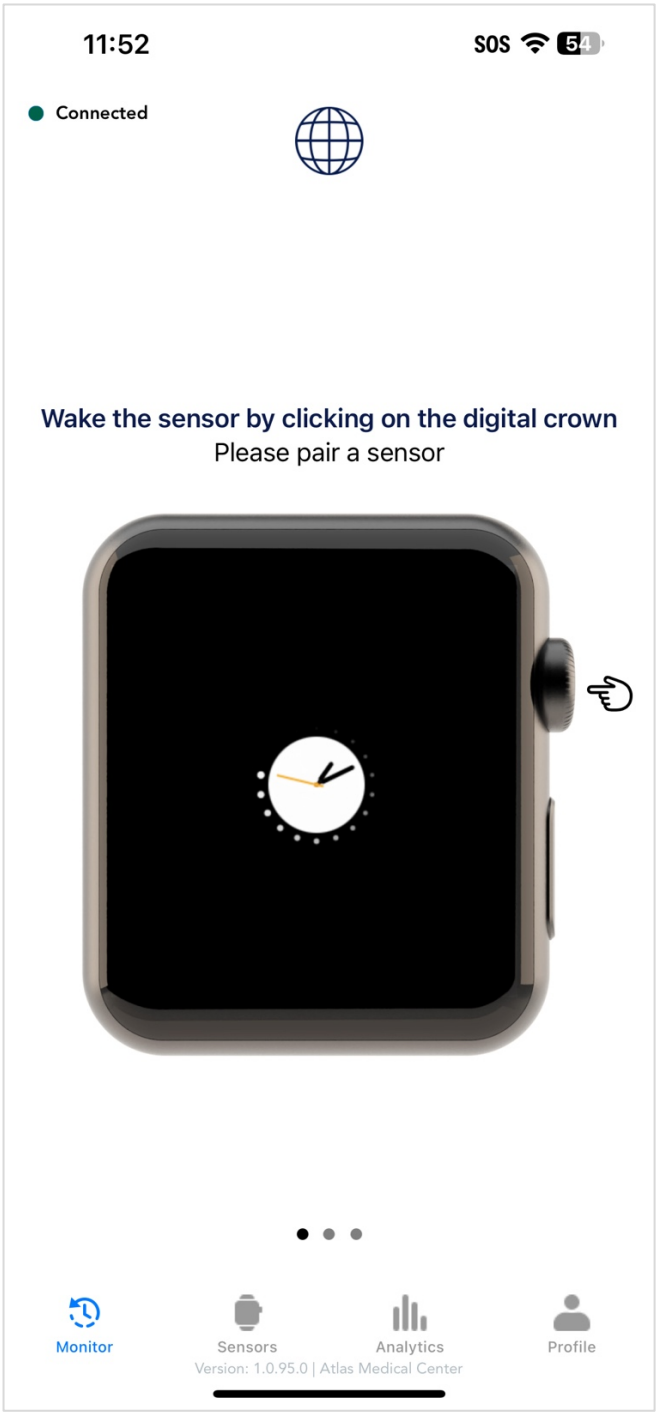


F. Select “Done”.

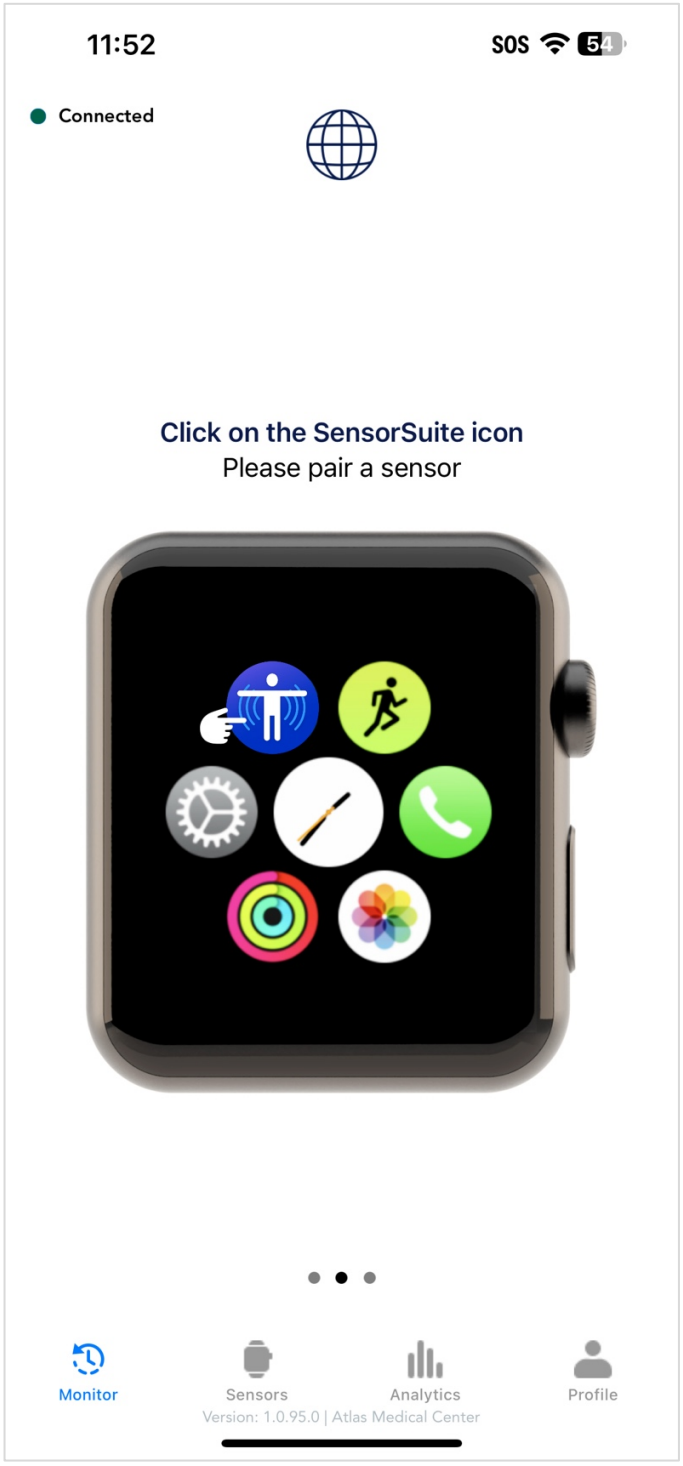


Start Pairing an Atlas Sensor

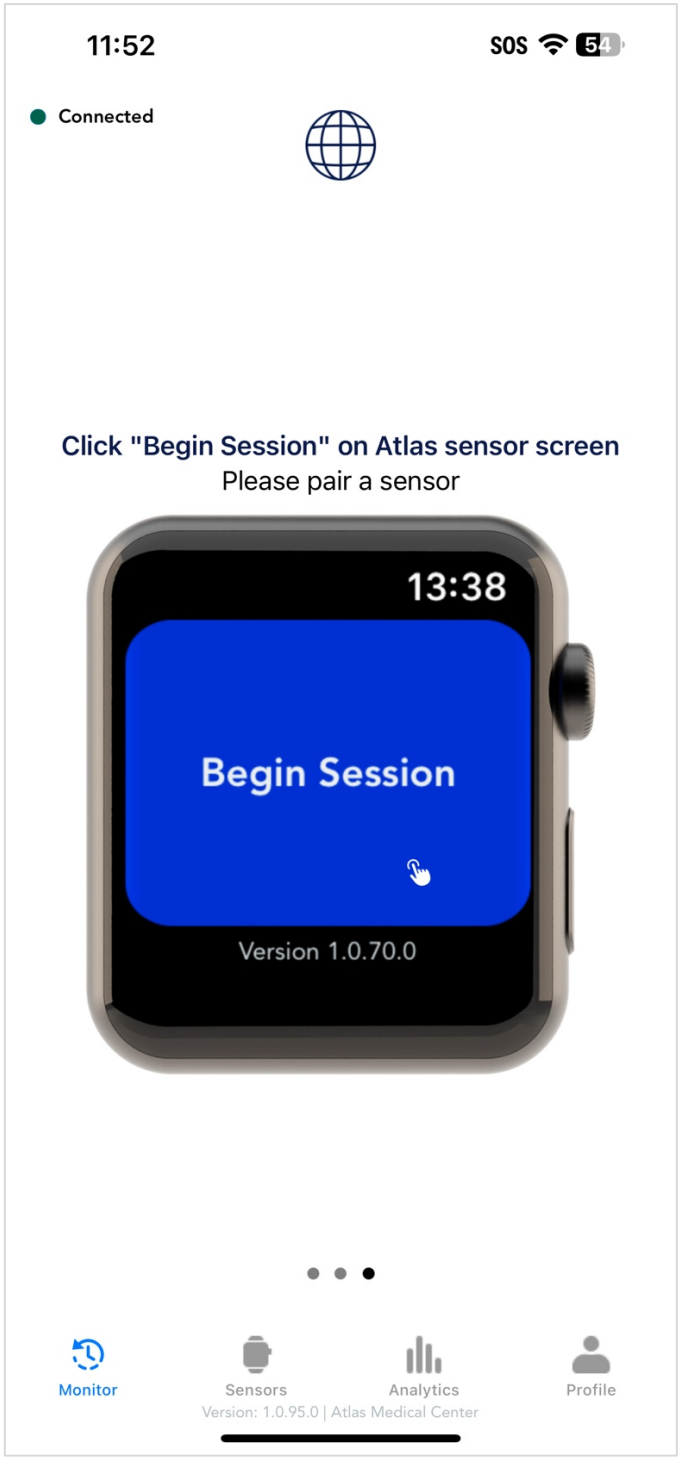
A. Press and release the crown on the right side of the Atlas Sensor to launch the home view.



B. Select the blue SensorSuite icon to launch the app.

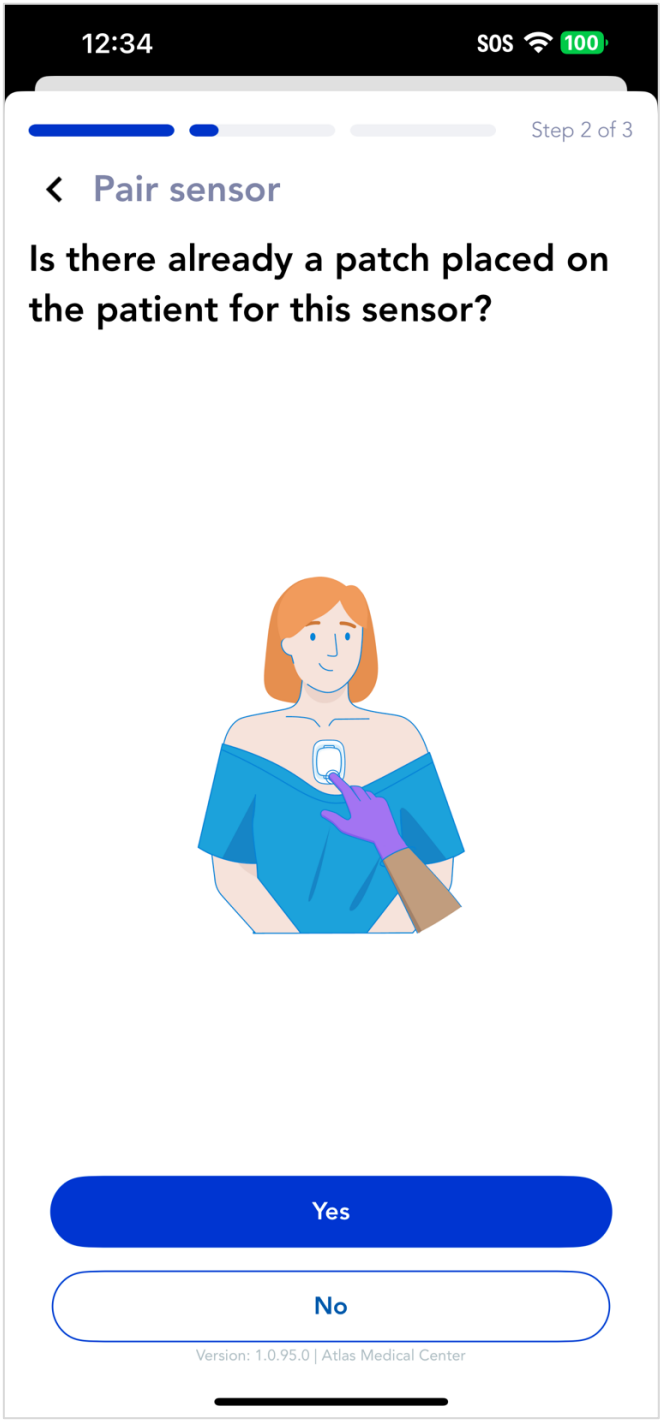


C. Select “Begin Session” on the Atlas Sensor screen to begin the pairing setup process.

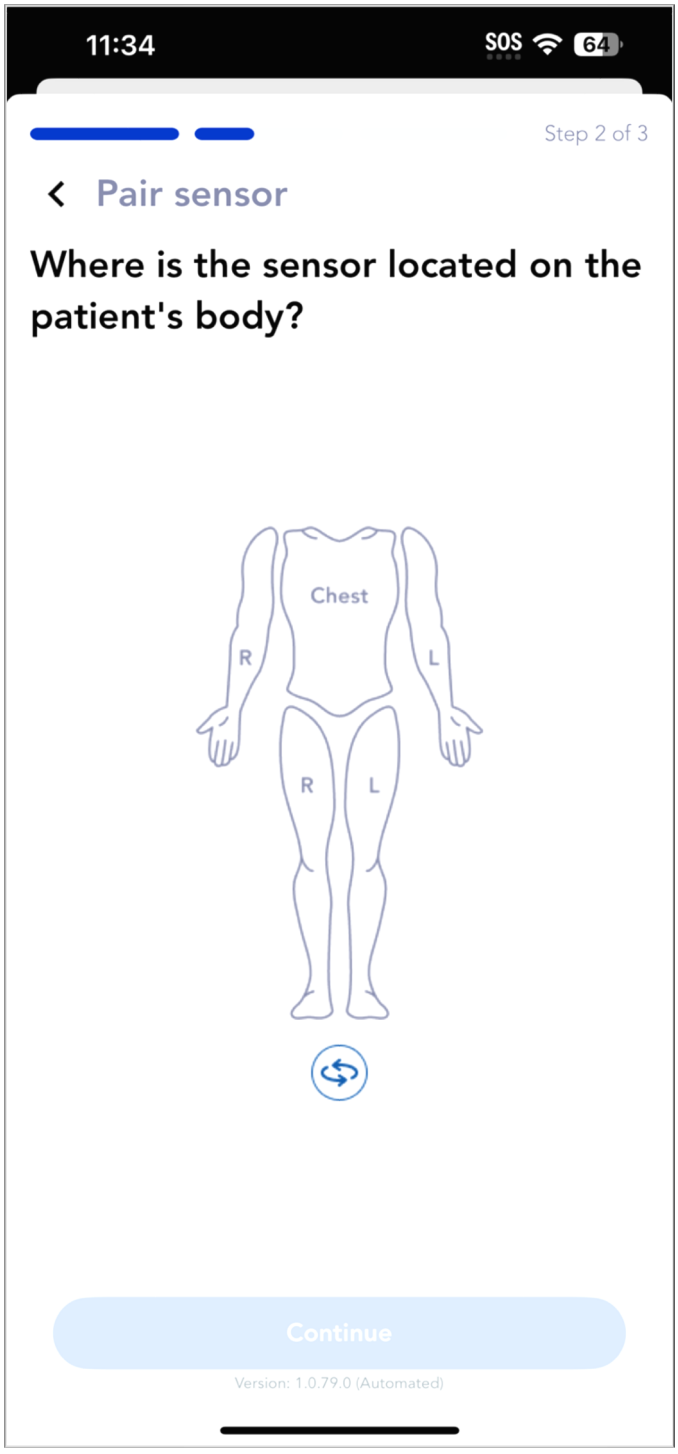


D. Select “Pair” on the Beside Mobility Monitor.

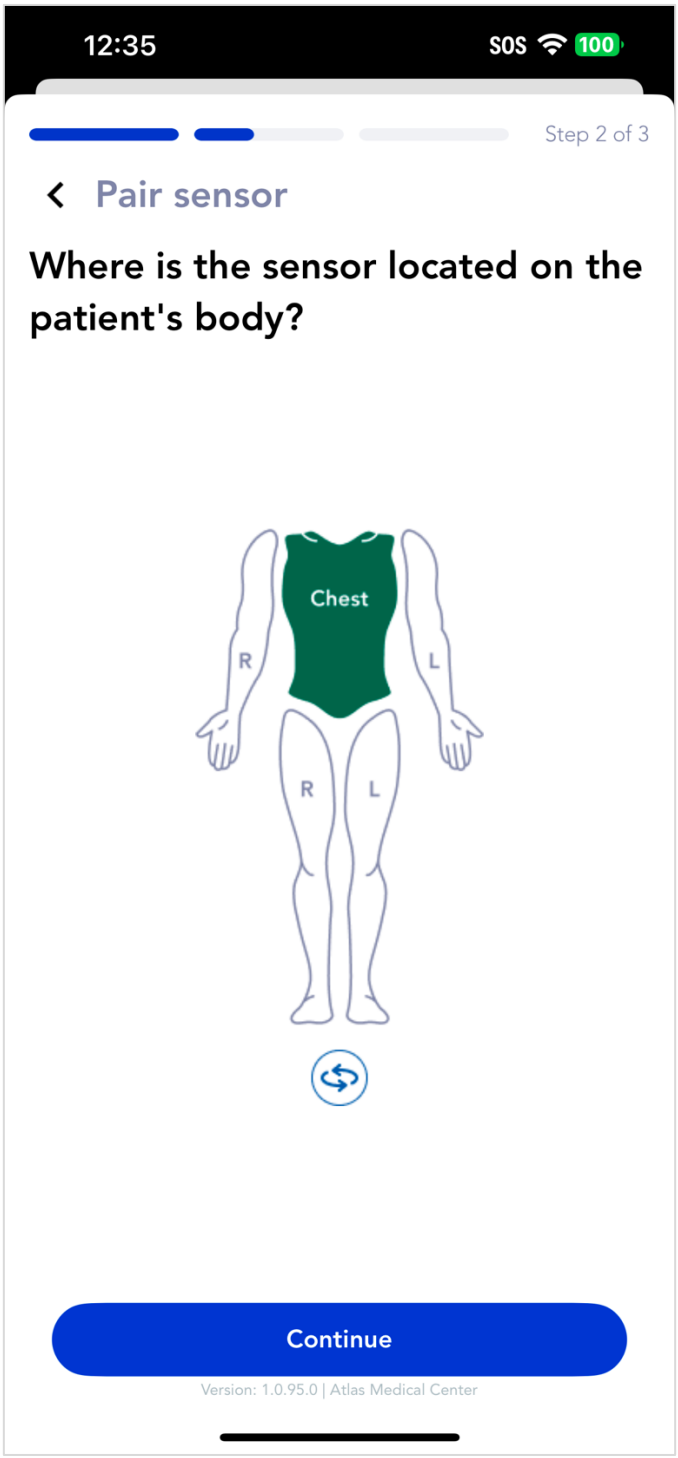
E. If the Atlas Wearable Patch has been applied, select “Yes”. If the Atlas Wearable Patch has not been applied, select “No” and follow the instructions. Then place the sensor on the patient. Refer to the “How to Apply the Atlas Wearable Patch and Atlas Sensor” instructions.



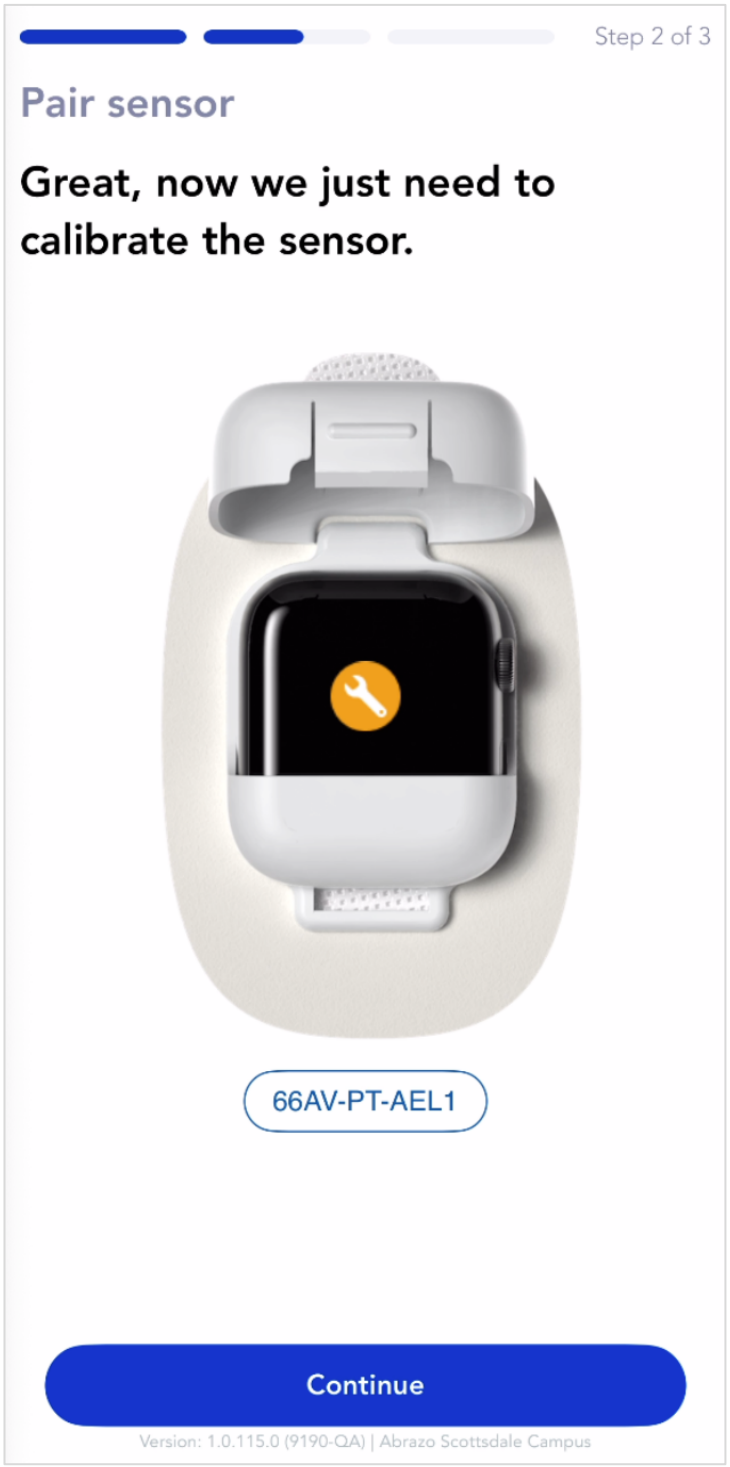
F. Select the location where the Atlas Wearable Patch is located. Note that only the "Chest" location can be selected at this time.



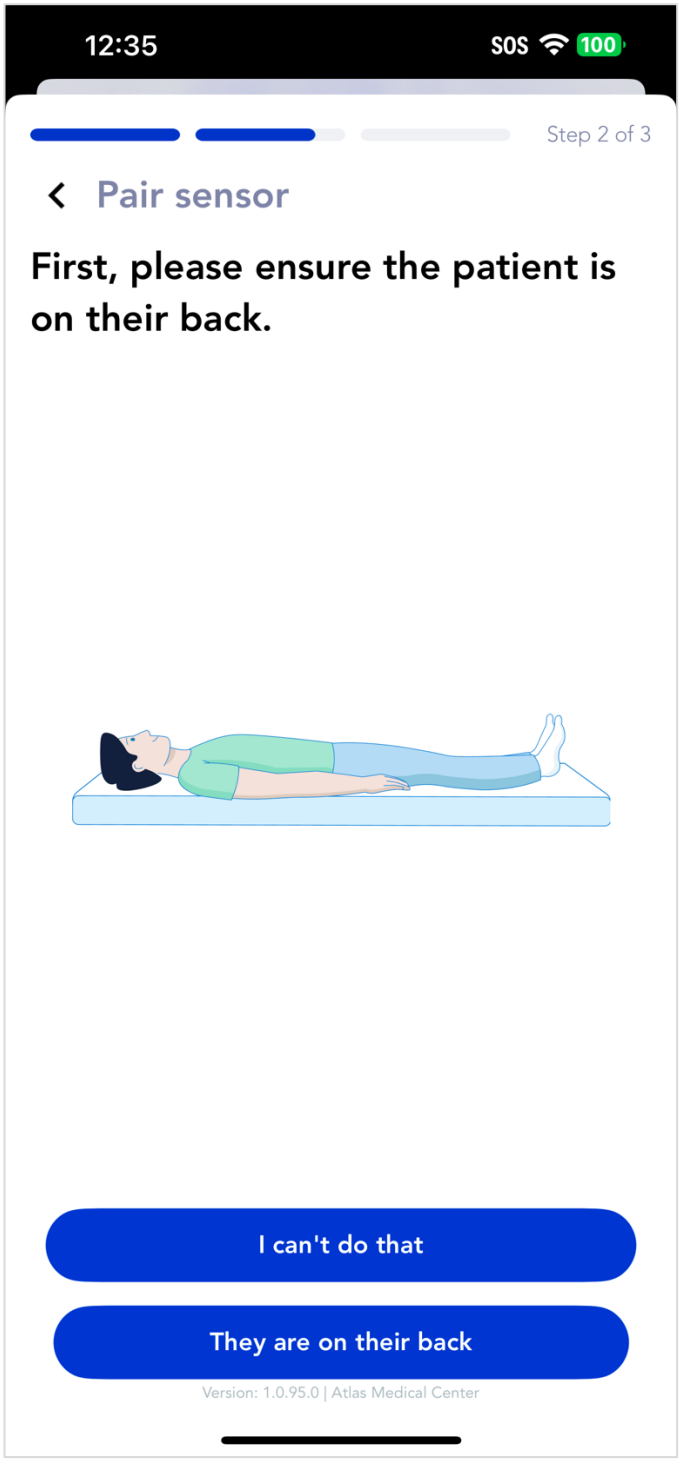
G. Select “Continue” to begin calibration.



H. Select “Continue” to start the calibration process.

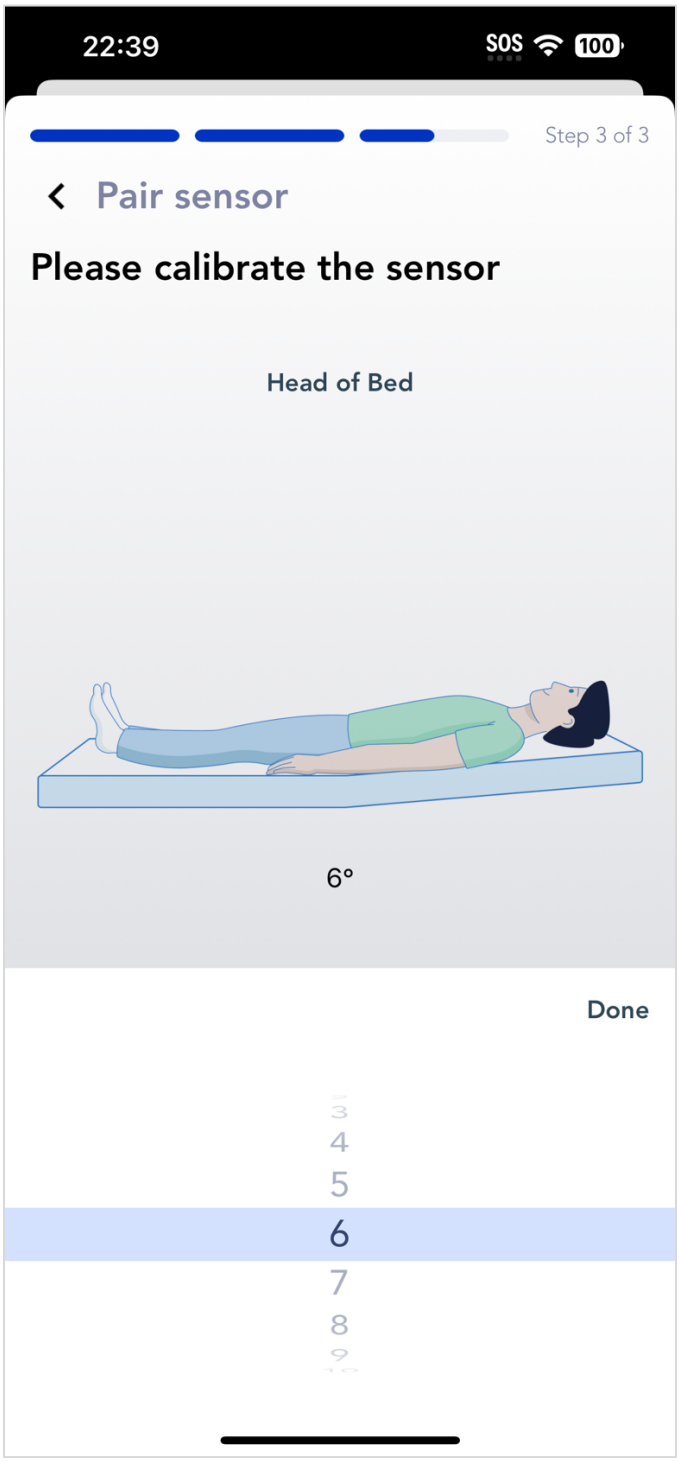


I. Ensure that the patient is lying on their back with the bed fully flattened. Select "They are on their back" for the sensor to calibrate.



J. Flatten the bed and ensure the patient is on their back to get the correct calibration for the patient. Then select “The bed is flat, begin calibration”.

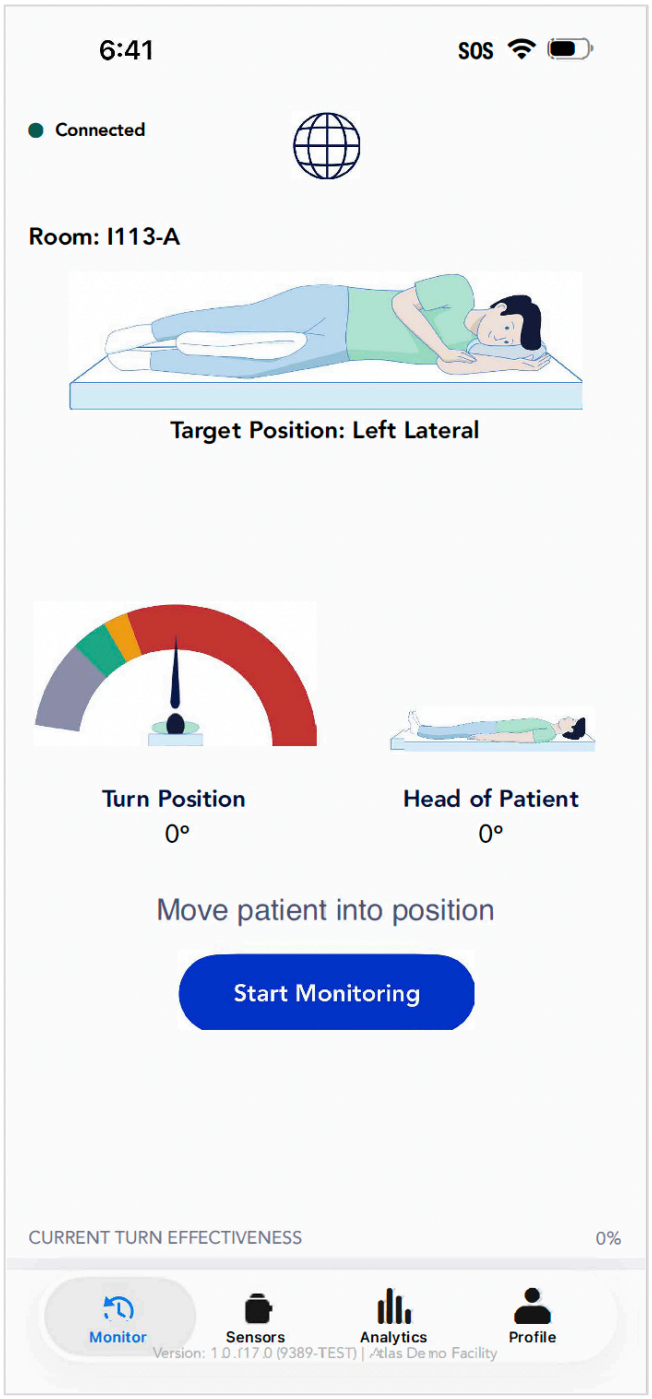
K. If the patient is unable to lie on on a flat surface and “I can’t do that” was selected in Step I, select the appropriate head of bed angle. Once selected, press Done.



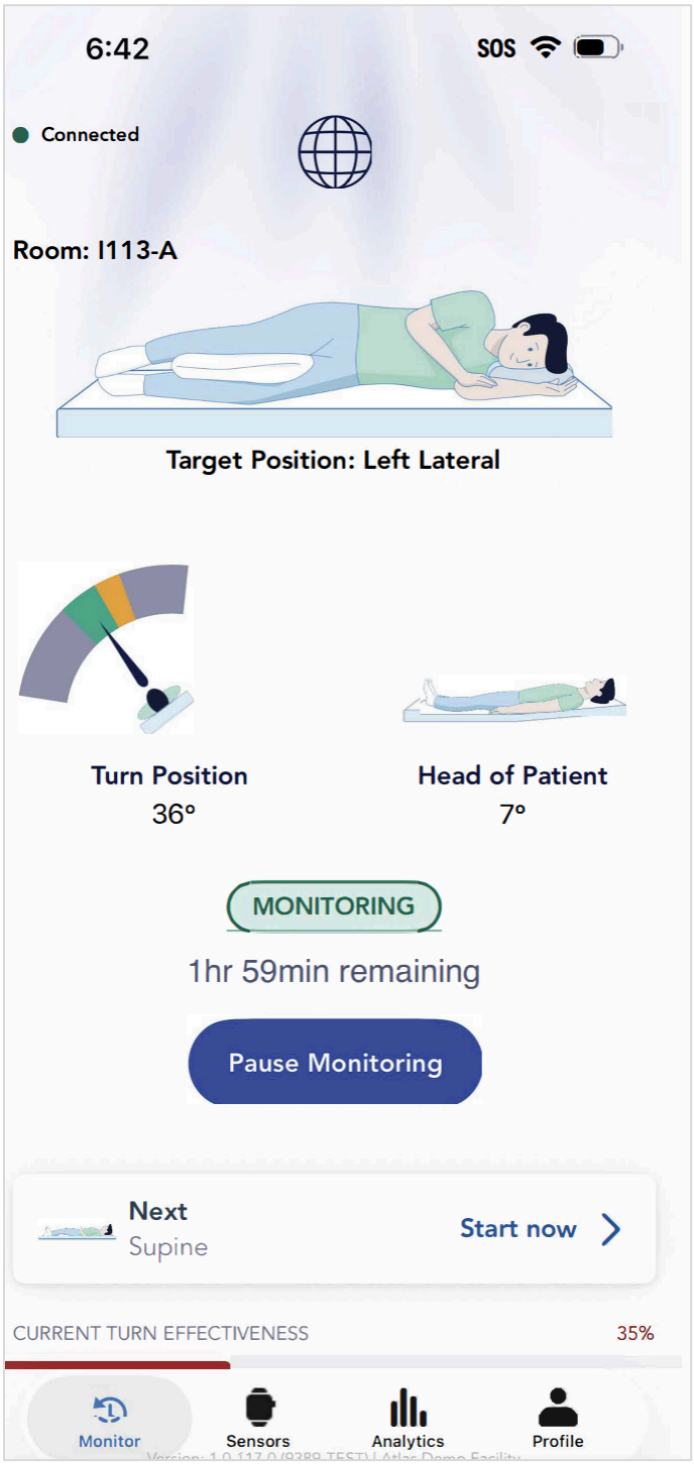
L. Select “Continue”.

Monitoring the Patient's Movement

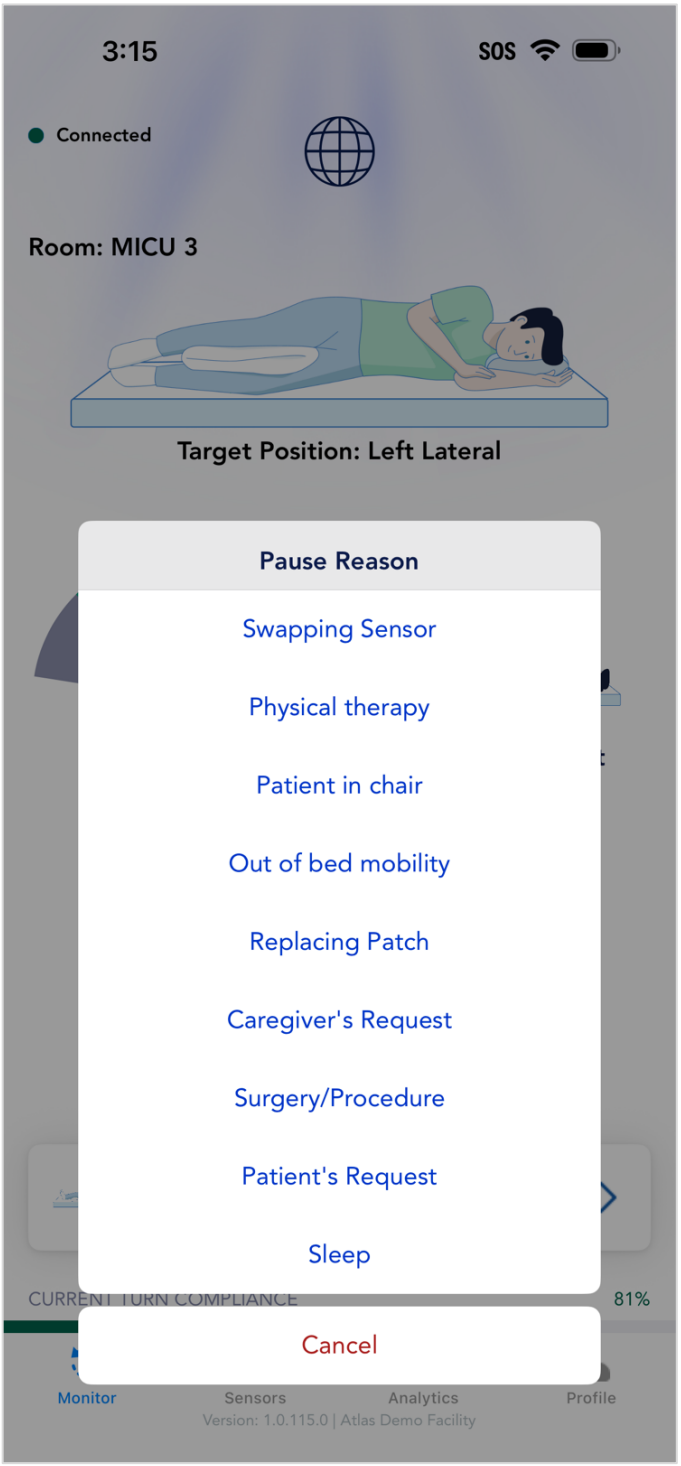
A. Select "Start Monitoring" to start a patient monitoring session.



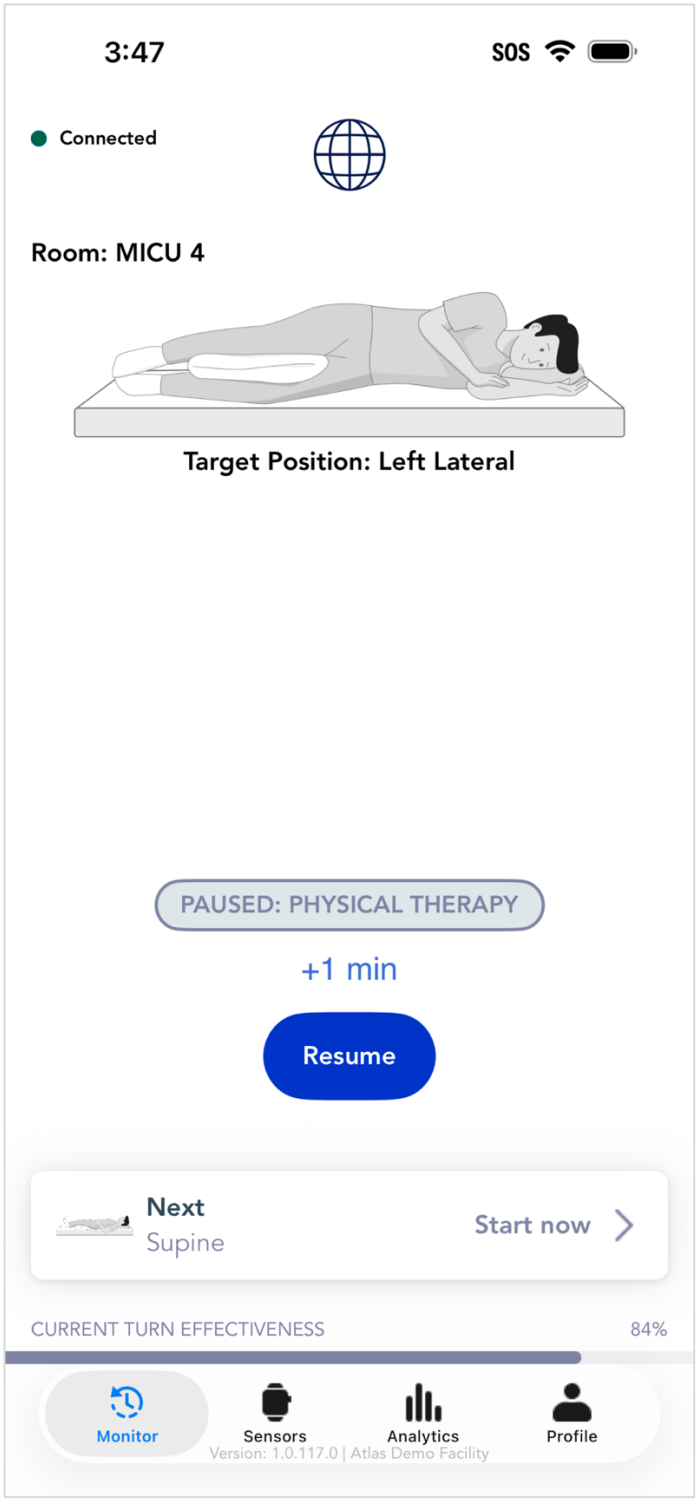
B. To pause monitoring, select “Pause Monitoring.”



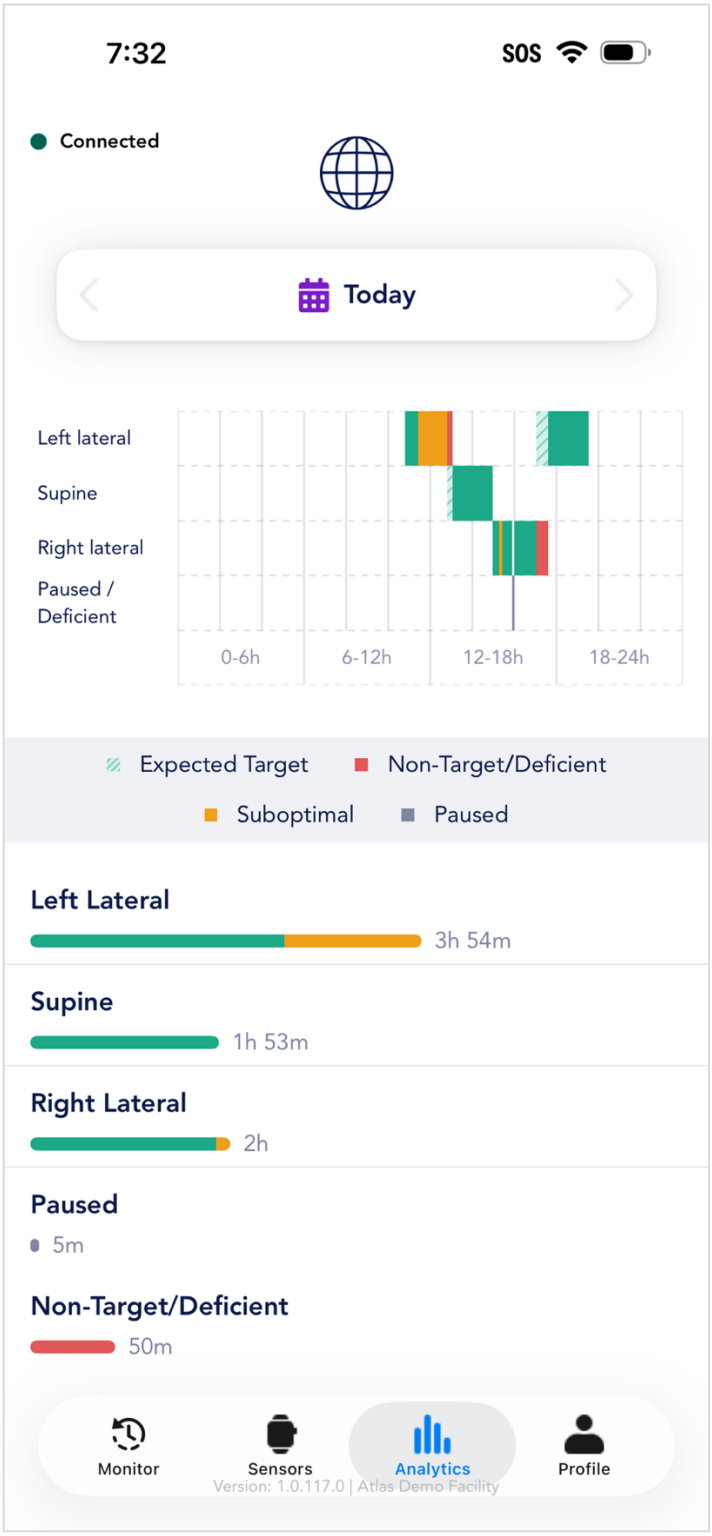
C. Identify Pause Reason based on options provided.



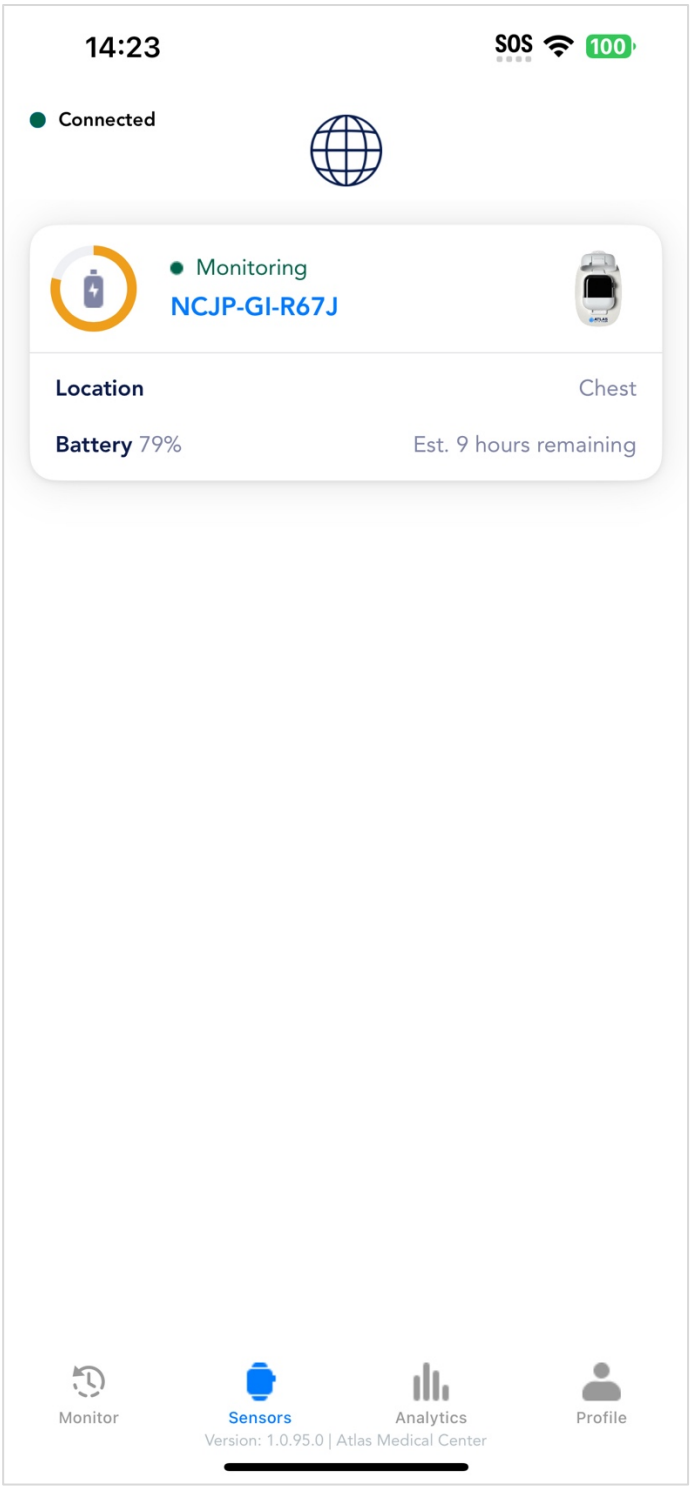
D. To resume monitoring, select “Resume.”



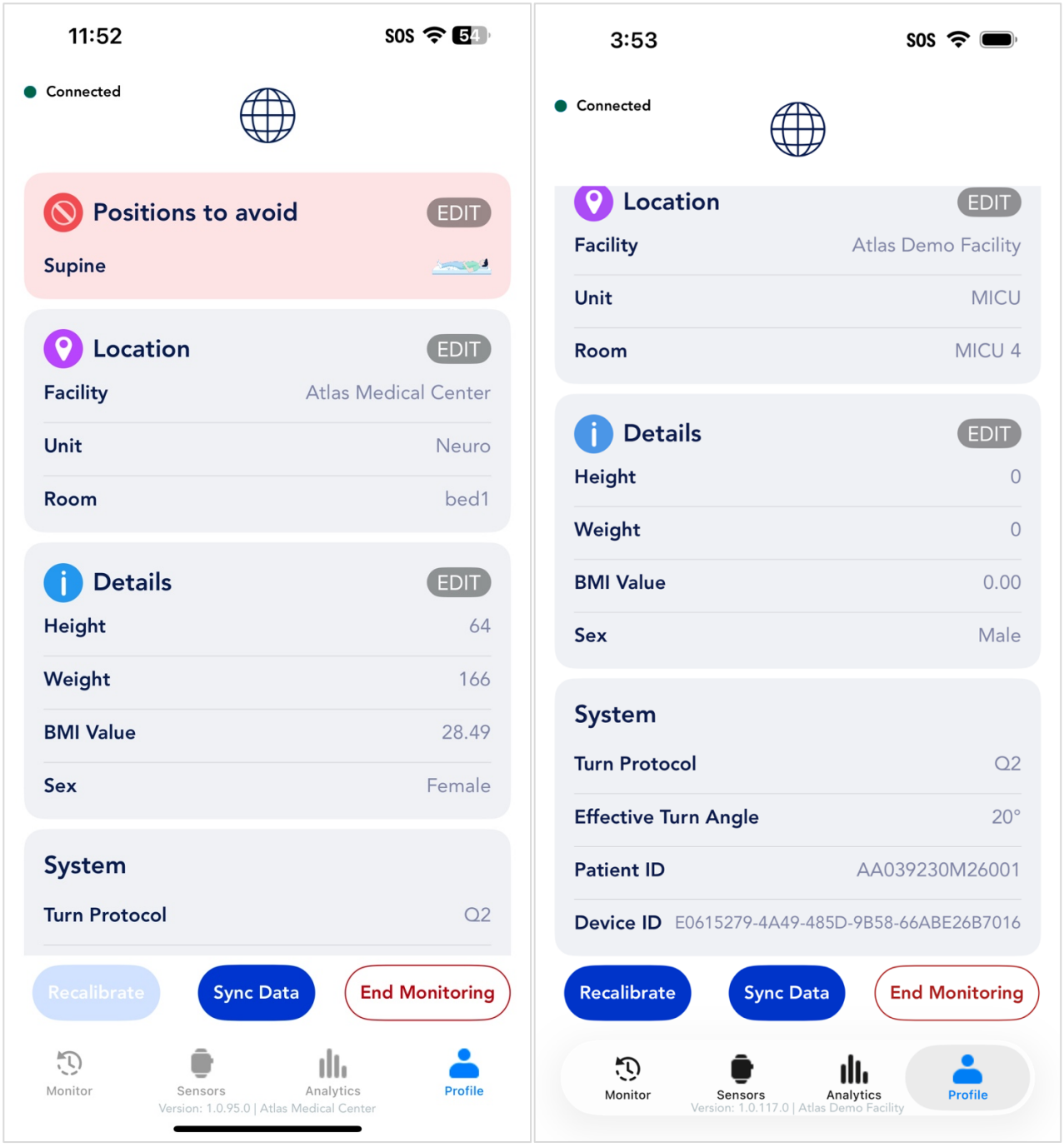
E. The analytics tab displays a snapshot of the patient's position over that last 24 hours



F. The Sensors tab displays the Atlas Sensor details – monitoring status, sensor location, and battery life.



G. The Profile tab displays the patient setup details.



H. Upon the completion of monitoring or upon discharge, select “End Monitoring” within the “Profile” tab.

Taking Care of the Device

A. Cleaning Instructions

The Atlas Sensor and Bedside Mobility Monitor can be wiped clean with commonly used facility-approved alcohol wipes using the label's safety precautions and directions for use. It is recommended to clean them with damp wipes to ensure no excess liquid residue gets inside the power circuit.
Every time the sensor is swapped with a new sensor, the used sensor should be cleaned before being placed back onto the Bedside Mobility Monitor charging dock.

Do not use acetone or attempt to sterilize the sensor. This may damage the sensor and cause it to malfunction.

B. Disposal

The Atlas Wearable Patch should be disposed in biomedical or medical waste bins to prevent any cross-contamination.

Disposal of product - Comply with local laws in the disposal of the instrument and/or its accessories.

C. Service and Maintenance

Maintenance can be performed by qualified Atlas Mobility personnel only. Contact customer service for servicing details.

D. Sensor Battery Life and Patch Wear Time

The Atlas Sensor is designed to work until the battery is depleted. To ensure optimal performance, it is recommended to swap the sensor every 12 hours. The Atlas Wearable Patch is recommended to be changed every 96 hours for optimal performance.

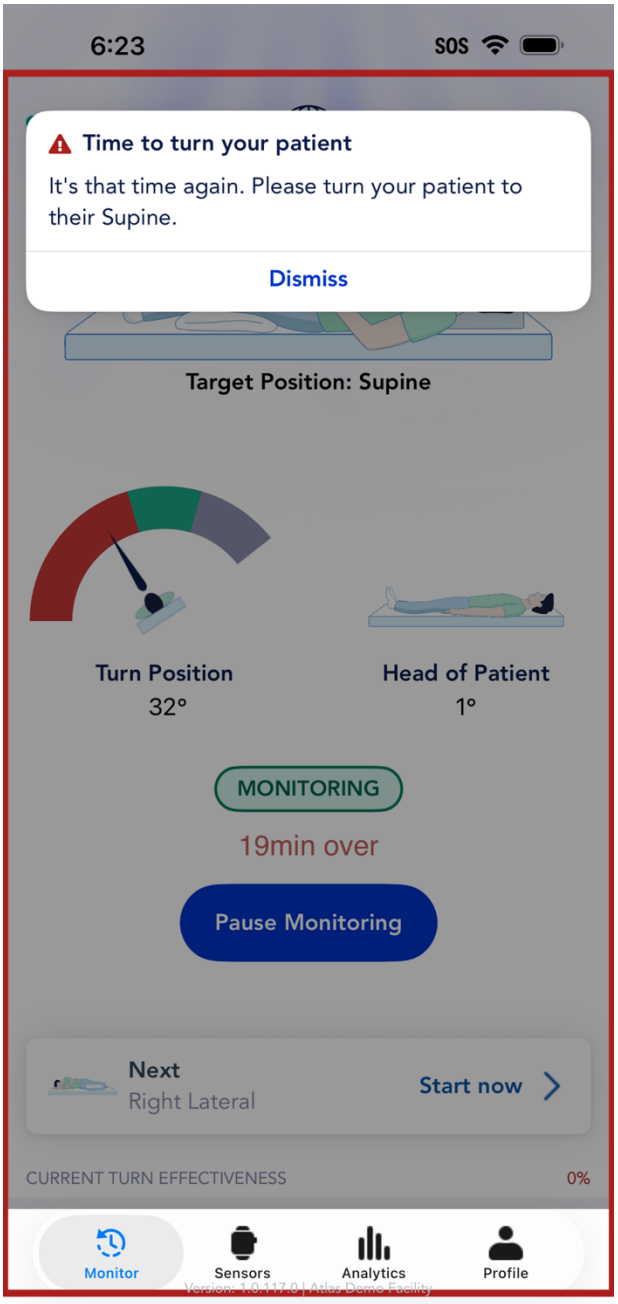
List of Notifications

The notifications displayed by the system and the actions that will resolve the notifications are listed below. This device is not a substitute for sound medical judgment and individualized patient management.

- “Time to turn your patient”
- “Non-Target position detected”
- “Sensor Disconnect”
- “Low Battery”
- “Your patch has expired”
- “Are you still swapping?”
- “Are you still paused?”

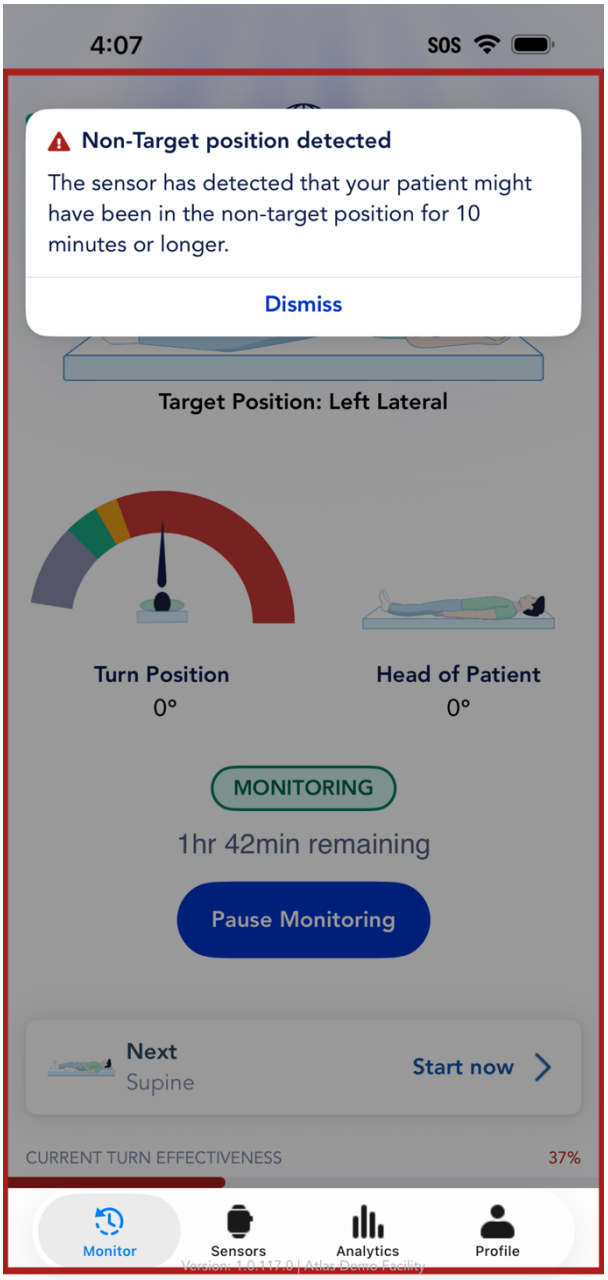
“Time to turn your patient” Notification

This notification appears when a patient is due for their next Q2 turn.



The Bedside Monitor will display this notification banner on top of the monitoring screen 10 minutes before a turn is needed. For example, when the patient only needs to be in Supine position for 10 more minutes, this notification will appear with a dismiss button. When this notification appears, it will play a sound every 30 seconds until dismissed.

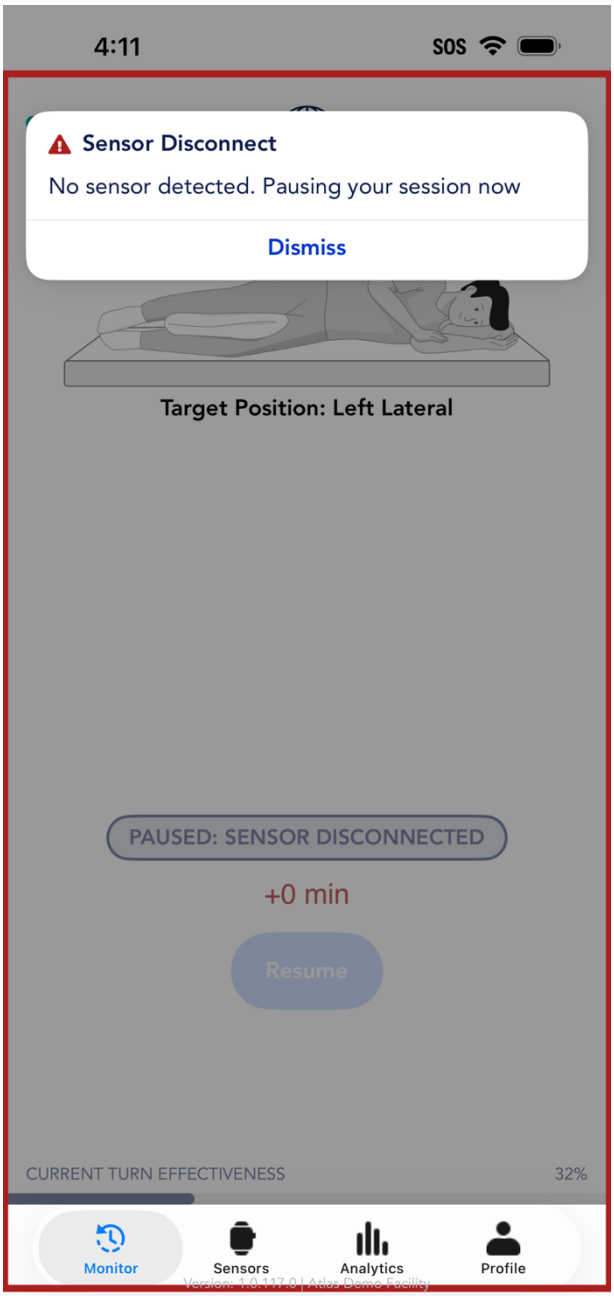
“Non-Target position detected” Notification



This notification appears when a patient is not matching the expected position set by the Bedside Mobility Monitor.

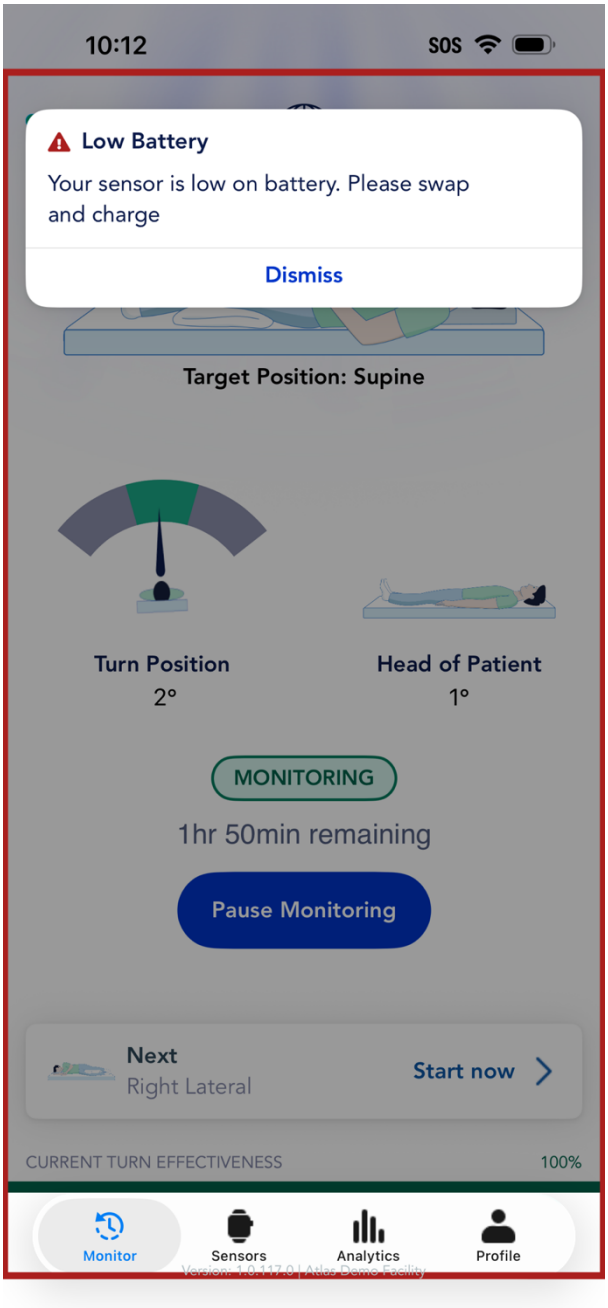
The Bedside Mobility Monitor will display this notification banner on top of the monitoring screen when the patient position is not compliant for more than 10 minutes. This notification can be dismissed by correcting the position of the patient or selecting “Dismiss”. If the notification is dismissed and the patient position remains out of compliance for 10 more minutes, this notification will reappear.

“Sensor Disconnect” Notification



The Bedside Mobility Monitor will display this notification banner on top of the monitoring screen when the sensor is disconnected from the Bedside Mobility Monitor, or vice versa. When this happens, the BMM will pause the current session and this notification banner will appear at the top of the screen. After dismissing this notification, the nurse must reconnect the Atlas Sensor with the Bedside Mobility Monitor.

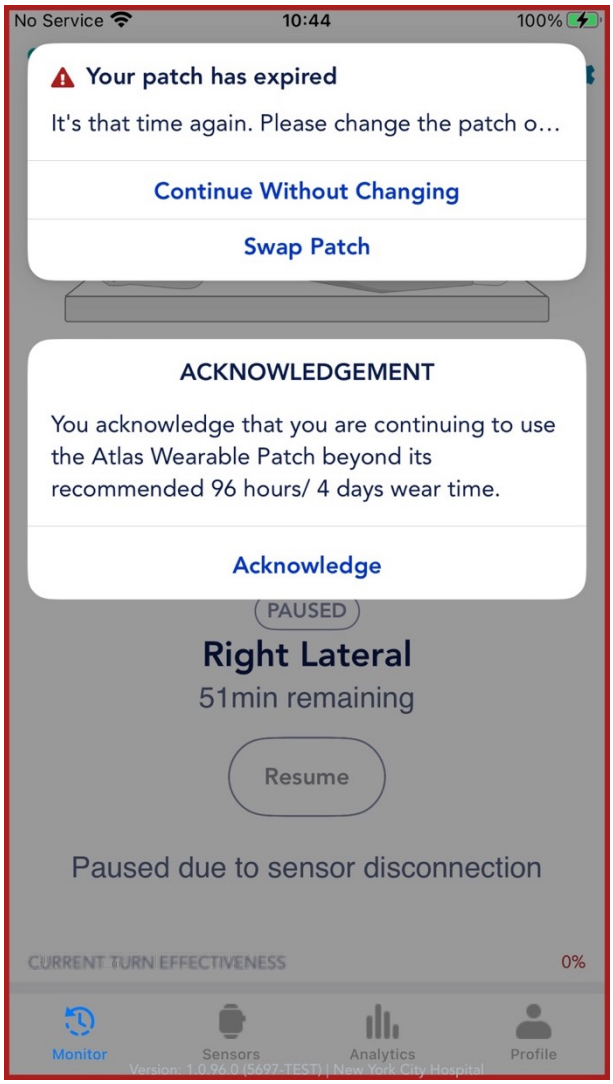
“Low Battery” Notification



This notification appears when the Atlas Sensor battery is running low to let the caregiver know to swap the sensor.

The Bedside Mobility Monitor will display this notification banner on top of the monitoring screen when the sensor battery is at 10% or less. This is to notify the nurse to charge the sensor and swap it with a fully charged one. When this notification appears, it will play a sound every 30 seconds until dismissed.

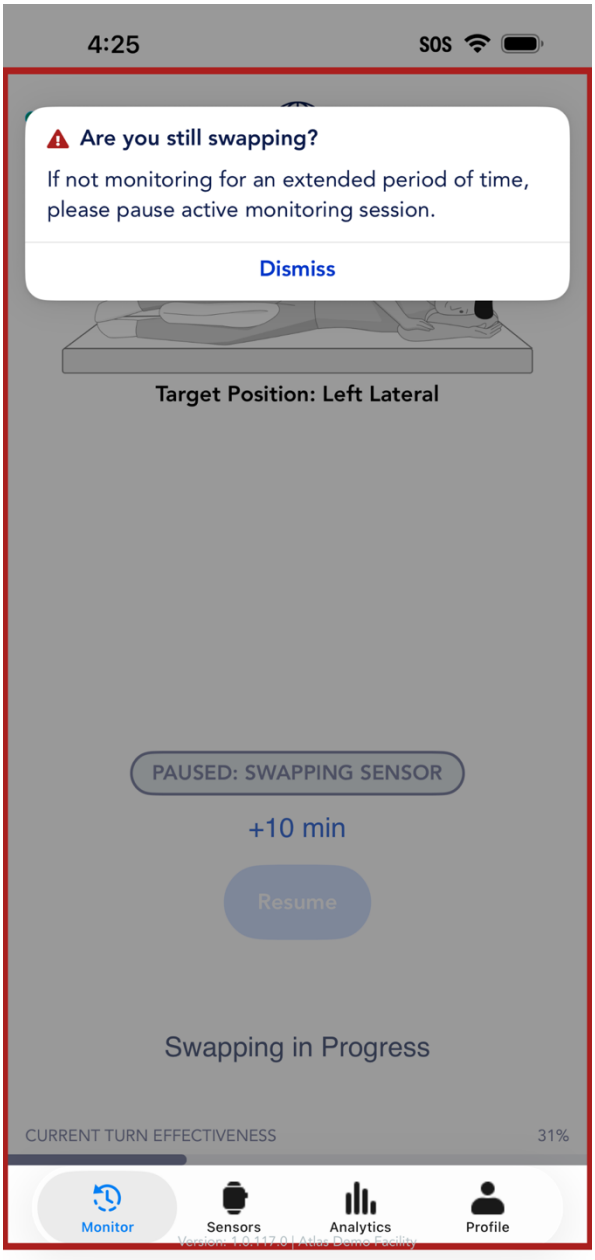
“Your Patch has expired” Notification



This notification appears when it is time to change the Atlas Wearable Patch.

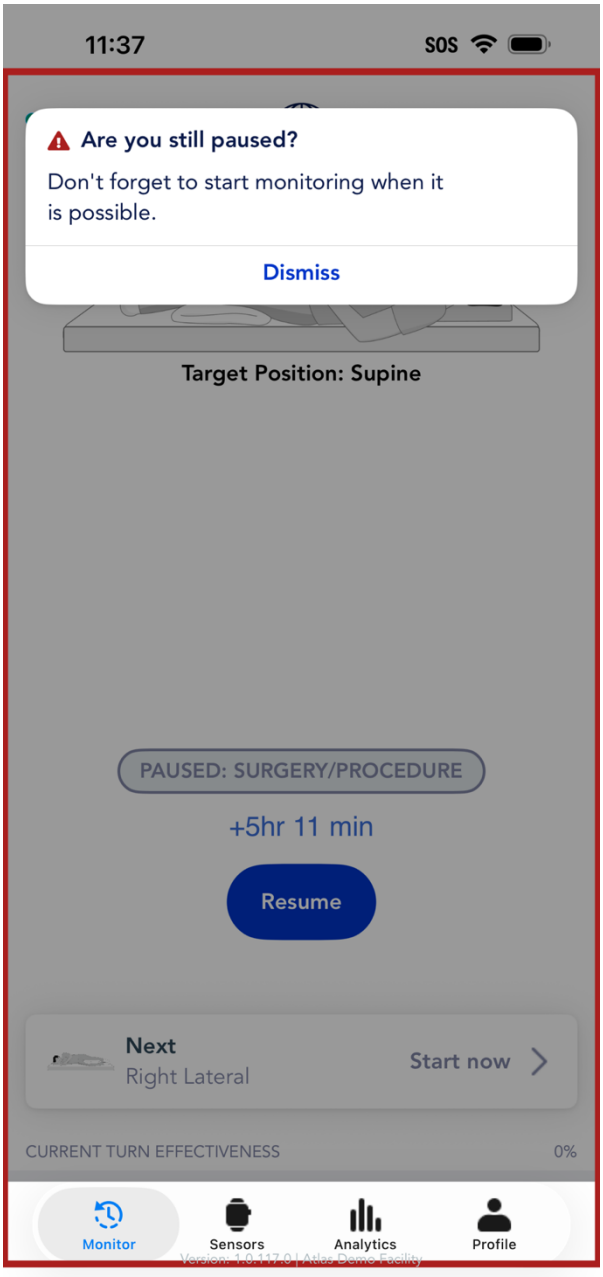
The Bedside Mobility Monitor will display this notification banner on top of the monitoring screen when the patch has been on the patient for over 96 hours. Selecting “Continue Without Changing” will allow the nurse to continue without changing the patch. If the nurse selects this button, another notification will appear to acknowledge this choice. Selecting “Swap Patch” will dismiss the notification and allow the nurse to change the patient’s patch.

“Are you still swapping?” Notification



The Bedside Mobility Monitor will display this notification banner on top of the monitoring screen after 10 minutes have passed during a patch or sensor swap.

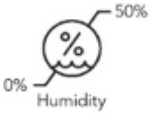
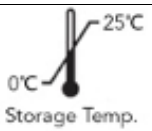
“Are you still paused?” Notification



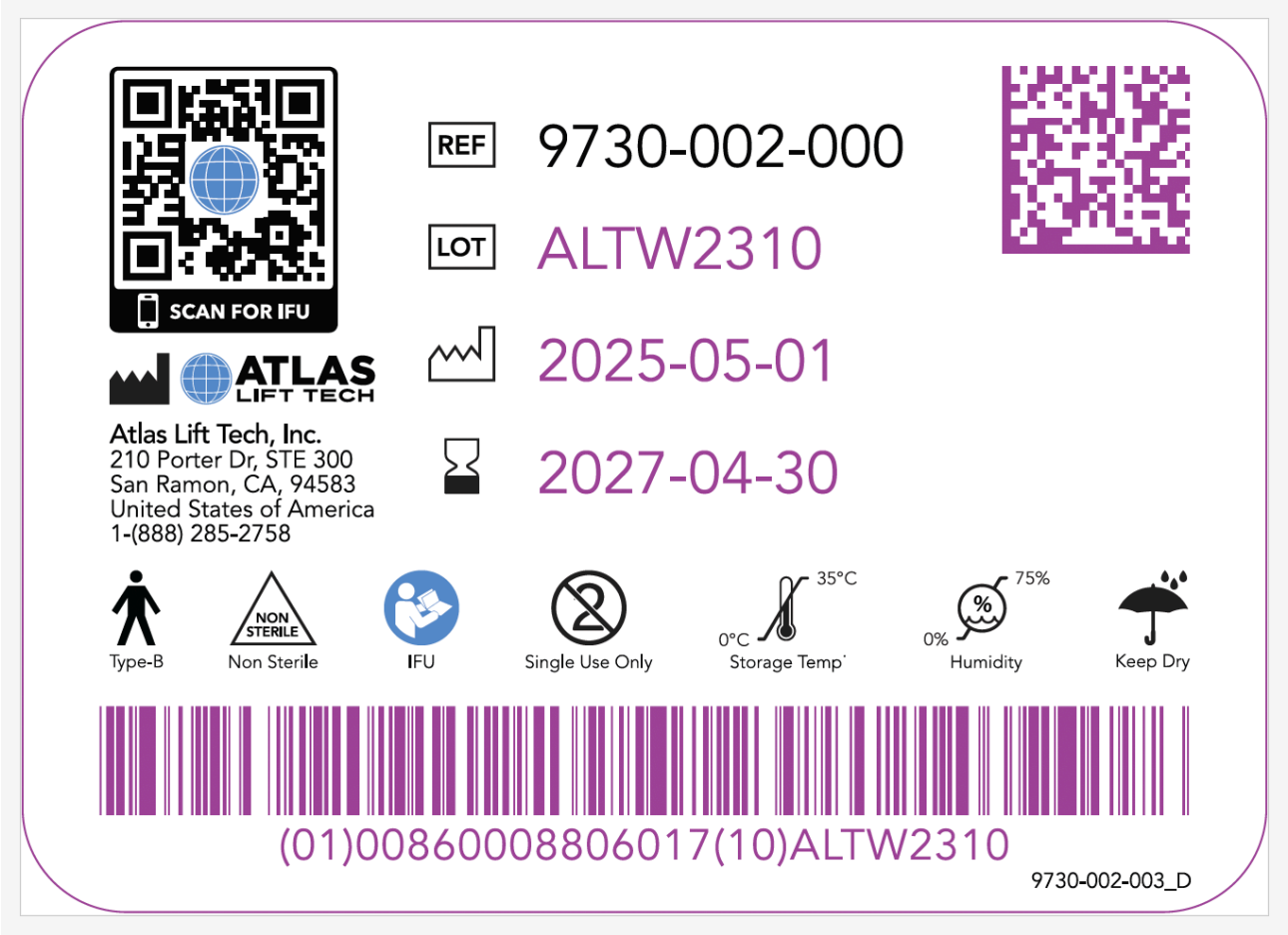
The Bedside Mobility Monitor will display this notification banner on top of the monitoring screen when the monitoring session has been paused for one hour.

Explanation of Safety Signs and Symbols

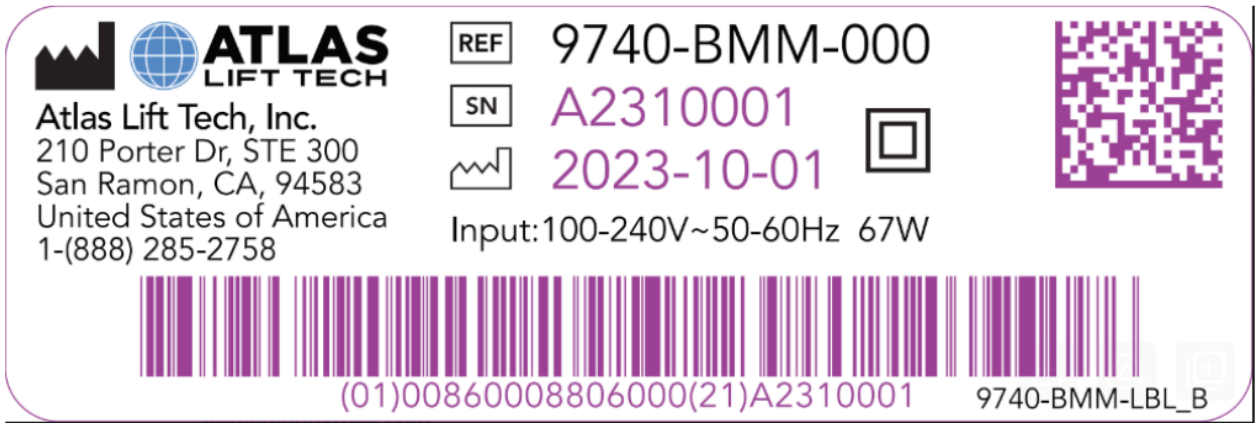
The following signs and symbols are present on the immediate packaging of the Atlas Wearable Patch and/or Bedside Mobility Monitor.

	Date of Manufacture
	Use By Date
	Serial Number
	Lot Number
	Reference Number
	Humidity Range
	This is Non-Sterile product
	Product needs to be stored in Dry place
	Storage Temperature
	Atlas Wearable Patch is Single Use Only

Wearable Patch:



Bedside Mobility Monitor:



Troubleshooting the Bedside Mobility Monitoring System

Component	Issues	Possible Causes	Recommended Solutions
Atlas Sensor	Sensor will not turn on	Battery is dead	Swap the Atlas Sensor with a charged sensor Make sure the Bedside Mobility Monitor is plugged in and charging the Atlas Sensor(s). It may take 1-2 hours to fully charge the sensor
Atlas Sensor	Atlas Sensor low battery warning	General usage for an extended period	Swap the Atlas Sensor with a charged sensor
Atlas Sensor	Sensor damaged	Sensor damaged	Contact Customer Support
Atlas Sensor	Screen is unresponsive	Interaction on screen is not needed Something else is touching the screen	Complete any actions needed on the Bedside Mobility Monitor Make sure nothing else is touching the Atlas Sensor screen and then try again
Atlas Wearable Patch	Atlas Wearable Patch is not sticking to patient skin	Protective film on adhesive is not fully removed Patient skin is not clean and dry Patch has lost its adhesion Expired patch	Make sure the protective film on adhesive is fully removed Ensure the patient's skin is clean and dry before trying to place a new Atlas Wearable Patch Check the Use by Date. If expired, discard the patch and replace it with new Atlas Wearable Patch
Atlas Wearable Patch	Atlas Wearable Patch packaging damaged	Damaged in shipping and handling User handling error	Discard the Atlas Wearable Patch and use a new one
Bedside Monitor	Low battery warning	Power disconnected	Check that the Bedside Mobility Monitor is plugged into a working power source Contact Customer Support

Bedside Monitor	Device display is off or dim	Battery is on power save mode Battery is dead	Check that the Bedside Mobility Monitor is plugged into a working power source If the device completely died, please contact Customer Support
Bedside Mobility Monitor	Shutting off the device	Turning off Bedside Mobility Monitor in case of emergency or Malfunction	Call Customer Support to turn off device from phone settings
Sensor	Shutting off the sensor	Turning off the sensor in case of emergency or malfunction	Call Customer Support to turn off device from phone settings

Bedside Mobility Monitoring System Hardware Specifications

Electrical Voltage (mains input)	100-240VAC ~ 1.8A (70 watts maximum)
Electrical Voltage (USB hub)	In DC 5-20.3V/3A 61W Out DC 3x 5V/1.5A, 1x 5-20.3V 3A
Electrical Voltage (Apple iPhone)	Internal Battery, Li-ion
Electrical Voltage (Atlas Sensor)	Internal Battery, Li-ion
Atlas Sensor Power source	Internal Battery, Li-ion
Bedside Mobility Monitor Power	 IEC 60417-5172 CLASS II Equipment
Atlas Wearable Patch size	54.5 x 45 x 16.75mm adhesive extents 54 x 79 mm
Atlas Wearable Patch Weight	8.6 grams
Atlas Sensor Size	Height 40 mm, Width 34 mm & Depth 10.7mm
Atlas Sensor model and Weight	40 mm (GPS) 26.4 grams

Atlas Wearable Patch Adhesive Materials	Front: Avery Dennison MED 8345 Back: Avery Dennison MED 5719P
Atlas Sensor Applied Part Type	Type B Applied Part 
Atlas Wearable Patch material (base)	LDPE (DOW 955i 95A Shore)
Atlas Wearable Patch material (cap)	ABS (Lustran 348)
Optimal Distance between Atlas Sensor and Bedside Mobility Monitor	15 Feet
Wireless Transmission Protocol (Atlas Sensor)	Bluetooth 5.0 wireless technology
Wireless Transmission Frequency	2.402 GHz and 2.480 GHz
Wireless Transmission output power	+20 dBm
Atlas Antenna Classification	IEC 60601 Class II
Ingress Protection (IP) Rating	Atlas Sensor IPX7
Intended System Operation	Continuous Operation
Battery Use Life per session (Atlas Sensor)	Up to 18 hours
Operating Conditions	32 °F – 95° F, 5 - 90 RH

Storage and Transportation	-4 °- 113° F, 5 - 90 RH
Altitude	Up to 2000 M, 6561.68 fts
Product Shelf Life	• Bedside Mobility Monitor – 10yrs • Atlas Sensor – 5yrs • Atlas Wearable Patch – 2 yrs.

EMC Precautions

The Bedside Mobility Monitoring System has been tested and found to comply with the limits for medical devices to IEC 60601-1-2. These limits are intended to provide reasonable safety regarding electromagnetic disturbances when the system is used in a typical medical installation.

The Bedside Mobility Monitoring System is intended for use in the professional healthcare environment. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

To ensure proper operation of the Bedside Mobility Monitor and to maintain basic safety and essential performance regarding EM disturbances for expected service life: do not use the Bedside Mobility Monitor near any sources of EM interference.

The Bedside Mobility Monitor is tested to limits and levels below which are derived from IEC 60601-1-2 edition 4.1 professional healthcare environment. There are no deviations from this collateral standard and allowances used.

Guidance and Manufacturer's Declaration

(Electromagnetic Emission)

Emission Test	Compliance Level
Radiated RF EMISSIONS	CISPR 11, Group 1, Class A
Conducted RF EMISSIONS	CISPR 11, Group 1, Class A
Harmonic distortion	IEC 61000-3-2
Voltage fluctuations and flicker	IEC 61000-3-3

Guidance and Manufacturer's Declaration

(Electromagnetic Immunity)

Immunity Test	Compliance Level
Electrostatic discharge	IEC 61000-4-2 ± 8 kV contact ± 2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields	IEC 61000-4-3 3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3 See table 1 below
Rated power frequency magnetic fields	IEC 61000-4-8 30 A/m 50 Hz or 60 Hz
Electrical fast transients/bursts	IEC 61000-4-4 ± 2 kV 100 kHz repetition frequency
Surges	IEC 61000-4-5 ± 0.5 kV, ±1 kV L-L ± 0.5 kV, ±1 kV, ±2 kV L-G
Conducted disturbances induced by RF fields	IEC 61000-4-6 3 V 0.15 – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11 0 % UT; 0,5 cycle , @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles ,@ 0°
Voltage Interruptions	IEC 61000-4-11 0 % UT; 250/300 cycle
Proximity Magnetic fields	See table 2 below

Table 1: Proximity fields from RF wireless communications equipment specification

Test frequency (MHz)	Band (MHz)	Service	Modulation	Immunity test level[2] (V/m)
385	380 –390	TETRA 400	Pulse modulation, 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM, ± 5 kHz deviation, 1 kHz sine[1]	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation, 217 Hz	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation, 18 Hz	28
1720 1845 1970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE-Band 1, 3, 4, 25; UMTS	Pulse modulation, 217 Hz	28
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation, 217 Hz	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation, 217 Hz	9

Table 2: Proximity magnetic field specifications

Test frequency (MHz)	Modulation	Immunity test level[2] (V/m)
30	CW	8
134.2	Pulse Modulation 2.1 kHz	65
13.56	Pulse Modulation 50 kHz	7.5

Radio Information

Wireless Technology	Frequency Band of reception	Type of frequency characteristics and modulation	Effective radiated power
Bluetooth	2.4 GHz	GFSK (Bluetooth 5.0)	≤ 21 dBm
Wi-Fi	2.4 and 5 GHz	802.11a•02.11b•802.11g•802.11n	≤ 25 dBm

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