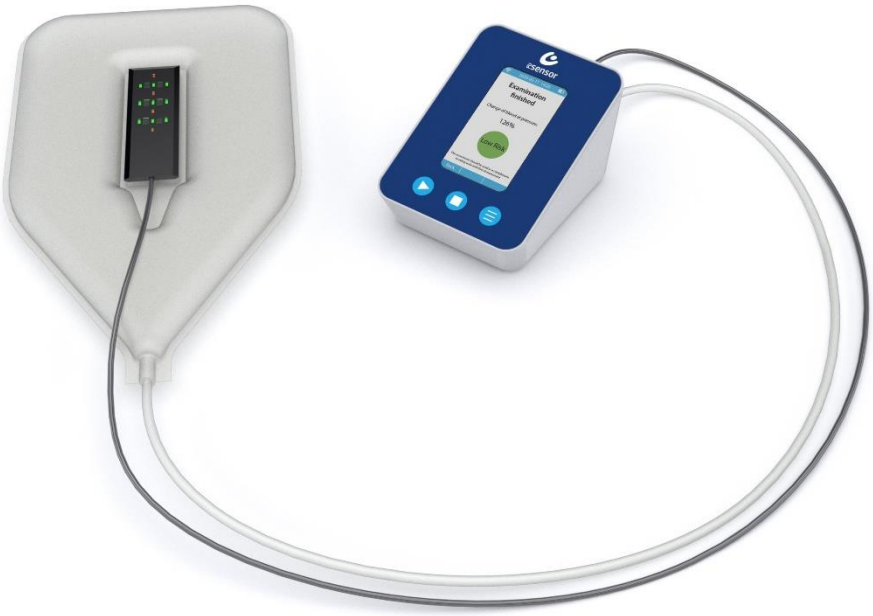
User Manual



Version 2.8
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This manual applies to:
Hardware version 1.3
Software version 1.4
Installation guide rev 3
Quick start guide rev 3

Document revision history

Revision	Date	Informative description of changes
1.0	2020-06-10	First approved revision.
2.0	2020-12-12	Remade layout and wording, added all error messages.
2.1	2020-12-17	Revision history added, correction of heading number for *Symbols and abbreviation*, added text on restart under *Error messages*.
2.2	2021-01-15	Changed wording, corrected figure references and improved table design.
2.3	2021-01-26	Added information on 0.2 m distance from main unit in user environment.
2.4	2021-02-23	Specified that applies to new SW version.
2.5	2021-03-10	Updated with new symbol to match new labels in hardware 1.1 (Ch 9). Included information that charging should only be done with the charger belonging to the PU sensor kit (Ch 2.1). Included information about selecting language. (Ch 2.5)
2.6	2021-03-18	Included information about LED indicating charging and about the start-up process (Ch 2.1).
2.7	2021-03-31	Updated which Hardware and Software version the manual applies to. Added which guides the manual applies to.
2.8	2021-04-21	Updated Ch 2.3 to match Quick start guide. Updated Ch 2.4 with a clearer description of the analysis of the results. Removed the examples of different scales (Ch 1.1). Updated text for E04/E05 (Ch 6). Updated applicable versions.

Contents

1 About PU sensor

1.1 Intended use

PU sensor is a device intended for identifying individuals who are at risk of developing pressure ulcers. It is meant to be an objective and more precise complement to the clinical evaluation and scales currently used to examine the risk of pressure ulcers. The device is intended to be used on people who would normally undergo a risk assessment for pressure ulcers, except in cases where there is damage to the tissue in the area where the device is used, or when the person has an allergy to any of the materials in the sensor plate, inflatable, or tape.

The device is intended to be used by healthcare staff. The user must have read the user manual and understood its contents before using the device.

1.2 The parts of the device and accessories

The device consists of a main unit, a sensor plate, and an inflatable pillow. The sensor plate and inflatable are type B applied parts. A necessary accessory to the device is a Qi charger, with a USB cable, a net adaptor, and a holder. A double-sided adhesive tape is supplied together with the device, which is needed to properly attach the sensor plate to the skin. For further information see table "Parts of the device" in chapter 5.2.

1.3 The examination process in short

The user ensures that the sensor plate and inflatable have been properly cleaned. The sensor plate is attached to the person undergoing risk assessment at the sacrum, using the double-sided adhesive tape. The inflatable is placed around the active part of the sensor plate. The person is placed in a supine position in his or her normal bed and the examination is started by pressing the Start button. The process is then automatic. The inflatable is inflated and releases the air after a period of time, meanwhile the reflected light is detected and analysed for a comparison of blood flow in the skin both with and without the pressure of the person's own body weight.

1.4 Internet connection

The device is to be connected to the Internet for access to the latest software, timely delivery of consumables and support.

2 Instructions for use

2.1 Charging

To charge the device, place the main unit on top of the charging plate, centred as shown in Figure 2. Charging should only be done with the supplied charger. The charger holder helps placing the device correctly on the charger. An LED on the charging plate changes from red to blue to indicate charging. Given enough battery capacity in the device a short beep indicates that the device receives charge, as this happens the display appears as in Figure 1. The device will charge wirelessly as long as the main unit is on the charging plate. It is recommended to place the main unit on the charging plate between examinations. Charging may not take place while an examination is in progress.

The device wakes up from sleep mode when it is taken away from the charger. The device can also be started by pressing any button. A short beep indicates that the device is in the process of starting up. The start-up process takes up to a minute and the screen will be black during parts of the process.

Figure 1. Charging indication.

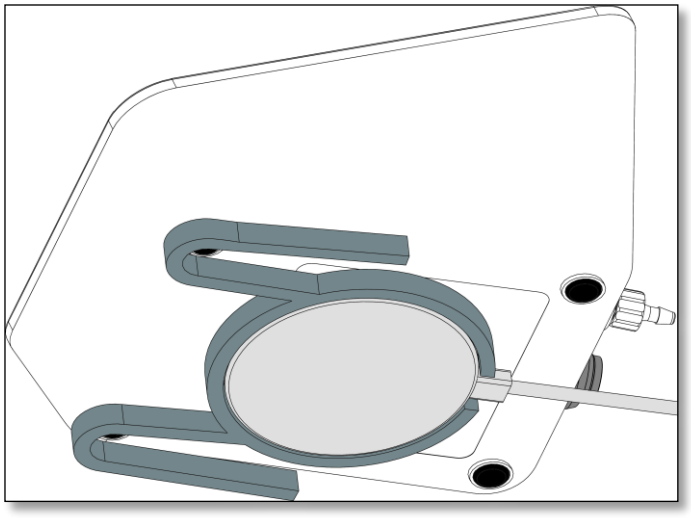

Figure 2. Position of charging plate.

2.2 Connecting the sensor plate and inflatable

Connect the sensor plate and inflatable to the main unit. The tube of the inflatable should be screwed securely in the left socket A. The cable of the sensor plate is connected to the right socket B and is connected correctly when a click is heard, see Figure 3.

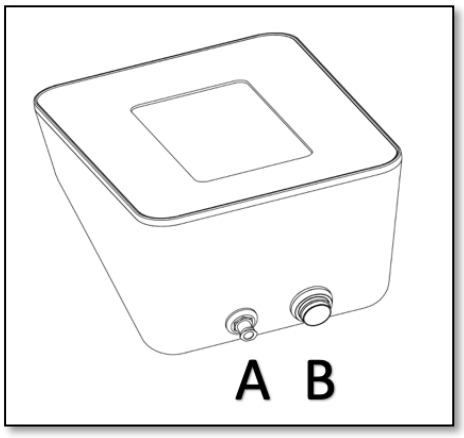

Figure 3. Rear of main unit. Connect the inflatable to A and the sensor plate to B.

2.3 Performing an examination

1. Start the device by pressing any button or removing it from the charger. The start-up can take up to a minute, it starts with a short beep and the display can be black during parts of the process. Make sure the sensor plate and inflatable are connected.

2. Attach the tape to the sensor plate, press to remove any bubbles, then remove the protective plastic, see Figure 4.

Figure 4. Handling of the adhesive tape.

3. Place the sensor plate in the lower back, over sacrum at the bony projections, with the cord facing up from the mattress, see Figure 5a.

4. Place the inflatable over the sensor plate, see Figure 5b. The hole of the inflatable should match the sensor plate and the tube should go along the cord of the sensor plate. Turn the individual to his or her back. Make sure the inflatable does not fold and stays in the right place.

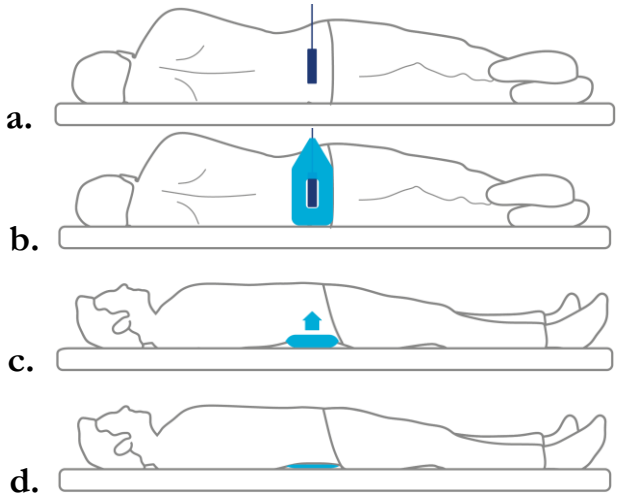

Figure 5. a) Placement of sensor plate. b) Placement of inflatable. c) Inflated inflatable. d) Deflated inflatable.

5. Press any button to wake PU sensor from sleep mode. Press Start to start the examination, which will take around 5 minutes. The examination can be cancelled by pressing Stop.

6. After the device has been started the process will run continuously until the result is shown. The inflatable is inflated in small steps during the first half of the examination to unload the skin under the sensor plate, se Figure 5c. After half of the examination the inflatable is deflated and the device evaluates the blood flow in the loaded skin, see Figure 5d. If any error occurs during the examination, the device will automatically end the examination. The reason for ending the examination will then be shown on the display.

7. The result is interpreted as described in Chapter 2.4, *Analysis of results*.

8. Once the examination is complete, turn the individual to their side and remove the inflatable and sensor plate. Dispose of the tape as general waste. Clean the device in accordance with Chapter 3 and place the main unit on the charger.

2.4 Analysis of results

When the examination is complete, the results will be displayed on the main unit as shown in Figure 6. The result is comprised of a percentage and a coloured circle indication the risk level.

The device analyses how the blood flow in the skin is changed with and without the pressure from the individual´s own body. A healthy reaction to a light pressure is an increase of the blood flow. This reaction is called pressure induced vasodilation, or PIV. Some individuals lack PIV, and their blood flow decreases when the skin is subjected to pressure. A decreased blood flow at pressure is connected to a higher risk of developing pressure ulcers.

An increase of the blood flow at pressure results in a percentage above 110% and the risk level "Low risk" which is indicated by a green circle, see Figure 6a. A decrease of the blood flow at pressure results in a percentage below 100% and the risk level "High risk" which is indicated with a red circle, see Figure 6c. When the blood flow neither decreases nor shows a distinct increase (percentage between 100 and 110%) the risk level is "Medium risk" which is indicated by a yellow circle, see Figure 6b. Some variation of the result for the same individual may occur due to time, mattress, and placement.

The device is intended to be used as a complement to the scales and assessments in current use, which evaluate other important factors for pressure ulcer risk. The results should **never** be used to claim that an individual that has been deemed as having a risk of pressure ulcers with current assessment is without risk, it should only add individuals to the risk group. Hence, individuals with the result high or medium risk level should be considered part of the risk group and receive preventive actions if they have reduced motility. Individuals with a low risk level should be treated according to the conventional risk assessment.

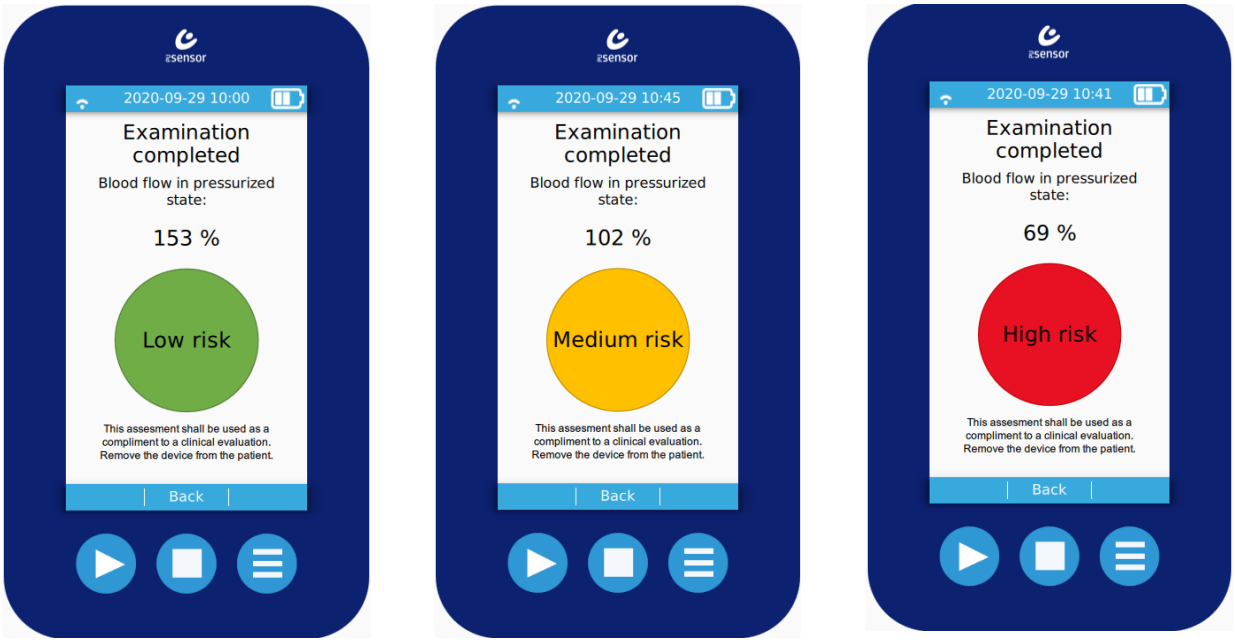

Figure 6. a) Green: low risk of pressure ulcers. b) Yellow: medium risk. c) Red: high risk.

2.5 General information about the user interface

When the main unit is awakened from sleep mode, the opening page is displayed as shown in Figure 7a. To begin an examination, press the Start button (1) or press 'Start' on the touchscreen.

When an examination is in progress, the screen appears as in Figure 7b. To cancel an examination, press the Stop button (2).

At the top of the screen is a list showing the Wi-Fi status, date, time, and battery level.

To access the Information page, shown in Figure 7c, press the Information button (3) or press 'Info' on the touchscreen. The Information page contains information about the serial number and software version of the main unit and sensor plate. Information is also shown about how many examinations the sensor plate can perform before it should be replaced, the Wi-Fi status, network name, signal strength and contact details to PU sensor AB.

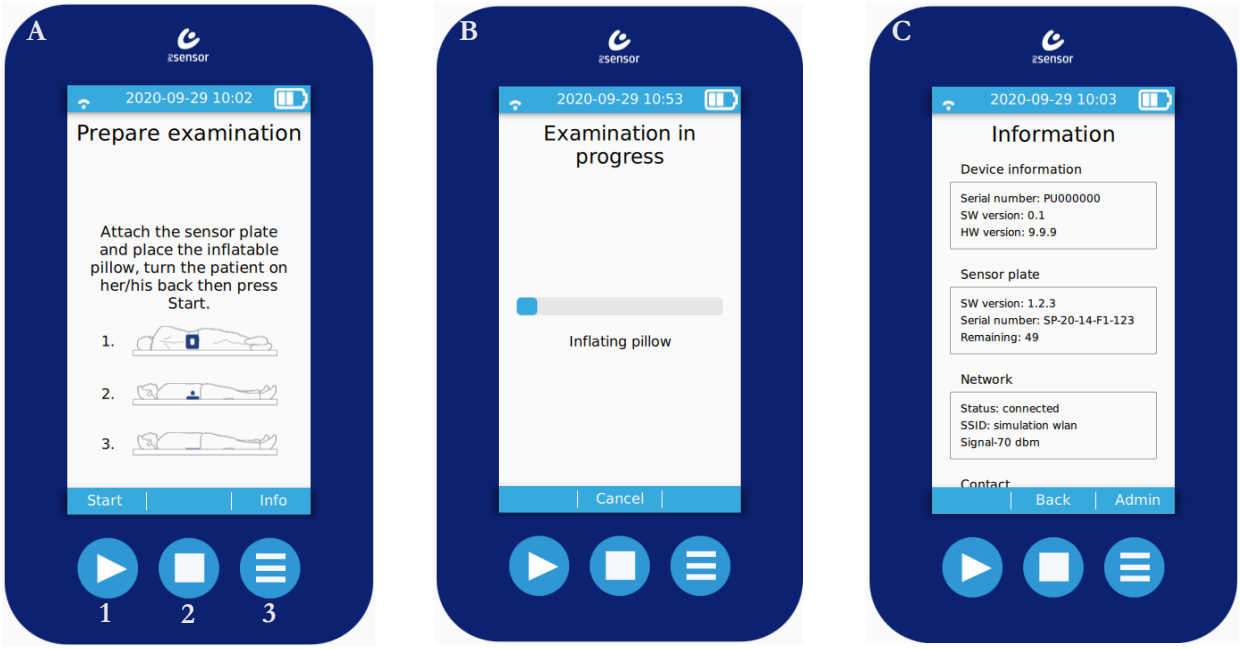

Figure 7. a) Prepare examination: opening page of main unit. 1) Start button, 2) Stop button, 3) Information button b) Examination in progress: describes the various stages of the examination. c) Information page.

To access the Administrator page, press the Information button on the Information page, or "Admin" on the touchscreen. A password is required, which consists of the last four digits of the serial number. The serial number can be found on the bottom of the main unit and is in the format MU-20-01-1234, where 1234 is the password. On the Administrator page, there are options to set the date and time, select language, connect the device to a WLAN and save settings.

The device should be connected to a Wi-Fi network, 2.4 GHz WLAN. On the Administrator page, the network can be selected from a list and the password can be entered via the touchscreen.

3 Cleaning and waste disposal

Ensure that no tape remains on the sensor plate. Clean the inflatable and sensor plate using a disinfectant, for example 45% isopropanol. Allow to work for 30 seconds and air-dry. Wipe the main unit with a cloth. Examine the inflatable and sensor plate for cracks and wear during cleaning. If any part of the equipment is damaged, that part should be replaced.

The tape is for single use only and must not be reused. The sensor plate is disposed of as electronic waste, while the double-sided adhesive tape and inflatable are disposed of as general waste.

4 Contraindications

Contraindications	Description
Correct supine position	The device should not be used with people who, in some way, are prevented from lying still in a supine position as this may affect the results of the device. People undergoing examination should be informed that they will be raised somewhat and that they must lie as still as possible.
Fever	The device should not be used with people who have a fever as this may affect the results of the device. The device will stop an examination if the temperature exceeds 41°C.
Existing pressure ulcer or skin damage	The device should not be used on people with pressure ulcers or skin damage in the area where the inflatable or sensor plate is to be placed.
Maximum weight	The device should not be used on people weighing more than 200 kg.
Allergy and sensitivity	The PU sensor should not be used on anyone who is allergic or sensitive to any of the materials present in the sensor plate, inflatable or adhesive tape. The materials are shown in the table below.

Part of device	Item number	Material
Inflatable	IF001	TPU plastic in inflatable, bio based plastic material in tube.
Sensor plate	SP001	Silicone based enclosure of the sensor plate, mPPE plastic in the coating of the wire.
Double-coated adhesive tape	TD001	Silicone based adhesive towards the skin, TPE plastic carrier, acrylic based adhesive towards sensor plate.

All materials that are in contact with the skin are biocompatible.

5 Service

To guarantee operation, the device should be serviced annually by certified personnel. Without annual servicing, there is a high risk that the results from the device will not be reliable and that the device will not work as intended. Contact PU Sensor AB for more technical information.

5.1 Replacement of inflatable and sensor plate

The inflatable and sensor plate can be replaced by non-certified personnel. The used inflatable and sensor plate should be disposed of in accordance with Chapter 3, *Cleaning and waste disposal*. A new inflatable and sensor plate can easily be connected to the main unit without the need to make any other adjustments.

5.2 Parts of the device

Part of device	Item number	Description
PU sensor kit	PU001	Contains a main unit, sensor plate, inflatable, double-sided adhesive tape, Quick Start guide, installation guide and charging plate with mains adapter and holder.
Main unit	MU001	The main unit, which controls the rest of the device.
Sensor plate	SP001	The sensor plate is designed to perform 200 examinations. The sensor plate should then be replaced. The sensor plate is a type B applied part.
Inflatable	IF001	The inflatable is designed to perform 200 examinations. The inflatable should then be replaced. The inflatable is a type B applied part.
Double-sided adhesive tape	TD001	For single use only.
Charging plate	QI001	Charging plate, mains adapter and charging plate holder.

6 Error messages

If an error occurs, the error message will be shown on the display of the main unit as shown in Figure 8.

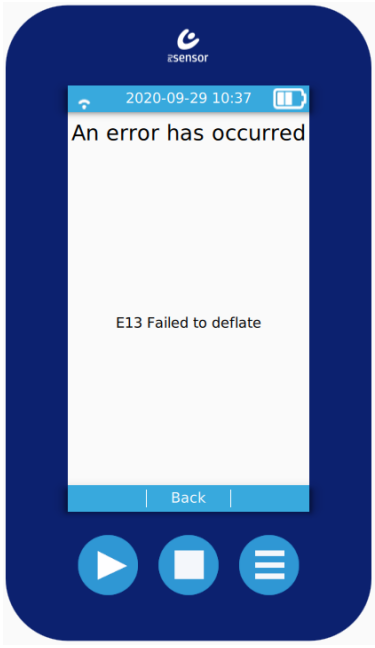

Figure 8. Error message E13

The table below states the possible error messages, with an explanation and measures to be taken. If the error persists after measures have been taken, contact the supplier of the device.

If the device seems to be locked it can be restarted by pressing down the Start button and Info button simultaneously for three seconds, until a beep is heard. Wait 10 seconds, then press any button to restart the device.

Code	Message	Explanation and measures to be taken
E02	Examination terminated due to poor signal quality	The position of the sensor plate may need to be adjusted somewhat. Replace the tape and reposition the sensor plate. If the error message persists, this may be due to the individual's physiological characteristics.
E04, E05	Inflation failed	Check the inflatable and its tube. There should be no blocking of the airflow, such as folds or knots. Ensure that the tube of the inflatable is connected correctly to the main unit and that the inflatable has no visible damage. If there is any damage to the inflatable, replace it. If the error persists, contact the supplier.
E06, E19, E26, E27, E30, E31, E35, E38-E50, E53, E55, E57	Internal communication error	If the error occurs repeatedly, contact the supplier.
E07	Too high pressure in inflatable	The pressure in the inflatable is too high. Let the inflatable deflate, either by itself or by unplugging it, then start a new examination. If the error persists, contact the supplier.

E08, E20	Software update failed	An update to the software has failed. Contact the supplier.
E09	No pressure on the sensor plate	Check that the individual is lying correctly on the sensor plate. If the inflatable is inflated, deflate the inflatable and repeat the examination.
E10	Inflatable is not empty	Ensure that the inflatable is deflated before starting an examination.
E11	Internal error sensor plate	Disconnect and reconnect the sensor plate. If the error persists, replace the sensor plate.
E12, E28, E29	Light calibration failed	Reposition and reattach the sensor plate and try again.
E13	Failed to deflate	Check that nothing is blocking the airflow in the tube to the inflatable. Disconnect the inflatable from the main unit and deflate by hand. Restart the examination.
E14	Too high skin temperature	Make sure the individual does not have a fever. If not, reattach the sensor plate, wait a minute and restart the examination.
E16	Connection to server failed	If the error message occurs several times, contact the supplier.
E17	Failed to upload data	If the error message occurs several times, contact the supplier.
E21-25, E58	Server communication error	If the error occurs repeatedly, contact the supplier.
E32-E34, E36, E37	Sensor plate communication error	Try replacing the sensor plate. If the error occurs repeatedly, contact the supplier.
E51, E52	Wifi error	If the error occurs repeatedly, contact the supplier.
E54	Examination cancelled due to connected charger.	The device cannot be used while charging. Remove the device from charger and restart the examination.

7 Operating environment

Environmental parameter	Interval
Room temperature	Room temperature during use should be between 10°C and 35°C
Distance from main unit	During normal use the main unit should not be placed closer to a person than 0.2 m.
Humidity	Humidity during use should be between 30 and 75%
Atmospheric pressure	Atmospheric pressure during use should be between 70.0 kPa and 106.0 kPa
Lighting conditions	Lighting conditions during use should be normal indoor conditions
Mains supply	The charging plate can be connected to a 100–230 V and 50/60 Hz mains supply
Power	The charging plate has a power of 5W
Transportation temperature	Temperature during transportation should be between -40°C and 70°C. Humidity during transportation should be between 10 and 100%.
Storage temperature and humidity	Temperature during storage of the single use tape should be 23°C and humidity should be 50% for maximum shelf life. Store out of direct sunlight. The device can be stored at operating environment as described above.

8 Hazards

Hazard relating to the device	Description
LEDs	The sensor plate emits wide-angle green and near-infrared light. Near-infrared light is not visible to the eye, and prolonged exposure of the eyes is not recommended. The intensity of the light is low enough to be considered safe for both skin and eyes.
 **Incorrect battery replace-ment**	If the battery is replaced incorrectly, the results from the device will no longer be reliable and the device may constitute a hazard. Batteries should be replaced by certified personnel only.
Using the wrong type of tape	Use only the tape supplied. Using the wrong tape can lead to unreliable or no results.
Reusing tape	The tape supplied is intended for single use and should be disposed of in accordance with Chapter 3, *Cleaning and waste disposal*, after use. A new tape should be used each time the device is used. If the same tape is used for several examinations, there is a risk that the sensor plate will receive an impaired signal and that the results of the examination will be unreliable or absent. There is also a risk of infection if the tape is reused for several people.
 **Non-certified modification of the device**	The device may not be modified without authorisation from the manufacturer. If the device has been modified, it must undergo inspection by certified personnel in order to ensure that it remains safe for use.
Mechanical bending	The sensor plate should not be bent more than necessary. Excessive bending may cause damages to the sensor plate.

Hazard relating to use	Description
Pressure from prolonged exposure to sensor plate	The device should be removed once the examination is complete to ensure that the individual does not receive unnecessary prolonged pressure from the sensor plate.
Number of examinations	Once the sensor plate has performed the recommended number of examinations, an error message will be displayed on the screen. The sensor plate should then be replaced.
Leakage in the inflatable	If there is leakage in the inflatable, an error message will be displayed on the screen. In the event of leakage, the inflatable must be replaced.

Individual feels exposed	Minimize the individual's discomfort and exposure by informing them about the examination and not exposing the individual's body more than necessary.
Examination of confused individual's	Examination with the device should be supervised if the person does not understand the instructions or appears to be confused.

Contact the manufacturer in the event of any accident or failure in the use of the PU sensor.

9 Symbols and abbreviations

Below you will find explanations of the symbols found on the components of the device.

Symbol	Code	Explanation
	ISO 7000-1641	Read manual before use
	ISO 7000-1051	For single use only
	CE marking	The product has been deemed to meet the stringent safety and environmental requirements that apply to products sold within the EEA. The product meets the requirements for sale within the EEA.
	WEEE	The product contains electronic parts that must be disposed of as electronic waste.
	ISO 7000-2607	Expiration date
	ISO 7000-2497	Date of product manufacture
	ISO 7000-3082	Product manufacturer
	ISO 7000-2492	Batch code
	ISO 7000-2493	Item number
	ISO 7000-2498	Serial number
	ISO 7000-5840	Type B applied part
	-	Medical device
	-	Wireless charging