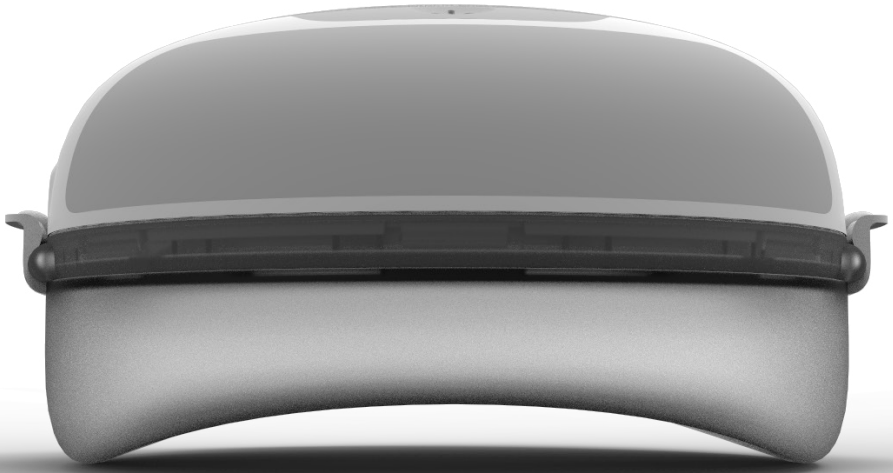
COMS® One

Instructions for Use

DE Gebrauchsanweisung
FR Mode d'emploi
IT Istruzioni per l'uso
ES Instrucciones de uso



Ref.: 01.0000

ASSISTANCE FOR LAY USERS / HILFE FÜR LAIENANWENDER ASSISTANCE POUR UTILISATEURS PROFANES / ASSISTENZA PER UTENTI COMUNI / AYUDA PARA USERIOS LEGOS

EN: Please read the entire instructions for use before trying to operate this device. If you have any questions about your COMS One system, please contact your healthcare professional at the number below:

DE: Bitte lesen Sie die Gebrauchsanweisung vollständig durch, bevor Sie dieses Gerät in Betrieb nehmen. Wenn Sie Fragen zu Ihrem COMS One System haben, wenden Sie sich bitte unter der untenstehenden Nummer an das medizinische Fachpersonal:

FR: Lire l'intégralité du mode d'emploi avant d'essayer d'utiliser ce dispositif médical. Pour toute question au sujet de votre système COMS One, veuillez vous adresser à votre professionnel de santé au numéro ci-dessous:

IT: Leggere l'intero manuale di istruzioni prima di provare a mettere in funzione il dispositivo. Per qualsiasi domanda sul sistema per la COMS One, contattare il proprio medico al seguente numero:

ES: Lea las instrucciones de uso en su totalidad antes de empezar a utilizar este dispositivo. Si tiene alguna pregunta sobre el sistema COMS One, póngase en contacto con su profesional sanitario en el siguiente número:

EN :Healthcare professional contact information / DE: Kontaktinformation medizinischen Fachpersonal
FR: oordonnées du professionnel de santé / IT: Dati di contatto del medico/
ES: Información de contacto del profesional sanitario

1. INTRODUCTION

The COMS One Therapy System for Combined Optical and Magnetic Stimulation, hereinafter called "COMS One", is approved exclusively for the use as specified in these Instructions for Use.

Please read the information and note that these Instructions for Use must be kept with the device.
The compact and portable COMS One offers simple and comfortable wound therapy. Its use of optical and magnetic stimulation is clinically proven to be effective in promoting wound healing.

Intended purpose/Indications (When to use the device)

The COMS One Therapy System is intended to promote wound healing by combined optical and magnetic stimulation, in addition to standard of care. Indications for the COMS One Therapy System are chronic leg and foot ulcers.

Contraindications (When *not* to use the device)

- Active skin cancer, history of skin cancer or any other localized cancer, precancerous lesions or large moles in the areas to be treated
- Pregnancy

Intended User Population

The COMS One should only be operated by properly instructed adults. Lay users including patients shall only use the device upon instruction by a professional. All users shall not be hard of hearing or deaf, must have adequate visual faculty and shall be comfortable with the use of electronic devices.

Intended patient population

The COMS One is intended to be used on patients only exhibiting conditions as described in the indications for use.

Intended Use Settings

The COMS One system is intended for use in professional healthcare and home care settings.

2. WARNING AND SAFETY INSTRUCTION

⚠ WARNING

- *Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.*

⚠ CAUTION

- *Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.*

Safety related tip

- *Indicating useful information about the safe use of the device*

The COMS One is intended for use as described in these Instructions for Use.

Piomic only takes responsibility for the effect on safety, reliability and performance of the COMS One if it is used in accordance with the Instructions for Use.
Please read and observe these cautions and safety instructions before operation. Note that these Instructions for Use are a general guide for the use of the product. Medical situations must be addressed by a physician.

These Instructions for Use must be kept with the device.

⚠ WARNING

- *Pacemaker operation may be adversely affected by exposure to pulsed electromagnetic fields. Physicians should not prescribe a therapy in case the treatment is in close proximity to the pacemaker in order to prevent malfunctioning of the pacemakers.*
- *Do not re-use articles labelled "single-use" in order to prevent from infections and cross-contaminations.*
- *Do not use consumable when the sterile packaging is damaged or has expired. Using unsterile consumables can lead to infections.*
- *Unplug the device before cleaning and disinfection. It may result in electric shock if the device is plugged in*

during cleaning and disinfection.

- *Do not clean, disinfect or perform other service and maintenance tasks during use of the device.*
- *Do not apply the device while it is charging. Non-observance can lead to electric shocks.*
- *Do only use the original power supply certificated with IEC 62368 -1 and USB cable for charging. Using other power supplies or cables may result in electric shock or electromagnetic interference that prevents the device or other devices from operating properly.*
- *Store the system out of the reach of children and babies to minimize the risk of strangulation from cables and straps*
- *The strap is not sterile. Cover other wounds in proximity of the strap before fixating the strap in order to prevent infections.*
- *Do not open or modify the device. Non-observance can lead to electric shocks.*

⚠ **CAUTION**

- *Do not immerse the device directly in water or other liquids (not suitable for use while bathing, showering) and do not use in a hazardous explosive environment. Non-observance can lead to electric shocks.*
- *Do not use accessories other than those specified or sold by Piomic in order to ensure therapeutic performance.*
- *Fix the strap carefully to ensure no pressure oedemas are created.*
- *Do not use any damaged parts in order to ensure therapeutic performance.*
- *Do not apply device more than once within 12 hours on the same location to prevent overstimulation of the tissue.*
- *Do not apply device in case of known allergies to incorporated surface materials (Silicone, Elastan, PolyAmid, Polypropylen, Synthetic Rubber) to prevent allergic reactions.*
- *Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.*
- *Do not use the device if you use photosensitizing agents / medications in order to prevent from photo-allergic*

reactions.

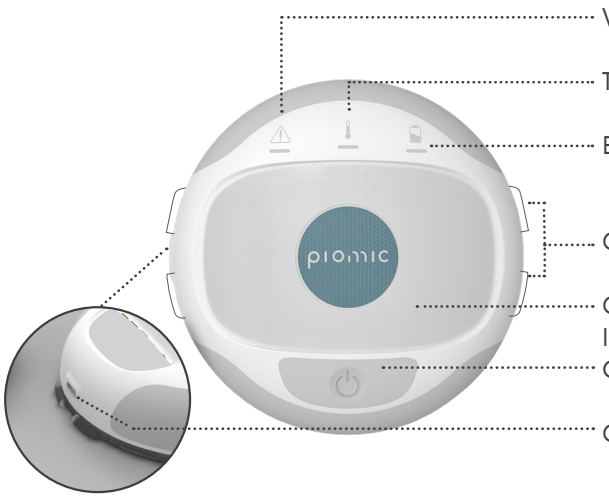
- *Do not look directly into the light source on the bottom of the device. It may result in eye injuries.*
- *Do not operate HF (high-frequency) surgical equipment in combination with the device. It can influence the operation of the device.*
- *Do not use the device if it is closer than 30 cm (12 inches) to wireless communications equipment, such as wireless home network routers, mobile phones, cordless telephones and their base stations. This can prevent the device from working properly.*
- *Do not use the device adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.*

Safety related tip

- *Do not dry the device with a microwave in order to prevent from device damage.*
- *Do only use cleaning and disinfection agents as described in the section "Cleaning and Disinfection" to prevent device damage*
- *Do not use the device in proximity to an MRI (Magnetic Resonance Imaging) scanner. Non-observance can lead to considerable danger.*

3. MAIN ELEMENTS OF THE SYSTEM

COMS One (Ref. 01.0000)



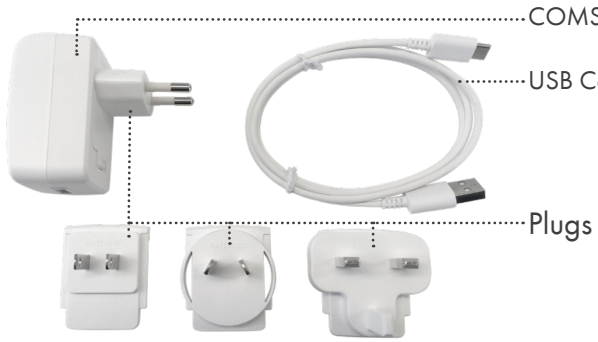
COMStouch (Single Use/Applied Part /Ref. 01.0001)

STERILE EO

COMSfix (Single Use/Ref. 01.0002)

COMSrefix (Single Patient Use/Ref. 01.0004)

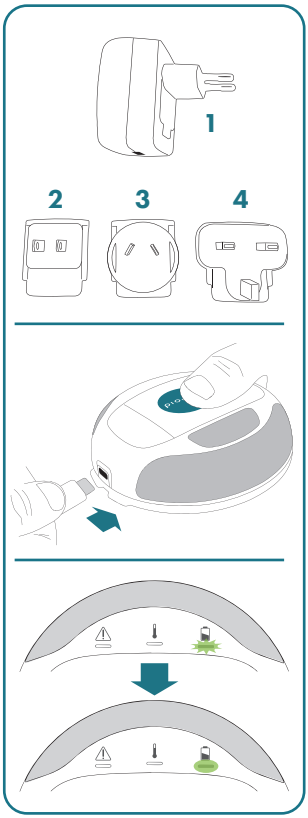
Charger (Ref. S008ACM0500200)



Upon delivery, check the COMS One system for completeness and general condition.

The COMS One system was verified in combination with the accessories listed above. For correct and safe operation use the COMS One with Piomic accessories only.

4. BATTERY CHARGING



The charger has not been IP tested. Please charge device at a dry location.
The USB cable can only be used for charging COMS One with the charger and COMS One shall not be connected to computers or other devices with the USB-cable.

1. Select plug matching your wall outlet and attach it to the charger (initial use only).

⚠ CAUTION

- *Do not apply the device while it is charging. Non-observance can lead to electric shocks.*
- *Do only use the original power supply certificated with IEC 62368-1 and USB cable for charging. Using other power supplies or cables may result in electric shock or electromagnetic interference that prevents the device or other devices from operating properly.*

2. Plug the charger into a wall outlet and attach the USB cable to the COMS One power supply and the COMS One.

3. The battery indicator will indicate charging. During charging the light below the battery symbol will be blinking green. When the battery is fully charged the battery indicator will stop blinking and indicate battery full with a solid green light.

It takes approximately 2 hours to fully charge the device. When the device is fully charged, it has enough power for at least 6 treatments. The battery has an expected lifetime of 3 years. After 3 years of intensive usage, it may no longer be sufficient for 6 treatments with one charge.

Remove the charger from the wall socket and pull the USB plug out of the USB socket to disconnect device from the mains supply.
Therefore charger and device must be placed easily accessible. Let the device rest 5 minutes after charging.

5. THERAPY DURATION AND REPETITION

The COMS One offers a non-invasive and non-toxic therapeutic approach to promote wound healing. The system combines the technologies of pulsed electro-magnetic fields and photon emission applied locally to the wound area.
A therapy takes **16 minutes**. In order to reach the scientifically proven promotion of wound healing the therapy shall be performed **2-3 times per week** and be **repeated over the course of two months**.

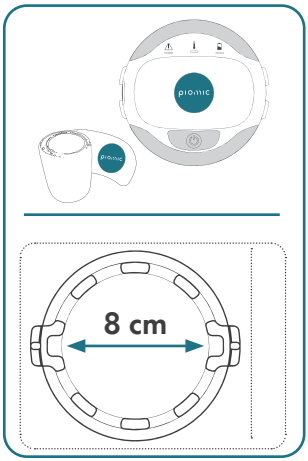
⚠ **CAUTION**

- *Do not apply device more than once within 12 hours on the same location to prevent overstimulation of the tissue.*

Temporary increased exudate production and modified pain perception cannot generally be excluded for this therapy.

Applicable accompanying wound care measures such as inflammation control, pain and exudate management, moisture control and removal of wound debris must be addressed.

6. THERAPY

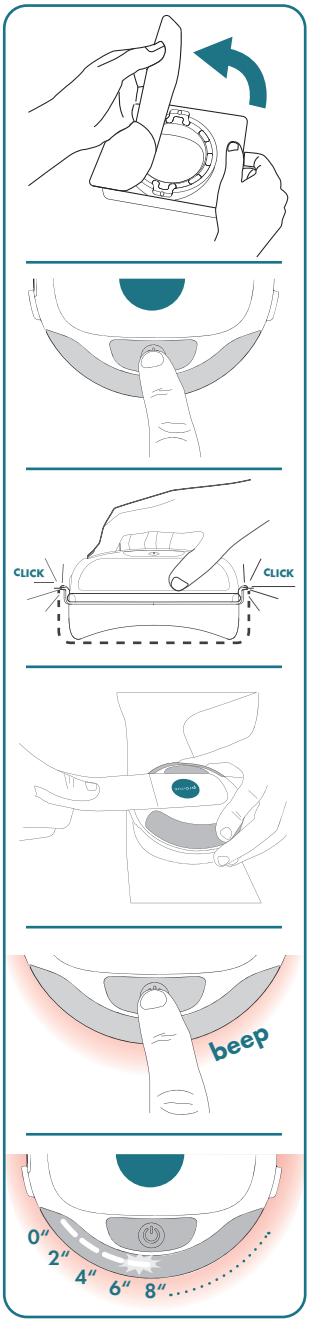


1. Open the COMSfix packaging and place strap within reach of the device.

2. Take a packaged COMStouch and check that maximal wound size is within the diameter of the COMStouch.

⚠ **WARNING**

- *Do not use the COMStouch if the sterile packaging is damaged or has expired.*



3. Carefully open the sterile packaging without touching the COMStouch.

⚠ WARNING

- *The COMStouch is for single-use only and cannot be reused.*

4. Take the device and press the On/Off – Button for longer than 3 seconds to switch the device on.
The device will then do a Power On Self Test. After the test the device will go into Standby Mode. In Standby Mode the battery indicator will show if the battery charge level is sufficient for a full therapy (green, proceed with next step) or insufficient (red, go to chapter "Battery Charging").

5. Take the COMS One and mount it to the COMStouch.
The proper fixation of the COMStouch to the COMS One will be indicated by a click-in noise.

6. Carefully mount the device with the attached consumable to the patient using the strap (Loops shall face towards the device / Logo on Logo).

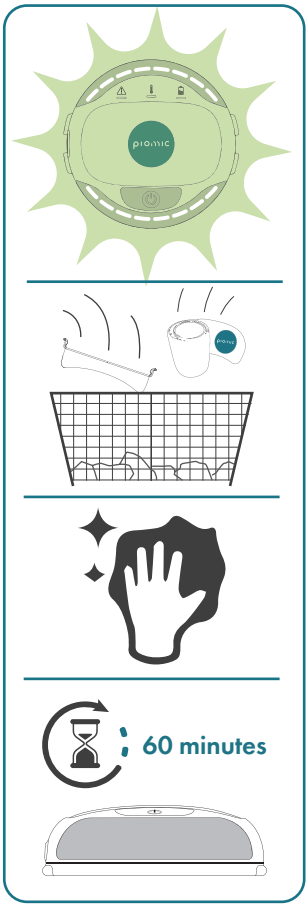
⚠ CAUTION

- *Fix the strap carefully to ensure no pressure oedemas are created.*

7. Press On/Off-Button (<1s) to start the therapy
(you will hear a single beep and a red shining on the bottom side of the device)

   To pause therapy, press On/Off-Button anytime (<1s).

8. The therapy progress is indicated by the blinking progress bars. Each one representing 2 minutes elapsed time.



9. Therapy has been completed.
(You will hear 3x beep-sound).

Turn device off by pressing the On/Off button for longer than 3 seconds.

10. Carefully remove the strap (COMSfix/COMSrefix)and COMS One from patient and dispose the single-use material (COMStouch & COMSfix).

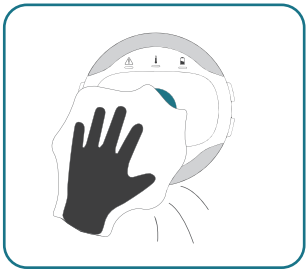
11. Clean and disinfect device before using it on next patient (see next chapter).

12. Let the device rest before the next use (60min). This prevents heating of the device at high ambient temperatures and allows the disinfectant to act optimally.

⚠ CAUTION

- *Do not apply device more than once within 12 hours on the same location to prevent overstimulation of the tissue.*

7. CLEANING AND DISINFECTION



⚠ WARNING

- *Unplug the device before cleaning and disinfection.*
- *Do not clean, disinfect or perform other service and maintenance tasks during use of the device.*

The COMS One device is reusable. Thorough cleaning and disinfection between use on different patients is important.

1. Cleaning: Wipe off with a clean, damp cloth (water or non-abrasive detergent).

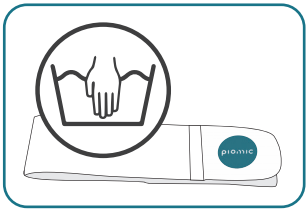
2. Disinfection: Disinfect with wipes from the disinfecting agent group «alcohol»: E.g. CaviWipes™ (Metrex Research, LLC) or Mikrozid® AF (Schülke & Mayr GmbH).

⚠ CAUTION

- *Do not immerse the device directly in water or other liquids*

Safety related tip

- *Do not dry the device with a microwave*
- *Do only use cleaning and disinfection agents as described above.*



The strap COMSrefix is single patient use and may be cleaned by hand with non-abrasive, standard hand wash detergents. Air-dry, do not tumble dry or iron.
Store the system in a way that only authorized persons have access for usage.

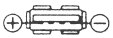
8. STATUS INDICATIONS & TROUBLESHOOTING

Indicator	Definition	Troubleshooting	Remarks
	Battery good	n.a.	Blinking during charging until full (change to static green)
	Battery low	Charge now or after next therapy	At least one more therapy is possible but charging is recommended
	Battery empty	Charge now	Charge before next therapy (Charging for one therapy takes around 16 min)
	Device overheated	Cool device before use	Let device cool down before next therapy. Best to use another device
	Device error	Switch the device off and turn it back on.	If the error persists, contact Piomic Customer Service

Problem	Possible Cause	Troubleshooting
The charger becomes warm during charging	This is normal	No action required
The Battery indicator does not flash green while charging	The charger is not inserted properly into the wall outlet	Plug the charger into a wall outlet properly
"	The USB plug is not inserted properly into the charger	Insert the standard USB plug into the charger properly
"	The wall socket is not live	Check the wall socket with another appliance. If the wall socket is live but the COMS One does not charge please contact Piomic Customer Service
The COMS One becomes warm during use	This is normal	No action required
The COMS One does not react to button press	Battery is very empty	Please charge the device and try again. If the error persists, contact Piomic Customer Service
Only 4 light sources are emitting red light on the bottom side of the device	This is normal. The other 4 light sources emit light invisible to the human eye	No action required. ⚠ **CAUTION:** *Do not look directly into the light source on the bottom of the device. It may result in eye injuries*

9. SIGNS & SYMBOLS

	This symbol indicates a safety related tip.		To identify the battery condition.
	This symbol indicates a general warning.		This symbol indicates temperature or function associated with temperature.
	This symbol indicates standby (located on On/Off button).		This symbol indicates to follow the Instructions for Use.
	This symbol indicates the date of manufacture.		This symbol indicates that the device should not be used after the date shown.
	This symbol indicates the name and the address of the manufacturer.		This symbol indicates to not use the device if package is damaged.
	This symbol indicates the device is sterilized using ethylene oxide.		This symbol indicates the number of items (1 pcs in this case).
	This symbol indicates a prescription device. CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician (for US only).		This symbol indicates a single use device. Do not reuse the device.
	This symbol indicates a type BF applied part.		This symbol indicates the temperature limitation for operation, transport and storage.
	This symbol indicates manufacturer's catalogue number.		This symbol indicates the atmospheric pressure limitation for operation, transport and storage.
	This symbol indicates manufacturer's serial number.		This symbol indicates the humidity limitation for operation, transport and storage.
	This symbol indicates manufacturer's batch code.		This symbol indicates MR unsafe.

	This symbol indicates to handle the fragile device with care.		This symbol indicates the correct upright position of the transport package.
	This symbol indicates to keep the device dry.	CE 1250	This symbol indicates that the device is in conformance with the Medical Device Directive 93/42/EEC.
	This symbol indicates to keep the device away from sunlight.		This symbol indicates a general warning. Refer to chapter 2 warning and safety instructions.
IP22	This simboly indicates the device is protected against ingress of solids larger than 12.5 mm and dripping water.		This symbol indicates that the marked item or its material is part of a recovery or recycling process.
	This symbol indicates to not dispose the device together with household refuse (for EU only).		This symbol indicates the direct current socket.
	This symbol indicates that the mains adapter is a class II device.		This symbol indicates alternating current.
	This symbol indicates that the mains adapter is for indoor use only.	CE	This CE-mark indicates compliance with the low voltage and electromagnetic compatibility directive.
	This symbol indicates the compliance with AUS/NZ regulatory requirements		This symbol indicates polarity of d.c. power connector.
 115V for US	This symbol indicates the compliance with energy efficiency requirements.	c UL us LISTED	This symbol indicates the compliance with USA and Canada safety requirements.

10. TECHNICAL SPECIFICATIONS (INCL. WARRANTY AND MAINTENANCE)

The COMS One is certified as medical non-laser light source equipment. While in operation it generates light in the red and near-infrared spectrum around 660 nm and 830 nm. On the bottom of the device there are four emission apertures for 660 nm LEDs and 830 nm each.

Device	Ref. 01.0000
Optical output classification	Exempt Group according to IEC 62471:2006. Meaning safe under reasonably foreseeable conditions.
Power Density	**Pulse Peak Power:** 25 mW/cm²; **Duty cycle:** ≈20%; **Average Power:** 5 mW/cm² The local variation across the treatment area between maximum and minimum power density is < factor 2.5
Maximum treatment dose	5 J/cm²
Pulse Specifications	Maximum pulse width of 0.3 ms at a repetition rate of 1 KHz for 16 min treatment.
Maximum Spectral Irradiance	660nm: 5.5 mW/(m² nm) 830nm: 2.2 mW/(m² nm)

Specifications			
kg	265 g without Accessories	+30 +5 C° 1060 700 hPa 90 15	Operating Conditions
H x W x D	113 x 110 x 37 mm	+50 -20 C° 95 20 1060 700 hPa	Transport/Storage Conditions (also applicable between uses)
§	Medical Device Class IIa		**Power Supply** Model S008ACM0500200 **Input:** 100-240 VAC, 50/60 Hz 300 mA **Output:** 5.0 VDC 2.0 A
	Device: [VDC] 5 [W] 7.5 IP 22		**Battery (Lithium-Ion)** 3.7 VDC Rated Capacity 3000 mAh

Materials	
COMS One Housing	Acrylnitril-Butadien-Styrol-Copolymer (ABS), Methylmethacrylate Acrylnitril-Butadien-Styrol (MABS), Thermoplastic Elastomer (TPE)
COMStouch	Silicone, Polybutylenterephthalat (PBT) **Sterilization Method:** Ethylene Oxide (EO)
COMSfix / COMSrefix	Polyamid (PA), Elastan, Polypropylen (PP), Synthetic Rubber

Warranty

The warranty period for the COMS One is 3 years, if used in accordance with the Instructions for Use. The manufacturer is not liable for any damage or consequential damage caused by incorrect operation, inappropriate usage or unauthorized persons using the device. The warranty does not cover wear and tear.

Maintenance

The COMS One is maintenance free and will not require service. If the device fails within the warranty period due to a manufacturing defect, the device will be replaced.
The original device will need to be returned to the supplier.
The battery cannot be removed.

The expected service life of the device is 5 years.

Safety-related checks

The COMS One is a Class II electrical appliance. The safety-related checks are confined to visual inspection of the device and power supply for damage. These checks must be performed prior to each use.

Class II electrical appliances do not have a protective earth conductor. There is no need to check the earth leakage current.

The COMS One device enclosures are made entirely of electrically insulating material. Tests of the enclosure leakage

current using common measuring instruments will therefore not reveal measurable values.

The device does not have patient circuits or functional earth connections.

Storage to therapy time

Note that if you store the product at very low temperature (below +5 degree of Celsius) or very high temperature (>30 degree Celsius) it may take up to 30 minutes to reach operating temperature.

Disposal

COMS One comprises metals and plastics and should be disposed of in accordance with the European directives 2011/65/EU and 2012/19/EU. The electronic components must be disposed of separately, in accordance with the local regulations. This product contains a lithium-ion battery which bear risk of fire, explosion and burns, if disposed of improperly. Please take care that you dispose of COMS One and its accessories in accordance with the local regulations and applicable disposal guidelines.

Do not throw away the device with the normal household waste at the end of its life, but hand it in at an official collection point for recycling. By doing this, you help to preserve the environment. This symbol is only valid in the European Union. Please respect the relevant state laws and rules in your country for the disposal of electrical and electronic equip-

Manufacturer's legal address
Piomic Medical AG
Reitergasse 6
8004 Zürich
Switzerland
www.piomic.com
Tel.: +41 44 244 19 70

Please contact the manufacturer in case you encounter or detect any abnormalities with the device.