Compremium

CPMX1 System
Instructions For Use

Version 7.0 - JANUARY 2025 DCR#: 24-056

These Instructions for Use are applicable to the following CPMX1 System:
Catalogue number: CPMX1
Software version: 1.3.0

Notices:
Compremium shall not be liable for errors contained herein or for incremental or consequential damages in connection with the furnishing, performance, or use of this material.

Changes:
Information in this document is subject to change without notice. Some feature components may not be available to certain user groups based on national or local regulatory restrictions. All images are for informational purposes only, the delivered components may deviate from photos shown in this IFU.

CAUTION

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

Contents

1 Symbols Glossary

Symbol Graphic	Symbol Title	Description	Standard or Regulation	Registration number / Reference
	Warning	Indicates a potentially hazardous situation which, if not avoided, could cause injury or harm to the operator or patient.	ISO 7000	0434A
	Caution	Indicates a potentially hazardous situation which, if not avoided, may result in minor injury or harm to the equipment.	ISO 7000	0434A
	MR Unsafe	Indicates an item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.	ASTM F2503-1	F2503 - 13 3.1.14
	Manufacturer	Indicates the medical device manufacturer	ISO 7000	3082
	Date of manufacturing	Indicates the date when the medical device was manufactured	ISO 7000	2497
	Catalogue number	Indicates the manufacturer's Catalogue number so that the medical device can be identified	ISO 7000	2498

Symbol Graphic	Symbol Title	Description	Standard or Regulation	Registration number / Reference
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 7000	2498
IPX2	Ingress Rating	Signifies that the device is rated to level 2 for water ingress protection, and that water splashing against the enclosure from any direction shall have no harmful effect	IEC 60529	Non applicable
	Fragile handle with care	Indicates a medical device that can be broken or damaged if not handled carefully	ISO 7000	0621
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	ISO 7000	2606
	Keep away from sunlight	Indicates a medical device that needs protection from light sources	ISO 7000	0624

Symbol Graphic	Symbol Title	Description	Standard or Regulation	Registration number / Reference
	Keep dry	Indicates a medical device that needs to be protected from moisture	ISO 7000	0626
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	ISO 7000	0632
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed	ISO 7000	2620
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed	ISO 7000	2621
	Refer to instruction manual/ booklet	To signify that the instruction manual/booklet must be read	ISO 7010	M002
℞ ONLY	Prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician, dentist, or licensed practitioner	21 CFR 801.109	Non applicable
MD	Medical Device	Indicates that the item is a medical device	ISO 15223	5.7.7 23.2(q)

Symbol Graphic	Symbol Title	Description	Standard or Regulation	Registration number / Reference
	Type BF Applied Part	B = body F = floating applied part	IEC 60417-5333	Non applicable
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021	5.7.10

2 Introduction

These Instructions for Use (IFU) are intended to provide information to guide users in the safe and effective operation and proper maintenance of the Compartmental Compressibility Monitoring System (hereafter referred to as CPM#1 System or CPMX1 System). It is important that you read and understand all instructions in this manual before operating the system and pay careful attention to the warnings and cautions throughout the IFU. Please review this manual carefully before using the CPMX1 System.

Contact Compremium if you have any questions.

WARNINGS

- The CPMX1 System is intended for use by healthcare professionals capable of interpreting image quality, and clinical utility of the system.
- The results given by the device are not meant for trend analysis.

CAUTIONS

- Do not use the CPMX1 System until the materials present in this manual have been reviewed and fully understood. Do not operate the CPMX1 System for purposes other than intended in this manual.

- Handle the front membrane of the CP Probe and the cable attachment at the other end of the CP Probe with care. Keep the front membrane of the CP Probe away from sharp objects to avoid damage. This will protect the CPMX1 System and the delicate front membrane of the CP Probe. Do not put stress on, or use the USB-C Cable to carry the CP Probe, as this may damage the CP Probe and the USB-C Cable.

3 Safety Information

Basic Safety /Usage Environment

WARNINGS

- The CPMX1 System is classified as MR Unsafe and may pose unacceptable risks to the patient, medical staff, or other persons within the MR environment.

- The device should only be used in a professional healthcare environment by medical professionals.
- The CP Probe must not be used with any other devices or components than the ones delivered by Compremium.
- Do not insert the CP Probe connector into any USB ports other than those on the Tablet delivered by Compremium.
- Do not use the CPMX1 System in the presence of flammable gases or anesthetics. Doing so can result in a possible fire or explosion.
- The CP Probe does not exhibit excessive surface temperat-res under normal use. Disconnect the CP Probe immediately if unsafe temperatures are observed.
- Portable and mobile radiofrequency (RF) communications equipment can affect Medical Electrical Equipment.
- Do not use the CPMX1 System if it is believed to be faulty. Use of damaged equipment may cause the device to perform improperly and/or result in injury to the patient or operator.
- No modification is allowed. Modification to equipment may cause the system to perform improperly or may cause injury to the patient or operator.
- There are no user-serviceable parts. Do not open, remove covers, or attempt repair.
- The CP Probe must be cleaned after each use. Cleaning the CP Probe is an essential step before effective disinfection.

⚠ CAUTIONS

- Special precautions should be considered when using the transducer on patients who may have pre-existing conditions or sensitivity to temperature.
- Disposal of the device should be carried out in accordance with all applicable Federal, State, and local medical/hazardous waste practices.

Electrical safety

⚠ WARNINGS

- Before use, carefully inspect the CP Probe. Always inspect the probe before and after cleaning, disinfection, or use. Check the membrane, cable, housing, seams, and connector for signs of any damage such as cracks, chips, abrasions, or leaks. To avoid the risk of electrical hazards, do not use the probe if there is any sign of damage.
- The CPMX1 System has not been evaluated or approved for use in hazardous locations as defined in the National Electric Code standard. In compliance with IEC 60601 classification, the device is not to be used in the presence of flammable substances/air mixtures.
- The use of AC adapters which have not been tested for electrical safety could potentially cause harm to the Tablet, the CP Probe, the operator and/or the patient. Compremium recommends using only the AC adaptor supplied by the manufacturer of the Tablet.
- Do not use the CPMX1 System when the Tablet is connected to an external power supply. Only use the CPMX1 System when the Tablet is not charging.
- Use of the CPMX1 System 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.

- Electrical shock to the patient or operator may result if voltages exceeding IEC 60601-1 limits for patient-applied parts are exceeded.
- Use of probes and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromgnetic immunity of this equipment and result in improper operation.
- The cable on the CP Probe is not designed to be removed by the user. Removing the cable could cause injury to the patient or operator.
- Do not touch the CP Probe USB cable connector and the patient simultaneously.
- The CP Probe is designed to remain sealed. Do not attempt to open the probe or tamper with the device internals. Doing so may cause injury to the patient or operator.
- Do not immerse the CP Probe. Immersion may result in electrical shock.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CPMX1 System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Equipment protection

CAUTIONS

- Do not ship, store, or use the CPMX1 System outside the defined environmental operating conditions.
- Store the CPMX1 System only within the range of environmental operating conditions specified in the technical specifications.
- Do not use device past the service life.
- Do not sterilize or autoclave the CP Probe.

- Do not allow sharp objects, such as needles, scalpels, or cauterizing knives, to touch the CPMX1 System.

Biological Safety

WARNINGS

- Do not place probe on injured skin. Avoid contact with mucous membranes (e.g. eye, nose, mouth) and non-intact areas of the skin that have been opened by cuts, abrasions, dermatitis, chapped skin, etc.
- Use compliant gel only, the use of non-ISO 10993-compliant Ultrasound Transmission Gel could potentially cause harm to the CP Probe, operator and/or the patient.
- Always use the ALARA (As Low As Reasonably Achievable) principle when using the ultrasound features. Additional information on the ALARA principle can be found in AIUM's "Medical Ultrasound Safety" publication.

Operator Safety

WARNINGS

- No modification is allowed. Do not modify cable, CP Probe or charger specified for use with the CPMX1 System. Modifications to equipment may cause the system to perform improperly or may cause injury to the patient or operator.
- Use of damaged equipment or accessories may cause the device to perform improperly and/or result in injury to the patient or operator.
- Do not use, connect, or operate the CPMX1 System with non-approved or nonspecified equipment or accessories. Doing so may result in injury to the patient or operator.

CAUTION

- Follow your institution's personal protective equipment (PPE) and infection control procedures (e.g. eye, respiratory, and hand protection) when operating, cleaning, or disinfecting the device.

4 Device Description

The Compartmental Compressibility Monitoring System (CPMX1) is a point-of-care device for non-invasive, real-time, and intermittent monitoring of relative compartment compressibility, expressed as CP Value.

The device combines a linear ultrasound array with an integrated pressure sensor into a single handheld probe (CP Probe) to obtain cross-section ultrasound views of the compartment of interest. The device provides a surrogate metric of the compartment's compressibility in one ultrasound image plane only, using a linear measurement of distance between two points of the compartment, as a function of applied external pressure.

Based on this measurement, a compressibility percentage is calculated and displayed on-screen as the CP Value.

4.1 Components

The CPMX1 System consists of:

A) A Tablet
- commercial off-the-shelf (COTS) Windows tablet
- providing the user interface of the CP Software
- allowing software-based parameter controls and recording
- acting as a power source to the CP Probe

B) The CP Probe including
- flat linear ultrasound array
- pressure sensor
- analog to digital converter
- microcontroller
- control logic
- USB-C interface and control
- USB-C cable, providing data connectivity with the tablet (C)

CPMX1 system consisting of (A) Tablet, (B) CP Probe and (C) Cable

The expected service life of the CPMX1 System is two (2) years.

5 Intended Use

5.1 Indications for Use

The Compartmental Compressibility Monitoring System (CPMX1) is intended for real-time and intermittent monitoring of relative compartment compressibility. The relative compartment compressibility (CP Value) is not meant for trend analysis.

5.2 User Group

The Compartmental Compressibility Monitoring System (CPMX1) is for prescription use only. It should only be used by health care professionals who have received appropriate training and have gained thorough knowledge and understanding of the information presented in this IFU.

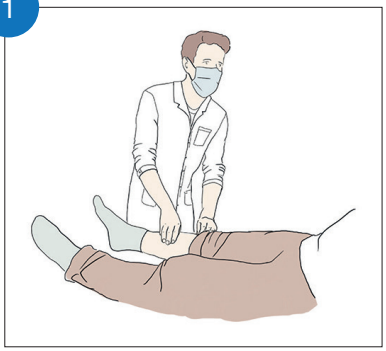
6 Contraindications

The Compartmental Compressibility Monitoring System (CPMX1) is intended to be used on intact skin, only.

The Compartmental Compressibility Monitoring System (CPMX1) is not indicated for ophthalmic use or any application that causes the acoustic beam to pass through the eye.

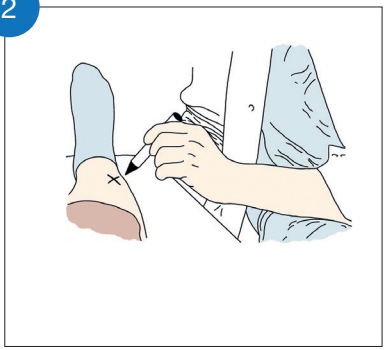
7 Workflow Overview

1



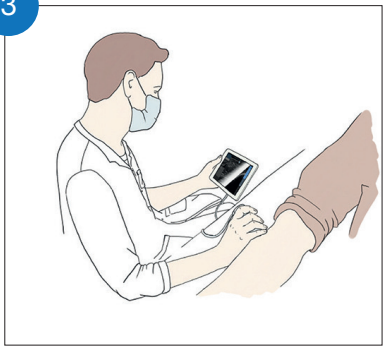
Manual investigation
Identifying the compartment of interest by manual palpation.

2



Location marking
Marking the location for measurement with a medical marker, followed by the application of ultrasound gel on the skin.

3



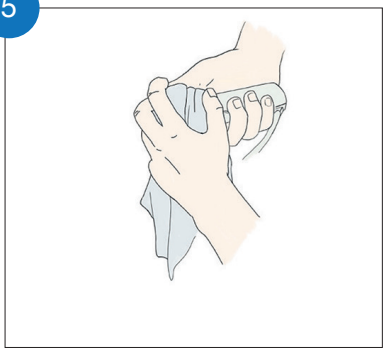
Examination with CPMX1 System
Measuring the relative compartment compressibility percentage (picture showing examination of anterior tibia compartment).

4

Setting landmarks

Setting the landmarks on the images displayed on the Tablet.
Data readout and saving.

5



CP Probe cleaning and disinfection

Details see chapter 9.2.

Additional meassurements

For additional measurements go back to step 3.

8 Operational Instructions

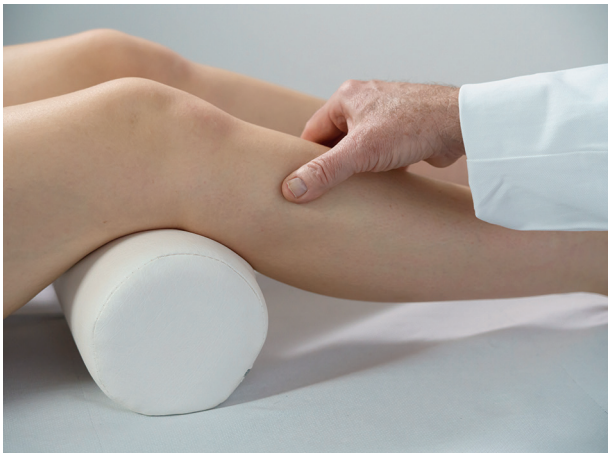
Care and Handling of CPMX1 System
Although CPMX1 Systems are very durable, reasonable care must be taken to avoid damaging them.

8.1 System Set-Up

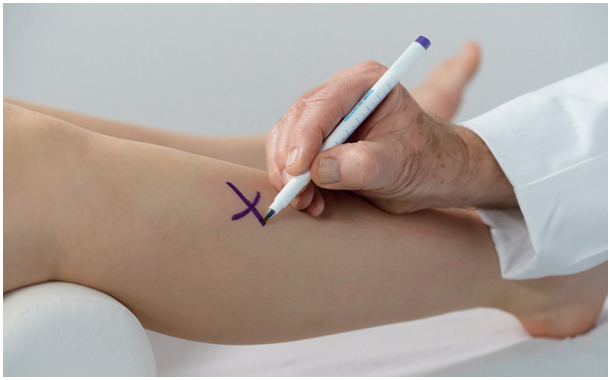
The CPMX1 System setup requires the CP Probe to be connected to the Tablet via its USB-C cable.

8.2 Step by Step Workflow

Step 1 - Manual investigation
The user identifies the compartment of interest by manual palpation.



Step 2 - Location marking
The user marks the location for measurement with a medical marker and then applies ultrasound gel to the skin.



WARNING

The site should be marked before ultrasound gel is applied and in a way that ensures that a subsequent measurement may be performed at the same location.

WARNING

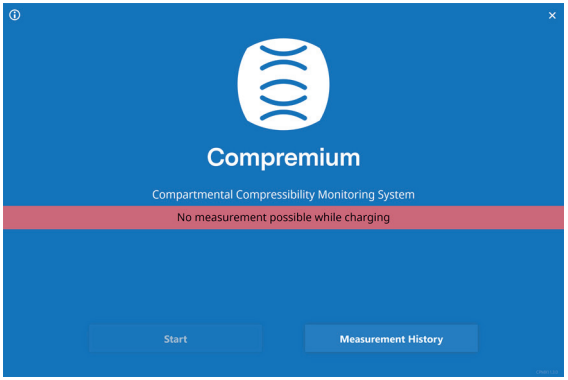
Measurements shall only be taken on intact skin.

Step 3 - Examination with CPMX1 System

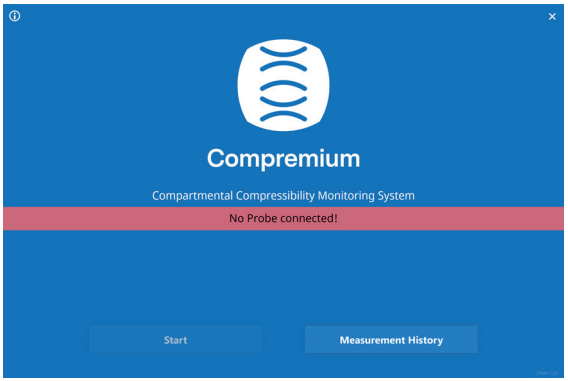
The Tablet should be positioned in clear sight of the user to operate it easily by hand. Preferably, the user sits next to the patient, the Tablet is positioned in landscape orientation.

The user ensures that the CP Probe is connected to the Tablet.

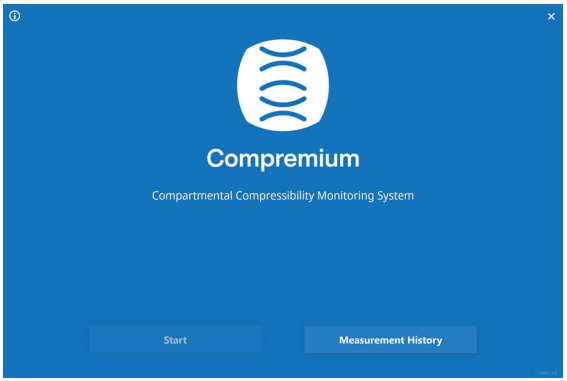
The CPMX1 System can only be used when the Tablet is not charging. If the Tablet is connected to the external power supply, the software displays the error message “No measurement possible while charging”.



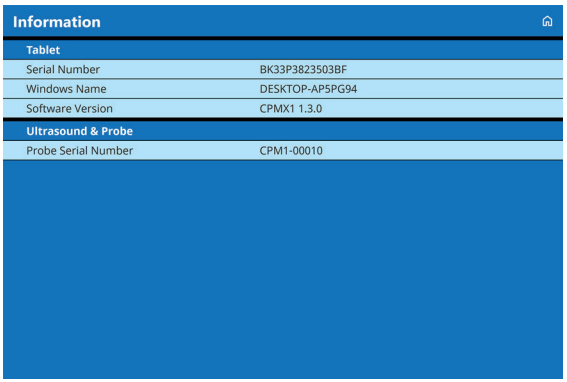
If no CP Probe is connected to the Tablet, the software displays the error message: “No Probe connected!”.



The CPMX1 System will become operational by pushing the power button on the Tablet. After the CP Software has been fully loaded, the start screen will show two buttons: “Start” and “Measurement History”. The current software version is shown on the bottom-right corner of the screen.
All along the use of the software, de-identified data is collected for internal use by Compremium.



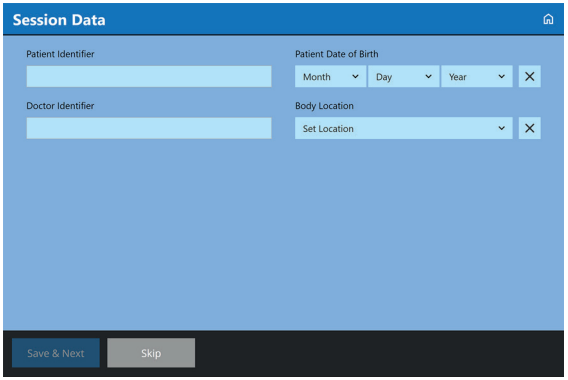
When selecting the information icon on the top left side, the following information is displayed: serial number of the tablet, Windows name, software version, and if the CP Probe is connected, its serial number.



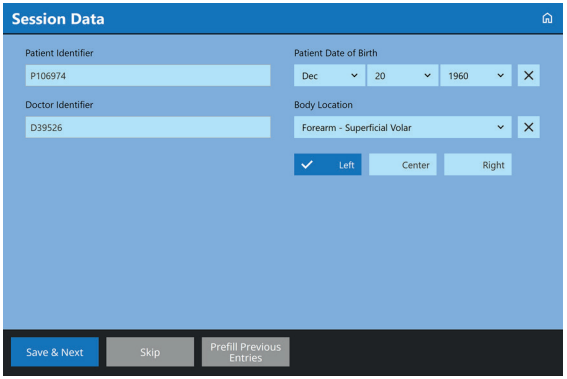
Start of the examination

When the “Start” button is pressed, before starting the examination, the user has the possibility to fill some information about the ongoing examination. The identifier fields follow the configured environment-specific format. All fields are optional and the user can go directly to the examination by pressing on the “Skip” button.

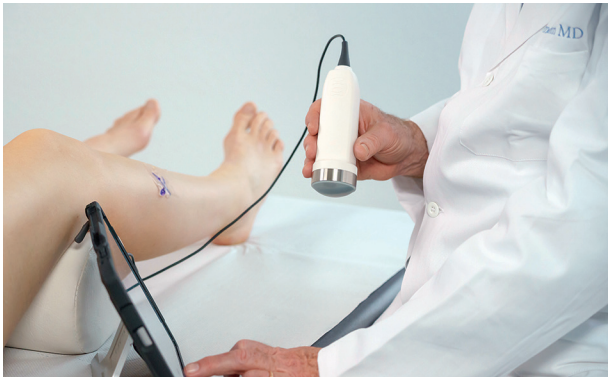
In case the software has not been closed between subsequent examinations, the user can choose to re-use the information entered for the previous examination by pressing on the “Prefill previous entries” button.



After filling the desired information, the user can start the examination by pressing the “Save & Next” button.

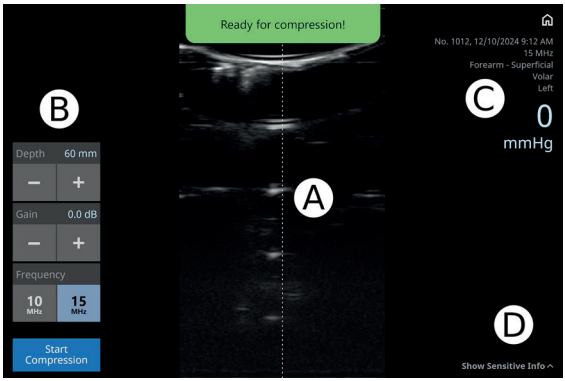


At the beginning of an examination, the user needs to hold the CP Probe in his/her hand facing the measurement direction and without exerting any pressure on the membrane to calibrate the device.



When the “Skip” or “Save & Next” buttons are pressed, the screen changes to ultrasound and the CP Probe calibrates automatically. The Tablet must indicate 0 mmHg before the measurement begins.

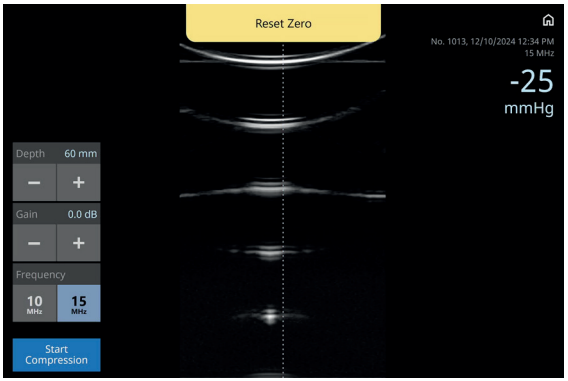
The following image appears on the screen:



The screen shows: a) the ultrasound signal with a vertical line, b) the buttons for manual adjustment of the ultrasound image depth,

gain and frequency, c) the measurement information (number, date, time, default frequency of the device, and measurement body location), d) the button to show/hide sensitive information (only if available), pressure indicator (displayed in mmHg) and the start compression button.

An error message will be displayed when the CPMX1 System is unable to calibrate properly due to external forces on the membrane.



WARNING

During the calibration, the front membrane of the CP Probe must only be in contact with the surrounding air, so that there is no contact pressure.

Ultrasound settings

Depth: The user can select an optimal depth of the ultrasound beam in order to reach the relevant target. The default setting is 60mm.

Gain: With the “Gain” button, the user can change the image brightness. The default setting is 0.0 dB.

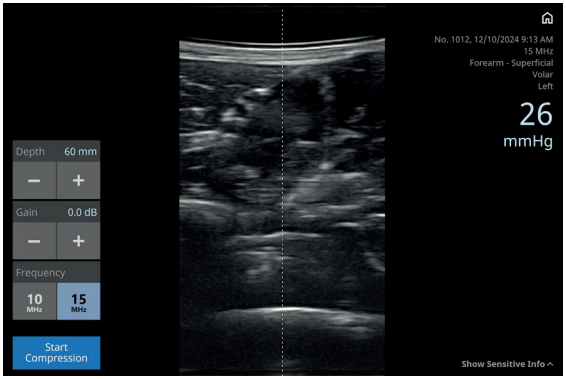
Frequency: Higher ultrasound frequencies improve the resolution of the image. However, the depth of penetration of the ultrasound beam decreases.

The “Frequency” and “Depth” functions are displayed on the screen.

Positioning of the CP Probe
In general, best results can be obtained when the compartment is compressed against a bone.

The user must hold the CP Probe perpendicular to the skin surface and keep the center line on a landmark during the entire measurement process.

With the help of the ultrasound image and the center line indicating the trajectory of the ultrasound beam, the user searches for a landmark in the area of interest that can be easily identified and on which the center line can be maintained during the measurement.

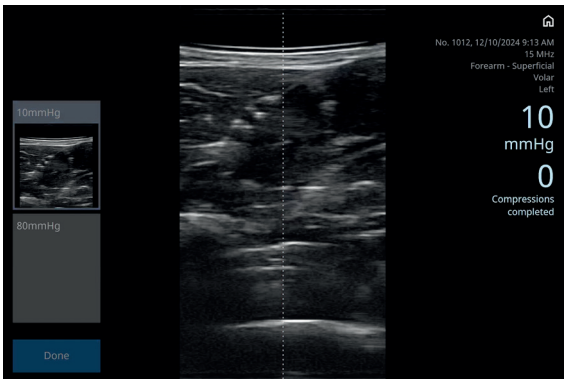


WARNING
During the entire measurement process, the CP Probe must be oriented perpendicular to the skin surface.

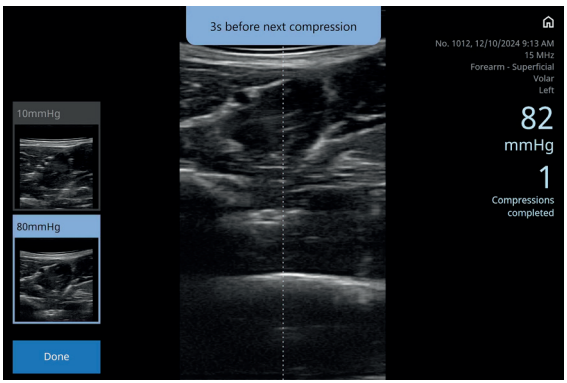
Start Compression
Tapping the “Start Compression” button on the left side of the screen initiates the measurement. The user aims the beam at the landmark via the center line and starts to compress the compartment, keeping the center line on the landmark.

If the user compresses too quickly, no picture will be taken, and the procedure must be repeated. The pressure applied by the CP Probe must start below 10mmHg and increase steadily to at least 80 mmHg.

The first picture is taken automatically at 10 mmHg and the second picture is taken automatically at 80 mmHg.

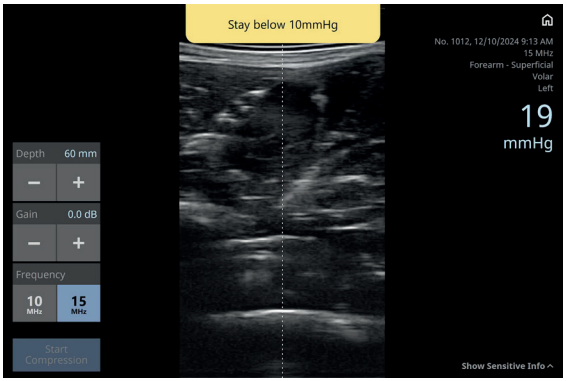


First picture:
10 mmHg

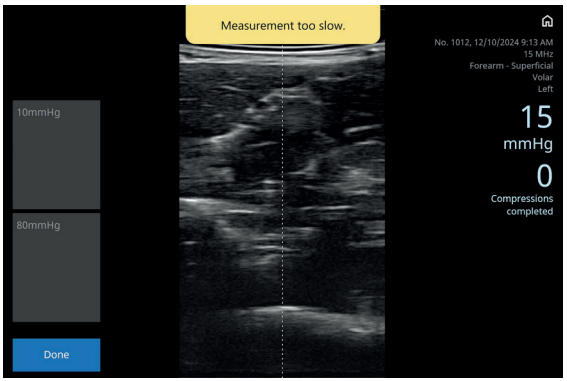


Second picture:
80 mmHg

The measurement can only be initiated when the contact pressure on the skin is below 10 mmHg, otherwise, a fault message “Stay below 10 mmHg” is displayed.



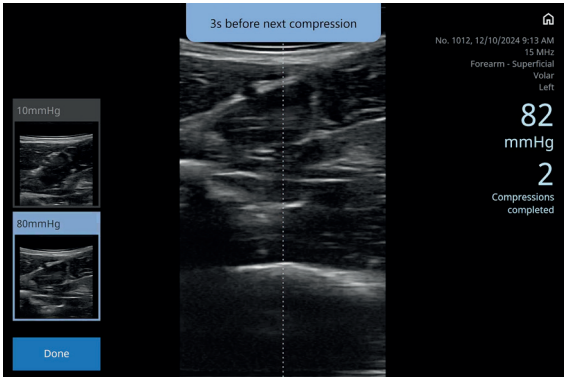
The measurement must be taken within 15 seconds, otherwise the fault message “Measurement too slow.” will appear and the measurement process has to be started from the beginning.



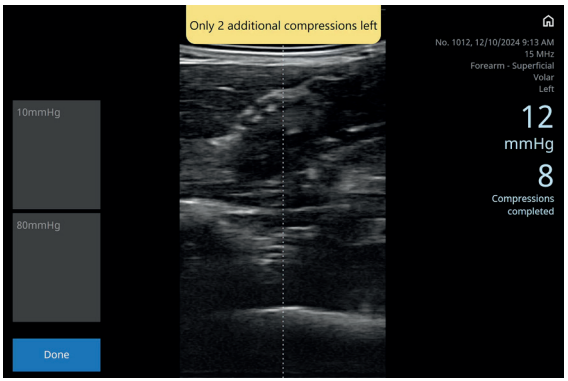
Consecutive measurements

Multiple measurements in one single session are supported. Several measurements can be performed until the user decides to stop or the maximal number of consecutive measurements is reached (10 measurements). During this time, the probe should not be removed from the target area. The number of completed

measurements is shown on the right-hand side of the screen. A 3-second countdown indicates when the next measurement can be taken. To exit the measurement function, the user can press the button “Done”.



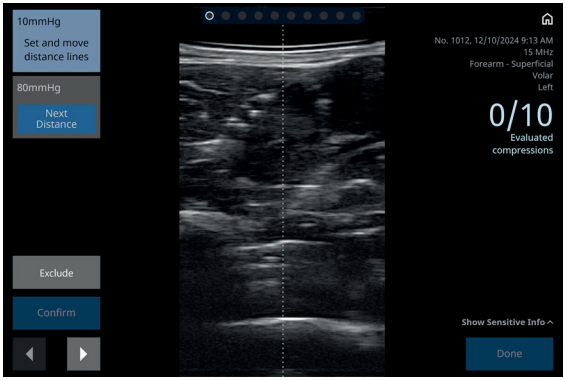
After 8 compressions the user is notified how many compressions can still be made.



Step 4 - Setting landmarks
The CP Probe can now be put down to allow for easier use of the Tablet.

The pictures taken at 10 mmHg and 80 mmHg for the different measurements can be selected using the small windows on the

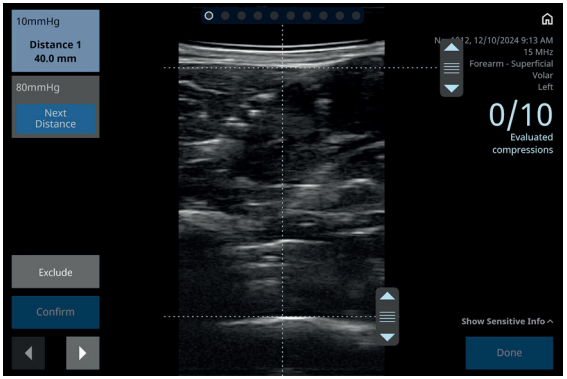
left. The user can navigate between all compressions using the bottom left arrows and confirm or exclude the measurements taken using the buttons displayed on the left bottom of the screen. The user can also show/hide sensitive information with the button on the bottom-right corner (only if available).



For the measurements of interest, the user locates an outer landmark, e.g. external fascia, and marks it with his finger by tapping on the screen. A transverse line is placed automatically for its identification on the screen.

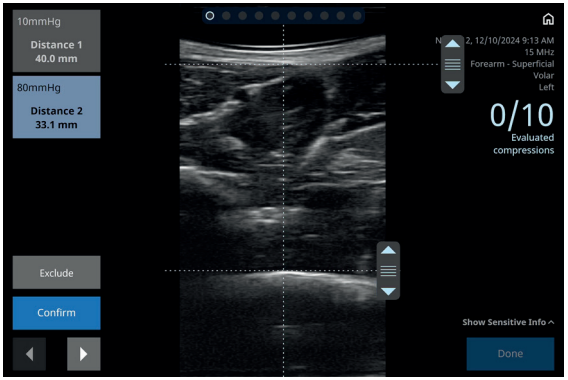
Next, the inner landmark, the bottom of the compartment, is located and marked. A second transverse line appears on the screen as well as two arrow buttons.

The transvers lines can be adjusted to fine-tune their location on the intended landmarks by tapping on the arrow buttons or sliding with the finger.



Once the landmarks are placed for 10 mmHg, the user can proceed to the 80-mmHg compression by tapping the grey 80 mmHg selection button. On the 80 mmHg picture, the measurement is performed in the same way as at 10 mmHg.

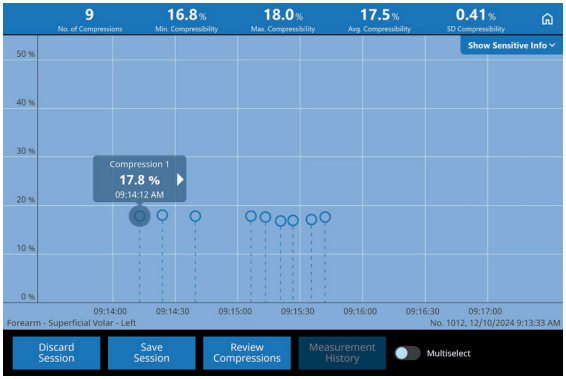
The user then confirms or excludes the distances measured. On the right side of the screen, all evaluated measurements compared to the total number of measurements recorded are displayed.



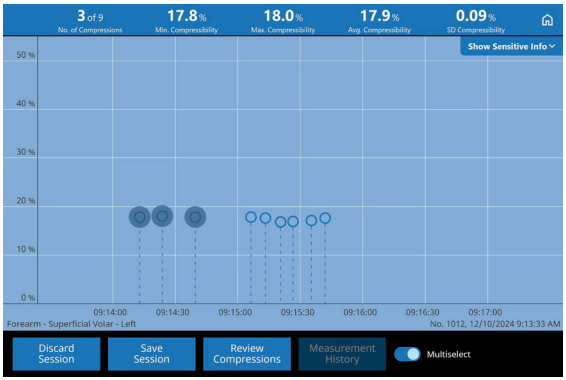
Display of the result

After completion of all the measurements, the compressibility percentages will be calculated and displayed after tapping the “Done” button. At the top of the screen, the following statistical

values of the current session are shown: minimum compressibility, maximum compressibility, average compressibility and standard deviation. The user can show/hide sensitive information by pressing the button on the top-right corner (only if available).

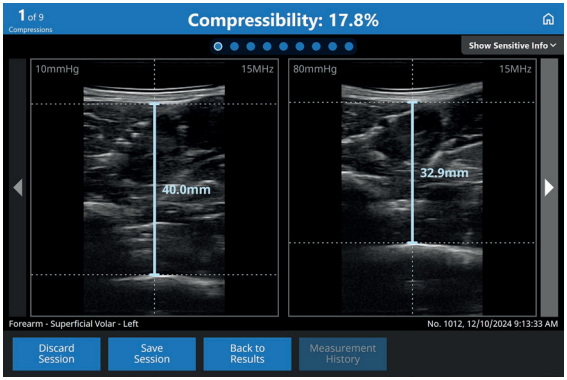


The user can also use the “Multiselect” option to select some compressions of interest and get statistics on them. After enabling “Multiselect” with the button on the bottom-right corner and selecting the desired compression, the statistics at the top of the screen are updated based on the current selection.



By tapping the “Review Compressions” button, the two pictures appear side by side on the screen for the different measurements. The compressibility value of each measurement is displayed at the top of the screen and the user can navigate between measurements by pressing on the left and right arrow on the screen.

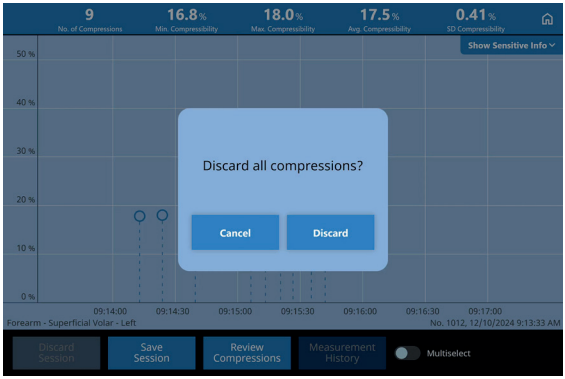
At the top-left of the screen, the number of measured compressions is indicated. The user can show/hide sensitive information by pressing on the button on the top-right corner (only if sensitive information is available).



The compressibility percentage (“CP Value”) indicates in % by how much the compartment had been compressed at 80 mmHg relative to 10 mmHg and is thus a measure of the relative compressibility.

$$CP\ Value = \left(\frac{D_{10} - D_{80}}{D_{10}}\right) \times 100\ [\%]$$

Tapping the “Discard Session” button will delete all saved compressions from the session. When selecting the “Discard Session” a dialogue to confirm that the user wants to discard all compressions appears on the screen.

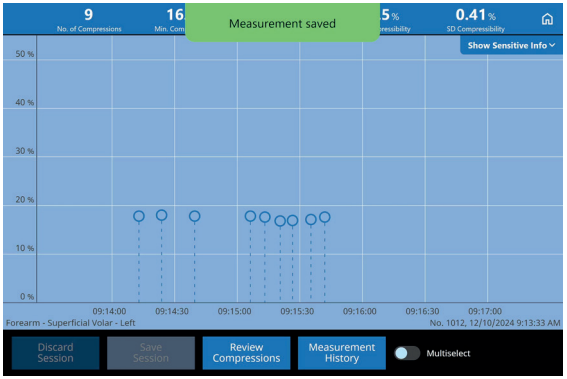


WARNING

The Compartmental Compressibility Monitoring System (CPMX1) is intended for real-time and intermittent monitoring of relative compartment compressibility. The results given by the device are not meant for trend analysis.

Save Measurement

By tapping the button “Save Session”, the results of the compressions from the session are recorded in the “Measurement History”. The saved information consists of: the ID number of the session (counted consecutively), date and time, count (number of measurements saved per session), average CP Value of the compressions in the session, average distance lines of the compressions in the session, any information entered in the session data screen, and the CP Probe serial number. The format of the date is: MM/DD/YYYY.

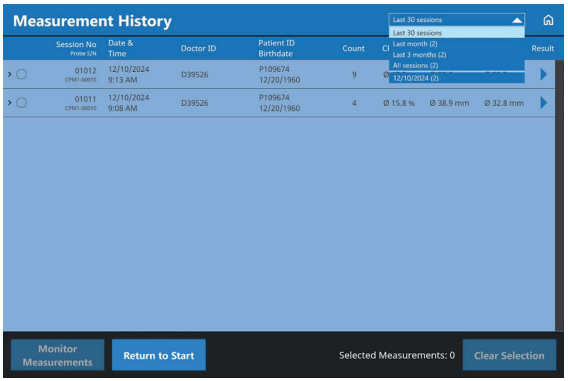


CAUTION

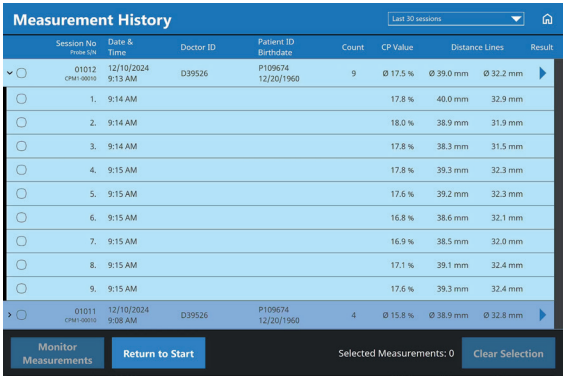
For unique assignment of the measurement, the following must be recorded in the patient file: time and date of measurement compressibility percentage, identification/location of measured compartment.

Measurement History

Tapping the “Measurement History” button will display a scrollable list of all sessions taken with the device. Through a variety of view modes, sessions can be quickly filtered to find the desired one. Tapping the blue triangle will display the details and results page of a session.

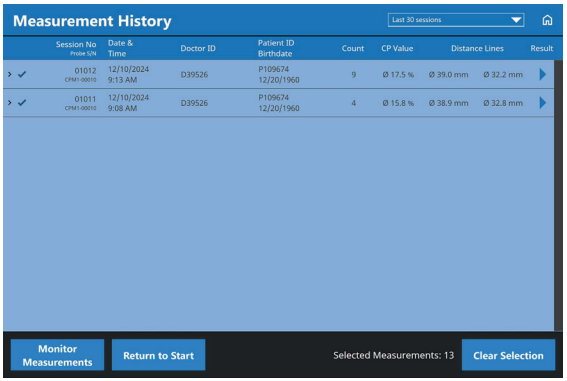


Tapping on a session will display the details of all the measurements in the selected session.

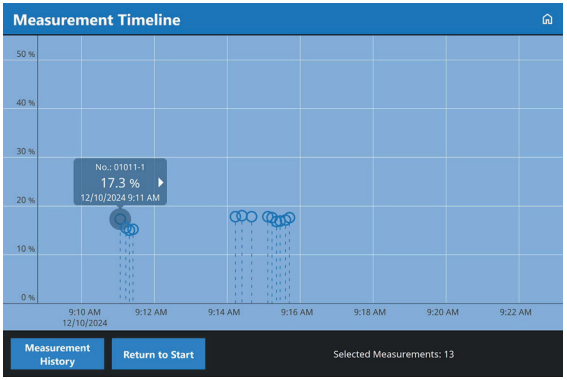


Measurement Diagram

Several measurements can be selected from the measurement history screen. The number of measurements selected is displayed at the bottom of the screen. The number of measurements corresponds to the total number of measurements taken at each of the selected sessions.



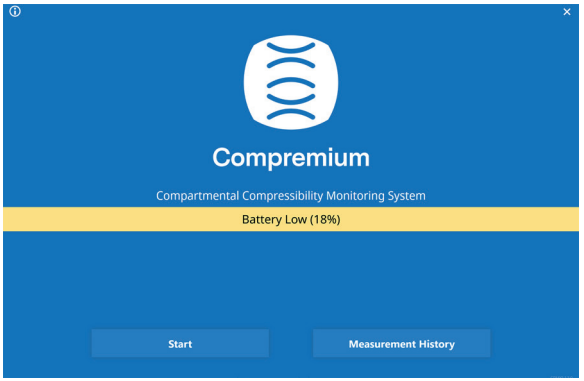
Tapping the “Monitor Measurements” button will display the measurement diagram of the measurements selected. When the diagram is displayed, tapping on a measurement point will display a popup with the details of the selected point.



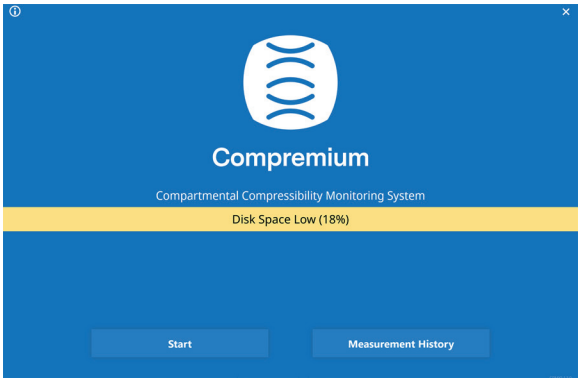
Start New Measurement

The return arrow in the upper right corner of the Measurement History screen takes the user back to the main menu from where a new measurement can be started.

Always make sure that the tablet is sufficiently charged before use. A warning appears on the start screen when the battery is too low for proper operation (< 20%).



A warning appears on the start screen when disk space is getting too low for proper operation (<20%). Please contact Compremium for proper data backup and disk space cleaning.



9 Maintenance

9.1 Storage and Transport

CAUTIONS

- Avoid storing the CPMX1 System where the probe or its cable could be easily damaged
- Avoid placing or storing with other equipment or objects that may inadvertently damage the probe, particularly the membrane.
- Avoid transporting the CP Probe unless it is well supported and secured. Secure the cable tightly to the CP Probe when transporting it or carrying it. Never swing the CP Probe or support the CP Probe solely from its cable.
- Keep the CPMX1 System in a dry and clean environment. Store at ambient temperature -10°C to 50°C (14°F to 122°F).
- When the CPMX1 System is not being used, it should be stored in a clean, dry area.
- Avoid contamination by:
  - Following the cleaning and disinfecting instructions.
  - Making sure the equipment is dry.
  - Carefully handling the probe to prevent damaging the equipment.

WARNINGS

- In the event of the packaging being damaged or exposed to environmental conditions outside of those specified, return the CPMX1 System to Compremium AG.
- A bubble of gas may appear on the CP Probe membrane if heated up. This phenomenon does NOT impact the quality and precision of the CPMX1 System.
- Repeated exposure to UV light sources may over time lead to changes in the color of the membrane. This color change does NOT impact the quality and precision of the CPMX1 System.

9.2 CP Probe Cleaning and Disinfection

WARNINGS

- Failure to disinfect the CP Probe may result in an increased spread of pathogens.
- Always disconnect the CP Probe from the tablet before performing cleaning or disinfecting activities.

Materials

Liquid saturated wipes: Super Sani-Cloth® Germicidal Disposable Wipes by PDI

Spray containing Isopropanol solution (70% IPA); e.g., STERIS Septihol® Sterile Alcohol Solution

WARNING

Follow the recommendations of the liquid saturated wipes and cleaning solution manufacturer. Using non-recommended liquid saturated wipes and cleaning solution can damage the CP Probe and voids the CP Probe warranty.

Preparation before cleaning and disinfection

Use the recommended liquid saturated wipes to clean and disinfect the CP Probe.

CAUTIONS

- When cleaning and disinfecting the CP Probe, do not allow any fluid to enter electrical connections or metal portions of the USB connector.
- Prevent any fluid from splashing on your mobile device's touchscreen during scanning and during cleaning. Damage due to fluid may result.

Cleaning the CP Probe

1. Use a fresh liquid saturated wipe, wipe the CP Probe, strain relief, USB cable and connector for at least three (3) minutes and until entirely cleaned from ultrasound transmission gel and visually clean.
2. Make sure to thoroughly clean the silicone membrane, the metal ring, and the crevice areas (the dashed lines shown in the figure below). Especially, ensure that there are no residuals left in these crevice areas. If residuals are left, repeat the cleaning step as described in point 1 above.

3. Repeat the above steps until the CP Probe is visibly clean. Repetitions have to be performed with new wipes as per point 1 above.
4. Inspection: visually check that there are no residuals left under appropriate lighting. If the probe is not clean, repeat the cleaning steps above as many times as needed.

5. Spray the silicone membrane, the metal ring, and the crevice areas evenly and from all sides until thoroughly wetted with isopropanol solution. Do so, by slowly rotating the CP Probe while spraying.
6. Use a fresh liquid saturated wipe, wipe the CP Probe, strain relief, USB cable and connector. Make sure the treated surface of the CP Probe remains visibly wet for three (3) minutes, paying attention to the crevice areas (see figure above).
7. Repeat the previous step at least two (2) times and as many additional times as needed. Allow the surface to air dry completely.

Disinfection the CP Probe

1. Use a fresh liquid saturated wipe, wipe the CP Probe, strain relief, USB cable and connector for at least three (3) minutes.
2. Make sure to thoroughly clean the silicone membrane, the metal ring, and the crevice areas (the dashed lines showed in the figure above).
3. Spray the silicone membrane, the metal ring, and the crevice areas evenly and from all sides until thoroughly wetted with isopropanol solution. Do so, by slowly rotating the CP Probe while spraying.
4. Use a fresh liquid saturated wipe, wipe the CP Probe, strain relief, USB cable and connector. Make sure the treated surface of the CP Probe remains visibly wet for three (3) minutes, paying attention to the crevice areas (see figure above).
5. Repeat the previous step at least two (2) times and as many additional times as needed. Allow the surface to air dry completely.




WARNING

Always inspect the probe before and after cleaning, disinfection, or use. Check the membrane, cable, housing, seams, and connector for signs of any damage such as cracks, chips, abrasions, or leaks. To avoid the risk of electrical hazards, do not use the probe if there is any sign of damage.

Additional Information
Dispose of cleaning material in accordance with all applicable regulations.

These instructions have been validated by Compremium as being capable of preparing the CP Probe for reuse. It remains the responsibility of the health care professional to ensure that the processing, as actually performed using equipment, materials, and personnel in the health care facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

9.3 Software Maintenance

Updates to the CP Software are handled by Compremium AG.

10 System Specifications

10.1 Technical Specifications

Tablet Specifications

Open System Architecture	Specifications
Operating system	Windows 10 Pro
Software	CP Software
Min Processor	12th Gen Intel Core i5 1235U
Min RAM	8GB
Min HDD	128GB
GPU	Intel® Iris® Xe-Graphics
Display size and resolution	13” 2880x1920 (267 PPI) resolution
Digital port	2 x USB-C
Battery hours	Up to 15.5 hours of typical device usage
Wireless connectivity (disabled by default)	WIFI: Wi-Fi 6E 802.11ax compatible; Bluetooth Version 5.1
Dimensions	287 x 209 x 9.3 mm
Weight	878 grams

CP Probe Specifications

Description	Specifications
CP Probe protection class	IPX2
CP Probe length	139 mm
CP Probe largest width	50 mm
Ultrasound parallel scan sector array	38 mm
Ultrasound nominal operating frequency	15 MHz
Ultrasound lower range operating frequency	10 MHz
Ultrasound operating mode	B-Mode
Ultrasound image resolution	0.1 to 2.0 mm
Ultrasound grey shades	True 256 (8 bits)
Ultrasound depth selections	20 mm, 40 mm, 60 mm
Pressure sensor range	0 to 0.35 bar (o to 262 mmHg)
Pressure sensor resolution	0.1 mbar (0.075 mmHg)
Pressure sensor measurement rate	20 Hz

Description	Specifications
Connectivity	USB 2.0
Cable type and length	USB Type C – Mini-B, 2 m
Power Supply Requirements	DC 5.0 VDC, ±5% at 500 mA (max), 2.5 watts (max) obtained from the USB 2.0 port
Environmental operating conditions	Maximum operating temperature: 39°C (102°F) Minimum operating temperature: 5°C (41°F) Operating humidity range: 20-80% non-condensing Atmospheric pressure range: 70.0 kPa to 106.0 kPa
Storage and transportation conditions	Temperature range: -10°C to 50°C (14°F to 122°F) Humidity range: 20-80% non-condensing Atmospheric pressure range: 70.0 kPa to 106.0 kPa

10.2 Acoustic Output

Achieving ALARA

The acoustic power of diagnostic ultrasound and its possible effects on human tissue has been studied for many years. The acoustic power of ultrasound imaging transducers must be below specific limits that are established by international standards bodies as well as required by governmental regulatory controls. While modern ultrasound imaging transducers are well below the allowable limits, it is standard practice to abide by the principle to set the power and limit the use to “As Low As Reasonably Achievable” (ALARA). The concept is quite simple: keep the acoustic exposure at the lowest possible levels and use the shortest amount of time that is necessary to obtain the desired diagnostic image. As the acoustic power can only be set lower than the allowed limit, the combination of lowering the transmit power and reducing the exposure time will minimize any possible biological effects.

ALARA Guidelines

ALARA puts responsibility to lower the power from the maximum level on the operator. As was mentioned above, acoustic power can only be lowered from its maximum and the maximum is well below the allowable limit. How does the operator determine what power level to set? ALARA directs the operator to use the lowest possible acoustic power that still allows a diagnostic quality image to be obtained. Using a higher transmit frequency results in lower biological effects. Therefore, using the highest possible frequency that still allows the operator to see to the required depth would be applying ALARA correctly. The quality of the image is also determined by the receiver controls such as gain, intensity, and contrast. As receiver controls do not affect acoustic transmit power, it is always good practice to adjust the receiver controls before considering an increase in acoustic transmit power. ALARA also directs the operator to use the transducer for the minimum amount of time that is necessary to obtain the desired diagnostic-quality image.

Indices

Mechanical and Thermal indices are acoustic safety limits used to properly practice the ALARA principles of keeping the acoustic exposure to a minimum.

Thermal Index (TI) is the estimate of the temperature increase of soft tissue or bone. There are three types of Thermal Indices: the TIB is related to potential heating near the focus after ultrasound has transitioned through fluid or soft tissue, the TIC gives information of potential heating of bone at or near the surface and the TIS indicates any heating effect in soft homogeneous tissue.

Mechanical Index (MI) is the estimated likelihood of tissue damage due to cavitation.

Acoustic Output Tables

The CPMX1 System only operates in B-Mode at 10 or 15 MHz, for these frequencies THERMAL INDICES and the MECHANICAL INDEX are below 1.0 for all device settings. Values reported in tables below correspond to the output at 7.5 MHz, which represents the worst-case condition.

Acoustic output table: B-Mode

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At surface	Below Surface	
Maximum Value			1.00	7.04E-02		7.04E-02		0.45
Index Component Value				7.04E-02	7.04E-02	7.04E-02	7.04E-02	
Acoustic Parameters	$P_{r,\alpha}$ at Z_{MI}	(MPa)	2.39					
	P	(mW)		10.03		10.03		10.03
	P_{1x1}	(mW)		2.61		2.61		
	Z_s	(cm)			N/A			
	Z_b	(cm)					N/A	
	Z_{MI}	(cm)	0.90					
	$Z_{pii,\alpha}$	(cm)	0.93					
	f_{awf}	(MHz)	5.70	5.70		5.70		5.70
Other Information	prr	(Hz)	6350.0					
	srr	(Hz)	25.0					
	n_{pps}		2					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	2.4E+02					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	14.18					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or z_{sii}	(mW/cm^2)	19.31					
	P_r at z_{pii}	(MPa)	2.61					
Operating control conditions	7.5 MHz, 25 mm focus, B-mode; compressed							

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

NOTE 3 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

NOTE 5 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 6 Unshaded cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

Measurement uncertainties
Measurement uncertainties were assessed and reduced as much as possible. Type B uncertainties include systematic errors of measurement devices (e.g. calibration uncertainty and design limitations), systematic sources of essentially random error (e.g. temperature) as well as uncertainties estimated from measurement of the device in question (spatial averaging and non-linear distortion. Type A uncertainties are derived from statistical analysis. Type A and Type B uncertainties were both considered and combined into an overall assessment of measurement uncertainty.

10.3 Electromagnetic Compatibility (EMC) Information

The CPMX1 System has been designed and tested to comply with IEC 60601-1-2 requirements for EMC with other devices.

Like other medical equipment, the CPMX1 System requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure electromagnetic compatibility (EMC), the CPMX1 System must be installed and operated according to the EMC information provided in this manual.

CAUTION

- In case the CPMX1 System stops working due to electrostatic discharge (ESD), reestablish the USB-C cable connection and/or restart the CP Software.
- In case radiated and/or conducted electromagnetic disturbances which affect the performance of the CPMX1 System (i.e., slight disturbances of ultrasonic image on the tablet during image acquisition) are observed, the operator should take measures to mitigate, including relocation or reorientation of the CPMX1 System.

Guidance and manufacturer's declaration – electromagnetic emissions	
The CPMX1 System is suitable for use in professional healthcare facility environment as per definition of IEC 60601-1-2.	
Emission Test	**Compliance**
CISPR 11:2015/AMD2:2019 EN 55011:2016+A1:2017+A11:2020+A2:2021 CISPR 11:2009+A1:2010 EN 55011:2009+A1:2010 CISPR 32:2015/AMD1:2019 EN 55032:2015+A1:2020+A11:2020	Group 1, Class B

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2:2008	±2 kV, ±4 kV, ±6 kV, ±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	±2 kV, ±4 kV, ±6 kV, ±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8:2009	440 A/m @ 16.7 Hz; 50 and 60 Hz; x-/y-/z-axis for 60 seconds	440 A/m @ 16.7 Hz; 50 and 60Hz; x-/y-/z-axis for 60 seconds	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Radiated radio frequency IEC 61000-4-3:2020	10 V/m 80 MHz to 6 GHz	10 V/m 80 MHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the CPMX1 System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Please refer to separation distances listed in the table below.
Conducted disturbances induced by RF fields IEC 61000-4-6:2013	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz to 80 MHz 6 V in amateur radio bands between 0.15 MHz to 80 MHz 80% AM at 1kHz and 2 Hz	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz to 80 MHz 6 V in amateur radio bands between 0.15 MHz to 80 MHz 80% AM at 1kHz and 2 Hz	

Guidance and manufacturer's declaration – electromagnetic immunity		
Immunity Test	**IEC 60601 test level**	**Compliance level**
Immunity to proximity fields from RF wireless communications equipment IEC 60601-1-2:2014+AM D1:2020	380 MHz -390 MHz: 27 V/m 430 MHz -470 MHz: 28 V/m 704 MHz -787 MHz: 9 V/m 800 MHz -960 MHz: 28 V/m 1.7 GHz -1.99 GHz: 28 V/m 2.4 GHz -2.57 GHz: 28 V/m 5.1 GHz -5.8 GHz: 9 V/m	380 MHz -390 MHz: 27 V/m 430 MHz - 470 MHz: 28 V/m 704 MHz -787 MHz: 9 V/m 800 MHz -960 MHz: 28 V/m 1.7 GHz -1.99 GHz: 28 V/m 2.4 GHz -2.57 GHz: 28 V/m 5.1 GHz -5.8 GHz: 9 V/m
Immunity to proximity magnetic fields IEC 61000-4-39:2017	30 kHz: 8 A/m 134.2 kHz: 65 A/m 13.56 MHz: 7.5 A/m	30 kHz: 8 A/m 134.2 kHz: 65 A/m 13.56 MHz: 7.5 A/m

Separation distances:
Devices such as cellular/mobile phones, radio transmitters, and transceivers transmit radio waves (RF) which can create disturbances. The CPMX1 System is intended for use in a professional healthcare facility environment in which radiated RF disturbances are controlled.

Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the CPMX1 System is specified below. The operator can help to prevent electromagnetic disruptions of the CPMX1 System by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CPMX1 System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter (P, in watts)	Separation distance according to frequency of transmitter (d in meters)		
	0.15 MHz to 80 MHz $d = 1.2*\sqrt{P}$	80 MHz to 1 GHz $d = 0.7*\sqrt{P}$	1 GHz to 6 GHz $d = 0.7*\sqrt{P}$
0.01	0.12	0.07	0.07
0.1	0.38	0.23	0.23
1	1.2	0.7	0.7
10	3.8	2.22	2.22
100	12	7	7

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´s manufacturer.
Note 1: At 80 MHz and 1 GHz, 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 reflections from structures, objects, and people.

10.4 Maximum CP Probe Temperature

The CP Probe will not exhibit excessive surface temperatures under normal use. Disconnect the equipment if unsafe temperatures are observed. The CP Probe has been tested to conform with IEC 60601-2-37.

Location	Max allowable temperature (°C)	Max measured temperature (°C)	Remarks
CP Probe - membrane	50	29.1	Based on IEC 60601-2-37 a "Still air" test was performed for 30 min – output active. Max. allowed temperature for the applied part is 50 °C at an ambient temperature of 23 °C. "Still air" means without air movement
CP Probe – plastic enclosure	51	24.6 (41.7)	Calculated based on 40 °C ambient temperature.
CP Probe – metal ring	60	30.7 (47.2)	
USB cable insulation	60	26.3 (42.8)	
USB connector	60	27.2 (43.7)	

10.5 Disposal

Dispose the CPMX1 System at the end of its useful life and in accordance with local, state, provincial, and/or national regulations.

11 Warranty

The CPMX1 System comes with a 24-month return-to-factory warranty.

12 Contact Details

Legal Manufacturer:

Compremium AG
Worbstrasse 46
3074 Muri b. Bern
Switzerland

+41 58 580 08 78

info@compremium.ch

www.compremium.ch

NOTE: In case of issues, please contact Compremium AG. To report a complaint or incident, please contact Compremium AG and the FDA Problem Reporting Program, MedWatch at 1-800-332-1088 or on the Internet www.fda.gov/Safety/MedWatch/.

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