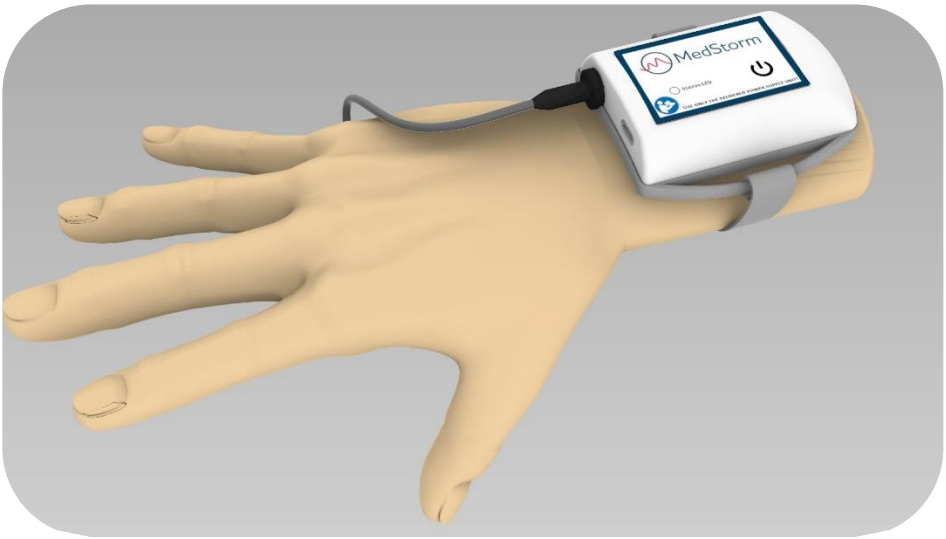
Med-Storm PainSensor



User manual

VERSION 1.0 ENGLISH DHF-00069-01-PainSensor-REF1002, Part number 400102

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IMPORTANT

The user manual covers the operation of the MED-STORM PainSensor.

Read all instructions, warnings and precautions prior to use.
Only a trained physician or nurse should use the system.

Users of the equipment must be familiar with the medical aspects of the conditions for which the MED-STORM PainSensor is used. All users must complete the training program and the questionnaire provided by MED-STORM before using the PainSensor.

MED-STORM considers itself responsible for any effects on safety, reliability and performance of the equipment only if:

- assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by MED-STORM, and
- the electrical installation complies with national standards, and
- installation and configuration of software is carried out by persons authorized by MED-STORM, and
- no other software is installed on the computer or the PainSensor unless explicitly accepted by MED-STORM, and
- the equipment is used in accordance with the product documentation.

MED-STORM makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

MED-STORM shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

DISCLAIMER

THE MED-STORM PAIN SENSOR IS NOT A SUBSTITUTE FOR YOUR PROFESSIONAL JUDGMENT. MED-STORM SHALL NOT BE LIABLE IN ANY MANNER WHATSOEVER FOR THE RESULTS OBTAINED THROUGH THE USE OF THE PAIN SENSOR. PERSONS USING THE PAIN SENSOR ARE RESPONSIBLE FOR THE SUPERVISION, MANAGEMENT AND CONTROL OF THE PAIN SENSOR.

TABLE OF CONTENTS

1 Introduction

The manual corresponds to hardware of series A or higher.

1.1 Definitions

NRS	Numerical Rating Scale
VAS	Visual Analog Scale
NFSC	Number Fluctuations of Skin Conductance

1.2 Intended use

The PainSensor is intended to determine a patient's sensitivity to pain, awakening from pain during anaesthesia, withdrawal symptoms and nerve block.

1.3 Normal use

The PainSensor can be used whenever needed. However the battery capacity limited the continues use between charging, to around 8 hours. Please observe that charging during measuring is not possibly.
The same electrodes do not allow continuous use for more than 48 hours.
The PainSensor has no "Essential performance". The output of the device is one of several indicators that may be used to determine patient status, thus the absence of performance does not lead to an unacceptable risk.

1.4 Intended user

Only trained physicians or nurses shall use the system. The PainSensor can only be used in a professional healthcare environment e.g. hospitals.

1.5 Indications for use

Indications for use are:

- patients undergoing anaesthesia;
- postoperative patients;
- patients in the intensive care units;
- premature infants;
- patients exposed to regional nerve block.

1.6 Contraindications for use

- The device shall not be used at patients with skin conditions which may affect skin conductance. E.g. injury of the skin.
- More than one device shall not be used on patients with electrically sensitive life support systems (e.g. implantable pacemaker or defibrillator).
- The device shall not be used when the patient has an injury affecting the sympathetic skin nerves.

1.7 Pre use checks

Before using the device, we recommend filling in the pre use checklist from appendix F, for each patient.

2 Warnings

Read the entire operating manual before operating this PainSensor.

It is the responsibility of the user to ensure that any applicable regulations regarding the operation of the PainSensor are observed.

The PainSensor must be used together with dedicated accessories.

Only use Bluetooth devices that have the required software installed to connect to the PainSensor.

Position the device in such a way that you can disconnect the power plug from the device at any time.

2.1. Electrical shock hazard

There are exposed voltages inside the PainSensor. There are no user-serviceable parts inside. Do not open the PainSensor. Send to qualified personnel approved by Med-Storm Innovation for servicing.

2.2. Environmental conditions

Do not use, transport or store above or below the recommended environmental intervals in Appendix C.
Do not immerse the PainSensor or cables in any liquid or allow liquid to enter plugs or connections. Do not use cables if connectors become wet.

2.3. Warning and information symbols

The following symbols shown in Table 2-1 are used on the PainSensor as warning and information symbols.

Table 2-1: Warning and information symbols

WARNING: Modification of the PainSensor is not permitted

WARNING: Only use the PainSensor with the power supply and power cable delivered and specified by MedStorm Innovation AS.

WARNING: Do not use more than ONE PainSensor on patients with an implanted pacemaker or defibrillator. This may risk cardiac problems.

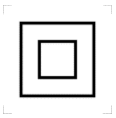
WARNING: Position the device in such a way that you can disconnect the power plug from the device at any time when the device is charging.

WARNING: The PainSensor cannot and must not be used on the patient during charging. During charging, the measurement is prevented by hardware. The power supply cable also has to be removed from the PainSensor while the PainSensor is used on the patient.

Warning symbol:

Follow the instructions for use.

Information symbols:

	Read the entire operating manual before operating this PainSensor
	Class II classification of medical device
IPXX	Degree of protection against ingress of water and particulate matter. Not required to be specified.
	TYPE BF APPLIED PART
	TYPE B APPLIED PART
	Do not dispose of this unit. It should be returned to Med-Storm Innovation for proper material reuse or recycling
	Product model identifier
	Serial number of device
	Batch designation
	Production date
	Production location

3 Technical overview/Technical manual

3.1 System overview

The PainSensor is an electronic conductance meter for detecting skin conductance changes on palmar and plantar skin sites to determine a patient's sensitivity to pain. A sketch of the system is shown in Figure 3-1.

Note.
The use of accessories, transducers and cables other than those specified may result in increased emission or decreased immunity of the system.

The following parts of the PainSensor are included in the package from MedStorm Innovation AS:

Measurement equipment	See Figure 3.1	Part #
PainSensor	1	1100
Power supply power cable	2	2100
Power supply unit for PainSensor	3	1101
Power supply with internal adapter plugs	4	1102
Electrode cable adult and children, European (Not detachable by user)	5	2101
Accessories		
Wristband	[not shown in fig. 3-1]	6100
Manual, version 1.0 English, Norwegian, German, Dutch	[not shown in fig. 3-1]	4100, 4101, 4102, 4103

From other suppliers you get:

Accessories	See Figure 3.1	Part #
Electrodes, adult and children	Figure 3-6	6001
Electrodes, preterm infants	[not shown in fig. 3-1]	6002
Electrodes, grounding anaesthesia	[not shown in fig. 3-1]	6003
PSM connectivity box	7	6015
External PC screen with power supply, power cable, and PainSensor Software (PSS) Application	8	6011, 6012, 6013

What you get from other suppliers is depending on your order.

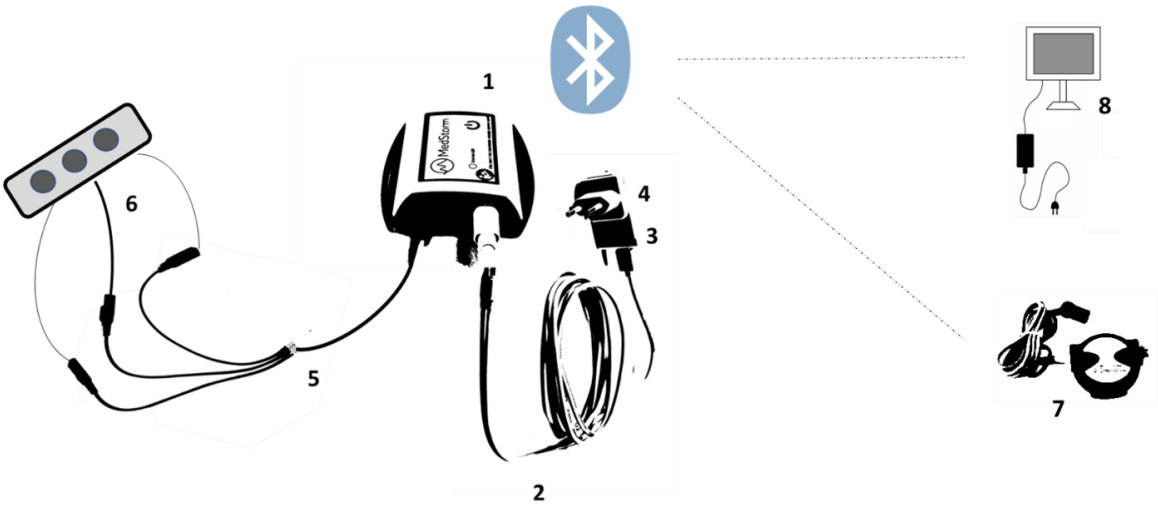


Figure 3-1: System overview sketch

Applied parts:

Description	Inside/ Outside	High touch probability	Low touch probability	Applied part (Typ)
Housing (+intermediate ring, bend relief and wristband)	Outside	x		Typ B
Sticker (HMI)	Outside	x		Typ B
Electrode cable	Outside	x		Typ B
Power supply	Outside		x	
USB cable	Outside		x	
Electrodes/ Electrode connectors	Outside	x		Typ BF

Bluetooth transmitter specification:

Feature	Specification
Bluetooth®	V5.0 – Single mode, Concurrent master and slave, Diffie-Hellman based pairing
Frequency	2.402 - 2.480 GHz
Maximum Transmit Power Setting	+4 dBm
Minimum Transmit Power Setting	-20 dBm

3.2 PainSensor

The PainSensor, Figure 3-2, has one connector, one button, and two LEDs. The electrode cable is fixed to the device [1]. The power supply inlet [2] is the one connector, and both are placed on one side of the PainSensor. The LEDs [3][4] and the button [5] are found at the front of the PainSensor. One LED [3] shows the status of the PainSensor, and one LED [4] shows the charging status of the PainSensor. There is a plug covering the charging USB port when the charging cable is not attached. The plug is shown in Figure 3-3.

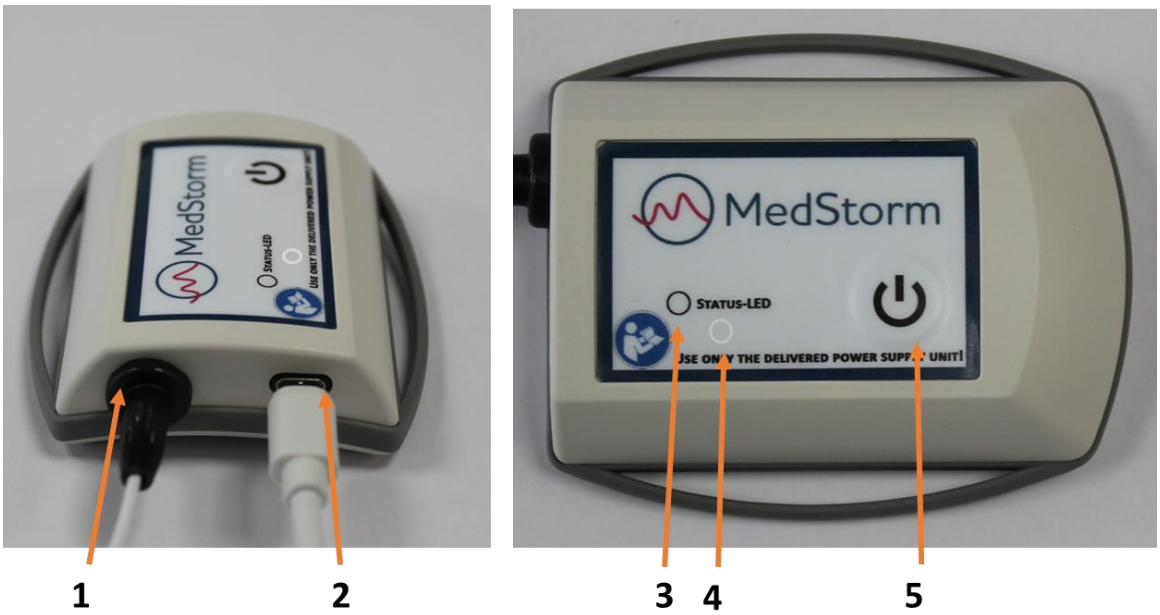


Figure 3-2: PainSensor

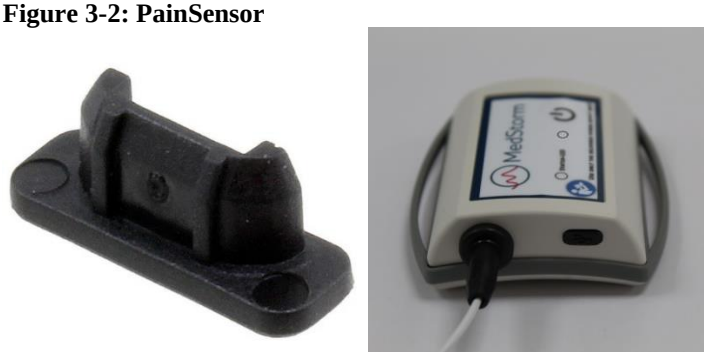


Figure 3-3: The plug covering the charging USB port when charging cable is not attached. The left image shows the plug, and the right image shows the plug inserted into the charging USB port.

3.2.1 Power supply and power cable

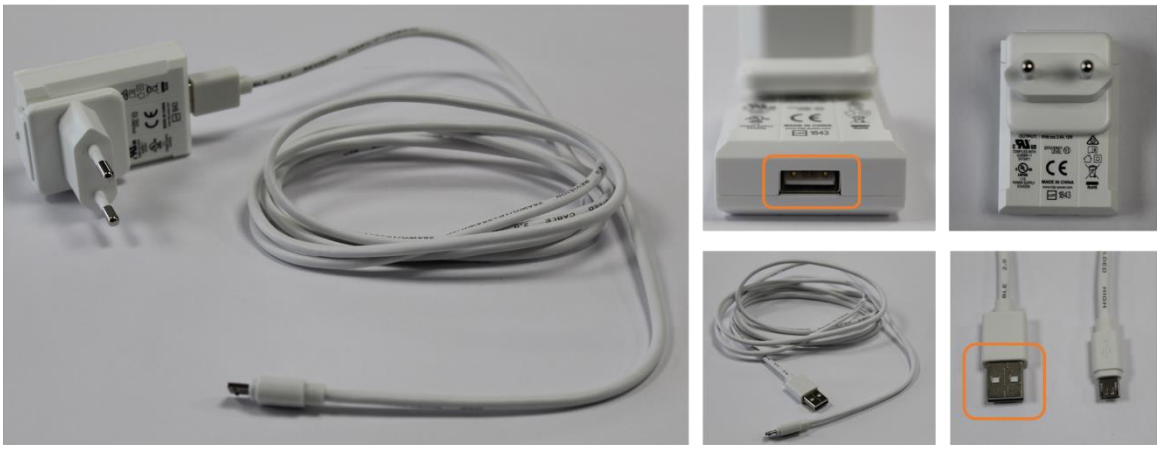


Figure 3-4: PainSensor power supply

The power supply unit and power cable used with the PainSensor is of medical grade and provides 2 MOPP.

Specifications:

Model	HDP12-MD05024U Certified to IEC 62368-1 and IEC 60601 standards. For Medical & ITE Applications.
Input Voltage	100 ~ 204 VAC
Frequency	50/60 Hz
Input Current	0.35A
Output Voltage	5.0V
Output Current (max)	2.4 A

Do not use any other than the recommended power supply unit and power cable (Qualtek 3025013-06).

The power supply unit and cable is shown in, Figure 3-4. The power supply unit has one input for connecting the cable. The orange rectangles mark which side of the cable should be connected with the power supply input. To disconnect the PainSensor from the mains supply, the mains plug must be pulled out of the socket. Charging of the device should take place a different place than where the patient is located.

3.3 Electrode cable

The electrode cable is attached to the PainSensor [1] and has three connectors for the electrodes [2], see Figure 3-5. The three wires are used for one function. This function is to measure the patients skin conductance. There is no difference between adults, children and premature infants in functionality.

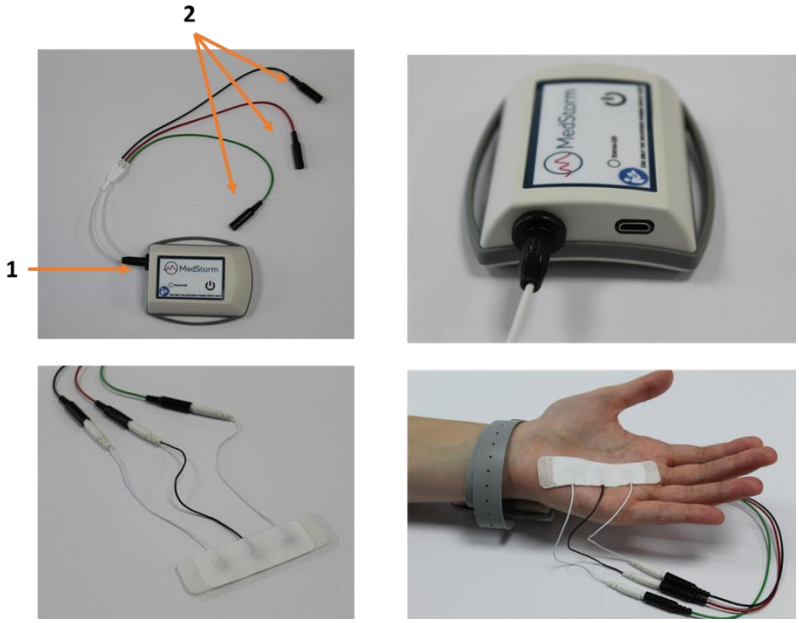


Figure 3-5: Electrode cable

3.4 Electrodes

Different electrodes can be used for adult, children and premature infants after being tested and recommended by Med-Storm. The electrodes supplied from Med-Storm (#6001 and #6002) are approved. Figure 3-6 shows the electrodes for infants, children and adult patients. Figure 3-7 shows the electrodes for preterm infants.

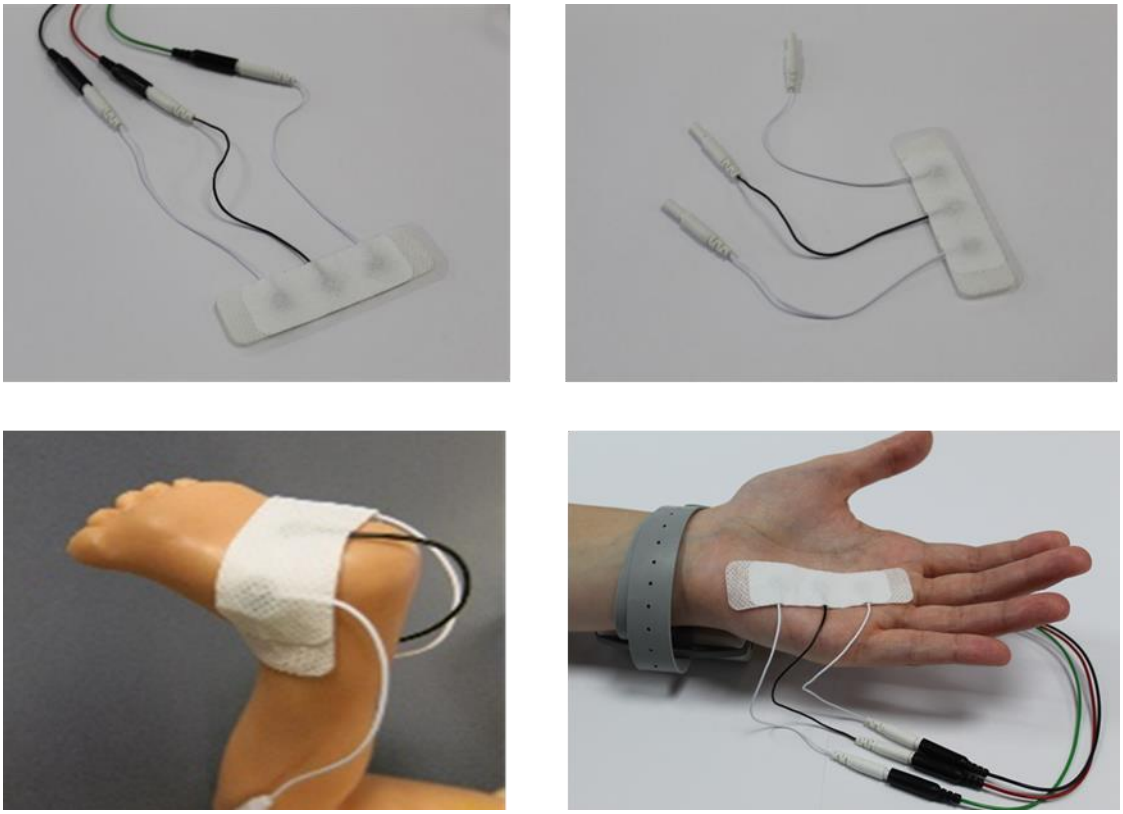


Figure 3-6: Electrodes for infants, children and adult patients. The first image shows the connection to the electrode cable. The pictures at the bottom shows the attachment of the electrodes on the plantar part of the foot (left) and palmar part of the hand (right).

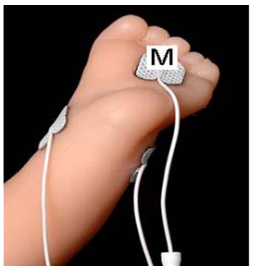


Figure 3-7: On preterm infants, electrodes that are split into three can be ordered and used.

4 Operating Instructions

The PainSensor is integrated into an IT network to transmit the measured and calculated data via Bluetooth Low Energy to a unit for display (as described in Appendix A and Appendix B).
The network consists of a two-node network between the PainSensor and the receiving unit. Only Bluetooth devices that have the required software to read out the data can be used. A BLE connection based on BLE V5.0 is used. The transmission frequency is 2.402-2.480 GHz.
Before the measured data of the patient is transmitted to a receiver, the receiver is verified by a verification algorithm. Only if the receiver passes the verification, the connection is maintained and the data is transmitted, otherwise the connection with the receiver is disconnected after verification. The transmitted data is encrypted by the Advanced Encryption Standard AES-128.
The information flow is purely from PainSensor to the respective recipient. The PainSensor cannot receive any data except during verification of the receiver.
No hazards arise if an IT network cannot provide the required features. A connection with the PainSensor is then not possible.

WARNING:
If the PainSensor is used with other devices in an IT network as an ME system, the commissioning person must verify that the system complies with the applicable safety requirements and regulations.

WARNING.
The PainSensor cannot and must not be used on the patient during charging. During charging, the measurement is prevented by hardware. Charging should take place at a different place than where the patient is located.

Attention:
The integration of the PainSensor into existing IT networks can lead to risks for the patient operator or for third parties which cannot be foreseen by the manufacturer.
The person commissioning the system should determine, analyze, evaluate and manage these risks.

The following changes to the IT network could lead to new risks and should therefore be analyzed:

- Changes to the IT NETWORK configuration.
- Connecting additional elements to the IT NETWORK
- Removing elements from the IT NETWORK;
- "Update" of devices connected to the IT NETWORK.
- "Upgrade" of devices connected to the IT NETWORK.

Intended position of the operator is less than 0,4m from the device. The following instructions describe all necessary steps required to set-up and operate the PainSensor.

Note.
Only use the PainSensor with the power supply and power cable provided by MedStorm Innovation AS.

Note.
Portable and mobile wireless communications equipment can affect medical electrical equipment.

Note.
Two or more of these systems must not be used on a patient with an implanted pacemaker or defibrillator.

Note.
The device shall not be used on patients with skin conditions which may affect skin conductance, e.g. injury of the skin below the electrodes or when the patient has an injury affecting the sympathetic skin nerves. Moreover, local nerve blocks at the measuring area will affect the method.

Note.
Only use Bluetooth devices that have the required software installed to connect to the PainSensor

Note.
Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Appendix F.

Note.
Do not touch the power supply unit /USB connector and the patient at the same time.

4.1 Instrument setup

Power supply:

1. Connect the power cable to the power supply unit (Only products delivered by Med-Storm Innovation AS, check label).

2. Remove the plug covering the USB port for charging on the PainSensor, and connect the power cable to the PainSensor (Only products delivered by MedStorm Innovation AS, check label).

3. Connect the power supply unit to a wall socket

Connection of PainSensor to patient:

4. Make sure that the charger is disconnected from the PainSensor. The device has a battery and can, when fully charged, be used without connection to the power supply. The battery life enables approximately 7 hours of continuous measurement.

5. Place the electrodes on the patient. See description in section 4.1.1.

6. Connect the electrode cable to the electrodes. See description in section 4.1.1.

7. Attach the wristband with the PainSensor to the wrist/ancle of the patient, or place the PainSensor next to the patient.

    6a. For infants in the NICU, the PainSensor can be placed inside or outside the incubator, or on the wrist of the parents during skin-to-skin care. The sensor should not be strapped directly on the infant.

    6b. For use in the operating room, the PainSensor can be placed on the underside of the arm as depicted in Figure 4-1 if that is considered more convenient.

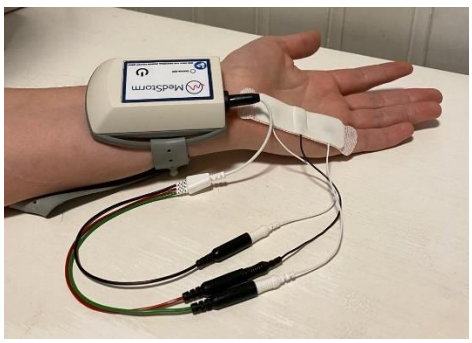


Figure 4-1: Example of placing the PainSensor housing on the underside of the arm if considered more convenient in the operating room

4.1.1 Skin electrode placement

The electrodes can be attached to the patient with reliable measurement result for a maximum time of 48 hours.

Note.
To disconnect, pull out each electrode connector separately. Do not pull on the electrode cable itself.

a. Artefacts

Artefacts can be seen when moving the hand/foot where the electrodes are attached or by pulling at an electrode. If the measuring electrode is wrapped, e.g. with a bandage, the movement artefacts should improve/be eliminated. It is therefore advised to wrap the electrodes if the patient is moving the hand/foot a lot.

If the measuring electrode is fastened to the extremity with regional block, no response to pain/noxious stimuli will be observed because the skin sympathetic nerves are blocked.

Artefacts can also be seen if the electrodes are attached to injured skin.

Artefacts have been seen in the registration during tetanic stimuli if there were more than one EEG (Electroencephalography) monitor connected to the patient.

b. Skin electrode placement on adults and children

The intended placement of the electrodes on adults and children is on the palm of the hand. The sole of the foot can be used in active patients or if the child is young. Use the sole where the skin is not thick so the sweat reach the upper part of the skin.

1. Place the electrodes according to Table 4-1 and Figure 4-2. The distance in between each electrode shall be at least 7 mm. The M-electrode is placed at the hypothenar eminence because this area on the palm gives highest stability and thus less movement artefacts.

2. Attach the connectors of the electrode cable to the electrodes according to Table 4-1.

Table 4-1: Skin electrode placement on adults

Electrode	Characterization	Colour	Placement
Reference	R	White	Palmar/plantar
Measure	M	Black	Palmar/plantar
Current	C	White	Palmar/plantar

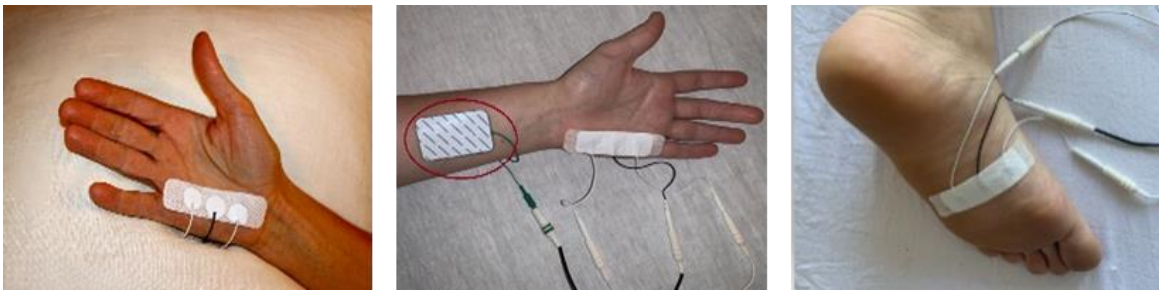


Figure 4-2: Skin electrode placement on adults. The second image shows the placement of the grounding elec-trode during anesthesia

c. Skin electrode placement on infants

The intended placement of the electrodes on infants is under the foot.

1. Place the electrodes according to Table 4-2 and Figure 4-3. The distance in between each electrode shall be at least 7 mm.

2. Attach the connectors of the electrode cable to the electrodes according to Table 4-2.

Table 4-2: Skin electrode placement on infants

Electrode	Characterization (in Figure 4-3)	Marking color	Placing
Reference	R	White	On either side of the ankle
Measure	M	Black	On the sole of the foot
Current	C	White	On either side of the ankle

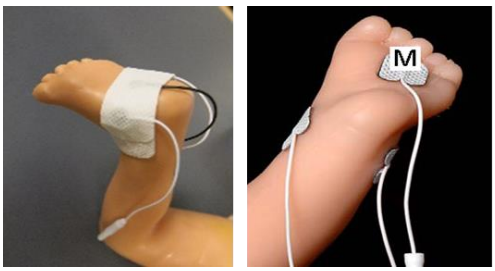


Figure 4-3: Skin electrode placement on infants

4.2 Button and LEDs

The LEDs show a continuous light in different colours, with different meanings. These are depicted in Figure 4-4.

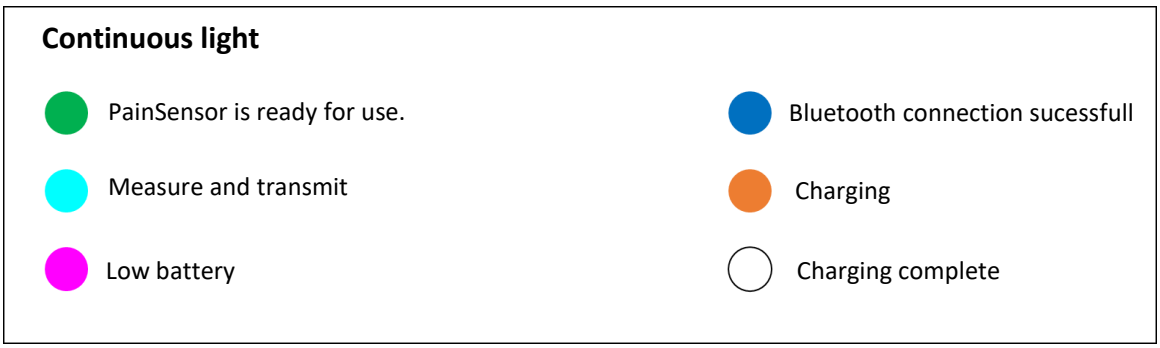


Figure 4-4: Meaning of the different colours of the LED.

The button can be pressed long or short, as depicted in Figure 4-5.

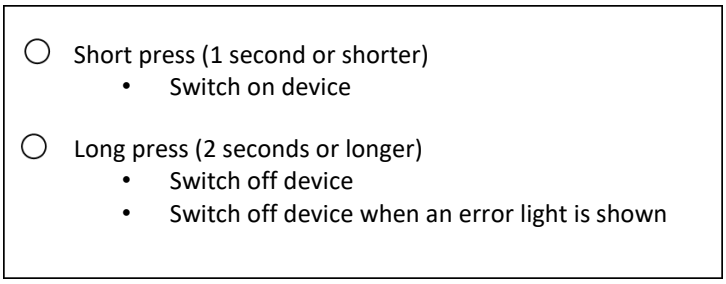


Figure 4-5: Functioning of the button press.

4.2.2 Error conditions

The PainSensor measures very small changes in skin conductance and is extremely sensitive. Simultaneous use of electro surgery will for example disturb the measurements made with the PainSensor.

If any interference occurs, if the PainSensor loses contact with the M electrode, if the microsiemens level is below 1 for a certain time, or other signal errors, like movement artefacts, the system will automatically recognize this and indicate this with a "bad signal quality" error bar on the PC/monitor.

4.3 Getting started

Note.
Ensure that the PSM connection box / stand-alone PC are prepared for connecting to the patient monitors. All information about the installing and operating the PSM connection box is found in Appendix A. For transmitting data to a stand-alone PC, please see Appendix B.

1. Make sure that the PainSensor is charged.

2. After the PainSensor is connected to the patient by following steps 4-8 in section 4.1, switch on the device. This is done by pressing the button one time. When the PainSensor is switched on, it automatically starts connecting to Bluetooth and starts measuring and transmitting data (if applicable).
   It is possible to see that the device is powered either by detecting a green LED, a blue LED showing that the device successfully connected to Bluetooth, or when the cyan LED is blinking for measuring.
   - In case of failure to connect to bluetooth, the magneta LED will be shown. Reattempt to connect to Bluetooth by pressing the button one time, again.
   - If the device still fails to connect due to an error in the system, a magneta light will be shown from the LED. Turn off the device and try again. If it keeps showing the magneta error light, turn off the device by holding the button for a few seconds, remove the device from patient, and contact the manufacturer from MedStorm Innovation at support@med-storm.com.

3. Check that the device is measuring and transmitting data by looking for the blinking cyan light. If this is detected, the pain index is shown on the monitor / PC, and the data is automatically collected.

4. Switch off the device by a long press of the button if you are done measuring, or if an error occur and the magneta light is shown.

4.3.3. Measurement values

One skin conductance peak is defined as a minimum followed by a maximum in conductance values. In the detailed graph the the maximum of one peak is marked with a red square, Appendix H – Physiological and clinical function of the Skin Conductance Monitor.

From the skin conductance peaks, number of measures can be calculated. The measures are calculated in a measurement window of 15 seconds. The refresh rate is each second.

Peaks per second [Hertz - Hz]
This is the number of peaks in a measurement window divided by the time span of the window.

Area huge peaks [micro Siemens seconds - µSs]
This measure is calculated by establishing a horizontal base line from the first peak minimum in the time window. The area that is calculated is the accumulated difference between the conductance values at the registration curve and the established baseline when they are larger than the baseline. This is illustrated in Figure 4-6.

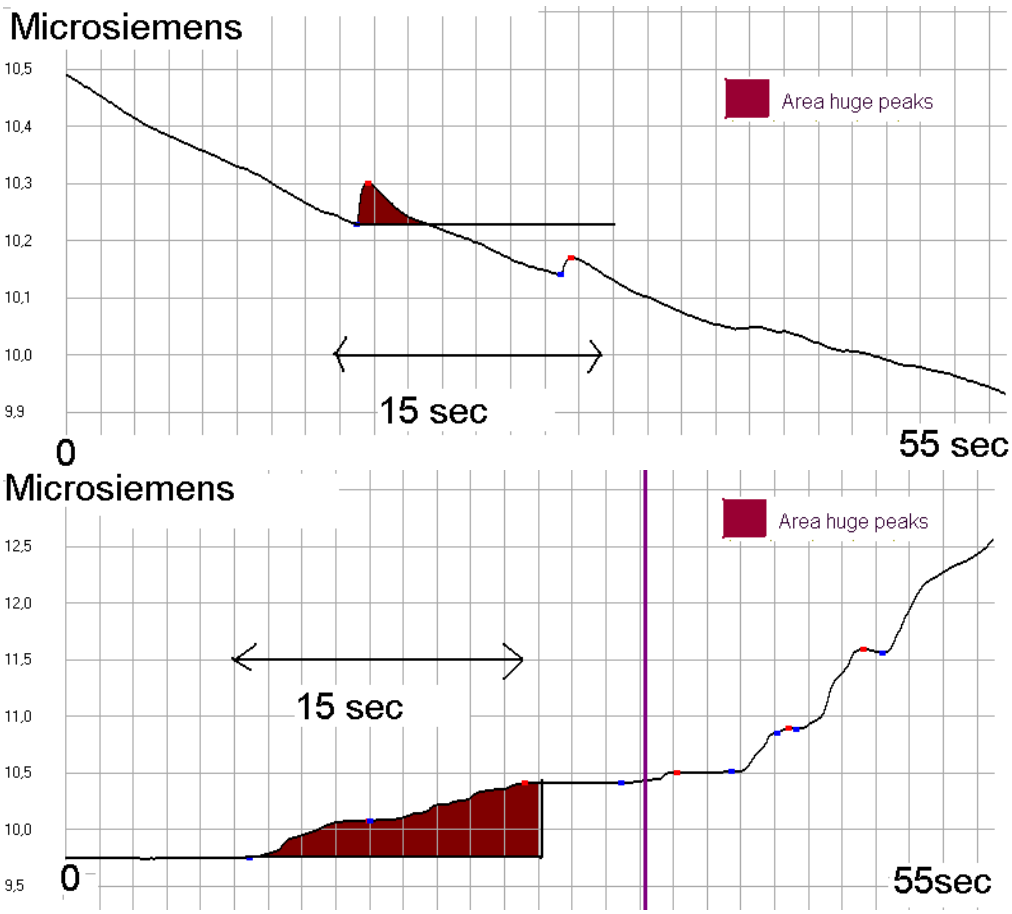


Figure 4-6: Calculation of area huge peaks

4.3.2.1 Operating theatres and Intensive care units (sedated patients)

In operating theatres, “peaks/second” and “area under curve” are used. If the “Peaks per sec” measure is 0 the patient is sufficiently or too sedated. If there are peaks, 2 or more in the analysing window of 15 sec, there are bursts in the sympathetic nerves and the patient’s sensitivity to pain is reached during anaesthesia. The Painindex is shown in Figure 4-7. If the “area under” the curve increases to 100 the patient is about to wake up from the stimulus,

and the patients possibly need more analgesics and hypnotics (forceful bursts in the sympathetic nerves when the patient is about to wake up). The awakening index is shown Figure 4-8.

Pain Index	Peaks per second Mirroring how often the skin sympathetic nerves are firing	Indication
0	0.00 – 0.06	No more analgesia is needed
1	0.07 – 0.12	No more analgesia is needed
3	0.13 – 0.19	More analgesia may be needed
5	0.20 – 0.26	More analgesia is possibly needed
7	0.27 – 0.32	More analgesia is probably needed
8	0.33 – 0.39	More analgesia is needed
10	0.40 or higher	More analgesia is needed

Figure 4-7: The PainIndex, the corresponding peaks/second for each value, and the indication.

Awakening index	Area under the curve Mirroring how forceful the skin sympathetic nerves are firing	Indication
0	0.00 – 1.99	No more hypnotics needed
40	2.00 – 4.99	More hypnotics is possibly needed
100	5.00 – 10	More hypnotics/analgesia is probably needed

Figure 4-8: The Awakening index, the corresponding area under the curve, and the indication

4.3.2.2 Post operative and ICU (awake patients)

The measurement values shown in “post operative” and “ICU” mode are shown in Figure 4-9.

Pain Index	Peaks per second Mirroring how often the skin sympathetic nerves are firing	Indication
0	0.00 – 0.06	No more analgesia is needed
1	0.07 – 0.12	No more analgesia is needed
2	0.13 – 0.20	No more analgesia is needed
3	0.21 – 0.26	More analgesia may be needed
4	0.27 – 0.32	More analgesia is possibly needed
6	0.33 – 0.39	More analgesia is probably needed
8	0.40 – 0.66	More analgesia is needed
10	0.67 or higher	More analgesia is needed

Figure 4-9: Pain index for Post-operative mode and ICU mode for awake patients, the corresponding values, and the indication.

For post operative pain and ICU (awake patients) the mode is based on peaks per sec. The peaks per sec increase when the patient’s sensitivity to pain measured by the Numeric Rating Scale (NRS) or Visual Analogue Scale (VAS) increases, where 0 is no pain and 10 is worst thinkable pain (Figure 4-10). The peaks per second (number fluctuations of skin conductance=NFSC) shows the rate of firing in the sympathetic nerves. This index changes

according to the increase in NRS or VAS score. The sensitivity to determine pain lower than or equal to 3 on the NRS or VAS has the peaks per sec lower than or equal to 0.21 peaks per sec, the sensitivity to determine pain more than 3 but less than or equal to 5 on the NRS or VAS has peaks per sec higher than 0.21 peaks per sec but lower than or equal to 0.27 peaks per sec, the sensitivity to determine pain higher or equal to 6 but lower than or equal to 10 on the NRS or the VAS, has peaks per sec more than 0.27 peaks per sec. The index is also validated for pain in children and adults. The index may also be influenced from other sympathetic nerve stimulation like nausea, vomiting and anxiety. The analysing window is preset to 15 seconds and the refresh time is each second.

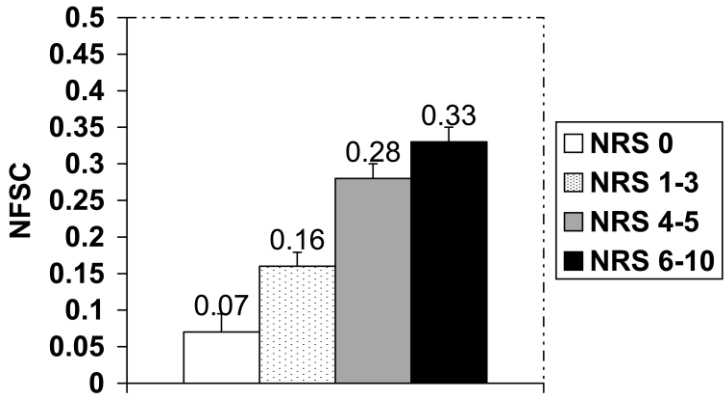


Figure 4-10: Level of pain (Ledowski T et al. The assessment of postoperative pain by monitor-ing skin conductance results of a prospective study. Anaesthesia 2007, 62:989-993).

The skin conductance pain score is valdidated with different behavioral and sedation scores: for adults Numeric Rating Score (NRS) and MAAS have been used, for children COMFORT sedation score, as well as 1–3 yr: FaceLegs Activity Cry Consolability Scale, 4–7 yr: Revised Faces Scale, 8–16 yr.

4.3.2.3 Infants

In the "**Infant**" application mode the measurement values shown are, Figure 4-11.

Pain Index	Peaks per second Mirroring how often the skin sympathetic nerves are firing	Indication
0	0.00 – 0.06	No more analgesia is needed
1	0.07 – 0.13	No more analgesia is needed
2	0.14 – 0.20	No more analgesia is needed
3	0.21 – 0.26	More analgesia is possibly needed
4	0.27 – 0.32	More analgesia is probably needed
6	0.33 – 0.39	More analgesia is probably needed
8	0.40 – 0.79	More analgesia is needed
10	0.80 or higher	More analgesia is needed

Figure 4-11: The pain index for infants, the corresponding values, and the indication.

The ‘Pain Index’ (peaks per sec) shows the rate of firing in the sympathetic nerves. It increases when the behavioural state increases. The behavioural state can be recorded according to Prechtl’s Five Point Scale, see Table 4-3.
The index, ‘peaks per second’, changes colour when the behavioural state changes, making it possible to determine the patient’s sensitivity to pain. When the infant is calm and moving a little (Prechtl’s scale 1-2-3), the peaks per sec are less than 0.21 peaks per sec. As the infant starts to be active/fuzzy (Prechtl’s scale 4), the peaks per sec are 0.21 peaks per sec or more, but less than 0.33 peaks per sec. Eventually, when the infant is crying or is in significant pain (Prechtl scale 4-5), the peaks per sec are more or equal to 0.33 peaks per sec, see Figure 4-11.

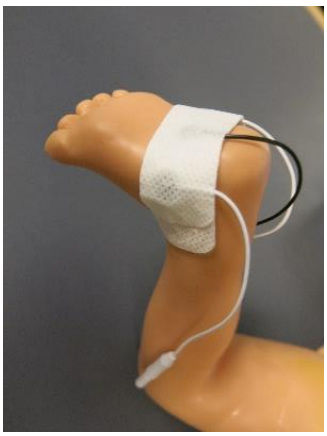
Table 4-3: Prechtl’s Five Point Scale

Prechtl’s Five Point Scale	
1	Eyes closed, regular respiration, no movements.
2	Eyes closed, irregular respiration, small movements.
3	Eyes open, no movements.
4	Eyes open, gross movements.
5	Crying (vocalisation)

Figure 4-12 shows the placement of electrodes on infants, depending on age. Preterm infants less than 37 weeks of gestational age use electrodes that are separated, where the measurement electrode is placed under the foot. Older infants can use the adult electrodes, as seen in the picture on the right.

The electrodes, always BLACK cable at the sole of the foot:

The cable marked black shall always be connected to sole of the foot or palmary (independent on the color code of the electrodes)



Less than 37 weeks of gestational age *Older than 37 weeks of gestational age*

Figure 4-12: Placement of electrodes for infants depending on age

4.3.2.4 During withdrawal/abstinence symptoms

The PainSensor index when tailoring the need of analgesia in children and adult intensive care unit patients and postoperative during withdrawal/abstinence symptoms is shown in Figure 4-13.

The withdrawal index is valdidated by Finnegan Scoring System

Withdrawal Index*	Peaks per second Mirroring how often the skin sympathetic nerves are firing	Indication
0	0.00 – 0.06	No analgesia is needed
1	0.07 – 0.13	No analgesia is needed
2	0.14 – 0.20	No analgesia is needed
3	0.21 – 0.26	Analgesia is possibly needed
4	0.27 – 0.32	Analgesia is probably needed
6	0.33 – 0.39	Analgesia is probably needed
8	0.40 – 0.79	Analgesia is needed
10	0.80 or higher	Analgesia is needed

Figure 4-13: Pain index during withdrawal/abstinence symptoms. The colour is visible when a PC is used to show the index. On the monitors, the values on the right hand side are shown

4.3.2.5 Nerveblock

The PainSensor indices to assess the effect of regional peripheral nerve block are shown in fig. 4-14.

Nerveblock index	Peaks per second Mirroring how often the skin sympathetic nerves are firing	Indication
0	0.00 – 0.06	0 for a period of time: The nerve is probably blocked
1	0.07 – 0.13	
2	0.14 – 0.20	
3	0.21 – 0.26	
4	0.27 – 0.32	
6	0.33 – 0.39	
8	0.40 – 0.79	
10	0.80 or higher	

Figure 4-14: Pain index to assess the effect of regional peripheral nerveblock.

5 Care and maintenance

Routinely inspect all electrical plugs and connections of the medical device. Check that none of the cables are destroyed, check that the LED is working, check that the button is functioning. Do not use if damaged. If you are unable to connect to Bluetooth or to measure data, contact support from MedStorm.

Note.
For optimal functionality of the battery of the PainSensor, the PainSensor should not be stored fully charged or completely empty for a longer period of time. Then the battery lifetime may suffer. This is not of risk to the patient, however, optimal functioning of the battery is recommended.

5.1. Lifetime

The minimum lifetime of the system is 3 years on the condition that the instructions in this manual are followed. If the instructions of storing the device are followed, optimal functioning of the battery is sufficient for the lifetime of the device.

5.1 Preventive maintenance:

The PainSensor does not need to be calibrated during the specified lifetime years, presuming the instructions in this manual are followed.

5.2. Support information

Email	support@med-storm.com
Skype	Med.storm.support
Tel	+47 909 398 10 +47 94 07 00 07

5.3. Cleaning

Always disconnect the PainSensor from its power supply before cleaning. Ensure that the plug for protecting the charging USB port is closed before cleaning.
For each time the device will no longer be used on the same patient, the electrodes used shall be removed, and the PainSensor and its accessories may be cleaned by wiping a clean cloth dampened with 70% isopropyl alcohol or mild hospital cleaning detergent/bactericide. For longer use on the same patient, the electrodes must be replaced after 48 hours.

Note.
Under no circumstances should the PainSensor and accessories be immersed in any liquid cleaning agent. Nor should it be exposed to steam or hot air sterilisation, or chemical sterilisation using ethylene oxide. Never use ether or petroleum-based solvents.

5.4. Scrapping instructions

All parts of the PainSensor are to be returned to Med-Storm Innovation AS for proper electronic material reuse or recycling. Do not dispose any part of this unit.

6 Testing of the device

The device is compliant with the following standards:

- IEC 60601-1-2
- EN 60601-1-2
- EN 60601-1
    - Pos. 1, Qu-01090580-1
    - Pos. 2, Qu-01090580-1
- EN 62304
- REQ-0014, REQ-034, REQ-050

For more detailed information, see Appendix C-F.

7 Appendix A: Set-up of the PSM connectivity box to connect with the PainSensor

7.1 Introduction

The purpose of the PSM connectivity box is to receive medical data from the PainSensor and forward it to medical monitors, e.g. Philips IntelliVue Monitor. The data is transferred from the PainSensor to the PSM connectivity box using Bluetooth Low Energy, BLE.

7.1.1 The Connectivity Box

The PSM connectivity box, Figure 7-1, has four USB connectors, one "pairing button" used to initiate a connection to a waiting sensor, one power supply inlet and four LED lights. The USB connectors [3] are placed on one side of the PSM connection box, and the power supply inlet [1] and the pairing button [2] are placed on the left side of the box.

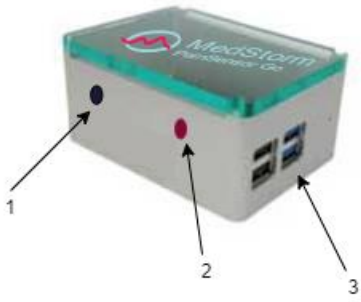


Figure 7-1: The PSM connectivity box and the components

7.1.2 LED lights

The four LED lights are found on top of the PSM connectivity box, see Figure 7-2.

- The power on LED [1] indicates that box batteries are at a sufficient level. The LED will turn on shortly after cable has been connected. It will remain on when the power is plugged in and continue to be on for quite some time after the power plug has been disconnected.
- When searching for a PainSensor, the Bluetooth LED [4] is blinking with a blue light. When connected to a PainSensor it changes to a constant light.
- The sensor LED [2] will have a constant green light when a sensor is connected and verified.
- When the connection between the box and a monitor has been verified, the monitor LED [3] is turned on with a constant green light.

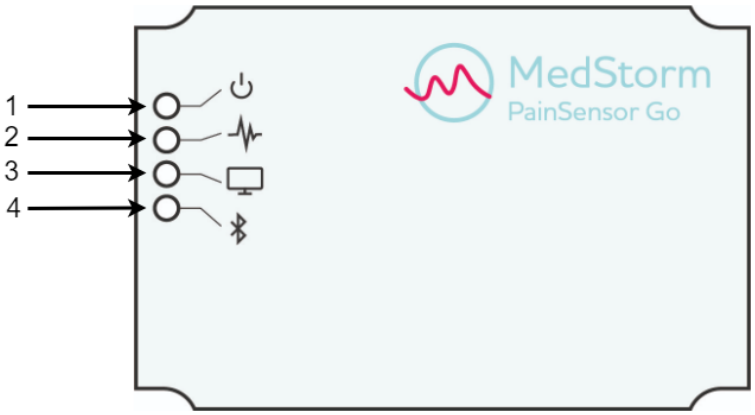


Figure 7-2: The four LEDs on top of the connectivity box

7.1.3 Connect to the PainSensor

The PSM connectivity box is connected to a sensor through BLE.

1. Click on PainSensor so that it is in searching mode (green light)
2. Click on Cubist Box pairing button to connect. The Bluetooth LED will first flash in blue, and when connected to the sensor switch to a steady blue light. The signal LED will then show a steady blue light until verification procedure is done asserting that the device is authentic. After the procedure succeeds it will switch to a steady cyan light.

7.1.4 Turn off the PSM connectivity box

Turning off the PSM connectivity box should rarely be needed. If needed, pull the power connection, and wait a few minutes until all LED lights are off.

If the power cable is disconnected, wait for the LED lights to go out until plugging back in.

7.2 Connecting to a Philips IntelliVue Monitor

7.2.5 Physical connections for PSM connectivity box to IntelliVue Monitor

Connect the PSM connectivity box to EC5 on an available serial port (possibly through a USB converter). The other end of EC5 shall be interfaced with the IntelliVue Monitor via an external/inbuilt EC10 module via Ethernet cable. See Figure 7-3 and Table 7-1 below.

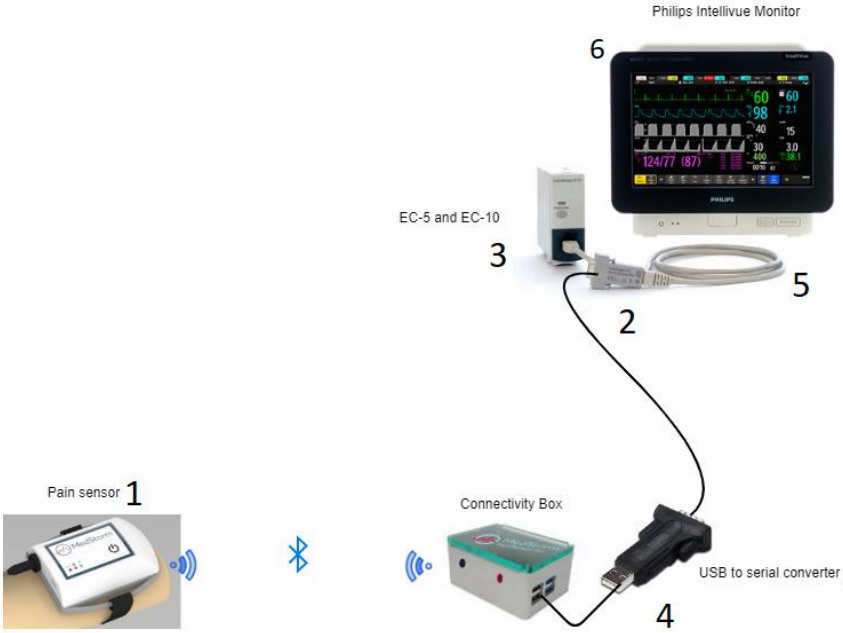


Figure 7-3: Connectivity to the Intellivue Monitor

Table 7-1 Equipment for connections and manufacturer for each part of the equipment.

#	Equipment	Manufacturer
1	Skin Conductance Pain Sensor	Med-Storm Innovation
2	IntelliBridge EC5, part nbr 865114 #104 (9 pin DSUB female connector)	Philips
3	IntelliBridge EC10, part nbr 865115 #A01, 101	Philips
4	USB serial adapter	Onyx Healthcare/Digitus
5	Ethernet cable (part of Philips 865114 #L0x)	Philips
6	Philips IntelliVue Monitor	Philips

7.2.6 Compatibility with Philips IntelliVue Monitor and System

Part as above indicate validated configuration. The communication to IntelliVue monitor is compatible with the following Philips IntelliVue Patient Monitoring Systems through the Philips IntelliBridge EC10 Interface module and/or the Philips EC40/EC80 hub as validated by Med-Storm:

- IntelliVue MP40/50/60/70/80/90 Software Revision H.15 or higher (with EC10)
- IntelliVue MX400/450/500/550 all Software revisions (with EC10)
- IntelliVue MX600/700/800, Software Revision H.15 or higher (with EC10)
- IntelliBridge System A.0 or higher (with EC40/80)
- Philips IntelliVue Infomation Center PIIC iX B.0 or higher (with EC40/80)
- Patient Information Center PIC iX C.02 or higher (with EC40/80)

7.2.7 Label shown on IntelliVue Monitor

There will be three labels shown on the IntelliVue monitor: the pain value (0-10), the awakening value (0-100) and the nerve block value (0-10). The label text for the pain value is "Pain-Nociceptive" and the numeric value in the range 0-10 is shown. For the awakening value, the label text is "Awakening" and the numeric value in the range 0-100 is shown. The label text for the nerve block value is "Nerve Block" and the numeric value in the range 0-10 is shown. There are no alarms or wave forms connected to these labels.

7.2.8 Setting up IntelliVue Monitor

If display of pain value does not automatically start, you may have to carry out the following steps:

a) On the IntelliVue monitor's screen, select **'Main Setup'**.
b) Select **'Equipment'** from the menu that shows up.
c) Click on the **'Measur. Select.'** button from the bottom panel.
d) Select the EC10 module to which the PC is interfaced from the pop-up window.
e) Select **'Activate'** to enable the selected EC10 to communicate with the PC.
f) Refer to Philips IntelliVue Instructions for Use for further detail. Contact your local Philips customer support in case you cannot make the connection work.

WARNING

For any issues related to the external products / monitors used with the PainSensor that are not delivered by MedStorm Innovation AS, contact the manufacturer for that respective product.

8 Appendix B – Connecting the PainSensor to a stand-alone PC with Bluetooth connection

The purpose of the PSS application is to receive medical data from the PainSensor and present it in the interface. The data is transferred from the pain sensor to the PSS application / standalone PC using Bluetooth Low Energy, BLE.

8.1 The PSS Application

The interface of the PSS Application is shown in Figure 8-1.

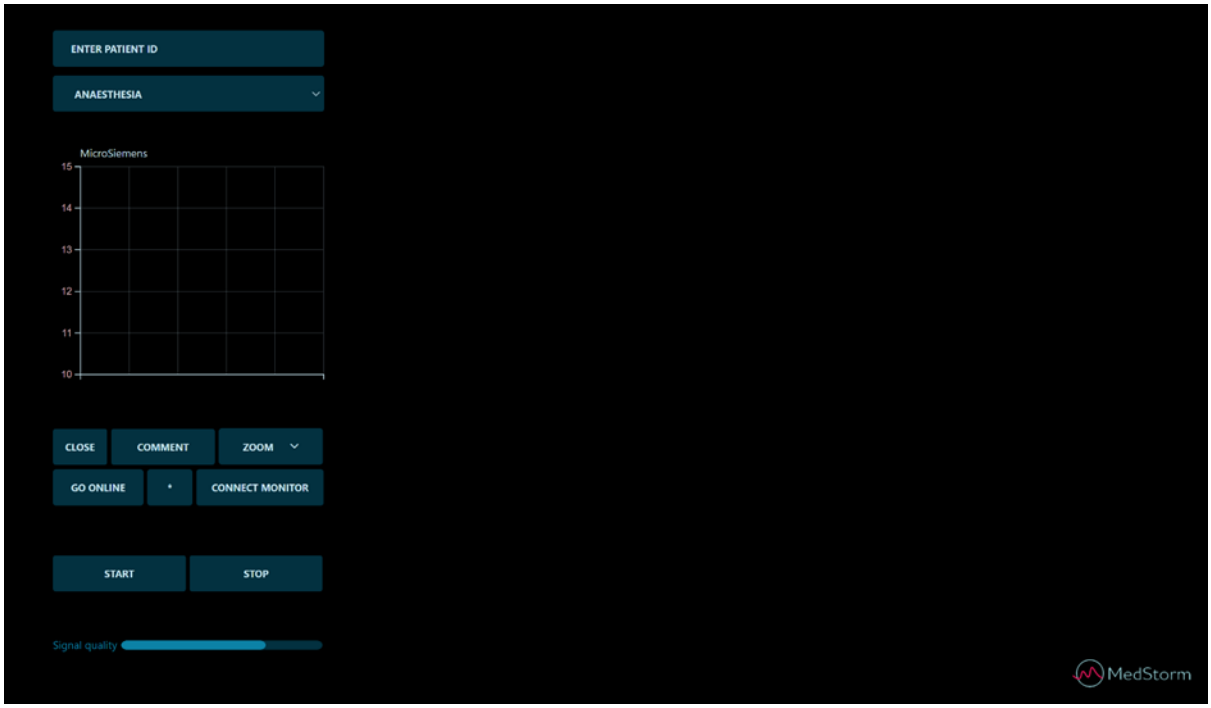


Figure 8-1: The interface of the PSS Application

8.2 Connect to PainSensor

The PSS Application is connected to a PainSensor through BLE.

- Click on the start button
- The PSS Application starts searching for PainSensors to connect with
- When finding a PainSensor, the PSS Application will connect to it

Note: If multiple sensors are found PC will connect to the sensor with the strongest signal.

- When the PSS Application is connected to the PainSensor and data is received, graphs showing the data will appear on the right side of the interface, Figure 8-2. The microSiemens graph will also show data.

Figure 8-2: The interface with example data

8.3 Application modes

Six different application modes can be selected: Anaesthesia, PostOperative, ICU, Infants, WithDrawal and Neural Block, Figure 8-3. Depending on which application mode is selected, the number of graphs on the right side of the application varies between 1-3. The different data that can be shown by the graphs are pain-nociceptive index, awakening index, nerve block index and withdrawal index.

- Anaesthesia: Pain-nociceptive index, awakening index and nerve block index
- PostOperative: Pain-nociceptive index
- ICU: Pain-nociceptive index and awakening index
- Infants: Pain-nociceptive index
- WithDrawal: Withdrawal index
- Neural Block: Nerve block index

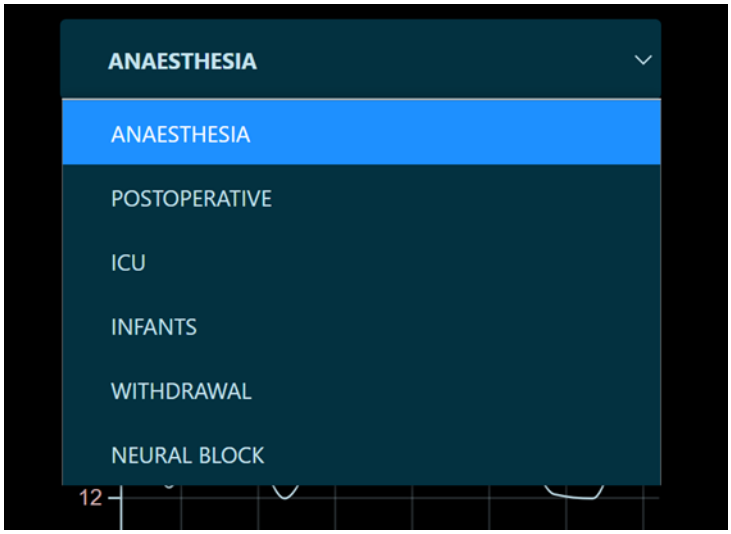


Figure 8-3: Applications as shown in the PSS Application

9 Appendix C - Environmental and handling conditions

Measuring Unit		
Operating	Ambient temperature	$+10^0$C – $+30^0$C (50^0F – 86^0F)
	Ambient pressure	700hPa – 1060hPa (10.2 PSI – 15.4 PSI)
	Ambient humidity	30% - 75%
Transport	Ambient temperature	-10^0C – $+70^0$C
	Ambient pressure	500hPa – 1060hPa (7.3 PSI – 15.4 PSI)
	Ambient humidity	10% - 90%
Storage	Ambient temperature	$+10^0$C – $+30^0$C (50^0F – 86^0F)
	Ambient pressure	700hPa – 1060hPa (10.2 PSI – 15.4 PSI)
	Ambient humidity	30% - 75%
Degree of enclosure protection	IP XX	
Transportation	It is possible to transport the system worldwide by air, road, ship and train.	
Drop / Free fall	It is possible to transport the system worldwide by air, road, ship and train.	
Altitude	The equipment cannot be used on altitudes higher than 2000 m above sea level.	
EMC/ESD	The PainSensor meets requirements in accordance with IEC 60601-1-2 Electromagnetic compatibility. The device complies with Part 15 of the FCC Rules.	

10 Appendix D - Technical specifications

Measurements accuracy	Noise level (1 – σ) below 0.0025 µS. This applies for resistive measurements on 100 µS.
Measurement range	1-200 µS
Classification of medical device	Class II A
Maximum current definition	36 µA RMS The maximum value of current that can be supplied to a patient trough the C electrode.
Power supply	The measuring unit operates on power from an external power supply of medical grade. Do not use any other than the provided power supply unit, unless it has been tested and verified by Med-Storm that it works together with the Measuring Unit Mains power input to measuring unit power supply is 90-264 VAC, 47-63Hz.
	Power consumption while loading is 2,5 W

Figure 10-1: Technical specifications

Mechanical dimensions

Part	Weight [kg]	Dimensions [mm]
PainSensor	~0.08	410 x 70 x 22 (with electrode cable) 85 x 70 x 22 (only housing)

Figure 10-2: Weight and dimensions

List of cables and maximum lengths of cables

Cable	Maximum length [m]	Manufacturer	Model or part #
Electrode cable, adult	0.33	Med-Storm Innovation AS	2010
Electrode cable, infant	0.33	Med-Storm Innovation AS	2011
Mains cable, PainSensor	2		

Figure 10-3: Cable lengths

11 Appendix E – Safety Standards and regulations

The PainSensor meets the requirements of the following safety standards and regulations:

Reference / referred to as	Description
93/42/EEC (MDD)	Directive 93/42/EEC Medical Device Directive (MDD)
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	EN 60601-1-2:2007 / IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2014)
EN 62304:2006	IEC 62304:2006 + A1:2015 / EN 62304:2006 + Cor.:2008 + A1:2015 Medical device software - Software life-cycle processes

The device complies with Part 15 of the FCC Rules.

12 Appendix F - Electromagnetic compatibility

The PainSensor has been designed and tested to comply with the electromagnetic compatibility (EMC) limits for medical devices to the EN/IEC 60601-1-2 standard for EMC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.
The PainSensor does not need to be maintained or checked regarding EMC aspects during its service life.

WARNING:
Use of the PainSensor 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.

Portable HF communication devices (radios) (including their accessories such as antenna cables and external antennas) should not be used within 30 cm (or 12 inches) of the parts and leads of the PainSensor designated by the manufacturer. Non-compliance may lead to a reduction in the performance characteristics of the device.

CAUTION:
Use of accessories and cables other than those specified or provided by Med-Storm could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radiofrequency electromagnetic interference (EMI) from portable or mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption. Evidence of disruption may include erratic readings (e.g. strong fluctuations in the measuring signals), equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site to determine the source of disruption, and take the following actions to eliminate the source(s):

- Turn equipment in the vicinity off and on to isolate the source
- Relocate or re-orient the interfering source
- Increase distance between source and the PainSensor unit
- Educate clinical staff to recognize potential EMI related problems
- Restrict use of cell phones, etc. near the PainSensor unit
- Purchase medical devices that comply with IEC 60601-1-2

Guidance and manufacturer's declaration – electromagnetic emissions		
The PainSensor is intended for use in the electromagnetic environment specified below. The customer or the user of the PainSensor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The PainSensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11	Class B	The PainSensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Figure 12-1: Electromagnetic compatibility 201

The device complies with Part 15 of the FCC Rules

Guidance and manufacturer's declaration – electromagnetic immunity			
The PainSensor is intended for use in the electromagnetic environment specified below. The customer or the user of the PainSensor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / Burst IEC 61000-4-4	+/- 2 kV for power supply lines	+/- 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 0.5 kV, +/- 1 kV (Line-to-line)	+/- 0.5 kV, +/- 1 kV (Line-to-line)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT for 0,5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT; 250/300 cycles	0% UT for 0,5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. Use of the PainSensor during power mains interruptions is no problem, because the PainSensor is powered by a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Figure 12-2: Electromagnetic immunity 202

Guidance and manufacturer's declaration – electromagnetic immunity			
The PainSensor is intended for use in the electromagnetic environment specified below. The customer or the user of the PainSensor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the PainSensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 3 Vrms in the ISM bands	3 V	**Recommended separation distance:** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 GHz
Radiated RF (IEC 60601-1-2:2014 4th edition	3 V/m 80MHz to 2700MHz	3 V/m	where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PainSensor is used exceeds the applicable RF compliance level above, the PainSensor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PainSensor. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Figure 12-3: Electromagnetic immunity 204

Guidance and manufacturer's declaration – immunity to high-frequency wireless communication equipment				
Service	**Test frequency in MHz**	**Frequency band in MHz**	**Modulation**	**Test level**
TETRA 400	385	380 – 390	18 Hz puls modulation	27 V/m
GMRS 460, FRS 460	450	430 – 470	1kHz sinus FM-modulated ± 5 kHz	28 V/m
LTE Band 13, 17	710, 745, 780	704 – 787	217 Hz puls modulation	9 V/m
GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	810, 870, 930	800 – 960	18 Hz puls modulation	28 V/m
GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	1720, 1845, 1970	1700 – 1990	217 Hz puls modulation	28 V/m
Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Bamd 7	2450	2400 – 2570	217 Hz puls modulation	28 V/m
WLAN 802.11 a/n	5240, 5500, 5785	5100 – 5800	217 Hz puls modulation	9 V/m

Figure 12-4: **immunity to high-frequency wireless communication equipment**

13 Appendix G – Pre use checklist

Check	Signature
Verify that the system is **not** used on a patient with a **skin condition which may affect skin conductance** (e.g. injury of the skin).	
Verify that maximum **one** PainSensor is used on a patient with an **electrically sensitive life support system** (e.g. implantable pacemaker or defibrillator).	
Verify that the system is **not** going to be used when the patient has an **injury affecting the sympathetic skin nerves**.	
Verify that the system is **not** going to be used more than **48 hours** in row, on the same patient, due to the electrodes that have to be changed.	
Verify that the **electrodes are placed** according to this manual. (Ch 4.1.1 b. for adults, Ch 4.1.1 c. for premature infants)	
Verify that the **electrodes are of the correct type** and approved by Med-Storm.	
Verify that if you **temporarily disconnect** any of the electrodes from the PainSensor, you see a magneta LED on the PainSensor.	
Verify that you have a **secondary monitor to determine** the patient's sensitivity to pain, such as e.g. blood pressure measurement.	
Verify that you are using **MedStorms charger cable and charger plug unit** to charge the device.	

For reasons of safety, the device may only be used if all of the requirements above are satisfied.

14 Appendix H – Physiological and clinical function of the PainSensor

Skin conductance is a measure of how easily electric current will travel through the skin based on the humidity of the skin. The Stress Detector system is measured in micro-Siemens [µS]. The physiological process is shown in Figure 14-1.

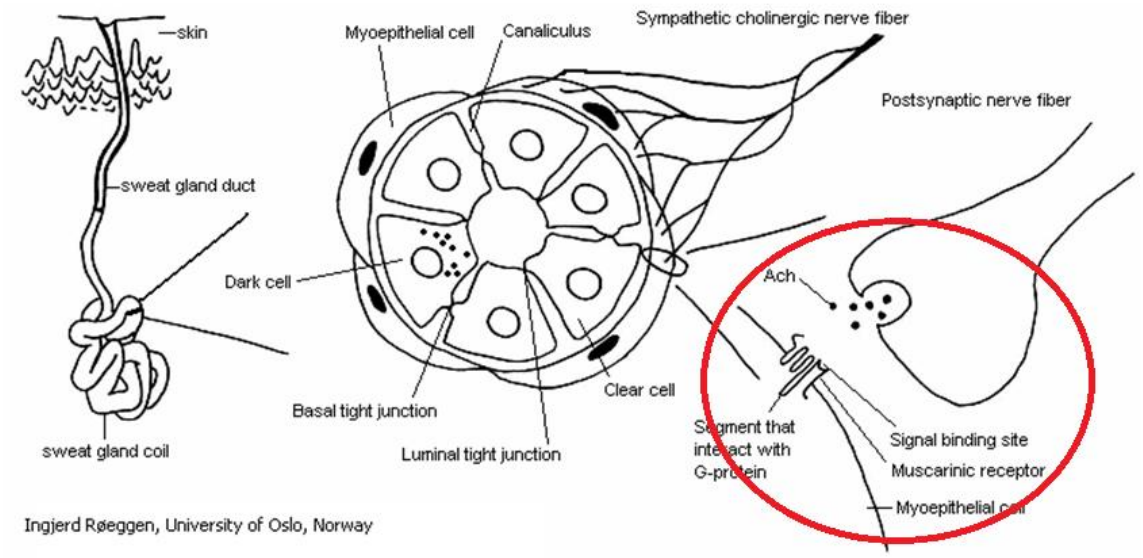


Figure 14-1: Physiological process which the PainSensor measures

The skin conductance is to a large extent determined by the number and activity of sweat glands. Sweat glands are controlled by the sympathetic nervous system. Since acetyl choline acts on the muscarine receptors, the skin conductance response is not influenced from changes in blood circulation or medication acting on the blood circulation. Moreover, the skin conductance response is not influenced from neuro muscular blockers (acting on nicotine receptors). When the skin sympathetic nervous system is firing, sweat is released within 1-2 sec and the conductance increase. When the sweat is reabsorbed the conductance decreases. This process creates one skin conductance peak. The number of skin conductance peaks correlates directly to the firing rate in the skin sympathetic nerves. Moreover, the amplitude of the peaks and the relatively area below the curve (accumulated difference between the conductance values at the registration curve when they are larger than the lowest microsiemens levels at the y-axis where the registration curve was observed in the analyzing window) correlate directly to how forceful the skin sympathetic nerves are firing. This is illustrated in Figure 14-2.

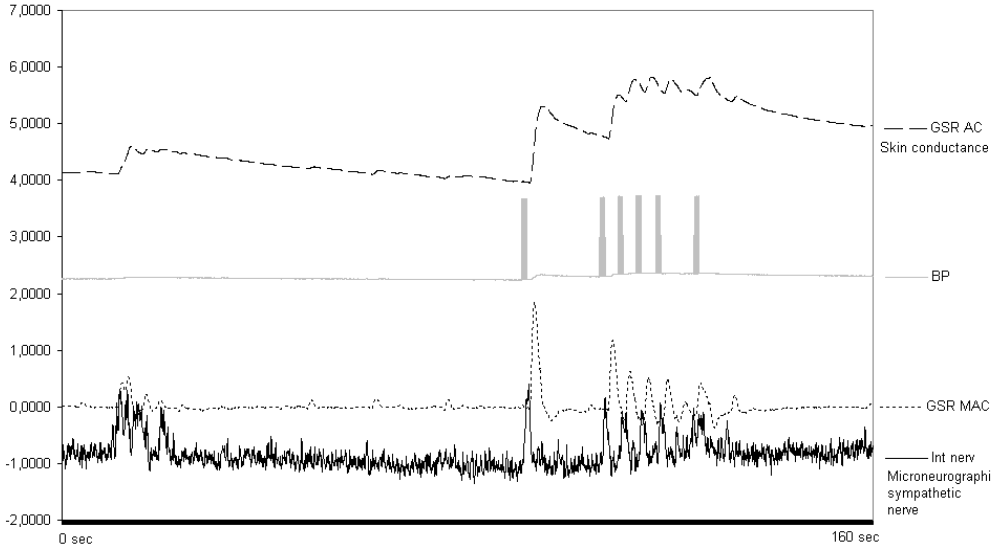


Figure 14-2: Correlation between the firing rate in the skin sympathetic nerves and the number of skin conduct-ance peaks. Moreover, small bursts in the sympathetic nerves give small skin conductance peaks and huge bursts in the sympathetic nerves give huge skin conductance peaks.