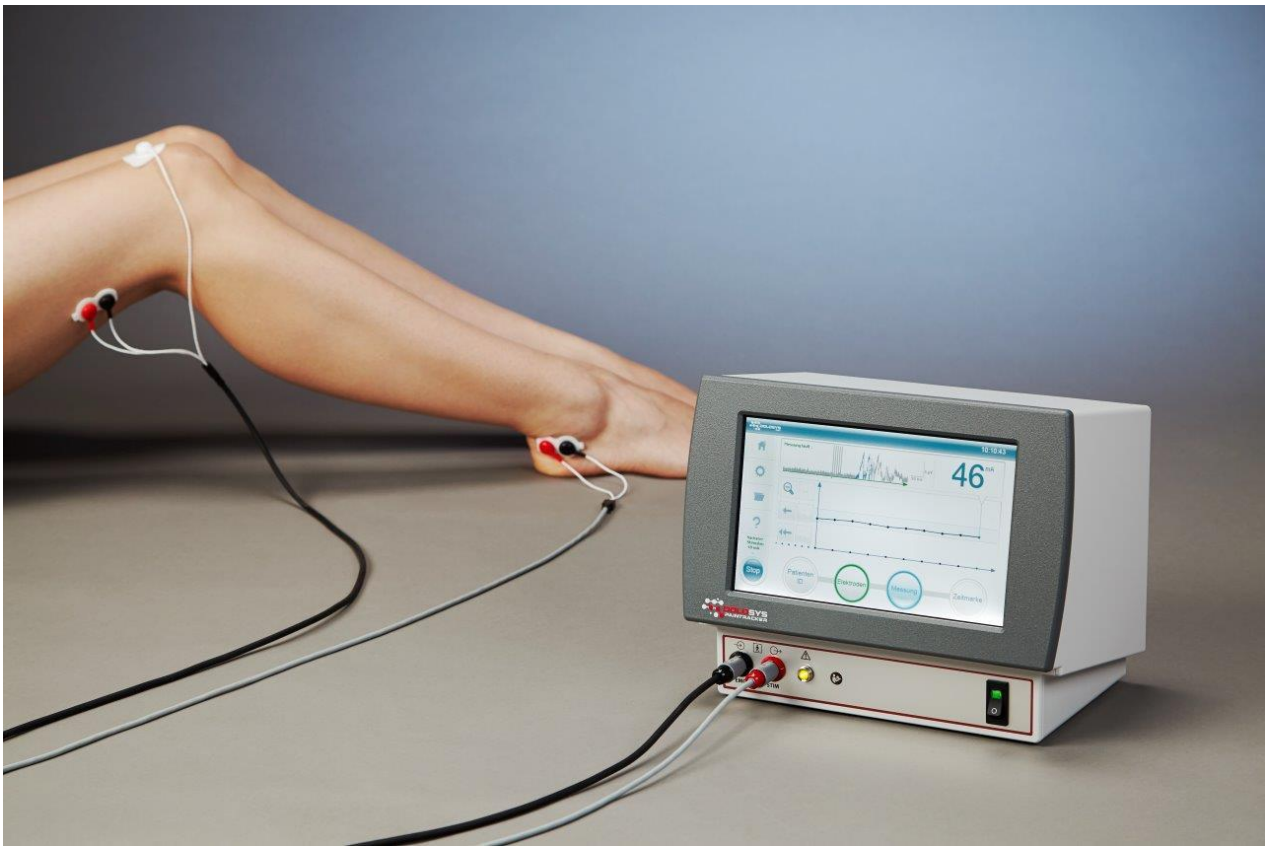
Instructions for use

Paintracker



Authors:
Prof. Dr-Ing. Bernhard Vondenbusch, Steinbeis Transfer Centre for Biomedical Technology
PD Dr med. Jan Baars, Dolosys GmbH

Date: 31.03.2015

DOLOSYS GmbH

Document information

The latest version of the instructions for use can be found on our website at:

www.dolosys.de

Version	Document name	Date
1.0	GA_Schmerzmonitor_V1.0_de	09.08.2013
2.0	GA_Schmerzmonitor_V2.0_de	28.03.2014
2.1	GA_Schmerzmonitor_V2_1_de	17.04.2014
2.2	GA_Schmerzmonotor_V2_2_de	07.07.2014
2.3	GA_Schmerzmonotor_V2_3_de	10.07.2014
2.4	GA_Schmerzmonotor_V2_4_de	11.07.2014
2.5	GA_Schmerzmonitor_V2_5_de	06.08.2014
2.6	GA_Schmerzmonitor_V2_6_de	26.08.2014
2.8	GA_Schmerzmonitor_V2_8_de	03.02.2015
2.9	GA_Schmerzmonitor_V2_9_de	31.03.2015

Manufacturer

Dolosys GmbH
Wöhlertstraße 8
10115 Berlin
Germany

Tel: +49 30 275 92842
Fax: +49 30 275 92847
Email: info@dolosys.de
Internet: www.dolosys.de

We retain the right to make technical changes.

Table of contents

Thank you for choosing the Paintracker monitoring system by Dolosys. This device is approved for medical use. To ensure that the device is used properly, please read the instructions for use carefully and pay attention to the safety instructions identified by the signal words Danger, Warning and Caution.

1 Information about the instructions for use

The safety advice in these instructions for use is identified as follows:

DANGER:
Indicates an imminent hazardous situation. Failure to follow the safety advice will result in death or severe injuries.

WARNING:
Indicates a hazardous situation. Failure to follow the safety advice may result in death or severe injuries.

CAUTION:
Indicates a potentially hazardous situation. Failure to follow the safety advice may lead to minor injuries or damage to property.

INFORMATION:
Indicates suggestions and directions for using the device. It is advised to follow the safety advice.

2 Use and function

2.1 Basic information

The Paintracker pain monitor is an electrical stimulation-conduction unit that evokes nociceptive reflexes (pain reflexes) which are then used to monitor pain therapy and to support optimal dosage of analgesics for non-communicative patients. The pain monitor is a transportable tabletop unit measuring 28 cm × 22 cm × 19 cm (W×H×D) that can be set up next to the patient's bed.

The measurement principle is based on stimulation of a nerve and recording and analysis of the electromyogram (EMG) for a muscle in an extremity.

2.2 Proper use

The device is operated using the touchscreen. A yellow warning light indicates when the device is in stimulation mode. The connections for the stimulation electrode (red) and the measurement electrode (black) are located on the front of the device at the bottom left. The power switch is located on the front of the device on the bottom right-hand side while the device's electrical socket with fuses and a USB port are located on the back of the device. The USB flash drive must not be removed during operation as this may cause errors in the file system. Removal of the USB flash drive during a measurement results in termination of the measurement and loss of data.

The Paintracker is a stimulation-conduction unit that determines the motor responses following electrical stimulation of a nerve in the form of electromyographic signals or other evoked potentials. The stimulation strengths reached are designed so that pain reflexes (nociceptive reflexes) can be evoked using the device. By determining the pain reflexes, the pain therapy can be objectively monitored using the device in sedated, anaesthetised and even awake patients. The information obtained about the excitability of the pain reflexes by monitoring a patient can provide the doctor with additional, objectifiable indications about the effect of pain therapy or the individual pain sensitivity. The data obtained by monitoring is used to expand the basis for the doctor's decisions regarding the pain therapy. The choice of pain therapy and the selected dosage must always be made by the doctor on the basis of the overall clinical impression and the individual patient's situation. It is not permitted to determine therapeutic measures solely on the basis of the excitability of pain reflexes recorded on the monitor.

Along with determining the pain reflexes, the device can also be used to stimulate and determine other non-nociceptive reflexes in the extremities (e.g. Hoffmann reflex). In this way, as for the pain reflexes, the integrity of the neuronal and muscular structures (afferent nerve, central nervous system [e.g. spinal cord], efferent nerve, muscle) involved in relaying the reflex can also be investigated as can pharmacological or (patho-)physiological effects on these structures. Furthermore, (mixed) motor nerves can also be stimulated with the device and the muscle response of the corresponding muscle can be determined. This application also provides information about the integrity of the impulse conduction system of the structures involved (nerve/muscle in this case).

Important instructions about using the Paintracker monitoring system in unconscious patients to measure analgesia

The pain reflex threshold used as the output parameter of the Paintracker monitoring system is suitable for assessing the excitability of the spinal section of the pain processing system in adult or paediatric patients. The afferent section of the reflex arc is made up of the Aδ and C fibres. These fibres are stimulated by the electrical stimulation of the monitor and conduct the stimulus to the spinal cord. Following polysynaptic relaying via a network of interneurons, motor neurons, which form the efferent branch of the reflex, are then activated. Activation of the motor neurons then leads to contraction or electrical activation of the individual muscle fibres which is measured by the Paintracker monitoring system. Opiates and other analgesics reduce the excitability of the reflex arc by, for example, reducing the release of transmitters from the presynaptic nerve endings of the Aδ and C fibres. A reduction in the excitability of the reflex arc is seen on the Paintracker monitoring system as an increase in the reflex threshold. Generally, changes in the reflex threshold reflect the sensitivity of the patient to nociceptive stimuli. However, this does not apply to the situation when changes to the excitability of the reflex arc are made by selectively influencing the efferent branch of the reflex arc (motor neurons, motor end plate, muscle). Examples of selective influences on the efferent branch of the reflex arc include the effect of muscle relaxants or myopathies such as critical illness myopathy.

Caution: When interpreting the measurements, possible effects on the efferent branch of the reflex arc must be taken into consideration. Measurements in patients who have been administered muscle relaxants are not useful. As expected, unconscious patients who have been sedated or anaesthetised have a higher pain reflex threshold than non-sedated patients and the Paintracker accordingly administers higher currents to these patients. It is possible that these stimuli may also affect other physiological parameters (heart rate, blood pressure, breathing rate).

Warning: To avoid possible complications that may occur in critically ill patients as a result of autonomic reactions, it is essential that a doctor or other medical personnel directly monitors the patient, particularly the circulatory parameters, during measurement.

3 Explanation of symbols used, safety advice

3.1 Nameplate

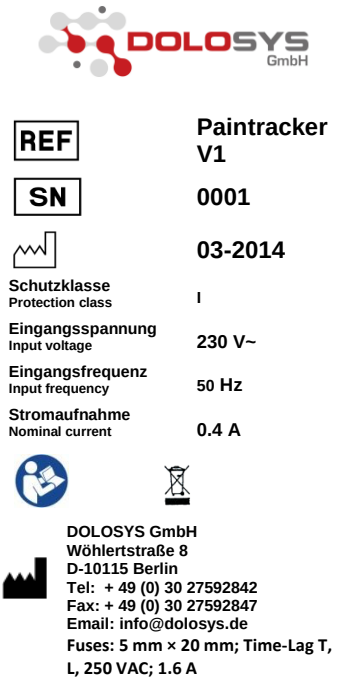


Figure 1 Nameplate of the pain monitor, Paintracker model

3.2 Legends for the symbols used on the nameplate and the front of the device

REF	Manufacturer's catalogue number for the device		Follow the instructions for use
SN	Device serial number	CE	CE marking (Conformité Européenne) as evidence of compliance with the European Medical Device Directive. The additional number indicates the notified body.
	Date of manufacture Month/Year		Manufacturer as defined by the Medical Device Directive 93/42/EC
	'Caution'; general warning		Indicates disposal separate from normal waste
	Applied part type BF (body floating)		'Off' voltage on the power switch
	Input		Output

3.3 Safety advice

The pain monitor is a class IIa medical device with two applied parts of type BF.

All limits for leakage currents required by the DIN EN 60601-1 standard are complied with, provided the **safety instructions** listed below are adhered to.

DANGER:
Risk of explosion – The monitor is not intended for operation in areas at risk of explosion used for medical purposes.

WARNING:
The device emits current densities of more than 2 mA/cm^2 which requires the user to pay close attention. The device may therefore only be operated in the presence of trained personnel instructed in the use of the device as defined by the German Ordinance on the Installation, Operation and Use of Medical Devices (MPBetreibV). The user must be a doctor, a registered nurse or a practice nurse. The healthcare establishment must keep a device log with the details of the trained users as defined by MPBetreibV.

WARNING:
Hazard for personnel – The device may only be connected to other electrical medical devices or with parts of systems if the user has ensured that the safety of patients, the user and the environment is not negatively affected by this connection. The relevant standards for electrical medical systems must be observed.

WARNING:
Hazard for personnel – The power supply cable (power cord) must be checked for damage before each use.
Personnel must not open the monitor themselves nor attempt to maintain or repair the monitor themselves.
The monitor must not be used if
- liquid has penetrated the device
- the device has been dropped and the housing is damaged
Do not immerse the device in liquids.
Before cleaning the device, the device's power plug must be disconnected from the mains.

WARNING:
Danger of suffocation – Dispose of the packaging material so that it is kept out of the reach of children and comply with the pertinent waste disposal guidelines.

WARNING:
Simultaneous connection of a high-frequency surgical device or defibrillator and the Paintracker to the patient can lead to burns on the skin under the electrodes and possibly damage the Paintracker. Before using a defibrillator, the Paintracker must be disconnected from the patient!

WARNING:
Using the Paintracker near a shortwave or microwave therapeutic device can lead to instabilities in the output of the electrical stimulator.

CAUTION:
Patients with an implanted electronic device (e.g. pacemaker or defibrillator) should not be exposed to any electrical stimulation with the Paintracker before a statement from a medical expert has been obtained.

CAUTION:
Malfunctions of the device – Magnetic and electrical fields may appear as background noise or other artefacts in the measurement trace or affect the function of the device. Ensure when using the device that all equipment being operated nearby comply with their relevant EMC requirements.

CAUTION:
If only one applied part (stimulation or EMG cable) is connected to the patient, prevent the connections to the other applied part not in use making contact with other conducting parts, including those connected to the protective earth conductor.

CAUTION:
Hazard to personnel, damage to the device – Ensure that the required environmental conditions are complied with.
To clean the monitor the user must switch the monitor off and disconnect the power cord. Liquid cleaning agents must not be sprayed directly onto the monitor. Spray the cleaner on a cloth and wipe the monitor gently. Do not apply excessive pressure to the touchscreen.

Do not place any objects on the signal leads.

Position the signal leads to the electrodes and the power cord so that they are not trip hazards.

CAUTION:
Damage to the device – Do not place the monitor directly next to a window or beneath an infusion solution or a dialysis bag. Rain, water, aqueous solutions and moisture may damage the monitor.

4 Installation and preparation for use

This section contains instructions for the installation of the Paintracker:

- Installation checklist
- Proper environment for operation
- Cable connections
- Start and shut-down procedures

4.1 Transport damage and unpacking

Check the carton for damage before installing your pain monitor and check that the delivery is complete.

Obvious transport damage must be immediately recorded in writing upon receipt of the goods and the transport company must be informed of the damage. Concealed transport damage must be reported to the supplier in writing within two working days.

Before unpacking the Paintracker, you should prepare an appropriate working surface for the monitor.

After unpacking your pain monitor, check whether the delivery is complete and that all parts are free of any faults:

Paintracker, model V1 with mounting clamp
Electrode cable for EMG measurement (cable with black plug, 3 electrodes)
Electrode cable for stimulator (cable with red plug, 2 electrodes)
1× USB flash drive
Set of adhesive electrodes
Instructions for use (this document)
1× power cord (EU)

4.2 Installing and testing the Paintracker

After unpacking the device, place it on a solid, non-slip surface at least 10 cm away from a wall or fix it with the mounting clamp to an infusion pole suitable to carry the load or to another mounting rail provided for this purpose.

Connect the power cord to the device and insert the power plug into an appropriate wall socket.

Check if the supplied USB flash drive is inserted. For safety reasons only the supplied USB flash drive is approved for operation with the Paintracker.

Start the monitor using the on/off rocker switch on the front of the device by pressing on the top half of the switch to bring the switch into the ‘On’ position. Ensure that the green lamp integrated into the switch turns on.

WARNING:
If the device does not pass the self-test on start-up, the user is informed about this on the display and no patients may be connected to the Paintracker.

WARNING:
Only the patient connection cables and the power supply cable provided with the device may be used.

WARNING:
The Paintracker is not a mobile device! It must not be used in the patient's bed or during patient transport.

4.3 Environment: Transport and storage

For storage and transport of the **switched off** device, the following limits must be adhered to:

Temperature	-10°C to +60°C
Air pressure	1067 hPa (corresponds to 460 metres below sea level) to 480 hPa (corresponds to 6100 metres above sea level)
Relative humidity	15% to 95% (non-condensing)

The device must be protected from fluctuations in temperature, particularly from cold to warm, because these can cause moisture to condense inside the device. It therefore makes sense to adjust the temperature of the storage room to the temperature of the rooms in which the device will be operated. When transporting the monitor from a cold storage area to a warm treatment area, it should be adjusted to the warm temperature before starting up the device until visible condensation can no longer be seen.

5 Explanation of the displays and connections

5.1 Explanation of the elements on the front

Figure 2 shows the front of the pain monitor.

Figure 2 Front of the pain monitor

1. **<u>Display</u>:** Displays all parameters and measurements; functions are selected using the touchscreen.

2. **<u>EMG connector, left (black)</u>:** Black socket to connect the EMG electrodes.

3. **<u>Stimulator connector, right (red)</u>:** Red socket to connect the stimulation electrodes. The connections are not interchangeable.

4. **<u>Yellow light</u>:** Lights up when a stimulation pulse is emitted and when the device is switched on.

5. **<u>Power switch</u>:** Switches on the device; green control light when the device is on.

5.2 Explanation of the elements on the back

Figure 3 shows the back of the pain monitor.

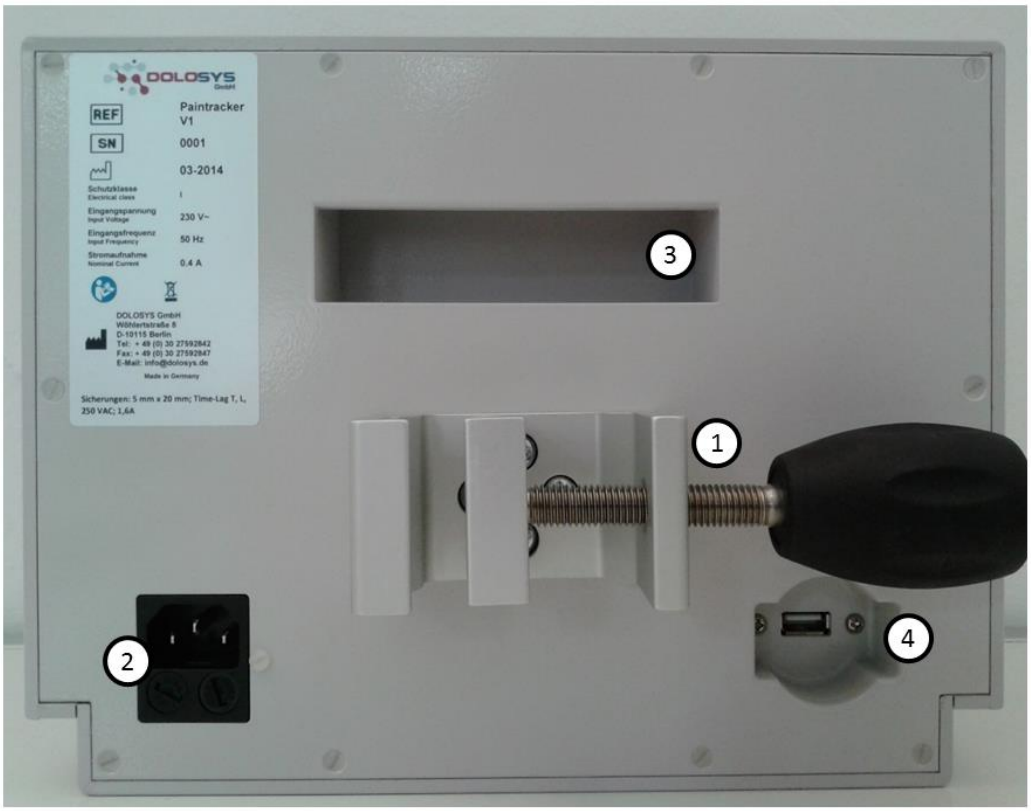


Figure 3 Back of the pain monitor

1. **<u>Mounting clamp:</u>** Clamp to mount the device to an infusion pole.

2. **<u>Power input</u>:** Connection for the power cord with the device port, 230 V alternating current (AC).

3. **<u>Recessed handle</u>:** Recessed handle to safely transport the device.

4. **<u>USB 2.0 port:</u>** Connection for the USB flash drive.

   <u>WARNING</u>: Hazard to personnel! Only USB flash drives authorised by the manufacturer may be used. It is forbidden to connect other devices, particularly mains-operated, to this USB port.

5.3 Electrode connections to the device

The **EMG electrodes** are connected to the black socket labelled with 'EMG' or the symbol using the cable with the **black plug**.

The **stimulation electrode** is connected to the red socket labelled with 'STIM' or the symbol using the cable with the **red plug**.

The plugs cannot be inserted into the wrong sockets because of the number of pins and the slot/key coding.

The colour of the electrodes is allocated as follows:

	Conduction cable	**Stimulation cable**
Colour of the device plug and port	Black	Red
Labelling on the device	EMG	STIM
Symbol on the device		
Positioning of the patient connections	Red: Thigh, proximal Black: Thigh, distal White (mass) / earthing electrode: e.g. above the knee	Red: Lateral malleolus, proximal Black: Lateral malleolus, distal

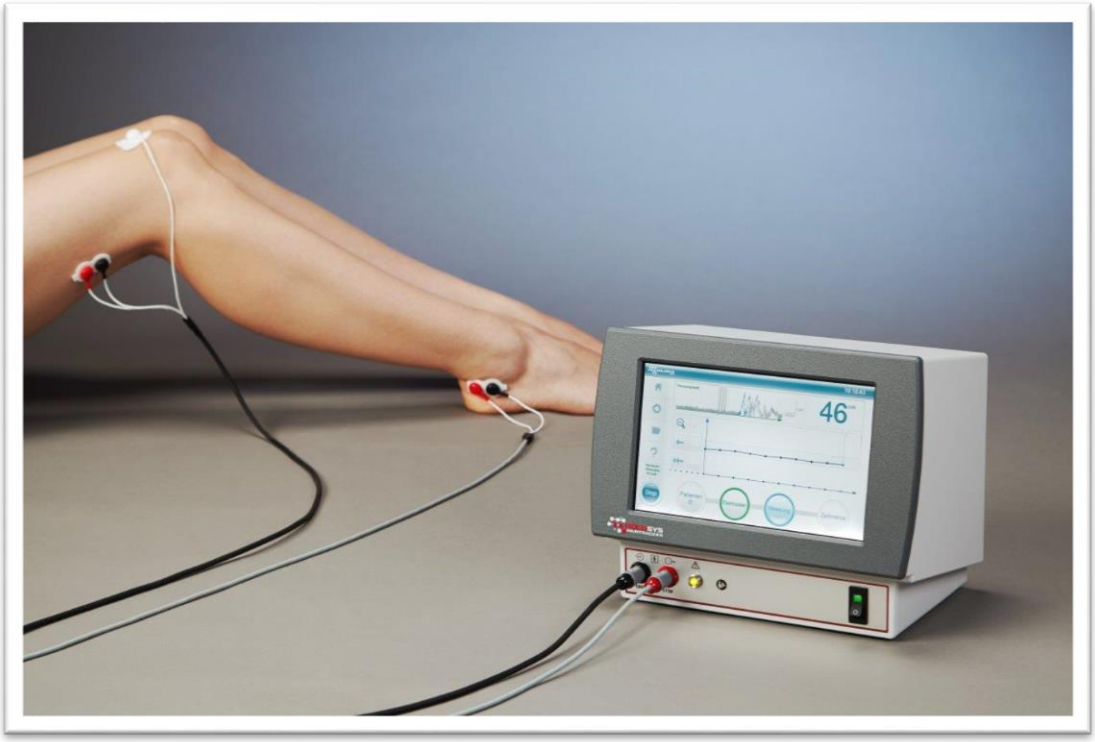


Figure 4 Pain monitor with stimulation- and conduction electrodes

6 Information on the display

6.1 Start screen

After switching on the device by pressing the power switch into the 'On' position, you will see the message 'System starting up…' during the start-up procedure. When this procedure is complete, the start menu is displayed.

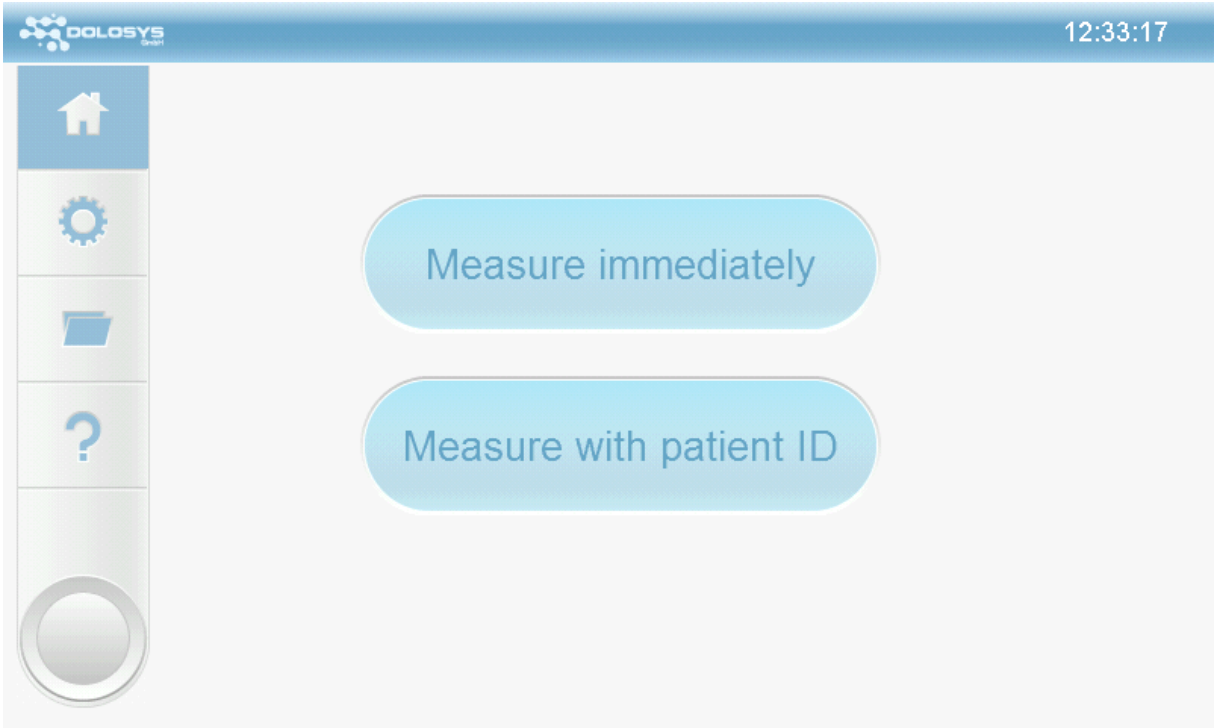


Figure 5 Start menu

From the start menu you can choose between 'Measure immediately' or 'Measure with patient ID' by pressing the corresponding buttons. Selecting 'Measure immediately' takes you to the electrode screen with no need to select a patient ID for saving the subsequent measurement. A patient ID can still be allocated once the measurement is complete. By pressing 'Measure with patient ID', you are taken to the screen to enter the patient ID (section 7.1).

Left menu bar:


Home button: Press this button to return to the start menu, which is the current screen.


Settings button: Press this button to go to the configuration menu to make changes to the stimulation settings and the threshold determination procedure (section 13).

Archive button: Press this button to go to the patient archive. Previous measurements that were allocated to a patient ID can be viewed again.

Help button: Press this button to go to the help menu.

6.2 Progress bar

After you have selected the measuring mode, the progress bar appears on the bottom section of the monitor. This bar leads you through the individual steps of the measurement process. The current active step is indicated by the blue ring. Steps that can be activated are indicated by blue text while steps that cannot be activated are indicated by grey text.

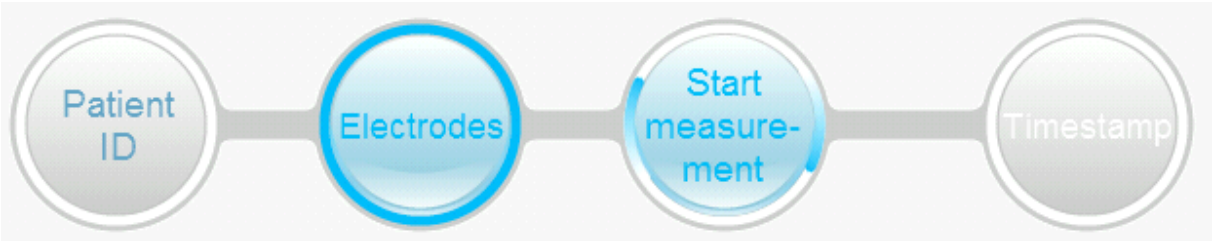


Figure 6 Progress bar

7 Entering the patient identification (patient ID)

Pressing the 'Measure with patient ID' button or pressing the 'Patient ID' button in the progress bar allows the patient ID to be entered. A new patient ID can be entered ('Create new patient', section 7.1) or an existing patient ID can be selected and the measurement can be allocated to this ID (section 7.2). The measurement can also be started without entering a patient ID ('Measure without ID', section 7.3).

7.1 Entering new patient ID on the monitor

You can enter a new patient ID via the 'Create new patient' button on the upper left-hand side using the keyboard on the monitor.

Figure 7 Entering the patient ID on the monitor

While entering the patient ID, previously entered patient IDs with the same combination of letters appear. To prevent duplicate entries, please check whether a patient ID has already been created for the same patient. You can select this patient ID at any time by pressing the patient ID field. The selected patient ID then appears in the entry field.

Confirm the selection of the patient ID by pressing the 'OK' button

.

7.2 Repeat measurement with an existing patient ID

Figure 8 Monitor to enter the patient ID

After starting the monitor, please select 'Measure with patient ID'. The records field displays the patient IDs sorted alphabetically. When starting the device, the last patient measured appears in the foreground as the standard option. Press the arrows on the right and left edges of the records field to change the patient ID displayed. Press 〈A or Z〉 to change the initial letter of the selection displayed. Press ◀ or ▶ to show the previous or next patient in the alphabetical list in the records field. Press the name field of the record to bring it to the foreground. Press the 'Select' button on the patient ID record to select this patient ID for the next measurement.

7.3 Measuring without patient ID

If the 'Measure immediately' button on the start screen or the 'Measure with ID' button on the patient ID entry screen is pressed, you are taken directly to the electrode application on the progress bar. You can still enter the patient ID by pressing the 'Patient ID' button during the ongoing measurement and once the measurement process is complete.

8 Applying the stimulation and conduction electrodes for pain reflex stimulation

WARNING:

Only electrodes with a measurement surface of greater than 90 mm^2 (for each electrode connection) may be used for the stimulation and conduction electrodes.
A change in the electrode properties can lead to malfunctions and injuries to the skin.
Please contact the manufacturer for recommendations about the electrodes.

Determining the optimal electrode arrangement and skin preparation involves achieving good signal amplitudes for the EMG conduction with a low noise level for the **conduction** side. Correct placement of the **stimulation** electrodes and appropriate skin preparation ensures that the voltage required to evoke the pain reflexes can be kept low.

The manufacturer recommends that the responsible doctor determines the optimal electrode arrangement. This arrangement can and should in most cases be retained throughout the entire monitoring period.

8.1 Preparing the skin

The hair is removed from the skin using a razor and the skin is then degreased with a swab that has been moistened with an alcohol-based, oil-free skin disinfectant using circular wiping movements. The skin is then abraded with an abrasive using circular movements for about 30–60 seconds. The abrasive is then removed with a swab. Ensure that the area of skin that is prepared matches the electrodes in terms of the shape and size.

8.2 Applying the stimulation electrodes

The stimulation electrodes are applied over the sural nerve lateral to and slightly below the lateral malleolus. First locate the lateral malleolus. The middle of the electrode should be placed on an imaginary line between the mid-point of the lateral malleolus and the lower end of the heel. The skin is prepared as described in section 8.1.

The stimulation electrode is then adhered to the prepared skin site so that it borders the lateral malleolus and the middle of the electrode is located on the line connecting the mid-point of the lateral malleolus and the lower end of the heel.

WARNING:

When using the monitor to conduct other reflexes or evoked potentials, the stimulation electrodes may only be fixed to the extremities or to the head but never to the trunk or the neck of the patient to exclude any effect of the cardiac conduction system.

8.3 Applying the EMG conduction electrode

The EMG conduction electrode is positioned on the skin above the musculotendinous junction of the biceps femoris muscle.

To isolate the musculotendinous junction, using the index and ring finger first locate the tendon of the biceps femoris muscle starting from the middle of the back of the knee and move towards the outside of the leg, applying light pressure and with the patient's knee slightly bent if possible. The tendons can be identified on the lateral side of the back of the knee as a solid, cable-like structure running along the length of the leg. They can usually be clearly palpated between the thumb and the index finger.

Follow the course of the tendon by touch towards the thigh until the cable-like structure can no longer be felt. In adults this area is usually reached after about 6–9 cm. Mark this area using a skin marking pen.

After preparing the skin (see section 8.1), adhere the conduction electrode to the corresponding site.

Attach the red snap fastener adapter of the EMG conduction cable to the proximal snap fastener of the electrode and the black snap fastener adapter on the distal snap fastener of the electrode.

Insert the EMG conduction cable with the black plug into the black socket on the monitor.

8.4 Applying the earthing electrode

The earthing electrode is applied to an area on the leg between the conduction and stimulation electrodes, approximately in the area above the kneecap. The skin must be prepared as described in section 8.1.

Caution:
Ensure that the cable only makes brief direct contact with intact skin of the patient. Contact with broken skin must be avoided.

9 Checking the electrical impedance

After entering the patient ID or selecting 'Measure immediately' on the start screen, you are taken to the electrodes screen:

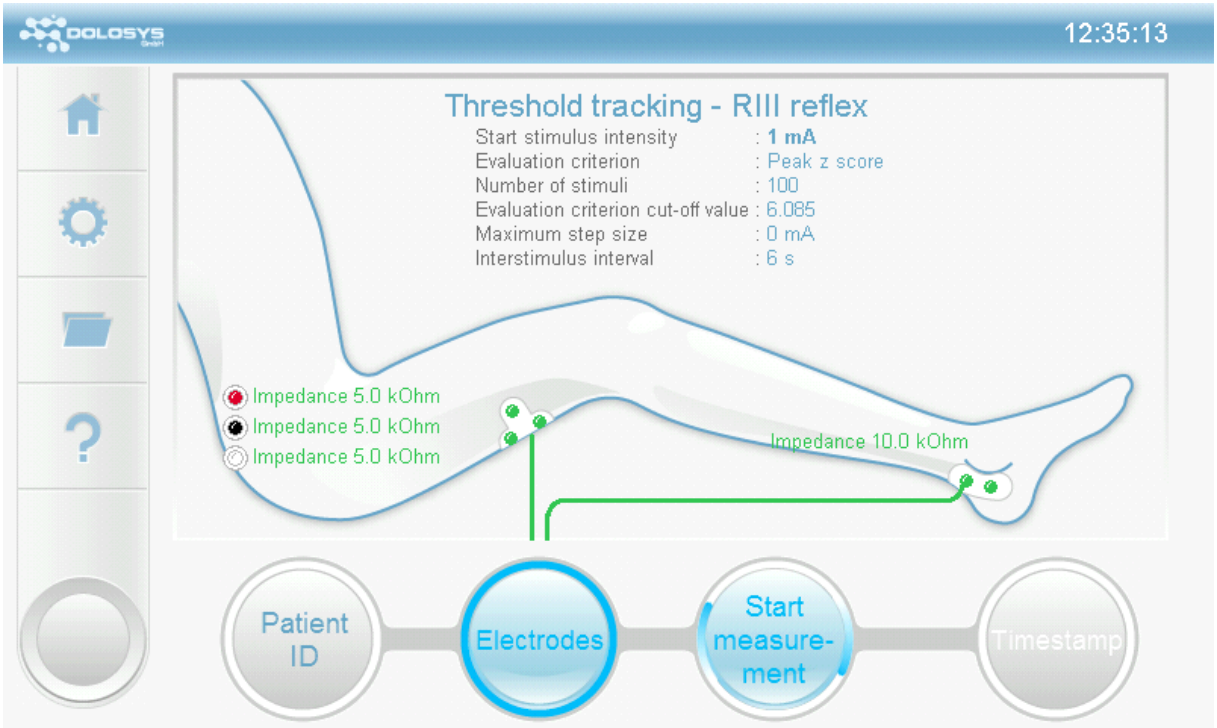


Figure 9 Electrodes screen

The impedance of the electrodes is measured at short intervals.

10 Starting the measurement

The measurement can be started if the impedance measured from the device is sufficiently low. An impedance that is sufficiently low to start the measurement is indicated on the electrodes screen by showing the leads in green or yellow. If a lead is shown in red, this means that the impedance for this lead is too high and the measurement cannot be started. If the impedance is too high, the skin must be abraded again (see section 8) and a new electrode applied. If the impedance is sufficiently low (the leads are shown in yellow or green) on the electrodes screen, the 'Start measurement' button is activated. Pressing this button starts the measurement and the measurement screen appears. If the electrodes are shown in yellow, this indicates high electrode impedance. Although the measurement can be done, the quality of the measurement may be negatively affected. The skin should therefore be prepared so that the electrode impedance is low, which is indicated by the leads being shown in green.

11 Measurement screen

The measurement screen comprises several windows each displaying different information and buttons. Figure 10 shows a picture of the display after several stimulations during an ongoing measurement.

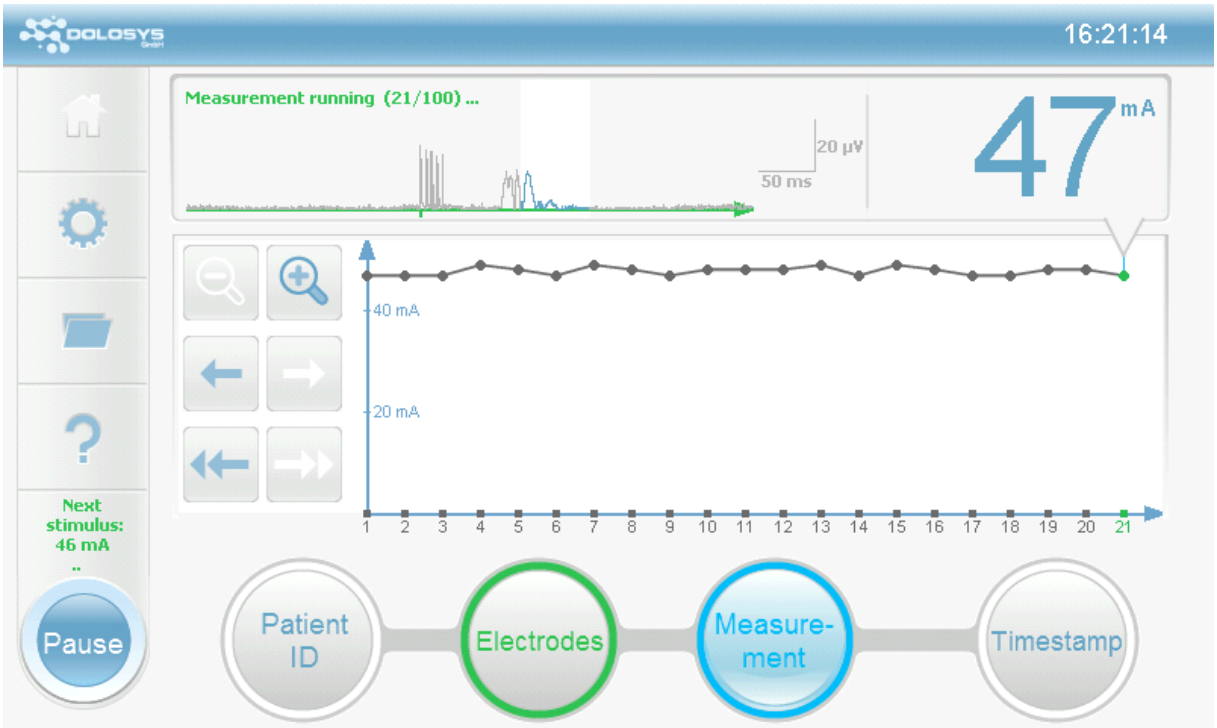


Figure 10 Display during a measurement (measurement screen)

Lower screen edge: Progress bar

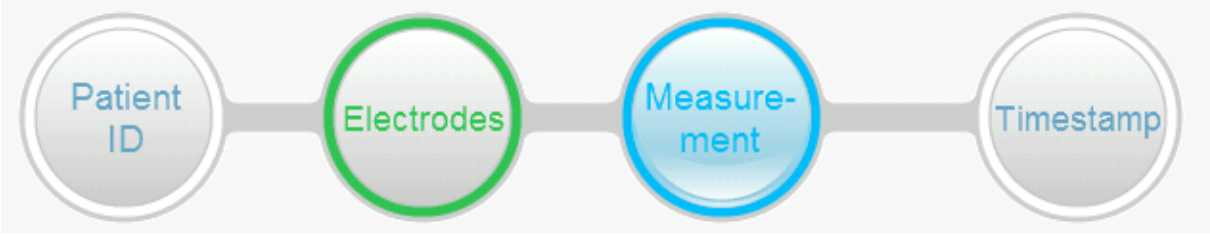


Figure 11 Progress bar

The progress bar comprises the four buttons shown above. These buttons have both display and entry functions. If the buttons and the surrounding ring are blue, this indicates that the device is currently running this process.

	If the patient ID button is pressed during a measurement, the record for the current patient is shown. The ongoing measurement can be allocated to another patient here. The patient ID for the ongoing measurement is shown on the upper edge of the middle of the screen.
	By pressing the electrode button, the electrodes screen appears which shows the impedances for the individual electrodes. When a measurement is running, the impedances for the electrode connections are indicated by the colour coding of the electrode buttons. Green indicates low impedances (good), yellow indicates borderline low impedances and red indicates impedances that are too high. If the impedance is too high, the stimulation is interrupted.
	Pressing the measurement button takes you to the measurement screen. If the measurement has been interrupted (section 12 'Pausing the measurement'), the measurement can be resumed using this button (button shows 'Continue measurement').
	Incidents can be marked on the monitor during a measurement. When the Timestamp button is pressed, a timestamp is inserted which can be allocated a marker label using the dropdown menu. The marker labels can be named in the settings menu. The timestamp can be allocated to any measurement point on the graph as a red line. To do this, the desired measurement point on the graph must be touched. If a timestamp is activated, this button changes to 'Delete timestamp' which allows you to delete the activated timestamp. Timestamps can also be inserted once the measurement is complete but only before saving.

EMG display with numeric display parameters

Figure 12 EMG display

Raw EMG This window shows the raw EMG that is conducted from about 200 ms before to 300 ms after stimulation via the EMG electrode on the thigh. The small green vertical line on the X axis indicates the start of the stimulation output. The scale is shown to the right of the EMG graph.

Reflex range The area with a white background, in which the EMG graph is marked in blue, identifies the section of the EMG in which the signal is being analysed (reflex range). The reflex range can be changed in the settings menu (see section 13.4 Stimulus parameters).

You must ensure that the EMG amplitudes that appear before the stimulation are low. High amplitudes before a stimulation is applied may be caused by muscular tension in the patient or poor electrode placement. The latter can be checked by examining the impedance.

High noise level If the maximum amplitude in the area before the stimulation ('noise area') exceeds an adjustable threshold ('maximum acceptable noise level'), the message 'High noise' appears in the display of the EMG trace (Figure 13). Noise values are not used to calculate the threshold and the stimulation is repeated with the current intensity until an EMG signal with no noise is determined.

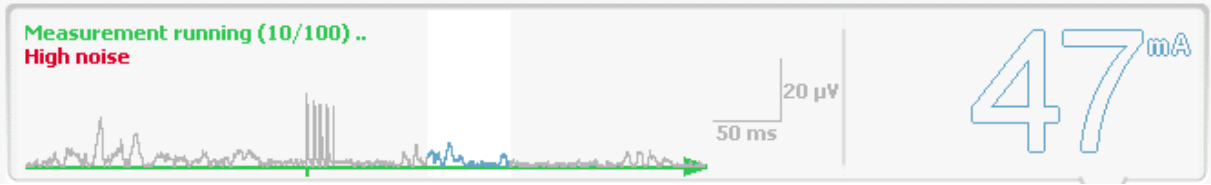


Figure 13 EMG display with high noise and unreliable reflex threshold

Threshold value On the right-hand side of the window the selected output parameter is shown numerically. If threshold tracking was selected as the measurement technique, this is the reflex threshold value in milliamperes. A reflex threshold value is only displayed once the number of stimulations that was defined in the settings menu, under the point 'Number of values for threshold determination,' has been administered.

Unreliable threshold value If more than four EMG conduction values are obtained with noise levels that are too high (see above), during the stimulations used to determine the threshold (defined by the parameter 'Number of values for threshold determination') the threshold calculated is evaluated as not reliable and shown as an outlined number only (Figure 13). In this case, try to reduce the noise level, for example, by having the patient relax the limb or by using new electrodes and, if necessary, abrading the skin of the patient again (see section 8.1 Preparing the skin)

Evaluation criterion If manual mode was selected, the 'Evaluation criterion' defined in the settings menu is displayed.

Graph

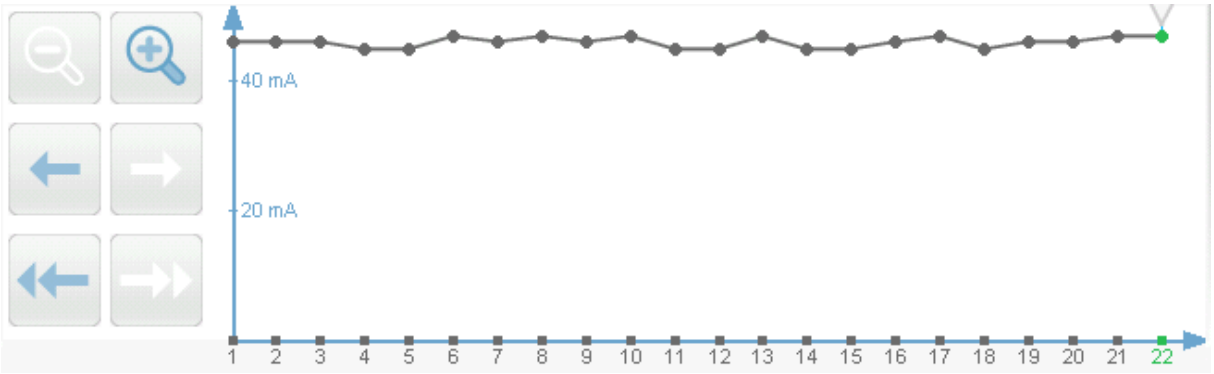


Figure 14 Graph

In the graph the calculated threshold values (threshold tracking) or the selected evaluation criterion (manual mode) are shown as a function of time. If threshold tracking will be carried out, at the start of the measurement several stimulations are carried out that are needed to determine the initial threshold value. These stimulations are indicated to the left of the Y axis on the graph. The number of stimulations administered before the first reflex corresponds to the settings parameter 'Number of values for threshold determination'. The graph is shown with a black line linking the individual values for the threshold or evaluation criterion, which are shown as black points. The last measured value is shown as a green point on the graph.

If more than ten values are determined during a measurement, the last ten values are shown with the most recent value on the far right-hand side. Using the buttons, the previous or the next value can be viewed. The corresponding EMG graph for the value is shown in the EMG display. By pressing the buttons, you can jump to the measurement point on the outer left or right edge of the screen respectively. The zoom function is used to increase or decrease the number of values displayed. Touching a measurement value on the graph shows the corresponding EMG graph in the EMG display.

12 Pausing the measurement

Pressing the 'Pause' button in the bottom left-hand corner of the screen interrupts the measurement and the stimulation. Stimuli are no longer administered to the patient.

The 'End' button is now shown in red. Above the 'End' button the text 'Paused' appears in red with information about the current for the following stimulus. At the same time the 'Measurement' button in the progress bar turns green and is shown with the legend 'Continue measurement', provided the measurement screen is active. Pressing this button continues the measurement at the displayed stimulation level.

Pressing the now red 'End' button again leads to a query about whether the measurement should be ended. Confirming by pressing the 'OK' button takes you back to the measurement screen where the graph can be viewed again and timestamps can be inserted. If the measurement is complete and has been saved or discarded, you press the 'End measurement' button.

13 Configuration menu

The pain monitor allows various settings for the stimulation or the evaluation of the reflex responses and these can be changed in the configuration menu. The date and time settings can also be updated here.

The configuration menu can be reached via the symbol on the bottom left-hand edge of the screen. To leave the configuration menu, press the symbol at the same location.

13.1 Setting the measurement technique

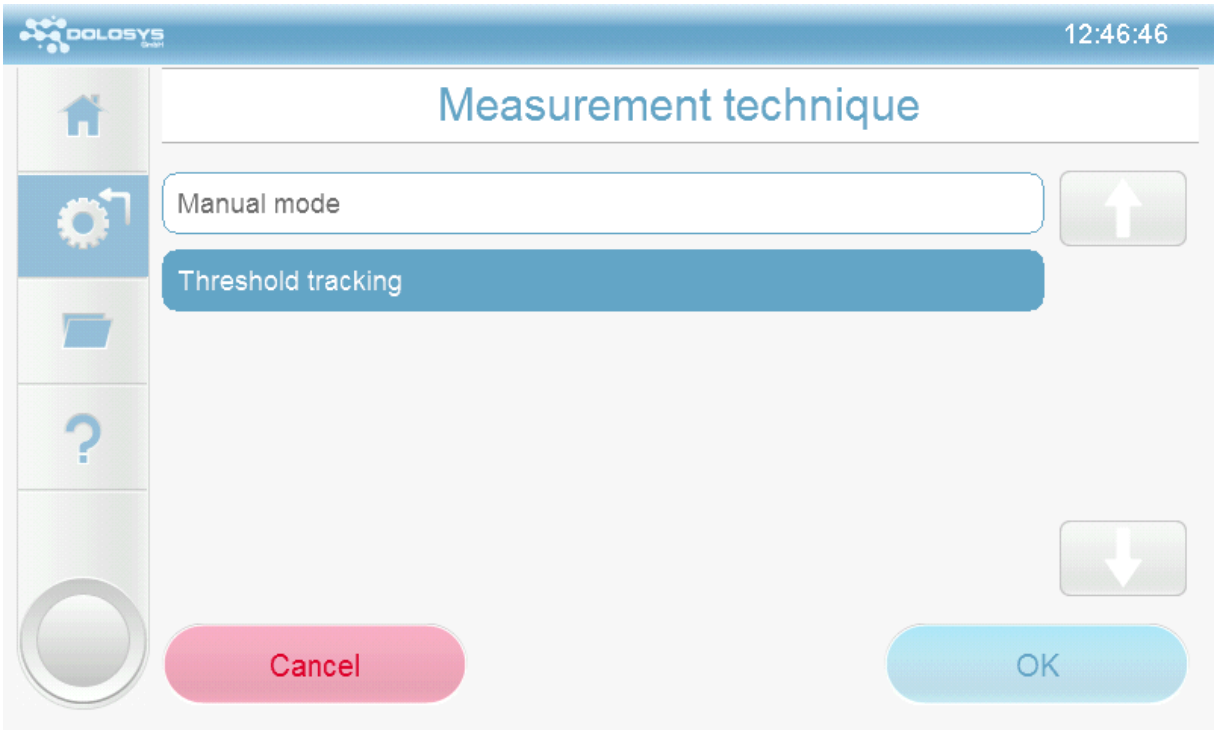


Figure 15 Settings screen

Pressing the 'Measurement technique' field in the settings screen allows you to select between two methods:

- Manual mode: The stimulator stimulates using constant current, which can be changed directly on the measurement screen (in 0.1, 1 and 5 mA increments). The measurement screen shows the evaluation criterion selected in the submenu 'Measurement technique parameters'.
- Threshold tracking: The stimulator automatically determines the reflex threshold by applying stimulations in the reflex threshold range.

When selecting a measurement technique, the last parameters set for the particular measurement technique are loaded and may therefore differ from the concrete parameter values for the previously selected measurement technique. They should therefore be checked with the new measurement technique prior to starting the measurement.

13.2 Setting the stimulus type

Pressing the 'Stimulus type' field allows you to choose between two types of stimulation:

- RIII reflex: Five individual rectangular pulses of 1 ms duration and with a 4 ms interpulse interval (200 Hz).
- H reflex: A single rectangular pulse of 1 ms duration.

When selecting a stimulation type, the last stimulus parameters set for the particular stimulus type are loaded and may therefore differ from the concrete parameter values for the previously selected stimulus type. They should therefore be checked with the new stimulus type prior to starting the measurement.

13.3 Measurement technique parameters

INFORMATION:

Each measurement technique has its own set of parameters. These may occasionally have the same name across several techniques (such as 'Number of stimulations') but for each measurement technique a separate value is saved.

Evaluation criterion: You can choose between various statistical values for reflex evaluation analyses:

- Sum: sum of the EMG amplitudes in the reflex range.
- Sum of squares: sum of squares of the EMG amplitudes in the reflex range.
- Mean: Mean of the EMG amplitudes in the reflex range.
- Maximum: Maximum value of the EMG amplitudes in the reflex range.
- Standard deviation: Standard deviation of the EMG amplitudes in the reflex range.
- Variance: Variance of the EMG amplitudes in the reflex range.
- Baseline-adjusted mean: Mean of the EMG amplitudes in the reflex range minus the mean of the EMG amplitudes in the noise range.
- Mean z score: Baseline-adjusted mean divided by standard deviation of the EMG amplitudes in the noise range.
- Baseline-adjusted peak: Maximum of the EMG amplitudes in the reflex range minus the mean of the EMG amplitudes in the noise range.
- Peak z score: Baseline-adjusted maximum divided by standard deviation of the EMG amplitudes in the noise range.
- Cohen's d: Baseline-adjusted mean divided by the pooled standard deviation of the reflex range and the noise range.

Evaluation criterion cut-off value: *(threshold tracking only)* Threshold value for the evaluation criterion above which a reflex response is evaluated as positive.

Number of stimuli: Determines the number of stimuli after which the measurement is automatically ended.

Start stimulus intensity: Determines the stimulation level used at the start of the stimulation.

Minimum step size: *(threshold tracking only)* The minimum step size used by the device with which the intensity of the next stimulus is lowered with a known reflex or increased with an unknown reflex. The device controls the current step size in the range between the minimum and maximum step

size depending on the stability of the current measured threshold (see 'Number of direction changes before halving step' and 'Aligned steps before doubling step size').

Maximum step size: *(threshold tracking only)* The maximum step size used by the device with which the intensity of the next stimulus is lowered with a known reflex or increased with an unknown reflex. The device controls the current step size in the range between the minimum and maximum step size depending on the stability of the current measured threshold (see 'Number of direction changes before halving step size' and 'Aligned steps before doubling step size').

Number of direction changes before halving step size: *(threshold tracking only)* This value indicates how often the device must stimulate around the threshold, that is, how often constantly changing between reflex and no reflex must occur directly after one another, until the current step size is halved. The step size is only halved down to the minimum step size set. This ensures that the threshold can be determined as precisely as possible using the smallest possible steps.

Aligned steps before doubling step size: *(threshold tracking only)* This value indicates how many times in a row the device must stimulate in the same direction, that is, either only high because no reflex is detected or only low because reflexes are constantly being detected, until the current step size used is doubled. The step size is only increased up to the maximum step size set. This ensures that stimulations are applied in as few steps as possible up to the current reflex threshold.

Number of values for threshold determination: *(threshold tracking only)* Indicates the number of previous stimulations that is used for the threshold calculation. A value of 7 (standard) indicates, for example, that each reflex threshold is calculated from the last 7 stimulation-response pairs. The number of values for the threshold determination is accordingly also the number of stimulations that must be carried out before the first threshold for a measurement can be calculated.

Maximum display range (graph): *(threshold tracking only)* Determines the scale range of the Y axis on the graph. If a reflex value should exceed the range set here, the Y axis is automatically scaled so that all reflex values are displayed.

13.4 Stimulus parameters

INFORMATION:
Each stimulus type has its own set of parameters. These may occasionally have the same name across several techniques (such as 'Interstimulus interval') but for each stimulus type a separate value is saved.

Interstimulus interval: The interstimulus interval indicates at what intervals the stimuli are administered.

Interstimulus interval randomisation: The percentage variation for the stimulus interval can be selected. If you select a stimulus interval of 10 s and an interstimulus interval randomisation of 50%, the interstimulus interval varies randomly in a range between 5 and 15 s.

Reflex range start: Time of the start of the reflex evaluation analysis after the start of the stimulation.

Reflex range end: Time of the end of the reflex evaluation analysis after the start of the stimulation.

Noise range start: Time of the start of the evaluation window of the noise level (baseline). The time is shown relative to the start of the stimulation and is therefore always negative.

Noise range end: Time of the end of the evaluation window of the noise level (baseline). The time is shown relative to the start of the stimulation and is therefore always negative.

Maximum acceptable noise level: The maximum noise level within which a measured value is used for the evaluation in the threshold tracking. If a value in the noise range (defined by noise range start – end) of a measurement exceeds this value, a message appears on the measurement screen and the value is not used to calculate the reflex threshold.

13.5 System parameters

In this menu the date, time and marker labels can be changed.

Date: After pressing 'Date' on the touchscreen, you can change the date using the arrow keys. The date is shown in day-month-year format.

Time: After pressing 'Time' on the touchscreen, you can change the time using the arrow keys. The time is shown in hour-minute format.

Marker labels: Allows setting, renaming and deleting of labels that can be entered and displayed as timestamps on the graph.

Reset to factory settings: Resets all parameters back to the factory settings.

14 Archive

The patient archive with the saved measurements can be retrieved at any time using the symbol. The patient ID selection for the archive appears, in which the individual patient IDs are displayed as records in alphabetical order.

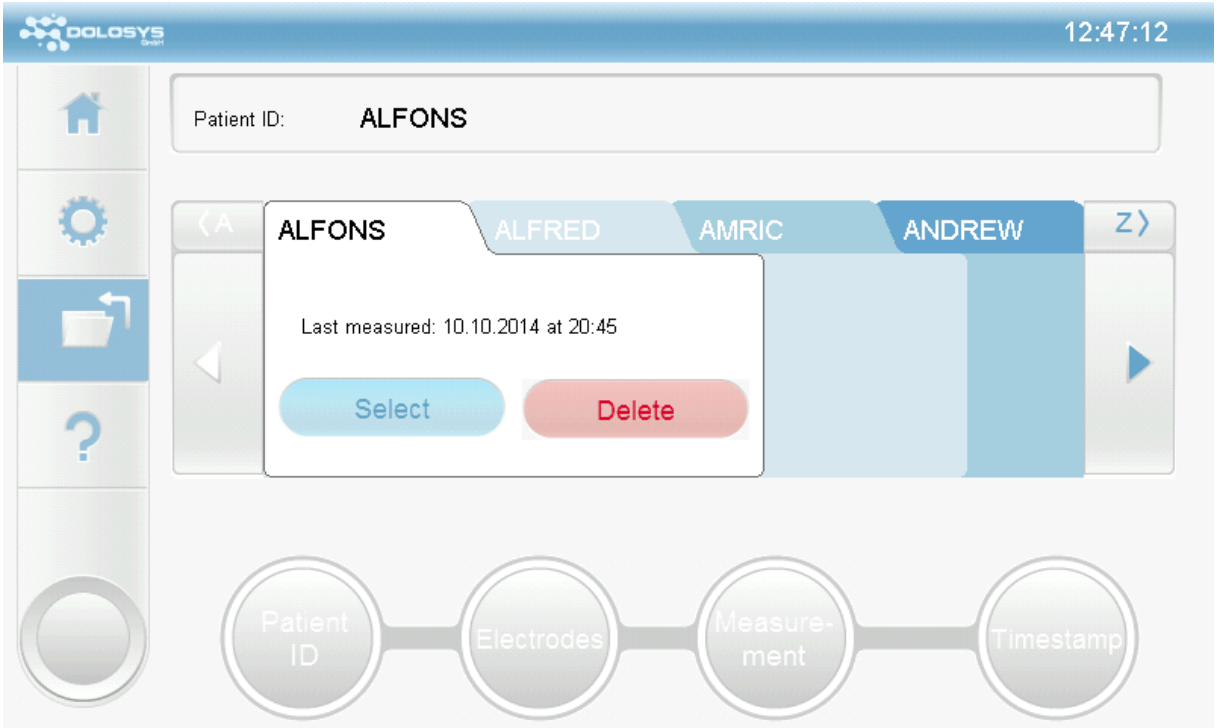


Figure 16 Patient archive

The record of the last patient measured is initially activated. By touching the arrow keys, the record that is displayed moves along one at a time. The buttons ⟨A and Z⟩ enable you to shift the record displayed to the next letter in the overall index.

Pressing the selection button on the record enables you to retrieve all the measurements that have been carried out for this particular patient ID. The archive for the selected patient ID then appears on the display. The bar chart on the lower edge of the picture shows the minima and maxima of the individual measurements. By selecting a bar, the corresponding measurement can be retrieved and this is then shown in the middle of the graph. The graph in the archive screen is manipulated analogously to the graph in the measurement screen.

The 'Delete' button in the patient ID selection screen of the archive is used to completely and irretrievably delete individual patients.

15 Cleaning and disinfecting

WARNING:

Electric shock hazard – The power plug must be removed from the monitor before starting to clean and disinfect the device surfaces.

Wait until all cleaned parts are completely dry again before reconnecting the device to the power supply.

Use standard precautionary measures to avoid making contact with infectious materials.

CAUTION:

Hazard to personnel , damage to the device – Carefully follow the manufacturer's directions for using the cleaning agent and disinfectant.

15.1 Cleaning the device

Only wipe off the surfaces of the device with a damp cloth and ensure that moisture does not penetrate inside the device. Always use a lint-free, absorbent cloth. The cloth should be immersed in lukewarm water containing cleaning agent (e.g. Hexaquart plus®) and thoroughly wrung out. Do not use any abrasive cleaners.

Blood or infectious materials as well as any spilt fluids should be removed as quickly as possible.

15.2 Cleaning the connecting cables

Remove the cables from the device before starting with the cleaning and disinfecting. Always remove a cable by holding the plug and not the cord itself.

To clean and disinfect the cables only wipe them down. Always use a lint-free, absorbent cloth. The cloth should be immersed in lukewarm water containing cleaning agent (e.g. Hexaquart plus®) and thoroughly wrung out. Do not use any abrasive cleaners. Never immerse the cables in liquid.

Ensure that the cables are dry before they are connected to the Paintracker again.

For moist disinfection by wiping the device, clear isopropanol solution can also be used.

16 Appendix

16.1 Technical data

Product description	**Paintracker**
Device class	IIa
Electrical protection class	I
Applied parts	Stimulator: Type BF EMG amplifier: Type BF
Monitor weight	2.8 kg
Monitor dimensions	28 cm × 22 cm × 19 cm (W×H×D)
Screen size	9 inch
Digital output	1 USB port
Internal power supply unit	230 VAC, 50 Hz
Nominal current	max. 0.4 A
Temperature range	Operating: 0°C to 40°C Storage: -10°C to +60°C
Relative air humidity	Operating: 20% to 85% (no condensation) Storage: 15% to 95% (no condensation)
Ambient pressure	1067 mbar to 480 mbar
Stimulator	
Output graph type	**Standard settings:** H reflex: a monopolar rectangular pulse RIII reflex: five monopolar rectangular pulses Special customised versions with other monopolar pulse types can also be installed by the manufacturer
Pulse duration	**Standard settings:** H reflex: a single rectangular pulse of 1 ms duration RIII reflex: five individual rectangular pulses of 1 ms duration and with a 4 ms interpulse interval (200 Hz) Hardware-limited: max. 70 ms
Pulse repetition frequency	Ranges from 1 min^{-1} to 30 min^{-1} with the option of a randomised deviation from the frequency of up to 50%.
Highest value for output voltage	300 V
Highest value for output current	150 mA
With changes to the load resistance from 0 Ω to 1.5 kΩ, the precision of the set or displayed parameters in the range ± 15% and a max. current of 150 mA is guaranteed. At values higher than 1.5 kΩ the maximum current can be calculated as follows: 280 V/load resistance in Ω gives max. current in amperes.	
EMG amplifier	
Amplification	80 dB (10,000)
Frequency range	(3 dB) 3 Hz to 800 Hz
Scanning frequency	10,000 Hz
Certifications	EN60601-1, EN60601-2-40, CE

16.2 Support and service

The manufacturer's customer service team is available to provide you with support and service. You can contact us using the following contact details:

Dolosys GmbH
Wöhlertstraße 8
10115 Berlin
Germany

Tel.: +49 30 275 92842
Fax: +49 30 275 92847
E-Mail: info@dolosys.de

16.3 Repairs

The buyer must contact the manufacturer directly for any repairs.

16.4 Warranty conditions

The manufacturer provides a warranty for first-time buyers of the Paintracker of a period of one year from the date the device was shipped to the customer. The electrode cables and disposable parts such as the electrodes are excluded from this warranty.

16.5 Disposal

The device must be disposed of separately from household rubbish.

Notes