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Azeer Sleep Diagnostic Devices

HOSPITAL HOMECARE DIAGNOSTICS

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MiniScreen plus
MiniScreen premium

Description and instructions for use

HOSPITAL

HOMECARE

DIAGNOSTICS

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REV 2021-06-15

1. Introduction

1.1. Assigned Purpose:

The MiniScreen plus and MiniScreen premium Sleep Diagnosis Systems are recording systems for use in professional health care environment. They serve as a differentiated pre-diagnosis for the sleep apnea syndrome and enable continuous recording of up to 40 channels for at least 15 hours without loss of data. The recording of data on battery power is also permitted in home care environment.

They record signals for the following physiological variables:

- Flow
- Oxygen saturation SpO2
- Pulse frequency
- Pulse wave
- Body position
- Respiratory and snoring sounds
- PAP (Positive Airway Pressure)
- Ambient Light
- Thorax effort
- Abdomen effort
- Breathing frequency
- Phase shift Thorax Abdomen

optional:

- Thermistor
- ECG
- Central heart Frequency
- PTT (Pulse Transit Time)
- Systolic Blood Pressure (Trend)
- Leg movement (LEG)
- EEG (Neuroport, only MiniScreen plus)
- 8 x Analogue channel
- 13 x channels of prismaLINE

1.2. Contraindications

There are no absolute or relative contraindications to using the device. In the following cases, the device must be used under the supervision of qualified medical personnel:

- in patients with acute life-threatening illnesses.
- in patients with acute, serious infections.
- in mentally confused patients.
- in infants and children

1.3. Accessories

The MiniScreen system as a whole (ME system) contains three components:

- The microprocessor controlled MiniScreen recording device
- PC software for measurement data presentation and PC analysis
- Optional: Analogue box for 8 analogue inputs incl. connection cable

It is also equipped with the following applied parts:

- SpO2 finger sensor with cable for obtaining pulse frequency and oxygen saturation values
- Velcro strap for securing the finger sensor to the wrist
- Flow prongs for obtaining the respiratory signal.
- Adapter hose for measurement during PAP Therapy
- Differential pressure adapter for measurement under PAP ventilation
- Flexible carry belt with integrated pressure transducers (thorax effort) to fasten the Mini-Screen unit to the patient
- Flexible belt with integrated pressure transducer to record abdominal effort
- Shoulder bag for storing the MiniScreen

Other accessories:

- USB Interface cable for data transfer between the MiniScreen and PC
- Battery recharger
- Transport case

Optional applied parts:

- LEG sensor for detecting leg movements
- ECG electrode for recording ECG signals
- Neuroport electrode cable
- Thermistor for additional breathing detection

Other optional accessories:

- Splitter box for connection the Leg and ECG sensors
- USB isolator for online measurement
- Viewer "Sleep Xpert App" for tablet.

The data can be displayed and analysed on a standard commercial PC. The measurement curves and the analysis results can be printed on all commonly available printers, including dot-matrix, laser or ink jet printers.

The MSV (MiniScreen Viewer) analysis program has the following minimum configuration requirements:

- PC with Windows operating system
- Microsoft Windows 7 or higher
- 512 MB of RAM (2 GB recommended)
- 1 GB of disk space on the hard drive
- CD-Rom drive for installation
- Mouse
- 128 MByte VGA graphics card with a resolution of at least 1024 x 768 (512 MB, 1280 x 1024 / True Colour recommended)
- Free USB port
- Printer with Windows driver

2. Information

2.1. Safety-related informations

⚠ Observe the instruction manual:
Every use of the device requires exact knowledge and observance of this instruction manual. The device is only intended for the use described herein.

⚠ No alarm function available!
The device is not suitable for continuous monitoring of vital or physiological functions (for example, intensive monitoring, monitoring operation) since there is no SpO2 alarm. No direct data analysis takes place in the device.

⚠ No SIDS Monitoring:
The device is not suitable for use as a SIDS monitor (SIDS: Sudden Infants Death Syndrome, sudden child death).

⚠ Patient instruction:
Patient instruction must be provided by a healthcare professional trained in the device. An attached short manual does not replace the manual instructions or the warning of possible hazards.

⚠ Separation from the supply network::
To isolate the device from the supply network, the plug of the power supply must be disconnected.

⚠ **Do not open the device!**

⚠ **Warning:**
Additional devices that are connected to medical electrical (ME) devices must be able to meet their IEC or ISO standards. Anyone connecting additional devices to ME devices is a system configurator and is responsible for the ME system being in compliance with the normative requirements (for example, IEC 60601-1).

⚠ **Warning:**
For online measuring you must use an electrical or optical isolator for connection of the device to the PC (available from your home care provider). A connection of the device to the PC without electrical or optical isolator is only allowed if all patient connections have been removed first. Only Physicians or trained staff is allowed to perform online measurements.

⚠ **Warning:**
Magnetic and electrical fields can impact on the functioning of the device. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. When operating the device, ensure that all third-party devices being operated in the vicinity are meeting their relevant EMC requirements. X-Ray equipment, HF surgical devices, tomography devices etc. can interfere with other devices as they may emit higher levels of electromagnetic interference.

⚠ **Warnung:**
The device has no defibrillator protected application parts! Disconnect the device before defibrillation! A direct application of the device to the heart (esp. ECG!) is not allowed!
While the device is being worn, no invasive or intracorporal measurements and interventions (e.g., electro- or HF-surgical devices) may take place.

⚠ **Warning:**
Using multiple devices for patient screening could result in excessive leakage current above the allowed value!

⚠ **Warning:**
When using the device on patients with active implants, such as Cardiac pacemakers, peripheral nerve stimulation devices, tongue pacemaker etc., medical professionals should be alert to possible interference with the device or the implant.

⚠ **Warning:**
Applying the device to more than one patient at any one time is not allowed.

⚠ **Warning:**
The device must not be operated in vehicles and aircraft.

⚠ **Warning**:
When applying sensors to the patient, please ensure that no electrical line of the device is in contact with any other electrical conductive parts including ground.

⚠ **Warning**:
Avoid placing this instrument in direct sunlight or in close proximity to intense heat. Prevent also the contact with dust, lint, dirt, moisture and liquids.

⚠ **Warning**:
Children or incompetent persons should not use this device unattended without first having obtained instructions for the safe use of the device. Ensure that infants, children and animals cannot touch the device unattended.

⚠ **Warning**:
Caution must be taken to ensure that cables do not encircle the patients neck. Special attention is needed in the case of children.

⚠ **Warning**:
Before the battery is charged, the power adapter must be checked for external damage!

Never use the power adapter with damaged housing or cable!

⚠ **Warning**:
Before every application, the housing of the device as well as the cables and sensors must be checked for external damage!

Never use the device with damaged housing, cables or sensors!

⚠ **Warning**:
The device and PC software are not intended for automatic diagnosis only. The measurement data must be always reviewed and evaluated manually by a qualified physician.

2.2. General information

This instruction manual should be regarded as a component of the device. It should be kept on hand somewhere near the device at all times. Reading and understanding the instruction manual is a prerequisite for proper use and correct handling of the device in order to maintain the safety of the patient and operator.

The guarantee is valid for a period of 24 months for the device and 6 months for the equipment from the date of sale.

Only accessories which are listed in this instruction manual should be used with the device. We cannot guarantee the safe operation and function of the device if unknown proprietary accessories / consumables are used that have not been tested. (E.g. Patient leads, Sensors, Consumables, Memory cards etc.)

Damages resulting from the use of third-party accessories or consumables shall render this warranty void.

The manufacturer will only assume responsibility for the device in terms of safety, reliability and function if:

1. **assembly, add-ons, reinstallation, changes and repairs are carried out by the manufacturer or a qualified agent authorized by the manufacturer to do so;**
2. **The device is used in accordance with the instruction manual.**

All printed material relates to the model of the device and the safety regulations at the time of printing. All devices, switches, processors, software programs and names contained herein are subject to copyright law.

LM shall only be liable for the malfunction of the device and its software if used in the normal operating conditions in accordance to this manual.

If a PC is included in delivery third party software is not allowed to be installed on this PC.

Medical devices must only be operated by a qualified experienced person(s) to ensure correct handling of such devices.

The operator must read and understand the user manual to operate the device correctly.

The operator must check the functionality of the device before each use to ensure it is in sound condition and in good working order.

Functional testing of the device must be carried out at regular intervals. It is recommended that this is conducted once a month.

Upon reaching the end of its service life, the device and its accessories should be disposed of in accordance with the WEEE Directives or relevant Electronic Disposal protocol.

For further details please contact LM.

2.3. Technical inspection

Only devices that are regularly checked and maintained are deemed safe to use. It is recommended that units are subject to a test protocol and the battery is replaced every 24 months.

For more details on servicing and service contracts, please contact the LM Customer Service Department or your service provider. A functional tester can not be used to assess the accuracy of the finger sensor or pulse oximeter of the device.

The following tests need to be carried out by the operator before each measurement:

- Visual inspection of the device and accessories for obvious damage which could result in mechanical failure.
- Testing all hose connections are air tight.
- Testing the thorax and abdominal sensors for leaks.
- Checking the display LEDs.
- Testing the pulse and SpO2 finger sensors and carrying out a plausibility test (timed pulse test using).
- Testing the battery capacity.

2.4. Liability for functioning or damage

In the event of improper use or repair by the owner or operator, the liability for the device will be transferred to those parties. LM shall not be liable for damages arising from non-observance of this instruction manual. The actual guarantee and warranty conditions in the LM terms of sale/delivery are not extendable.

3. Recording measurement data using the MiniScreen unit

3.1. Sensors

3.1.1. Sensors for flow and snoring noises

The detection of patient flow is determined by the use of a nasal flow prong that transmits the pressure signal to an internal pressure transducer of the device. The flow prong can be easily applied by the user and will have no adverse affect on the quality of sleep. The use of a flow prong also eradicates the problem where adhesive sensors cannot be used. (i.e.: patients with beards). In addition the flow prong is an economical choice of sensor as it is commonly available.

No additional sensor is required for respiratory and snoring detection. Respiratory sounds are transmitted to the MiniScreen unit via the flow prong. The built in microphone detects the sounds which are then electronically analysed. Therefore additional microphones are not required.

Due to the high sensitivity of the internal pressure transducer, the MiniScreen device is capable of measuring and recording ultra fine pressure differences associated with patients who mouth breathe.

In order to connect the flow prong, ensure the **blue** connector of the prong attaches into the **blue** connector of the device.

The flow prong should be used in accordance with the manufacturer's instructions.

⚠ Warning:
The flow prong is intended for single patient use. No attempt should be made to clean or use the flow prong the more than once. Multiple use can result in cross infection!

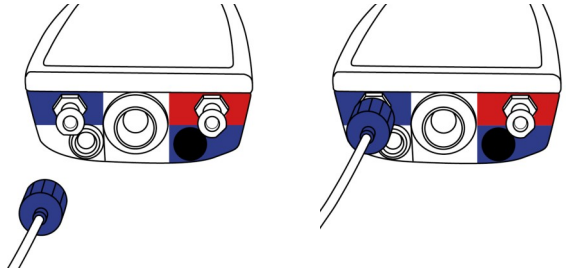
3.1.2. Thermistor sensor for breathing

Additional to the flow prong a Thermistor can be used to measure the breathing. Please also observe the instructions accompanying the sensor.

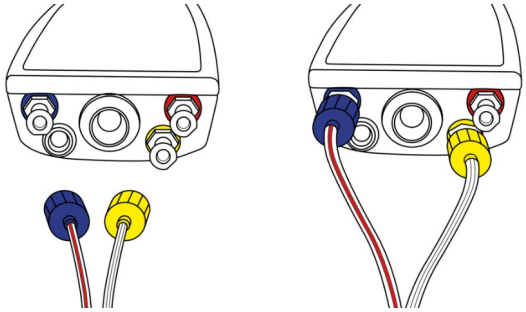
The **brown** connector of the Thermistor needs to be attached to the **brown** connector on the MiniScreen.

3.1.3. Sensor for PAP (pressure)

a.) MiniScreen plus
When performing measurements on a patient undergoing PAP therapy, a T-Adapter is used instead of the flow prong. This is to be placed between the respiratory mask and the therapy tube at the patient and is connected to the top of the MiniScreen plus with the **blue** marked LuerLock connection.



a.) MiniScreen premium
When performing measurements on a patient undergoing PAP therapy, a pressure diff adapter is used instead of the flow prong. This is to be placed between the respiratory mask and the therapy tube at the patient. It has two pressure measuring hoses with one **blue** and one **yellow** connection.



The near-patient red marked tube has a **blue** connection and is connected to the top of the MiniScreen premium with the **blue** marked LuerLock connection.

The patient-far colorless tube has a **yellow** connection and is connected to the top of the MiniScreen premium with the **yellow** marked LuerLock

3.1.4. Sensor for oxygen saturation and pulse frequency

A pulse oximeter has been integrated into the device for the purpose of measuring oxygen saturation and pulse frequency. A failure of the finger sensor or a missing data update by the pulse oximeter is indicated to the user by the red LED on the device. At the same time the values for SpO2 and pulse are fed to 0.
Please ensure that blood circulation at the point of measurement is not affected by the manner in which the sensor has been secured. Excessive pressure should not be exerted on the finger, especially if the temperature exceeds 41 ° C.
When using a finger sensor, please use the Velcro wrist/armband to secure the sensor and cable. All nail polish (coloured or clear) must be removed from the measuring finger to obtain usable data.
To minimize interference (e.g., motion artifacts), the pulse oximetry values are filtered by digital data processing. As a result of data averaging and signal processing, slight delays in the display of the pulse oximetric values occur. The internal pulse oximeter works with a time horizon of 4 seconds. By additionally considering the change tendency, the minimum value of saturation at the end of an apnea is correctly reproduced. The data is updated at every beat, so there are no measurable delays due to data refresh and transmission. Please read and understand the instructions accompanying the finger sensor.

3.1.5. Sensor for thorax and abdominal movement

The sensors used for recording thorax and abdominal movement consists of small rubber pressure

pads that are connected to the MiniScreen device via measuring hoses. The sensor for recording thorax movement comprises of two pressure pads whereas the sensor for abdominal movement contains only one. The sensors are inserted into the pockets of the elasticated effort belts. The thorax belt is applied at the height of the sternum, the abdominal belt in the stomach region.

For hygiene reasons and to avoid allergic reactions the belts should be **worn over clothes**.

The **red** connector of the thorax sensor needs to be attached to the **red** connector and the **black** connector of the abdominal sensor needs to be attached to the **black** connector of the device.

The effort belts are adjustable in size due to the Velcro fasteners, and should be suitable for most patients. These belts are however also available in special sizes.

Note:
Overstretching of the belts may result in poor signals and possible loss of data.

3.1.6. Sensor for body position

The position sensor integrated in the MiniScreen unit displays information related to the patient's body position during the study.

For accurate determination of body position, ensure the MiniScreen is applied to the patient correctly. The body positions detected are: Supine, Prone, Left side, Right side, Upright.

3.1.7. Sensor for leg movement

To diagnose restless or periodic leg movements (restless leg), the MiniScreen can be equipped with a leg sensor and internal recording software (optional). The device then enables continuous recording of leg movements and associated analysis results in the report.

Attaching the leg sensor:

The RLS sensor is attached to the leg using the Velcro wrist band. The sensor should be positioned approximately 10 cm below the knee joint, lateral to the shin bone.

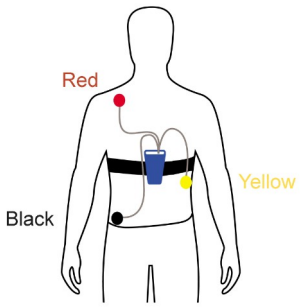
Since the leg sensor detects muscle movements, ensure that the sensor is placed on the muscle and not the shin bone!

The **red** and **black** safety plugs of the sensor have to be plugged into the **red** and **black** sockets of the splitter box.

3.1.8. Sensor for ECG

The supplied ECG cable (optional) is compatible with all commonly available adhesive electrodes and can be used as consumables.

Attaching the ECG electrodes:



The yellow, green and white safety plugs have to be plugged into the yellow, green and white socket of the splitter box.

Important: The ECG is not suitable for a differential cardiac diagnosis!

3.1.9. Sensor for Neuroport

The Neuroport signal is obtained via the supplied EEG cable (optional, MiniScreen plus only). We recommend special 3-part EEG electrode strips as consumables.

The 3 part EEG electrode strip needs to be applied to the forehead. Before applying the electrode the forehead must be cleaned with a sterile solution. A headband around the forehead will eliminate movement of the electrode during the study.

The **blue** marked connecting plug of the EEG electrode cable needs to be plugged into the **blue** socket on the MiniScreen plus unit.

3.2. Preparing for measurement (ambulatory)

In preparation of an ambulatory study where the patient will use the device at home, please ensure the following:

1. Charge the battery: see Page 7.
2. Start the MiniScreen software on the PC.
3. Fill out the fields relating to personal data of the patient in the menu item "Record / Initialize device (Offline)" and start the transfer.
4. Connect the MiniScreen with the USB interface cable. For testing purposes, both LEDs will light up initially. The red LED will then go off. The green LED on the MiniScreen unit will remain lit for the duration of the initialization process.
5. A dialogue window will be displayed in order for the operator to determine the start time for recording. Once confirmed the unit can then be disconnected from the PC. **Note**: (remove cable by pulling on the plug - **not** on the cable).
6. The MiniScreen unit is now ready for use. The unit will now rest in stand-by mode until the selected Start Time of the recording. The unit will then automatically switch on and start recording data.

3.3. Operating elements of the device

The MiniScreen device will automatically switch on / off when connected / disconnected to a PC. The device has an internal clock for timer recording. If the timer has been programmed, recording will start automatically at the predetermined time. Up to eight recordings can be programmed.

Note: If necessary the MiniScreen can be switched on by the patient before the selected Start Time by pressing and holding the Start button for one second. By pressing the start button (longer than 7 seconds), the device can be switched off by the patient.

The charging condition of the units battery can be displayed by pressing the "Akku" button on top of the device.
Attention: This function will only work when the device is switched off and disconnected from the PC.

3.4. Attaching the MiniScreen unit and starting the measurement

When apply the sensors, make sure that they are applied in such a way that strangulation is not possible due to their length (for example flow prongs, finger sensor). In order to ensure reliable recording of data, you need to observe the following points when attaching the MiniScreen unit and sensors. These steps should be demonstrated and practised with the patient beforehand in the clinic:

1. If applicable, attach the ECG electrodes.
2. Secure the MiniScreen unit to the thorax using the elasticated thorax belt (with the **two** built in pockets). Apply the belt whilst in the standing position and exhale. A correctly fitted belt should not slip up or down once fastened. To record abdominal breathing, attach the abdominal belt (with the **single** built-in pocket) around the stomach in the same way. Always ensure the belts are fitted over the night clothes and not directly onto bare skin.
3. Check the position of the pressure transducers (black rubber pads). The sensors should be fully inserted into the built-in pockets sewn onto the belt. **Never pull on the tubing connected to the pressure pads**.
4. Apply the flow prong and/or respiratory thermistor to the nose or fix the adapter hose to the oxygen mask.
5. If applicable, attach the leg sensor and EEG electrodes.
6. Apply the finger sensor (SpO2) to a finger and secure the cable to the wrist using the Velcro wrist band. Whilst doing so, ensure that you do not apply pressure to the finger thereby disturbing the blood flow.
7. The MiniScreen will automatically switch itself on at the predetermined time. Both LEDs light up briefly for testing purposes.
   If all sensors have been connected correctly, the red LED will go out. The green LED blinks at regular 4 second intervals.
   The red LED signals a faulty pulse signal. Check the finger sensor and cable.

Once the patient has been educated on fitting the device, the device can then be packed into its hard carry case for the patient to take home. The patient can refer to the quick reference guide when fitting the device at home.

When going to bed the patient needs to:

- Attach the MiniScreen using the elasticated thorax belt.
- Attach the flow prong and finger sensor.
- If applicable, attach the abdominal belt, leg sensor, ECG and EEG electrodes.
- Check that the sensors and their connectors are positioned correctly.

The next morning:

- The patient has to detach the MiniScreen unit and sensors and return all parts to the case. Cleaning of the sensors will be carried out by the technical staff at the clinic or hospital.
- Bring the case back to the clinic or hospital.
- For automatic evaluation the measurement can be transferred to the PC using the device software. Select the "Record" tab followed by "Read measurement from device".

4. Service and Maintaining the device

4.1. Charging the battery

The MiniScreen unit is equipped with a special fast-charge Li-Ion battery. The battery charging adaptor included with your device is specially designed for this type of battery and should only be used with your MiniScreen unit. It is recommended to charge the battery completely after each measurement.

Caution: It is not allowed to use a different battery charger than the one provided!

Battery charging procedure:

- Connect the battery charger adaptor to the MiniScreen device
- Plug the charger into a power outlet
- The integrated LED's in the top cover of the MiniScreen displays the charging status of the batteries. The device can remain connected to the charger adaptor for a long period of time without suffering any damage.

4.2. Cleaning instructions

General

As with any medical device, when using the MiniScreen plus / premium polygraphic systems, certain hygienic procedures are required for safe reuse on the patient. Reusable products must have safe

disinfectability to exclude any risk of infection from subsequent users / patients. The regulations of the Medical Devices Act stipulate that for such medical devices disinfection activities with procedures according to the RKI guideline are to be carried out in analogy to the methods of surface or instrument disinfection. It is recommended to create a hygiene plan for the MiniScreen plus / premium product. Sterilization of the products listed below is not necessary.

The MiniScreen plus / premium polygraphic systems are medical devices that are in the patient's environment when used as intended, with direct contact with the hands of the staff and the patient. These products are therefore classified as so-called "non-critical medical products" in accordance with the guidelines for hospital hygiene and infection prevention.

The recommendations are based on the following provisions:
Lists of tested and approved disinfectants and procedures by VAH, IHO, DGHM, RKI

As a disinfectant of the applied parts a product should be selected for rapid disinfection with short exposure times on an alcohol-free basis, which is listed in VAH, IHO or DGHM (for example Mikrozid® sensitive). The information given by the manufacturer regarding dosage and time of use should be considered.

Periods

Applied part	**Cycle**		**Clea-ning**		**Disin-fection**		
	After each use	After patient change	By hand	Washing machine	Spray disinfection	Wipe disinfection	Immersion disinfection
Basic device MiniScreen plus / premium		•	•			•	
Carrying case, outside		•	•			•	
Carrying case, inside		•	•		•		
Shoulder bag cloth bag with shoulder strap		•	•			•	
SpO2 finger sensor	•		•			•	
Velcro wrist strap for finger sensor	•		•			•	
Thorax- /Abdomen sensor		•	•			•	
Thorax- /Abdomen strap		•		•		•	
Pressure Diff Adapter	•		•				•
Thermistor	•		•			•	
EEG electrode cable (Neuroport)	•		•			•	
LEG sensor	•		•			•	
ECG electrode cable	•		•			•	
Splitter box for LEG-Sensor and ECG electrode cable	•		•			•	
Flow prong	Disposables (Single use)						
CPAP Adapter	Disposables (Single use)						
Tubes for Pressure Diff	Disposables (Single use)						

Cleaning
It is recommended that all components of the MiniScreen plus / premium be cleaned prior to disinfection to remove coarse dirt, adhesive residue, odours and the like. All components can be wiped with a slightly damp cloth and a light detergent. Allow all components to air dry completely before reinstalling.

⚠ **Warning:**
No liquid should enter the MiniScreen plus / premium or plug connections. The sensors must not be immersed in liquid. Before cleaning, close the pressure connections of the device with caps!

Disconnect the charging and data cable from the device before each cleaning.

In the washing machine
The thorax and abdominal straps can be washed in the washing machine at 60° C (use a laundry net!). Let the straps dry in the air.

Attention:
- Do not use a dryer
- Remove thoracic and abdominal sensor beforehand

Disinfection
It is recommended to subject all components to a disinfection procedure. The periods can be found in the table. In general, a product should be used for rapid disinfection with short exposure times on an alcohol-free basis. Observe the instructions for use of the disinfectant used.

- Wipe and spray disinfection with Mikrozid® sensitive liquid
- Dive disinfection with gigasept® FF (new)

Disposables
Disposables must not be used multiple times or on different patients. Follow the guidelines for waste disposal in hospitals.

4.3. Maintenance

We recommend the device including all accessories is serviced every two years. The servicing should only be carried out by the manufacturer or by an authorised agent. Calibration of the pressure channel should be carried out once at the first time when the device is used. In order to maintain basic safety and essential performance, no special measures need to be taken with regard to EMC.

4.4. Transport and storage conditions

The ambient temperatures for transport and storage lie between:
- -25 ° C and + 5 ° C,
- + 5 ° C to + 35 ° C with a relative humidity of up to 90%, without condensation,
- > 35 ° C to 70 ° C at a water vapor pressure of up to 50 hPa.

Condensation must always be avoided.

5. Evaluation software for PC

5.1. Installing the software

To install the MiniScreen software place the CD supplied with your device into the CD-ROM drive of your computer. The program will automatically run. If the program does not run automatically open the Explorer option on your operating system and select the CD-ROM drive. Once selected double click the Setup.exe file from the software.

You can check your computer and network (if applicable) for MiniScreen software versions that may have been previously installed. To ensure the correct up to date version is selected, open the software installed and click the Search button. The program will then automatically find and use the latest version installed.

After selecting the target drive the installation program will now automatically create the necessary directories and copy all the required files to the hard drive. The installation will automatically insert a new group containing an entry for the new software in the Programs folder of the Start Menu. In addition a shortcut on your Windows desktop will be created.

After successful installation, remove the CD and store it in a safe place.

5.2. Selecting a printer

The measurement curves and reports can be printed on any commonly available type of printer (ink jet, dot-matrix or laser printer) that is already installed on your Windows system. The correct printer driver can be selected using the Windows Control Panel application.

5.3. Viewer Software "Sleep Xpert App"

During an online measurement, the measurement curves can be displayed on a tablet (Windows or IOS) optionally with the help of the software "Sleep Xpert App". The tablet only serves to visualize the measured curves. There are no data stored and no findings or evaluation can be made.

6. Troubleshooting

Channels (e.g. pressure) are missing in the display.
The channels are deactivated and therefore do not appear during "Test" and "Record".
Check which channels are active for recording using the menu item *Options / Edit Channel sets.*

Channels are missing after loading a measurement.
They were not recorded or have been hidden for measurement data display.

Flow signal is missing during recording or follows the edge of the range.
The flow signal follows a straight flat line in the middle of the channel.
Check the flow prong on the patient and the connection on the MiniScreen unit. When measuring during PAP therapy, check the connection of the PAP adapter hose on the oxygen mask and on the MiniScreen unit.

Signal amplitudes are very small or do not appear.
Check the corresponding sensors on the patient and their connections to the MiniScreen unit. Whilst doing so, check that the tube hoses and the black pressure pads of the thorax sensors are intact. A leaking sensor can cause inaccurate readings in the thorax channel. The pressure pads should be attached to the patient securely without over tightening the belt and the tube hoses should be routed in such a way that they cannot kink.

Check all cables and connectors on the MiniScreen unit and the PC.

Pulse oximeters not responding.
The channels for oxygen saturation and pulse frequency are registering 50% and 30 P/min respectively despite the patient being connected.
First check that the finger sensor is seated correctly on the patient and remove any nail polish that may be present. A small red light should be present in the sensor when the finger is inserted. If the light doesn't switch on when the sensor is applied to the finger, then you need to check the connection at the MiniScreen unit and any intermediate extensions.
Printout not working.
The printer prints characters on the page but in no apparent format.
The wrong printer or printer driver has been installed.
The printer is not responding to the print command.
Check the printer cable and the connections to the printer and PC. The printer should be switched on and operational, i.e. the control LED's on the printer should be lit.
Cannot establish connection to the MiniScreen unit.
The USB cable is not connected correctly.
Check the connection of the USB cable to the MiniScreen unit and the PC.
USB interface was deactivated
The USB interface can be activated in the MiniScreen device software. Select the "Options" tab followed by menu "Device Settings".
Battery is discharged.
Charge the battery correctly.
For clarification and in case of problems during the installation, maintenance or use, please refer to your local distribution partner, or directly to the manufacturer.

7. Ordering informations

Art.-No.	*Spare parts / consumer material / Accessories*
200-0310	**Finger sensor SpO2** soft finger cuff, latex free
200-0311	**Velcro wrist strap** to fix finger sensor cable to the wrist
200-0312/10	**Flow prong** nose spectacles for flow and snoring measurement
200-0861	**Thermistor** for MiniScreen, with connection for flow prong and Lemo plug, reusable
200-0313/01	**Adapter tube**, 20cm, Luerlock
200-0155/22	**PAP adapter hose**, with 150cm tube
LM95066	**Pressure Diff Adapter** for MiniSreen premium
200-0316	**Thorax sensor, complete** 2 pressure pads, flexible connection tubes
200-0617	**Thorax strap**, Size S, blue, 98cm
200-0618	**Thorax strap**, Size M, black, 122cm
200-0619	**Thorax strap**, Size L, red, 142cm
200-0320	**Abdomen sensor, complete** 1 pressure pad, connection hose
200-0321	**Abdomen strap** for MiniScreen, flexible, blue, Size S, 98cm
200-0322	**Abdomen strap** for MiniScreen, flexible, black, Size M, 122cm
200-0323	**Abdomen strap** for MiniScreen, flexible, red, Size L, 142cm
200-0858	**Splitter box with cable** for connection of leg sensor & ECG cable to MiniScreen
200-0850	**ECG electrode cable** to record the ECG signal
200-0951	**EEG electrode cable** for Neuroport module (only MiniScreen plus)
200-0653/01	**LEG sensor** for detection of leg movements (restless legs)
200-0936	**USB cable** for data transmission between MiniScreen and PC
100-0815/03	**Electrical isolator USB** for galvanic separation between MiniScreen device and PC during online measurement
200-0910	**Power adapter Friwo** for MiniScreen with Lemo connector, medical approval
200-0812	**Shoulder bag** cloth bag with shoulder strap for carrying MiniScreen plus, blue
200-0872	**Shoulder bag** cloth bag with shoulder strap for carrying MiniScreen premium, grey
200-0813	**Carrying case** grey plastic case for unit and accessories

Art.-No.	*Spare Parts / Accessories for use with children*
200-0312/31	**Flow prong for children**, 50cm, Luerlock
200-0368/05	**Flow prong for infants**, 50cm, open end
200-0364	**Thorax sensor, complete**, 2 pressure pads with flexible connection tubes (red marked) and lengthened tube for positioning MiniScreen near child
200-0965/03	**Thorax strap**, **XS**, black, 79cm
200-0965/04	**Thorax strap**, **XXS**, black, 65cm
200.0965/05	**Thorax strap**, **XXXS**, black, 40cm
200-0366	**Abdomen sensor,** complete, 1 pressure pad with flexible connection tube (black marked) and lengthened tube
200-0967	**Abdomen strap, XS**, black, 79cm
200-0967/01	**Abdomen strap, XXS**, black, 65cm
200-0967/02	**Abdomen strap, XXXS**, black, 40cm
300-0201/02	**Infant sensor SpO2** (in combination with 200-0370), neonatal, 90cm
300-0201/01	**Soft clip sensor SpO2** (in combination with 200-0370), 15-50kg, 45cm
200-0370	**SpO2 connection cable**

8. Technical specifications

- Dimensions : 30,5mm x 62,7mm x 140mm (H x W x L, without bag)
- Weight : 160 g including storage battery, without bag
- Housing : metallized plastic (ABS, UL 94HB)
- Temperature range : +5°C...+40°C
- Moisture : 10% - 95%
- Atmospheric pressure : 70kPa - 106kPa
- Storage media : Internal flash memory
- Storage capacity : mind. 48 hours
- Registered parameters:
  - Respiratory activity : Differential pressure measurement via flow prong (with adaptor also during PAP therapy), alternative or additional measurement by means of thermistor possible (option)
  - Thoracic effort : Differential pressure measurement by means of rubber cuffs built into chest strap
  - Abdominal effort : Differential pressure measurement by means of rubber cuffs built into abdomen strap
  - Breathing sounds : Phonometric transducer via flow prong
  - SpO_2/Pulse : Built-in pulsoximeter, calibrated for functional oxygen saturation
    SpO_2 measurement range: 80%-100% ± 2% SpO_2
    60%-79% ± 4% SpO_2
    Pulse measurement range: 50 1/min - 150 1/min ± 2%
    (Reference: electrical pulse simulator)
    Finger sensor: special rubber-coated thimble finger sensor
  - Pulse wave : Plethysmogramm display; measurement via finger sensor
  - Position : Acceleration sensor for position recording (5 positions)
  - Ambient Light : Photometric measurement and light-Intensity display
  - PAP : Differential pressure measurement directly on oxygen mask
    Measurement range: 0cmH_2O - 45cmH_2O ± 5%
  - Neuroport : Special electrode for frontal lead (option, MiniScreen plus only)
  - Leg movement : Piezo pressure sensor (option)
  - ECG : One channel lead via adhesive electrodes (option), suitable for patients <10kg
  - Central heart frequ.: Measurement range: 30 1/min - 200 1/min ± 2% (option)
  - PTT : Measurement range: 100 ms – 355 ms ± 4% (option)
  - Syst. blood pressure : Trend (option)
  - External channels : External box with voltage input (RJ11; 0..2.5 V) for up to 8 external channels with galvanic separation and RJ11-jack
- Fault indicator : 2 LEDs on front of the device
- Power supply : Rechargeable Li-Ion storage battery 3.6 V with built-in Semiconductor safety
- Charger : Plug-in power supply with medical approval
- Output : USB interface with cable for data transmission
- Power consumption : Approx. 70mA
- Online operations : In online operation with a patient, an optical wave guide to the PC is indispensable (option)

9. Used Symbols

Symbol	*Meaning*	*Symbol*	*Meaning*
	Pay attention to the instructions for use!		Electrical and electronic devices may not be disposed of with domestic waste. Consumers are obliged by law to return electrical and electronic devices at the end of their service lives to the public collection points set up for this purpose or point of sale. Details to this are defined by the national law of the respective country. This symbol on the product, the instruction manual or the package indicates that a product is subject to these regulations. By recycling, reusing the materials or other forms of utilising old devices, you are making an important contribution to protecting our environment.
	Pay attention to the instructions for use!		
	Type BF		
	Protection class II		
	Best before date		
	Manufacturer	IP22	Device is protected against solid foreign bodies with diameter ≥ 12.5 mm. Device is protected against access with a finger. The device is protected against falling dripping water when the housing is tilted up to 15 °.
	Manufacturing date		Once product! Neither suitable for a preparation nor for a multiple application.
	Medical device		

10. EMC Information

Medical electrical devices subjected to special preventive measures regarding to electromagnetic compatibility (EMC). They must be put in operation and installed according to the EMC information in this manual. Portable and mobile RF communications equipment (e.g. mobile phones) can influence medical electrical devices. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MiniScreen, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. For an intended use of the MiniScreen, the specified equipment in this manual must be used. The application of other equipment can led to a higher emission and a reduction of the immunity.

Guidelines and Manufacturer‘s Declaration – Electromagnetic Emissions		
The MiniScreen is intended for use in an electromagnetic environment as specified below. The customer or user of the MiniScreen should ensure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidelines**
RF – Emission according to CISPR 11	Group 1	The MiniScreen uses RF energy only for it‘s internal function. So it‘s RF emission is very low and it‘s implausible that it cause any interferences to surrounding electronic devices.
RF – Emission according to CISPR 11	Class B	The MiniScreen is suitable for the use in all establishments, including domestic establishments and those, which are connected to the public power supply, which powers buildings for residential purposes.
Harmonic Emissions according to IEC 61000-3-2	Not applicable	
Voltage Fluctuations / Flicker Emissions according to IEC 61000-3-3	Not applicable	

Table 1: Table 201 EN 60601-1-2, Electromagnetic Emissions

Guidelines and Manufacturer‘s Declaration – Electromagnetic Immunity		
The MiniScreen is intended for the electromagnetic environment as specified below. The customer and user of the MiniScreen should ensure that it is used in such an environment.		
Immunity Test	**Test Specification**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Floors should consists of wood, concrete or should be covered with ceramic titles. If the floor is covered with synthetic material, the relative humidity must be at least 30 %.
Electrical fast Transient / Burst IEC 61000-4-4	± 2 kV for AC power line ± 1kV for input and output line 100 kHz	
Surges IEC 610004-5	± 1 kV differential mode ± 2kV common mode	
Voltage dips IEC 61000-4-11	0% U_T for ½ cycle (1 phase) 0% U_T for 1 cycle 70% U_T for 25/30 cycles [a]	
short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 250/300 cycles [a]	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	
Note	U_T is the a.c. mains voltage prior to application of the test level.	
a	25/250 cycles at 50 Hz or 30/300 cycles at 60 Hz	

Table 2: Table 4, 5, 7, 8 EN 60601-1-2, Electromagnetic Immunity

Guidelines and Manufacturer's Declaration – Electromagnetic Immunity		
The MiniScreen is intended for an electromagnetic environment as specified below. The user of the MiniScreen should make sure that is used in such an environment.		
Immunity test	**Test Specification**	**Electromagnetic Environment - Guidance**
Conducted RF disturbance IEC 61000-4-6	3 V_{eff} 150kHz - 80MHz 6 V_{eff} ISM/Amateur bands 80 % AM / 1 kHz	
Radiated RF disturbance IEC 61000-4-3	10 V/m 80MHz - 2,7 GHz 80 % AM / 1 kHz	Interferences may occur in the environment of devices, which are marked with the following symbol: 
Proximity fields from RF wireless communications equipment IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	

Table 3: Table 4, 5, 7, 8 EN 60601-1-2, Electromagnetic Immunity

Guidelines and Manufacturer's Declaration – Electromagnetic Immunity						
Test frequency MHz	**Frequency band [a] MHz**	**Radio service [a]**	**Modulation [b]**	**Max. Performance W**	**Distance m**	**Immunity test level V/m**
385	380 - 390	TETRA 400	Pulse Modulation [b] 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz Hub 1 kHz Sinus	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse Modulation [b] 27 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 - 2 570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation [b] 217 Hz	2	0,3	28
5 240	5 100 - 5 800	WLAN 802.11 a/n	Pulse Modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE: If necessary, to achieve immunity test levels, the distance between the transmit antenna and the MiniScreen can be reduced to 1 m. The 1 m test distance is permitted according to IEC 61000-4-3.

a	For some radio services, only the frequency for the radio link from the mobile communication device to the base station (en: uplink) has been included in the table. The carrier must be modulated with a square wave signal with 50% duty cycle.
b	The carrier must be modulated with a square wave signal with 50% duty cycle.
c	As an alternative to Frequency Modulation (FM), pulse modulation at 50% duty cycle at 18 Hz may be used, as this, if not the actual modulation, would be the worst case scenario

Table 4: Table 9 EN 60601-1-2, Test specifications for the immunity of enclosures to high-frequency wireless communication devices

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