

Specificație Tehnică Completată

Anexa 2 Monitor de pacient compatibil cu RMN 1.5Tesla

Model: MAGLIFE RT-1 Reg. SDM: DM000648501

Producător: SCHILLER MEDICAL

Țara: Franta

Specificarea tehnică deplină solicitată, Standarde de referință	Specificația tehnică propusă de ofertant
Monitor de pacient compatibil cu RMN 1.5Tesla Descriere: Monitor de pacient specific pentru monitorizarea funcțiilor vitale în timpul examinărilor cu Imagistică prin Rezonanța Magnetică. Atenție! Toate componentele monitorului cât și accesoriile, consumabilele trebuie să fie compatibile cu RMN 1.5T. Tip pacient - adult. Parametrii monitorizați cu posibilitate de afișare pe ecran: ECG cu detecția aritmiei; SpO2; NIBP; Gaze anestezice (SEV, ISO); CO2; Frecvența respiratorie; O2; Temperatura (1 canal); Se acceptă posibilitatea parametrilor monitorizați să fie măsurați prin tehnologie wireless.	Monitor de pacient compatibil cu RMN 1.5Tesla DA, Datasheet MAGLIFE RT-1, pag.2 din Prezentare MAGLIFE RT-1 Descriere: Monitor de pacient specific pentru monitorizarea funcțiilor vitale în timpul examinărilor cu Imagistică prin Rezonanța Magnetică. DA, Prezentare MAGLIFE RT-1, pag.10,11 din Manual de utilizare_MAGLIFE_RT-1 Atenție! Toate componentele monitorului cât și accesoriile, consumabilele trebuie să fie compatibile cu RMN 1.5T. DA, pag.2-3 Prezentare MAGLIFE RT-1, pag.10,11 din Manual de utilizare_MAGLIFE_RT-1 Tip pacient – adult, pediatric, neonatal. DA, Prezentare MAGLIFE RT-1 Pag.2 Parametrii monitorizați cu posibilitate de afișare pe ecran: ECG cu detecția aritmiei; DA, Datasheet MAGLIFE RT-1, pag.56-64 Manual de utilizare_MAGLIFE_RT-1 SpO2; DA, Datasheet MAGLIFE RT-1, pag.65-73 Manual de utilizare_MAGLIFE_RT-1 NIBP; DA Datasheet MAGLIFE RT-1, pag.74-80 Manual de utilizare_MAGLIFE_RT-1 Gaze anestezice (SEV, ISO); DA Datasheet MAGLIFE RT-1, pag.93, 112-116 Manual de utilizare_MAGLIFE_RT-1 (aditional Desfluran, Enfluran, Halotan) CO2; DA Datasheet MAGLIFE RT-1, pag.93, 101-111 Manual de utilizare_MAGLIFE_RT-1 (aditional EtCO2, FiCO2) Frecvența respiratorie; DA Datasheet MAGLIFE RT-1, pag.22,157 din Manual de utilizare_MAGLIFE_RT-1 O2; DA Datasheet MAGLIFE RT-1, pag.93,160 din Manual de utilizare_MAGLIFE_RT-1 Temperatura (1 canal); DA, Datasheet MAGLIFE RT-1, pag.89-91 Manual de utilizare_MAGLIFE_RT-1 Se acceptă posibilitatea parametrilor monitorizați să fie măsurați prin tehnologie wireless.

Anexa 2

Monitorizare agent (isofluran, sevofluran), auto identificarea gazelor anestezice, determinarea și afișarea valorii MAC. Display color tactil: ≥10 inch Alarmer vizuale și sonore Liniile câmpului magnetic ≥200 Gauss; Gauss alarmă – cu indicator vizual și/sau sonor Baterie reîncărcabilă cu autonomie minim 3 ore Suport mobil pe roți compatibil cu RMN 1.5 Tesla pentru fixare monitor sau suport specializat compatibil cu RMN 1.5Tesla pentru fixare monitor la mașina de anestezie din lotul nr.1 Suportul sau monitorul va fi echipat cu coș / raft / sertar sau cârlige pentru amplasarea în ordine a firelor de achiziție a semnalelor fiziologice. Accesorii: Cablu ECG cu minim 3 electrozi - 2 buc.(sau 1 buc în cazul unui modul/senzor de măsurare ECG wireless) Electrozi ECG adult, unică utilizare - 200 buc. Senzor SpO2 adult, reutilizabil tip clește - 2 buc. !Pentru senzorii SpO2 se acceptă un modul/senzor wireless cu adapter deget adult 2 bucăți Senzor Temperatură, reutilizabil -1 buc. Manjete NIBP, adult mediu, adult, adult mare, reutilizabile (1set/3buc) - 2 set. Consumabile pentru modulul de gaze – minim 20 seturi. Prezentarea certificatelor care confirmă compatibilitatea RMN 1.5T (de ex. scrisoare/document de la producător care atestă compatibilitatea, certificate care confirmă că produsul este non-feromagnetic sau produsul este din oțel inoxidabil RMN-compatibil) Manual de utilizator în limba română și engleză Manual de service și manual de utilizare în conformitate cu Legea Nr. 102 cu privire la dispozitivele medicale din 09.06.2017, capitolul 4 Articolul 14. P. 3.	Monitorizare agent (isofluran, sevofluran), auto identificarea gazelor anestezice, determinarea și afișarea valorii MAC. DA, pag.2 din Datasheet MAGLIFE RT-1, pag.93, 112-116 Manual de utilizare_MAGLIFE_RT-1 (aditional Desfluran, Enfluran, Halotan), valoarea MAC pag.116,131 din Manual de utilizare_MAGLIFE_RT-1 Display color tactil: 15.6inch DA, Prezentare MAGLIFE RT-1 Alarmer vizuale și sonore DA, Datasheet MAGLIFE RT-1 Liniile câmpului magnetic 800 Gauss; DA, pag.9 din Manual de utilizare_MAGLIFE_RT-1 Gauss alarmă – cu indicator vizual și sonor DA, pag.38,46 din Manual de utilizare_MAGLIFE_RT-1 Baterie reîncărcabilă cu autonomie minim 6 ore DA, Datasheet MAGLIFE RT-1 Suport mobil pe roți compatibil cu RMN 1.5 Tesla pentru fixare monitor TROLEU DA, Prezentare MAGLIFE RT-1 Suportul este echipat cu coș, raft pentru amplasarea în ordine a firelor de achiziție a semnalelor fiziologice. DA, Prezentare MAGLIFE RT-1, pag.24 din Manual de utilizare_MAGLIFE_RT-1 Accesorii: Modul ECG wireless cu 4 electrozi- 1 buc. DA, pag.62 din Manual de utilizare_MAGLIFE_RT-1 Electrozi ECG adult, unică utilizare - 240 buc. DA Modul SpO2 wireless adult, reutilizabil tip clește -1 buc. DA, pag.70-71 din Manual de utilizare_MAGLIFE_RT-1 Senzor Temperatură, reutilizabil -1 buc. DA pag.89 din Manual de utilizare_MAGLIFE_RT-1 Manjete NIBP, adult mediu, adult, adult mare, reutilizabile (1set/3buc) - 2 set. DA Consumabile pentru modulul de gaze – 35 seturi. DA Prezentarea certificatelor care confirmă compatibilitatea RMN 1.5T (de ex. scrisoare/document de la producător care atestă compatibilitatea, certificate care confirmă că produsul este non-feromagnetic sau produsul este din oțel inoxidabil RMN-compatibil) DA Manual de utilizator în limba română și engleză DA Manual de service și manual de utilizare în conformitate cu Legea Nr. 102 cu privire la dispozitivele medicale din 09.06.2017, capitolul 4 Articolul 14. P. 3. DA
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Technical data

MAGLIFE RT-1

System

Device

Dimensions: 1310 × 620 × 520 mm (h × l × w)

Weight: 46 kg

Power supply: 100 - 240 VAC, 150 VA, 50/60 Hz

Protection case: IP21

Battery: Lithium/ion 14.6 V, 6.4 Ah, 93.44 Wh

- Autonomy between 6 to 8 hours depending on built-in options
- Recharging duration: 5 hours

Environmental conditions: 10 °C ... 40 °C relative humidity at 20 - 90 % (non condensing) Atmospheric pressure 700...1060 hPa

Charging bay: 2 x ECG sensors, 2 x SpO2 sensors

Connections: NIBP, Temperature, IBP, breathing gases, Gating in/out and gas sample exhaust, Ventilation

Network: WLAN for communication with MAGSCREEN RT-1

Display: High-resolution TFT colour LCD capacitive touch screen, protected by tempered glass, 15.6 " (1366 × 768 pixels; 344 × 194 mm)

MRI rating:

- 3.0 T
- 50 cm distance for an active shielded 3 T magnet
- 5000 Gauss
- 4 W/kg SAR

MAGSCREEN RT-1 (remote display)

Dimensions: 364 × 195 × 422 mm (h × l × w)

Weight: 7.9 kg

Power supply: 100 - 240 VAC, 50/60 Hz, 84 VA

Display: High-resolution TFT colour LCD capacitive touch screen, protected by tempered glass, 15.6 " (1366 × 768 pixels; 344 × 194 mm)

Alarms

Visual and audible for each parameter

Quick set, All alarms off, Standard

Trigger

2x adjustable optical trigger outputs

Trends

24 hours for all parameters

Highest resolution without data loss

Network

Ethernet

Memory

Logfile

MAGLINK (Network equipment)

Dimensions: 115 × 205 × 160 mm (h × l × w) excl. antennas

Weight: 2.8 kg

Power supply: 100 - 240 VAC, 50/60 Hz, 84 VA

Interface: WLAN, Ethernet, Optical

MRI rating: 10 mT (100 Gauss)

Measured values

ECG

Wireless sensor

- Battery capacity: 4 hours
- Recharging duration: 4 hours

Simultaneous, synchronous recording of all 4 active electrodes giving 6 leads

Patented for gradient suppression, highest ECG quality

Filter settings for accurate QRS detection under MRI conditions:

- Monitoring
- MRI Default
- MRI Basic
- MRI Research

Defibrillation protection

Bandwidth:

- Monitoring: 0.5 Hz - 42.25 Hz (0.6 Hz - 42.25 Hz if BLW filter is on)
- MRI Default/Basic: 0.5 Hz - 25 Hz

HR: 30 - 350 bpm

Sensitivity: 0.25 / 0.5 / 1 / 2 cm/mV

Speed: 25 / 50 mm/s

SpO2 / pulse

Wireless sensor

- Battery capacity: 10 hours
- Recharging duration: 4 hours

Photo-spectrometry measurement with following sensors: W-SA (adult), W-SP (paediatric), W-SVS (Universal & Very Small patient)

Measurement range:

- SpO2: 1 - 100 %
- PP: 30 - 240 bpm
- PI: 0.1 - 20

Accuracy:

- Saturation: 70 to 100 % ± 2 Arms (no motion)
- Pulse rate: ± 2 BPM over the full range (no motion)

NIBP

Oscillometric measurement automatic or manual

Measuring range:

- Adults/child: Sys 30...255 mmHg, dia 15...220 mmHg
- Neonates: Sys 30...135 mmHg, dia 15...110 mmHg

Accuracy: ± 3 mmHg

IBP

Disposable and reusable sensors (non-magnetic). Adjustable for standard disposable sensors

Measurement range: -100 to 400 mmHg

Accuracy: 1 mmHg or ± 1% (whichever is greater)

Temperature

Direct method by optical interferometry

External/skin temperature measurement

Measuring range: 25 to 45 °C, without calibration

Accuracy: 0.3 °C from 25 to 45 °C

Resolution: 0.1 °C



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MAGLIFE RT-1

Capnography

Type: Multigas analyser, sidestream via infrared photo-spectrometry

CO₂, O₂ (permanent cell), N₂O and auto ID (any two of the five anaesthetic agents SEV, ISO, ENF, DES and HAL)

Inspiratory and expiratory data for CO₂, N₂O, O₂, anaesthetic agents

Respiration Rate accuracy:

- RR 2 - 60 bpm, ± 1 bpm
- RR 60 - 100 bpm, unspecified

Range:

- CO₂: 0 to 30 %
- O₂: 0 to 100 %
- N₂O: 0 to 100 %
- DES/SEV/ENF/ISO/HAL: 0 to 30 %

Accuracy:

As full accuracy gas specifications, but derated as follows:

- Add $\pm 0.3 \%_{\text{ABS}}$ to inaccuracy for CO₂
- Add $\pm 8 \%_{\text{REL}}$ to inaccuracy for all agents
- N₂O accuracy is $\pm (8 \%_{\text{REL}} + 2 \%_{\text{ABS}})$

For a single halogenated anaesthetic gas in a gas mixture that is concealed when the anaesthetic concentration falls:

- 0.15 % (Full accuracy)
- 0.3 % (ISO accuracy)

Basic ventilation

Type: Respiratory mechanics, flow, volume

Condition of use: Endotracheal tube 5.5 - 10 mm (adults) and 3 - 6 mm (paediatric)

Sampling line:

- Flow sensor adult (tidal volume above 150 ml)
- Flow sensor neonatal (tidal volume below 300 ml), 3.3 m

Measuring mode: Continuous differential pressure spirometry with fixed orifice flow sensor type. Automatic compensation for ambient pressure, side-stream gas sampling flow and gas composition

Measuring parameters:

- Airway pressure [cmH₂O]
- Airway flow (both direct.) [l/min]
- Tidal volume (insp. and exp.) [ml]
- Minute volume (insp. and exp.) [l/min]



MAGLIFE RT-1

MAGLIFE RT-1

Revolutionary patient monitoring in the MRI environment

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MAGLIFE RT-1

Revolutionary patient monitoring in the MRI environment

SCHILLER, manufacturer of MRI-compatible monitors since 1993, presents the MAGLIFE RT-1:

- ✦ Wireless ECG and SpO₂ sensors
- ✦ Spirometry
- ✦ Optical temperature measurement
- ✦ Touch screen interface



The wireless sensors are easily recharged onto their dedicated cradles.

The MAGLIFE RT-1 performs patient monitoring in an MRI environment including all necessary vital parameters during anaesthesia. The system is designed for all patients: adults, children and neonates. It allows for close monitoring during the examination and can be fully controlled from outside the Faraday cage.

EXTENDED AREA OF USE

The MAGLIFE RT-1 is compatible with MRI systems from any manufacturer that have a field strength between 0.2 and 3 tesla. The use is versatile: for everyday use, for monitoring under anaesthesia or for cardiac imaging.

ARTIFACT-FREE ECG

The MAGLIFE RT-1 uses a patented ECG processing that guarantees a very high gradient artefact immunity.

OPTICAL TEMPERATURE MEASUREMENT

Using the optical measuring principle for temperature guarantees safe operation and immunity to electromagnetic interference.

10 VITAL PARAMETERS AT A GLANCE

The quick and easy-to-use interface provides simultaneous monitoring of 10 vital parameters at a glance:

- ✦ ECG, SpO₂, NIBP (standard)
- ✦ IBP (optional)
- ✦ etCO₂, anaesthetic agents, O₂, N₂O (optional)
- ✦ Spirometry (optional)
- ✦ Temperature (optional)

The monitored parameters can be combined on the display in seven different ways, according to the customer's needs.

WIRELESS SENSORS

SCHILLER offers wireless ECG and SpO₂ sensors:

- ✦ Wireless: A technological innovation for ease of use.
- ✦ Compact: Thanks to their small size, the sensors are suitable for all types of patients, even premature babies.
- ✦ Safe connect: once paired, the sensors automatically reconnect to the MAGLIFE RT-1.

INTUITIVE INTERFACE

Equipped with a large 15.6" colour TFT touch screen, the MAGLIFE RT-1 offers a powerful Touch'n'Save interface.

SPIROMETRY MEASUREMENT

Spirometry monitors patient's respiratory mechanics in addition to the anaesthetic agent surveillance.

MOBILITY

The trolley allows the patient monitor to be used as close as 50 cm from the MR device.

In addition, mains or battery operation allow for greater mobility and flexibility between patient prep and the MR scan.



REMOTE CONTROL

The MAGLIFE RT-1 can be controlled remotely from the MAGSCREEN RT-1 outside the Faraday cage:

- ✦ View the patient's vital parameters from the control room.
- ✦ Full control of the MAGLIFE RT-1 monitor and adjustment of all parameters and functions.

WIRELESS DATA TRANSMISSION

The MAGLIFE RT-1 communicates with the remote display unit MAGSCREEN RT-1 via fibre optic, Ethernet and WLAN, offering a safe Faraday cage penetration.



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MAGLIFE RT-1 MAGSCREEN RT-1



User Guide



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Sales and Service Information

The SCHILLER sales and service centre network is world-wide. For the address of your local distributor, contact your nearest SCHILLER subsidiary.

In case of difficulty, you can find a complete list of all distributors and subsidiaries on our Internet site:

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CE 0459

The **MAGLIFE RT-1** and **MAGSCREEN RT-1** bear the CE-0459 mark (Notified Body GMED), indicating its compliance with the general safety and performance requirements of Annex I of the Medical Device Regulation (EU) 2017/745 regarding safety, functionality and labelling. The requirements apply to patients, users, and third persons who come into contact with this device within the scope of its intended use. The safety and clinical performance summary are available on the EUDAMED website.

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SW ≥ 1



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1 Safety Notes

i

- The **MAGLIFE RT-1** is a monitor for hospital use in an MRI environment.
- The **MAGSCREEN RT-1** is a remote/control display which may only be used in conjunction with **MAGLIFE RT-1**. **MAGSCREEN RT-1** must only be set up and operated outside the MRI room.
- The use of the **MAGSCREEN RT-1** involves using a **MAGLINK** and **MAGLIFE RT-1**. These 3 elements constitute a Medical Electrical System (ME System). Any instructions relating to the **MAGSCREEN RT-1** apply to the ME System.
- The term device is related either to **MAGLIFE RT-1** or the ME System.

1.1 User Profiles

This user manual is intended for clinical professionals. Clinical professionals must have a working knowledge of medical procedures, practices, and terminology for completing these examinations.

Training

An initial training of at least 30 minutes is necessary and sufficient to use the device. Since all user profiles are professional healthcare providers, a regular training course is not mandatory.

1.2 Intended Use

1.2.1 General intended purpose of the medical device

The **MAGLIFE RT-1** is a patient monitor designed to be used near MRI devices with magnetic fields between 0.2 and 3 Tesla. It is used for the monitoring of a patient during MRI procedures. An authorised person must be present throughout the procedure.

It is permitted to use the **MAGLIFE RT-1** only at a distance from the MRI device where the stray field is less than or equal to 80 mT (800 Gauss).

The **MAGSCREEN RT-1** is a remote/control display designed to be used outside the vicinity of MRI systems. It displays a copy of the monitoring information from **MAGLIFE RT-1** and allows the control of **MAGLIFE RT-1**.

Monitoring

- ▲ Depending on their configuration, the monitoring function of the **MAGLIFE RT-1** delivers the most important parameters ECG, SpO₂, Capnography Respiration rate, NIBP, IBP, Temperature, Anaesthetic Agents and Basic ventilation mechanics. It allows continuous patient monitoring with alarming for each parameter if a value is out of limits.
- ▲ The device is intended to be applied to one patient at a time.
- ▲ The devices are designed to meet the specific needs of hospital services.

1.2.2 Use environments



- The **MAGLIFE RT-1** is a monitor for hospital use in an MRI environment.
- The **MAGSCREEN RT-1** is a remote/control display which may only be used in conjunction with **MAGLIFE RT-1**. **MAGSCREEN RT-1** must only be set up and operated outside the MRI room.
- The use of the **MAGSCREEN RT-1** involves using a **MAGLINK** and **MAGLIFE RT-1**. These 3 elements constitute a Medical Electrical System (ME System). Any instructions relating to the **MAGSCREEN RT-1** apply to the ME System.
- The term device is related either to **MAGLIFE RT-1** or the ME System.

1.2.3 Monitoring functions

ECG

- ▲ The **MAGLIFE RT-1** is intended to monitor 6 ECG waveforms (3-leads), Heart Rate (HR).

NIBP

- ▲ The **MAGLIFE RT-1** is intended to make non-invasive measurements of arterial pressure. The measurements are done using an inflatable cuff on the patient's arm or leg: systolic, diastolic and mean pressure.

IBP

- ▲ The **MAGLIFE RT-1** is intended to make invasive measurements of arterial, venous or intra-cranial pressure: systolic, diastolic and mean pressure.

SpO₂

- ▲ The **MAGLIFE RT-1** is intended to make continuous non-invasive monitoring of functional oxygen saturation of arterial haemoglobin and peripheral pulse (pulse rate).
- ▲ The **MAGLIFE RT-1** can be equipped with either SCHILLER or BluePoint SpO₂ sensors.

CO₂ and Respiration rate

- ▲ The **MAGLIFE RT-1** is intended to make a continuous non-invasive measurement and monitoring of carbon dioxide concentration of the expired using the principle of infrared spectroscopy to monitor carbon dioxide concentration of the expired and inspired breath, other respiratory gases (such as FiO₂, EtO₂, O₂, ...) and respiration rates.

Temperature

- ▲ The **MAGLIFE RT-1** is intended to make continuous cutaneous body temperature measurements.

Anaesthetic Agent (GAS)

- ▲ The **MAGLIFE RT-1** is intended to make continuous surveillance of anaesthetic agents: Desflurane (DES), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV) and Halothane (HAL).

Basic Ventilation mechanics

- ▲ The **MAGLIFE RT-1** is intended to make continuous measurements of volume, flow and pressure of the breathing air.
- ▲ SPIRIT differential pressure respiratory mechanics analyser is intended to be connected to a patient breathing circuit to continuously measure gas flow and pressure and calculate a full set of derived respiratory mechanics parameters.

1.3 Expected Therapeutic Clinical Patient Benefits

Monitoring is applied to almost all patients presenting with some symptoms. It encompasses a wide variety of pathologies and allows for the professional user to detect dramatic changes in the status of the patient.

6-leads ECG monitoring

The benefit for patient is the recording of the ECG and the heart rate allowing professional to detect any changes in the patient condition during an MRI examination and establish a diagnostic to adjust the care management such as drug delivery.

NIBP/IBP monitoring

The NIBP/IBP monitoring benefit for patient is the determination of the systolic, diastolic and mean blood pressures allowing professional to detect any changes in the patient condition during an MRI examination and establish a diagnostic to adjust the care management such as drug delivery.

SpO₂ monitoring

The SpO₂ monitoring benefit for patient is the measurement of the functional oxygen saturation of arterial haemoglobin and peripheral pulse allowing professional to detect any changes in the patient condition during an MRI examination and establish a diagnostic to adjust the care management such as drug delivery.

Temperature

The temperature monitoring benefit for patient is the measurement of temperature allowing professional to detect any changes in the patient condition during an MRI examination and establish a diagnostic to adjust the care management such as drug delivery.

Capnometry, respiration gases and respiration rate monitoring

Capnometry and respiration gases monitoring benefit for patient is the measurement of carbon dioxide and other respiration gases (O₂, N₂O) concentration of expired and inspired air. This monitoring indicates to the professional the amount of CO₂, O₂ and N₂O present at the end of exhalation and the respiration rate. This information allows the professional to detect any changes in the patient condition during an MRI examination and establish a diagnostic to adjust the care management such as drug delivery.

Anaesthetic Agents monitoring

The Anaesthetic agents monitoring benefit for patient is the measurement of the concentration of maximum two anaesthetic agents allowing professional to detect any changes in the patient anaesthesia condition and to adjust the anaesthesia management if needed during an MRI examination.

Basic ventilation mechanics monitoring

The use of the SPIRIT flow sensor for basic ventilation monitoring is the continuous measurements of volume, flow and pressure of the breathing air allowing the professional to detect any changes in the patient ventilation status and to adjust the ventilation management if needed during an MRI examination.

Expected success of all these monitoring parameters is not defined by learned societies and bibliographic state-of-the-art does not provide information to define a quantified criterion.

Clinical criteria indicating the deterioration of patient's state of health are belonging to each physician medical knowledge and experience and depends on the patient condition and physiological status. Alarm warnings of the monitor **MAGLIFE RT-1** and its remote display screen **MAGSCREEN RT-1** and alarms sets help the physician to depict a trend in the patient's state of health.

Therefore, the success of these monitoring parameters to have a benefit on the patient health and care management depend directly on the professional knowledge and experience thus, no quantifiable data are available.

1.4 Contraindications for Use



- ▲ The device/ME System is not intended for use outdoors, in-home care, ambulances, helicopters, aeroplanes, submarines, boats, hyperbaric chambers, or in an explosive or flammable environment.
- ▲ **Danger of explosion.** The device/ME System must not be used in areas with any danger of explosion. There might be a danger of explosion in areas where flammable products (petrol), flammable anaesthetic agents or skin cleaning/disinfection products are in use or where the ambient air's oxygen concentration is higher than 25%.

1.5 Known Side Effects



- ▲ High levels of RF or induced current by electromagnetic gradient fields may cause patient heating or burning.
- ▲ Due to gradients in the MRI, connecting conductors to the patient can cause burns due to local heating of the conductors.

1.6 Responsibility of the User



- ▲ The numerical and graphical results and any interpretation given must be examined concerning the overall clinical condition of the patient and the general recorded data quality.
- ▲ The indications given by this equipment are not a substitute for regular checking of vital functions.
- ▲ Always check that the screen/alarm LED of the device can be seen in case the audible alarms cannot be heard or are turned off (refer to section [4.5.2 Operator's position](#))
- ▲ Do not start or operate the device unless the setup is verified to be correct.
- ▲ Operating a device with a defective casing, cables, and sensors constitutes a danger to the patient or the user. Therefore:
 - Immediately replace a damaged device, damaged cables, sensors and connections. Damaged or missing components must be replaced immediately.
 - When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, carry out the safety test before further use.
- ▲ The device, including sensors and accessories, must be serviced regularly. (refer to section [9.1.1 Maintenance interval table](#))
- ▲ Check that the battery is always sufficiently charged.
- ▲ Properly dispose of the packaging material and check that it is out of children's reach.
- ▲ Do not dispose of the device in the household waste.
- ▲ Do not monitor the patient with only one physiological parameter. Monitoring simultaneously with multiple physiological parameters is favoured.

1.7 Organisational Measures



- ▲ Before using the device, an introduction regarding the device's functions and safety precautions has been provided and understood.
- ▲ Check that the user has read and understood the user guide, especially the safety notes.
- ▲ Always keep the user guide at hand near the device. Check that the instructions are always complete, up-to-date and legible.

1.8 Safety Conscious Operation



- ▲ High levels of RF or induced current by electromagnetic gradient fields may cause signal artefacts.
- ▲ This user guide, especially the safety notes, must be read and observed at all times.
- ▲ For patient safety, check that neither the electrodes, including the neutral electrode, the patient, or persons touching the patient, come into contact with conducting objects, even if these are earthed.
- ▲ Immediately report any changes that impair safety (including operating behaviour, misuse or forgetting of accessories) to the person responsible.
- ▲ Only connect original SCHILLER accessories to the device.
- ▲ Before switching the device on, check if the device's casing and electrode connection are undamaged.
- ▲ Only operate the device per the specified technical data.
- ▲ Check that the environmental conditions (storage and operating temperature) mentioned in the technical data are respected.
- ▲ Do not expose the device to great temperature variations over a long period. Major temperature variations can cause water condensation on the device. Should condensation occur, dry the device, electrodes and all connections.
- ▲ Special caution must always be taken on the intracardiac application of medical equipment. It is important to check that no conducting parts connected to the device's isolated patient input (patient, plug, electrodes, sensor) come into contact with other, earthed conductive objects, as this might short-out the patient's isolation and remove the protection of the isolated input.
- ▲ Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- ▲ Prepare the patient's skin before sticking the electrodes according to section [5.2.1 Preparing the skin before placing ECG electrodes](#).
- ▲ Do not place the device where the patient can control the device.
- ▲ Position the device so it cannot fall on the patient or the floor.
- ▲ Do not reuse disposable accessories marked with the symbol  to prevent cross-infection.
- ▲ Check the expiry date of the electrodes before use.
- ▲ If unexpected readings are obtained, the operator should check the connections and verify the readings according to section [9.2.3 Functional test and measured value](#).
- ▲ All MRI-specific safety precautions must be observed during all interventions (setup, operation, service inspections). Interventions at the **MAGLIFE RT-1**, for example, in-service inspections must always be performed outside the hazard area (attraction of the magnet).

 WARNING

Shock Hazard. Observe the following warnings. Failure to do so may endanger the lives of the patient, the user and other persons present.

- ▲ **MAGLIFE RT-1, MAGSCREEN RT-1 and MAGLINK** are protection class I devices and must only be connected to a mains supply with protective earth. The devices must only be connected to properly installed, grounded wall outlets.
- ▲ Properly charge ECG/SpO₂ sensors on their charging sockets.
- ▲ Do not use Multiple Portable Socket Outlets (MPSO) to connect the devices to the power line.
- ▲ Do not connect items other than those specified as ME System.
- ▲ Before using the device, the operator must check the correct working order and operating condition. The cables, in particular, must be checked for signs of damage. Damaged cables and connectors must be replaced immediately before use.
- ▲ Immediately report any changes that impair safety (including operating behaviour, misuse or forgetting of accessories) to the person responsible.
- ▲ When disconnecting the device from the power supply, remove the plug from the wall outlet before disconnecting the cable. Otherwise, there is a risk of coming in contact with line voltage by inadvertently introducing metal parts in the sockets of the power cord.
- ▲ All system devices must be connected to the same power supply circuit. Devices not connected to the same circuit must be electrically isolated when operated (isolated interface).
- ▲ The device is suitable for intracardiac applications.
- ▲ During intracardiac use, it is imperative to avoid electrical contact with parts connected to the heart (pressure transducer, metal tube connections and stopcocks, guide wires). Prevent contact with conductive parts (connectors, electrodes, transducers) connected to the isolated patient signal input with other grounded conductive parts. Not doing so could bridge the patient's isolation and cancel the protection provided by the isolated input.
- ▲ Liquids must not be allowed to enter the devices. A service technician must immediately clean and check devices into which liquids have penetrated before they can be reused.

1.9 Operation with other Devices



- ▲ Use only accessories, and other parts recommended or supplied by SCHILLER. Using other than recommended or supplied parts may result in injury, inaccurate information or damage to the device.
- ▲ The patient can be endangered by too high leakage currents (summation of leakage currents) if:
 - Several devices are connected to the patient
 - Other equipment is connected to the **MAGLIFE RT-1**Therefore, devices that are not required should be disconnected from the patient, and only equipment approved by SCHILLER may be connected to the device.
- ▲ Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (for example, IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the system standard IEC/EN 60601-1. Anyone who connects additional equipment to the signal input or output part configures a medical system and is therefore responsible for that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult the technical service department or your local representative.
- ▲ Magnetic and electrical fields of X-ray equipment, tomographs, portable communication devices, HF radios and devices labelled with the  symbol can affect the operation of this device. (refer to section [9.8.5 Preventing electromagnetic interferences](#)) Avoid using such devices or keep a sufficient distance from them.
- ▲ The **MAGLIFE RT-1** radiates high-frequency electromagnetic energy during telemetric data transfer and can disturb other devices (particularly life-support devices) if not installed and operated per the user guide.
- ▲ Before connecting the device to the power line, check that the voltage and frequency ratings of your power line match the values indicated on the device nameplate.
- ▲ The **MAGLIFE RT-1** signal inputs are protected against damage from defibrillation and HF surgical voltages. However, precautions must be observed when defibrillators or HF surgical equipment is used. To reduce the risk of burns in the case of neutral HF electrode failure, a distance of at least 15 cm must always be kept between the defibrillation electrodes and the HF surgical electrodes. If in doubt, disconnect the electrodes and sensors from the device during the use of an HF surgical device. In addition, it may affect the accuracy or availability of the oximeter measurements.
- ▲ Do not set up **MAGLIFE RT-1**, **MAGSCREEN RT-1** and **MAGLINK** in the direct vicinity of a window. Rain, humidity and sunlight may damage the devices. Do not operate the devices near heating appliances (radiators). Device air vents must never be obstructed.

1.10 Maintenance



- ▲ Danger of electric shock. Do not open the device; there are no serviceable parts inside. Refer servicing to qualified personnel only.
- ▲ An authorised person may only carry out maintenance.
- ▲ No device/ME System modification, including sensor and accessories, is allowed.
- ▲ Before cleaning, switch the device off. Refer to section [9.4 Cleaning](#).
- ▲ Do not use high-temperature sterilisation processes (such as autoclaving). Do not use E-beam or gamma radiation sterilisation.
- ▲ Do not use solvent or abrasive cleaners on the device or cable assemblies.
- ▲ Do not, under any circumstances, immerse the device or cable assemblies in liquid.

1.11 Hygiene



- ▲ For cleaning and disinfection, observe the legal requirements applicable. Refer to sections [9.4 Cleaning](#) and [9.5 Disinfection](#).
- ▲ Only use cleaning agents and disinfectants recommended by SCHILLER. Unsuitable agents can damage the device. Clean and disinfect the device per the instructions given in this user manual.

1.12 Networks and Internet



- ▲ Appropriate security measures must be taken to protect stored patient data if the device is part of a LAN, WLAN, HIS or EMR, telephone network, Tx/Rx medium, exposed to the Internet or insecure network.
- ▲ Patient data and network security are the user's sole responsibility.
- ▲ A disconnected ECG or SpO₂ sensor alarm may indicate a wireless malfunction.
- ▲ To guarantee the security of the network, SCHILLER recommends the following:
 - Isolating the **MAGLIFE RT-1** network from other networks
 - Defining access authorisation for the configuration of the host system, including, **MAGLIFE RT-1**, so that no unauthorised alterations of the system are possible
 - Limiting the data transmission between the host and other systems/networks to a minimum.

1.13 Additional Terms

1.13.1 Implied authorisation

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorised sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

1.13.2 Terms of warranty

Your SCHILLER **MAGLIFE RT-1/MAGSCREEN RT-1** is warranted against defects in material and manufacture according to the general term of conditions. Excluded from this guarantee is damage caused by accident or as a result of improper handling. The warranty entitles free replacement of the defective part, and any liability for subsequent damage is excluded. The warranty is void if unauthorised or unqualified persons attempt to make repairs.

Send the device to your dealer or the manufacturer in case of a defect. The manufacturer can only be held responsible for the safety, reliability, and performance of the apparatus if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorised by him, and
- The **MAGLIFE RT-1/MAGSCREEN RT-1** and the approved attached equipment are used per the manufacturer's instructions.



There are no express or implied warranties which extend beyond the warranties herein above set forth. SCHILLER does not warranty of merchantability or fitness for a particular purpose to the product or parts thereof.

1.13.3 Additional information

Caution

The user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.



This equipment has been tested and found to comply with the limits for a Class A digital device under 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 per the instruction, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment causes harmful interference to radio or television reception, this can be determined by turning the equipment off 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 the receiver.
- Connect the equipment to an outlet on a circuit different from where the receiver is connected.
- Consult the dealer or an experienced technician for help.

1.14 Display Symbols and Indicators

1.14.1 Symbols used in this user guide

The safety levels are classified according to ISO 3864-2. The following overview shows the safety symbols and pictograms used in this user guide. Danger, Warning, and Caution are used in this user guide to point out potential dangers and indicate risk levels. You should familiarise yourself with their definitions and significance.



This symbol warns of possible direct danger, which could lead to severe personal injury or death.



This symbol warns of a dangerous situation that could lead to severe personal injury or death.



This symbol warns of a dangerous situation that could lead to personal injury and/or indicate possible property damage.



For general safety notes, as listed in this section.



Identifies MR-specific safety notes in conjunction with using the **MAGLIFE RT-1** and the accessories in an MR environment.



For electrical hazards, warnings or precautionary measures when dealing with electricity.



This symbol warns of dangerous situations that could damage property or system failure and provides other important user information.



Reference to other guidelines

Touch-sensitive areas

These symbols designate touch-sensitive areas and interactions that might not be self-evident.



Touch (to open/close menus and perform functions)



Move up or down



Move right or left

1.14.2 General used symbols

The following general symbol can be placed on the device sensor or cables to avoid multiple descriptions of symbols.



Signal input type CF. Highly isolated port, defibrillation protected. However, it is only defibrillation protected when used with the original SCHILLER accessories.



Notified body of the CE certification (GMED)



- The symbol for the recognition of electrical and electronic equipment.
- The device must be disposed of in a municipally approved collection point or recycling centre when it is no longer required.
- Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.



Manufacturer information



Manufacturing date



Read the Instruction For Use (IFU)

IP21

The device is protected against foreign bodies of a diameter greater than > 12.5 mm and dripping water only for indoor use.



Keep dry



Medical device

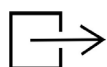


Biohazard

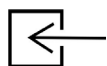


Do not reuse

1.14.3 Symbol used on the MAGLIFE RT-1



CO₂ gas sample exhaust port to the scavenging system of the hospital



CO₂ gas sample inlet port for the Nomoline sampling line



Temperature sensor input



NIBP Hose connection



Ventilation sampling line connection



IBP Sensor Connection



Gating output (digital output)



Gating input (digital input)



Standby



Alternating current



Unlock the water trap

1.14.4 Symbol used on the sensors



Device or sensor for use in the MR environment when used within the defined condition in this user guide.



Wireless devices

Attention

Non-ionising electromagnetic radiation. The device contains an RF transmitter.

The sensor radiates high-frequency electromagnetic energy during telemetric data transfer and can disturb other devices if not installed and operated per the user guide.

However, even in the case of correct installation/operation, there is no guarantee that no interferences can occur.

If the sensor causes interferences, these can be prevented by switching off or not sending data.

The user can take the following measures to solve this problem:

- Increase the distance between the disturbed device and the sensor. A minimum distance of 20 cm must be kept between the device and a pacemaker.
- Turn the device to change the antenna's angle of radiation.
- Connect the device to a different mains connector.

For more details, refer to section [9.8.5 Preventing electromagnetic interferences](#).

In case of an implanted Pacemaker, refer to the original manufacturer's recommendation according to MRI compliance.



Rechargeable battery



The item must be disposed of in a municipally approved collection point or recycling centre when it is no longer required.



ON/OFF Switch

1.14.5 Symbol used on the packaging



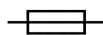
Humidity limit



Atmospheric pressure limit



Temperature limit



Fuse

2 Components and Operation

The **MAGLIFE RT-1** is a mains and battery-powered monitor with ECG, SpO₂, Capnography Respiration Rate, NIBP, IBP, Temperature, Anaesthetic Agents and Basic ventilation mechanics. It is designed for clinical use in an MRI environment.



Biocompatibility

The parts of the product described in this user guide, including all accessories that come in contact with the patient during the intended use, fulfil the biocompatibility requirements of the applicable standards. If you have any questions, contact SCHILLER.

2.1 Design

Power supply

The **MAGLIFE RT-1** is powered by mains or the integrated rechargeable battery.

A special Uninterruptible Power Supply (UPS) guarantees the monitor's reliable operation. The UPS is located below the **MAGLIFE RT-1** and connected to the **MAGLIFE RT-1** with a cable that passes inside the trolley pole. The battery is located inside the UPS. The **MAGLIFE RT-1** cannot operate without being connected to the UPS.

While the **MAGLIFE RT-1** is set up in the MRI room. A remote display, a **MAGSCREEN RT-1** (refer to sections [2.2.4 MAGSCREEN RT-1 front and rear views](#) and [3.3 MAGSCREEN RT-1](#)) allows the patient to be monitored outside the Faraday cage. The **MAGLIFE RT-1** can be remotely controlled from the **MAGSCREEN RT-1**.

Monitoring

Depending on its configuration, the **MAGLIFE RT-1** can provide the following monitoring function:

- ECG and Heart Rate (HR)
- SpO₂, Peripheral Pulse (PP), Plethysmogram
- CO₂ and Respiration rate (RR)
- NIBP
- IBP
- Temperature
- Anaesthetic Agents
- Basic ventilation mechanics

Display

The **MAGLIFE RT-1** is equipped with a large 15.6" colour LCD display and operated through a touch panel

Data storage

All intervention data ECG, SpO₂, CO₂ Respiration rate and NIBP, IBP, Temperature, Anaesthetic Agents, Basic ventilation mechanics trends, events, and patient data.

Data transmission

The **MAGLIFE RT-1** can export and send information over different communication media:

- USB
- WLAN

The details of communication capabilities are detailed in the table below:

USB	WLAN
Import/export configuration	Remote control through MAGLINK
Software update	

2.1.1 Standard units and options

Standard

- SpO₂
- NIBP

Options:

- 4-lead ECG cable and Heart Rate (HR)
- CO₂
- IBP x 2
- Temperature
- Anaesthetic Agents
- Basic ventilation mechanics
- **MAGSCREEN RT-1** (including Network)



The **MAGLIFE RT-1** exists in several versions that fit the user's needs. For more precise information, contact your local sales representative.

2.2 Operating Elements

2.2.1 Front view MAGLIFE RT-1



Fig. 2.1 Control elements at the front of the device

2.2.2 Back panel MAGLIFE RT-1



Fig. 2.2 Control elements at the rear of the device

2.2.3 MAGLIFE RT-1 LEDs

The LEDs give the following information:

- (1) The light is On when the device is connected to the main supply.
- (2) Flashes while the battery is being recharged

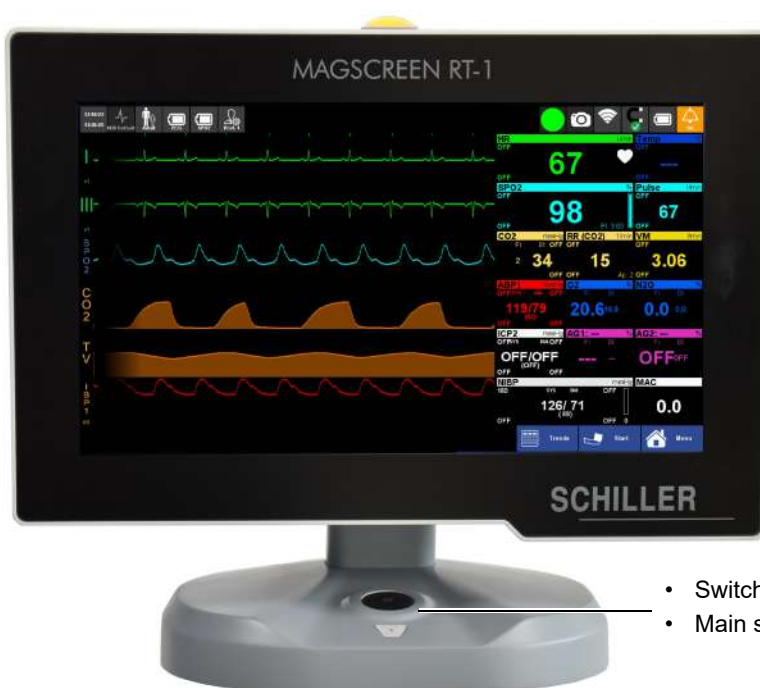


Fig. 2.3 LEDs

2.2.4 MAGSCREEN RT-1 front and rear views



Touch screen is adjustable to 35°



- Switching ON/OFF
- Main status LED



Mains supply connector

Network (Ethernet) connector

USB connector

2.2.5 Display

The display is the same for **MAGLIFE RT-1** and **MAGSCREEN RT-1**



Fig. 2.4 Display elements of the device

The display can vary according to the settings, options and selected views. The following screen is displayed when swiping from right to left.

Show the waveform field again:

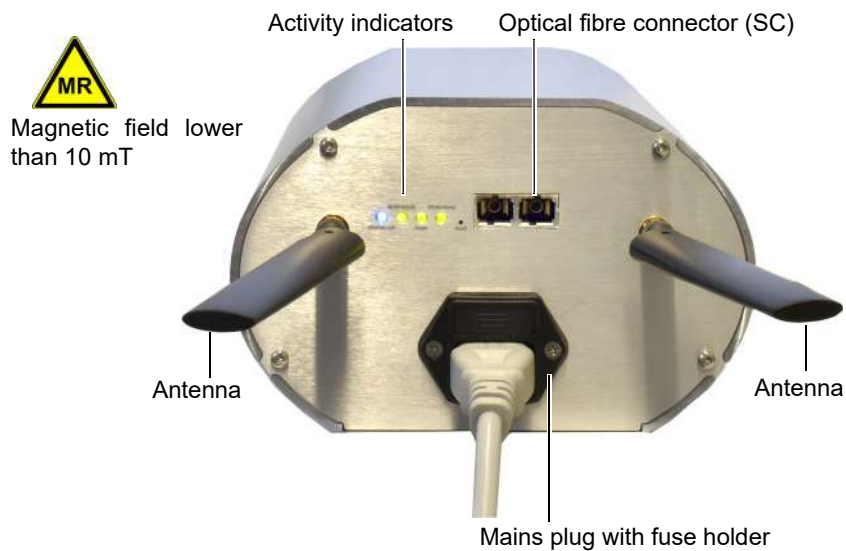
→ Swipe from left to right



2.2.6 MAGLINK



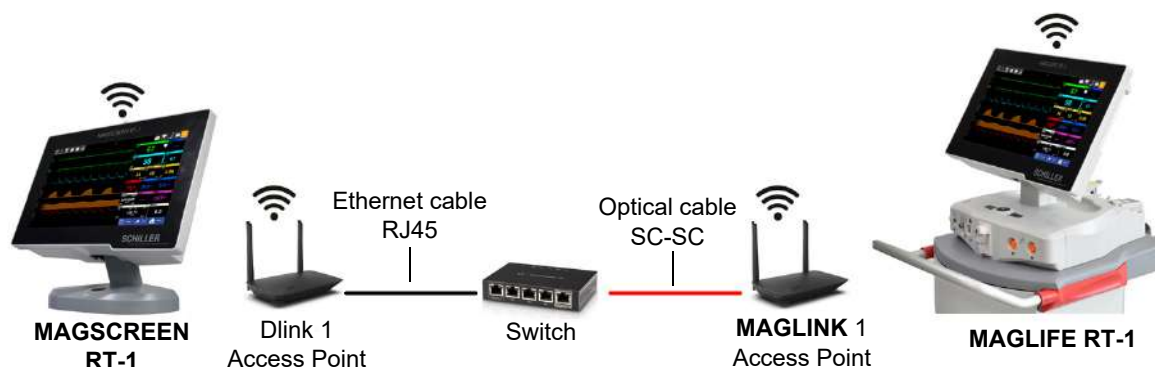
- **MAGLINK** is the connection device of the **MAGLIFE RT-1/MAGSCREEN RT-1** system. It is intended to provide an MR conditional access point to offer a link between **MAGLIFE RT-1** and **MAGSCREEN RT-1** and to fulfil the compliance to work inside a working MRI environment.
- **MAGLINK** is designed for permanent use; it does not require to be switched on or off.



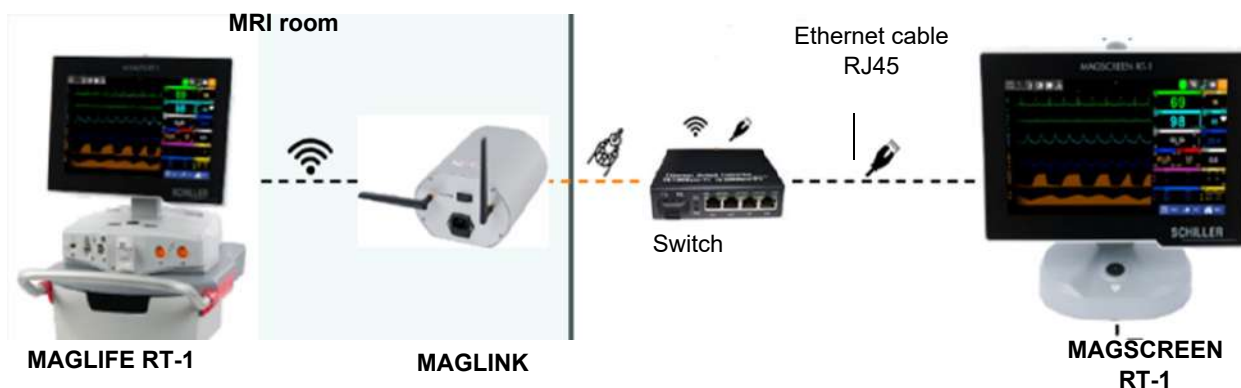
WARNING

- ▲ **MAGLINK** is MR conditional and contains magnetic items. It must be installed in an area where the magnetic field is lower than 10 mT. It must be fixed on the floor or a shelf, ensuring a fix position inside the Faraday cage.
- ▲ During installation, keep the **MAGLINK** away from the MRI; the magnetic field is permanent.

2.2.7 Network topology



- Wi-Fi restrictions: According to local regulations or commitments with authorities, Wi-Fi settings may be restricted. Restriction can affect the number of available channels or the frequency bands.
- Note: In case of other network topologies, contact your local SCHILLER representative.



- Ethernet restrictions: According to local regulations or commitments with authorities, Ethernet settings may be restricted.
- Note: In case of other network topologies, contact your local SCHILLER representative.

3 Initial Operation

⚠ DANGER



- ▲ Read the safety notes in chapter [1 Safety Notes](#), before initial operation.
- ▲ Danger of explosion. The device is not designed for use in areas where an explosion hazard may occur. Operating the device in an oxygen-enriched environment or in the presence of flammable substances (gas) is not permitted. Oxygenation in the vicinity of the monitor electrodes must be strictly avoided.
- ▲ The user must check that there are no conductive connections between the patient and other persons during ECG analysis and defibrillation.
- ▲ The equipment must only be connected to a mains supply with protective earth to avoid the risk of electric shock.

⚠ DANGER



- ▲ It is imperative to observe the minimum distances between the device and the entrance of the scanner tunnel. These distances differ with the magnetic field strength and magnet types. The **MAGLIFE RT-1**, including the power supply, must only be set up in a zone where the fringe field is less than or equal to 80 mT (800 Gauss). A magnetic field detector will respond when this value is reached. Above the limit of 80 mT the patient monitor may be exposed to the attractive forces of the magnetic field.
- ▲ This area must be identified with line markings on the floor.
- ▲ The cart castors must be locked before the device is put into operation.
- ▲ The magnetic field is always present, even when the MRI scanner is not in use. The same is true when the power supply is interrupted.
- ▲ Always monitor the magnetic field according to section [3.5 Monitoring the Magnetic Field](#).

Figure 3.1 shows a typical arrangement of **MAGLIFE RT-1** and an MRI scanner.

- (1) Faraday cage
- (2) MRI scanner
- (3) Mains supply MRI room
- (4) Power supply connector **MAGLIFE RT-1**
- (5) **MAGLINK** (Wi-Fi **MAGLIFE RT-1** to **MAGSCREEN RT-1**)



MAGSCREEN RT-1

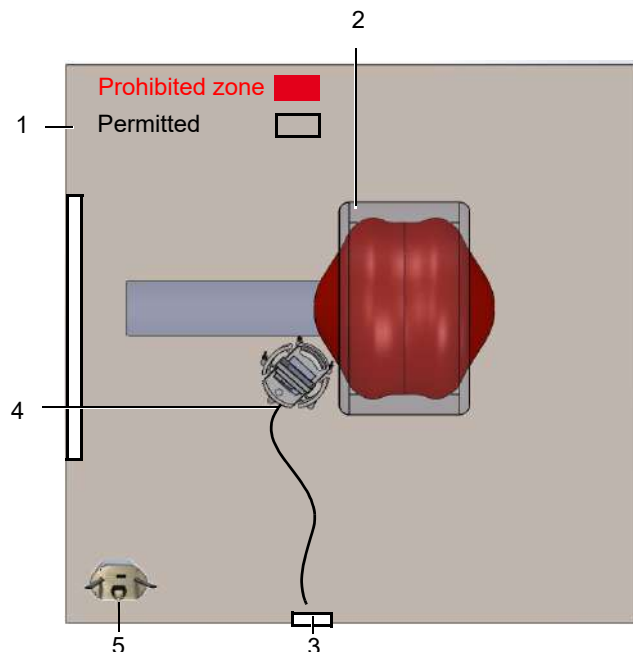


Fig. 3.1 Arrangement of **MAGLIFE RT-1** and MRI scanner

3.1 Mains Supply and Battery Operation



Important

The device is delivered in transport mode, preventing it from switching on. To wake up the battery, plug in the mains cable as described below.

3.1.1 Mains supply and charging battery



Fig. 3.2 Status LED supply



- Position the device so the mains cable can easily be unplugged from the device and mains socket.
- The internal battery is automatically recharged when connected to the mains. The battery requires approximately 2 hours to be 90% recharged.

3.1.2 Battery operation

Charging the battery



Fig. 3.3 LED battery operation

The recharging of the battery is indicated by the LED left of the battery symbol.

- LED (2) is continuously on = battery problem
- LED (2) is blinking = battery is charging
- LED (2) is continuously off = battery is fully charged



If the temperature in the device becomes too high, charging is stopped. When the temperature has decreased to an acceptable level, the charging resumes.

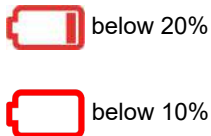


Fig. 3.4 Battery low indication

Low battery indication

When the battery is below 20%, a red battery symbol with one bar is displayed in the top right corner of the screen.

When the battery is below 10%, a red empty battery symbol is displayed in the screen's top right corner, a technical alarm is displayed, and a voice prompt reminds to connect the device to the mains supply.

The device shuts down automatically when the battery charge level is below 5%.



Fig. 3.5 Battery defect indication

Battery status unknown

- When the battery is unknown, a red battery symbol with a question mark is displayed in the top right corner of the screen.

Battery status

Press on the **Battery** button, and the following information will be displayed:

- Charge level in percentage
- Number of installed batteries

3.2 Switching Off and Disconnecting from the Mains Supply



1. To switch off the device, press the **ON/OFF** button and confirm, Yes when prompted.



2. Remove the mains cable device from the device if you do not want to recharge the battery.

3.2.1 Interruption of the mains supply



The device automatically switches to battery operation if the mains supply is interrupted. The user settings are maintained.

3.2.2 Ensuring operational readiness



Do not expose the device to direct sunlight or extremely high or low temperatures. The ambient temperature should be in the range of 0 to 40°C. Lower or higher ambient temperatures will have a negative impact on the battery's life.

3.2.3 Forced shutdown procedure

If no dialogue is displayed when switching off the device due to software problems, press the **ON/OFF** button until the device switches off. It can take up to 12 seconds for the device to switch off.

3.3 MAGSCREEN RT-1



MAGSCREEN RT-1 is a remote display for the **MAGLIFE RT-1**. It allows monitoring of the patient outside the MRI room and the remote control of the **MAGLIFE RT-1**.

The two devices communicate via a wireless and wired network. Both **MAGSCREEN RT-1** and **MAGLIFE RT-1** are operated in the same way.

3.3.1 Connecting the mains supply and switching the device on



1. Connect the **MAGSCREEN RT-1** to the main supply (1)
2. Check that LED (2) is **ON** when the mains supply is connected.
3. Switch On the device by pressing the **ON/OFF** button (3)
4. The **Connection** menu appears.
5. Select the name of the **MAGLIFE RT-1** and press the **Connect** button.



6. Once a connection is established, you can operate the **MAGLIFE RT-1** remotely. Only menus, Review and Control Panel are not accessible via the **MAGSCREEN RT-1**.
7. To display the connection status, press the **Green/Red circle** in the status line.
8. The Connection status menu opens.
9. Pressing the **Green** button will cause the **MAGSCREEN RT-1** to be disconnected from the **MAGLIFE RT-1**.

Fig. 3.6 Status LED supply

3.4 Operation

The menus can be accessed as follows:

- Direct access by pressing on the curve or measurement field
- By pressing the **Menu** button or any other buttons
- By pressing an icon
- By moving a finger up, down, left, or right to scroll or change the display.

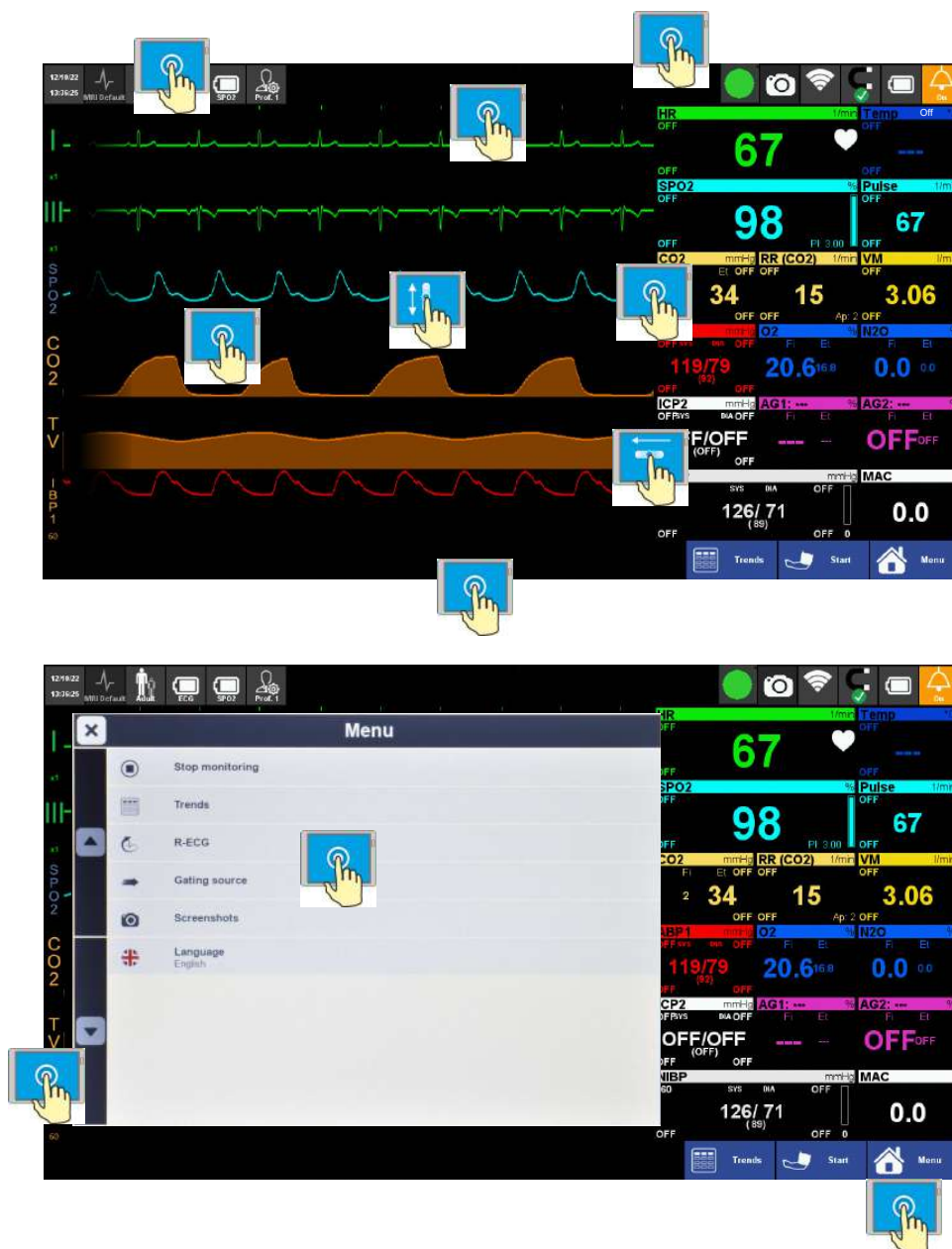
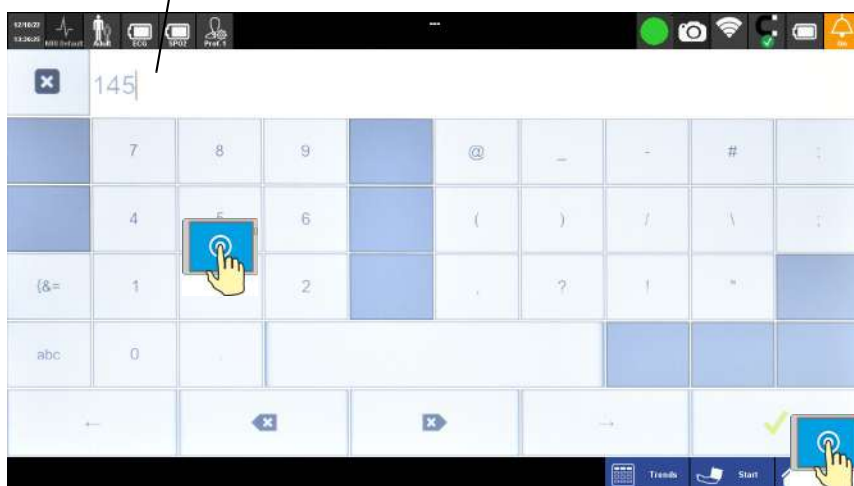


Fig. 3.7 Screen displays showing the main menu and the touch-sensitive areas

3.4.1 Opening alphanumeric keyboard



3.5 Monitoring the Magnetic Field

! WARNING



- ▲ The **MAGLIFE RT-1** must only be set up in a zone where the fringe field is less than or equal to 80 mT (800 Gauss). Above the limit of 80 mT, the patient monitor may be exposed to the forces of the magnetic field. Therefore, it will automatically switch itself off to prevent damage to electronic components.
- ▲ Before the device may be used in the vicinity of the MRI, a safety officer must first clearly identify/define a safe distance/area around the magnet in the examination room.
- ▲ During use in the MRI room, the influence of the magnet field on the **MAGLIFE RT-1** must be continuously monitored.
- ▲ Always check that all four brakes of the trolley are in the lock position.
- ▲ Do not use the **MAGLIFE RT-1** when one of the brakes is not locking.

3.5.1 Introduction



- The **MAGLIFE RT-1** is designed to withstand magnetic fields up to 80 mT. Magnetic fields stronger than 80 mT may lead to inaccurate parameter readings or damage the **MAGLIFE RT-1**.
- To avoid such situations, the **MAGLIFE RT-1** is equipped with a device that permanently monitors the strength of the magnetic field in all three directions in the room (Bx, By, Bz).
- Identifying the limits around the magnet in the examination room during setup is mandatory. The magnetic field indications on the monitor can assist here

3.5.2 Setup in the MRI room

1. Position the **MAGLIFE RT-1** in the safe area as defined by the safety officer.
2. Lock all 4 wheels of the trolley, and check that the trolley does not move.



3.5.3 Monitoring the magnetic field



Magnetic field indication

The MRI status is continuously displayed in the status line in the top right of the screen.

- Green = Magnetic within the limits
 - Red = Magnetic outside the limits
- Select the Magnetic field indication button to open the stray field value screen

Alarms

Alarm	Code	Cause	Remedy
Magnetic field: is out of range	T_MAGNETIC_01	• The device is too close to the MRI magnetic field	→ Position the device further away from the MRI.

As soon as the monitor approaches a magnetic field that exceeds the specified limit for the Alarm field:

- The MRI status button is red
- The message, Magnetic Limits appears in the status line,
- An audio signal is emitted.

These alarms clear automatically as soon as the device is out of the critical area.

When the monitor is brought into the critical area where the magnetic field exceeds the specified limit for the shutdown field:

- An audio signal is emitted
- And its power supply automatically switches off.

The monitor must be removed from the critical area before it can be restarted.

3.5.4 Magnetic field indication

The Magnetic field screen below displays the measured magnetic field values for x, y, z (orthogonal directions and B (the magnetic field Norm/Module) in mT (display range: 0 to 80 mT).



Art. no: 0-48-0353 Rev.: Rev: f

4 Monitoring Overview



Operation and menu access is detailed in section [3.4 Operation](#).

4.1 Pre-monitoring

The Pre-monitoring screen below is initially displayed to enter patient data.

Patient type setting is mandatory to set alarm limits and sampling flow rates for gas measurements. In addition, it is also the entry point for connection to EMR, HIS, and other patient data.



▲ The wrong setting of patient type could lead to extensive bodily injury or death.

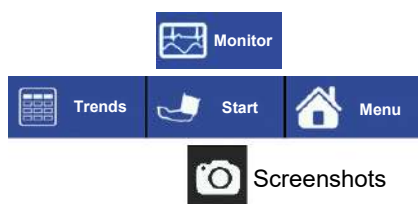
The following patient data can be entered:



- Patient ID number.
- Patient gender
- Patient type
- Patient name
- Patient first name

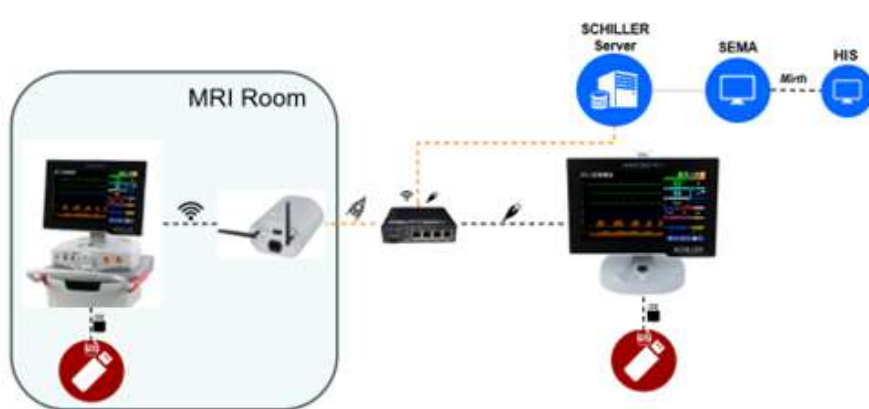
4.1.1 Start monitoring

1. To start monitoring, press the **Monitor** button. The recording of patient data begins.
 2. To stop recording, press the **Menu** function key and select **Stop Recording**.
 3. To confirm stop recording, press **Yes** when prompted.
- To review recorded patient data, press the **Review** button (refer to section [7.1 Log files](#))
- To configure the RT-1, press the **Control panel** button. (refer to section [8.1 General Setup](#))

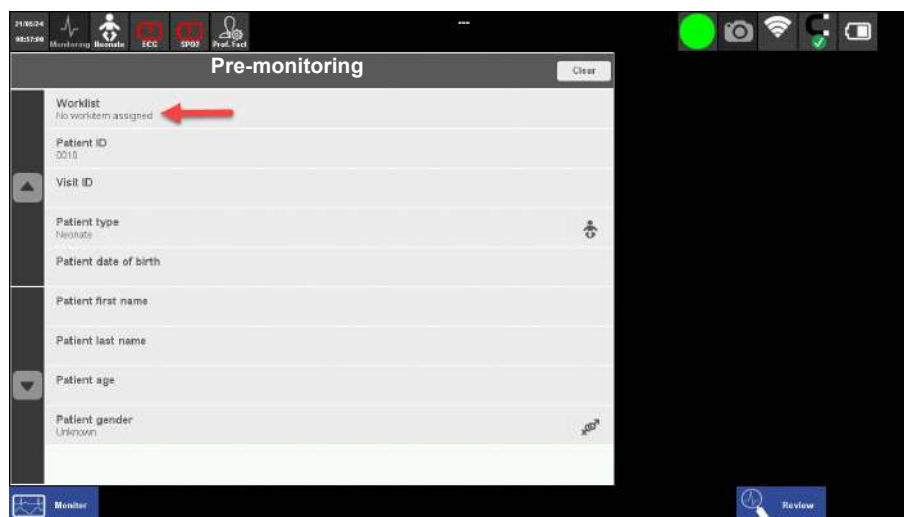


4.2 HIS Integration (optional)

You can connect the **MAGLIFE RT-1** with the Hospital Information System (HIS) via SEMA & Mirth.



This option allows you to retrieve Patient data via **PDQ** (Patient Data Query) or **Worklist**.

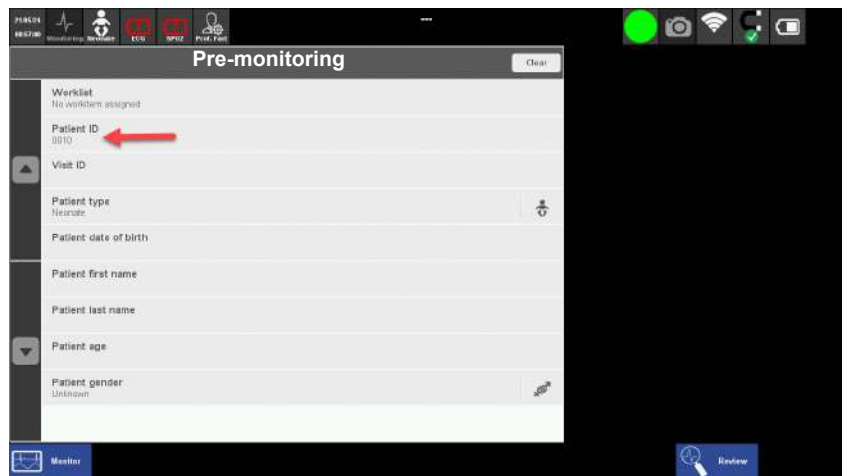


There are 3 ways to complete the patient information:

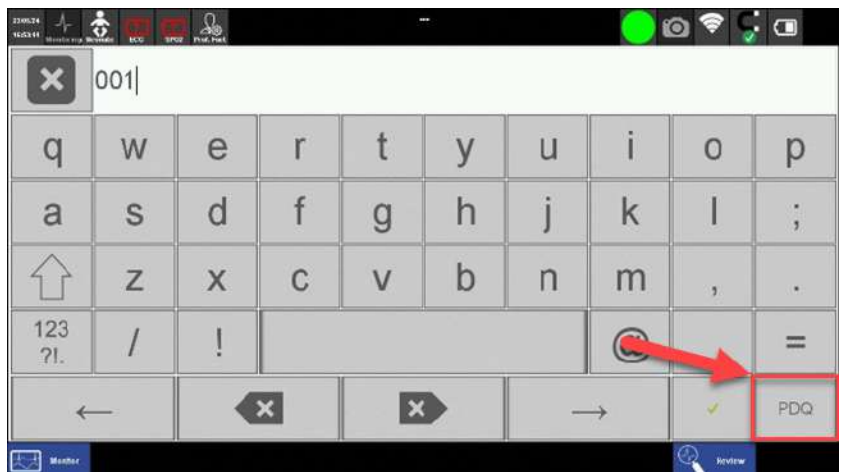
- Enter fields
- Use the PDQ function
- Use the workflow function

4.2.1 Patient Data Query (PDQ) (Optional)

1. In the **Pre-monitoring** panel, select the **Patient ID** option.

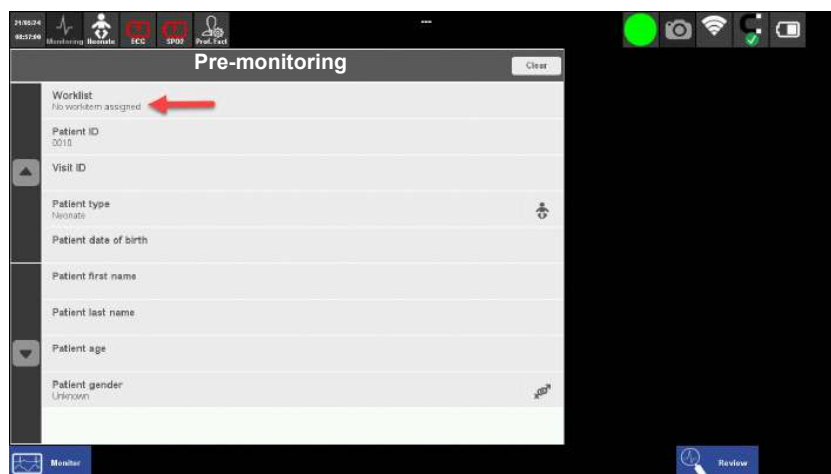


2. Enter the Patient ID and press the **PDQ** button.

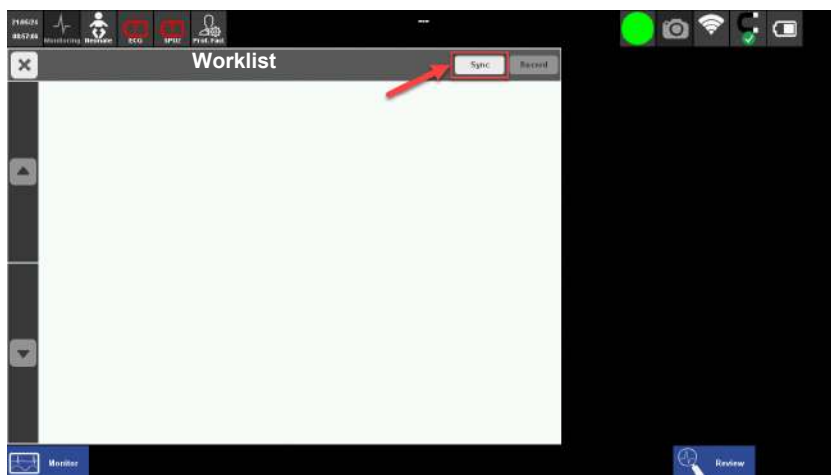


4.2.2 Worklist (optional)

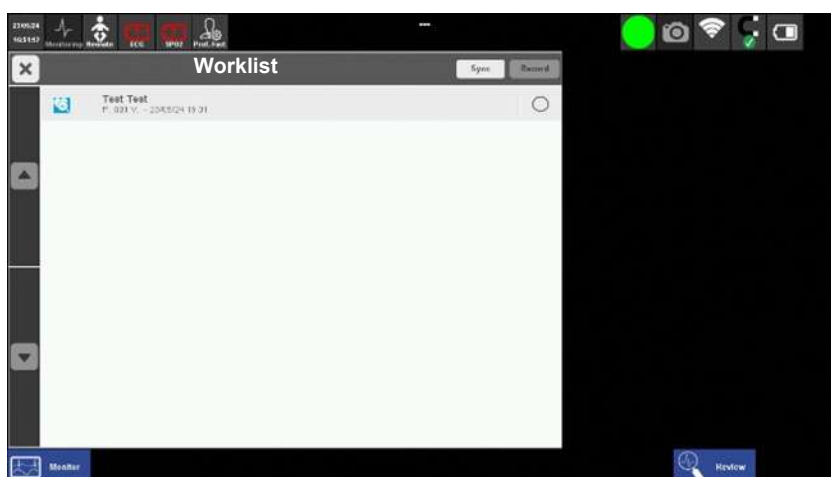
1. In the **Pre-monitoring** panel, select the **Worklist** option.



2. In the **Worklist** panel, choose the **Sync** button.



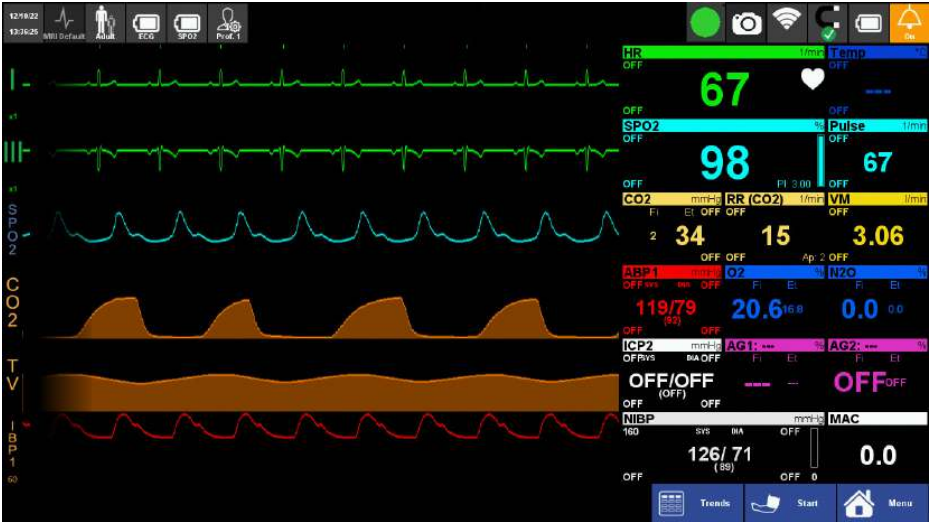
3. Select a record from the list.



4.3 Buttons, Waveforms and Measurement Fields

The waveform and measurement fields are automatically displayed when the device is switched on, and monitoring is started (if options are installed). The device can be operated via the touch screen. Button functions vary according to the selected screen.

Monitoring view



Settings

Predefined menu settings are set to default when the device is switched off.

4.4 View Trends

Trends of the current monitoring session can be viewed by selecting Trends. Trends are displayed with a standard interval of 20 seconds. However, each NIBP measurement adds another column independently from the standard interval.



- 1. Press the **Trends** button to open trends.
- 2. Use the function buttons to navigate around the trends screen.

Trends

Time	HH:MM:SS	11:58:38	11:58:58	11:59:18	11:59:38	11:59:58
HR	b/min	67	67	67	67	67
Pleth	b/min	98	98	98	98	98
SpO2	%	67	67	67	67	67
RR	r/min	14	6	---	---	---
NIBP	mmHg	--/--/--	--/--/--	--/--/--	--/--/--	--/--/--
IBP1	mmHg	221/38(99)	221/38(99)	221/38(99)	221/38(99)	221/38(99)

START

PREV

NEXT

END

CLOSE

- 3. Close the Trends screen by pressing the **X** or the **Close** button.

4.4.1 Review previous sessions

Reviewing previous monitoring sessions can be reviewed outside the monitoring function.



- 1. Press the **Preview** button to access previously saved trend sessions.
- 2. Select **Trends** from the Intervention Content screen shown below. A USB stick must be connected to select and export Trends as PDF files.

Intervention content	
Trends	
Export Trends to USB	

- 3. Now select a session to view from the Interventions List shown below.

Interventions list	
13/10/22 15:37:47	
13/10/22 11:36:57	
12/10/22 16:59:40	
12/10/22 13:29:25	

Note that the Interventions List is limited to the last 30 days or by the memory usage (MB) of the total stored sessions.

4. The selected session is displayed.

X

Trends

Time	HH:MM:SS	11:58:38	11:58:58	11:59:18	11:59:38	11:59:58
HR	b/min	67	67	67	67	67
	b/min	98	98	98	98	98
SpO ₂	%	67	67	67	67	67
RR	r/min	14	6	---	---	---
NIBP	mmHg	--/--/--	--/--/--	--/--/--	--/--/--	--/--/--
IBP1	mmHg	221/38(99)	221/38(99)	221/38(99)	221/38(99)	221/38(99)

START

PREV

NEXT

END

XCLOSE

4.5 Alarm System



- ▲ In some countries, it is not permitted to disable audio alarms permanently. Therefore, this function is configurable.
- ▲ Even high-priority alarms are paused/switched off when pausing or switching off the audio alarm.
- ▲ Pausing or switching off the audio alarm system is only allowed if the patient is permanently observed.

4.5.1 Alarm priority

Priority	Audible signal	Display	Alarm type and conditions
Low Triggered immediately on detection	One beep	- Text display in the alarm status field at the top - Displaying -?- in the parameter field - Yellow LED is lit 	Technical alarm - Sensor off patient - Communication with the module is not possible - Interference or technical problems identified by the monitoring module
Medium Triggered 3 seconds after detection	3 beeps: (beep beep beep)	- Text display in the alarm status field at the top - Red flashing parameter field - Yellow LED is flashing 	Physiological alarm Monitoring values out of currently defined limits
High Triggered 3 seconds after detection	10 beeps: (beep beep beep beep beep, beep beep beep, beep beep)	- Text display in the alarm status field at the top - Red flashing parameter field - Red LED is flashing 	Critical Physiological alarm

All alarms are immediately reported to the remote control device **MAGSCREEN RT-1** if available. There is no perceptible delay between both devices.

4.5.2 Operator's position

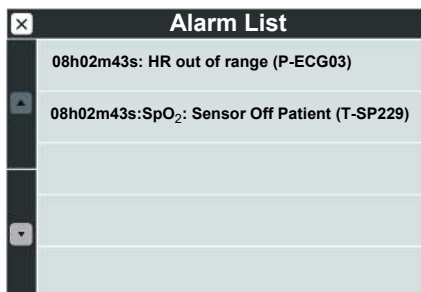


- ▲ Check that the environmental noise is below the alarm sound volume of 62 dB.

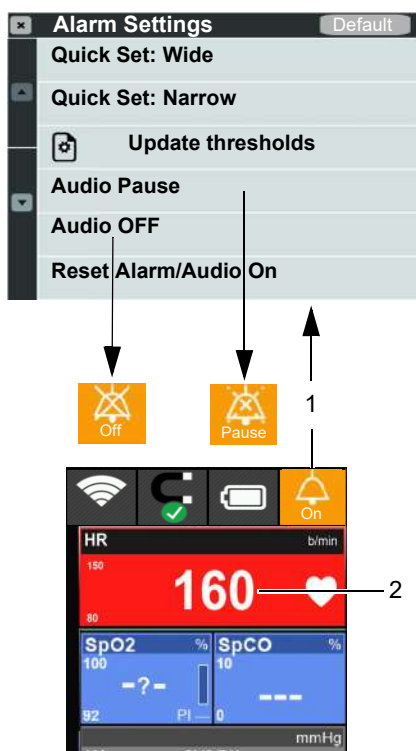
The visual alarm LED is visible from a distance of 4 meters, and the flashing value is visible at a distance of 1 meter.

4.5.3 Alarm list

The latest alarm text is displayed in the Alarm status box. An alarm list can be displayed anytime by touching the message status line.



4.5.4 Pausing, switching off or reactivating audio alarms



Pausing an audio alarm

- Pause the audio alarm by pressing the **Alarm** button (1) and selecting **Audio Pause**
 - The measurement reading is flashing red until it returns to the permissible range.
 - The audible alarm is reactivated automatically if the measured value does not return to the permissible range within 2 minutes.

Switching off the audio alarm system

- Press the **Alarm** button (1) and select **Audio OFF**.
- The audible alarm system is switched off permanently until it is reactivated by selecting **Reset Alarm/Audio on** or **Audio Pause**.

A reminder signal (buub-buub) is issued every 2 minutes.

Reactivation of the paused or switched-off audio alarm system

- Press the **Alarm** button (1) and select **Reset Alarm/Audio ON**.

Fig. 4.1 Alarm indicators

4.6 Operator Defined Alarm Thresholds

CAUTION

- ▲ Check that the patient's vital parameters are not critical before pressing the **Wide Quick set or Narrow quick set** button; otherwise, extreme values may render the alarm system unusable.
- ▲ Check that the right patient is selected (adult, child or neonate).
- ▲ The defined alarm thresholds are not a substitute for regular checking of vital functions.
- ▲ Setting the audio off is only allowed if the patient is permanently observed.
- ▲ Standard or user-defined alarm limits and quick settings may vary for similar or the same devices. Therefore, always check the set alarm limits for the current patient.
- ▲ Thirty seconds after switching off the device, the alarm threshold Wide Quick set, Narrow quick set, and the Update thresholds are set to default.

→ Access the threshold menu by pressing the **Alarm** button and selecting **Wide Quick set or Narrow quick set** (1).

- With the **Quick Set** selection, all values are derived from the current measured values (refer to table [4.6.2 Table of default threshold settings](#)).

Important

- Check that the patient's vital parameters are not critical before pressing the **Quick Set** button.

→ With the **Default** button, the default threshold values are activated (refer to table [4.6.2 Table of default threshold settings](#)).

→ The setup of new alarm thresholds can be verified in the parameter field:

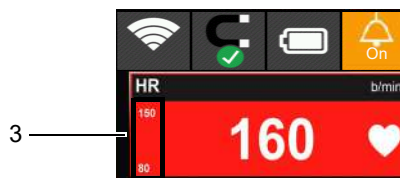
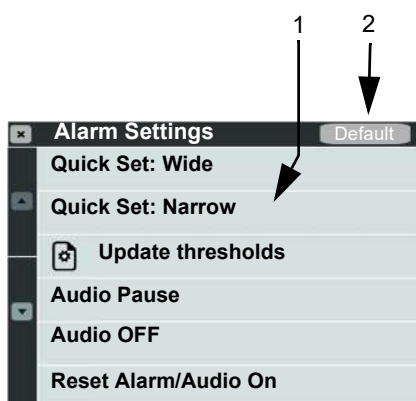


Fig. 4.2 Alarm Settings menu

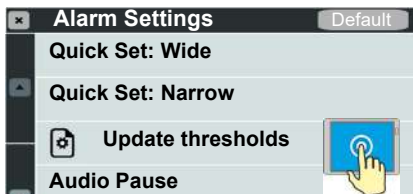


After switching off the device, the operator-defined Quick set thresholds will be set to the default values.

4.6.1 Update thresholds

CAUTION

- ▲ The defined alarm thresholds are not a substitute for regular checking of vital functions.
- ▲ Setting the **Threshold OFF** is only allowed if the patient is permanently observed.



Besides the Quick Set of alarm limits, the operator can setup all alarms individually via the menu **Update Thresholds** or via the parameter field.



- Select **Default** in the alarm Setting menu to set all user defined Thresholds to default.

Fig. 4.3 Alarm thresholds setting

4.6.2 Table of default threshold settings

The default limit values are set after switching on or when the default is selected in the Alarm settings menu (refer to [Fig. 4.2 Alarm Settings menu](#)). The default alarm limits are predefined for each patient type as specified in the following table:

Parameter	Default limit	Adult	Child	Neonate
HR [bpm]	Upper	130	160	180
	Lower	45	60	75
SpO ₂ [%]	Upper	off	off	off
	Lower	93	93	93
NIBP SYS [mmHg]	Upper	160	130	115
	Lower	80	85	70
NIBP DIA [mmHg]	Upper	115	80	85
	Lower	60	50	45
NIBP SYS [kPa]	Upper	21.33	17.33	15.33
	Lower	10.66	11.33	9.33
NIBP DIA [kPa]	Upper	15.66	10.66	11.33
	Lower	8	6.66	6
IBP SYS [mmHg]	Upper	160	130	115
	Lower	80	85	70
IBP DIA [mmHg]	Upper	115	80	85
	Lower	60	50	45
IBP SYS [kPa]	Upper	21.33	17.33	15.33
	Lower	10.66	11.33	9.33
IBP DIA [kPa]	Upper	15.33	10.66	11.33
	Lower	8	6.66	6
RR [rpm]	Upper	40	40	70
	Lower	4	4	30
Inspired CO ₂ (Fi) [mmHg]	Upper	4	4	4
	Lower	off	off	off
Expired CO ₂ (Et) [mmHg]	Upper	50	50	50
	Lower	20	20	20
Temperature [°C]	Upper	39.0	39.0	39.0
	Lower	35.0	35.0	35.0
Temperature [°F]	Upper	102.2	102.2	102.2
	Lower	95	95	95
Inspired NO ₂ (Fi) [%]	Upper	75	75	75
	Lower	off	off	off
Expired NO ₂ (Et) [%]	Upper	off	off	off
	Lower	off	off	off
Inspired O ₂ (Fi) [%]	Upper	99	99	75
	Lower	18	18	18
Expired O ₂ (Et) [%]	Upper	off	off	off
	Lower	off	off	off
Inspired Desflurane (DES) (Fi) [%]	Upper	18.0	18.0	18.0
	Lower	off	off	off

Expired Desflurane (DES) (Et) [%]	Upper	12.0	12.0	12.0
	Lower	off	off	off
Inspired Enflurane (ENF) (Fi) [%]	Upper	5.0	5.0	5.0
	Lower	off	off	off
Expired Enflurane (ENF) (Et) [%]	Upper	3.4	3.4	3.4
	Lower	off	off	off
Inspired Halothane (HAL) (Fi) [%]	Upper	2.2	2.2	2.2
	Lower	off	off	off
Expired Halothane (HAL) (Et) [%]	Upper	1.5	1.5	1.5
	Lower	off	off	off
Inspired Isoflurane (ISO) (Fi) [%]	Upper	3.4	3.4	3.4
	Lower	off	off	off
Expired Isoflurane (ISO) (Et) [%]	Upper	2.3	2.3	2.3
	Lower	off	off	off
Inspired Sevoflurane (SEV) (Fi) [%]	Upper	6.1	6.1	6.1
	Lower	off	off	off
Expired Sevoflurane (SEV) (Et) [%]	Upper	4.1	4.1	4.1
	Lower	off	off	off
Tidal volume (VT) Inspired (Fi) [ml]	Upper	700	150	30
	Lower	400	80	15
Tidal volume (VT) Expired (Et) [ml]	Upper	700	150	30
	Lower	400	80	15
Inspired Flow (V) [l/min]	Upper	20	10	5
	Lower	3	1	0.5
Expired Flow (V) [l/min]	Upper	20	10	5
	Lower	3	1	0.5

4.6.3 Table of wide and narrow threshold setting

The values before the brackets, for example, ECG 0 to 350 (), are the measuring range. The values in the brackets (30/300) are the maximum low/high alarm setting range.

With the **Narrow/Wide Quick Set** selection refer to [Fig. 4.2 Alarm Settings menu](#), all values are derived from the current measured values as shown in the following table:

	Current measured Patient value	Wide limits		Narrow Limits	
		Low	High	Low	High
HR [bpm] Range: ECG 0 to 350 (30/300 bpm) Range: Pleth 30 to 240 (30/240) bpm	< 60	-20	+35	-10	+25
	60-79	-25	+40	-20	+30
	80-104	-30	+40	-30	+30
	≥ 105	-35	+45	-25	+25
Allowed values		[30-150]	[100-250]	[30-150]	[100-250]
CO₂ [mmHg] Range: 5 to 70 mmHg (0/100 mmHg), (4/5.9%) (4/6 kPa) Allowed values [mmHg]/[%]		Low	High	Low	High
		-10	+15	-10	+15
		[5-60] / [0.7-7.9]	[20-70] / [2.7-9.2]	[5-60] / [0.7-7.9]	[20-70] / [2.7-9.2]
RR [rpm] Range: 0 to 60 (2100) resp/minute		Low	High	Low	High
	< 15	-8	+8	-4	+4
	≥ 15	-15	+15	-8	+8
Allowed values		[5-15]	[10-60]	[5-15]	[10-60]
SpO₂ [%] Range: 85 to 100 (85/100)%		Low	High	Low	High
	≥ 90	-5	+3	-5	+3
	< 90	-5	+3	-2	+2
Allowed values		[85-100]	[90-100]	[85-100]	[90-100]
NIBP SYS [mmHg] Range SYS: 30 to 255 (30/255) mmHg		Low	High	Low	High
	< 90	-20	+35	-10	+25
	90-114	-20	+35	-10	+25
	115-140	-25	+35	-10	+20
	> 140	-25	+35	-10	+20
Allowed values		[30-245]	[30-245]	[30-245]	[30-245]
NIBP DIA[mmHg] Range DIA: 15 to 220 (15/220) mmHg		Low	High	Low	High
	< 65	-15	+25	-10	+25
	65-90	-15	+25	-15	+10
	> 90	-15	+25	-15	+10
Allowed values		[12-210]	[12-210]	[12-210]	[12-210]
NIBP MAP [mmHg] Range MAP: 15 to 223 (20/235) mmHg		Low	High	Low	High
	-	-	-	-	-

IBP SYS [mmHg]		Low	High	Low	High
Range SYS: -100 to 400 (-30/300) mmHg	< 90	-20	+35	-10	+25
	90-114	-20	+35	-10	+25
	115-140	-25	+35	-10	+20
	> 140	-25	+35	-10	+20
Allowed values		[30-245]	[30-245]	[30-245]	[30-245]
IBP DIA [mmHg]		Low	High	Low	High
Range DIA: -100 to 400 (-30/300) mmHg	< 65	-15	+25	-10	+25
	65-90	-15	+25	-15	+10
	> 90	-15	+25	-15	+10
Allowed values		[12-210]	[12-210]	[12-210]	[12-210]
IBP MAP [mmHg]		Low	High	Low	High
Range MAP: 15 to 223 (20/235) mmHg	-	-	-	-	-
Temperature [°C]		Low	High	Low	High
Range: 20 to 45 (25/45)°C	-	-3	+3	-1	+1
Allowed values		[31-41]	[31-41]	[31-41]	[31-41]
NO ₂ inspired and expired [%]		Low	High	Low	High
Range: 0 to105 (0/99)%	< 40	-20	+20	-15	+15
	40-70	-30	+30	-17	+17
	> 70	-40	+40	-24	+24
Allowed values					
O ₂ inspired and expired [%]		Low	High	Low	High
Range: 18 to 100 (18/100)%	< 20	-10	+10	-6	+6
	20-50	-18	+18	-11	+11
	> 50	-35	+35	-22	+22
Allowed values					
Desflurane (DES) inspired and expired [%]		Low	High	Low	High
Range: 0 to 30 (0/30)%	< 8	-4	+4	-2.5	+2.5
	8-15	-6	+6	-4	+4
	> 15	-10	+10	-6	+6
Allowed values					
Enflurane (ENF) inspired and expired [%]		Low	High	Low	High
Range: 0 to 30 (0/30)%	< 8	-4	+4	-2.5	+2.5
	8-15	-6	+6	-4	+4
	> 15	-10	+10	-6	+6
Allowed values					
Halothane (HAL) inspired and expired [%]		Low	High	Low	High

Range: 0 to 30 (0/30)%	< 8	-4	+4	-2.5	+2.5
	8-15	-6	+6	-4	+4
Allowed values	> 15	-10	+10	-6	+6
Isoflurane (ISO) inspired and expired [%]		Low	High	Low	High
Range: 0 to 30 (0/30)%	< 8	-4	+4	-2.5	+2.5
	8-15	-6	+6	-4	+4
Allowed values	> 15	-10	+10	-6	+6
Sevoflurane (SEV) inspired and expired [%]		Low	High	Low	High
Range: 0 to 30 (0/30)%	< 8	-4	+4	-2.5	+2.5
	8-15	-6	+6	-4	+4
Allowed values	> 15	-10	+10	-6	+6
Tidal volume (VT) inspired and expired [ml]		Low	High	Low	High
Range: 10 to 3000 (15/2000) ml	< 100	-20	+25	-15	+20
	100-300	-45	+55	-30	+40
Allowed values	> 300	-150	+200	-100	+150
Flow (V) inspired and expired [l/min]		Low	High	Low	High
Range: 1.5 to 15 (1.5/15) ml l/minute	< 2	-0.5	+0.5	-0.25	+0.25
	2-20	-3	+4	-2	+3
Allowed values	> 20	-20	+25	-12	+20

5 Monitoring ECG, SpO₂, NIBP, IBP and Temperature

5.1 Safety Notes Monitoring

5.1.1 Safety notes when connection sensors

WARNING

Equipment Failure, Equipment Damage, Patient Hazard

- ▲ Use only original accessories offered by SCHILLER for use with the **MAGLIFE RT-1** (refer to section [11.1 Accessories and Disposables](#)).
- ▲ Follow all instructions concerning the application of electrodes and sensors and for routing leads and cables.
- ▲ The use of unsuitable accessories or incorrect application may cause skin burns:
 - At the electrodes and transducers
 - In the vicinity of leads and cables, if they have direct contact with the patient's skin.
- ▲ Using unsuitable accessories or the wrong application may cause interference and artefact while acquiring vital signs.
- ▲ Arrange cables connecting the sensors to the **MAGLIFE RT-1** in parallel with each other with the main axis of the scanner tunnel.
- ▲ Cables and sensors must never come in contact with the inside of the scanner tunnel or the pole surfaces of the magnet; keep them as far apart as possible.
- ▲ The cables must not form loops.
- ▲ Avoid direct contact between the skin and the cables. Place insulating material under the cables.
- ▲ Placing electrical conductive wires inside the magnet bore might cause them to burn. Always follow the recommended procedure for the specific accessory. If in doubt, do not use the accessory.

CAUTION

- ▲ Placing sensors in the magnet bore might cause image artefacts. Therefore always place sensors to avoid image artefacts in the investigation area.

5.1.2 Safety notes during monitoring

CAUTION

- ▲ Do not monitor the patient with only one physiological parameter. Monitoring simultaneously with multiple physiological parameters is favoured.
- ▲ The indications given by this equipment are not a substitute for regular checking of vital functions.

5.2 ECG and Heart Rate Monitoring



Intended Purpose

- The **MAGLIFE RT-1** is intended to monitor 6 ECG waveform (3 leads), Heart Rate (HR).

Intended Users

- The device is intended for clinical professionals. Clinical professionals must have a working knowledge of medical procedures, practices, and terminology for completing these examinations.

Medical indications

- **MAGLIFE RT-1** ECG monitoring allows identification and interpretation of cardiac rhythms or dysrhythmias and calculation of the heart rate (HR in beats per minute) of unstable and/or anaesthetized patients pre/per/post MRI examinations.

Contraindications for use

- It is not recommended to use CLARAVUE PM electrodes with monophasic defibrillators. To ensure safety during defibrillation, removing the ECG prewired electrodes from the patient's thorax is highly recommended.
- ECG monitoring is contraindicated on patients with conductive or active implant devices, including pacemakers or electrical simulators.
 - Additional general contraindications for use are indicated in [1.3 Expected Therapeutic Clinical Patient Benefits](#).

Side effects

See [1.5 Known Side Effects](#)

Target population

- The device can be used with accessories for adults, children and neonates.

Affected Body Regions

- ECG electrodes Pads are placed on the chest of the patient.

WARNING

- ▲ False diagnosis. Only use silver/silver-chloride electrodes if the patient may have to be defibrillated while the ECG is displayed. Other electrodes may create high polarisation voltages, and the ECG trace on the monitor and the recording may simulate cardiac arrest.
- ▲ Danger of destroying the device during defibrillation. The device is type CF protected if the original SCHILLER patient cables are used.
- ▲ The numerical and graphical results and any interpretation given must be examined with the overall clinical condition of the patient and the general recorded data quality.

CAUTION

- ▲ If Heart Rate is available from both ECG and SpO₂ sources, priority is given to Heart Rate measure from SpO₂. It is advised to always measure with the SpO₂ module in addition to the ECG sensor whenever possible.
- ▲ When the ECG filter is set to SHF filter, the HR is no more accurate above 250 bpm, as the SpO₂ pulse is also unavailable; another system must monitor HR.



Important

- The guidelines for patient electrode placement are provided as an overview only and are not a substitute for medical expertise.
- If an electrode is faulty or has come off, a message indicates the faulty electrode.

! WARNING



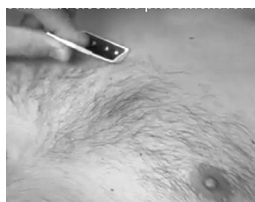
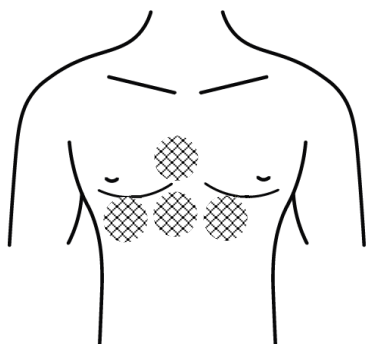
- ▲ **False diagnosis, Patient Hazard.** The ECG is used for monitoring the patient's cardiac rhythm. The static magnetic field influences the ECG signal. The ECG signal may also be affected more or less by imaging sequences (RF and gradient pulse sequences). This ECG signal is not suitable for diagnostic purposes.
- ▲ **Risk of skin burns.** Prevent excessive temperatures, electrodes must be applied in the vicinity of the heart and with a minimum distance between them. The distance between the individual electrodes must not exceed 10 cm. Electrodes and lead wires must never come in contact with the inside of the scanner tunnel or parts of the magnet. Check an adequate distance between these parts, electrodes and lead wires (5 cm minimum for field strengths up to 1.5 T and 10 cm minimum for field strengths up to 3 T). If the patient's body measurements do not permit these distances, electrodes, lead wires, and ECG sensors must be removed.
- ▲ Lead wires must never form loops or cross diagonal patterns.



Important

- The ECG sensor was specially developed for the **MAGLIFE RT-1** during MRI examinations.
- Special MRI-compatible electrodes must be connected to this sensor (refer to section [11.1 Accessories and Disposables](#)). The disposable electrodes are pre-gelled and self-adhesive. The ECG sensor, when used in conjunction with these ECG electrodes, limits the effects of the imaging field on the signal traces to the largest possible extent. Furthermore, it reduces the potential temperature risk due to the scanner operation (RF signal). In rare cases, skin reddening or skin burns may occur simultaneously.

5.2.1 Preparing the skin before placing ECG electrodes



Careful application of the electrodes and good electrode contact is important for good monitoring.

A minimal resistance between skin and electrode is required to obtain the best ECG signal and good quality ECG monitoring. Note the following points:

1. Only use electrodes that are recommended by SCHILLER Medical (refer to section [11.1 Accessories and Disposables](#))
2. Before using disposable electrodes, check that the expiration date has not yet passed.
3. To increase the electrode's conductivity and adherence:
 - Shave the areas (see left) where the electrodes are to be placed
 - Thoroughly clean the areas.
 - Let the skin dry before applying the electrodes.
 - When applying the electrodes, check that there is a gel layer between the electrode and the skin.
4. Check the amplitude of the ECG curves on display.
5. If the electrode resistance is higher than the acceptable level (small amplitude ECG curve):
 - Remove the electrode and use an abrasive cleaning pad or abrasive cleaning gel^a to remove the uppermost layer of the epidermis.
 - Reapply new electrodes.

a. Dedicated abrasive cleaning gel gives very good results in reducing skin-electrode resistance.

5.2.2 Placing electrodes and connecting a 4-wire ECG patient cable



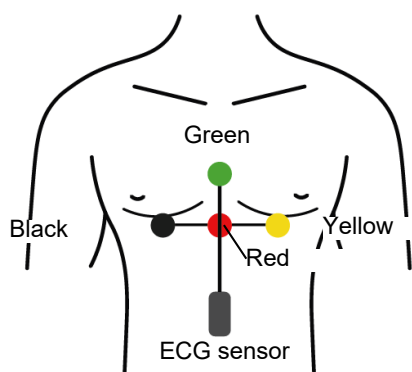
▲ The electrodes are designed for single use only, do not reuse them.

The 4-wire cable provides the equivalent of 3-limb monitoring leads.

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Important

- Follow the instructions below to achieve optimum signal quality and reduce interference to a minimum.
- The lead wires must be routed as shown in [Fig. 5.1 4-wire cable](#) without tensioning the wires.
- The ECG sensor and electrodes can be located inside the magnet bore, where the static magnetic field can be up to 3 Tesla (distance sensor and electrodes greater than 10 cm to scanner tunnel or parts of the magnet).



1. Prepare the patient's skin. Refer to section [5.2.1 Preparing the skin before placing ECG electrodes](#).
2. Apply the electrodes as shown in [Fig. 5.1 4-wire cable](#) without tensioning the wires.
 - Red: at the centre of the chest, at the lower extremity of the sternum
 - Yellow: on the side of the heart
 - Black: opposite the yellow electrode.
 - Green: above the red
3. Connect the electrodes to the ECG sensor.
4. Switch the ECG sensor on and check the pairing/connection of the ECG sensor with the **MAGLIFE RT-1**.
5. Check the status of the battery capacity on the **MAGLIFE RT-1**. Refer to section [5.2.5 Starting ECG monitoring](#).

Preventing magnetic artefacts

The W-ECG sensor, placed in the gradient field, generates a magnetic artefact which results in an image artefact (area without signal) directly below this sensor. Move the W-ECG sensor away from the area of investigation.

Standard Placement



Alternative Placement

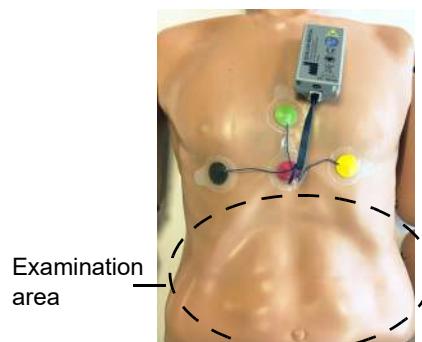


Fig. 5.1 4-wire cable

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The first display curve calculates the HR unless the HR source is set to Pleth.



Important

- All three electrodes (black, red and yellow) must be arranged in a straight line.
- The red, yellow and green must be arranged in a triangle; see the images above.
- The electrodes must be applied at a maximum distance of 8 to 10 cm to the centre electrode.
- The lead wires must be routed as shown in [Fig. 5.1 4-wire cable](#) without tensioning the wires.
- The 1 mV pulses continuously superimposed on the ECG help find the maximum amplitude.
- The ECG sensor, electrodes and other applied parts need to be located inside the magnet bore, where the static magnetic field can be up to 3 Tesla.

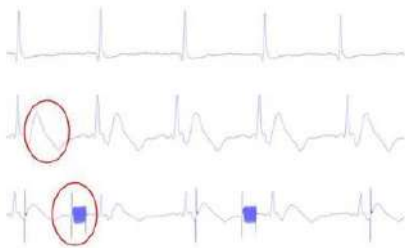
5.2.3 Signal artefacts



- Signal quality can be affected by magnetic disturbances inducted in the human body by the MRI's magnetic gradients during a scan. In most cases, the amplitude of those artefacts stays very low.
- If the examination area (centre of the field of view) has a certain distance from the ECG electrodes, where the gradients are highest and become non-linear. In that case, the artefacts can reach amplitudes that affect the ECG signal and lead to an inaccurate heart rate reading.
- The gradients that generally affect signal quality are Diffusion, and Turbo Spin Echo with high turbo factor when the examination area is focused on the head or lumbar spine (far away from the ISO centre).

Example of recorded ECG signals

These signals have been recorded with the ECG sensor of **MAGLIFE RT-1** on a patient:



— ECG signal recorded outside the MRI.

— The ECG signal was recorded in the MRI room. An example of an artefact due to the Magnetohydrodynamic effect (MHD) is circled in red.

— The ECG signal during an MRI sequence. The effect of the sequence is circled in red.

5.2.4 Remedy signal artefacts

Those negative effects of the MRI on the ECG signal can be decreased by optimising the ECG electrode placement and conditions.

- Prepare the patient's skin according to section [5.2.1 Preparing the skin before placing ECG electrodes](#).
- Use a new set of high-quality ECG electrodes.

5.2.5 Starting ECG monitoring



1. Prepare the patient's skin according to section 5.2.1 Preparing the skin before placing ECG electrodes.
2. Apply the electrodes as described in section 5.2.2 Placing electrodes and connecting a 4-wire ECG patient cable.
3. Switch the ECG sensor. Pre-paired sensors will connect automatically according to pre-settings.
4. Check the sensor status and battery capacity on the **MAGLIFE RT-1**.
5. Define the ECG settings directly via the touch screen curve or measurement field.
6. Open the HR module (ECG menu) and check the settings.
7. Check the quality of the ECG signal.

If an adequate ECG signal cannot be achieved:

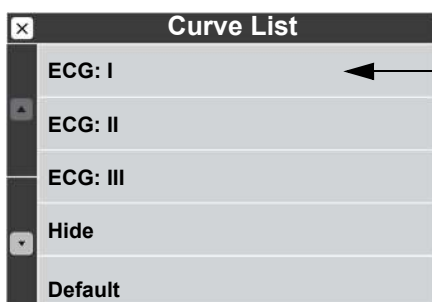
- Select the range providing the maximum possible amplitude
- Shave and clean the patient's skin at the application sites to reduce the impedance between the skin and an electrodes
- Wait at least 2 minutes before beginning to monitor the ECG.

Fig. 5.2 ECG Sensor and status

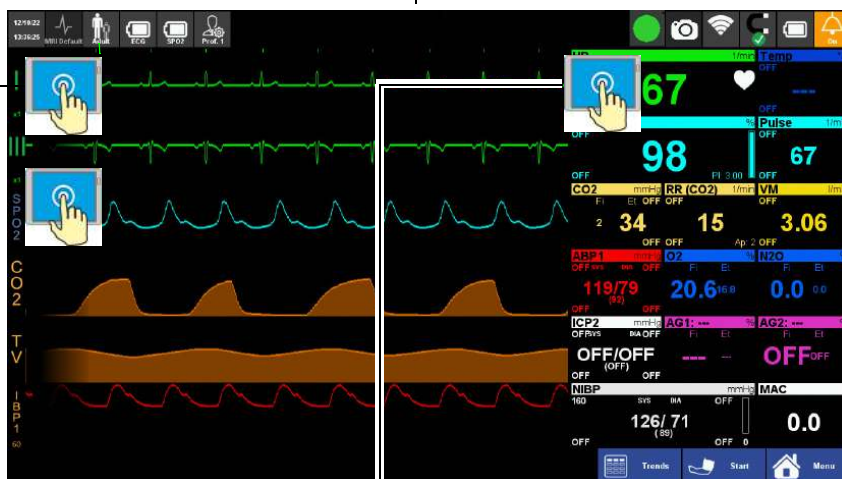
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The sweep speed can be set to either 25 or 50 mm/s.

Curve list with a 4-wire cable



Green vertical dashes above the top ECG curve represent QRS complexes.



5.2.6 Curve list

Menu	Parameter	Description	Value
Curve list	Touch the first curve	Selection of the displayed first curve. The first display curve calculates the HR unless the HR source is set to Pleth.	ECG: I, ECG: II, ECG: III, Hide Default: ECG II
	Touch curves 2, 3 and 4	Selection of the displayed curve	ECG: I, ECG: II, ECG: III, aVR, aVL, aVF, SpO ₂ , Plethysmograph , EtCO ₂ : Respiration Airway Press, Airway Flow, IBP: IBP1 and IBP2, Hide, Default

5.2.7 HR Module (ECG) settings

Menu	Parameter	Description	Value
ECG	Amplitude Auto	Automatic scale of the ECG amplitude	OFF/ON
	Amplitude	ECG amplitude setting	0.25/0.5/1/2 cm/mV
	ECG Filter	QRS Source selection Filter Mode Powerline Filter (Notch) Baseline Filter (BLW) ADAS LP Filter ADAS lead off Hall gradient gain	Filter setting next table below
	ECG curve speed	Setting of the curve speed	25 or 50 mm/second
	QRS sound level	Volume of the systolic sound	Off/Low/ Medium /High
	Thresholds	Manual setting of the thresholds min/max.	31 to 299 bpm
	Parameter activation	Switching ECG parameter display off when not used	On/Off . The measuring field shows Off.

ECG Filter settings

Sub Menu	Parameter	Description	Value
ECG Filter	QRS Source selection	QRS Source selection	QRS Source selection I, II, III or
	Filter Mode		Out of MRRI LP filter Adaptive filter SHF filter
	Powerline Filter (Notch)	Set the frequency of the used power supply	None/50 Hz/60 Hz
	Baseline Filter (BLW)		On/Off
	LP Filter 45	Setting of low pass filter	45/150/250/450
	Lead off	Set lead-off detection On/Off	On/Off
	Hall gradient gain	-	On/Off, if set to On

5.2.8 ECG Alarm messages

Alarm (measurement field)	Code	Cause	Remedy
ECG: VF/VT	P_ECG_01	• Fibrillation ventricular or Tachycardia ventricular up to 180 bpm	→ Check the patient
ECG: Asystole	P_ECG_02	• Asystole detected	→ Check the patient
ECG: HR out of range	P_ECG_03	• HR is out of the set alarm limits.	→ Check the patient → Check the narrow/wide HR alarm limit and adjust it if necessary.
ECG: Measurement not valid	T_ECG_01	• ECG sensor defective • Peripheral board defective	→ Technical alarm. Call the service department.
Sensor: ECG not connected	I_SENSOR_ECG_01	• ECG sensor not connected	→ Check the ECG sensor battery and connectivity
Sensor: Communication error	T_SENSOR_ECG_01	• ECG sensor defective	→ Contact technical service

5.3 SpO₂ Monitoring



Intended Purpose

- The **MAGLIFE RT-1** is intended to make continuous non-invasive monitoring of functional oxygen saturation of arterial haemoglobin and peripheral pulse (pulse rate).
- The **MAGLIFE RT-1** can be equipped with either SCHILLER or BluePoint SpO₂ sensors.

Intended Users

- The device is intended for clinical professionals. Clinical professionals must have a working knowledge of medical procedures, practices, and terminology for completing these examinations.

Medical indications

- **MAGLIFE RT-1** pulse oximeter is indicated in patients that are at risk of presenting hypoxemia of unstable and/or anaesthetized patients pre/per/post MRI examinations.

Limitations

- Perfusion might be limited when a NIBP cuff is inflated, if placed on the same arm as the oximetry sensor.

Contraindications for use

- The pulse oximeter sensor must not be applied on limbs used for other medical measurements (for example, IV catheter or NIBP cuff) as this may lead to low perfusion and incorrect measurements.
 - Additional general contraindications for use are indicated in [1.3 Expected Therapeutic Clinical Patient Benefits](#).

Side effects

- A prolonged contact of the oximeter sensor with the patient skin may cause skin redness or superficial burns.
 - Additional general side effects for use are indicated in [1.5 Known Side Effects](#).

Target population

- The device can be used on any type of patient with the appropriate sensor model: adults, children and very small children sensors.

Affected Body Regions

- The SpO₂ sensor is placed on a patient finger (generally forefinger) or a toe.



- ▲ The pulse rate issued from the SpO₂ parameter is limited up to 240 bpm; no higher pulse rate can be displayed.

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- The pulse oximeter enables the continuous, non-invasive monitoring of functional oxygen saturation of arterial haemoglobin and the pulse rate. The signal received from the patient sensor is used to calculate the patient's functional oxygen saturation and pulse rate.
 - The display shows the continuous progress of the numeric SpO₂ value, pulse rate, plethysmographic waveform and signal quality.
 - The displayed plethysmographic curve is not proportional to the pulse volume.
 - The update period of the measurement readings on display is 2 seconds.
 - According to the relevant standards, the temporary alarm suppression must not exceed 2 minutes.
 - Equipment used to perform functional tests cannot be used to indicate the accuracy of the SpO₂ module.
 - SpO₂ are empirically calibrated in healthy adult volunteers with normal levels of Carboxyhaemoglobin (COHb).
 - The peak wavelength and maximum optical power of the light emitted by the pulse oximeter probes have to be considered in certain cases. For example, when performing photodynamic therapy. They are as follows:
 - Range of peak wavelengths: 660 to 905 nm
 - Maximum optical power output sensor < 3.5 mW
 - Sensors use LEDs that are non-laser with the SpO₂ module
 - High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor may not allow the pulse oximeter to obtain vital sign readings.
 - Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient's cabling.
 - Additional information specific to the BluePoint sensors compatible with the pulse oximeter may be found in the sensor's directions for use, including information about parameter/measurement performance during motion and low perfusion.
- Pulse oximeter equipment measurements are statistically distributed. Only about two-thirds of pulse oximeter equipment measurements can be expected to fall within $\pm A_{rms}$ of the values measured by a co-oximeter.

! WARNING



Patient Hazard, Incorrect Measurement Results

- ▲ Only use the SpO₂ sensors listed in the order information for the **MAGLIFE RT-1**. Other oxygen transducers (sensors) may lead to improper performance.
- ▲ The information in this user guide does not overrule any instructions given in the sensor's user guide, which must be consulted for full instructions.
- ▲ Never use the pulse oximeter as the sole means of monitoring a patient or as an apnoea monitor. Always use the pulse oximeter with an ECG trace or NIBP.
- ▲ **False diagnosis, Patient Hazard.** The SpO₂ signal may also be affected more or less by imaging sequences (diffusion sequences).
- ▲ An incorrect application or sensor usage can cause tissue damage. Inspect the sensor application location as described in the sensor directions to ensure skin integrity and correct positioning and adhesion of the sensor.

! WARNING

Patient Hazard, Incorrect Measurement Results

- ▲ Do not use damaged patient cables, damaged sensors or sensors with exposed optical components.
- ▲ Change the position of the sensor at least every 4 hours and every 2 hours if perfusion is low.
- ▲ When patients are undergoing photodynamic therapy, they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision and only for short periods to minimise interference with photodynamic therapy.

5.3.1 Inaccurate measurement results

CAUTION

- ▲ Incorrect application or exposition of the sensor to some external variable such as excessive light, patient movement, venous variability or temperature may lead to inaccurate measurements.
- ▲ Inaccurate measurements can be caused in general by:
 - Improper sensor application
 - Low arterial perfusion
 - Motion artefact
 - Elevated levels of bilirubin
 - Intravascular dyes such as indocyanine green or methylene blue
- ▲ Inaccurate SpO₂ measurements can be caused by:
 - Elevated COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO₂. When elevated levels of COHb or MetHb are suspected, laboratory analysis (Oximetry) of a blood sample should be performed
 - Elevated levels of dyshemoglobin
 - Vasospastic diseases, such as Raynaud's and peripheral vascular disease
 - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, and sickle cell.
 - Hypocapnic or hypercapnic conditions
 - Severe anaemia
 - Very low arterial perfusion
 - Extreme motion artefact
 - Abnormal venous pulsation or venous constriction
 - Severe vasoconstriction or hypothermia
 - Arterial catheters and intra-aortic balloon
 - Intravascular dyes, such as indocyanine green or methylene blue
 - Externally applied colouring and texture, such as nail polish, acrylic nails, and glitter.
 - Birthmarks, tattoos, skin discolourations, moisture on the skin, deformed or abnormal fingers.
 - Skin colour disorders
- ▲ Interfering substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- ▲ If SpO₂ values indicate hypoxaemia, a laboratory blood sample should be taken to confirm the patient's condition.
- ▲ If the Low Perfusion message is frequently displayed, find a better-perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- ▲ Change the application site, replace the sensor or patient cable when a Replace sensor, Replace patient cable, or a persistent poor signal quality message (Low SpO₂ confidence) is displayed on the monitor. These messages may indicate that the patient monitoring time is exhausted on the cable or sensor.

 CAUTION

- ▲ Ionising radiation: If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to radiation, the reading might be inaccurate, or the device might read zero for the active irradiation period.
- ▲ Non-ionising radiation: If using pulse oximetry during an MR scan (RF fields or Magnetic gradient fields), the reading might be inaccurate during high field exposure. Check the clinical status or refer to another physiological parameter.
- ▲ Variations in haemoglobin measurements may be profound and may be affected by the sampling technique and the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional test data. Before clinical decision-making, laboratory devices should analyse blood samples to understand the patient's condition.
- ▲ The pulse oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
- ▲ The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
- ▲ Replace the cable or sensor when a Low SpO₂ confidence message is consistently displayed while monitoring consecutive patients after completing the troubleshooting steps listed in this manual. Refer to section [5.3.5 SpO₂ Physiological alarms](#).

5.3.2 Apply wireless SpO₂ sensor

Paediatric considerations

Selecting a SpO₂ sensor appropriate for the patient's weight is important. For example, a clean pulse oximetry waveform may not be obtainable when an adult sensor is used on a small child. Weight range information can be found in the packaging that comes with the SpO₂ sensor.

Placing finger sensors (adult)

Insert and check that the patient's forefinger and fingertip cover the probe window to prevent extraneous light from reaching the photodetector.

Adult sensor



Placing hand sensors (paediatric)

Place the sensor on the hand, as shown below.

Paediatric sensor

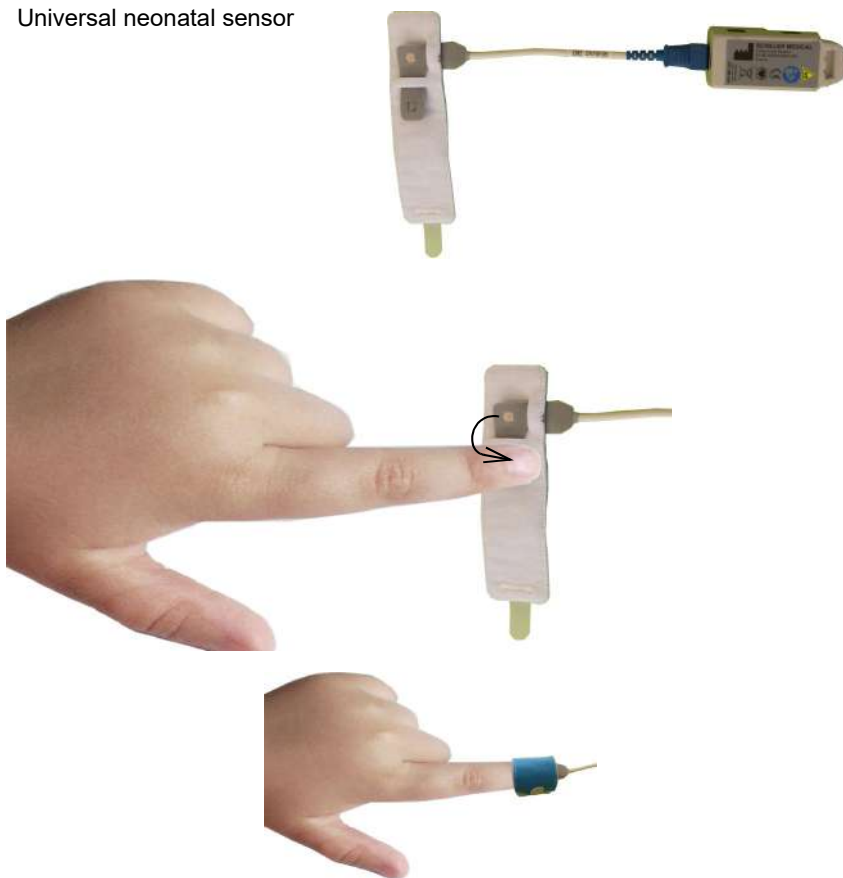


Placing neonatal sensor

1. Place the patient's forefinger or hand (neonate) on the detector window, as shown below.
2. Check that the finger tip covers all of the detector window.
3. Wrap the belt around the finger, and check that the LED window aligns directly opposite the detector window (on the finger nail).

4. Fix the belt with the Velcro fastener.

Universal neonatal sensor



5.3.3 Starting SpO₂ monitoring and test

1. Select a sensor that is appropriate for the patient's weight.
 2. Switch the ECG sensor ON  
 3. Apply the SpO₂ sensor to the patient according to section [5.3.2 Apply wireless SpO₂ sensor](#).
 4. Check the battery capacity status on the **MAGLIFE RT-1**.
 5. Define the SpO₂ settings directly via the touch screen curve or measurement field.
 6. Check the bar graph for signal quality (1).
 7. Check the Perfusion Index PI level (3).
 8. Set the SpO₂ alarm limit. Refer to section [4.6 Operator Defined Alarm Thresholds](#).
 9. An alarm is issued when the SpO₂ value exceeds the alarm limit (2).
- Set the alarm limit to narrow or wide when the vital data are not critical.

Perfusion Index (PI) see (3) indicates arterial pulse signal strength and may be used as a diagnostic tool during low perfusion.

PI display ranges from 0.02% (very weak pulse strength) to 20% (very strong pulse strength).

Display -?- or --- instead of the value:

- --- Sensor not connected to the device
- -?- Sensor not attached to the finger



Fig. 5.3 SpO₂ Measurement field

5.3.4 SpO₂ Module

Menu	Parameter	Description	Value
SpO ₂	Response time	SpO ₂ response time averaging signal	Stable /Standard/Sensitive 8 beat averaging 4 beat averaging
	Mains frequency	Setting of the mains frequency	50 or 60 Hz
	SpO ₂ curve speed	Setting of the curve speed	25 or 50 mm/s
	Pulse sound level	Volume of the systolic sound	Off/Low/ Medium /High
	Thresholds	Manual setting of the thresholds minimum/maximum	31 to 299 bpm
	Parameter activation	Switching SpO ₂ parameter display off when not used	On /Off. The measuring field shows Off.

5.3.5 SpO₂ Physiological alarms

Alarm (measurement field)	Code	Cause	Remedy
SpO ₂ : Sat. Is out of range	P_SPO2_01	• SpO ₂ saturation is out of range	→ Check the patient
SpO ₂ : Pulse off limits	P_SPO2_02	• SpO ₂ pulse is out of range	→ Check the patient

5.3.6 SpO₂ Technical alarm

Alarm (measurement field)	Code	Cause	Remedy
SpO ₂ : Sat. measurement not valid	T_SPO2_01	• SpO ₂ sensor is defective • Peripheral board is defective	→ Replace the SpO ₂ sensor → Replace the peripheral board
SpO ₂ : Pulse measurement not valid	T_SPO2_02		
SpO ₂ : Sensor disconnected	T_SPO2_03		
SpO ₂ : Sensor defective	T_SPO2_04		
SpO ₂ : Wrong sensor	T_SPO2_05		
SpO ₂ : Finger out	T_SPO2_06	• No patient	→ Check the sensor placement
SpO ₂ : Searching for pulse	T_SPO2_07	• Check the sensor placement • Contact technical service	→ Check the sensor placement → Contact technical service
SpO ₂ : Pulse searching longer than 30 seconds	T_SPO2_08		
SpO ₂ : Low pulsation strength	T_SPO2_09		
SpO ₂ : Low transmission	T_SPO2_10	• Sensor is too far away • SpO ₂ sensor is defective	→ Get the sensor closer → Contact technical service
SpO ₂ : Ambient light	T_SPO2_11	• Ambient light detected	→ Check the sensor placement → Shield the SpO ₂ sensor application site with opaque material
SpO ₂ : Interferences detected	T_SPO2_12	• Interferences detected	→ Check the sensor on the patient, check the cable connector, eliminate sources of interference, for example, high-frequency devices or strong light sources.
SpO ₂ : Motion artefacts	T_SPO2_13	• Motion detected	→ Check sensor placement
SpO ₂ : Vital parameter is out of range	T_SPO2_14	• Vital parameter is out of limits	→ Check the patient
SpO ₂ : Supply voltage is out of range	T_SPO2_15	• SpO ₂ sensor is defective • Peripheral board is defective	→ Replace the SpO ₂ sensor → Contact technical service
SpO ₂ : Unknown channel	T_SPO2_16		
SpO ₂ : Unknown identifier	T_SPO2_17		
SpO ₂ : Invalid value	T_SPO2_18		
SpO ₂ : Baud rate too slow	T_SPO2_19		
SpO ₂ : Receive buffer overflow	T_SPO2_20		
SpO ₂ : Frame corrupt, CRC error	T_SPO2_21		

Alarm (measurement field)	Code	Cause	Remedy
SpO ₂ : Red LED is defective	T_SPO2_22	• SpO ₂ sensor is defective	→ Replace the SpO ₂ sensor
SpO ₂ : Infrared LED is defective	T_SPO2_23		→ Contact technical service
SpO ₂ : Photodiode is defective	T_SPO2_24		
SpO ₂ : Short circuit	T_SPO2_25		
SpO ₂ : Boot error	T_SPO2_26		
SpO ₂ : Self-test error	T_SPO2_27		
SpO ₂ : Buffer overflow	T_SPO2_28		
SpO ₂ : Auto scaled pleth. not accepted	T_SPO2_29		
Sensor: Communication error	T_SENSOR_SPO2_01	• SPO ₂ sensor is defective	→ Contact technical service
Sensor: SPO ₂ not connected	I_SENSOR_SPO2_01	• SPO ₂ sensor is not connected	→ Check the SpO ₂ sensor battery and connectivity

5.4 NIBP Monitoring



Intended Purpose

- The **MAGLIFE RT-1** is intended to make non-invasive measurements of arterial pressure. The measurements are done using an inflatable cuff on the patient's arm or leg: systolic, diastolic and mean pressure.

Intended Users

- The device is intended for clinical professionals. Clinical professionals must have a working knowledge of medical procedures, practices, and terminology for completing these examinations.

Medical indications

- **MAGLIFE RT-1** NIBP module is intended to detect presence of hypertension or hypotension (external measurement with an inflatable cuff) of unstable and/or anaesthetized patients pre/per/post MRI examinations.

Limitations

- Inflation of NIBP cuff can influence Oximetry measurement if both sensors are placed on the same arm.

Contraindications for use

- The NIBP cuff must not be attached to a limb that is already used for interventions such as:
 - Infusions or
 - If an arterio-venous shunt is present.
- The cuff must not be placed over or near a wound that could cause further injury.
 - Additional general contraindications for use are indicated in See [1.3 Expected Therapeutic Clinical Patient Benefits](#).

Side effects

See [1.5 Known Side Effects](#).

Target population

- The device can be used on any type of person either adults, children or neonates with the appropriate cuff size, see the following recommendations:
 - Adult: 27,5 to 46cm arm circumference
 - Child: 13,8 to 28,5cm arm circumference
 - Neonate: 3 to 13cm arm circumference

Affected Body Regions

- The measurements are performed using an inflatable cuff on the patient's arm or leg.



- The non-invasive blood pressure is measured by the oscillometric method.
- The module performs single measurements and automatic measurements at selectable intervals.
- The automatic measurements are also suitable for a pregnant or pre-eclamptic patient.
- Check that the cuff is on a level with the heart during blood pressure measurements. If this is not, the hydrostatic pressure of the liquid column in the blood vessels will lead to incorrect results. The cuff is automatically at the correct level when the patient is sitting, standing or supine during measurements.
- Factory default cuff inflation pressure adult = 180 mmHg, children = 150 mmHg, neonates = 50 mmHg
- The initial cuff pressure is configurable. The maximum cuff pressure configuration in neonatal mode is 150 mmHg.

! WARNING

- ▲ It is very important to choose the correct cuff size and select the correct patient type, adult, child or neonate, to avoid extensive pressure on the patient's extremities.
- ▲ With neonatal patients, it is imperative first to select neonatal mode. An erroneous mode selection will lead to a higher pressure which can cause haematoma or an osseous deformation.
- ▲ When neonatal mode is selected, the maximal pressure is lowered, and the time measure is shorter. An erroneous mode selection on neonatal patients would engender inadequate pressure and time measure.
- ▲ In case of long-term monitoring or automatic operation, the patient's body contact areas and the extremity to which the cuff is attached must be checked regularly for signs of ischaemia, purpura or neuropathy. It is especially important for patients with decreased pain sensitivity (due to medication) or older patients with decreased blood circulation at the extremities.
- ▲ The cuff must not be attached to a limb that is already used for interventions such as:
 - Infusions or
 - SpO₂ measurement (loss of data can occur during cuff inflation) or
 - If an arterio-venous shunt is present.
- ▲ To prevent extensive pressure on the extremity and incorrect measurement results, check that the tube is not kinked or compressed.
- ▲ The cuff must always be installed on the level of the right atrium to achieve the correct arterial pressure measurement.
- ▲ To reduce interferences and the danger of burns for the patient, keep the cuff and hose as far away as possible from the operated area and the electrosurgical cables. Check that the electrosurgical return conductor (neutral) is well attached to the patient and that good contact is guaranteed.
- ▲ In some patients, petechiae, haemorrhages or subcutaneous haematomas may occur. All patients must be told when putting on the cuff that if they experience pain during the recording, they should switch off the equipment and inform the doctor.
- ▲ When an automated measurement interval is defined, bruising or decreased blood circulation can occur in the arm. Only carry out recordings with automated measurement intervals under constant medical supervision.
- ▲ It must be certain that, according to the patient's health, the device will not damage blood circulation in the arm.

! CAUTION

- ▲ As with occasional blood pressure measurements, petechial bleeding can occur in patients with coagulation disorders or having anticoagulant treatment, even with the correct cuff size.
- ▲ The cuff can be placed on the opposite arm in patients with a single mastectomy.
- ▲ The cuff must not be placed over or near a wound that could cause further injury.
- ▲ To prevent incorrect measurement results, check that the tube is not pinched or compressed.
- ▲ A cuff applied to a patient in the recumbent or sitting position is normally located at the same level as the heart. If the cuff is located at a level higher than the heart (for instance, if the arm of a patient in bed is lifted), this may result in lower than actual measurement readings (approximately 7.5 mmHg per 10 cm rise).
- ▲ Replace cuffs whose material shows signs of ageing or permanent creases.

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The measurement may be inaccurate or impossible:

- If the cuff size is not correctly chosen
- If a regular arterial pressure pulse is hard or impossible to detect, for example, with cardiac arrhythmias, severe shock, hypothermia or with obesity or an edematous extremity
- With excessive and continuous patient movement, for example, shivering or convulsion.
- The accuracy of the NIBP measurements can be affected by extremes of temperature, humidity and altitude
- If unexpected readings are obtained, follow the procedure below, and if error messages are displayed, refer to section [5.4.7 NIBP Information and error messages](#).

5.4.1 Procedure for good NIBP measurements

- Attach the NIBP cuff to the patient. Refer to section [11.2 Accessories](#) for a list of approved NIBP cuffs. Obtaining good quality NIBP measurements, it is important to use a cuff that is the correct size for the patient. Measure the circumference of the patient's limb and compare this to the size marked on the NIBP cuff.
- The patient should be sitting or lying down, and the patient's arm or leg should be relaxed, extended, and resting on stationary support. The legs should be uncrossed and flat on the floor for a seated patient.
- A deflated cuff must be comfortably but securely wrapped around the patient's arm or leg.
- If wrapping around the arm, wrap the cuff at 2 to 5 cm above the elbow crease, and place the artery mark over the patient's brachial artery, pointing to the patient's hand.
- Instruct the patient to remain quiet and still during the measurement.
- Connect the NIBP cuff to the NIBP hose, and connect the hose to the **MAGLIFE RT-1**.
- Start the NIBP measurement by pressing the **NIBP START** button.
- It is recommended that 5 minutes elapse before the first reading is taken.
- Configure the **MAGLIFE RT-1** to take measurements manually or automatically at preset intervals.

5.4.2 Paediatric and neonate considerations

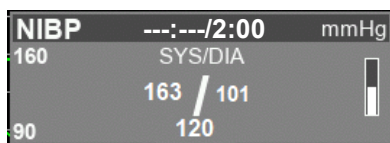
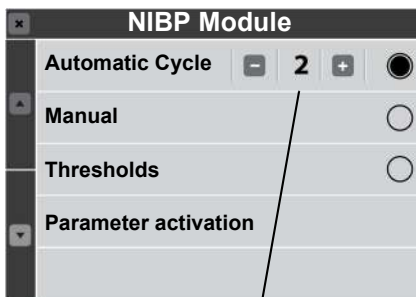
The initial inflation pressure can be adjusted with the patient type button. The default is for children = 150 mmHg and 50 mmHg for neonates.



5.4.3 Hypertensive considerations

For hypertensive patients (for example, systolic pressure greater than 220 mmHg), it may be necessary to repeat an NIBP measurement if the first attempt is unsuccessful. The **MAGLIFE RT-1** will register the patient's blood pressure profile from the first attempt, even if unsuccessful, and use a higher inflation pressure on a subsequent measurement attempt.

5.4.4 Starting NIBP monitoring



1. Note the cuff size for the respective patient type. Refer to section [11.2 Accessories](#)
 2. The cuff is attached to the left or right upper arm, about 4 cm above the elbow, a little closer for children.
 3. Connect the cuff tubing to the connection sleeve (1) and check that it properly locks into place.
 4. Define the NIBP settings directly via the touch screen NIBP measurement field.
 - Patient type adult, child or neonate (indicated, top right of the screen)
 5. Open the NIBP menu and check the settings.
 - The setting of the Automatic cycle time or manual measurement
 6. Start the NIBP measurement by pressing the **Start** button.
- To disconnect the cuff tube, press the milled shell of the connecting sleeve backwards.
- Clean and disinfect the cuff after each use. Refer to sections [9.4 Cleaning](#) and [9.5 Disinfection](#).

The following settings are available for the cycle time:

Automatic Cycles 2/3/5/10/15/30 minutes

Manual The measurement is manually initiated by pressing the button.



Bar graph applied pressure



Remaining time until to the next NIBP measurement



- When the measurement is started, the increasing cuff pressure is displayed on the bar graph.
- The last four measurements are displayed in the window.
- The latest NIBP measurement is always displayed in the NIBP parameter box. Should the value be older than 5 minutes, it will be displayed in yellow.

5.4.5 NIBP Menu

Menu	Parameter	Description	Value
NIBP	Automatic cycles	Cycle time setting	Automatic cycle of 2/3/5/10/30 minutes
	Manual	The measurement is manually initiated by pressing the Start button	Start
	Thresholds	Manual setting of min/max NIBP thresholds for systolic and diastolic pressure	Refer to section 4.6 Operator Defined Alarm Thresholds
	Parameter activation	Switching NIBP parameter display off when not used	ON/OFF

5.4.6 NIBP Physiological alarms

NIBP Alarm	Code	Cause	Remedy
NIBP: SYS out of range	P_NIBP_01	The NIBP module failed	→ Replace the device
NIBP: DIA out of range	P_NIBP_02	- No pressure can be measured - The device is defective	→ Check the cuff and connection. → Replace the device

5.4.7 NIBP Information and error messages

NIBP Alarm	Code	Cause	Remedy
NIBP: Invalid measurement	T_NIBP_01	SYS and or DIA values are higher or lower than the limits	→ Check the patient → Check for leaks at the cuff and hose
NIBP: Invalid measurement	T_NIBP_02	NIBP module defective	→ Contact technical service
NIBP: Self-test failed	T_NIBP_03		
NIBP: Loose cuff	T_NIBP_04	Loose cuff: cuff not completely secured or not attached	→ Check for leaks at the cuff and hose
NIBP: Air leak	T_NIBP_05	Air leak detected in cuff, hose, internal pneumatics or inoperative valves	→ Check for leaks at the cuff and hose → Contact technical service
NIBP: Air pressure error	T_NIBP_06	Air pressure error: module cannot maintain stable cuff pressure	→ Check for leaks at the cuff and hose → Contact technical service
NIBP: Weak signal	T_NIBP_07	- The patient's pulse pressure is very low - Loosely wrapped cuff	→ Check the patient → Check the cuff and hose
NIBP: Range exceeded	T_NIBP_08	- SYS and or DIA values are higher or lower than the limits - NIBP module defective	→ Check the patient → Check for leaks at the cuff and hose → Contact technical service
NIBP: Excessive motion	T_NIBP_09	Measurement disturbed by motion during measurement	→ Check the patient → The patient must not move during the measurement
NIBP: Overpressure	T_NIBP_10	- Cuff pressure exceeds normal limit - Sudden rise in pressure (for example, a hard squeeze of the cuff, bumping)	→ Check the cuff and hose → Check the cuff is correctly applied
NIBP: Signal saturated	T_NIBP_11	Measurement disturbed by extreme motion during the measurement	→ The patient must not move during the measurement

NIBP Alarm	Code	Cause	Remedy
NIBP: Pneumatic leak	T_NIBP_12	Air leak detected in pneumatic test mode	→ Check for leaks at the cuff and hose → Contact technical service
NIBP: System failure	T_NIBP_13	NIBP module defective	→ Contact technical service
NIBP: Timeout	T_NIBP_14	- Pressure time exceed - Pumping duration is exceeded	→ Check for leaks at the cuff and hose
NIBP: Calibration error	T_NIBP_15	NIBP module defective	→ Contact technical service
NIBP: Invalid measurement	T_NIBP_16	Neonat cuff detected in adult mode	→ Check the cuff and hose → Check the cuff is correctly applied

5.5 IBP Monitoring



Intended Purpose

- The **MAGLIFE RT-1** is intended to make invasive measurements of arterial, venous or intracranial pressure: systolic, diastolic and mean pressure.

Intended Users

- The device is intended for clinical professionals. Clinical professionals must have a working knowledge of medical procedures, practices, and terminology for completing these examinations.

Medical indications

- **MAGLIFE RT-1** IBP module is intended to detect presence of hypertension or hypotension (direct arterial measurement) of unstable and/or anaesthetized patients pre/per/post MRI examinations.

Contraindications for use

- The arterial pressure catheters must not be applied on limbs used for other medical measurements (for example, IV catheter or SpO₂ sensor).
 - Additional general contraindications for use are indicated in [1.3 Expected Therapeutic Clinical Patient Benefits](#).

Side effects

See [1.5 Known Side Effects](#).

Target population

- The device can be used on any type of patient with the appropriate consumables.

Affected Body Regions

- The IBP catheter is placed directly in a blood vessel.

 WARNING

- ▲ Carefully read the manufacturer's instructions before using the invasive blood pressure kit.
- ▲ When applying the kit to the patient, check that no air penetrates the system.
- ▲ The device does not provide an air bubble alarming system. The user must periodically visually check the non-presence of air bubbles, leakage or occlusion.
- ▲ To achieve correct arterial pressure measurement, the pressure sensor must be installed on the level of the right atrium.
- ▲ Do not apply arterial pressure catheters on limbs used for other medical measurements (for example, IV catheter or SpO₂ sensor).
- ▲ If the pressure sensor's position is changed after calibration, this might lead to wrong low or high values.
- ▲ If an invasive catheter for blood pressure measurement is introduced into an arterial vessel, the circulation in the terminal vessels must be checked at regular intervals.
- ▲ Do not use an IBP kit if the packaging is opened or damaged.
- ▲ For the patient's safety, check that neither the electrodes, the patient, or persons touching the patient, come into contact with conducting objects, even if these are earthed.
- ▲ Special care must be exercised when the device is used with high-frequency equipment. To prevent incorrect IBP measurements, only use sensors protected against high-frequency radiation.
- ▲ **False diagnosis, Patient Hazard.** The static magnetic field influences the IBP sensor accuracy. The IBP signal may also be affected more or less by imaging sequences (gradient pulse sequences). The IBP sensor must be placed where the static magnetic field is not higher than 40 mT (400 Gauss).
- ▲ Single-use sensors and valves must not be reused and must be disposed of after use.



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- The kit and operating procedure vary according to the manufacturer. Consult the manufacturer's documentation for connection.
- For the warm-up time, ready for measurement and displacement for invasive transducers, refer to the documentation of the transducer manufacturer.

IBP Adapter cable and IBP sensors



IPB Adapter cable



Disposable IBP kit example



IPB Adapter cable



Reusable IBP sensor example

5.5.1 Preparing an IBP measurement



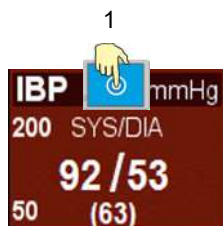
Connect the rinse to the system and check a minimum rinse flow of approximately 6 ml per hour to prevent occlusion of the catheter tip.



1. Unpack the disposable measuring kit and check all tube connections for tightness.
2. Secure the infusion bag and connect the infusion tube to the bag.
3. Fill up the system with liquid to completely remove any air.
4. Hang the measuring kit in the holder and secure the holder.
5. Connect the cable of the transducer to the adaptor cable.
6. Connect the adapter cable to the **MAGLIFE RT-1** IBP input (1).
7. Connect the system to the catheter.
8. Check that there is a minimum flow of rinse.

5.5.2 Start IBP measurement

1. Select the IBP measurement field (1) to open the IBP menu.
2. Zeroing the IBP (refer to section [5.5.4 IBP Zeroing](#))
3. Check the IBP curve on the display to see if the connections have been made correctly and if the IBP value is in the expected range.



IBP Curve display

One or two
IBP curves



IBP Measurement field with
systolic/diastolic and mean
arterial pressure

5.5.3 IBP Menu settings

Access the IBP menu via the IBP measurement field.

The default settings are printed in **bold**.

Menu item	Parameter	Description	Description
IBP Menu	Amplitude auto	Auto curve amplitude setting	ON/OFF
	Curve amplitude (kPa)	Manual setting of the curve amplitude	Set the range for the IBP measurement: 4 , 8, 20, 40 kPa
	Curve amplitude (mmHg)	Manual setting of the curve amplitude	Set the range for the IBP measurement: 30 , 60, 150, 300 mmHg
	Mode	Setting of the location of the IBP measurements	Arterial, Pulmonary artery, Central venous, Left atrial, Intra-Cranial, default
	Zero	Zero adjustment of the IBP	Refer to section 5.5.4 IBP Zeroing
	IBP curve speed	Setting of the curve speed	25 mm/s or 50 mm/s
	Thresholds	Manual setting of minimum/maximum IPB thresholds for Systolic and diastolic pressure	---
	Parameter activation	Switching IBP parameter display off when not used	ON/OFF

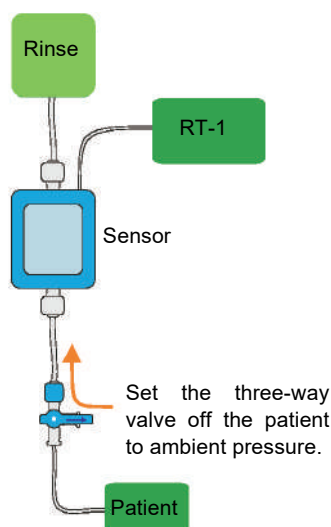
5.5.4 IBP Zeroing



- Zeroing must be carried out before every application and after every patient displacement or modification of the position (high) of the sensor.
- To prevent incorrect measurement readings due to the sensor's physical null drift, calibrate the sensor every 24 hours.

Note

If the pressure sensor's position changes after or during calibration, it might lead to an incorrect, low or high values.



1. Per the manufacturer's instructions, open the relevant valve(s) to equalise the system pressures and isolate the system from the patient, as shown in this example left.
2. Select the IBP measurement field to display the IBP menu.
3. Select the parameter **Zero** to carry out the zeroing.
4. Replace the valve(s) in a coherent position for pressure monitoring.
5. Check that zeroing has been properly performed, confirmed by a green check mark on the menu.

5.5.5 IBP Physiological alarms

Alarm	Code	Cause	Remedy
IBP 1/2: SYS out of range	P_IBP1/2_01	• Systolic pressure higher/lower than the alarm limits	→ Check the patient and alarm limits.
IBP 1/2: DIA out of range	P_IBP1/2_02	• Diastolic pressure higher/lower than the alarm limits	→ Check the patient and alarm limits.

5.5.6 IBP Technical alarms and messages

Alarm	Code	Cause	Remedy
IBP 1/2: Catheter disconnected	T_IBP1/2_01	Catheter disconnected	→ Check the catheter connection → Check the catheter valve
IBP 1/2: No sensor	T_IBP1/2_02	No cable is connected	→ Check the cable connection
IBP 1/2: Zeroing required	T_IBP1/2_03	- No zeroing has been done - Zero point sensor too high/low by more than ± 30 mmHg or unsteady pressure.	→ Check the tube system, sensor and valves → Perform zeroing
IBP 1/2: Measurement not valid	T_IBP1/2_04	IBP module defective	→ Contact technical service
IBP Module inoperative	T_IBP_01/02/03/	IBP module defective	→ Contact technical service
IBP 1/2: Zeroing not possible	I_IBP1/2_01	- Try zeroing during a valid patient measurement - Try zeroing without a sensor connected	→ Check the catheter valve is closed during zeroing → Connect sensor
IBP 1/2: Zeroing is suggested	I_IBP1/2_02	Zeroing is suggested	→ Perform zeroing
IBP Calibration is suggested	I_IBP_01	Calibration is suggested	→ Contact technical service

5.6 Temperature Monitoring

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Intended Purpose

- The **MAGLIFE RT-1** is intended to make continuous cutaneous body temperature measurements.

Intended Users

- The device is intended for clinical professionals. Clinical professionals must have a working knowledge of medical procedures, practices, and terminology for completing these examinations.

Medical indications

- **MAGLIFE RT-1** temperature sensor is intended to detect the presence hypothermia or hyperthermia of unstable and/or anaesthetized patients pre/per/post MRI examinations.

Contraindications for use

See [1.3 Expected Therapeutic Clinical Patient Benefits](#).

Side effects

See [1.5 Known Side Effects](#).

Target population

- The device can be used on any type of patient.

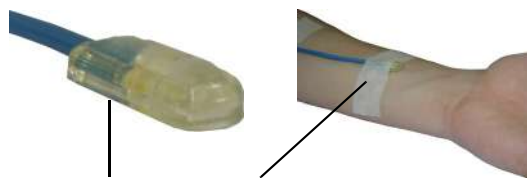
Affected Body Regions

- The temperature sensor is applied on the patient skin.

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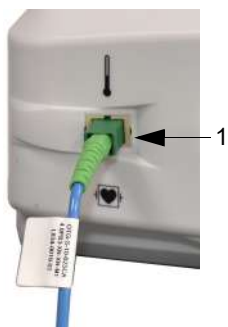
- The sensor must be applied to the skin
- The measurement duration must be at least 2 minutes to achieve a reliable measured value independent of the measuring site.
- The temperature measurement method is direct mode.

Skin temperature probe



Flat part in contact with the skin

5.6.1 Start temperature monitoring



1. Connect the sensor to the temperature input (1).
2. Apply the edge of the temperature sensor to the skin and secure it with adhesive tape or other fixing strap.
3. Cover the site to avoid the influence of ambient temperature.
4. Select the **TEMP** measurement field to open the **Temperature** menu.
5. Press the **Parameter activation** button to start the measurement.

5.6.2 Temperature menu settings

Access the temperature menu via the TEMP measurement field.

The default settings are printed in **bold**.

Menu item	Parameter	Description
Temperature	Averaging	ON/OFF
	Thresholds Setting minimum/ maximum	Maximum 39°C Minimum 35°C
	Parameter activation	ON/OFF

5.6.3 Temperature alarms

Alarm	Code	Cause	Remedy
Temperature: Out of range	P_TEMP_01	Temperature is out of set alarm limits.	→ Check the patient → Check the Narrow/Wide alarm limit and adjust it if necessary.
Temperature: Measurement is not valid	T_TEMP_01	Temperature module is defective	→ Contact technical service
Temperature: Sensor disconnected	T_TEMP_02	No cable connected	→ Check the cable connection
Device: Internal temperature is out of range	T_DEV_TEMP_01	The internal temperature is out of range	→ Check ambient temperature (10 to 40°C) → Turn the device off for 5 minutes and then re-start the device. → Contact technical service
Device: The internal temperature is out of range	T_DEV_TEMP_02	Internal temperature is out of range	→ Check ambient temperature (10 to 40°C) → Turn the device off for 5 minutes and then re-start the device. → Contact technical service

5.7 ECG Gating module

The ECG Gating module is used to pass ECG signals from **MAGLIFE RT-1** ECG sensor to the MRI scanner, allowing then to start certain imaging sequences, in synchronous way with the physiological parameter.

Applying the Gating module:

1. Plug the optic fiber connector of the Gating module to the ECG sensor of **MAGLIFE RT-1**.
2. Connect the module Gating to the MRI scanner by inserting the specific connector of the Gating module directly to the MRI scanner.
3. Press the ON/OFF button on the middle of the module to the ON position (green lamp on).



- Please contact your local distributor or SCHILLER for details.
- Only use non-magnetic batteries for the power supply of Gating module.
- Do not forget to turn the module off when not in use (battery inside).

6 Monitoring CO₂, N₂O, O₂ and Agents

6.1 Introduction

The Anaesthetic Gas (AG) module (sidestream measurement) measures the patient's anaesthetic and respiratory gases and incorporates the features of the O₂ module.

6.1.1 Measuring method

The Gas measurement (CO₂, N₂O, and halogenated anaesthetic agents) is performed with the same module as the measurement, which operates on the principle of infrared spectroscopy.

O₂ does not absorb IR light as other breathing gases and is therefore measured relying on its paramagnetic properties.

The following respiratory flow parameters can be measured and monitored:

- CO₂ waveform
 - Measured parameters
 - RR
 - EtCO₂
 - FiCO₂
 - FiO₂
 - EtO₂
 - Fi_{agents}
 - Et_{agents}
 - O₂
 - FiN₂O
 - MAC^a
- Following agents can be measured: Desflurane (DES), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV) and Halothane (HAL).



a. MAC is a basic index indicating the depth of inhaled anaesthetics. ISO 80601-2-55 defines MAC as follows: alveolar concentration of an inhaled anaesthetic agent that, in the absence of other anaesthetic agents and at equilibrium, prevents 50% of subjects from moving in response to a standard surgical stimulus.

6.1.2 Safety notes

WARNING



- ▲ The **MAGLIFE RT-1** is not intended to be used as an apnea monitor.
- ▲ Do not use a high-volume water trap with Infant patients. Otherwise, patient injury could result.
- ▲ In the adult and child mode, the gas mixture aspires with a flow of 170 ml/minute; in the neonatal mode, the flow is 100 ml/minute. Therefore, selecting the correct patient type is important to compensate for the loss of delivered gases. The adult water trap can be used in both modes, and a special water trap and gas sample tube for the neonatal mode are available.
- ▲ The sample gases should be returned to a scavenging system (refer to section [6.1.3 Connecting the exhaust](#))
- ▲ Used water traps and tubes must be disposed of per local regulations for contaminated and biologically hazardous fluids.

CAUTION



Erroneous Measurements, Equipment Damage

- ▲ The use of Oxygen 93 with the capnography sensor may lead to inaccurate measurements.
- ▲ Operate the module only in conjunction with the original sample line. Other sample lines may lead to incorrect results and damage the measuring system (loss of warranty).
- ▲ Replace the sample line when the module displays a prompt to do so, even when it is not kinked or squeezed.
- ▲ Excessive temperature may cause a gas leakage in the sampling system, which may involve reading inaccuracy.
- ▲ Measuring errors may also be caused by the following:
 - Leaks in the measuring system. Check that all connections are reliable. Any leak in the system can result in erroneous readings due to the patient's breathing gas mixed with ambient air.
 - Elevated levels of nitrous oxide (laughing gas, N₂O), oxygen and halogenated anaesthetic agents in the respired gases.
- ▲ Water traps must be replaced once a month or earlier if the user is prompted to do so by the message, Change water trap. The message will appear if the gas flow becomes inadequate due to the high fill level in the water trap.
- ▲ The sample line is intended for single use and must not be reused.

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- In most cases, the end-tidal CO₂ value (EtCO₂) is below the CO₂ partial pressure (PaCO₂) determined by blood gas analysis. Possible clinical causes are (see Literature):
 - Hyperventilation, ventilation/perfusion mismatch
 - Decreased cardiac output
 - Alveolar shunts
 - Incomplete emptying of the alveoli.
- Periodic maintenance must be carried out to minimise the following risks (refer to section [9.1 Maintenance Interval](#)):
 - Incorrect zero reference due to a gas leakage after the pump
 - Gas leakage in the sampling system due to wear of parts
 - Break down of the zero reference that causes its permanent occlusion
 - Inaccuracy due to the ageing of the device
 - Gas sample moisture is too high due to saturated Nafion tubings.
- Sample Compensation: The sample volume of anaesthetic agents must be considered and compensated for, particularly in monitoring children and neonates.
- The intubation system or nasal prong for CO₂ and gas measurement, as well as the other applied parts, need to be located inside the magnet bore, where the static magnetic field can be up to 3 Tesla.

! WARNING

- ▲ The system will flush the line if the sample line is more or less clogged. The measurement is suspended while the line is being flushed. The message, purge in progress will be seen when the system tries to flush the line. The system will initiate a technical alarm and display the message occlusion if unsuccessful.

! CAUTION

- ▲ In re-circulating systems, the gas shall always be returned upstream of the CO₂-absorber. Failure to do so may result in incorrect readings and increases the risks of cross-contamination between patients.

6.1.3 Connecting the exhaust

! DANGER

- ▲ We strongly recommend connecting the exhaust port on the back of the monitor to the hospital's scavenging system to avoid an increased concentration of anaesthetic gas in the MRI room.

- Connect the exhaust to the hospital scavenging system or the anaesthetic machine if applicable.



6.1.4 Overview sampling lines and water trap



▲ The sampling line and airway adapter are single-use only, do not reuse them.



Water trap
adult/paediatric



Water trap neonatal



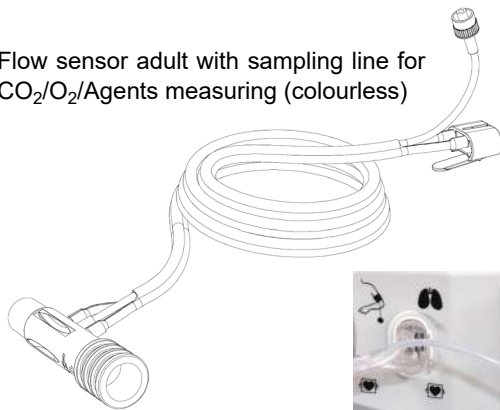
Sampling line adult

Sampling line neonate
(blue)

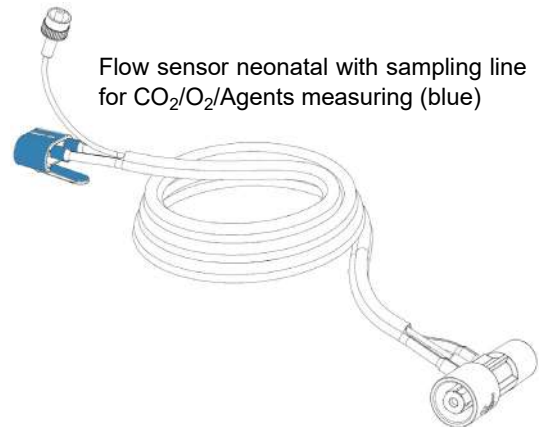


Airway adapter

Flow sensor adult with sampling line for
CO₂/O₂/Agents measuring (colourless)



Flow sensor neonatal with sampling line
for CO₂/O₂/Agents measuring (blue)



▲ The water trap, sampling line and airway adapter must be handled and disposed of as biohazardous waste.



The same sample line and water trap are used for all measurements and are directly connected to the water trap at the front of the monitor.

6.1.5 Installing the water trap and connecting the sampling line



Neonate considerations

→ It is important to select a water trap and sampling line appropriate for the patient type, adult, children or neonates.



Fig. 6.1 Water trap installing

Water trap and sample tube adult/
Child (colour-less)

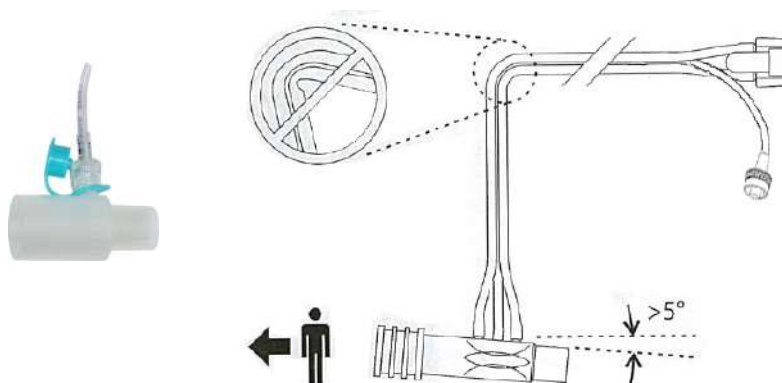


Water trap and sample tube neonatal
(blue)



1. Select a water trap appropriate for the selected patient type setup in the Pre-monitoring screen.
2. Align the water trap with the water trap docking station and push it gently into place. Check that the locking mechanism is fully engaged by pulling the water trap, which should be firmly seated.

3. Connect one end of the sample line to the water trap.
4. Connect the other end to the intubation system via the airway adapter or the bacteria filter of the ventilator.



5. Place the airway adapter so the gas sampling tube points upwards to prevent occlusion by condensed water or patient secretions.
6. Perform a pre-use check. Refer to section [6.1.7 Pre-use check](#) to verify that the gas analyser and sample system are working properly.

Nasal prongs

CO₂ and O₂ can also be measured via nasal prongs. The prongs of the nasal cannula must be securely positioned in the nostrils of the patient to avoid dilution with room air.

6.1.6 Emptying and replacing the water trap



- ▲ The water trap, sampling line and airway adapter must be handled and disposed of as biohazardous waste.



Replace the complete water trap every month or more often if the host instrument indicates this.

1. Push the **Release** button upwards and remove the water trap.

Attention:

2. Lift the lid and empty the reservoir. Caution, biohazardous waste.
3. Push the water trap back into position until the release button clicks.
4. Connect the sampling line.



Fig. 6.2 Water trap replacement and emptying

6.1.7 Pre-use check



The following pre-use check must always be performed to verify that the gas analyser and sample system are working correctly:



- ▲ Do not block the flow sensor for longer than 4 seconds, as this will cause the SPIRIT analyser to go into permanent error mode. The error mode is cleared by power-cycling the device.

1. Check that the water trap is properly attached, a correct DRYLINE
2. The Adult/Neonate/Paediatric sampling line is connected to the water trap, and the container of the water trap (DRYLINE II) is not more than half full.
3. Check that the patient type is set to the right patient.
4. Occlude the sampling line and verify that the occlusion alarm is working properly.
5. Breathe into the sampling line and check that the CO₂ waveform is correctly displayed on the monitor.
6. In systems using an oxygen sensor, sample room air for 30 seconds and check that the monitor oxygen output is within 20.95% ($\pm$ sensor inaccuracy).
7. In systems using SPIRIT Respiratory Mechanics, check that the flow sensor is correctly connected to the host instrument.
8. In systems using SPIRIT Respiratory Mechanics, briefly (< 0.5 seconds) occlude the two patient circuit connections (22 and 15 mm) of the flow sensor with your fingers and verify that the airway pressure reading displayed decreases.
- After having connected the SPIRIT flow sensor to a host instrument, the following shall be performed:
9. Check that the SPIRIT flow sensor is correctly installed in the patient circuit and that the pressure and gas sampling tubes are routed in such a way as to avoid kinking and entry of liquids.
10. Perform a patient circuit leakage test according to the recommendations given by the supplier of the mechanical ventilation equipment used.

CAUTION

- ▲ Gas leakage may cause incorrect readings.

6.2 CO₂ Measuring



Intended Purpose

- The **MAGLIFE RT-1** is intended to make a continuous non-invasive measurement using the principle of infrared spectroscopy to monitor carbon dioxide concentration of the expired and inspired breath, other respiratory gases (such as FiO₂, EtO₂, O₂, ...) and respiration rates.

Intended Users

- The device is intended for clinical professionals. Clinical professionals must have a working knowledge of medical procedures, practices, and terminology for completing these examinations.

Medical indications

MAGLIFE RT-1 capnometry function can be used to monitor spontaneous breathing or insufflations in acute care of unstable and/or anaesthetized patients pre/per/post MRI examinations.

Contraindications for use

See [1.3 Expected Therapeutic Clinical Patient Benefits](#).

Side effects

See [1.5 Known Side Effects](#).

Target population

- The device can be used on any type of person either adults/pediatric or neonates with the appropriate water trap.

Affected Body Regions

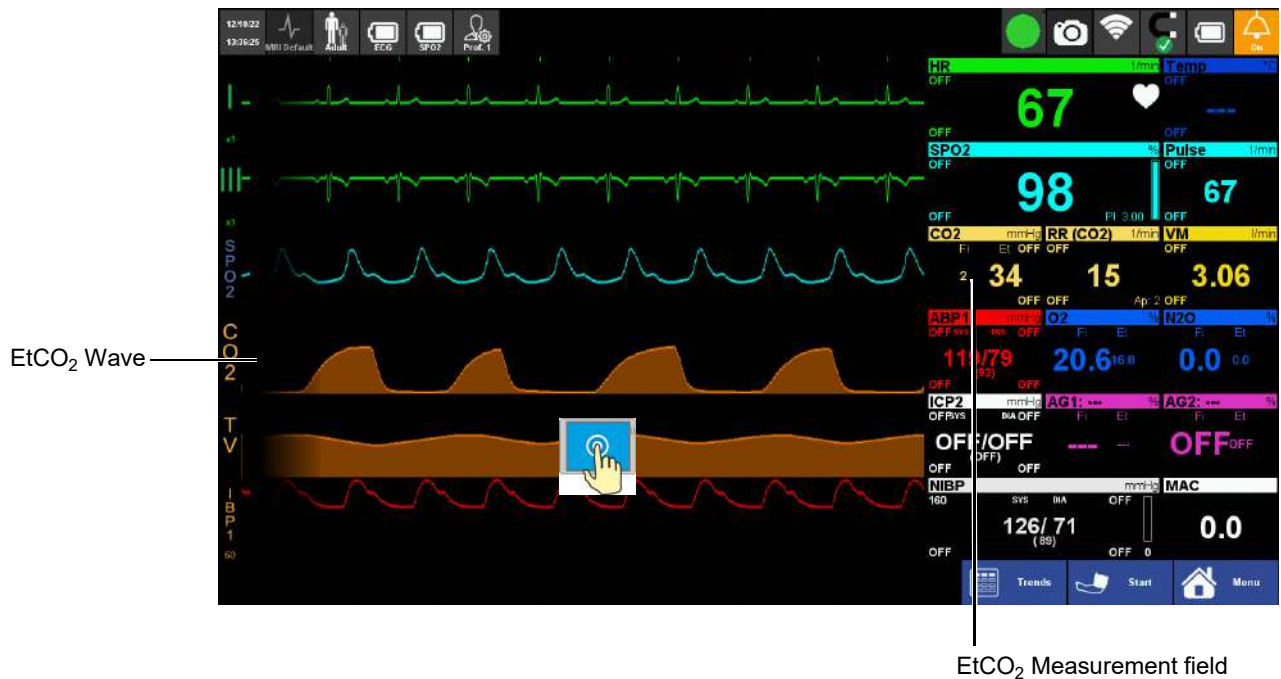
- The gas samples are collected by infrared spectroscopy on intubated or non-intubated patients.

The module measures the CO₂ concentration of the breathing gases using the sidestream method. The sample gas is aspirated via a measuring tube with a water trap at 100 ml/minute flow rate for neonates and 170 ml/minute for adults and children. In the water trap, the gas is separated from moisture. Then it flows through the measuring cuvette with an infrared spectroscopic sensor. The method of infrared spectroscopy is based on the fact that different gases absorb infrared radiation at wavelengths that are characteristic of the specific gas. The IR portion drops with increasing CO₂ partial pressure. The measuring values are corrected for ambient temperature and atmospheric pressure and are given in mmHg or kPa as the lung-related partial pressure, standard, Body Temperature Pressure Saturated (BTPS).

The module considers a breath valid when the CO₂ concentration rises and drops at least 1% within 0.4 second maximum. The respiration rate is the number of breaths per minute.

6.2.1 Start CO₂ measuring

1. Connect the sample line to the device. Refer to section [6.1.5 Installing the water trap and connecting the sampling line](#).
2. Perform a pre-use check (refer to section [6.1.7 Pre-use check](#)) to verify that the gas analyser and sample system are working properly.
3. Select the appropriate settings in the CO₂ Menu.



6.2.2 CO₂ Setting menu

Access the CO₂ menu via the CO₂ measurement field.

The default settings are printed in **bold**.

Menu item	Parameter	Description	Value
CO ₂ Menu	Reset the gas module	-	Activate a reset
	Amplitude auto	Auto curve amplitude setting	ON/OFF
	Amplitude	Manual setting of the curve amplitude	1, 2, 3
	Gas CO ₂ curve speed	The setting of the curve speed	25 mm/s or 50 mm/s
	Thresholds	Manual setting of FiCO ₂ minimum/ maximum and EtCO ₂ minimum/ maximum thresholds	---
	Parameter activation	Switching CO ₂ parameter display off when not used	ON/OFF

6.2.3 CO₂ Alarm messages

Alarm	Code	Cause	Remedy
RR: Respiration Rate out of range	P_GAZ_RR_02	• Respiration Rate (AION) out of range	→ Check the patient
RR: Apnea out of range	P_GAZ_RR_03	• Apnea	→ Check the patient
FiCO ₂ : Out of range	P_GAZ_CO2_01	• FiCO ₂ is out of range	→ Check the patient
EtCO ₂ : Out of range	P_GAZ_CO2_02	• EtCO ₂ is out of range	→ Check the patient

6.2.4 Information messages and instructions - CO₂

Alarm	Code	Cause	Remedy
Gas: Change the water trap	I_GAZ_01	• Water trap needs to be changed	→ Change the water trap
Gas: Change galvanic O ₂ sensor	I_GAZ_02	• The Gas module is defective	→ Contact technical service
Gas: A leakage test is recommended	I_GAZ_10	• Leakage test recommended	→ Execute a leakage test
Gas: Meas. accuracy verification is recommended	I_GAZ_11	• Measurement accuracy verifying recommended	→ Execute measurement accuracy verifying
Gas: Ref. A valve test is recommended	I_GAZ_12	• Ref. valve test recommended	→ Execute ref. valve test

6.2.5 Technical alarm messages - CO₂

Alarm	Code	Cause	Remedy
Gas: No water trap detected	T_GAZ_160	• The water trap is not connected	→ Connect the water trap
Gas: Occlusion	T_GAZ_161	• The sample line is clogged	→ Remove occlusion or replace sample line and/or water trap
Gas: Permanent occlusion	T_GAZ_162	• The sample line is clogged	→ Remove occlusion or replace sample line and/or water trap → Restart Device
Gas: Calibration lost/missing	T_GAZ_163	• Gas calibration lost/missing	→ Contact technical service
Gas: RR is out of range	T_GAZ_RR_01	• RR is out of limits (AION) • The Gas module is defective	→ Contact technical service →
Gas: APNEA is out of range	T_GAZ_RR_03	• Apnea is out of limits • The Gas module is defective	→ Contact technical service
Gas: CO ₂ is out of range	T_GAZ_CO2_01	• CO ₂ is out of limits • The Gas module is defective	→ Check the patient → Contact technical service
Gas: CO ₂ data limit error	T_GAZ_13	• AION gas CO ₂ data limit error	→ Check that the right gases are used → Contact technical service
Gas: CO ₂ unspecified accuracy	T_GAZ_27	• AION gas CO ₂ unspecified accuracy	→ Check that the right gases are used → Contact technical service
Gas: CO ₂ calibration error	T_GAZ_40	• AION gas CO ₂ calibration error	→ Contact technical service
Gas: CO ₂ span calibration error	T_GAZ_53	• AION gas CO ₂ cspan calibration error	→ Contact technical service
Gas: CO ₂ reference measurement. error	T_GAZ_66	• AION gas CO ₂ reference measurement error	→ Contact technical service

6.2.6 Technical alarm messages AION GAS module

Alarm	Code	Cause	Remedy
Gas: O ₂ no sensor	T_GAZ_01	• AION gas module defective	→ Contact technical service
Gas: HW Error BM	T_GAZ_02		
Gas: HW Error GMB	T_GAZ_03		
Gas: HW Error PM	T_GAZ_04		
Gas: Software error	T_GAZ_05		
Gas: Internal voltage error	T_GAZ_06	• AION gas module error	→ Contact technical service
Gas: Pump error	T_GAZ_07		
Gas: Temp/Press error	T_GAZ_08		
Gas: IR Signal error	T_GAZ_09		
Gas: Motor speed error	T_GAZ_10		
Gas: O ₂ Error	T_GAZ_11		
Gas: Self-test error	T_GAZ_12		

Alarm	Code	Cause	Remedy
Gas: CO ₂ data limit error	T_GAZ_13	• Gas data limit error	→ Check that the right gases are used
Gas: N ₂ O data limit error	T_GAZ_14		→ Contact technical service
Gas: O ₂ data limit error	T_GAZ_15	• Agent data limit error	→ Check that the right agents are used → Contact technical service
Gas: Hal data limit error	T_GAZ_16		
Gas: Enf data limit error	T_GAZ_17		
Gas: Iso data limit error	T_GAZ_18		
Gas: Sev data limit error	T_GAZ_19		
Gas: Des data limit error	T_GAZ_20		
Gas: Pressure data limit error	T_GAZ_21	• Data limit error	→ Check that the right gases/agents are used → Contact technical service
Gas: Flow data limit error	T_GAZ_22		
Gas: TempBM data limit error	T_GAZ_23	• Reference measurement error • Unspecified accuracy	→ Contact technical service → Check that the right concentration levels are used
Gas: TempGMB data limit error	T_GAZ_24		
Gas: Breathing rate, data limit error	T_GAZ_25		
Gas: O ₂ reference measurement error	T_GAZ_26		
Gas: CO ₂ unspecified accuracy	T_GAZ_27		
Gas: N ₂ O unspecified accuracy	T_GAZ_28		
Gas: O ₂ unspecified accuracy	T_GAZ_29		
Gas: Hal unspecified accuracy	T_GAZ_30		
Gas: Enf unspecified accuracy	T_GAZ_31		
Gas: Iso unspecified accuracy	T_GAZ_32		
Gas: Sev unspecified accuracy	T_GAZ_33		
Gas: Des unspecified accuracy	T_GAZ_34		
Gas: Pressure unspecified accuracy	T_GAZ_35		
Gas: Flow unspecified accuracy	T_GAZ_36		
Gas: TempBM unspecified accuracy	T_GAZ_37		
Gas: TempGMB unspecified accuracy	T_GAZ_38		
Gas: Breath rate unspecified accuracy	T_GAZ_39		

Alarm	Code	Cause	Remedy
Gas: CO ₂ calibration error	T_GAZ_40	• Calibration error	→ Contact technical service
Gas: N ₂ O calibration error	T_GAZ_41		
Gas: O ₂ calibration error	T_GAZ_42		
Gas: Hal calibration error	T_GAZ_43		
Gas: Enf calibration error	T_GAZ_44		
Gas: Iso calibration error	T_GAZ_45		
Gas: Sev calibration error	T_GAZ_46		
Gas: Des calibration error	T_GAZ_47		
Gas: Pressure calibration error	T_GAZ_48		
Gas: Flow calibration error	T_GAZ_49		
Gas: TempBM calibration error	T_GAZ_50		
Gas: TempGMB calibration error	T_GAZ_51		
Gas: Breathing rate, calibration error	T_GAZ_52		
Gas: CO ₂ span calibration error	T_GAZ_53	• Span calibration error	→ Contact technical service
Gas: N ₂ O span calibration error	T_GAZ_54		
Gas: O ₂ span calibration error	T_GAZ_55		
Gas: Hal span calibration error	T_GAZ_56		
Gas: Enf span calibration error	T_GAZ_57		
Gas: Iso span calibration error	T_GAZ_58		
Gas: Sev span calibration error	T_GAZ_59		
Gas: Des span calibration error	T_GAZ_60		
Gas: Pressure span calibration error	T_GAZ_61		
Gas: Flow span calibration error	T_GAZ_62		
Gas: TempBM span calibration error	T_GAZ_63		
Gas: TempGMB span calibration error	T_GAZ_64		
Gas: Breathing rate, span calibration error	T_GAZ_65		

Alarm	Code	Cause	Remedy
Gas: CO ₂ reference measurement error	T_GAZ_66	Reference measurement error	→ Contact technical service
Gas: N ₂ O reference measurement error	T_GAZ_67		
Gas: O ₂ reference measurement error	T_GAZ_68		
Gas: Hal reference measurement error	T_GAZ_69		
Gas: Enf reference measurement error	T_GAZ_70		
Gas: Iso reference measurement error	T_GAZ_71		
Gas: Sev reference measurement error	T_GAZ_72		
Gas: Des reference measurement error	T_GAZ_73		
Gas: Pressure reference measurement error	T_GAZ_74		
Gas: Flow reference measurement error	T_GAZ_75		
Gas: TempBM reference measurement error	T_GAZ_76		
Gas: TempGMB reference measurement error	T_GAZ_77		
Gas: Breath rate reference measurement error	T_GAZ_78		
Gas: Prot. bad acknowledge	T_GAZ_79	Gas wrong alarm message acknowledgement	→ Contact technical service

Alarm	Code	Cause	Remedy
Gas: HW Error: CPU	T_GAZ_80	AION gas module defective → Contact technical service	→ Contact technical service
Gas: HW Error: RAM	T_GAZ_81		
Gas: HW Error: CPU flash PROM	T_GAZ_82		
Gas: HW Error: BM EEPROM checksum	T_GAZ_83		
Gas: HW Error: GMB EEPROM checksum	T_GAZ_84		
Gas: HW Error: PM EEPROM checksum	T_GAZ_85		
Gas: HW Error: Incompatible HW/SW GMB mod.	T_GAZ_86		
Gas: HW Error: Incompatible type	T_GAZ_87		
Gas: HW Error: Internal voltage fail	T_GAZ_88		
Gas: HW Error: Ref. voltage fail	T_GAZ_89		
Gas: Internal voltage error	T_GAZ_90		
Gas: HW Error: IR voltage is low	T_GAZ_91		
Gas: HW Error: IR voltage is high	T_GAZ_92		
Gas: HW Error: BM EEPROM write	T_GAZ_93		
Gas: HW Error: GMB EEPROM write	T_GAZ_94		
Gas: HW Error: PM EEPROM write	T_GAZ_95		
Gas: HW Error: System overheated	T_GAZ_96	Gas module overheated → Contact technical service	→ Contact technical service

Alarm	Code	Cause	Remedy
Gas: HW Error: IR signal lost	T_GAZ_97	AION gas module defective	→ Contact technical service
Gas: HW Error: IR signal is degraded	T_GAZ_98		
Gas: HW Error: IR signal is high	T_GAZ_99		
Gas: HW Error: IR drive power error	T_GAZ_100		
Gas: HW Error: Baseline low warning	T_GAZ_101		
Gas: HW Error: Baseline high warning	T_GAZ_102		
Gas: HW Error: Baseline high or low error	T_GAZ_103		
Gas: HW Error: Flow sensor	T_GAZ_104		
Gas: HW Error: Temperature sensor	T_GAZ_105		
Gas: HW Error: Pressure sensor	T_GAZ_106		
Gas: HW Error: BM temp. sensor	T_GAZ_107		
Gas: HW Error: GMB temp. sensor	T_GAZ_108		
Gas: HW Error: Motor speed	T_GAZ_109		
Gas: HW Error: Paramagnetic O ₂ sensor	T_GAZ_110		
Gas: HW Error: Galvanic O ₂ sensor	T_GAZ_111		
Gas: HW: Galvanic O ₂ sensor cap. low	T_GAZ_112		
Gas: Galvanic O ₂ sensor output below error level	T_GAZ_113		
Gas: HW Error: Data send	T_GAZ_114	- Gas Ref. Measure fail: - Occlusion - AION gas module defective	→ Remove occlusion cause → Contact technical service
Gas: HW Error: Gas data	T_GAZ_115		
Gas: Gas task timeout	T_GAZ_116		
Gas: Ref. Measure fails	T_GAZ_117		
Gas: Ref. Measure: ATM pressure, no zero flow	T_GAZ_118		
Gas: Ref. Measure: occlusion/bad flow	T_GAZ_119	- Gas Ref. Measure: - Occlusion/bad flow	→ Remove occlusion cause

Alarm	Code	Cause	Remedy
Gas: Ref. Measure: bad O ₂	T_GAZ_120	• AION gas module defective	→ Contact technical service
Gas: Ref. Measure: no cuvette flow	T_GAZ_121		
Gas: Ref. Measurement fail	T_GAZ_122		
Gas: HW Error: Self-test 1 (bad pump flow)	T_GAZ_123		
Gas: HW Error: Self-test 2 (pressure error in GMB)	T_GAZ_124		
Gas: HW Error: Self-test 5	T_GAZ_125		
Gas: HW Error: Self-test 6	T_GAZ_126		
Gas: SW Error: watchdog alarm	T_GAZ_127		
Gas: SW Error: stack low/overflow	T_GAZ_128		
Gas: SW Error: unexpected interrupt	T_GAZ_129	• Gases data limit error	→ Check that the right gases are used
Gas: CO ₂ data limit error	T_GAZ_130		
Gas: N ₂ O data limit error	T_GAZ_131		
Gas: O ₂ data limit error	T_GAZ_132	• Agent data limit error	→ Check that the right agents are used
Gas: Hal data limit error	T_GAZ_133		
Gas: Enf data limit error	T_GAZ_134		
Gas: Iso data limit error	T_GAZ_135		
Gas: Sev data limit error	T_GAZ_136		
Gas: Des data limit error	T_GAZ_137	• Gas/agent data limit error	→ Check that the right agents are used
Gas: Pressure data limit error	T_GAZ_138		
Gas: Flow data limit error	T_GAZ_139		
Gas: TempBM data limit error	T_GAZ_140		
Gas: TempGMB data limit error	T_GAZ_141		
Gas: Breathing rate, data limit error	T_GAZ_142		
Gas: TempPM data limit error	T_GAZ_143		

Alarm	Code	Cause	Remedy
Gas: CO ₂ unspecified accuracy	T_GAZ_144	Unspecific gas/agent accuracy	→ Check that the right concentration levels are used
Gas: N ₂ O unspecified accuracy	T_GAZ_145		
Gas: O ₂ unspecified accuracy	T_GAZ_146		
Gas: HAL unspecified accuracy	T_GAZ_147		
Gas: ENF unspecified accuracy	T_GAZ_148		
Gas: ISO unspecified accuracy	T_GAZ_149		
Gas: SEV unspecified accuracy	T_GAZ_150		
Gas: DES unspecified accuracy	T_GAZ_151		
Gas: Pressure unspecified accuracy	T_GAZ_152		
Gas: Flow unspecified accuracy	T_GAZ_153		
Gas: TempBM unspecified accuracy	T_GAZ_154		
Gas: TempGMB unspecified accuracy	T_GAZ_155		
Gas: Breath rate unspecified accuracy	T_GAZ_156		
Gas: TempPM unspecified accuracy	T_GAZ_157	Software error	→ Contact technical service
Gas: Command not accepted	T_GAZ_158		
Gas: Unimplemented command	T_GAZ_159		

6.3 Anaesthetic Agents and Gas



Intended Purpose

- The **MAGLIFE RT-1** is intended to make continuous surveillance of Anaesthetic agents: Desflurane (DES), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV) and Halothane (HAL).

Intended Users

- The device is intended for clinical professionals. Clinical professionals must have a working knowledge of medical procedures, practices, and terminology for completing these examinations.

Medical indications

- **MAGLIFE RT-1** anaesthetic agents monitoring system can be used to monitor anaesthetized patients during pre/per/post MRI examinations.

Contraindications for use

See [1.3 Expected Therapeutic Clinical Patient Benefits](#).

Side effects

See [1.5 Known Side Effects](#).

Target population

- The device can be used on any type of person either adults, pediatric or neonates with the appropriate water trap.

Affected Body Regions

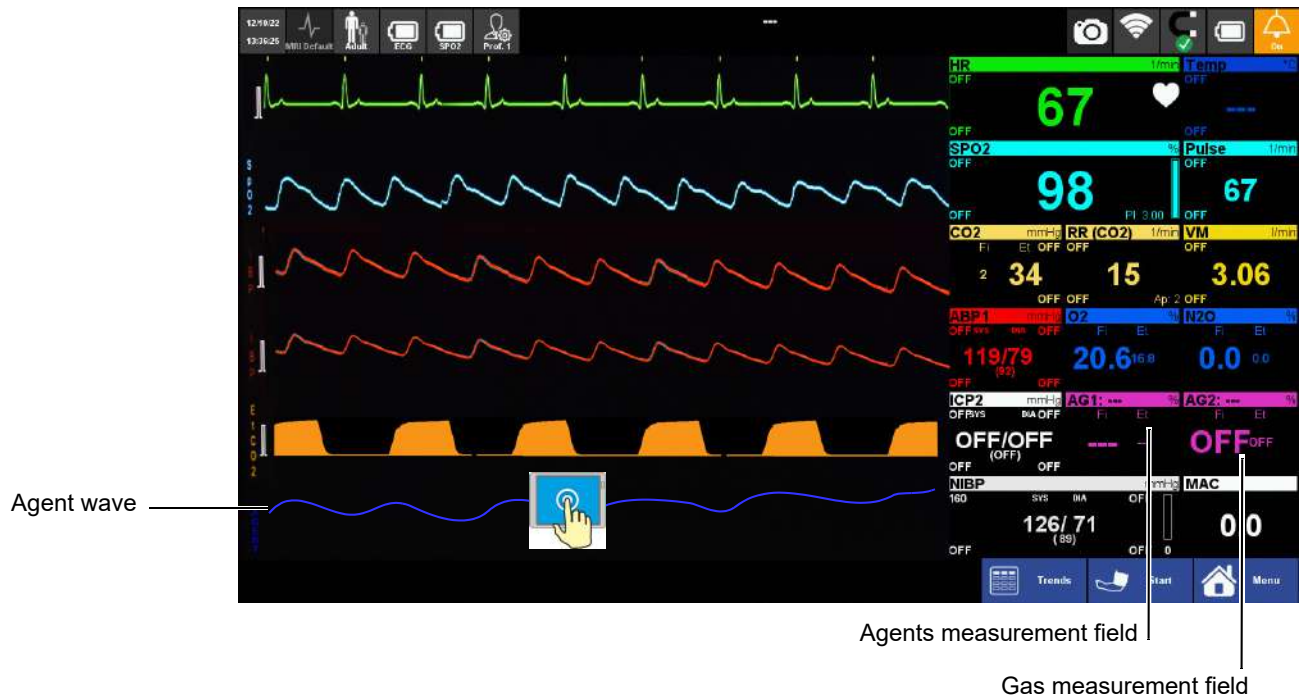
- The gas samples are collected by infrared spectroscopy on intubated or non-intubated patients.



- The system automatically performs several settings: when started, for instance, the module initiates a warm-up phase indicated by the message, Wait while starting. This phase will last for a few minutes. No measurements take place during the warm-up phase.
- Zeroing and calibrations are also automatic. The user is informed by the corresponding messages.
- Anaesthetic agents are automatically identified. Two gases can be measured simultaneously.

6.3.1 Start agents and gas measuring

1. Connect the sample line to the device. Refer to section [6.1.5 Installing the water trap and connecting the sampling line](#).
2. Perform a pre-use check (refer to section [6.1.7 Pre-use check](#)) to verify that the gas analyser and sample system are working properly.
3. Select the appropriate settings in the Agents menu.



6.3.2 Gas agents setting menu

Access the Gas menu via the Agents measurement field.

The default settings are highlighted in **bold**.

Menu item	Parameter	Description	Value
CO ₂ Menu	Reset the gas module	-	Activate reset
	Thresholds	Manual setting of FiO ₂ /EtO ₂ min/max. and FiNO ₂ /EtNO ₂ min/max. thresholds	---
	Parameter activation	Switching gas parameter display off when not used	ON/OFF

6.3.3 Gas others setting menu

Access the Gas menu via the Gas measurement field.

The default settings are printed in **bold**.

Menu item	Parameter	Description	Value
CO ₂ Menu	Reset the gas module	-	Activate reset
	Thresholds	Manual setting of FiO ₂ /EtO ₂ min/max and FiNO ₂ /EtNO ₂ thresholds	---
	Parameter activation	Switching the gas parameter display off when not used	ON/OFF

6.3.4 Gas physiological alarm messages

Alarm	Code	Cause	Remedy
N ₂ O Fi: Low is out of range	P_GAZ_N2O_01	• N ₂ O Fi lower bound is out of range	→ Check the patient
N ₂ O Fi: High is out of range	P_GAZ_N2O_02	• N ₂ O Fi upper bound is out of range	→ Check the patient
N ₂ O Et: Low is out of range	P_GAZ_N2O_03	• N ₂ O Et lower bound is out of range	→ Check the patient
N ₂ O Et: High is out of range	P_GAZ_N2O_04	• N ₂ O Et upper bound is out of range	→ Check the patient
O ₂ Fi: Out is of range	P_GAZ_O2_01	• O ₂ Fi is out of range	→ Check the patient
O ₂ Et: Out is of range	P_GAZ_O2_02	• O ₂ Et is out of range	→ Check the patient
O ₂ Fi: < 18%	P_GAZ_O2_03	• O ₂ Fi < 18%	→ Check the patient
Agent 1 Fi: Low is out of range	P_GAZ_AX1_01	• Agent 1 Fi lower bound is out of range	→ Check the patient
Agent 1 Fi: High is out of range	P_GAZ_AX1_02	• Agent 1 Fi upper bound is out of range	→ Check the patient
Agent 1 Et: Low is out of range	P_GAZ_AX1_03	• Agent 1 Et lower bound is out of range	→ Check the patient
Agent 1 Et: High is out of range	P_GAZ_AX1_04	• Agent 1 Et upper bound is out of range	→ Check the patient
Agent 2 Fi: Low is out of range	P_GAZ_AX2_01	• Agent 2 Fi lower bound is out of range	→ Check the patient
Agent 2 Fi: High is out of range	P_GAZ_AX2_02	• Agent 2 Fi upper bound is out of range	→ Check the patient
Agent 2 Et: Low is out of range	P_GAZ_AX2_03	• Agent 2 Et lower bound is out of range	→ Check the patient
Agent 2 Et: High is out of range	P_GAZ_AX2_04	• Agent 2 Et upper bound is out of range	→ Check the patient
Agents: Multiple agents	P_GAZ_AX_01	• Presence of multiple agents (MAC < 3)	→ Check the patient
Agents: Multiple agents	P_GAZ_AX_02	• Presence of multiple agents (MAC ≥ 3)	→ Check the patient

6.3.5 Gas technical alarm messages

Alarm	Code	Cause	Remedy
Gas: A leakage test is required	T_GAZ_280	• A leakage test is required	→ Execute a leakage test
Gas: Measurement accuracy verification is required	T_GAZ_281	• Measurement accuracy verification required	→ Execute measurement accuracy verification
Gas: Ref. A valve test is required	T_GAZ_282	• Ref. A valve test is required	→ Execute ref. valve test

6.3.6 Gas technical alarm messages N₂O, O₂, AX, VOL

Alarm	Code	Cause	Remedy
Gas: N ₂ O is out of range	T_GAZ_N2O_01	- N₂O is out of limits - The Gas module is defective	→ Check the patient → Replace the Gas module
Gas: O ₂ is out of range	T_GAZ_O2_01	- O₂ is out of limits - The Gas module is defective	→ Check the patient → Replace the Gas module
Gas: Agent is out of range	T_GAZ_AX_01	- The agent is out of limits - The Gas module is defective	→ Check the patient → Replace the Gas module
Gas: Volume is out of range	T_GAZ_VOL_01	- Volume is out of limits - The Gas module is defective	→ Check the patient → Replace the Gas module

6.3.7 MAC



MAC is a basic index indicating the depth of inhaled anaesthetist. ISO 80601-2-55 defines MAC as follows: alveolar concentration of an inhaled anaesthetic agent that, in the absence of other anaesthetic agents and at equilibrium, prevents 50% of subjects from moving in response to a standard surgical stimulus.



▲ MAC could indicate erroneous values. It is important to continue to monitor clinical status during anaesthesia.

6.4 Ventilation



Intended Purpose

- The **MAGLIFE RT-1** is intended to make continuous measurements of volume, flow and pressure of the breathing air.
- SPIRIT differential pressure respiratory mechanics analyser is intended to be connected to a patient breathing circuit to continuously measure gas flow and pressure and calculate a full set of derived respiratory mechanics parameters.

Intended Users

- The device is intended for clinical professionals. Clinical professionals must have a working knowledge of medical procedures, practices, and terminology for completing these examinations.

Medical indications

- **MAGLIFE RT-1** spirometry system can be used to monitor anaesthetized patient ventilation pre/per/post MRI examinations.

Contraindications for use

See [1.3 Expected Therapeutic Clinical Patient Benefits](#).

Side effects

See [1.5 Known Side Effects](#).

Target population

- The device can be used on any type of person either adults, pediatric or neonates with the appropriate SPIRIT flow sensor and DRYLINE II water trap.

Affected Body Regions

- SPIRIT module can be connected to a patient breathing circuit.

6.4.1 SPIRIT differential pressure respiratory mechanics analyser



- SPIRIT differential pressure respiratory mechanics analyser is intended to be connected to a patient breathing circuit to continuously measure gas flow and pressure and calculate a full set of derived respiratory mechanics parameters.
- The SPIRIT flow sensor incorporates a flow restriction, over which the flow of the gas respired by the patient creates a pressure difference. The pressure difference is proportional to the rate of the gas flow.

WARNING

- ▲ The SPIRIT respiratory mechanics flow sensor is not intended to be used with high-frequency ventilators.
- ▲ The type of flow sensor used shall be determined by patient type. Factors to consider are dead space, tidal volume and flow rate; using an incorrect flow sensor type could lead to inadequate patient ventilation.

⚠ CAUTION

- ▲ Combine the SPIRIT flow sensor and water trap as described in the table below. Other combinations might lead to incorrect measurements.
- ▲ The pressure tube and gas sampling lines of the flow sensor should always be routed from the patient circuit to the host instrument in such a way as to avoid kinking.
- ▲ Flow sensors that have suffered damage to the sensor head, tubing or tubing connector must not be used
- ▲ Liquid removed from the flow sensor and used flow sensors should be disposed of per local regulations for contaminated and biologically hazardous items.
- ▲ The flow sensor is intended for single-patient use only and must not be re-used to avoid cross-infection between patients.
- ▲ Do not use accessories other than the ones recommended in this manual. Note that other compatible tubing may be available in the clinic, for example, IV- lines.
- ▲ The use of closed suction systems can damage the analyser. Check that the vacuum used is within the pressure limits of the analyser. Refer to the SPIRIT Respiratory Mechanics Product Specification.

Patient category	SPIRIT Flow sensor	Water trap
Adult	Adult and Paediatric	Adult
Paediatric	Adult and Paediatric	Adult
Neonate	Paediatric	Neonate (blue)

6.4.2 Overview of flow sensors

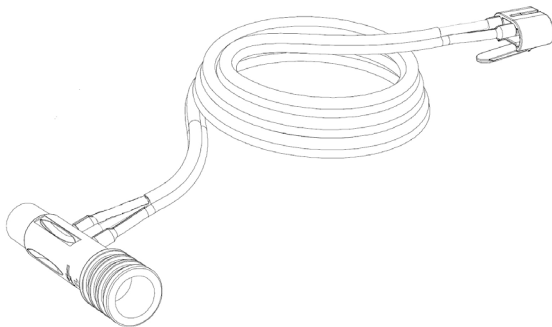


- ▲ The SPIRIT flow sensor is designed for single use only; do not reuse them.
- ▲ The SPIRIT flow sensors are divided into two application categories:
 - SPIRIT flow sensor with a gas sampling line
 - SPIRIT flow sensor without a gas sampling line.

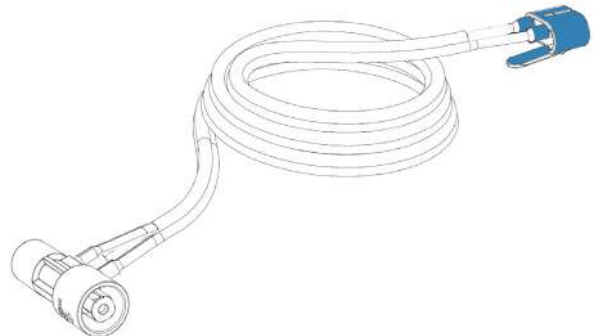


- ▲ The water trap, sampling line and airway adapter must be handled and disposed of as biohazardous waste.

Spirometry Flow sensor Adult
and Paediatric



Spirometry Flow sensor neonatal
(blue connector)



Flow Sensor Adult with sampling line for
CO₂/O₂/Agents measuring



Flow Sensor Neonatal with sampling line
for CO₂/O₂/Agents measuring



6.4.3 Connect and start measuring with the Spirometry flow sensor



Neonate considerations

→ Selecting a spirometry flow sensor appropriate for the patient type, adult/ paediatric or neonate, is important.

1. Connect the sensor (1) to the Maglife RT-1
2. Place the sensor in the patient's breathing circuit between the tracheal tube and the Y-piece of the mechanical ventilation.
3. Perform a pre-use check (refer to section [6.1.7 Pre-use check](#)) to verify that the gas analyser and sample system are working properly.
4. Place the sensor so the sampling line points upwards to prevent occlusion by condensed water or patient secretions.

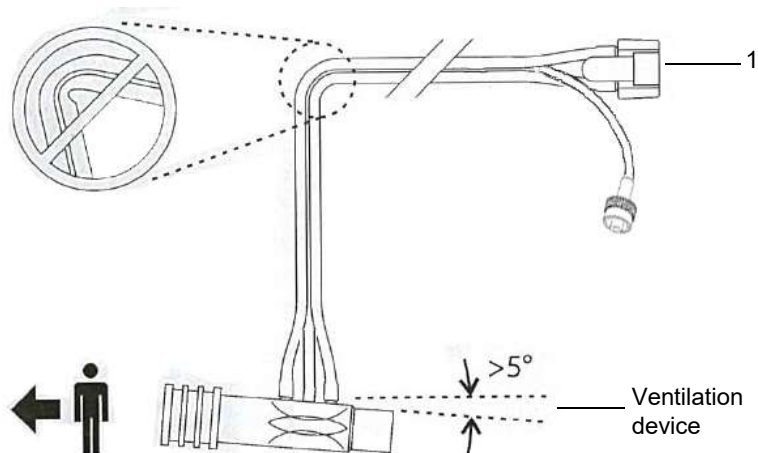


Fig. 6.3 Spirometry flow sensor Adult/ Paediatric and Neonatal (blue)

6.4.4 Connect and start measuring with the Spirometry flow sensor and gas sampling line



Neonate considerations

→ Selecting a spirometry flow sensor appropriate for the patient type, adult/ paediatric or neonate, is important.



1. Connect the sensor (1) to the Maglife RT-1
2. Place the sensor in the patient's breathing circuit between the tracheal tube and the Y-piece of the mechanical ventilation.
3. Perform a pre-use check (refer to section 6.1.7 Pre-use check) to verify that the gas analyser and sample system are working properly.
4. Place the sensor so the sampling line points upwards to prevent occlusion by condensed water or patient secretions.

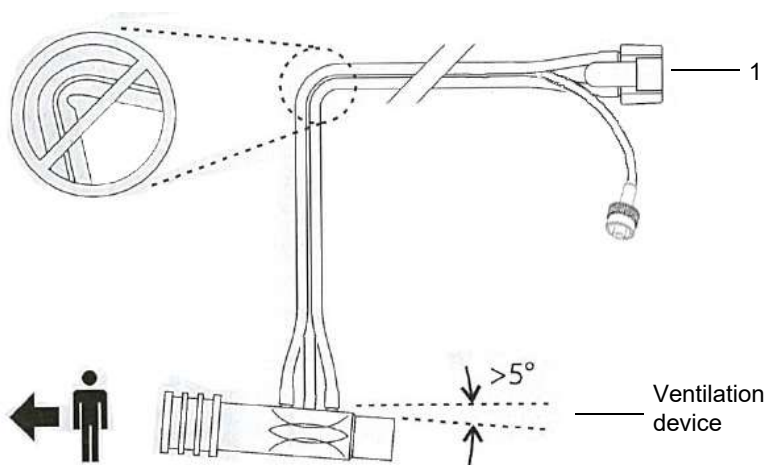


Fig. 6.4 Spirometry flow sensor Adult/ Paediatric and Neonatal (blue)

6.4.5 Ventilation physiological alarm messages

Alarm	Code	Cause	Remedy
RR: Respiration Rate is out of range	P_GAZ_RR_01	• Respiration Rate (SPIRIT) is out of range	→ Check the patient
Volume Tidal Fi: Is out of range	P_GAZ_VT_01	• Volume Tidal Fi is out of range	→ Check the patient
Volume Tidal Et: Is out of range	P_GAZ_VT_02	• Volume Tidal Et is out of range	→ Check the patient
Volume Fi: Is out of range	P_GAZ_V_01	• Volume Fi is out of range	→ Check the patient
Volume Et: Is out of range	P_GAZ_V_02	• Volume Et is out of range	→ Check the patient

6.4.6 Technical alarm messages SPIRIT gas module

Alarm	Code	Cause	Remedy
SPIRIT: HW error	T_GAZ_164	• The SPIRIT gas module is defective	→ Contact technical service
SPIRIT: Temp/press. error	T_GAZ_165		
SPIRIT: Self-test error	T_GAZ_166		
SPIRIT: Software error	T_GAZ_167	• Data limit error	→ Replace the gas SPIRIT module
SPIRIT: Gauge press. data limit error	T_GAZ_168		
SPIRIT: Diff press. data limit error	T_GAZ_169		
SPIRIT: Flow data limit error	T_GAZ_170		
SPIRIT: Temp data limit error	T_GAZ_171		
SPIRIT: Tidal volume data limit error	T_GAZ_172		
SPIRIT: Minute volume data limit error	T_GAZ_173		
SPIRIT: Total volume per sec data limit error	T_GAZ_174		
SPIRIT: Press data limit error	T_GAZ_175		
SPIRIT: Compliance data limit error	T_GAZ_176		
SPIRIT: Resistance data limit error	T_GAZ_177		
SPIRIT: IE ratio data limit error	T_GAZ_178		
SPIRIT: Resp rate data limit error	T_GAZ_179		

Alarm	Code	Cause	Remedy
SPIRIT: Gauge press. reference meas. error	T_GAZ_180	Reference measurement error	→ Replace the gas SPIRIT module
SPIRIT: Diff press. reference meas. error	T_GAZ_181		
SPIRIT: Flow reference meas. error	T_GAZ_182		
SPIRIT: Temp reference meas. error	T_GAZ_183		
SPIRIT: Tidal volume reference meas. error	T_GAZ_184		
SPIRIT: Minute volume reference meas. error	T_GAZ_185		
SPIRIT: Total volume per sec reference meas. error	T_GAZ_186		
SPIRIT: Press reference meas. error	T_GAZ_187		
SPIRIT: Compliance reference meas. error	T_GAZ_188		
SPIRIT: Resistance reference meas. error	T_GAZ_189		
SPIRIT: IE ratio reference meas. error	T_GAZ_190	Unspecific accuracy	→ Check that the right concentration levels are used
SPIRIT: Resp rate reference meas. error	T_GAZ_191		
SPIRIT: Gauge press. unspecified accuracy	T_GAZ_192		
SPIRIT: Diff press. unspecified accuracy	T_GAZ_193		
SPIRIT: Flow unspecified accuracy	T_GAZ_194		
SPIRIT: Temperature unspecified accuracy	T_GAZ_195		
SPIRIT: Tidal volume unspecified accuracy	T_GAZ_196		
SPIRIT: Minute volume unspecified accuracy	T_GAZ_197		
SPIRIT: Total volume per sec unspecified accuracy	T_GAZ_198		
SPIRIT: Press unspecified accuracy	T_GAZ_199		
SPIRIT: Compliance unspecified accuracy	T_GAZ_200		
SPIRIT: Resistance unspecified accuracy	T_GAZ_201		
SPIRIT: IE ratio unspecified accuracy	T_GAZ_202		
SPIRIT: Resp rate unspecified accuracy	T_GAZ_203		

Alarm	Code	Cause	Remedy
SPIRIT: Gauge pressure calibration error	T_GAZ_204	• Calibration error	→ Contact technical service
SPIRIT: Diff pressure calibration error	T_GAZ_205		
SPIRIT: Flow calibration error	T_GAZ_206		
SPIRIT: Temperature calibration error	T_GAZ_207		
SPIRIT: Tidal volume calibration error	T_GAZ_208		
SPIRIT: Minute volume calibration error	T_GAZ_209		
SPIRIT: Total volume per sec calibration error	T_GAZ_210		
SPIRIT: Press calibration error	T_GAZ_211		
SPIRIT: Compliance calibration error	T_GAZ_212		
SPIRIT: Resistance calibration error	T_GAZ_213		
SPIRIT: IE ratio calibration error	T_GAZ_214		
SPIRIT: Resp rate calibration error	T_GAZ_215		
SPIRIT: Internal CPU error	T_GAZ_216	• The SPIRIT gas module is defective	→ Contact technical service
SPIRIT: RAM error	T_GAZ_217		
SPIRIT: Flash error	T_GAZ_218		
SPIRIT: SW error	T_GAZ_219		
SPIRIT: Input or internal volt. not within specification.	T_GAZ_220		
SPIRIT: Differential pressure sensor error	T_GAZ_221		
SPIRIT: Gauge pressure sensor error	T_GAZ_222		
SPIRIT: Temperature sensor error	T_GAZ_223		
SPIRIT: Data transmission error	T_GAZ_224		
SPIRIT: Receive data error	T_GAZ_225		
SPIRIT: Zero measurement failed	T_GAZ_226		
SPIRIT: Self-test error 1	T_GAZ_227		
SPIRIT: Self-test error 2	T_GAZ_228		
SPIRIT: Software error: watchdog	T_GAZ_229		
SPIRIT: Software error: stack	T_GAZ_230		

Alarm	Code	Cause	Remedy
SPIRIT: AION gas analyser disconnected	T_GAZ_231	• The SPIRIT gas module is defective	→ Contact technical service
SPIRIT: Gauge press. data limit error	T_GAZ_232	• Data limit error	→ Check that the right concentration levels are used
SPIRIT: Diff press. data limit error	T_GAZ_233		→ Contact technical service
SPIRIT: Flow data limit error	T_GAZ_234		
SPIRIT: Temperature data limit error	T_GAZ_235		
SPIRIT: Tidal volume data limit error	T_GAZ_236		
SPIRIT: Minute volume data limit error	T_GAZ_237		
SPIRIT: Total volume per sec data limit error	T_GAZ_238		
SPIRIT: Press data limit error	T_GAZ_239		
SPIRIT: Compliance data limit error	T_GAZ_240		
SPIRIT: Resistance data limit error	T_GAZ_241		
SPIRIT: IE ratio data limit error	T_GAZ_242		
SPIRIT: Resp rate data limit error	T_GAZ_243		

Alarm	Code	Cause	Remedy
SPIRIT: Gauge press. unspecified accuracy	T_GAZ_244	Unspecified accuracy	→ Check that the right concentration levels are used
SPIRIT: Diff press. unspecified accuracy	T_GAZ_245		
SPIRIT: Flow unspecified accuracy	T_GAZ_246		
SPIRIT: Temp unspecified accuracy	T_GAZ_247		
SPIRIT: Tidal volume unspecified accuracy	T_GAZ_248		
SPIRIT: Minute volume unspecified accuracy	T_GAZ_249		
SPIRIT: Total volume per sec unspecified accuracy	T_GAZ_250		
SPIRIT: Press unspecified accuracy	T_GAZ_251		
SPIRIT: Compliance unspecified accuracy	T_GAZ_252		
SPIRIT: Resistance unspecified accuracy	T_GAZ_253		
SPIRIT: IE ratio unspecified accuracy	T_GAZ_254	No sensor connected	→ Connect the sensor
SPIRIT: Resp rate unspecified accuracy	T_GAZ_255		
SPIRIT: No flow sensor connected	T_GAZ_256		
SPIRIT: Calibration lost/missing	T_GAZ_257	Calibration lost/missing	→ Contact technical service

6.5 Printer

The printer setup is displayed on the **MAGSCREEN RT-1**, a button is used to start and stop the printer.

- You can print the trends or 10s of curves.

6.5.1 Printer Start/Stop

You initiate a recording with the **MAGSCREEN RT-1** button.

- "Print" button is also used to stop the printer.

6.5.2 Replacing printer paper

- The device is delivered without printing paper installed. The thermo-paper is sensitive to heat, humidity and chemical vapours. The following points, apply both to storage of paper and the archiving of results, must be observed:
 - before use, keep the paper in its original cardboard cover. Do not remove the cardboard cover until the paper is to be used,
 - store the paper in a cool, dark and dry area,
 - do not store the paper near chemicals e.g. sterilisation liquids,
 - In particular do not store the paper in a plastic cover,
- Certain glues can react with the paper, therefore, do not attach the printout onto a mounting sheet with glue.
- SCHILLER can only guarantee perfect printouts when SCHILLER original chart paper or chart paper of the same quality is used.

7 Data Management

7.1 Log files



The device records every action in log files. Each log file can contain up to 20,000 lines. A circular buffer overwrites the oldest log files entries when the limit of 20,000 lines are reached. Data is stored on the device in non-volatile memory and is not lost after power-off.

8 Main Menu

8.1 General Setup



To monitor vital parameters, physiological alarm thresholds are preset in the **MAGLIFE RT-1** and activated when the device is turned on. The operator-defined thresholds (wide/narrow) can be set in the respective menus (refer to section [4.6 Operator Defined Alarm Thresholds](#)).

1. Press the **Menu** button to display the Menu



Fig. 8.1 Main menu

8.1.1 Device settings menu

Access the device settings menu via the menu button.

Menu	Sub-menu/Parameter	Description	Note
Stop Monitoring	Yes/No	Yes stops the recording of all data, saves data under the monitoring file and resets the Stop-watch on the screen to zero. A new monitoring is started.	Monitoring that has stopped can be reviewed/transmitted in the Post-intervention menu. The number under the Stop Intervention parameter shows the Intervention ID with the date and time.
Trends	---	Shows the trend since the start of the intervention	Refer to section 4.4 View Trends
ECG	---	Shows the ECG	-
Gating source	- Gating source in - Gating source out	Selecting	* Gating option is not available yet.
Screenshots	Selecting screenshot	List of the screenshots completed since the start of the intervention. Screenshots can be displayed, transmitted or printed.	Future function
Language	List of available languages	Select the desired language for the current use.	The language setting here is only for current use. Once the device is switched off, the device will use the default language set in the configuration.

8.2 Control Panel

8.2.1 Pairing wireless sensors



1. Press either the **ECG** or **SpO₂** battery symbol to access the wireless sensor settings
2. Press **Wireless pairing**
3. The total list can be deleted by pressing **Clear**
4. Set Scan → ON
5. Press **List** (all configured sensors are indicated with their MAC address)
6. Select a Paired (P) or Connected (C) sensor. Each sensor can be connected, disconnected or removed.

If a problem occurs with pairing or if the sensor does not pair. Delete the sensors list in the device as described in step 3 above, then delete the list by pressing the sensor's power button for 20 seconds.

The following wireless sensor are available:

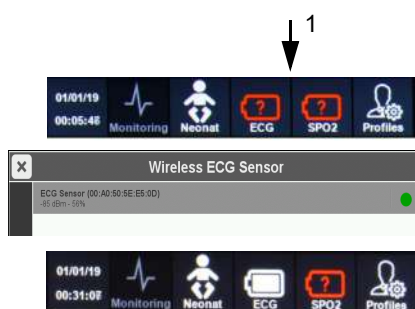
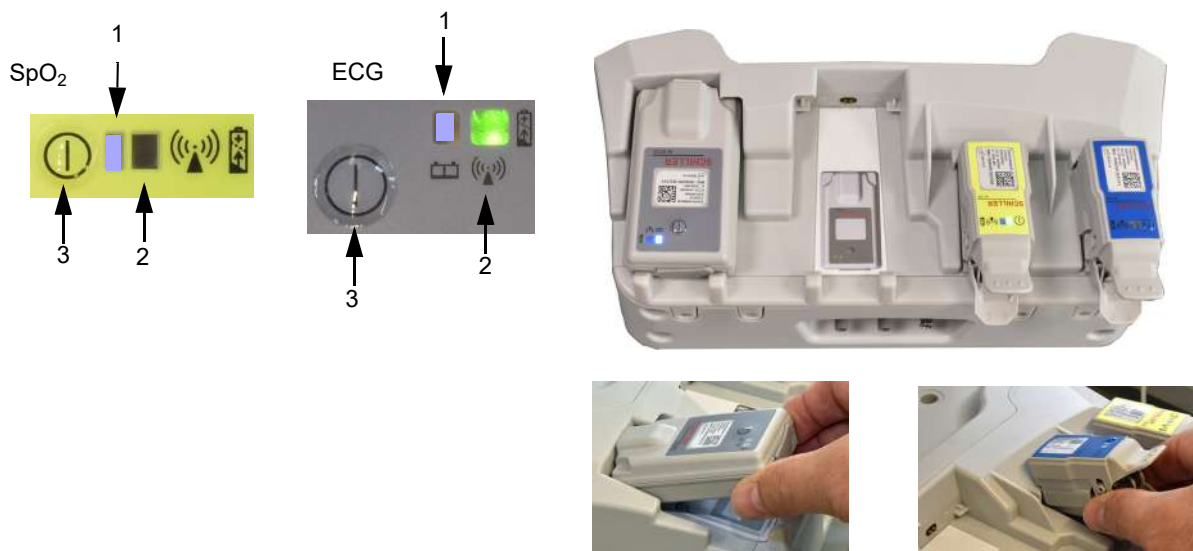


- (1) ECG
- (2) SpO₂ Adult
- (3) SpO₂ Children
- (4) SpO₂ Very small children

To place the sensor (4) into the battery charging bay, first, remove the sensor cable.

8.2.2 Sensor battery charging and pairing with the MAGLIFE RT-1

1. Check that the sensor is placed in the charging station of the **MAGLIFE RT-1**. Charging is indicated with the blue LED (1). When fully charged, LED (1) is off.
2. Press the **ON/OFF** button on the sensor. The green LED (2) starts to blink periodically every 4 seconds when connected and 2 seconds when disconnected. Sensors reconnect automatically.

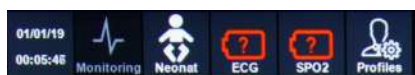


Checking sensor connections

3. Access the Maglife RT-1 and press the ECG or SpO₂ **Battery** button (1). The Wireless sensor menu opens. The connected sensor will be indicated.
4. Verify if the MAC address on Maglife RT-1 and the sensor are identical.
5. Always keep the sensor in the charging bay when not in use. Charging of the sensor continues even when the Maglife RT-1 is switched off, or the mains is unplugged.

For wireless pairing of sensors, refer to section [8.2.1 Pairing wireless sensors](#).

8.2.3 Status display sensor on the MAGLIFE RT-1



The following status for each sensor is displayed:



- (1) No sensor connected, sensor removed
- (2) Sensor connected, and the battery is empty
- (3) Sensor connected, and the battery is fully charged.

8.2.4 Disconnect or remove sensors

Disconnecting and selecting a new sensor from the sensor list

1. Access the **MAGLIFE RT-1** and press the **ECG** or **SpO₂** battery button. The **Wireless sensor** menu opens.
2. Select the **Disconnect** function.
3. Select **Wireless > List**. All scanned sensors are displayed.
4. Select the desired sensor to connect. The **BLE device management** menu opens.
5. Press the **Connect** function to pair a new sensor.

9 Maintenance

9.1 Maintenance Interval



- The device must be serviced regularly. The test results must be recorded and compared with the values in the accompanying documents.
- A qualified technician or the user must perform the maintenance work described in this chapter according to the maintenance and interval table below.
- The following table indicates the intervals and responsibilities of the maintenance work required. Local regulations in your country may stipulate additional or different inspection intervals and tests.

9.1.1 Maintenance interval table

Interval	Maintenance	Responsible
Before or after each use, respectively	Check the following: • Visual inspection of the device and accessories (refer to section 9.2.1 Visual inspection of the device and accessories) • Check the locking mechanism of the trolley wheels • Switch on the device and check that the battery is sufficiently charged (refer to section 9.2.2 Battery check) After every intervention • Visual inspection of the device and accessories (refer to section 9.2.1 Visual inspection of the device and accessories) • Battery check (refer to section 9.2.2 Battery check) • Self-test in the test setting menu (refer to section 9.2.3 Functional test and measured value)	→ User
Every 12 months	• Measuring, safety tests and inspections according to the instructions in the service handbook • NIBP Check • IBP Check • ECG Check • SpO₂ Check • EtCO₂ Gas span and leakage check • Agent gas span and leakage check • Ventilation	→ Service staff authorised by SCHILLER
Life item replacement	The following parts must be checked and replaced if necessary • Replace the power battery. Refer to section 9.3.1 Replacing the batteries. • Replace the internal button cell every 10 years • Replace the water trap holder every 2 years	→ Service staff authorised by SCHILLER

9.1.2 Service and shelf life

Device	The device has a lifetime of 10 years.
Accessories shelf life	• Power battery: approximately 5 years • Button cell: approximately 10 years.

9.2 Functional Test

A detailed description of the maintenance steps is listed in table 9.7. Enter the results in the checklist. Refer to section 9.7 [Inspection and Checklist Tables](#).

9.2.1 Visual inspection of the device and accessories

Check the device and accessories for the following:

- A sufficient number of all required disposables are available
- The device housing is undamaged
- Check the expiration date on the electrode package and the package is not damaged.
- Check the expiration date invasive blood pressure kit
- Check the locking mechanism of the trolley wheels
- ▲ Defective devices or damaged cables and damaged or expired accessories must be replaced immediately.

9.2.2 Battery check

The recharging of the battery is indicated by the LED left of the battery symbol.



- LED (2) is continuously on = battery problem
 - LED (2) is blinking = battery is charging
 - LED (2) is continuously off = battery is fully charged
- Connect the device to the power supply and switch it on. The start screen is displayed.
- The main voltage indicator (1) is lit.
- When the battery indicator (2) is flashing, the battery is being charged. Check the charging status once the indicator goes off.
 - The battery indicator (2) is off when the battery is fully charged the full battery symbol (3) is displayed. The charging process can be reactivated and checked by disconnecting shortly from the external DC supply; indicator (2) is flashing.

Battery status

- Press the **Battery** button (3) and check the following:
- Charge level
 - Estimated autonomy
 - Safety cell voltage level

9.2.3 Functional test and measured value

Heart rate	→ Perform the functional test according to section 5.2.5 Starting ECG monitoring and verify the heart rate with the measured pulse rate of the SpO ₂ .
SpO₂	→ This test is performed on a volunteer (finger measurement; section 5.3.4 SpO₂ Module).
NIBP	→ This test is performed on a volunteer (arm measurement; section 5.4.4 Starting NIBP monitoring) Manometer Test , refer to the technical manual
IBP	During the IBP functional test, only the zeroing of the transducer is tested (refer to section 5.5.4 IBP Zeroing) without connecting the sensor to the patient.
Temperature	→ Perform the functional test according to section 5.6 Temperature Monitoring , and verify that the sensor temperature shows the ambient temperature when not applied to the patient.
Basic ventilation	Perform a pre-use check (refer to section 6.1.7 Pre-use check) to verify that the gas analyser and sample system are working properly.
CO₂ Sidestream	Perform a pre-use check (refer to section 6.1.7 Pre-use check) to verify that the gas analyser and sample system are working properly.

9.2.4 Alarm tests

Alarm volume	Check during the following tests that the alarm sound is higher than 65 dB.
Heart rate	1. Start ECG monitoring (refer to section 5.2.5 Starting ECG monitoring) 2. Set the alarms with the narrow quick set function (refer to section 4.6 Operator Defined Alarm Thresholds) 3. When the measured value exceeds the alarm thresholds, an alarm is issued. 4. Reset the alarm limits to their original values.
SpO₂	Refer to section 5.3 SpO₂ Monitoring .
NIBP	1. Start NIBP monitoring (refer to section 5.4.4 Starting NIBP monitoring) 2. Set the NIBP alarm limits below/above the measured values and take a new measurement. 3. When the measured value exceeds the alarm thresholds, an alarm is issued. 4. Reset the alarm limits to their original values.
CO₂	1. Start CO₂ monitoring according to section 6.2.1 Start CO₂ measuring 2. Set the alarms with the narrow quick set function (refer to section 4.6 Operator Defined Alarm Thresholds). 3. When the measured value exceeds the alarm thresholds, an alarm is issued. 4. Reset the alarm limits to their original values.
IBP	1. Start IBP monitoring according to section 5.5.2 Start IBP measurement 2. Set the alarms with the narrow quick set function (refer to section 4.6 Operator Defined Alarm Thresholds). 3. When the measured value exceeds the alarm thresholds, an alarm is issued. 4. Reset the alarm limits to their original values.

Temperature

1. Start Temp monitoring according to section [5.6.1 Start temperature monitoring](#)
2. Set the alarms with the narrow quick set function (refer to section [4.6 Operator Defined Alarm Thresholds](#)).
3. When the measured value exceeds the alarm thresholds, an alarm is issued.

Basic ventilation

1. Start Ventilation monitoring according to section [6.4.1 SPIRIT differential pressure respiratory mechanics analyser](#)
2. Set the alarms with the narrow quick set function (refer to section [4.6 Operator Defined Alarm Thresholds](#)).
3. When the measured value exceeds the alarm thresholds, an alarm is issued.



Important

If the device does not behave as described in this user guide, there is an error that must be repaired.

9.3 Maintenance Interval of the Batteries



Important

- The battery's performance and life largely depend on how and under ambient conditions the battery is used.

Power battery

- The rechargeable power battery is maintenance-free during its normal life.
- The battery must be replaced according:
 - After approximately 3 to 5 years
- Only store the device with fully charged batteries. If a device is not used, recharge the battery every 6 months.

9.3.1 Replacing the batteries



- ▲ A new or replaced power battery must first be charged to 100% after installing it into the **MAGLIFE RT-1** before it can be used on a patient.
- ▲ Only authorised personal can replace the battery.

Replacing the power battery

- The power battery needs to be replaced if the operating time in monitoring mode is less than 2 hours with a fully charged battery (refer to section [9.2.2 Battery check](#))
- Power batteries need replacing every 3 to 5 years.

9.3.2 Battery disposal



- ▲ Danger of explosion. The battery may not be burned or disposed of with domestic refuse.
- ▲ Danger of acid burns.
- ▲ Do not open or heat the battery.



The battery must be disposed of in municipally approved areas or sent back to SCHILLER.

Do not dispose of the device in the household waste.

9.4 Cleaning



Cleaning removes dust, dirt and stains; however, this does not constitute disinfection. Use commercially available detergents intended for clinics, hospitals and practices.

9.4.1 Detergents

Refer to the manufacturer's information regarding the use of detergents.

Admissible detergents

- Isopropyl alcohol (70%)
- Neutral detergents
- Soap water
- All products that are suitable for ABS plastic

Non-admissible detergents

Never use products containing the following:

- Ethyl alcohol
- Acetone
- Hexane
- Abrasive cleaning powder
- Plastic-dissolving products

9.5 Disinfection



- Use commercially available disinfectants for clinics, hospitals and practices to disinfect devices.
- Wipe disinfection removes certain bacteria and viruses. Always refer to the manufacturer's information.

9.5.1 Disinfectant

Admissible disinfectants

- Isopropyl alcohol 70%
- Propanol (70 to 80%)
- Ethyl hexanal
- Aldehyde (2 to 4%)
- Ethanol (70 to 80%)
- All products that are suitable for ABS plastic

Non-admissible disinfectants

Never use products containing the following:

- Organic solvents
- Ammonia-based detergent
- Abrasive cleaning agents
- 100% alcohol, Virex, Sani-Master
- Sani-Cloth, Ascepti or Clorox wipes
- HB Quat
- Conventional cleaner (for example, Fantastic, Tilex)
- Conductive solution
- Solutions or products containing the following ingredients:
 - Ketone (Acetone)
 - Ammonium chloride
 - Betadine
 - Chlorine, wax or wax compound
 - Sodium salt

9.5.2 Cleaning and disinfecting the device, cable and sensors



- ▲ Disconnect the device from the mains supply before cleaning. Refer to section [3.2 Switching Off and Disconnecting from the Mains Supply](#).
- ▲ Do not immerse the device, the cable or the sensors in liquid and do not sterilise them.
- ▲ Do not apply tension to the sensor cable.
- ▲ Do not use aggressive cleaners.
- ▲ Do not use any phenol-based agents or peroxide compounds for cleaning.
- ▲ Reusable sensors must be treated as biologically dangerous material after usage and sterilised according to the manufacturer's instructions.
- ▲ Observe the manufacturer's notes when cleaning the sensors and cables.



1. Disconnect the device from the mains and remove the plug and sensors.
2. Wipe the equipment, cable and sensors with a dampened cloth and a mild cleaning solution. The manufacturer recommends using 70% alcohol.
3. Dispose of single-use sensors and protective coverings according to the relevant regulations.

Notes on the cleaning and disinfection

NIBP cuff	The manufacturer recommends using 70% alcohol to clean and disinfect the NIBP cuff and tube.
SpO₂ sensor	The manufacturer recommends using 70 % alcohol to clean the cable and sensor. Dry the sensor before reuse.
ECG sensor	The manufacturer recommends using 70% alcohol to clean the sensor. Dry the sensor before reuse.
Water trap	Water trap may be cleaned using a cloth moistened (not wet) with a maximum of 70% ethanol or isopropyl alcohol.

9.6 Device disposal at the End of its Useful Life



When no longer used, this device must be disposed of in a municipally approved collection point or recycling centre.

If no such collection point or recycling centre is available, you can return the device to your distributor or the manufacturer for proper disposal. In this way, you contribute to the recycling and other forms of utilisation of old electrical and electronic equipment.

Improper disposal harms the environment and human health due to the presence of dangerous substances in electrical and electronic equipment.

9.7 Inspection and Checklist Tables

Per the maintenance interval detailed previously, the following check list should be copied and followed.

Checking functions

The following tests (refer to sections [9.2.1 Visual inspection of the device and accessories](#) to [9.2.4 Alarm tests](#)) must be performed before or after each intervention, respectively. Enter the results in the check list.

- Visual inspection of the device and accessories (refer to section [9.2.1 Visual inspection of the device and accessories](#)).
- For battery charging status information, refer to section [9.2.2 Battery check](#).

Year	Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Jan																															
	Feb																															
	Mar																															
	Apr																															
	May																															
	June																															
	July																															
	Aug																															
	Sept																															
	Oct																															
	Nov																															
	Dec																															

9.7.1 Every 12 months

Inspection	Results	Inspection				
Functional safety checks and inspections → Confirm the date of the last factory inspections and tests	Return the device to your nearest authorised service point or your SCHILLER agent for safety and functional checks.	☐	☐	☐	☐	☐
	Date of inspection:					
	Inspector:					

9.7.2 Life item replacement every 5 to 10 years

Inspection	Results	Replacement				
Battery → Replace the battery	- The battery needs to be replaced: - When the operating time is less than 2 hours or after 3 to 5 years, refer to section 9.3.1 Replacing the batteries - Replace the internal button primary cell (every 10 years)	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐
	Date of replacement:					
	Inspector:					

9.8 Error Detection

9.8.1 General errors

Error	Cause	Remedy
The screen is not lit when the device is switched on	- The device is in transport mode - The battery is empty - The device is defective	→ Connect to the power supply and switch the device on → Connect to the power supply and charge the battery → Replace the device
The device cannot be switched OFF	- Software hangs - The device is defective	→ Turn the rotary switch to the OFF position. The device will initiate a shutdown after a maximum of one minute. → Replace the device
No analysis	- ECG signal too weak - ECG signal interference through electromagnetic waves - The patient moved or was touched during the analysis - The device is defective	→ Perform cardiac massage again → Turn off the source of signal interference, for example, radio equipment or cell phone, or move the patient outside the field of interference → Do not move or touch the patient during the analysis → Replace the device
The battery is not being charged	The temperature in the device or the battery is too high	→ Let the device cool down, if possible; charging is continued once the temperature has reached an acceptable level.

9.8.2 Temperature alarms

Alarm	Code	Cause	Remedy
Device: Internal temperature is out of range	T_DEV_TEMP_01	The internal temperature is out of range	→ Check ambient temperature (10 to 40°C) → Turn the device off for 5 minutes and then restart the device. → Contact technical service
Device: Internal temperature is out of range	T_DEV_TEMP_02	The internal temperature is out of range	→ Check ambient temperature (10 to 40°C) → Turn the device off for 5 minutes and then restart the device. → Contact technical service

9.8.3 Battery alarms

Alarm	Code	Cause	Remedy
Battery: Empty battery	T_BATTERY_01	• Empty main battery	→ Check the main power cable → Contact technical service
Battery: Low battery	T_BATTERY_02	• Low main battery	→ Check the main power cable → Contact technical service
Battery1/2: Main battery is not connected	T_BATTERY_03/04	• Battery 1 or 2 not connected	→ Contact technical service
Battery1/2: Replace the defective main battery	T_BATTERY_05/06	• The battery is defective	→ Contact technical service
Battery1/2: Check the main battery	T_BATTERY_07/08		
Battery1/2: Empty battery	T_BATTERY_09/10		
Battery1/2: Check the main battery	T_BATTERY_11/12		
Battery1/2: Replace the defective main battery	T_BATTERY_13/14		
Battery: Check the internal backup cell	T_BATTERY_15	• The internal battery is defective	→ Contact technical service
Battery: Check the internal backup cell	T_BATTERY_16		
Battery: Internal backup cell is empty	T_BATTERY_17	• The internal battery is empty	→ Contact technical service
Battery: Internal backup cell is empty	T_BATTERY_18		
Battery1/2: Replace the defective main battery	T_BATTERY_19/20	• Battery 1 or 2 is defective	→ Contact technical service

9.8.4 WLAN Connection alarms

Alarm	Code	Cause	Remedy
		• Remote disconnected	→ Try manual reconnection → Check network connection status on MAGLIFE RT-1/MAGSCREEN RT-1 → Check network configuration on MAGLIFE RT-1/MAGSCREEN RT-1 → Contact technical service
Remote connection: Disconnected	T_REMOTE_CONN_01		
		• Remote is unable to connect	→ Check the network connection status on MAGLIFE RT-1/MAGSCREEN RT-1 → Check the network configuration on the MAGLIFE RT-1/MAGSCREEN RT-1 → Contact technical service
Remote connection: Unable to connect	T_REMOTE_CONN_02		

9.8.5 Preventing electromagnetic interferences



Non-ionising electromagnetic radiation

The user can help avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the **MAGLIFE RT-1**. The distance depends on the output performance of the communication device, as indicated below.

HF source Wireless communications devices	Transmitter frequency [MHz]	Testing frequency [MHz]	Maximum power P [W]	Distance d [m]
Various radio services (TETRA 400)	380-390	385	1.8	0.3
- Walkie-talkies (FRS) - Rescue service, police, fire brigade, servicing (GMRS)	430-470	450	2	0.3
LTE band 13/17	704-787	710/745/780	0.2	0.3
- GSM800/900 - LTE band 5 - Radio telephone (microcellular) CT1+, CT2, CT3	800-960	810/870/930	2	0.3
- GSM1800/1900 - DECT (radio telephone) - LTE Band 1/3/4/25 - UMTS	1700-1990	1720/1845/1970	2	0.3
Wireless, WLAN 802.11a/n	5100-5800	5240/5500/5785	0.2	0.3



- ▲ Portable HF telecommunication devices must not be used within a radius of 0.3 meters from the **MAGLIFE RT-1** and its cables.
- ▲ Do not place the **MAGLIFE RT-1** on top of other electric/electronic devices, that is, maintain a sufficient distance from other devices (this includes the patient cables).

For permanent HF telecommunication devices (for example, radio and TV), the recommended distance can be calculated using the following formula: $d = 1.2 \times \sqrt{P}$ for 150 kHz to 800 MHz and $d = 2.3 \times \sqrt{P}$ for 800 MHz to 2.7 GHz

d = recommended minimum distance in Meters

P = transmitting power in Watts

For more detailed information, refer to section [10.6 Electromagnetic Interferences](#).



9.8.6 Measures to prevent electromagnetic interference

The user can take the following measures to prevent electromagnetic interference:

- Increase the distance to the source of interference.
- Turn the device to change the angle of radiation.
- Connect the device to a different mains connector.
- Only use original accessories, especially patient cables.
- Immediately replace defective cables, especially patient cables, with defective sheathing.
- Check the patient cable is securely screwed on.
- Observe the maintenance intervals as stated in section [6.1 Maintenance interval](#).

10 Technical Data



Data refer to standard testing conditions.

10.1 MAGLIFE RT-1

Manufacturer	SCHILLER MEDICAL
Device type	Monitor
Device name	MAGLIFE RT-1
Dimensions	1310 x 620 x 520 mm (h x l x w)
Weight	46 kg
Protection case	IP21
Mains supply	100 to 240 VAC, 150 VA, 50/60 Hz
Power Battery	1 or 2 batteries depending on built-in options.
Battery type	Lithium/ion 14.6V, 6.4 Ah, 93.44 Wh
Autonomy	Battery's autonomy: between 6 and 8 hours depending on available options.
Charging	Charging time: 5 hours to reach 100% after a discharge and device switched off.
Environmental conditions	
For operation	10 to 40°C relative humidity at 20 to 90% (non-condensing) - Atmospheric pressure 700 to 1060 hPa
Environmental conditions	
For Transport and storage between uses	-10 to +50°C relative humidity at 15 to 95% (non-condensing)
Time for warming up/cooling down	1 hour - Time required for the MAGLIFE RT-1 to warm or cool from the minimum/maximum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20°C.
Display	
Type	High-resolution TFT colour LCD capacitive touch screen, protected by tempered glass
Dimensions	15.6" (1366 x 768 pixels, 344 x 194 mm)
Alarm sound level	62 to 73 dBA for all alarm levels
Connections	NIBP, Temperature, IBP, Breathing gases and gas sample exhaust.
Charging bay	For 2 x ECG amplifiers, 2 x SpO ₂ sensors
Interfaces	USB (only for maintenance and software updates). WLAN

Memory	Log file
Safety standard	IEC/EN 60601-1 The device is designed for continuous use.
EMC	• IEC/EN 60601-1-2 • CISPR 11 class A – NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. The device can be exposed to the following interferences without any impairment: • Static discharges up to 15 kV • Field strength up to 3 V/m in the radio frequency range of (80 to 2700 MHz, 5 Hz/ 1 kHz modulated) • Magnetic fields of 30 A/m, 50 to 60 Hz
Conformity	CE according to Medical Device Regulation (EU) 2017/745 class IIb
Protection class	Class I according to IEC/EN 60601-1 for continuous use

10.1.1 WLAN Standard

Modules	TEXAS INSTRUMENT WL1831MODGBMOC
FCC ID IC ID	Z64-WL18SBMOD 451I-WL18SBMOD
Transmission standards	IEEE 802.11 b,g,n
Frequency range	2.412 to 2.484 GHz
Maximum power output 2.4 GHz (1DSSS)	+17.3 dBm
Bandwidth	20 MHz (default) and 40 MHz
Minimum sensitivity	-96.3 dBm (1 Mbps DSSS)

10.2 MAGSCREEN RT-1

Manufacturer	SCHILLER MEDICAL
Device type	Remote display
Device name	MAGSCREEN RT-1
Dimensions	364 x 195 x 422 mm (h x l x w)
Weight	7,9 kg
Protection case	IP21
Mains supply	100 to 240 VAC, 84 VA, 50/60 Hz
Environmental conditions For operation	10 to 40°C relative humidity at 20 to 90% (non-condensing) - Atmospheric pressure 700 to 1060 hPa
Environmental conditions For Transport and storage between uses	-10 to +50°C relative humidity at 15 to 95% (non-condensing)
Environmental conditions Time for warming up/cooling down	1 hour Time required for the MAGLIFE RT-1 to warm or cool from the minimum/ maximum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20°C.
Display Type Dimensions	- High-resolution colour LCD capacitive touch screen, protected by tempered glass 15.6"(1366 x 768 pixels; 344 x 194 mm)
Alarm sound level	62 to 73 dBA for all alarm levels
Interfaces	WLAN, USB 2 x (one dedicated for maintenance)

Memory	Log file
Safety standard	IEC/EN 60601-1 The device is designed for continuous use.
EMC	• IEC/EN 60601-1-2 • CISPR 11 class A – NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. The device can be exposed to the following interferences without any impairment: • Static discharges up to 15 kV • Field strength up to 3 V/m in the radio frequency range of (80 to 2700 MHz, 5 Hz/ 1 kHz modulated) • Magnetic fields of 30 A/m, 50 to 60 Hz
Conformity	CE according to Medical Device Regulation (EU) 2017/745 class IIb
Protection class	Class I according to IEC/EN 60601-1 for continuous use

10.3 MAGLINK

Manufacturer	SCHILLER MEDICAL
Device type	Network equipment
Device name	MAGLINK
Dimensions	115 x 205 x 160 mm (h x l x w) excluding antennas
Weight	2.8 kg
Protection case	IP21
Mains supply	100 to 240 VAC, 84 VA, 50/60 Hz
Environmental conditions For operation	• 10 to 40°C relative humidity at 20 to 90% (non-condensing) Atmospheric pressure 700 to 1060 hPa
Environmental conditions For Transport and storage between uses	• -10 to +50°C relative humidity at 15 to 95% (non-condensing)
Time for warming up/cooling down	• 1 hour Time required for the MAGLIFE RT-1 to warm or cool down from the minimum/ maximum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20°C.
Interfaces	WLAN, optical

Safety standard

IEC/EN 60601-1
The device is designed for continuous use.

EMC

- IEC/EN 60601-1-2
- CISPR 11 class A
 - **NOTE:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The device can be exposed to the following interferences without any impairment:

- Static discharges up to 15 kV
- Field strength up to 3 V/m in the radio frequency range of (80 to 2700 MHz, 5 Hz/ 1 kHz modulated)
- Magnetic fields of 30 A/m, 50 to 60 Hz

WLAN Modules

ACKSYS EMBEDAIR100/T

**FCC ID
IC ID**

Z9W-RMB
11468A-RMB

Transmission standards

IEEE 802.11 a,b,g,n

Frequency range

2.4 GHz; 2.402 to 2.494 GHz for 802.11 b/g/n
5 GHz; 5.170 to 5.835 GHz for 802.11 a/n

**Maximum power output 2.4 GHz
(1DSSS)**

2.4 GHz: 23.5 dBm/5 GHz: 21 dBm

Bandwidth

20 MHz (default) and 40 MHz

Minimum sensitivity

-92 dBm for 802.11 b/g/n
-96 dBm for 802.11 a/n

10.4 Technical Data and Monitoring

10.4.1 ECG

Leads	Simultaneous, synchronous recording of all 4 active electrodes giving 6 leads
Patient cable	4-wire cable type CF
Heart rate	
Range	• 30 to 350 bpm
Accuracy	• $\pm 10\%$ or 5 bpm, whichever is greater
Lead display	Selection from 1 to 6 leads
Sensitivity	0.25, 0.5, 1, 2 cm/mV programmable
ECG sensor temperature	Up to 43°C
Blockage caused by a defibrillation shock	Maximum 5 seconds
Input impedance	$\geq 2.5 \text{ M}\Omega$
Current electrode test	$< 0.5 \mu\text{A}$
Suppression of large T-waves	Maximum amplitude of T-wave according to IEC 60601-2-27 section 201.12.1.101.17: 0.75 mV
HR averaging method	The heart rate calculation is done using the 4 previous RR intervals. The RR intervals are reset, and the heart rate is set to zero whenever an asystole condition has been detected
Response time HR measurement	Change from 80 to 120 bpm: < 3 seconds Change from 80 to 40 bpm: < 6 seconds
Reaction to an irregular rhythm	• A1: 80 per minute • A2: 60 per minute • A3: 120 per minute • A4: < 90 per minute (according to IEC specifications 60601-2-27, 6.8.2.b) 5)
Duration until an alarm is triggered in the case of tachycardia	• B1 and B2: 10 seconds (according to IEC specification 60601-2-27, 6.8.2.b) 6) • B1 and B2 when one-half or twice the indicated amplitude (0.5 or 2 mV): no alarm is generated
ECG amplifier	
Sampling rate	250 Hz
QRS detection range	Duration: 40 to 120 ms, amplitude: 0.5 to 5.0 mV
Protection	Fully isolated, defibrillation protected up to 5 kV
Mains filter	Ensures a distortion-free suppression of superimposed 50 to 60 Hz sinusoidal interferences through adaptive digital filtering.
Frequency range	The ECG frequency range depends on the selected filter mode: • Out of MRI: 0.05 to 42.25 Hz (0.6 to 42.25 Hz if BLW filter is ON) • LP filter/Adaptive filter: 0.05 to 25 Hz

10.4.2 NIBP Non-invasive blood pressure

Measurement	Automatic or manual
Measuring method	Oscillometric
Connection	Type CF
Measurement range Adult/Child Neonate	- Sys 30 to 255 mmHg, dia 15 to 220 mmHg - Sys 30 to 135 mmHg, dia 15 to 110 mmHg
Accuracy	± 3 mmHg
Standards	Complies with ISO 81060-2: 2013

10.4.3 IBP Invasive blood pressure

Measuring range	-100 to +400 mmHg
Accuracy	1 mmHg or ± 1% (whichever is greater)
Sampling rate	250 Hz
Amplifier	Type CF, defibrillation-protected up to 5 kV, galvanic isolation between applied parts and monitor (4 kV)
Zeroing	Manual

10.4.4 Temperature

Measuring method	Direct method by optical interferometry
Sensor	External/skin application
Amplifier	Type CF, defibrillation-protected > 5 kV
Sampling rate	50 Hz
Measurement interval	1 x per second
Measuring range	25 to 45°C
Resolution	0.1°C
Accuracy	± 0.3 °C from 25 to 45°C

10.4.5 SpO₂ Pulse oximetry

Sensor name	W-SA (adult), W-SP (paediatric), W-SVS (universal and very small patient)
Measuring range	
SpO ₂	1 to 100%
PP	30 to 240 bpm
PI	0.1 to 20%
Accuracy	
Saturation	70 to 100% ± 2 A _{rms} (no motion) ^a
Pulse rate	± 2 BPM over the full range (no motion)
Delay time	
SpO ₂ and PP rate	Up to 31 seconds
Blockage caused by a defibrillation shock	Maximum 10 seconds
Skin surface temperature	Less than 41°C in a 35°C environment

a. As inherent to their functional principle, pulse oximetry measurements are statically distributed; therefore, only about two-thirds of the measurement data are expected to fall within ± A_{rms} of the value measured by a CO oximeter.

Accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges (70 to 100%). Subjects comprised men and women between 21 and 49 years old and spanned a range of skin pigmentations. Pulse oximeter SpO₂ readings were compared to SaO₂ values of drawn blood samples measured by hemoximetry.

10.4.6 AG module (CO₂ Capnography)

The Mindray AION Rhodium agent module is a compact, low-flow sidestream gas analyser with an integrated pump, zeroing valve and flow controller.



The Mindray AION Rhodium sidestream gas analyser is equipped with automatic barometric pressure and temperature compensation.

Trademarks	AION Rhodium CO ₂ gas analyser
Sampling lines and water trap	DRYLINE and DRYLINE II water traps 2.5 m adult/paediatric DRYLINE and DRYLINE II water traps 2.5 m neonatal
Measuring mode	Sidestream
Resolution	0,01%
Warm-up time	ISO accuracy mode: 10 seconds to 5 minutes Full accuracy mode: < 5 minutes
CO₂ zero Threshold	Gas concentration set to zero if level below: • In full accuracy mode: 0.1% • In ISO accuracy mode: 0.3% For more than 3 seconds
System delay time (t0-10%)	< 4 seconds
System rise time (t10-90%)	200 ms
Measurement specification	The full accuracy is valid for a dry gas at 15 to 30°C, 800 to 1100 hpa and after 5 minutes of warm-up
Full accuracy	± 0,263% abs (± 2 mmHg)
ISO accuracy	± (0,43% abs + 8% rel) Corresponding to requirements in ISO 80601-2-55:2011
Sampling rate	• 70 ml per minute • Accuracy: ± 10 ml/minute or ± 10%, whichever is greater
Breath detection	• Adaptive threshold (> 1% ABS change in CO₂ concentration)
Respiration rate accuracy	• 2 to 60 bpm, ± 1 bpm • 60 to 150 bpm, ± 2 bpm
Gas contaminants interference	Interferences [% _{abs}]
< 100% Xenon	0.1
< 50% Hel	0.1
Meter dose inhaler proellants	Unspecific
< 0.1% Ethnaol	0
Saturated Isopropanol vapour	0.1
< 1% Acetone	0.1
< 1% Methane	0.1

10.4.7 AG Module (O₂, N₂O and anaesthetic)

The Mindray AION Platinum agent module is a compact, low-flow sidestream gas analyser with an internal paramagnetic oxygen sensor, integrated pump, zeroing valve and flow controller.



The Mindray AION Platinum sidestream gas analyser is equipped with automatic barometric pressure and temperature compensation.

Trademarks	AION Platinum multigas analyser
Sampling lines and water trap	DRYLINE and DRYLINE II water traps 2.5 meters adult/paediatric DRYLINE and DRYLINE II water traps 2.5 meters neonatal
Measuring mode	Sidestream
Resolution	0,01%
Respiration rate accuracy	• 2 to 60 bpm, ± 1 bpm • 60 to 100 bpm, unspecified
Sampling rate	• 120 ml/minute for neonates, 200 ml for adults/paediatric • Accuracy: ± 10 ml/minute or $\pm 10\%$, whichever is greater
Data sample rate	• 25 Hz. Data presentation is 50 Hz, and every second data point is interpolated.
Gas	• CO₂, O₂ (Paramagnetic O₂ module), N₂O, and any of the five anaesthetic agents: DES, ISO, ENF, SEV and HAL.
Range	• CO₂: 0 to 30% • O₂: 0 to 100% • N₂O: 0 to 100% • DES/SEV/ENF/ISO/HAL: 0 to 30%
Warm-up time	ISO accuracy mode: < 45 seconds Full accuracy mode: < 10 minutes
ISO Accuracy	As full accuracy gas specifications, but de-rated as follows: • Add $\pm 0.3\%_{\text{ABS}}$ to inaccuracy for CO₂ • Add $\pm 8\%_{\text{REL}}$ to inaccuracy for all agents • N₂O accuracy is $\pm (8\%_{\text{REL}} + 2\%_{\text{ABS}})$.
Highest GAS LEVEL	For a single halogenated anaesthetic gas in a gas mixture that is concealed when the anaesthetic concentration falls: • 0,15% (Full accuracy) • 0,3% (ISO accuracy)
System Rise time @ 120/200 ml/minute	CO ₂ : 250 ms O ₂ : 600/500 ms at 15 to 21% O ₂ and 800/700 ms at 21 to 60% O ₂ N ₂ O: ≥ 250 ms% ENF: ≥ 350 ms DES/SEV/ISO/HAL: ≥ 350 ms
System Delay time	< 4 seconds

Identification	Dual agent
Primary agent ID threshold	0.15% (0.4% during ISO accuracy mode)
Secondary agent ID threshold	0.3% (0.5% during ISO accuracy mode) or 5% _{REL} (10% _{REL} for Isoflurane) of the primary agent if the primary agent > 10%. For HAL, add 0.1% _{ABS} to threshold values.
Agent ID time	Less than 3 breaths, in typically, 12 seconds
Breath rate (BR) and end-tidal (ET) ET is measured at I:E ratio of 1:1 using a breath simulator according to ISO 80601-2-55:2011 figure 201.101.	The breath rate limit for accurately resolved ET values (for I:E ratio 1:1): 60 bpm at 200 ml/minute using DRYLINE Adult accessories 60 bpm at 120 ml/minute using DRYLINE Neonate accessories The following methods are used to calculate ET values: - EtCO₂ concentration readings are identified using the lowest and highest values, respectively, of the temporal CO₂ curve. Corresponding readings of N₂O and anaesthetic agents are taken at the same point in time. - When breathing is detected, the time between the detecting EtCO₂ values is used to calculate the BR. - The effect of other I:E ratios may be calculated by determining the length of the shortest inspiratory/expiratory event that can be resolved accurately: $t_{\text{resolved}} = 60 / (2 \times BR_{\text{limit}} (1:1))$ $BR_{\text{limit}} (I:E) = 60 / ((I + E) \times t_{\text{resolved}})$
Known adverse effects	- The multigas analyser uses a fixed correction of 11 hPa (corresponding to 22°C and 40% RH) to compensate for the influence of water vapour in the gas sample when converting the gas readings to ATPD. Any other ambient H₂O partial pressure will dilute the gas sample to a different extent, causing a certain measurement error. Under typical operating conditions, however, this effect is not noticeable. An increase in the ambient H₂O partial pressure to 30 hPa (that is, 28°C and 80% RH or 33°C and 60% RH) will cause a general error for all gases of only -2%_{REL}. - Gas leakage inside or outside the module may cause incorrect gas readings. - The multigas analyser is not in any way affected by cyclical pressures of up to 10 kPa as, apart from the automatic pressure compensation, the pump automatically regulates flow so that not only gas readings but also gas sample flow is unaffected.

Full accuracy mode

Gas	Concentration ^a [% _{ABS}]	Inaccuracy ^{b, c} [% _{ABS}]	Interference ^{d, e} [% _{ABS}]	
CO ₂	0 to 1	± 0.1%	N ₂ O	0.1
	1 to 5	± 0.2%		
	5 to 7	± 0.3%	O ₂	0.1
	7 to 10	± 0.5%	Any agent	0.1 ^f
	> 10	unspecific		
N ₂ O	0 to 20	± 2	O ₂ /CO ₂	0.1
	20 to 100	± 3	Any agent	0.1 ⁶

ENF/ISO/HAL	0 to 1	± 0.15	CO ₂	0
	1 to 5	± 0.2	N ₂ O/O ₂	0.1
	> 5	unspecific	2 nd agent	0.1
SEV	0 to 1	± 0.15%	CO ₂	0
	1 to 5	± 0.2%	N ₂ O/O ₂	0.1
	5 to 8	± 0.4%	2 nd agent	0.1
	> 8	unspecified		
DES	0 to 1	± 0.15%		
	1 to 5	± 0.2%	CO ₂	0
	5 to 10	± 0.4%	N ₂ O/O ₂	0.1
	10 to 15	± 0.5%	2 nd agent	0.1
	15 to 18	± 1%		
	> 18	unspecified		
O ₂	0 to 25	± 1	CO ₂	0.2
	25 to 80	± 2	N ₂ O	0.2
	80 to 100	± 3	Any agent	0.1

- a. Gas data is reported as zero if the measured concentration is below the defined threshold level during more than 3 seconds: CO₂ - 0.1/0.3%; N₂O - 3/3%; O₂ - 0/0%, Agents - 0.15/0.3% (Full/ISO accuracy).
- b. Inaccuracy is specified at 10 to 55°C operating temperature and default compensated for an H₂O partial pressure of 11 mBar (that is, 22°C at 40% RH ambient conditions) and using an Artema Technology DRYLINE sampling system. For automatic compensation of the ambient humidity effect on the gas sample composition, the actual ambient H₂O partial pressure can be input to AION Platinum from the host via the communication interface.
- c. Inaccuracy specifications include stability and drift.
- d. Maximum interference from each gas at concentrations within specified accuracy ranges for each gas. Total interference for all gases never larger than 5% REL.
- e. Multiple agent interference on CO₂, N₂O and O₂ is typically the same as single agent interference.
- f. For AION Platinum MG and MP: provided that input of anaesthetic agent in use has been done.

10.4.8 Basic ventilation**Trademarks**

SPIRIT Respiratory Mechanics

Sampling lines

SPIRIT flow sensor adult (tidal volume above 150 ml) and neonatal (tidal volume below 300 ml) 3.3 m.

Measuring mode

Continuous differential pressure spirometry with fixed orifice flow sensor type. Automatic compensation for ambient pressure, sidestream gas sampling flow and gas composition.

Pressure sensor calibration

Automatic

Condition of use

Endotracheal tube 5.5 to 10 mm (Adults) and 3 to 6 mm (Paediatric)

Full accuracy^a

Sensor type	Adult		Paediatric	
Range	Normal	Extended	Normal	Extended
Airway pressure [cmH ₂ O]	-20 to 100 ± 1 cmH ₂ O	-20 to 120 ± 3%	-20 to 100 ± 1 cmH ₂ O	-20 to 120 ± 3%
Airway flow (both direct.) [l/min]	1.5 to 100	1.5 to 120	0.25 to 25	0.25 to 30
Tidal volume (insp. and exp.) [ml]	150 to 2000 ± 6% or 30 ml ^b	100 to 2000 ± 10% or 15 ml ^{2,c}	15 to 300 ± 6% or 4 ml ²	15 to 500 ± 10% or 6 ml ^{2,3}
Minute volume (insp. and exp.) [l/min]	2 to 20	2 to 60	0.5 to 5	0.5 to 15

a. Patient airway gas at 30°C and 50% RH. For other conditions add $\pm 0.15\%/^{\circ}\text{C}$ and $\pm 0.1\%/10\%$ RH. Data presentation in ATPD or BTPS adds a conversion factor (refer to the user manual). It also assumes HME or filter placed between the endotracheal tube and flow sensor.

b. Whichever is greatest

c. In range outside of the normal range

10.5 Device Configuration



To modify the settings of the device, contact your technical representative.

10.5.1 General configuration

Parameter	Values	Description
Notch filter	- None 50 Hz* 60 Hz	This option will be activated if artefacts are detected on ECG signals when the device is plugged into the mains. The notch filter must be chosen according to the location. 50 Hz: Europe, Africa, Middle East (except Saudi Arabia), Asia-Pacific (except Japan, Taiwan and the Philippines), Australia 60 Hz: The American continent (except Chile, Argentina, Uruguay, Paraguay, Bolivia, and French Guyana)
Monitoring display mode	Monitoring - Monitoring big values 3 ECG leads	Sets the desired default view in monitoring. Monitoring big values: No curves are displayed by default, only big monitoring values
Default heart rate source	Auto* - ECG: I - ECG: II - ECG: III - Pleth	Sets the behaviour of the HR parameter box between the following possibilities: - Auto: The device automatically detects the HR source with a predefined priorities level. ECG higher than SpO₂ (pulse) - ECG I: Always force the HR calculation on ECG lead I - ECG II: Always force the HR calculation on ECG lead II - ECG III: Always force the HR calculation on ECG lead III - SpO₂: Always force the HR calculation on SpO₂ (pulse)
Audio pause at start	2 minutes* - Off	When this option is activated, the device will always remain silent for 2 minutes at the start, even if an alarm occurs
Periodic test frequency	Daily* - Weekly	The device wakes up by default weekly to perform a self-test. It is possible to set a daily test. The following details of the content of the automatic and manual self-test
Time of test	12	This parameter specifies when the device will automatically wake up to perform its self-test. This field must be specified in hours in 24 hours format. Always specify the time in HH and not in HH:MM. For example, 13 refers to 1 PM, 13:30 is not allowed
Technician password	0000	Sets the password that will be asked for to enter the Control Panel
Default language	English*, German, French, Spanish and Italian	Sets of the language the device will always start up in by default. Even if the language is modified during use, the device will start again with the language specified here.
Alarm sound level	- Low Medium* - High	Selection of the overall sound level applied to technical and physiological alarms
Idle automatic shutdown	30 minutes Disabled*	If enabled, the device will automatically shut down if no sign of activity (vital sign measurement) is detected within 30 minutes.
Audio off allowed	- False True*	If this option is activated, the user will have the possibility to shut down sound alarms.

10.5.2 ECG

Parameter	Values	Description
ECG curve amplitude	0.25 mV 0.5 mV 1 mV 2 mV Auto*	Sets the default ECG curve amplitude; if Auto is selected, the displayed amplitude will be automatically adapted depending on the signal amplitude.
ECG lead wire	IEC - AAMI/AHA	IEC Displays ECG lead colours per IEC standards AAMI/AHA Displays ECG lead colours per AHA standards
ECG 16,7 Hz filter	False* - True - Off	Not used at the moment, it has no impact on the device
Pulse sound level	Low* - Medium - High	Sets the audio level of the pulse sound issued by the ECG

10.5.3 NIBP

Parameter	Values	Description
Deflation rate	3, 4, 5, 6, 7, 8, 9 mmHg/s	Sets the cuff deflation rate
NIBP unit	mmHg* - kpa	Sets the device in which the NIBP values will be displayed and stored
Automatic cycles at the start	False* - True	Automatic NIBP measurement cycle starts once the first measurement is initiated manually
Initial pressure for adults	90, 120, 150, 180*, 210, 240, 270 mmHg	Sets the initial cuff pressure for measurement in adult mode
Initial pressure for children	90, 120, 150*, 180, 210, 240, 270 mmHg	Sets the initial cuff pressure for measurement in child mode
Initial pressure for neonate	50*, 70, 90, 110, 130, 150 mmHg	Sets the initial cuff pressure for measurement in neonate mode

10.5.4 IBP

Parameter	Values	Description
IBP curve amplitude	30, 60, 100, 300 mmHg 4, 8, 20, 40 kPa	Sets the default IBP curve amplitude
IBP unit	mmHg* - kPa	Sets the device in which the IBP values will be displayed and stored.

10.5.5 SpO₂

Parameter	Values	Description
SpO ₂ average	4, 6, 8, 10, 12*, 14, 16 seconds	Sets the integration time for the calculation of the displayed average value.
SpO ₂ sensitivity	Normal* - Adaptive Probe Off Detection	Sets the measurement sensitivity. Adaptive Probe Off Detection is optimised for detecting a sensor that has come off, regardless of the signal quality.
SpO ₂ sound level	- Off - Low Medium* - High	Sets the audio level of the pulse sound

10.5.6 Temperature

Parameter	Values	Description
Temperature unit	Celcius* - Fahrenheit	Sets the displayed temperature unit for the device.

10.5.7 EtCO₂

Parameter	Values	Description
Respiration curve amplitude	50*, 75, 100 mmHg 8, 12, 15% 7, 10, 14 kPa	Sets the displayed respiration curve amplitude for the device.
EtCO ₂ unit	- Vol% mmHg* - kPa	Sets the displayed EtCO ₂ unit for the device.

10.5.8 Anaesthetic agents (Gas)

Parameter	Values	Description
O ₂	Fi, ET	Indicates the fraction of inspired/expired O ₂
N ₂ O	Fi, Et	Indicates the fraction of inspired/expired N ₂ O
Agent	HAL, ISO, DES, SEV, ENF	Indicates the detected agent (2 of 5 types)
Agent unit	%, mmHg	Sets the displayed anaesthetic agent unit for the device.

10.5.9 Basic ventilation

Parameter	Values	Description
Respiration curve type	- Tidal Volume - Flow	Sets the respiration curve type to the default value
Curve Amplitude	- Auto 3000 ml 300 ml	Sets the default respiration curve amplitude

10.5.10 Time and date

Parameter	Values	Description
Date format	• DD/MM/YY*, MM/DD/YY • YY/MM/DD	Sets the format in which the date will be displayed
Time format	• AM/PM • 24H*	Sets the time format
Time zone	• Europe/Berlin • Europe/Paris* • Europe/London • GMT -12 to -1 • GTM 0 • GTM 2 to +12	Sets the time zone to calculate the appropriate date and time

10.5.11 Event

Parameter	Values	Description
Event (from 1 to 20)	• Event (1 to 20)	Enter an event name (for example, a medication). This event can be selected on the event list device during an intervention. Once selected, it is stored in the memory and flagged in the intervention report (20 customisable fields).

10.6 Electromagnetic Interferences

The **MAGLIFE RT-1** is intended to be used in the electromagnetic environments listed in the following tables. The user of the **MAGLIFE RT-1** must check that the device is operated in a good environment.

10.6.1 Electromagnetic emissions

Emission measurement	Compliance with the regulations	Electromagnetic environment explanations
HF emissions CISPR 11	Group 1	MAGLIFE RT-1 only uses HF energy for internal functions. Therefore, HF emissions are very low, and interferences with electronic devices nearby are very unlikely.
HF emissions CISPR 11	Class A ^a	MAGLIFE RT-1 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Voltage fluctuations IEC 61000-3-3	Compliant	

a.NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

10.6.2 Electromagnetic immunity

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment explanations
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 15 kV air	IEC 60601-1 conformity	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	IEC 60601-1 conformity	Mains power quality should be equal to that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	± 1 kV between conductors ± 2 kV conductor-earth	IEC 60601-1 conformity	Mains power quality should be equal to that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	> 95% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180° 225°, 270° and 315° > 95% UT; 1 cycle 30% UT; 25 (50 Hz) /30 (60 Hz) cycles h) Single phase: at 0° 95% UT; 250 (50 Hz) 300 (60 Hz) cycle	IEC 60601-1 conformity	Mains power quality should be equal to that of a typical commercial or hospital environment. If the user of the MAGLIFE RT-1 is reliant on permanent operation even in the case of a power failure, it is suggested connecting the MAGLIFE RT-1 to an UPS or used with a battery.
Power frequency (50 to 60 Hz) magnetic field 131	30 A/m	30 A/m	Power frequency magnetic fields should be equal a typical commercial or hospital environment.

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment explanations
Proximity magnetic fields IEC 61000-4-39	30 kHz - 8 A/m ^a 134.2 kHz -65 A/m 150kHz to 26 MHz 13.56 MHz -7.5 A/m	- 65 A/m 7.5 A/m	Proximity magnetic fields should be used not closer than 50 mm to any part of this device including cables. Recommended minimum distances Portable and mobile HF telecommunication devices must keep at the recommended minimum distance (d) from the Maglife RT-1 and all its components, including cables. The recommended minimum distance is calculated based on the transmitter's frequency.
Conducted RF IEC 61000-4-6	3 V _{rms} outside ISM band 6 V _{rms} in the ISM and amateur radio band 150 kHz to 80 MHz	[V ₁] = 3 V _{rms} [V ₁] = 6 V _{rms}	$d = \frac{3.5}{V_1} \times \sqrt{P}$
Radiated HF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	[E ₁] = 3 V/m 80 to 2700 MHz	$d = \frac{3.5}{E_1} \times \sqrt{P} \quad \text{for 80 to 800 MHz}$ $d = \frac{7}{E_1} \times \sqrt{P} \quad \text{for 800 MHz to 2.7 GHz}$
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Refer to section 10.6.3 Immunity to proximity fields from RF wireless communications equipment	10.6.3 Immunity to proximity fields from RF wireless communications equipment	The recommended separation distance for this tested frequency is 0.3 meter.

Note: U_T indicates the AC voltage of the mains before the test level.

a.30 KHz is not applied because MAGLIFE RT-1 is for professional healthcare only

Interference testing	IEC 60601 test level	Conformity level	Electromagnetic environment explanations
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P is the maximum power in Watts, and d is the recommended separation distance in meters.

Field strengths from fixed transmitters, as determined by an electromagnetic site^a survey, should be less than the compliance^b levels (V_1 and E_1).

Interference may occur in the vicinity of equipment marked with the following symbol



Non-ionising electromagnetic radiation

Note 1: For 80 to 800 MHz, the higher frequency range applies.

Note 2: These guidelines might not always be applicable. Electromagnetic radiation is influenced by absorption and reflection on structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts, cannot be predicted theoretically with any accuracy. An electromagnetic site survey should be considered to assess the electromagnetic environment due to fixed RF transmitters. If the measured field strength in the location where the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. Additional measures may be necessary if abnormal performance is observed, such as re-orienting or re-locating the device.

b. Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than [E1] V/m.

10.6.3 Immunity to proximity fields from RF wireless communications equipment

Test frequency [MHz]	Band ^a [MHz]	Service	Modulation	Maximum Power P [W]	Distance d [m]	Immunity level [V/m]
385	380 to 390	Various radio services (TETRA 400)	Pulse modulation ^b 18 Hz	1.8	0.3	27
450	430 to 470	- Walkie-talkies (FRS) - Rescue service, police, fire brigade, servicing (GMRS)	FM ^c ± 5 kHz ± 1 kHz sine	2	0.3	28
710 745 780	704 to 787	LTE band 13/17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800 to 960	- GSM800/900 - LTE band 5 - Radio telephone (microcellular) CT1+, CT2, CT3	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700 to 1990	- GSM1800/1900 - DECT (radio telephone) - LTE Band 1/3/4/25 - UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth, Wireless, WLAN 802.11 b/g/n - LTE Band 7 - RFID 2450 (active and passive transponders and reading devices)	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

a. For some services, only the uplink frequencies are included.

b. The carrier shall be modulated using a 50% duty cycle square wave signal.

c. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst case

11 Appendix

11.1 Accessories and Disposables



▲ Always use SCHILLER replacement parts and disposables or products approved by SCHILLER. Failure to do so may endanger actual performance and life or invalidate the warranty.

Your local representative stocks all the disposables and accessories for the **MAGLIFE RT-1**. A full list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch).

11.2 Accessories

Article no.	Article description
ECG	
0-21-0046	ECG patch for MAGLIFE RT-1 W-ECG adult/child
0-21-0047	ECG patch for MAGLIFE RT-1 W-ECG neonate
0-13-0051	Wireless sensor MAGLIFE RT-1 W-ECG
NIBP	
U50143	Cuff for Neonatal soft, 2.5 cm
U50142	Cuff for Neonatal soft, 4 cm
0-04-0001	Cuff for Neonatal soft, 6 cm
0-04-0002	Cuff for Child, 8 cm
0-04-0003	Cuff for Child, 10 cm
0-04-0004	Cuff for Adult, 14 cm
0-04-0005	Cuff for Adult, 17 cm
0-04-0006	Cuff for Adult, 20 cm
SpO₂	
0-13-0052	Wireless adult sensor type W-SA
0-13-0053	Wireless child sensor type W-SP
0-13-0060	Wireless child sensor type W-SVS (for very small child)
0-13-0059	SpO ₂ SoftWrap cable sensor for W-SVS sensor (0-13-0060)
0-45-0004	Spare SpO ₂ Wrap Tapes for SoftWrap cable sensor (12 pcs.)
Capnography	
6-14-0006	Airway T-Adapter (ordered in multiples of 100)
6-14-0101	Airway 90° adapter (ordered in multiples of 100)
0-40-0000	CO ₂ monitor Sample line adult/paediatric 3 meters (ordered in multiples of 25)

Article no.	Article description
0-40-0001	CO ₂ monitor Sample line neonate 3.0 meters (ordered in multiples of 25)
0-26-0002	DRYLINE II water trap adult/paediatric
0-26-0003	DRYLINE II water trap neonate
Temperature	
9-01-0187	Temperature probe, based on optical principle, for external/skin application
Basic Ventilation	
0-13-0056	SPIRIT Flow sensor, adult/paediatric, 3.3 meters, without gas sampling
0-13-0058	SPIRIT Flow sensor, paediatric/neonate, 3.3 meters, without gas sampling
0-13-0055	SPIRIT Flow sensor, adult/paediatric, 2.5 meters, with gas sampling
0-13-0057	SPIRIT Flow sensor, paediatric/neonate, 2.5 meters, with gas Sampling
General accessories	
1-131-5881	MAGSCREEN RT-1
Printer	
0-50-0004	PAPIER IMPRIMANTE RT-1 210MM X 30ML

11.3 Disposables

Article no.	Article description
NIBP	
0-22-0003	Cuff pipe 5 meters
IBP	
3-10-0221	Adaptor for BIOSENSORS sensors
3-10-0225	Adaptor for EDWARDS sensors
3-10-0224	Adaptor for BECTON DICKINSON sensors
3-10-0226	Adaptor for ABBOTT/ICU sensors
3-10-0232	Adaptor for BBRAUN sensors
3-10-0230	Adaptor for SMITH sensors
W1412109	Adaptor for MEDEX Logical sensors
3-10-0235	Adaptor for PVB Xtrans sensors
Capnography	
0-32-0002	Calibration gas canister (Need 3-39-0076 as regulator)
0-32-0003	Calibration Gas with isoflurane anaesthetic agent (Need 3-39-0087 as regulator)
3-39-0076	Regulator for calibration gas canister (0-32-0002)
3-39-0087	Calibration Gas Regulator for Calibration Gas with isoflurane anaesthetic agent (0-32-0003)
General accessories	
4-15-0009	Mains cable, 2P+PE, 5 meters CEE type – Straight
77323	Mains cable, 2P+PE, 5 meters US Type HG (Hospital Grade)
4-15-0082	Mains cable, 2P+PE, 5 meters UK type straight
4-15-0067	Mains cable, 2P+PE, 5 meters Swiss/BR type straight
4-15-0032	Mains cable 5 meters EU
U32010	Mains cable, 2P+PE, 2 meters CEE type - Straight
72285	Mains cable, 2P+PE, 2 meters UK Type BS 1363/A (fused)
1-131-5581	MAGLINK
5-30-0023	Ethernet switch FO/RJ45 - 4 ports
5-30-0024	Wireless access point
Gating	
0-36-0003	Gating NG (Pulsed)
0-05-0078	Gating adaptor cable for Siemens
Printer	
0-80-0054	ETUI DE PROTECTION POUR ROULEAU PAPIER RT-1
2-99-0008	IMPRIMANTE BROTHER MAGLIFE RT-1
4-04-0015	ADAPTATEUR SECTEUR 15V IMPRIMANTE RT-1
4-07-0064	BATTERIE LI-ION IMPRIMANTE RT-1

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