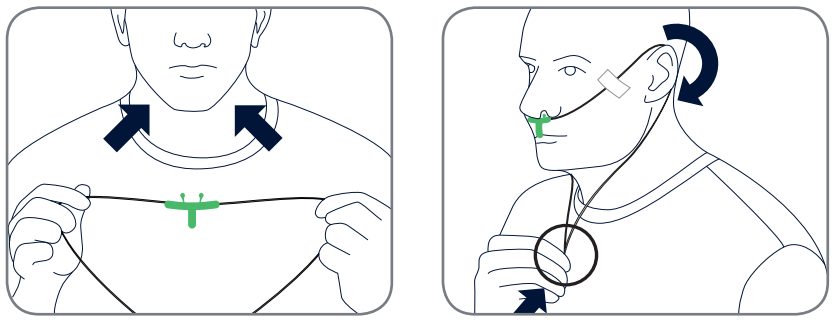
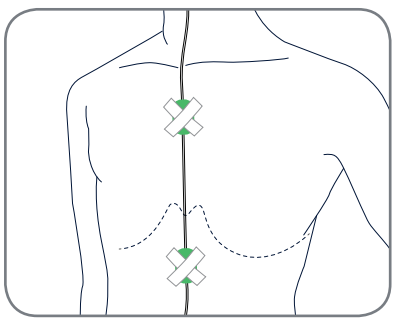
Putting on the sensors.

Step 1. Breathing and chest movement sensors.



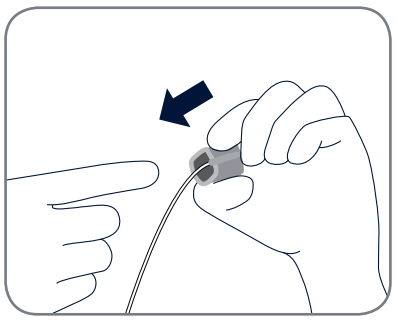
A. Put on the T-shaped breathing sensor with horizontal arm with black sensors pressed against the nostrils and vertical arm touching the upper lip.

B. Pull the cord behind your ears as shown and stick the cords to your cheeks with a woven tape.

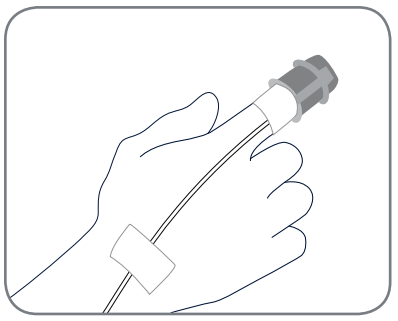


C. Stick the rectangular chest movement sensors with a woven tape against your sternum and abdomen as shown. Make sure the sensors are tightly fitted.

Step 2. Fingertip pulse oximeter.

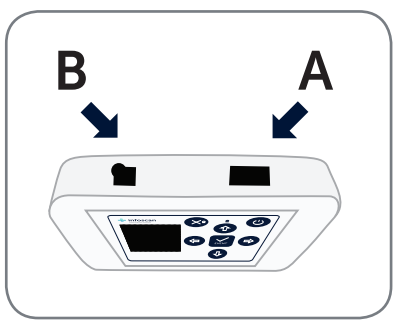


A. Stick the cord with a woven tape around the edging and to your wrist.



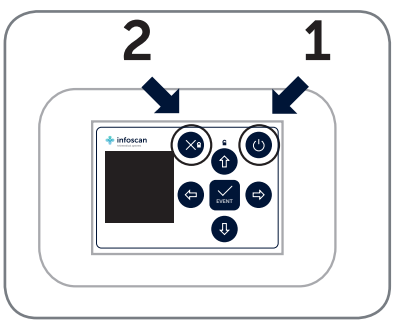
Device preparation.

Step 3. Connecting the sensors to the device and initiating diagnostic session.



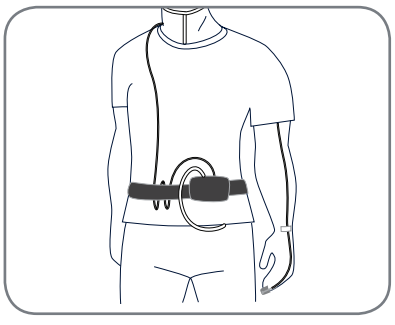
A. pulse oximetry sensor
B. breathing/airflow sensor

Step 4. Starting diagnostic session.



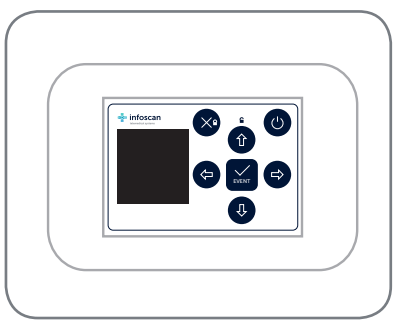
A. Turn the device on by pressing and holding the „1" button for approx. 2 secs.

B. Lock the device by holding the „2" button for approx. 2 secs. Padlock symbol will appear on top of the screen.



C. Put the cords behind the belt so they don't limit your movement.

Step 5. Ending diagnostic session



A. Unplug the sensors after waking up in the reverse order to that shown in section 'Putting on the sensors'.

Infoscan MED Recorder

Patient Manual

infoscan
telemedical systems

Producer:

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V1.0 December 2016

Indications for Use

The Infoscan MED Recorder is indicated for use by Health Care Professional (HCP), where it may aid in the diagnosis of sleep disordered breathing for adult patients. The Infoscan MED Recorder records the following data: patient respiratory airflow, snoring, blood oxygen saturation, pulse and body position during sleep. The device uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing for further clinical evaluation. The device is intended for home and hospital use under the direction of a HCP.

Device Description

The Infoscan MED Recorder is a medical device used in the diagnostic evaluation of adults suspected of having sleep apnea.

Warnings and Cautions

- MED Recorder is an at home use prescription device. Federal restricts the use of this device to sale or use by physician, or as predicated by physician. MED Recorder uses built-in rechargeable battery.
- Patients with artificial pacemakers or internal cardiac defibrillators (ICD) MUST NOT use the device.
- Device MUST NOT be used while the battery is being charged.
- Device MUST NOT be used during bath or shower.
- MED Recorder Device uses an internal date and timer. Precision of the date and time depends on the accurate setting of the internal clock.
- The usage of accessories, sensors or cables other than those provided by Infoscan may have a negative impact on device performance and may affect measurement accuracy.
- MED Recorder Device should not work at less than 3 feet from other electronical devices that generate electromagnetic fields, due to the possibility of interference.
- Device should be used only during the recording to avoid skin irritation from prolonged contact with the accessories.
- Device should be kept and used away from particulate and do not expose it to intense sunlight.
- Device should be protected from exposure to high humidity (such as rain), which may cause damage or affect its performance.
- DO NOT use the device, sensors, leads or cables that appear damaged or are defective.
- Protect the device from damage caused by unintentional drop, collision, strong vibration or other mechanical force during servicing.
- Use the supplied belt and do not lift the device by its sensor or cables to avoid disconnection.
- Store and use the device away from pets, pests and children, their action can cause damage to the device or accessories.
- Changes or modifications not expressly approved by Infoscan S.A. could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Battery Information

Your MED Recorder has a built-in rechargeable battery and will be fully charged when you receive it.

Device MUST NOT be used while battery is being charged.

Troubleshooting

If Nonin pulse Oximeter does not detect a finger it is necessary to ensure that the sensor is connected properly to socket. If "Data Unavailable" message is still displayed check whether the sensor is shining.
If you see red light and none of your fingers can catch measurement contact with Infoscan service.
If body position and airflow sensors do not record data is necessary to ensure that they are connected properly to socket. If they are but no movement or airflow data are registered contact with Infoscan service.
If you notice that one of the pieces of medical tape is coming off secure it with additional medical tape.

Range and Accuracy of Measurements

Pulse Oximetry

- SpO2: 0 to 100%
- Pulse rate range: 18 to 321 beats per minute
- SpO2 accuracy (70-100%) +/- 2 digits
- Pulse rate accuracy (18-300 BPM): +/- 3 digits

Airflow

- Data sampling rate: 45 times/second, qualitative measurement determining airflow in different passage of the respiratory system

Body movement (accelerometers)

- Data sampling rate: 45 times/second, qualitative measurement

Technical Parameters

- Operating temperature: 5°C to 40°C (41°F to 104°F)
- Temperature of storage: -25°C to 70°C (-13°F to 158°F)
- Humidity: 15% to 90% non-condensing
- Maximum altitude: 2000m a.s.l
- Power requirements: 170mW (screen off), 350mW (screen on)
- Power supply: Internal battery Li-Polymer, constant voltage 3.6-4.2V
- Dimensions (without sensors): 120 mm (depth) × 75 mm (width) × 32 mm (height) (4.72" × 2.95" × 1.26")
- Weight: 135 g (with battery)
- Accuracy of internal timer < ±1 s/day
- Blood saturation sensor specifications: in accordance with NONIN® PureLight® series 8000
- Airflow and body movement sensors: provided only by Infoscan
- Fully charged battery life is sufficient for up to 24 hours continuous operation
- Life of battery: up to 12 months
- Technical inspection recommended: every 12 months

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment o and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help