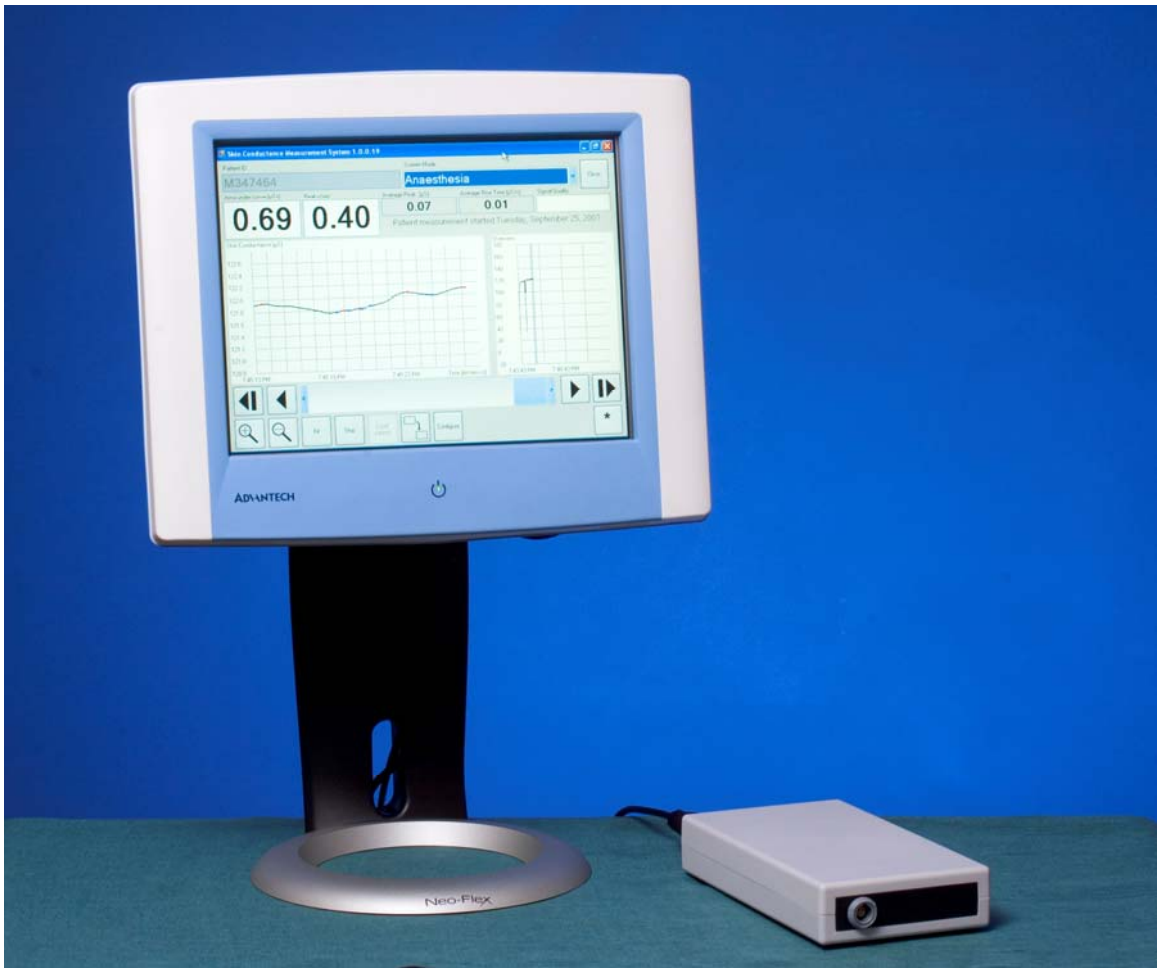
# Med-Storm
# Pain Monitor™




# User manual

**VERSION 1.0 ENGLISH MA001- 25, Part number 4001**


| | |
|---|---|
| **Manufacturer/Distributor:** | Med-Storm Innovation AS<br>Gimle Terrasse 4<br>NO-0264 Oslo<br>Norway |
| **Telephone:** | +47 90 93 98 10 |
| **Internet:** | http://www.med-storm.com/ |


CE 0413

# IMPORTANT

The user manual covers the operation of the MED-STORM Pain Monitor.

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 Pain Monitor is used.

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 Measuring unit 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 MONITOR 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 MONITOR. PERSONS USING THE PAIN MONITOR ARE RESPONSIBLE FOR THE SUPERVISION, MANAGEMENT AND CONTROL OF THE PAIN MONITOR.

# TABLE OF CONTENTS

1 Introduction ..... 4
1.1 Definitions ..... 4
1.2 Intended use ..... 4
1.3 Normal use ..... 4
1.4 Intended user ..... 4
1.5 Indications for use ..... 4
1.6 Contraindications for use ..... 4
1.7 Pre use checks ..... 4
2 Warnings ..... 5
2.1 Electrical shock hazard ..... 5
2.2 Environmental conditions ..... 5
2.3 Warning and information symbols ..... 5
3 Technical overview/Technical manual ..... 6
3.1 System overview ..... 6
3.2 Measuring Unit (MU) ..... 7
3.2.1 Power supply ..... 8
3.3 Computer ..... 8
3.3.1 Power supply ..... 9
3.3.2 PC stand ..... 9
3.3.3 Power supply holder ..... 9
3.3.4 Pain Monitor application software ..... 9
3.4 Electrode cable ..... 9
3.5 Electrodes ..... 9
4 Operating Instructions ..... 10
4.1 Instrument setup ..... 10
4.2 Skin electrode placement ..... 11
4.2.1 Artifacts ..... 11
4.2.2 Skin electrode placement on adults ..... 12
4.2.3 Skin electrode placement on infants ..... 13
4.3 Software and settings ..... 13
4.3.1 Stress Detector user interface overview ..... 14
4.3.2 Getting started ..... 15
Calculated measurement values ..... 17
4.3.3 Choose application mode ..... 17
4.3.4 Features in Pain Monitor ..... 20
4.3.5 Data transfer ..... 23
4.4 Error conditions ..... 23
5 Care and maintenance ..... 24
5.1 Life time ..... 24
5.2 Preventive maintenance ..... 24
5.3 Simplified function tests ..... 24
5.4 Support information ..... 24
5.5 Cleaning ..... 24
5.6 Scrapping instructions ..... 25
Appendix A - Environmental and handling conditions ..... 26
Appendix B - Technical specifications ..... 27
Appendix C - Safety Standards and regulations ..... 29
Appendix D - Electromagnetic compatibility ..... 30
Appendix E - Protection against data virus ..... 34
Appendix F – Pre use checklist ..... 35
Appendix G – Physiological and clinical function of the Skin Conductance Monitor ..... 36

# 1 Introduction

The manual corresponds to hardware of series C or higher and software of version 1.0 or higher.

## 1.1 Definitions

| | |
|---|---|
| SCMS | Skin Conductance Monitoring System= Skin ConductanceAlgesimeter = Pain Monitor |
| MU | (Skin conductance) Measuring Unit |
| NRS | Numerical Rating Scale |
| VAS | Visual Analog Scale |
| NFSC | Number Fluctuations of Skin Conductance |

## 1.2 Intended use

The Pain Monitor is intended to determine a patient's sensitivity to pain.

## 1.3 Normal use

Normal use is 24 hours/day 200 days a year. The electrodes do not allow continuously use for more than 48 hours, after 48 hours they have to be changed.

## 1.4 Intended user

Only trained physicians or nurses shall use the system.

## 1.5 Indications for use

Indications for use are for

- patients undergoing anaesthesia
- postoperative patients
- patients in the intensive care units
- infants from 25 weeks of gestational age

## 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.
- The device shall not be used with 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 Pain Monitor.

It is the responsibility of the user to ensure that any applicable regulations regarding the installation and operation of the Pain Monitor are observed.

The Pain Monitor must be used together with dedicated software and accessories.

## *2.1 Electrical shock hazard*

There are exposed voltages inside the measuring unit. There are no user-serviceable parts inside. Do not open the measuring unit. 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 A.

Do not immerse the Pain Monitor 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 are used on the Pain Monitor as warning and information symbols.

| | |
|---|---|
| **Warning symbol:** | |
|  | Read the entire operating manual before operating this Pain Monitor |
| **Information symbols:** | |
|  | The parts applied to the patient are insulated from the box and mains according to body floating (BF) model described in IEC60601-1. |
|  | Do not dispose of this unit. It should be returned to Med-Storm Innovation for proper material reuse or recycling |

**Table 2-1 Warning and information symbols**

# 3 Technical overview/Technical manual

## *3.1 System overview*

The Pain Monitor is an electronic conductance meter for detecting skin conductance changes on palmar and plantar skin sites to determine a patient's sensitivity to pain.

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

The Pain Monitor from Med-Storm consists of:

| Measurement equipment | # in sketch | Part # |
|---|---|---|
| Measuring Unit (MU) | 1 | 1001 |
| Power supply unit for MU with a power cable | 4 | 1002 |
| Mains cable for power supply MU, European | 6 | 2001 |
| Electrode cable adult, European | 2 | 2010 |
| Communication cable | 3 | 2012 |
| Presentation software | [not in sketch] | 3001 |
| Manual, version 1.0 English | [not in sketch] | 4001 |
| Short manuals, infants, postoperative and intensive care, and anaesthesia | [not in sketch] | 4002 |

| Operator station | # in sketch | Part # |
|---|---|---|
| PC | 7 | 6001 |
| Power supply unit with power cable | 8 | 6002 |
| Mains cable for power supply PC, European | 9 | 6003 |
| PC table stand | 10 | 6008 |
| Accessories | # in sketch | Part # |
| Mains cable for power supply MU, American | 6 | 2002 |
| Electrode cable, infant European | 2 | 2011 |
| Electrode cable, adult American | 2 | 2013 |
| Electrode cable, infant American | 2 | 2014 |
| Mains cable for power supply PC, American | 9 | 6004 |
| Power supply holder with rubber rings and cable collector band | [not in sketch] | 5001 |

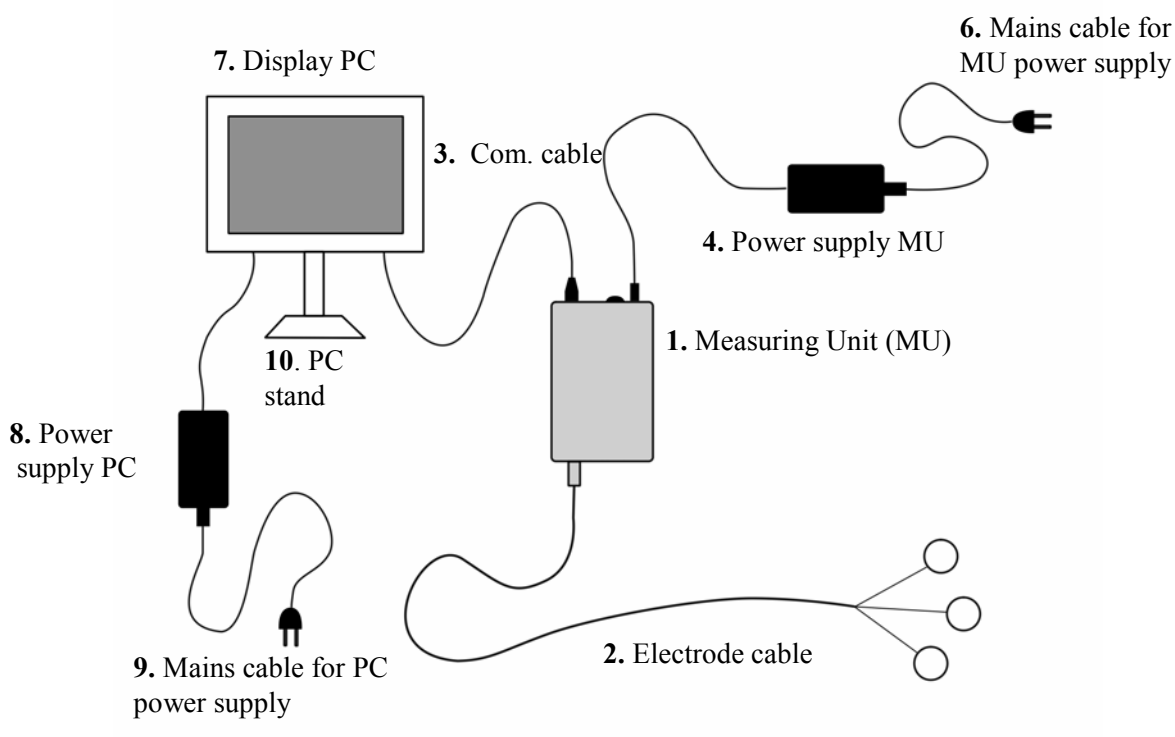



**Figure 3-1 System overview sketch**

## 3.2 Measuring Unit (MU)

The measuring unit, Figure 3-2 has three connectors and one power ON/OFF button. The electrode cable connector [4] is placed on one side. The power supply inlet [1], ON/OFF button [2] and communication connector [3] are found at the opposite side.

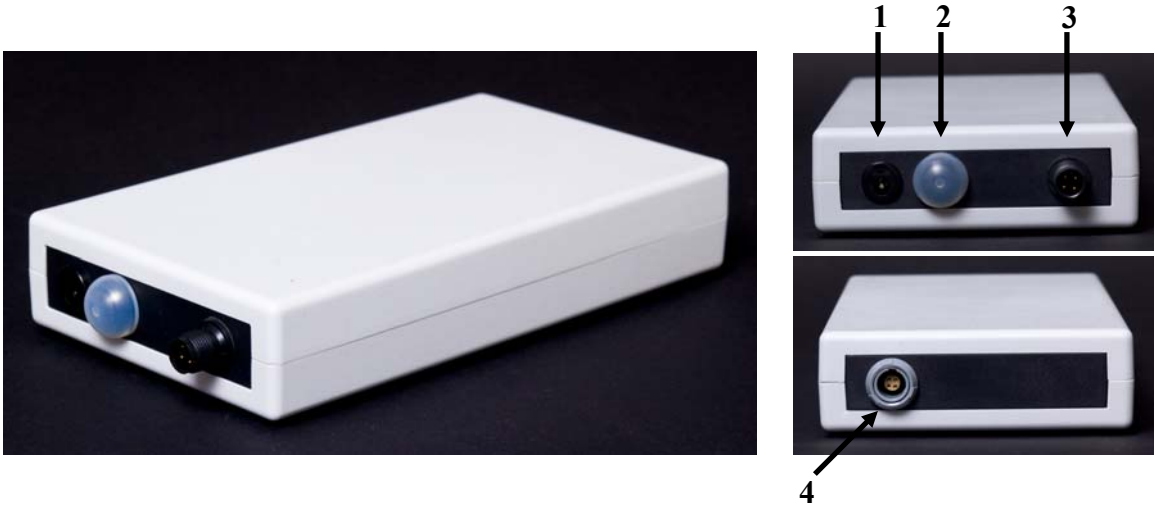



**Figure 3-2 Measuring Unit**

### 3.2.1 Power supply

**Figure 3-3 Measuring Unit power supply**

The power supply unit used together with the Measuring Unit is of medical grade. Do not use any other than the recommended power supply unit, unless it has been tested and verified by Med-Storm that it works together with the Measuring Unit.

The power supply unit, Figure 3-3 has a cable which connects to the Measuring Unit. On the opposite side is a stick for power.

## *3.3 Computer*

The computer recommended by Med-Storm is of medical grade with a display screen and PC in the same housing. The PC can be manoeuvred using the touch screen or by connecting an external keyboard and mouse (USB).

The connectors and ON/OFF button are placed on the rear side of the screen.

**Figure 3-4 Connectors at the rear side of the screen.**

To connect the Med-Storm Pain Monitor the following connectors and buttons (Figure 3-5) are used:

- power supply inlet [1]
- ON/OFF button [2]
- Communication cable connector [5]

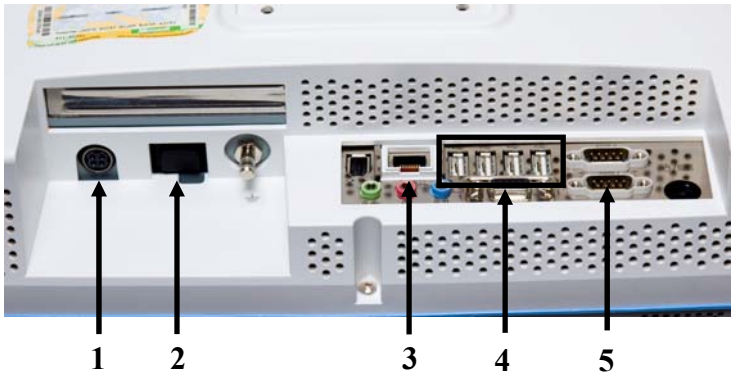



**Figure 3-5 PC connectors**

For data transfer or system management, the following connectors (Figure 3-5) can be used:

- Network cable connector [3]
- 4 USB connector [4]
  (for optional connection of Keyboard, Mouse and/or Memory stick)

If any other PC than the by Med-Storm recommended one is used, make sure the system specifications in Appendix B are followed.

### 3.3.1 Power supply

The PC power supply unit (Figure 3-6) has a cable connecting to the computer. The connector for the mains cable [1] is on the opposite side.


**Figure 3-6 PC power supply unit**

### 3.3.2 PC stand

A table stand can be used to operate and work comfortably with the system. The mounting mechanism of the stand has to be VESA-75 compatible.

### 3.3.3 Power supply holder

Rubber rings can be used to attach the measuring unit power supply and the PC power supply to the holder at the back of the computer.

### 3.3.4 Pain Monitor application software

The Pain Monitor application software allows the user to view and analyze a graph of the conductance in real time. It also allows the user to record the measurements for analysis at a later time.

The software is operated by using the touch screen (recommended) or an external keyboard and mouse.

## *3.4 Electrode cable*

There are two different electrode cables. One is used for adult patients (Figure 3-7) and the other for premature infants.

The electrode cable has one connector for the MU [1] and three connectors for the electrodes [2]. Se Figure 3-7.

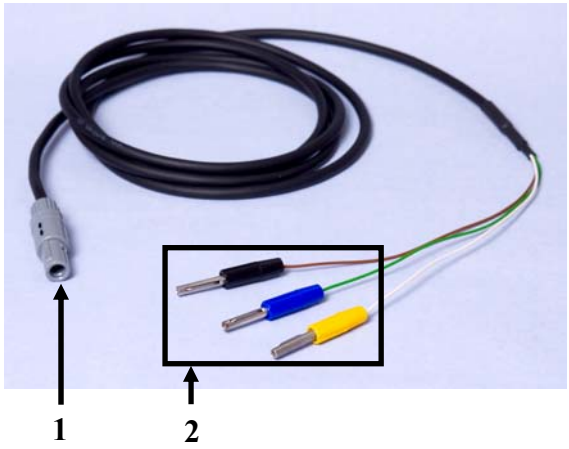



**Figure 3-7 Electrode cable**

## *3.5 Electrodes*

Different electrodes can be used for adult patients and premature infants after tested and recommended by Med-Storm.

Med-Storm recommends that electrodes from Med-Storm are used.

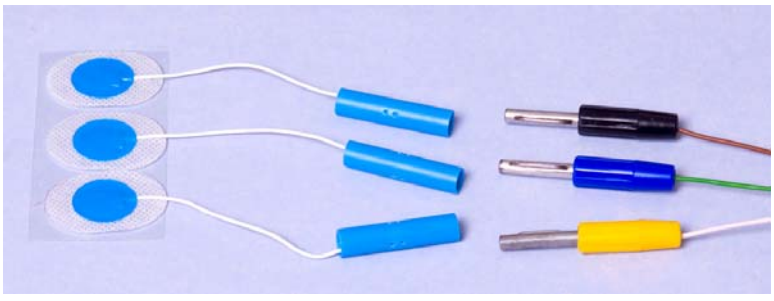


**Figure 3-8 Electrodes for adult patients**

# 4 Operating Instructions

The following instructions describe all necessary steps required to set-up and operate the Pain Monitor.

**Note.**
*This system 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 bellow 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.**
*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 D.*

**Note.**
*Portable and mobile RF communications equipment can affect medical electrical equipment.*

## *4.1 Instrument setup*

When assembling the system, a power supply holder could be mounted together with the table stand. The holder is placed between the PC and the table stand and shares the same screws as the stand.

**Connect the power cable to the MU. See**

1. Figure 3-41.

2. Connect the communication cable to the MU. The connector is keyed for correct connection. Make sure the groove [1] is aligned with the peg on the MU connector. Tighten the threaded locking collar for a secure connection.

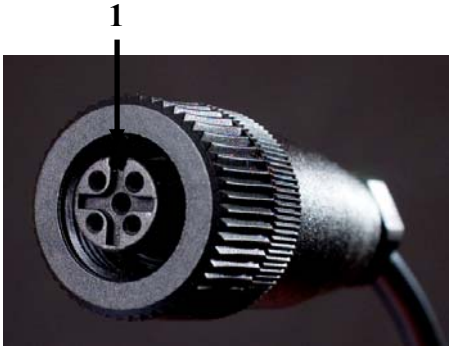



**Figure 4-1 Communication cable connecting to the MU**

3. Connect the communication cable to the COM1 port on the PC. Secure the cable by tightening the screws clockwise.

4. Connect the power cable to the PC. Make sure the connector is orientated according to the key in the power connector.

5. Connect the electrode cable to the MU. The cable connector has a peg marked with two arrows, to be aligned with the groove in the MU connector.

**Note.**
*To disconnect the electrode cable, pull straight out. Do not twist the connector.*

6. If the power supply holder is used, attach both power supply units to the holder at the back of the computer using the rubber rings. Use the two smaller rings to attach the MU Power supply to the holder and the two larger rings to attach the PC power supply to the holder.

   Slip one of the large rubber rings over the PC power supply unit. Place it towards the end, opposite the fixed power cable.

   Place the PC power supply unit in the holder with the mains cable connector pointing down. Slip the other large rubber ring over both the power supply unit and the metal holder from the lower end, until it fits in the fixing position. Roll the upper attaching ring to the top of the holder and then down until it fits in the fixing position.

7. Slip one of the small rubber rings over the MU power supply unit. Place it towards the end opposite the fixed power cable.
   Place the MU power supply unit in the holder with the mains cable connector pointing down. Slip the other small rubber ring over both the power supply unit and the metal holder from the lower end until it fits in the fixing position. Roll the upper rubber ring to the top of the holder and then down to the fixing position.

8. Connect the mains cables to both power supply units and a wall socket.

## 4.2 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.*

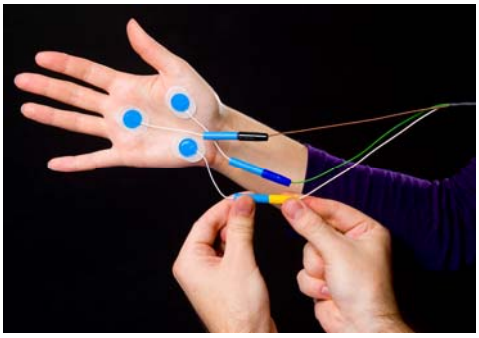


**Figure 4-2 Correct way of disconnecting the electrodes**

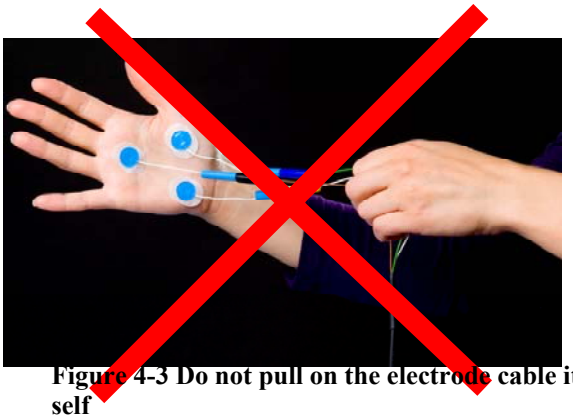


**Figure 4-3 Do not pull on the electrode cable itself**

### 4.2.1 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, the movement artefacts should be improved / eliminated.

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.

### 4.2.2 Skin electrode placement on adults

The intended placement of the electrodes on adults is on the palm of the hand.

1. Place the electrodes according to Table 4-1 and Figure 4-4.

   The distance in between each electrode shall be at least 7 mm. The M-electrode is placed at the hypothenar emminence because this area on the palm gives highest stability and thus less movement artifacts.

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

| Electrode | Characterization in Figure 4.4 | Connector color | Placing |
|---|---|---|---|
| Reference | R | Blue | Below long finger of the hand |
| Measure | M | Black | Hypothenar eminence of the hand |
| Current | C | Yellow | Hyperthenar eminence side of the hand |

**Table 4-1 Skin electrode placement on adults**

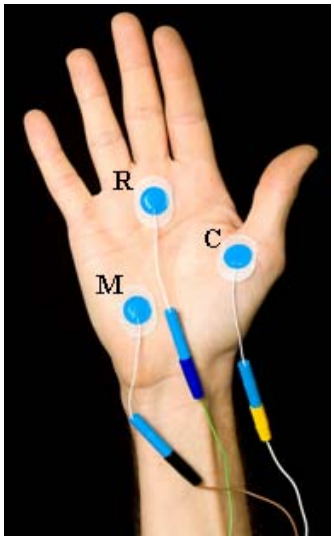



**Figure 4-4 Skin electrode placement on adults**

### 4.2.3 Skin electrode placement on infants

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

1. Place the electrodes according to Table 4-2 and Figure 4-5. 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

| Electrode | Characterization in Figure 4.5 | Marking color | Placing |
|---|---|---|---|
| Reference | R | Blue | On either side of the ankle |
| Measure | M | Black | On the sole of the foot |
| Current | C | Yellow | On either side of the ankle |

**Table 4-2 Skin electrode placement on infants**

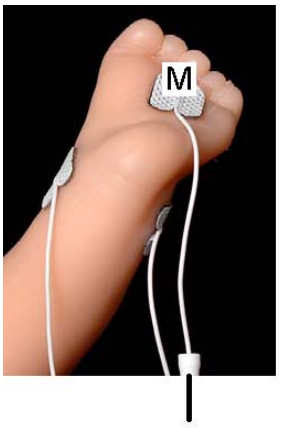



**Figure 4-5 Skin electrode placement on premature infants**

## *4.3 Software and settings*

No other software than Med-Storm approved software shall be installed on the display unit (PC).
The Med-Storm application software comes pre-installed on systems delivered with the recommended touch screen computer.
Software is also supplied on a CD. The 'Setup' file on the CD automatically installs the software on computers running Windows XP or Vista. For detailed computer requirements, please refer to Appendix B of this manual

Areas outlined in red in the figures are areas on the screen that have to be touched to perform specific actions. Areas outlined in black are areas referred to in the text.

The software is developed for touch screen use but can also be operated with a mouse connected to the PC.

### 4.3.1 Stress Detector user interface overview

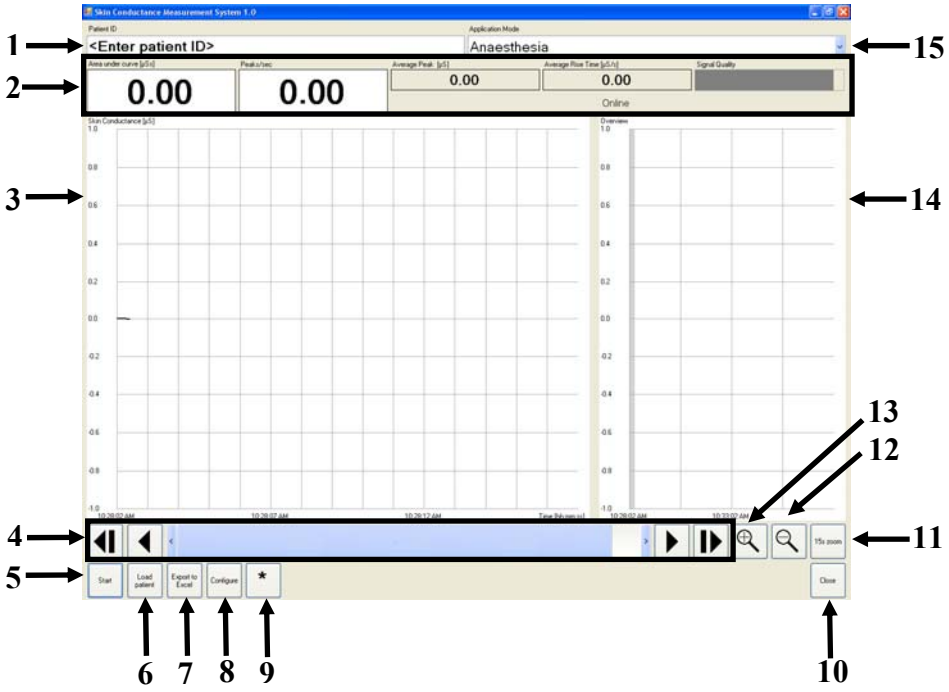



**Figure 4-6 Stress Detector user interface overview**

1. Patient ID field
2. Current measurement values
3. Skin conductance graph
4. Time scroll bar
5. Start/Stop/Go online button
6. Load saved data
7. Export data to Excel format
8. Configure settings
9. Event marker
10. Close the Stress Detector Application software
11. Auto fit time scale to 15 sec
12. Zoom out
13. Zoom in
14. Overview graph
15. Choose application mode

### 4.3.2 Getting started

1. Turn on the computer using the on/off button. Se part **3.3 Computer**.

2. The Pain Monitor application software should auto start. If not, touch the desk-top icon "**SCMS**" to start the Pain Monitor application software.

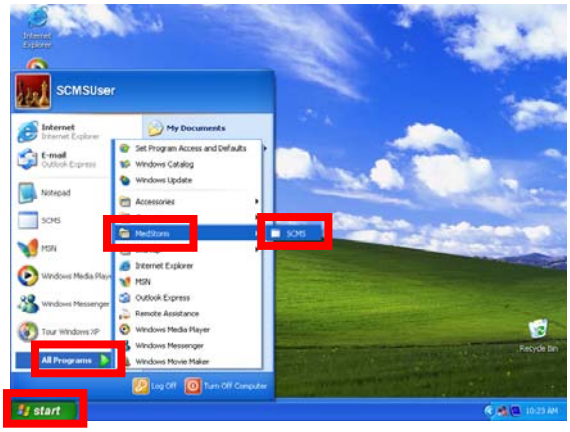



**Figure 4-7 Start SCMS software**

3. The Pain Monitor application software starts and following window will be visible on the screen. The software starts in a mode that shows measured data without saving it.

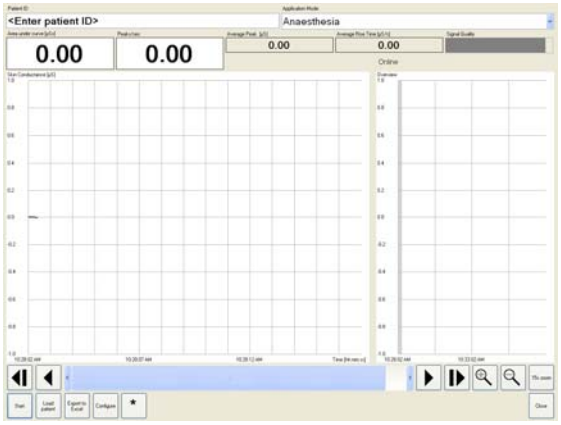



**Figure 4-8 Pain Monitor software**

4. To enter an ID for a patient touch the "**Patient ID"** box and a keyboard win-dow will appear on top of the Pain Monitor software window.

   Write a patient ID by typing on the on-screen keyboard. When finished, touch the on-screen keyboard "**Enter**" button. When the ID is written the data starts to be saved.

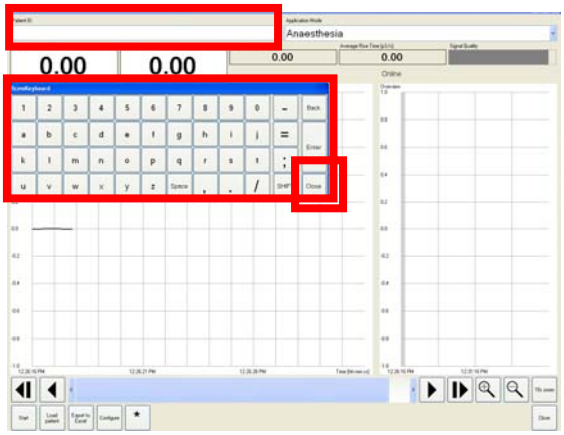



**Figure 4-9 Enter Patient ID**

5. Choose application mode by touching anywhere within the "**Application Mode"** field and then point on the desired mode.

   In these "Getting started" instructions we choose the "**Anaesthesia**" mode.

   For further information about the different modes se chapter 0.

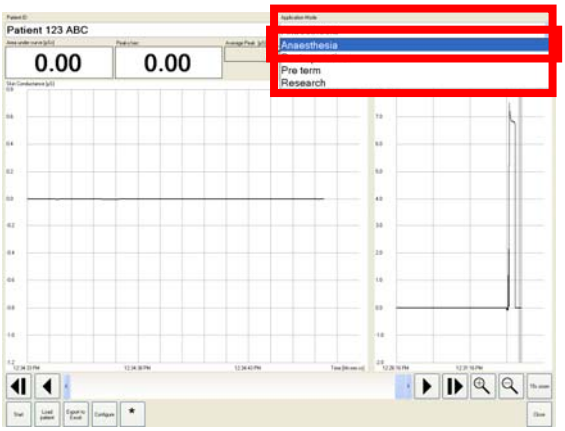



**Figure 4-10 Screen mode Anaesthesia**

6. The "**Start**" button automatically turned into a "**Stop**" button, when the patient id was entered. The date and time when the measurements took place are shown above the graphs.

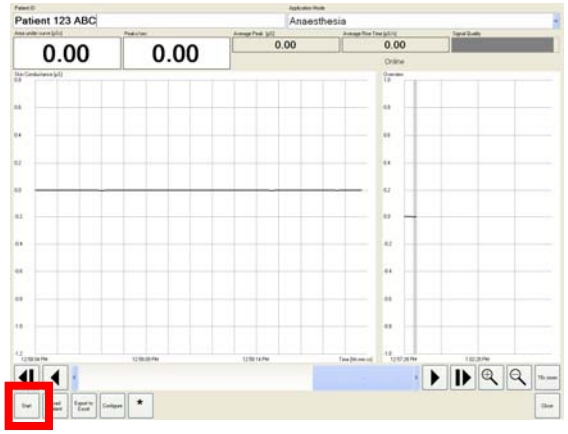



**Figure 4-11 Start/Stop button**

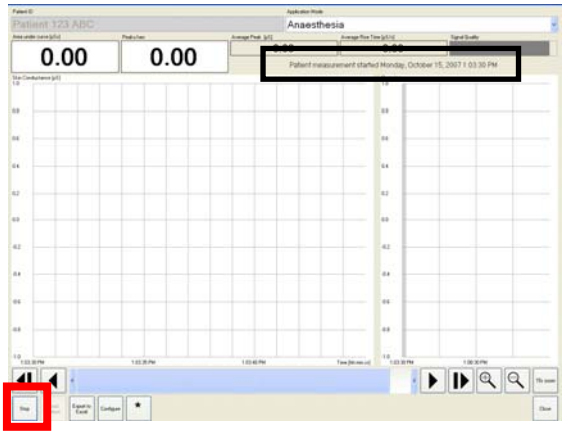



**Figure 4-12 Measurement date and time**

7. Verify that a graph is seen in the "**Skin Conductance [µS]**" window and that an overview is created in the graph window to the right.

   Calculated measurement values for the data visible in the left graph are updated continuously.

8. To end and store a session, use the "**Stop**" button. The button will turn into a "**Go online**" button and the location where the file is stored is shown above the graphs.

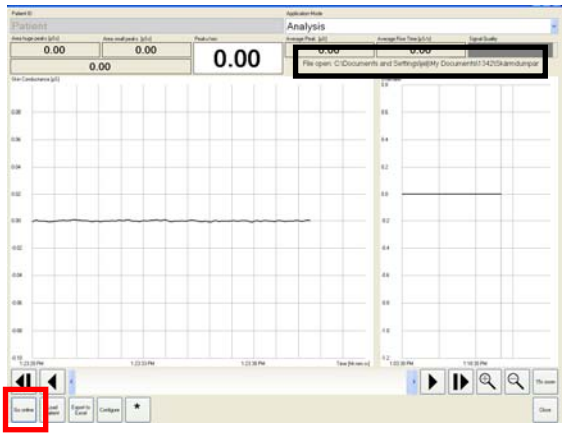



**Figure 4-13 End and store session**

9. To start measuring again, touch the "**Go online**" button. To start a new session start again from number 4.

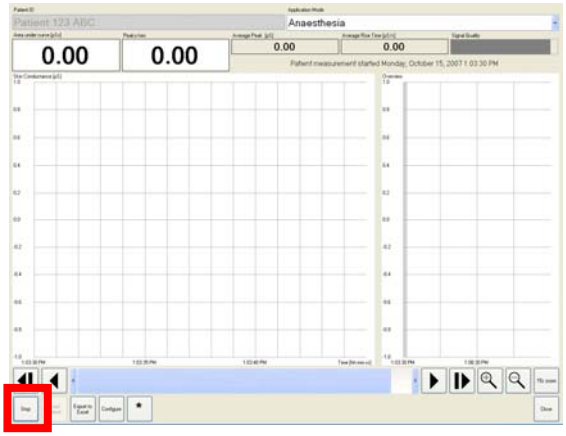



**Figure 4-14 Go online after ending session**

## Calculated measurement values

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

From the skin conductance peaks, number of measures can be calculated. The measures are calculated within the time window shown by the detailed graph (typically 15 seconds). The refresh rate is each sec.

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

**Average Peak [micro Siemens - µS]**
The difference in conductance value between the identified maximum and minimum of one peak is its peak value. The average is calculated from all peaks in the time window.

**Rise time [micro Siemens per second - µS/s]**
Rise time is the rate of increase or decrease from the start to the end of the measurement 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 4-15

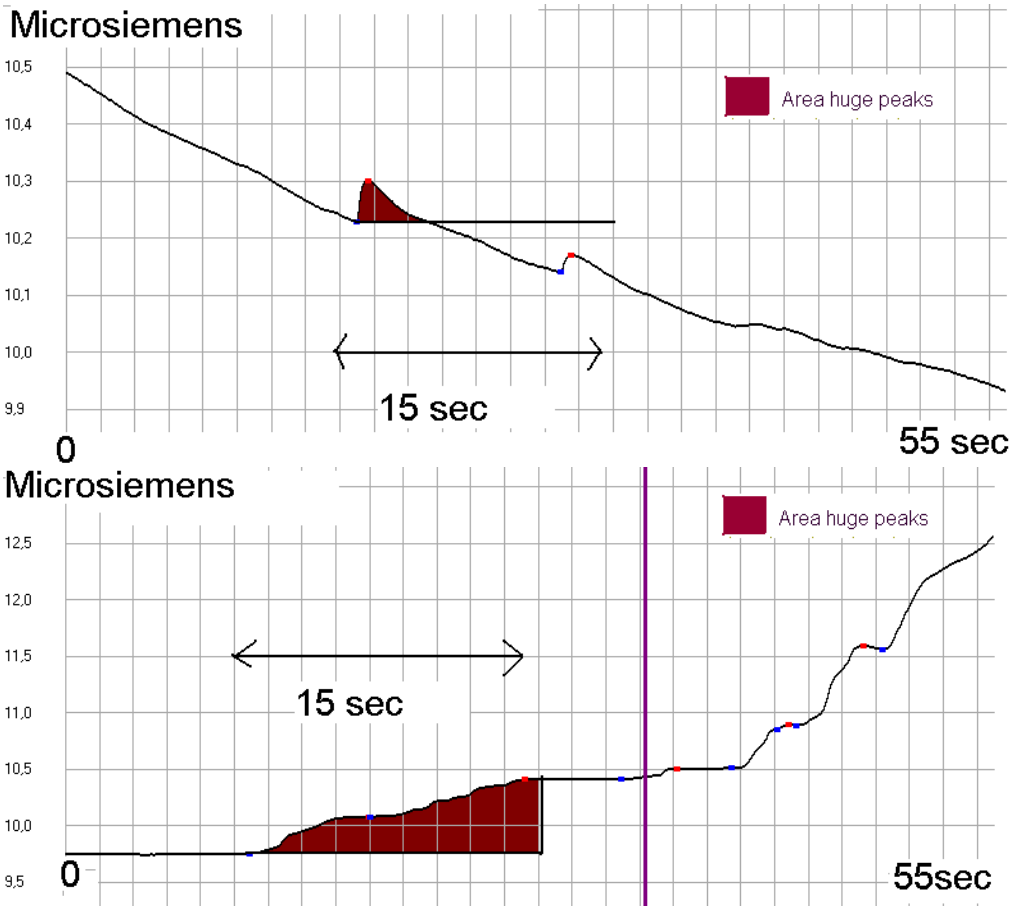



**Figure 4-15 Calculation of area huge peaks**

**Area small peaks [micro Siemens seconds - µSs]**
This measure is calculated by establishing a line between two adjacent peak minimum points. The area is the accumulated difference between the line and the skin conductance registration curve values when they are larger than the line. This is illustrated in Figure 4-16.

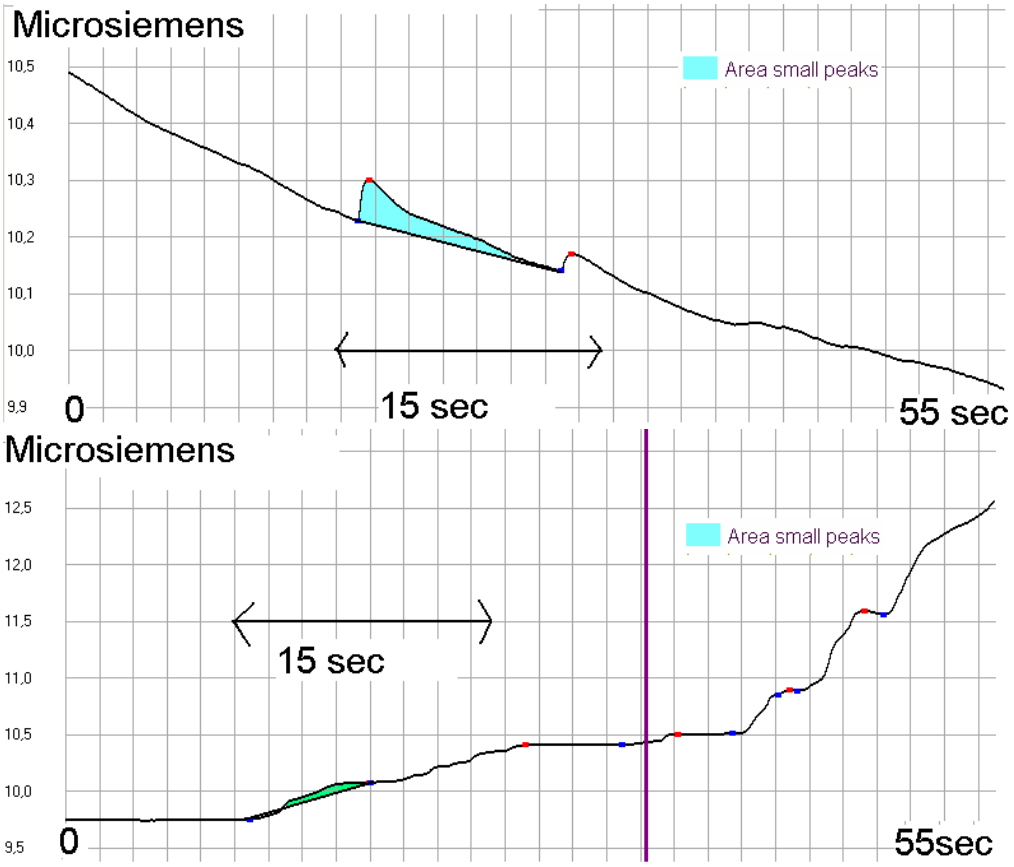



**Figure 4-16 Calculation of area small peaks**

**Area under curve [micro Siemens seconds - µSs]**
In some situations it is valuable to look at the larger of the two measures "Area huge peaks" and "Area small peaks". This is then referred to as "Area under curve".

**Signal quality**
Signal quality is not a measurement value but is used to determine when measurement values are reliable. It is shown as a horizontal bar in the interface and when the signal quality falls below a certain limit, the background of the detailed graph gets a yellow colour. There are two ways signal quality is measured, for each the warning limit giving yellow background can be set in the configuration dialog.

The first quality index measures the distortion of the reference signal applied to the skin. Normally, the signal is clean and the index has a small value. However, it will increase in the presence of other electrical devices attached to the patient (such as electrocoagulation devices), that disturb the reference signal. The second quality index provides a check of the integrity of the measured signal. It detects external interference, such as ESD discharges near the equipment, which may cause spikes in the measurement data. Both indices are compared to the threshold settings, in order to provide a warning that the quality of the measurement may not be trustworthy.

For further information on the quality index see also chapter 4.4.

### 4.3.3 Choose application mode

Choose between different application modes by touching anywhere in the "**Application Mode"** field and then mark one of the modes, fig. 4-17.

The different modes affect which measurement values are displayed above the graph windows.

**Figure 4-17 Choose application mode**


**Figure 4-17Anaesthesia mode**

## During anaesthesia

In the "**Anaesthesia**" application mode the measurement values shown are, fig. 4-18:

- **Peaks/sec**
- **Area under curve**

If the "Peaks per sec" measure is 0 the patient is sufficiently or too much 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 colour coded peaks per sec is yellow and may turn into red, the patient needs more analgesics, fig. 4.18. If the "area under" the curve increases to 10 the patient is about waking up from the stimulus. When the "area under" the curve turns to blue, the patients need more analgesics and hypnotics (forceful bursts in the sympathetic nerves when the patient is about waking up); fig. 4.19, the preset refresh time of one sec is recommended.

| |
|---|
| WHITE: 0.00-0.07 peaks per sec |
| LIGHT YELLOW: 0.14 peaks per sec |
| YELLOW: 0.21-0.27 peaks per sec |
| ORANGE: 0.33 peaks per sec |
| RED: 0.40 peaks per sec or more |

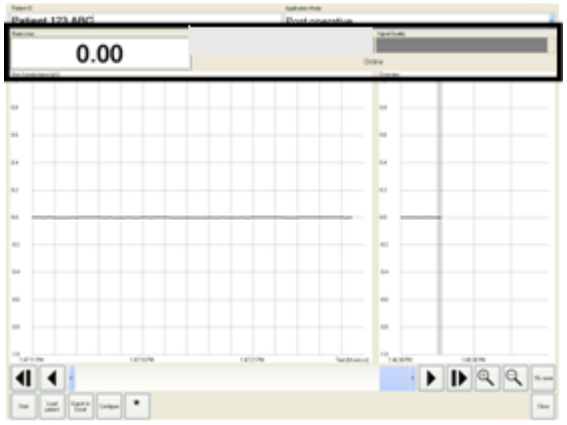
**Figure 4-18**

| |
|---|
| WHITE: 0.0-2.0 |
| LIGHT BLUE: 2.0-5.0 |
| BLUE: 5.0-10.0 |

**Figure 4-19**

## Post operative

In "**Post operative**" application mode the measurement values shown are, fig. 4-20:




- **Peaks/sec**

**Figure 4-20 Post Operative mode**

For post-operative pain 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) increase, 0 is no pain and 10 is worst thinkable pain (Fig 4-21). The peaks per second (number fluctuations of skin conductance=NFSC) shows the rate of firing in the sympathetic nerves. This index changes background colour (from white to yellow to orange to red) according to the increase in NRS or VAS score (Fig. 4.22): the sensitivity to determine pain less than 3 or like 3 on the NRS or VAS has the peaks per sec less than or like 0.21 peaks per sec (color from white to light yellow), the sensitivity to determine pain more than 3 but less or like 5 on the NRS or VAS has the peaks per sec more than 0.21 peaks per sec but less than or like 0.27 peaks per sec (color yellow), the sensitivity to determine pain more or like 6 but less or like 10 on the NRS or the VAS, has the peaks per sec more than 0.27 peaks per (colour orange to red). The index is also validated for pain in children and adult. The index may also be influenced from other sympathetic nerve stimulation like nausea, vomiting and anxiety. The analysing window should be 15 sec and the refresh time should be each sec.

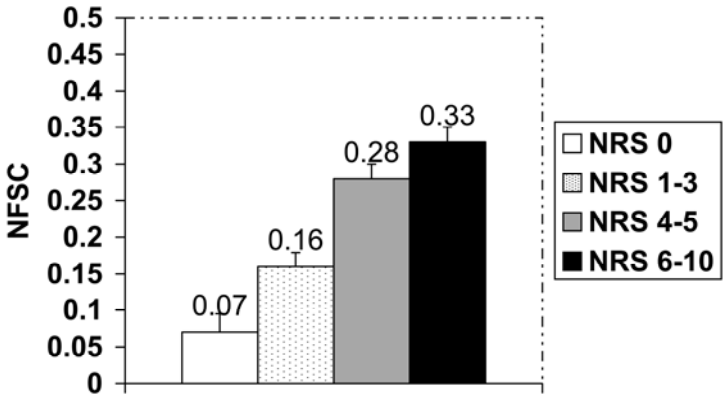



**Figure 4-21 Level of pain (Ledowski T et al. The assessment of postoperative pain by monitoring skin conductance results of a prospective study. Anaesthesia 2007, 62:989-993).**

| | |
|---|---|
| WHITE:<br>0.00 – 0.07 peaks per sec | No pain |
| LIGHT YELLOW: 0.13 - 0.21 peaks per sec | No pain or VAS 1-3 |
| YELLOW:<br>0.27 peaks per sec | Patient is active, can be pain VAS 4-5 or other stressors |
| ORANGE:<br>0.33 peaks per sec | Patient is possible in pain, VAS 6-8, go and evaluate the situation |
| RED:<br>0.40-0.70 peaks per sec | The patient is probably in pain, VAS 8-10, go and find out how to help the patient |

**Figure 4-22**

## Infants

In the "**Infant**" application mode the measurement values shown are, fig. 4.23:

- **Peaks/sec**

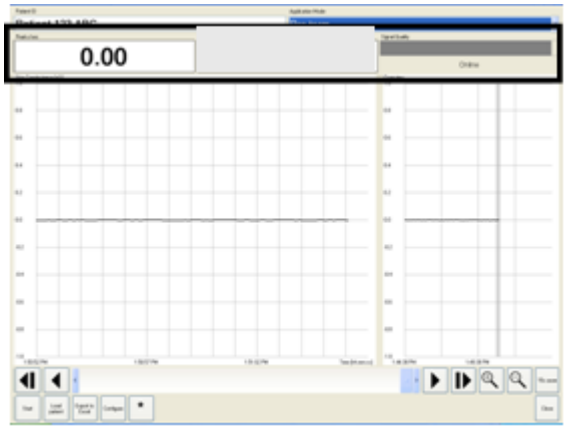



**Figure 4-183 Pre term mode**

The 'peaks per second index' 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, se Table 4.
The index, 'peaks per second', changes colour when the behavioural state changes and then it is 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., the background colour is white or light yellow/yellow. 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, the index is yellow. Eventually, when the infant is crying or is in significant pain (Prechtl scale 4- 5), then the peaks per sec are more or like 0.33, and the index turns from orange to red, figure 4-24. The analyzing window should be 15 sec and the refresh time each sec.

| 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) |

**Prechtl's Five Point Scale,**

| | |
|---|---|
| WHITE: 0.00-0.07 peaks per sec | The infant is calm |
| LIGHT YELLOW: 0.14 peaks per sec | The infant is calm and move a little |
| YELLOW: 0.21-0.27 peaks per sec | The infant is active, observe the infant, pain / discomfort threshold is reached |
| ORANGE: 0.33 peaks per sec | The infant is probably in pain / discomfort, evaluate the situation |
| RED: 0.40 peaks per sec or more | The infant is in increasing pain /discomfort |

**Figure 4-24**

## Analysis/Research

Depending on if the Pain Monitor application is used online or offline, the title displayed is "**Research**" or "**Analysis**". The measurement values shown are in both cases, Fig. 4-25:

- **Area huge peaks**
- **Area small peaks**
- **The hugest of these areas are also seen.**
- **Peaks/sec**
- **Average Peak**
- **Average Rise Time**
- **Signal Quality**

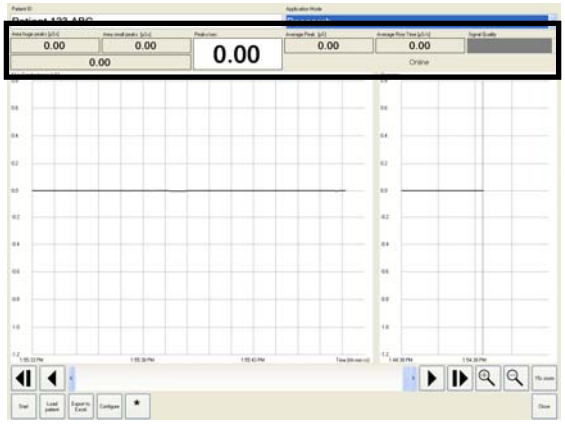



**Figure 4-25 Research mode**

### 4.3.4 Features in Pain Monitor

**Time scale**

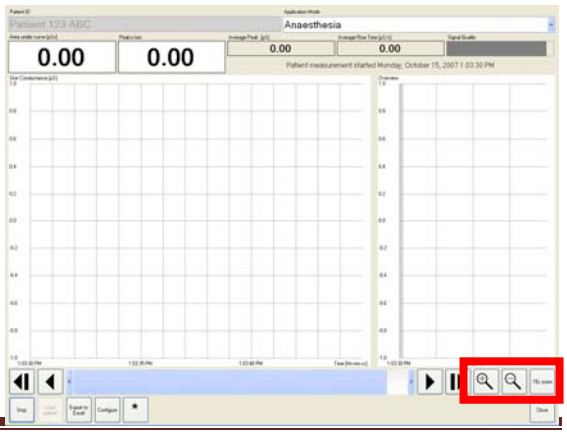
Adjust the time scale by using the three buttons in the lower right corner, Fig. 4-26.


Zoom in

Zoom out

Auto fit time scale to 15 s zoom

**Figure 4-196 Features in Pain Monitor**



**Mark event**

To mark events of interest during a measuring session, press the button in the left lower corner, fig. 4-27. The event will be marked in the graph as a vertical line with a * at the top. An on-screen keyboard will appear on top of the Pain Monitor program window to allow writing a comment corresponding to the event in the "**Enter comment**" area, Figure 28. If a comment is written to a marked event, the * will automatically change into a C (for Comment). When analyzing the recorded data the comment can be read if pointing at the marked event.

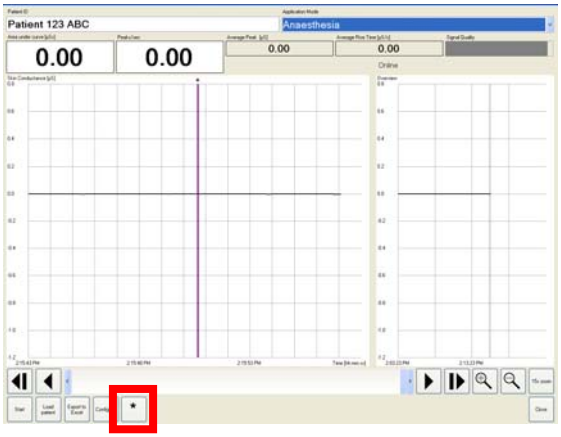



**Figure 4-27 Mark event**

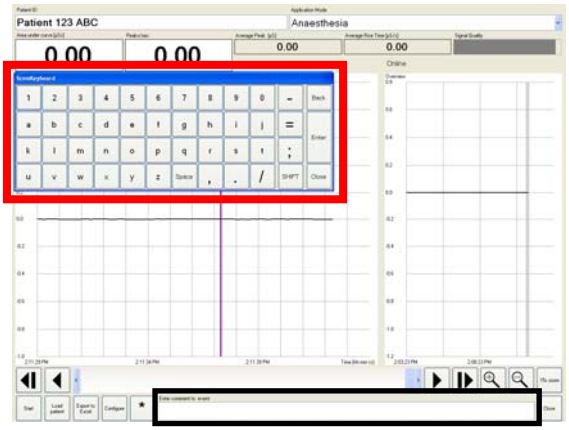



**Figure 4-208 Enter comment**

**Scrolling**

To look in detail on a specific measurement time period you can use the scroll bar together with the time scale buttons. When you offset your viewpoint from the latest measurement values, the automatic scrolling will stop. To restart automatic scrolling press the rightmost button on the scroll bar.

**Configuration**

To change settings for the program, touch the "**Configure**" button. A window will appear on top of the Pain Monitor program window where changes to the settings can be made, Fig. 4-29.

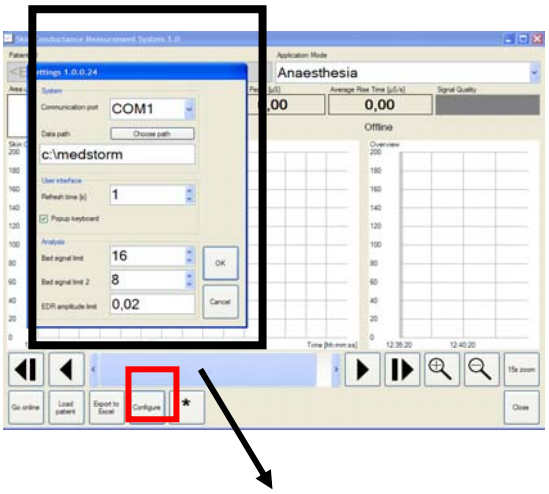
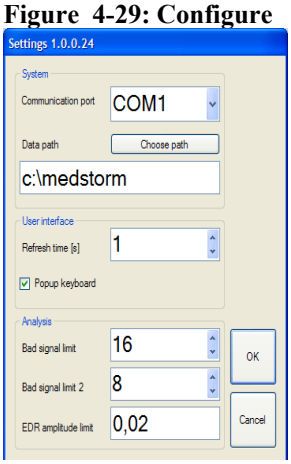



**Figure 4-29: Configure**




To select communication port, touch the communication port down pointing arrow and select the desired port. The default communication port is set to COM 1.

To choose data path for data recording, select "**Choose data path**" and browse the desired path. The default data path is set to C:\Medstorm to set the refresh time, touch the refresh time area and set the desired refresh time.

The recommended refresh time is 1s.

If the box "Popup keyboard" is chosen, the system is set to show an on screen keyboard when needed in the application (recommended when using touch screen).
Under the heading "Analysis", the settings for "Bad signal limit", "Bad signal limit 2" and "EDR amplitude limit" can be changed by selecting each area. The default settings for these values are the values shown in Figure 4.28. All signal limit values are reset to their default values when starting the program. If a setting is changed, the user is asked to confirm. Press "O**k"** to confirm the changed settings or "**Cancel**" to leave the settings unchanged.

**Analyze recorded session**

To load a session recorded earlier, use the "**Load patient**" button on the screen, Fig.4-30. A window will appear on top of the Pain Monitor program window where available patient measurements can be chosen. Choose a recorded session and then choose the data and time point of the session and touch the "**Ok**" button
If no or the wrong files are available when touching the "**Load patient**" button, another path than the desired are chosen in settings. The files available depend on which data path that has been set.

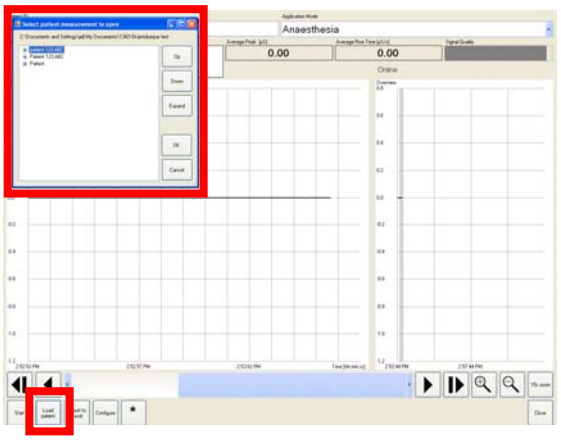



**Figure 4-30 Load patient**

**Export recorded data**

To use the "**Export**" feature, a mouse and keyboard must be used, Fig. 4-31. The Export feature will work on computers with Microsoft Excel and Med-Storm software installed.
If Microsoft Excel is not installed on the computer used for recording measurement data, then the data file can be moved from the recording computer to the "Excel computer" with e.g. a USB memory stick. (See chapter 4.3.5). On the "Excel computer" the data can be read with the "Load Patient" function in the Med-Storm software program, and then exported to Excel.

To export recorded data to Excel, use the button "**Export to Excel**". An export tool will appear on the screen where the export preferences can be set.

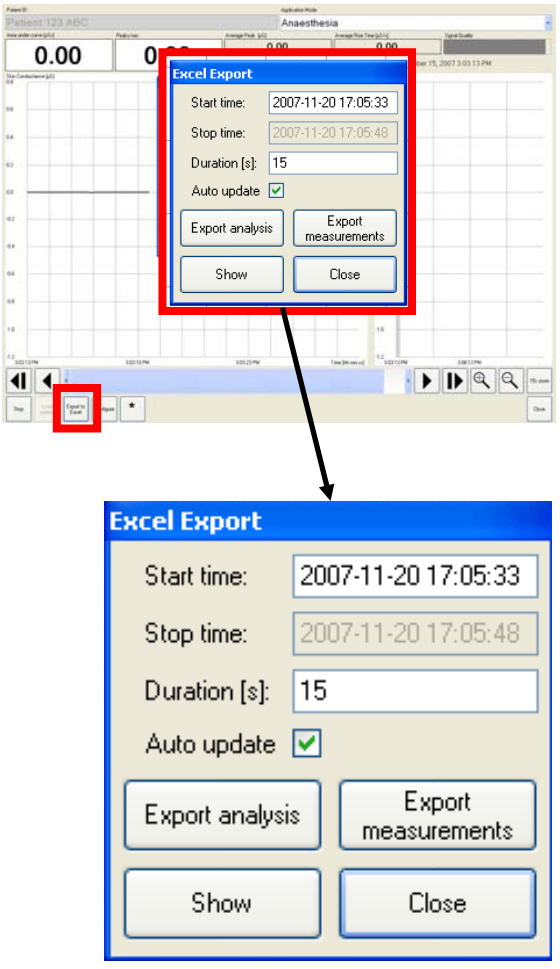



**Figure 4-31 Export data**

The export tool will export information that is inside the detailed graphs timeframe. By using the scroller under the detailed graph, or by changing the value in the start time field inside the export tool, the start time for the export can be changed.

The timeframe can be changed either by using the zoom buttons, or by changing the value in the duration field inside the export tool.

The box “Auto update” will be unchecked if the “Start time” and “Duration” fields in the export tool are used to set the time window. If measurement data is to be exported, change the “Duration” or the “start time” until the whole timeframe of interest is shown in the detailed graph after using “Show”. Alternatively use the time scroller and zoom tool to select the timeframe of interest. Keep the “Auto update” box checked if using the zoom buttons or the scroller to set the desired time window.

When the button “**Export Measurements**” is selected, the user will be able to insert a comment in the excel sheet before Microsoft Excel is started and the measurement values are exported.

If the button “**Export Analysis**” is selected, all derived analysis values will be inserted to one row in an excel workbook. For each time the button “**Export Analysis**” is selected, a new row with the analysis values for the detailed graph in view is exported.

To change the workbook to which the values are exported, the current workbook must be closed. A new workbook will then be created at the next export.

The data saved by the “**Export**” button is limited to a maximum of eight minutes (one limit in excel of maximum data points accepted).

### 4.3.5 Data transfer

To transfer data from the PC to another PC, connect a USB memory stick to one of the USB connectors in the Computer. Se Figure 3-5. Touch the “**Start**” button and chose “**My Computer**”. Browse and choose the files which are to be transferred.

## *4.4 Error conditions*

The Pain Monitor 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 Pain Monitor.

If any interference occurs, the system will automatically recognize the interference and indicate this by a red warning text “Bad signal quality”. The graph window will also turn yellow for the duration of the interference to indicate that the recorded signal is not reliable. See Figure 4-32

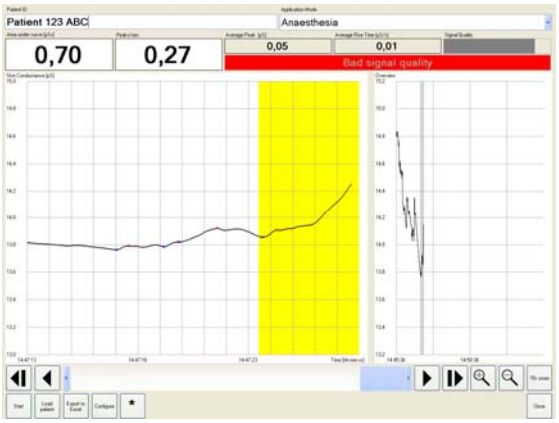



**Figure 4-32 Interference warning**

If the measuring unit looses contact with the M electrode, the error state will be indicated by a red warning text “Electrode error”, and with a brown background in the graph.

If the measuring unit looses contact with the operator PC, fig. 4-33, the error state will be indicated by a red warning text “Connection lost to MU” and with an orange background in the graph.

.

Using heating mattress, GVP Elettronica, SCL-MED (DM-WARM-12 commercial brand) gvp_md1@gvp.it, interference has been observed at the Skin Conductance registration curve.


**Figure 4-33 Contact lost warning**

# 5 Care and maintenance

Routinely inspect all electrical plugs and connections. Do not use if damaged.

## *5.1 Life time*

The minimum life time of the system is 5 years conditional that the instructions in this manual are followed.

## *5.2 Preventive maintenance*

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

The latest version of the Med-Storm application software will always be available for download from www.med-storm.com .
Please follow the setup instructions when installing or upgrading

## *5.3 Simplified function tests*

1. Start the PC unit and the measuring unit.
2. Make sure that the needed connections do not have any visible damage and are connected correctly according to instructions in chapter **4.1 Instrument setup**.
3. Start the Pain Monitor application software according to chapter **4.3.2 Getting started**
4. Verify that a graph is created in the Pain Monitor application software window and that the current measurement values are presented.

## *5.4 Support information*

| | |
|---|---|
| **Email** | support@med-storm.com |
| **Skype** | Med.storm.support |
| **Tel** | +47 909 398 10 |

## *5.5 Cleaning*

Always disconnect the Pain Monitor and accessories from its power supply before cleaning.

After each patient, the electrodes used shall be removed, and the Pain Monitor and its accessories may be cleaned by wiping a clean cloth dampened with 70% isopropyl alcohol or mild hospital cleaning detergent/bactericide.

***Note.***
*Under no circumstances should the Pain Monitor 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.*

## 5.6 Scrapping instructions

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

# Appendix A - Environmental and handling conditions

| **Measuring Unit** | | |
|---|---|---|
| Operating | Ambient temperature | +10$^0$C – +30$^0$C (50$^0$F – 86$^0$F) |
| | Ambient pressure | 700hPa – 1060hPa (10.2 PSI – 15.4 PSI) |
| | Ambient humidity | 30% - 75% |
| Transport | Ambient temperature | -10$^0$C – +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$^0$F – 86$^0$F) |
| | Ambient pressure | 700hPa – 1060hPa (10.2 PSI – 15.4 PSI) |
| | Ambient humidity | 30% - 75% |
| Degree of enclosure protection | IP X0 | |
| Vibration / Shock / Bump | 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. | |
| EMC/ESD | The Pain Monitor meets requirements in accordance with IEC 60601-1-2 Electromagnetic compatibility. The device complies with Part 15 of the FCC Rules" | |

# Appendix B - Technical specifications

| | |
|---|---|
| **Measurements accuracy** | Noise level (1 – σ) below 0,002 µS.<br><br>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<br>The maximum value of current that can be supplied to a patient trough the C electrode. |
| **Storage capacity** | Disc capacity is 2 GB. |
| **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<br><br>Mains power input to measuring unit power supply is 100-240VAC, 50-60Hz. |
| | PC operates on power from an external power supply. Mains power input to PC power supply is 100-240VAC, 50-60Hz. |
| | Power consumption is 53 W (PC: 50 W, MU 3W) |

**Table B-1 Technical specifications**

| **PC minimum configuration** |
|---|
| • Windows XP or Windows Vista<br>• Minimum 512 Mbytes RAM<br>• Minimum 10GB Hard drive<br>• CD-ROM drive or compatible media<br>• RS232-port or USB-RS232 adapter<br><br>When a PC is connected, the user must ensure that the entire system meet requirements in IEC 60601-1-1.<br>• The PC must be IEC 60601-1 graded if used within the patient environment.<br>• The PC must be IEC 60950 or similar graded if used outside the patient environment. It should always be grounded (protective earth) in the same room as the patient, if the PC should be outside the room of the patient. |

**Table B-2**

## Mechanical dimensions

| Part | Weight [kg] | Dimensions [mm] |
|---|---|---|
| Pain Monitor Measuring unit | ~0,37 | 210x113x41<br><br>(incl. On/Off button and rubber feet) |
| PC | 4.54 | 348 x 287 x 92 |

**Table B-3 Weight and dimensions**

List of cables and maximum lengths of cables

| Cable | Maximum length [m] | Manufacturer | Model or part # |
|---|---|---|---|
| Electrode cable, adult | 2 | Med-Storm Innovation AS | 2010 |
| Electrode cable, infant | 2 | Med-Storm Innovation AS | 2011 |
| Communication cable | 2,5 | Med-Storm Innovation AS | 2012 |
| Mains cable, PC | 2 | | 6003 |
| Mains cable, MU | 2 | | 2001 |

**Table B-4 Cable lenghts**

The table of cable lengths also represents the list of cables and transducers sold by the manufacturer as replacement parts for internal components.

Alternative mains cables might be used, but a mains cable that complies with the requirements in IEC60601-1 and any national deviations must be used when installing the Pain Monitor.

# Appendix C - Safety Standards and regulations

The Pain Monitor meets the requirements of the following safety standards and regulations:

| Standard | Referred to as |
|---|---|
| The DIRECTIVE 93/42/EEC | 93/42/EEC |
| IEC 60601-1 Medical electrical equipment | IEC 60601-1 |
| IEC 60601-1-1 Safety requirements for medical electrical systems | IEC 60601-1-1 |
| IEC 60601-1-2 Electromagnetic compatibility | IEC 60601-1-2 |
| IEC 60601-1-4 Programmable electrical medical systems | IEC 60601-1-4 |
| UL 60601-1 Medical Electrical Equipment | UL 60601-1 |

The device complies with Part 15 of the FCC Rules.

# Appendix D - Electromagnetic compatibility

| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The Pain Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Pain Monitor should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions<br>CISPR 11 | Group 2 | The Pain Monitor must emit electromagnetic energy in order to perform its internal function. Nearby electronic equipment may be affected. |
| RF emissions<br>CISPR 11 | Class B | The Pain Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | Class B | |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | Complies | |

**Table D-1 Electromagnetic compatibility 201**

The device complies with Part 15 of the FCC Rules"

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The Pain monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Pain Monitor should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | +/- 6 kV contact<br>+/- 8 kV air | +/- 6 kV contact<br>+/- 8 kV air | |
| Electrical fast transient / Burst<br>IEC 61000-4-4 | +/- 2 kV for power supply lines<br>+/- 1 kV for input/output lines | +/- 2 kV for power supply lines<br>+/- 1 kV for input/output lines | |
| Surge<br>IEC 61000-4-5 | +/- 1 kV differential mode<br>+/- 2 kV common mode | +/- 1 kV differential mode<br>+/- 2 kV common mode | |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | <5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 0,5 cycle<br><br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br><br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><br><5 % UT<br>(>95 % dip in UT))<br>for 5 sec | <5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 0,5 cycle<br><br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br><br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><br><5 % UT<br>(>95 % dip in UT))<br>for 5 sec | |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m | 3 A/m | |
| NOTE $U_T$ is the a.c. mains voltage prior to application of the test level. | | | |

**Table D-2 Electromagnetic immunity 202**

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The Pain Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Pain Monitor 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 Pain Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 V | **Recommended separation distance**<br>$d = 1{,}2\sqrt{P}$<br>$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80MHz to 2,5GHz | 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).<br>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]<br>Interference may occur in the vicinity of equipment marked with the following symbol.<br>  |
| NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.<br>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 Pain Monitor is used exceeds the applicable RF compliance level above, the Pain Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pain Monitor.<br>[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

**Table D-3 Electromagnetic immunity 204**

| Recommended separation distances between portable and mobile RF communications equipment and the |
|---|

| Pain Monitor | | | |
|---|---|---|---|
| The Pain Monitor delivery system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pain Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pain Monitor as recommended below, according to the maximum output power of the communications equipment. | | | |
| **Rated maximum output power of transmitter (W)** | **Separation distance according to frequency of transmitter (m)** | | |
| | **150 kHZ to 80 MHz** | **80 MHz to 800 MHz** | **800 MHz to 2,5 GHz** |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,38 | 0,38 | 0,78 |
| 1 | 1,2 | 1,2 | 2,3 |
| 10 | 3,8 | 3,8 | 7,8 |
| 100 | 12 | 12 | 23 |
| For transmitters rated at maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.<br><br>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br><br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

**Table D-4 Recommended separation distances 206**

# Appendix E - Protection against data virus

Data virus is a threat to the functionality of the Pain Monitor PC Unit. The following actions reduce the risk for virus attacks on the PC.

1. Do not use diskettes or CD´s in the computer.
2. Protect the network on which the PC resides with a firewall.
3. If considered necessary, install virus protection software on the PC Unit.

## Management of virus protection software

A virus protection software running on the same computer as the PC Unit may interfere with the Pain Monitor application software functionality. It may slow down the computer while inspecting files for virus or it may affect the Pain Monitor application software when removing a detected virus. New data viruses appear and thus the virus software needs to be updated. This update procedure may also affect the Pain Monitor application software functionality temporarily or permanently.

To avoid potential hazards associated with the management of virus protection software, the following rules shall be followed.

1. All installation or update of virus protection software on the PC Unit shall be supervised.
2. After installation or update of virus protection software or definition files, a functional test must be executed.
3. If virus has been detected on the PC Unit and rendered harmless, a functional test must be executed to verify that functionality was not affected.

# Appendix F – Pre use checklist

| Check | Signature |
|---|---|
| Verify that the system is **not** going to be used with a patient with **skin condition which may affect skin conductance** (e.g. injury of the skin). | |
| Verify that the system is **not** going to be used with a patient with **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.<br>(Ch 4.2.2 for adults, Ch 4.2.3 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 measuring unit, you get an error, reporting "electrode error" or "Bad signal quality". | |
| Verify that you have a **secondary monitor to determine** the patient's sensitivity to pain, such as e.g. blood pressure measurement. | |

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

# Appendix G – Physiological and clinical function of the Skin Conductance Monitor

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 G-2.

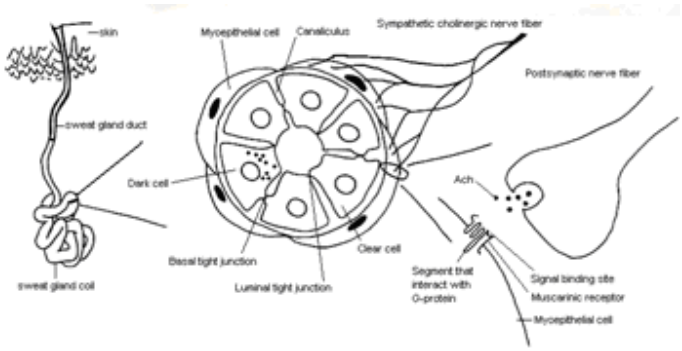



**Figure G-1 Physiological process which the Stress Detector measures**

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 G-2.

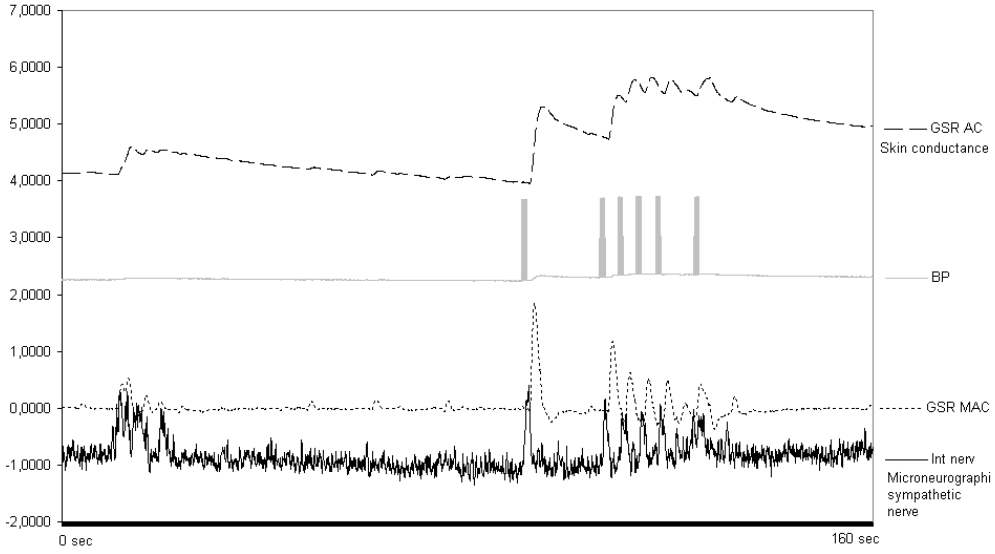



**Figure G-2 Correlation between the firing rate in the skin sympathetic nerves and the number of skin conductance peaks. Moreover, small bursts in the sympathetic nerves give small skin conductance peaks and huge bursts in the sympathetic nerves give huge skin conductance peaks.**