VENTI*remote* alarm

Remote alarm case

LÖWENSTEIN
medical

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1 Introduction

1.1 Intended use

The VENTI*remote* alarm is for the remote transmission and display of acoustic and visual alarm signals issued by the approved devices. Respiratory physiology alarms and device faults can be monitored remotely using the VENTI*remote* alarm.

VENTI*remote* alarm is of particular assistance to nursing staff and relatives when looking after a ventilated patient in a domestic environment.

1.2 Description of function

VENTI*remote* alarm is connected to the device via a cable (10 m and 30 m long). If the device issues alarms, VENTI*remote* alarm converts these into visual and acoustic signals and outputs them. The device is powered by a 9 V battery pack (lithium).

1.3 Compatibility

The VENTI*remote* alarm can be used with the following devices:

• LUISA (LM150TD)

• prisma VENT series (WM110TD/WM120TD)
  (In combination with the prisma CHECK module)

• VENTI*logic* LS/VENTI*logic* plus series

2 Safety

Please read these instructions for use carefully. They are a constituent part of the device and must be available at all times. Only use the device for the intended purpose described (see "1.1 Intended use", page 4).

For your own safety and the safety of your patients, and in accordance with the requirements of (EU) Regulation 2017/745, observe the following instructions:

2.1 Safety information

Operating the device

Individuals may be injured if the product is damaged or its function is impaired.

⇒ Ensure that the VENTI*remote* alarm is free-standing and not covered up, otherwise alarm volume is reduced. This can lead to a risk to the patient and to damage to the device.

⇒ Ensure that the cable is connected correctly to prevent the connector being pulled out inadvertently and to ensure that the VENTI*remote* alarm works correctly.

⇒ If the VENTI*remote* alarm has been stored or transported outside the operating temperatures quoted in the instructions for use, the VENTI*remote* alarm should be started up only once the temperature of the device is within the permitted range for operation.

Electromagnetic compatibility

The product is subject to special precautions with regard to EMC (electromagnetic compatibility). If these precautions are not followed, the product may malfunction and individuals may be injured.

⇒ Maintain a safety distance between the VENTI*remote* alarm and equipment that emits HF radiation (e.g. cell phones), otherwise there may be malfunctions.

2.2 General information

- Always keep a fully-charged U9VL-BP-type battery to hand. Remove the battery if the VENTI*remote* alarm is being stored or not used for an extended period.

- To avoid infection or bacterial contamination, follow Section "5 Hygiene treatment", page 17.

- Have measures such as repairs, servicing, and maintenance work, as well as modifications to the product, carried out exclusively by the manufacturer or by specialists expressly so authorized by the manufacturer.

- The use of third-party articles may lead to incompatibility with the device. In such cases, please be aware that any claim under warranty and liability will be void if original spare parts are not used.

- In the EU: As a user and/or patient, you must report any serious incidents occurring in conjunction with the product to the manufacturer and to the responsible authority.

2.3 Safety information in these instructions

⚠ WARNING	Indicates an unusually significant hazardous situation. If you ignore this instruction, severe irreversible or fatal injuries may result.
⚠ CAUTION	Indicates a hazardous situation. If you ignore this instruction, mild or moderate injuries may result.
NOTICE	Indicates a harmful situation. If you ignore this instruction, material damage may result.
ⓘ	Indicates useful information within procedures.

3 Overview

3.1 Overview of remote alarm case
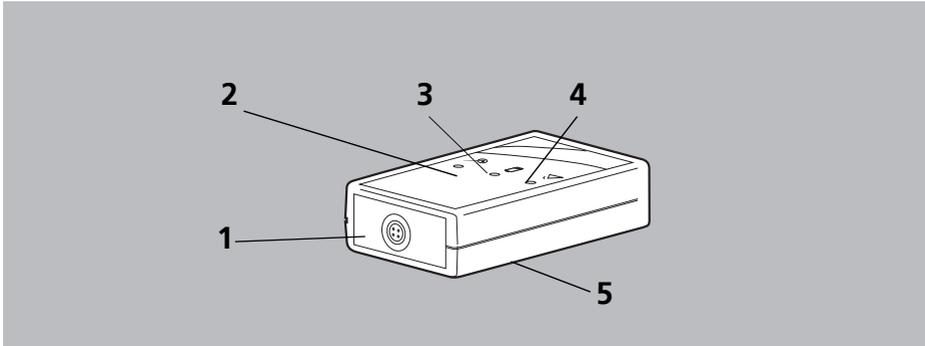
1 ODU socket
This is where the ODU connector (two white arrows) of the cable is connected to the VENTI*remote alarm*.

2 Stand-by indicator
This green LED indicates that the VENTI*remote alarm* is working correctly.

3 Battery indicator
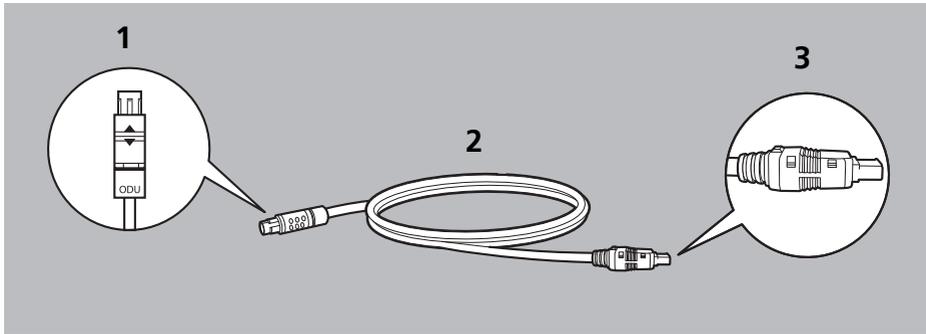If this yellow LED flashes, the battery needs changing.

4 Alarm indicator
In combination with the buzzer, this red LED indicates a therapy device alarm or a malfunction of the VENTI*remote alarm*.

5 Device ID plate (Rear)
Provides information about the device, such as serial number and year of manufacture.

3.1.1 Cable for LMT150TD

1 ODU connector
This connects the cable to the VENTI*remote alarm*.

2 Cable
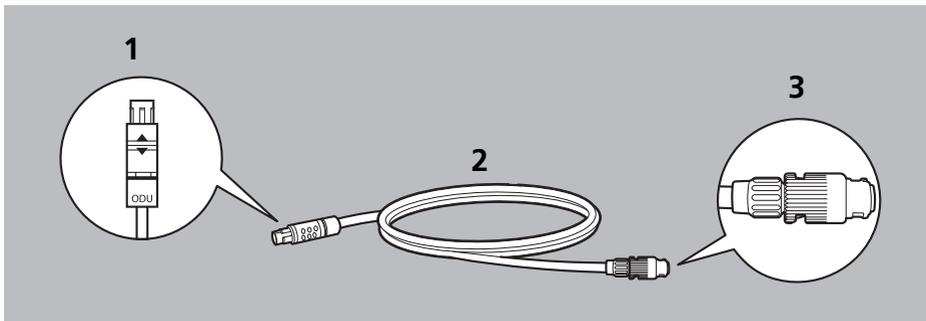This cable passes device alarms on to the VENTI*remote alarm*.

3 HRS connector
This connects the cable to the device.

3.1.2 Cable for VENTIlogic LS/VENTIlogic plus series, prisma CHECK

1 ODU connector
This connects the cable to the VENTI*remote alarm*.

2 Cable
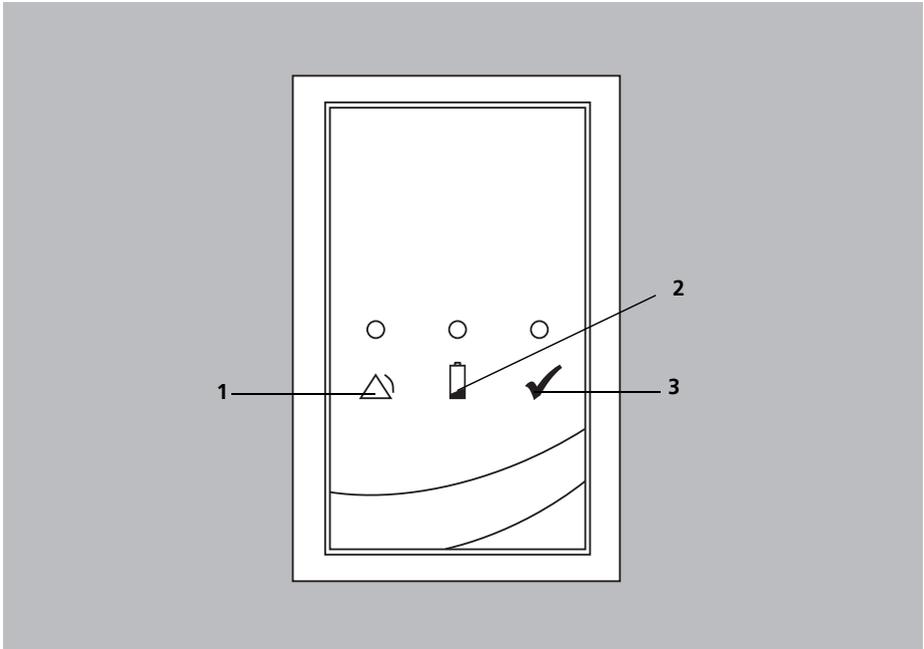This cable passes device alarms on to the VENTI*remote alarm*.

3 Bayonet connector
This connects the cable to the device.

3.2 Display film

	SYMBOL	MEANING
1	⚠	Red LED on: Alarm
2	🔋	Yellow LED flashing every six seconds: Battery almost dead
3	✔	Stand-by indicator: The green LED must light briefly every six seconds during operation.

4   Preparation and operation

4.1 Before operating for the first time

Before you can operate the VENTI*remote* alarm, you must insert the U9VL-BP-type battery included in the scope of delivery.
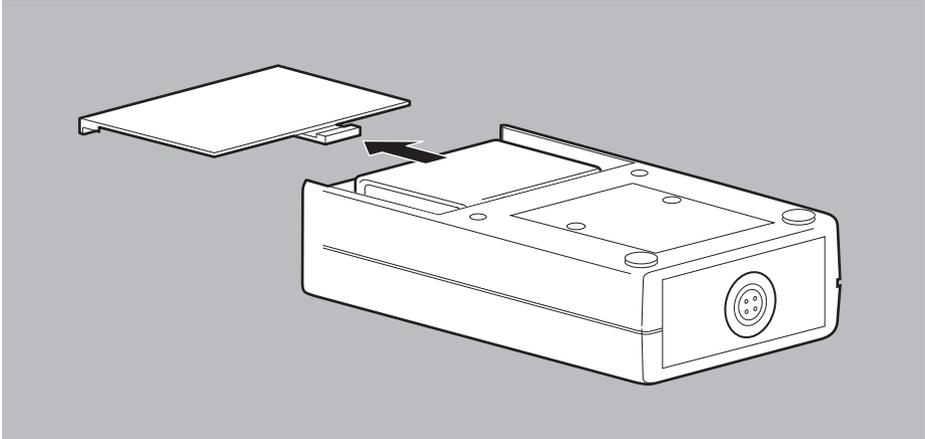
1. Open the battery compartment.
2. Connect the battery to the connecting cables.

LMT 66735a 04/2021
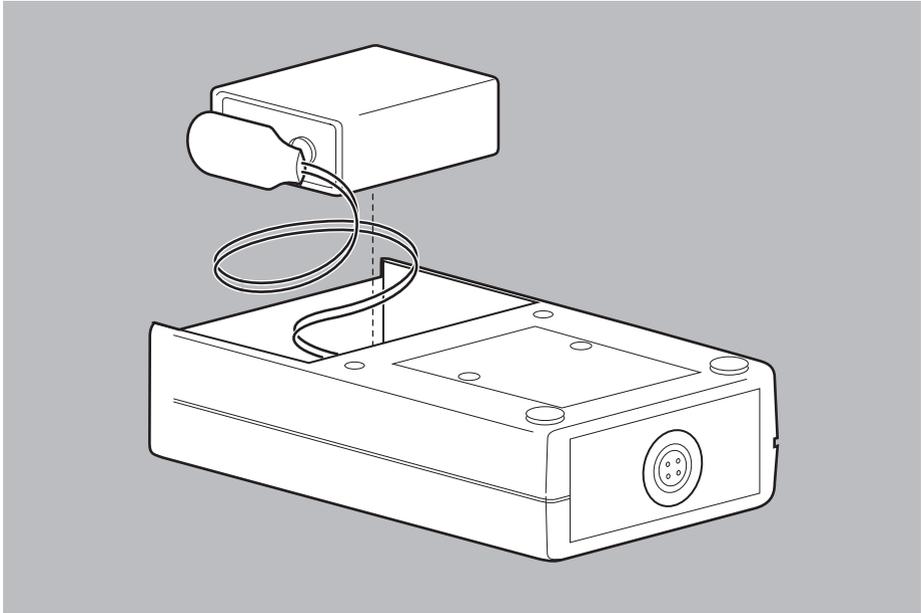
3. Put the battery and the connecting cables in the battery compartment.

NOTICE

Notice!
⇒ Ensure that the connecting cables are underneath the battery in the battery compartment, so that the connecting cables are not trapped when the battery compartment is closed.

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4. Push the battery compartment cover closed until it engages with an audible click.

The VENTI*remote* alarm is now ready for operation.

4.2 Setting up and connecting the device

1. Place the VENTI*remote* alarm on a level surface.

⚠ WARNING

Warning!
⇒ Ensure that the VENTI*remote* alarm is free-standing and not covered, otherwise alarm volume will be reduced. This can lead to a risk to the patient and to damage to the device.

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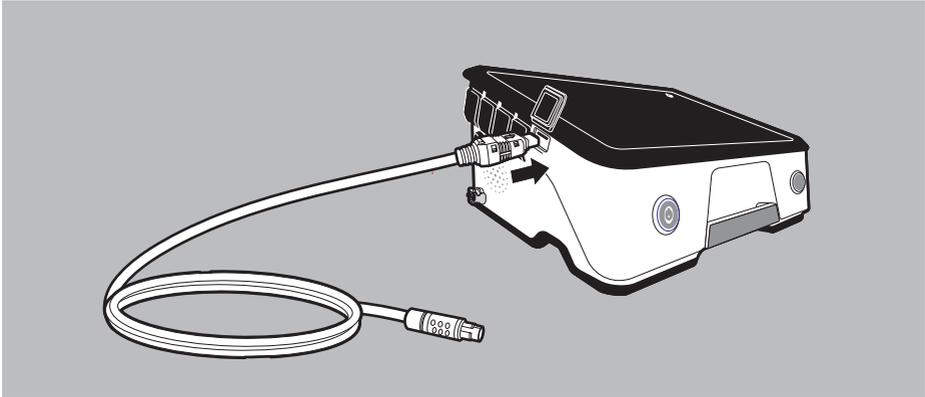
2. Connecting to LMT150TD: Connect the ODU connector to the remote alarm connection of the device.
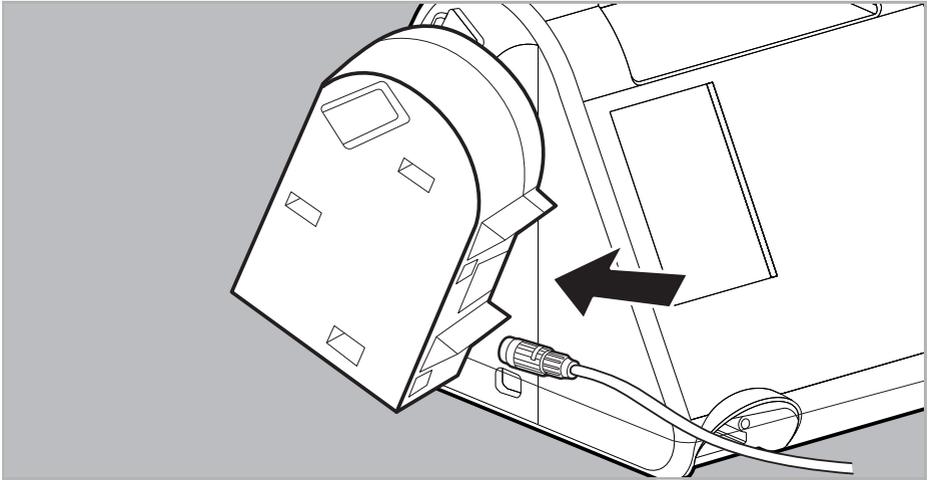
3. Connecting to prisma CHECK: Connect the bayonet connector to the remote alarm connection of the device.
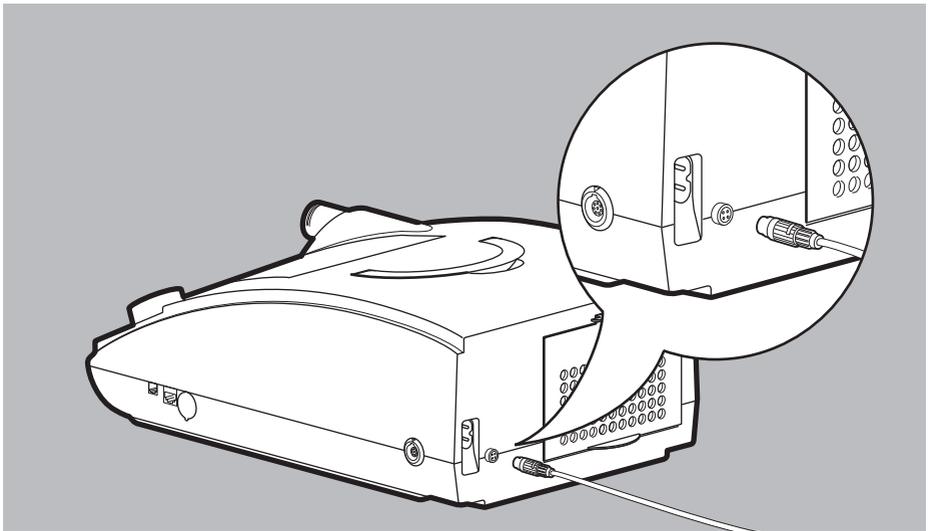
4. Connecting to VENTI*logic* LS/VENTI*logic* plus series: Connect the bayonet connector to the remote alarm connection of the device.
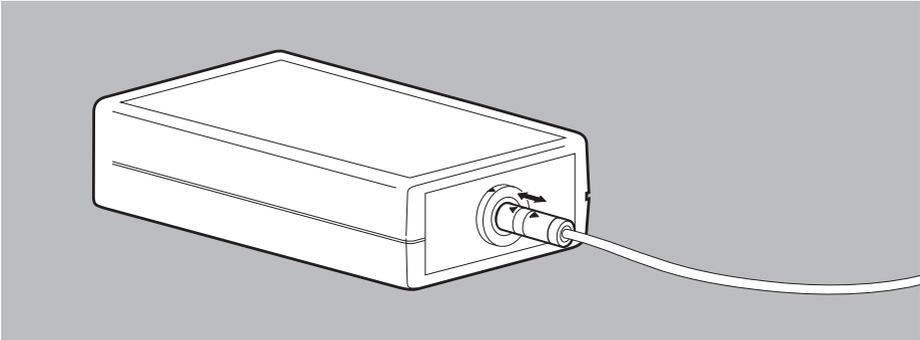
5. Connect the ODU connector (two white arrows) of the cable to the ODU socket of the VENTI*remote* alarm. To do so, turn the ODU connector so that the arrows on it and the arrow on the ODU socket are pointing at one another.

As soon as the ODU connector is connected to the VENTI*remote* alarm, the VENTI*remote* alarm automatically performs a function check.

NOTICE

Notice!
⇒ Ensure that the connector engages correctly in the socket.

4.3 Operation with the therapy device

4.3.1 Switching on the VENTI*remote* alarm

The VENTI*remote* alarm is switched on as soon as it is connected to the device by the cable. The stand-by indicator (green LED) on the VENTI*remote* alarm comes on briefly every six seconds during operation to indicate operational readiness.

4.3.2 Output of alarms

If an alarm is issued on the therapy device, the alarm indicator (red LED) of the VENTI*remote* alarm comes on permanently and a continuous acoustic signal sounds. All alarms of medium and high priority, together with the power failure alarm (low priority if the internal battery of the therapy device is charged), are passed on to the VENTI*remote* alarm. In combination with prisma CHECK, all alarms of all priorities are passed on. Look at the display of the therapy device to establish which alarm is involved. A precise description of the alarm can be found in the instructions for use for the therapy device. The alarm can be canceled by switching off/acknowledging the alarm on the therapy device.

4.3.3 **Switching off the VENTI*remote* alarm**

Switch off the VENTI*remote* alarm at the end of therapy by pulling out the ODU connector of the cable of the VENTI*remote* alarm.

4.4 **Changing the battery**

The VENTI*remote* alarm is operated with a battery of the U9VL-BP type. As soon as the battery indicator (yellow LED) comes on every six seconds and an acoustic alarm is issued every six seconds, the battery of the VENTI*remote* alarm must be replaced. To do so, proceed as follows:
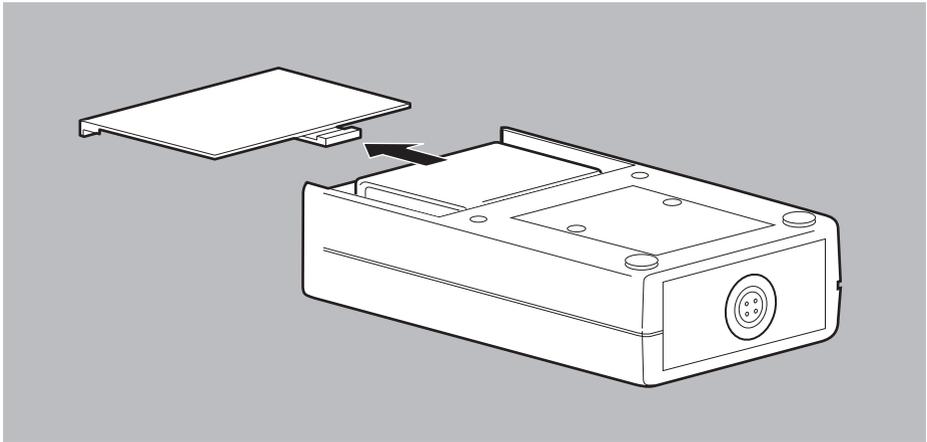
1. Open the battery compartment.

2. Disconnect the battery from the connecting cables.

3. Connect the new battery to the connecting cables.
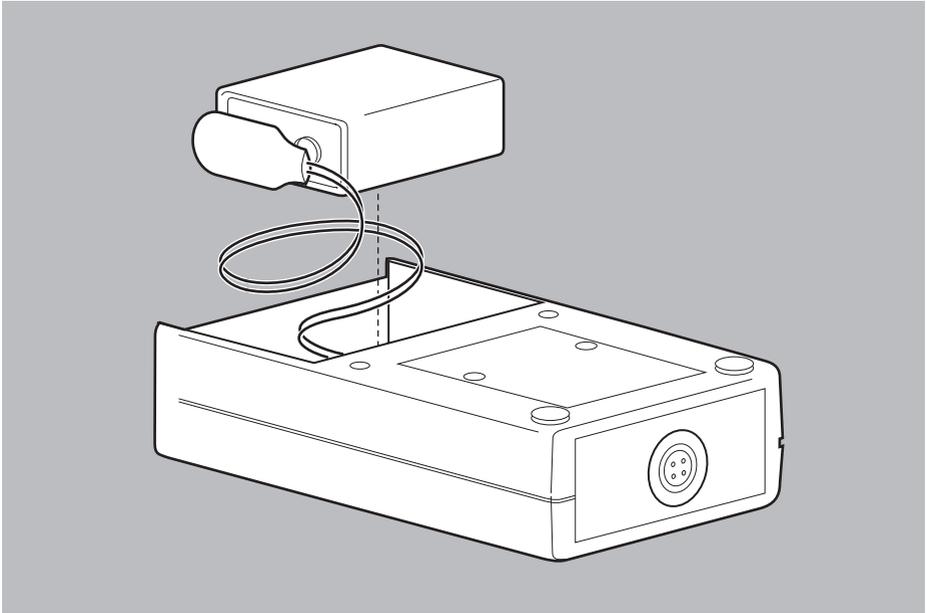
4. Put the battery and the connecting cables in the battery compartment.

NOTICE

Notice!
⇒ Ensure that the connecting cables are underneath the battery in the battery compartment, so that the connecting cables are not trapped when the battery compartment is closed.

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5. Push the battery compartment cover closed until it engages with an audible click.

5 Hygiene treatment

5.1 Cleaning

> **⚠ CAUTION**
>
> *Caution!*
> The VENTI*remote* alarm must be completely dry before being started up.

Wipe the VENTI*remote* alarm and the cable with a soft, damp cloth.

5.2 Disinfection

If required, e.g. following infectious diseases or unusual contamination, you can also disinfect the housing of the VENTI*remote* alarm and the cable. We recommend TERRALIN**®** for this purpose. See also the instructions for use for the disinfectant used. We recommend using suitable gloves (e.g. household or disposable gloves) when disinfecting.

5.3 Sterilization

Sterilization is not permitted.

5.4 Change of patient

On change of patient, disinfect the VENTI*remote* alarm .

6 Function check

As soon as the ODU connector is connected to the VENTI*remote* alarm, the VENTI*remote* alarm automatically performs a function check.

> **NOTICE**

Notice!
VENTI*remote* alarm starts the function check even if the connector is not yet fully engaged.

⇒ Ensure that the connector engages correctly in the socket.

If you find faults during the function check, you may not use the VENTI*remote* alarm.

Try to eliminate the fault (see "7 Troubleshooting", page 20). If this should prove impossible, have the VENTI*remote* alarm repaired by the manufacturer or by specialists expressly
authorized by the manufacturer.

A complete function check includes the following:

• Function check of the VENTI*remote* alarm (see "6.2.1 Function check of the VENTIremote alarm", page 18)

• Function check of the battery (see "6.2.2 Function check of the battery", page 19)

• Function check of the entire system (see "6.2.3 Function check of the entire system", page 19)

6.1 Intervals

Perform a function check daily and before the device is used each time.

6.2 Performing the function check

6.2.1 Function check of the VENTI*remote* alarm

To perform a function check, connect the cable to the VENTI*remote* alarm (see "4.2 Setting up and connecting the device", page 12).

> **NOTICE**

Notice!
If the cable is already connected to the VENTI*remote* alarm, briefly pull out the ODU connector and then reconnect it to the ODU socket.

VENTI*remote* alarm is working correctly if all three LEDs come on briefly at the same time and a short acoustic signal sounds.

6.2.2 **Function check of the battery**

To establish the charging state of the battery, proceed as follows:

1. Check the battery indicator:

- The charging state of the battery is OK if the battery indicator does not come on.

- If the battery indicator comes on every 6 seconds, the battery needs replacing.

2. Check the stand-by indicator:

- The charging state of the battery is OK if the stand-by indicator comes on every 6 seconds.

- If the stand-by indicator and the battery indicator do not come on every 6 seconds, the battery needs replacing.

6.2.3 **Function check of the entire system**

To check the connection between the VENTI*remote* alarm and the device, proceed as follows:

1. Connect the VENTI*remote* alarm to the device (see "4.2 Setting up and connecting the device", page 12).

2. Switch on the therapy device and then unplug it from the power supply.

The therapy device and thus also the VENTI*remote* alarm are working correctly if both now issue an alarm:

- VENTI*remote* alarm is working correctly if the alarm indicator (red LED) comes on continuously and a continuous acoustic signal sounds.

- The therapy device is working correctly if the yellow LED comes on and an acoustic signal sounds. The alarm window "No power supply voltage" appears in the display.

7 Troubleshooting

FAULT	CAUSE OF FAULT	REMEDY
VENTI*remote alarm* does not switch on	Battery discharged	Insert new battery
Buzzer and/or LEDs not working		
Battery indicator (yellow LED) flashes and buzzer sounds every 6 seconds		
Alarm indicator (red LED) on + acoustic alarm	Cable is damaged	Check cable for damage and replace if necessary
	HRS connector/bayonet connector not connected to the device	Check fit of HRS connector/ bayonet connector in device
	Alarm on therapy device	Check alarm on therapy device
Stand-by indicator (green LED) does not come on after 6 seconds	Battery discharged	Insert new battery
	ODU connector not correctly connected to VENTI*remote alarm*	Make sure ODU connector is engaged in ODU socket

8 Servicing

The VENTI*remote* alarm requires no servicing.

The device is designed for a service life of 6 years.

9 Transport and storage

Always transport and store the VENTI*remote* alarm dry. Remove the battery if the VENTI*remote* alarm is in storage or not being used for an extended period.

9.1 Disposal

Do not dispose of the device, nor of any batteries/battery packs, in domestic waste. To dispose of the device properly, contact a licensed, certified electronic waste disposal merchant. This address is available from your Environment Officer or from your local authority. The device packaging (cardboard and inserts) can be disposed of in paper recycling facilities.

10 Annex

10.1 Technical specifications

SPECIFICATION	Device
Product class to MDR (EU) 2017/ 745	I
Dimensions W x H x D in mm	60 x 25 x 96
Weight	250 g
Temperature range Operation Transport and storage	+5 °C to +40 °C −25 °C to +70 °C
Permitted humidity for operation, transport, and storage	Relative humidity 10 % to 95 %, no condensation
Signal volume	80 dB ± 4 dB(A) with a full battery at a distance of 1 m
Battery type	9 V lithium, U9VL-BP
Battery life	approx. 100 days at 1 min alarm a day
Classification to EN 60601-1:2006/A1:2013	Internal power supply 9 V
Standards applied	EN 60601-1-8:2007/A11:2017 There may be a delay of up to 2 seconds in passing on the call.

The right to make design modifications is reserved.

10.2 Safety distances

Recommended safety distances between portable HF telecommunication devices (e.g. cell phones) and the VENTI*remote alarm*			
Nominal power of the HF device **in W**	**Safety distance depending on transmission frequency** **in m**		
	150 KHz – 80 MHz	**80 MHz – 800 MHz**	**800 MHz – 2.5 GHz**
0.01	0.04	0.04	0.08
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.10	1.10	2.20
100	3.50	3.50	7.00

10.3 Markings and symbols

The following symbols may be applied to the device, the device ID plate, accessories or packaging.

SYMBOL	MEANING
SN	Serial number
	Manufacturer and date of manufacture
	Follow the instructions for use
	Do not dispose of the product in domestic waste
	Fragile. Do not throw or drop.
	Permitted temperature range for transport and storage
	Permitted humidity range for transport and storage

SYMBOL	MEANING
☂	Protect from moisture
REF	Order number
$C \epsilon$	CE symbol (confirms that the product conforms to the applicable European directives/regulations)
▭	Battery
MD	Indicates the product is a medical device
UDI	Unique device identifier

10.4 Standard scope of delivery

VENTI*remote* alarm, 10 m, packed, for LM150TD   **LMT 31560**

DESCRIPTION	ORDER NUMBER
VENTI*remote* alarm	WM 27764
Cable 10 m, VENTI*remote* alarm for LM150TD	LMT 31595
Battery, 9 V, lithium	WM 12166
Instructions for use for VENTI*remote* alarm	LMT 67735

VENTI*remote* alarm, 30 m, packed, for LM150TD   **LMT 31570**

DESCRIPTION	ORDER NUMBER
VENTI*remote* alarm	WM 27764
Cable 30 m, VENTI*remote* alarm for LM150TD	LMT 31596
Battery, 9 V, lithium	WM 12166
Instructions for use for VENTI*remote* alarm	LMT 67735

VENTI*remote* alarm, 10 m, packed, for WM110TD/ WM120TD, VENTI*logic* LS/VENTI*logic* plus series **WM 22745**

DESCRIPTION	ORDER NUMBER
VENTI*remote* alarm	WM 27764
Cable 10 m, VENTI*remote* alarm for WM110TD/WM120TD, VENTI*logic* LS/ VENTI*logic* plus series	WM 27789
Battery, 9 V, lithium	WM 12166
Instructions for use for VENTI*remote* alarm	LMT 67735

VENTIremote alarm, 30 m, packed, for WM110TD/ WM120TD, VENTI*logic* LS/VENTI*logic* plus series **WM 22755**

DESCRIPTION	ORDER NUMBER
VENTI*remote* alarm	WM 27764
Cable 30 m, VENTI*remote* alarm for WM110TD/WM120TD, VENTI*logic* LS/ VENTI*logic* plus series	WM 27758
Battery, 9 V, lithium	WM 12166
Instructions for use for VENTI*remote* alarm	LMT 67735

10.5 Accessories and spare parts

A current list of accessories and spare parts can be ordered on the manufacturer's website or through your authorized specialist dealer.

10.6 Warranty

Löwenstein Medical Technology gives the customer a limited manufacturer warranty on a new original Löwenstein Medical Technology product and on any spare part fitted by Löwenstein Medical Technology in accordance with the warranty conditions applicable to the product in question and in accordance with the warranty periods from date of purchase listed below. The warranty conditions are available on the manufacturer's website.
We will also send you the warranty conditions on request.
In the event of a claim under warranty, contact your specialist dealer.

PRODUCT	WARRANTY PERIODS
Devices including accessories (exception: masks) for sleep diagnosis, home ventilation, oxygen medicine and emergency medicine	2 years
Masks including accessories, rechargeable batteries, batteries (unless quoted differently in the technical documentation), sensors, patient circuits	6 months

PRODUCT	WARRANTY PERIODS
Disposable products	None

10.7 Declaration of Conformity

Löwenstein Medical Technology GmbH + Co. KG, Kronsaalsweg 40, 22525 Hamburg, Germany, the manufacturer of the devices described in these instructions for use, hereby declares that the product complies with the relevant regulations of the Medical Device Directive (EU) 2017/745. The unabridged text of the Declaration of Conformity can be found on the manufacturer's website.

CE

LMT 66735a

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