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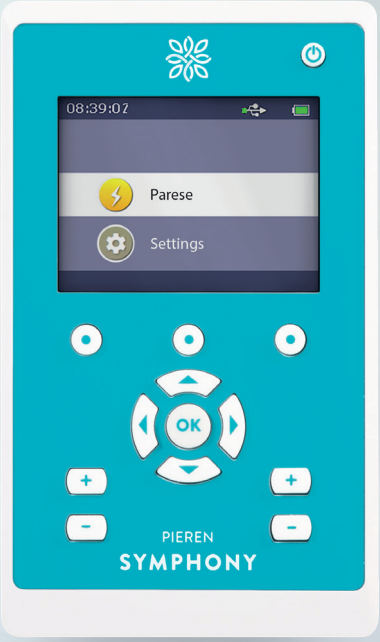


PIERENSYMPHONY P

2-channel electrostimulation device for paresis treatment

EN Instructions for use REF 10007405 Version 01 Last updated: 2022-12-08

Contents

1. General

NOTE: In these instructions for use, **"patient"** means a person (both male, female and diverse) on whom the PIERENSYMPHONY P is used, even if the device is operated by someone other than the patient. The term **"user"** means the person operating the device. If the product is used independently, "patient" and "user" are one and the same person.

1.1 PIERENSYMPHONY P Intended purpose

PIERENSYMPHONY P is intended for transcutaneous electrical muscle stimulation for peripheral paresis in humans. The PIERENSYMPHONY P triggers contractions for partially or fully denervated muscle, helping to preserve it and its associated tissues and structures such as tendons, ligaments and joints, or restore it in the event of atrophy and regression. Muscle stimulation also promotes blood circulation in the stimulated areas. Stimulation can help prevent pressure ulcers in the stimulated areas.

The PIERENSYMPHONY P works with medical programs designed for use by or under the guidance of therapists as they require medical expertise.

Treatment with the PIERENSYMPHONY P can be administered several times a day and as long-term use. Treatment can be carried out in a clinical and home environment.

Before the first use, the patient must be trained by a doctor or therapist.

The PIERENSYMPHONY P can be used to treat anyone who is mentally and physically capable of positioning the electrodes and adjusting the current strength, taking into account the contraindications, or who are capable of expressing pain or want to modify or end treatment in the event of non-independent treatment.

Prior to treatment with the PIERENSYMPHONY P, the instructions for use, in particular safety information, warnings, contraindications and side effects, must be checked.

1.1.1 Indications

The spectrum of indications of the Pierensymphony P includes incomplete and complete peripheral, flaccid paresis. This includes traumatic and atraumatic paresis, e.g.

» post-traumatic, post-operative, post-infectious

» with plexus lesions

» with nerve root lesions, e.g. after herniated discs

» with cauda equina syndrome

» with polyneuropathy

1.2 Safety precautions

Please read the instructions for use carefully prior to using the product! Keep for future reference!

1 **Caution: Consult a physician** before applying electrodes over or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.
Warning: Application of electrodes near the thorax may increase the risk of cardiac fibrillation. In case of electrode placement in the thorax area, intensive high frequency stimulation (above approx. 15 Hz) may lead to respiratory disorders during stimulation.

2 **Warning:** It is not allowed to use the product during operating machines or during operations which require elevated concentration. Especially don't use it while using a vehicle!
The stimulation in the face (trigeminal nerve stimulation) can lead to sleepiness. That's why you should continue the above-mentioned activities only if you don't feel sleepy anymore. For an optimal security you should stimulate in the face only while sitting or lying.

3 **Never use the product if it functions incorrectly or has been damaged.** If, contrary to expectations, malfunctions occur, please contact our service team or your dealer. **Technical checks and repairs may only be performed by qualified and authorised persons** in order to keep the safety and warranty (addresses can be found on the last page of the instructions for use).
Caution: If the product is modified, appropriate examinations and tests must be carried out to ensure continued safe use. Otherwise, it leads to the loss of any guaranty and warranty.

4 **The product may only be used with original accessories.** The use of other accessories (especially of electrodes with a smaller surface than 2 cm^2) may lead to a deficient operation. The electrodes in the delivery amount can be used without worries.

5 **Keep the product away from water and other liquids** as this may cause uncontrolled current flows, electric shocks and damage to the product.

6 **Caution:** Simultaneous connection of a patient to a high frequency surgical ME (medical electrical) equipment may lead to burns beneath the electrodes and it may damage the product.

7 **Caution:** Operation in the vicinity (e.g. 1m) of a short wave or microwave ME device for shortwave or microwave therapy may cause fluctuations in the output value of the product which may turn into painful results.

8 **Caution:** Keep a distance of min. 30 cm (12 inches) between the parts and the wires of this product and a high frequency communication device (mobile phone or a radio device including their accessories such as antenna cable or external antenna). Non-observance may result in a reduction of the device's performance characteristics and a deficient operation.

9 **Caution:** Do not use this device next to or stacked with other devices, as this may result in deficient operation. If, however, use in the manner described above is still necessary, this device and the other devices should be observed to ensure that they are working properly.

10 **Do not allow the product to be dropped and handled incorrectly.** Only use at temperatures between 5 °C and 35 °C, at a relative humidity between 30 % and 75 % and a pressure between 70 kPA and 106 kPA. So do not use the product e.g. in bathroom or similar humid environments.

Warning: Do not operate the device in the vicinity of explosive and/or flammable substances or steam!

Caution: If you expose this device to sudden temperature changes from cold to warm, do not turn on the device until it reaches the same temperature as the environment in which it will be used; wait at least 30 minutes. Otherwise, condensation inside the unit may result in electric shocks, fire, and damage to the device and/or personal injuries.

11 Care must be taken when the product is used on or in the proximity of children. Store the product and its packaging **out of reach for children**. **Danger of strangulation** with the cables and wires of the device and/or its accessories!

12 Placing of the electrodes:

a. The TENS device may only be connected to just 1 patient.

b. Before applying the electrodes, clean the skin surface on which the electrodes are to be attached. Otherwise incorrect operation cannot be excluded.

c. Take care that **metallic objects** (e.g. jewellery or piercings) **do not get in contact with the electrodes during the stimulation** because otherwise isolated skin burns may appear.

d. Tattoo colours may consist of metallic pigments which – in cooperation with the current flow - can lead in rare cases to too high current densities and skin damages. If possible, the stimulation should not take place in body areas with tattoos. If that is not possible, the stimulation should be carried out with raised attention and should be immediately stopped in case of an emergency.

e. Any electrodes with current densities exceeding 2 mA/cm² may require the special attention of the operator as it may lead to painful results. The electrodes in the delivery amount can be used without worries.

f. **Caution:** Attach the electrodes to the skin so that the electrode surface has even and complete skin contact. **Additionally** make sure that the electrodes are placed at least 2 cm apart from each other. Otherwise, high current densities may occur at certain points on the skin, resulting in painful skin lesions.

g. **Special caution** is required for patients with metallic implants who have **sensory loss** in the area of the metal. The sensory loss can tempt to a raised setting of the stimulation intensity; this could lead to skin irritations, flush and pain in the area of the metal. In this case the stimulation has to be stopped at once.

13 Store the product in the original packaging after use to protect it against damage and soiling.

14 In the case of commercial use in Germany, the operator is obligated to carry out technical safety controls for the product in regular and appropriate periods of time according to § 11 MPBetreibV. The manufacturer recommends to carry out technical safety controls for the product at intervals of at least 24 months.
Please observe the applicable legal regulations of your country.

15 **Caution!** Please also consider the instructions for use, especially the safety instructions, of the electrodes you use.

16 **General warnings about muscle stimulation**
During every muscle load, enzymes (e.g. creatine kinase) and proteins (e.g. myoglobulin) are released.
Warning: In the case of heavy muscular load, but also due to genetic factors or in combination with various

medicines or drugs, it can lead in certain people to severe muscle breakdown (rhabdomyolysis). The amount of enzymes and proteins released and electrolyte shifts can also damage internal organs such as the kidneys, liver and heart. This danger also exists with electrical muscle stimulation, because it can be a form of intensive muscle training. The muscles can quickly reach their load limit, especially during the first training sessions. This is associated with the risk of muscular overload, which can occur even in trained patients.

Muscular overload can manifest itself during training through discomfort, circulatory reactions, muscle pain and other complaints. The most common consequence of overload is pain in the muscles after training. Pain and irritation in tissues connected to the muscles, such as ligaments, tendons, joints and bones, are also possible.

The overloading of the musculature by electrical muscular stimulation occurs especially during the first training units. Within a regular training session, the musculature usually adapts to the to the load and the release of muscle enzymes and muscle proteins decreases significantly.

1.3 General contraindications

On whom should the PIERENSYMPHONY P not be used or only used after consultation with the doctor?

» Central and spastic pareses
» Patients with metallic implants in the area of current flow
» »Patients with electronic implants such as pacemakers or pumps in the area of current flow
» Patients with cardiac arrhythmia
» Patients with seizure disorders (epilepsy)
» Patients with skin lesions/skin conditions (such as wounds, eczema, radiation damage) in the area of current flow
» Patients with malignant disorders in the area of current flow
» Patients with pathogenic infections (e.g. tuberculosis, osteomyelitis) in the area of current flow
» Patients with phlebitis and blood clots (thrombophlebitis and thrombosis) in the stimulation area
» Patients with an increased risk of bleeding as a result of illness or medications or with fresh bleeding in the stimulation area
» Stimulation in the abdomen in the case of hernias in this area
» Stimulation in the abdomen and pelvic floor area in cases of uterine and vaginal prolapses
» Patients with bone disorders at higher risk of fracture, such as increased bone decalcification (osteoporosis)
» Patients with a known high increase in the serum levels of muscle enzymes and proteins (creatinine kinase, myoglobulin) following muscular stress.
» Patients who are not healthy enough to carry out sports.

1.4 Additional contraindications during pregnancy

The use of the PIERENSYMPHONY P during pregnancy should always be agreed upon with the attending doctor and the midwife, taking into account the benefits and risks.

» The PIERENSYMPHONY P should not be used during pregnancy in patients who have experienced a miscarriage or a premature birth.
» The PIERENSYMPHONY P should not be used on patients in early labour.
» The PIERENSYMPHONY P should generally not be used or only after careful consideration of the risks during the first 3 months of pregnancy. In particular, stimulation near the womb should be avoided. It will affect all placements of the electrodes in the abdomen, pelvis and lower back.

» From the 4th month of pregnancy onward PIERENSYMPHONY P should never be used near the womb. It will affect all placements of the electrodes in the abdomen, pelvis and lower back.

1.5 Side effects

Due to a higher current flow in connection with the broad pulses and special pulse shapes of the PIERENSYMPHONY P, and also due to the frequently sensitive impairments in peripheral nerve lesions, the following side effects may occur:

» Pain aggravation: After extensive and intense session, pain aggravation can occur. Shorten the treatment time (not more than 30 minutes) and choose a low intensity of stimulation during the first treatment sessions to avoid pain aggravation.

» Skin intolerance: Skin intolerance can result from the electrodes, the electrode gel or the electric current impulses. A physician should be consulted in cases of longer lasting reddening, burning, itching or blistering under the electrodes or in the vicinity of the electrodes following the stimulation. Slight skin reddening of short duration in the area of the electrodes following stimulation is quite normal because blood circulation has been improved by the effects of the stimulation.

» Muscular pain: After extensive and intense muscle stimulation session muscular aches in terms of sore muscle can occur. Shorten the treatment time and choose a low intensity of stimulation during the first treatment sessions to avoid pain aggravation.

2. Information about the muscle stimulation program(s)

Enzymes (e.g. creatine kinase) and proteins (e.g. myoglobulin) are released during every muscle strain.

In the case of severe muscle strain, but also due to one's constitutional predisposition or in conjunction with certain medications or drugs, certain individuals **may** experience more severe **muscle breakdown** (rhabdomyolysis). **In rare cases** (especially with overtrained muscles or pre-existing conditions), the amount of enzymes and proteins released as well as electrolyte imbalances can also **damage internal organs** such as the kidneys, liver and heart. This danger also exists in the case of electrical muscle stimulation, as it may be intensive muscle training. This danger is generally very rare and, in most cases, is avoided by observing the information in the following chapter ("Measures for avoiding physical overload reactions"). No such harm has occurred to date with our products.

The muscles can quickly reach their stress limit, especially during the first training sessions. This is associated with the risk of muscular overload, which can also occur in healthy and trained users. Muscular overload may already manifest itself during training through discomfort, circulatory reactions, muscle pain and other complaints.

The most frequent consequence of overload is pain in the muscles after the training. Pain and irritation of tissues connected to the muscles - such as ligaments, tendons, joints and bones - are also possible. Muscle overload due to electrical muscle stimulation occurs particularly during the first treatment sessions. Over the course of regular training, the muscles usually adjust to the demand placed on them and there is a significant decrease in the release of muscle enzymes and muscle proteins.

2.1 Instructions for avoiding physical overload reactions due to muscle stimulation

2.1.1 Before each treatment

» The patient and the user must have read and understood the contraindications, safety instructions, side effects and the instructions for avoiding physical overload reactions.

» Only undergo stimulation if you are feeling calm and fit.

» Do not undergo stimulation if you have a fever or any other symptoms that impair your physical performance capacity. If you have chronic, long-term conditions, seek a doctor's advice and approval before starting any training.

» The patient adjusts the stimulation intensity to a comfortable level and readjusts it themself if necessary. The aim is to trigger non-painful muscle tension in the area of the current flow. The intensity of the current is perceived differently by individuals and depending on the situation and may vary from treatment to treatment.

» The stimulation and treatment must never be painful.

» Only medically necessary medications should be taken prior to treatment.

» **Before/during treatment drink 2 glasses,** e.g. of water to support kidney function.

» **Do not undergo stimulation on an empty stomach.** Instead, have a small meal 1-2 hours before treatment to avoid any drop in blood sugar.

2.1.2 After each treatment

» Severe muscle pain after treatment is a sign of overload and should result in a reduction in the intensity and frequency of treatment. Persistent or especially severe muscle pain and muscle weakness following treatment can also indicate muscle breakdown (rhabdomyolysis). **In these cases, medical advice must be sought.** In the event of doubt (e.g. in the case of discomfort or similar symptoms), medical advice should always be sought.

» To support kidney function, **after treatment 1-2 glasses**, e.g. of water should be drunk.

2.1.3 Treatment in the acclimatisation period (first to seventh treatment)

» As the therapy begins, the muscles must be given sufficient time to get used to the strain. This also applies to trained muscles. Particularly **during the first two sessions, only light stimulation** with short periods of muscle tension may be carried out, **without full muscular strain**. In addition, during the first two sessions the stimulation must **not be applied for more than 10 minutes** at a time. The device's longer programs should be stopped after this time. Programs with lower frequencies and longer pause times are preferable.

» There should be **at least 4 days between the first two sessions**.

» In the next 5 training units, the intensity of the training can be slowly increased until the desired level of strain is reached and a training duration of 20 minutes is achieved. The interval between the treatments can be gradually shortened.

2.1.4 Training after the familiarisation phase

» The duration of training should **not be longer than 20 minutes** per training session.

» Muscle pain should not occur during the training session; constant muscle tension must be avoided.

2.2 Contraindications due to muscle stimulation

The product should not be used or only used after consulting the responsible doctor in the following cases:

» Persons in whom muscle training leads to a high release of muscle enzymes and proteins (e.g. creatine kinase, myoglobulin). This release can also be caused by the simultaneous taking of medications, e.g.

cholesterol-lowering drugs (e.g. statins), and requires medical supervision.

» Muscle disease (myopathies)

» Drug use (e.g. alcohol) or those taking medications (e.g. lipid-lowering agents, muscle relaxants, cortisone) that lead to the increased release of muscle enzymes and muscle proteins in the blood serum

» Diseases, such as of the kidneys or the liver as well as heart diseases, which are associated with a reduced compensation of increased values of muscle enzymes, muscle proteins and electrolyte imbalances

2.3 Side effects due to muscle stimulation

» Muscle cramps with possible damage to the muscle and neighbouring muscle structures such as connective tissue, ligaments, tendons and bones

» Muscular overload reactions with
- Muscle pain that may last for several days
- Muscle weakness that may last for several days
- The release of muscle enzymes and muscle proteins as well as electrolyte shifts due to muscle strain and muscle breakdown (rhabdomyolysis)

» The consequences of long-term electrical muscle stimulation (for more than 6 weeks at a time) are not known, so negative long-term effects cannot be ruled out. We are not aware of any such cases when handling our products.

» **Notice:** Especially when stimulating with user programme settings, make sure to stimulate carefully with large pulse ranges and not for too long in order to avoid musculare overloads or skin irritations!

3. Scope of delivery

Art.-Nr.	REF	Article	Quantity
10003568	109200	PIERENSYMPHONY P	1 pc.
10003563	106370	Charger cradle	1 pc.
10005868	104796	Power supply unit (USB charger 5V 2000mA)	1 pc.
10005866	104795	USB charger cable for power supply unit	1 pc.
10002245	106351	Electrode cable type 5.15	2 pcs.
10003976	462042	Surface electrode = (Sponge patch 50 x 70 mm Silicone rubber electrode 48 x 68 mm)	2 pcs.
10002362	104781	Belt strap (400x50 mm)	2 pcs.
10002363	104782	Belt strap (600x50 mm)	2 pcs.
10007405	-	Instructions for use	1 pc.
-	-	Storage box	1 pc.

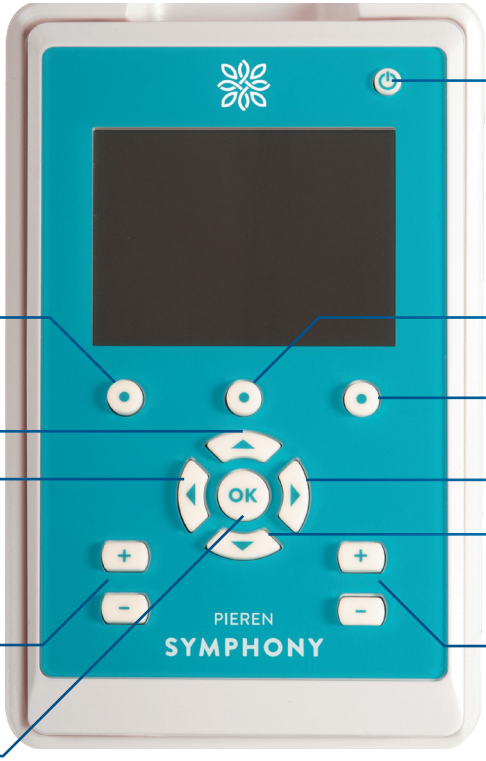
4. Description of the device

The PIERENSYMPHONY P is a 2-channel electrostimulator with various stimulation and therapy modules, which have been designed specifically for each user's applications in terms of the software. Individual upgrades can be used to expand or combine it at any time with specific modules required for the therapeutic purpose.

The PIERENSYMPHONY P contains low-frequency stimulation programs.

A treatment diary is an ideal and meaningful companion to the manifestation of the treatment defined by the doctor/therapist following a thorough diagnosis and thus allows a personal observation of the progress of treatment, for example, in reducing pain or building muscles.

4.1 Controls



A On/off, standby

B Button 1

C Button 2

D Button 3

E pointing up

G to the left

H to right

F pointing down

I Intensity control channel 1

J Intensity control channel 2

K OK / confirm, pause stimulation

5. Operating the PIERENSYMPHONY P

5.1 Connecting the cables and electrodes set

Refer to the chapter "Application of the electrode set".

5.2 Turn on the device

Press the on/off button A for 2 seconds. The PIERENSYMPHONY P turns on and the main menu is displayed with the individual menu items that can be selected (see main menu).

5.3 Turn off the device

Press the on/off button A for 3 seconds. The PIERENSYMPHONY P will then turn off. If the battery power is not strong enough, the device switches off automatically.

5.4 Charging the battery

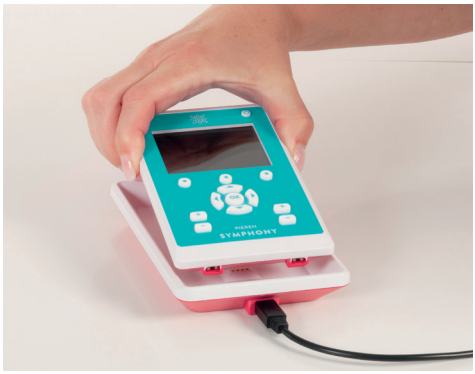
Only charge PIERENSYMPHONY P with the charger provided.

Plug the micro USB cable into the micro USB port on the charger.

To charge the battery, connect the micro USB cable to a USB port, or use a mobile phone charger to connect to a 230V socket.

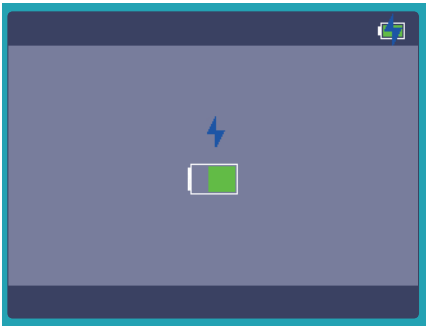
Remove the electrode cables from the PIERENSYMPHONY P...

... and place it in the charger.



Check that the device is lying correctly on the charging slot, it must lie flat in the charger.

When the device lies switched off in the charger, the display shows the following charging indicator:



The voltage of the battery is shown on the display in the header on the right by means of an icon.

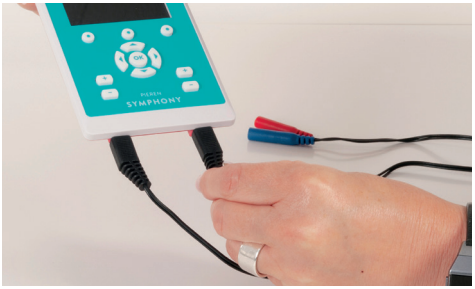
- Battery full
- Battery half full
- Battery almost empty
- Charging

Attention! Stimulation is not possible during charging.

Important! After charging, disconnect the charger from the 230V socket and only then remove the PIERENSYMPHONY P from the charger.

5.5 Electrode connections

The electrode connections are located below the control buttons. Connect the appropriate electrodes here.



Due to the fit of the electrode sets included as accessories, the connection is protected against reverse voltage. Only use original accessories.

5.6 Program selection

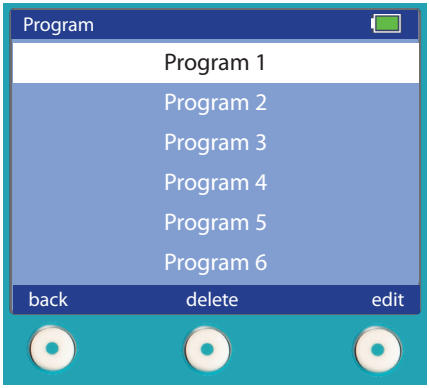
After you have started the PIERENSYMPHONY P, you are taken directly to the main menu.

Use the ▲ button and the ▼ button to select the desired menu item.

The menu item currently selected is indicated by a light-coloured rectangle. Press the OK button to access one of the submenus “Paresis”, “Treatment memory”, or “Settings”.

Select the "Paresis" submenu.

Now select the program group "Paresis" and the following screen will appear:



The respective functions of the buttons 1 ⊙, 2 ⊙ and 3 ⊙ are displayed directly above them.

5.7 Starting stimulation

Once a program has been selected, start stimulation by pressing the intensity control +.

If channels 1 and 2 are to be used, these can be adjusted up and down together with the buttons ▲▼.

6. To the programs

The PIERENSYMPHONY P has six programs that differ mainly in terms of the pulse shape.

Programs with rectangular pulses (Program 1, program 4)

Programs 1 and 4 are, in principle, the first choice, especially in the case of incomplete or more recent paresis. Stimulation should firstly be attempted with program 1. Program 4 can also be used as an alternative to program 1.

Programs with trapezoidal pulses (Program 2, program 5)

If rectangular pulses (program 1 and 4) fail to trigger adequate muscle tension, stimulation with a trapezoidal impulse (program 2) can be attempted. Program 5 can also be used as an alternative to program 2.

Programs with triangular pulses (Program 3, program 6)

If trapezoidal pulses (program 2 and 5) fail to trigger adequate muscle tension, stimulation with a triangular impulse (program 3) can be attempted. Program 6 can also be used as an alternative to program 3.

6.1 Stimulation time

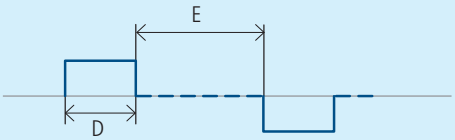
The programs stimulate over 15 minutes. However, the stimulation time depends on the clinical situation and, if there is a muscular degeneration reaction, can initially be only a few minutes per session. If the musculature has a positive reaction, the session duration can then be slowly increased over the course of treatment.

6.2 Explanation and area of application of the programs

6.2.1 Program 1

Rectangular pulse current with alternating polarity

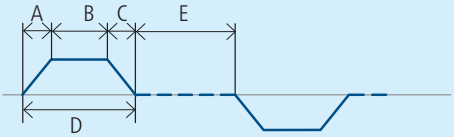
D Pulse width 50 ms
E Pause 500 ms (E = 10 x D)
Treatment time 15 min
Usage Treatment of minor damage (paralysis)
Alternatively Program 4



6.2.2 Program 2

Trapezoidal pulse current with alternating polarity

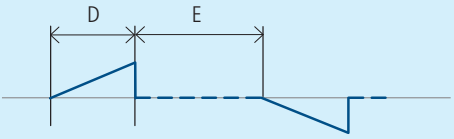
D Pulse width 150 ms
A Rising time (A = 1/4 x D)
B Working time (B = 2/4 x D)
C Falling time (C = 1/4 x D)
E Pause 1.5 s (E = 10 x D)
Treatment time 15 min
Usage Treatment of moderate paralysis
Alternatively Program 5



6.2.3 Program 3

Triangular pulse current with alternating polarity

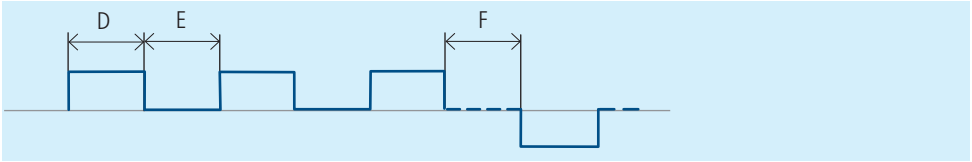
D Pulse width 300 ms
E Pause 3.0 s (E = 10 x D)
Treatment time 15 min
Usage Treatment of severe paralysis
Alternatively Program 6



6.2.4 Program 4

Rectangular pulse group with alternating polarity

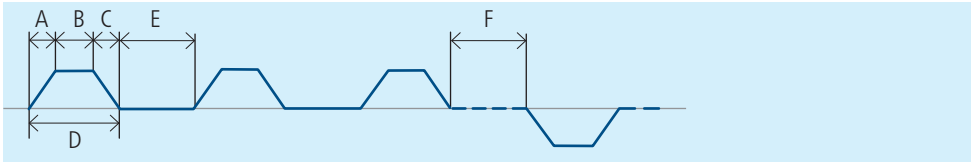
D Pulse width 50 ms
E Pause 500 ms (E = 10 x D)
F Pulse group pause 1.5 s (F = 3 x E)
Treatment time 15 min
Usage Treatment of mild paralysis, alternatively to P1



6.2.5 Program 5

Trapezoidal pulse group with alternating polarity

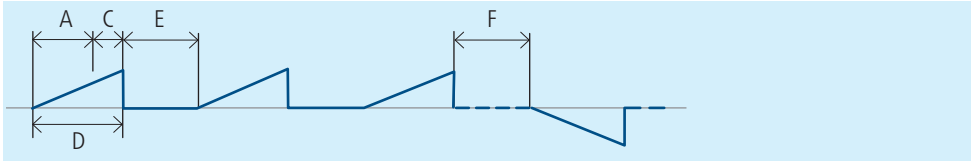
D Pulse width 150 ms
A Rising time (A = 1/4 x D)
B Working time (B = 2/4 x D)
C Falling time (C = 1/4 x D)
E Pause 1.5 s (E = 10 x D)
F Pulse group pause 4.5 s (F = 3 x E)
Treatment time 15 min
Usage Treatment of moderate paralysis, alternatively to P2



Program 6

Triangular pulse group with alternating polarity

D Pulse width 300 ms
E Pause 3.0 s (E = 10 x D)
F Pulse group pause 9.0 s (F = 3 x E)
Treatment time 15 min
Usage Treatment of severe paralysis, alternatively to P3



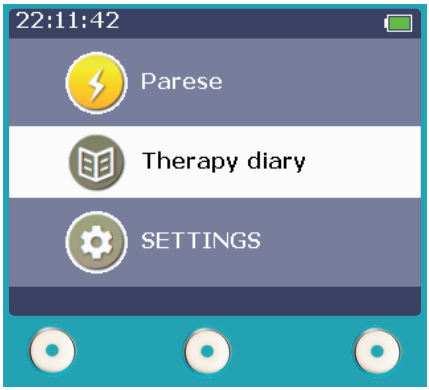
7. Menu description

The menu description contains the selection and navigation through the menu items.

Also read the quick guide, Chapter 8!

7.1 Main menu

After you have started the PIERENSYMPHONY P, you are taken directly to the main menu.



Use the ▲ button and the ▼ button to select the desired menu item.

The menu item currently selected is indicated by a light-coloured rectangle. Press the OK button to access one of the following submenus:

Paresis

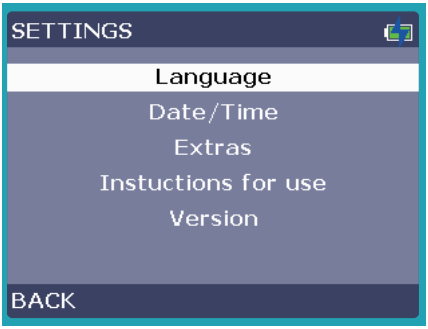
Treatment memory

Settings

7.2 Settings

In the Settings menu, you can change the device's general settings. To do this, use the ▲ ▼ buttons to select the desired menu item and you will be taken to one of the following submenus after confirming by pressing the confirmation button OK:

» Select language
» Set date and time
» Other settings (beeps)
» Software version display



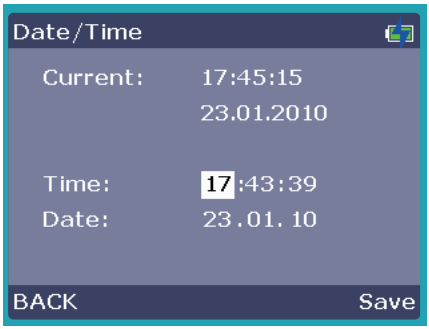
More function-specific settings can be made in the respective function under button 2 ⊙ "Options".

7.2.1 Select language

The desired language can be selected using the ▲ ▼ buttons. Use the confirmation button OK to apply the language and you will return to the main menu. To cancel the selection without making any changes, press button 1 ⊙ "Back".

7.2.2 Set date/time

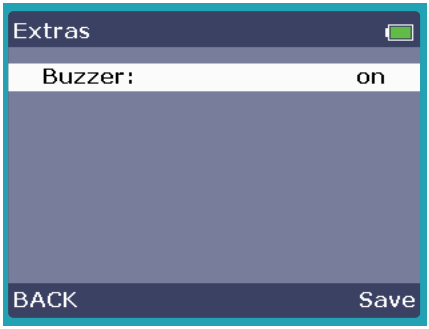
You will always see the current time and date shown at the top.



The ▲ ▼ ◀ ▶ buttons allow you to select individual numbers of "Time" and "Date" and change them with the "Parameters" buttons + and −.

To apply the new time and date, use button 3 ⊙ "Save". Press button 1 ⊙ "Back" to exit the menu.

7.2.3 Other settings



This menu item allows you to switch the beeps on and off. To do this, use parameters buttons + and − and confirm the setting with button 3 ⊙ "Save".

To exit the menu, use button 1 ⊙ "Back".

7.2.4 Treatment memory

The PIERENSYMPHONY P is equipped with a treatment memory, which allows the user to retrieve the following parameters as needed:

» Treatment date, treatment time, treatment duration, treatment/indication

In the main menu, you can access the "Treatment memory" menu by pressing the buttons ▲ ▼.

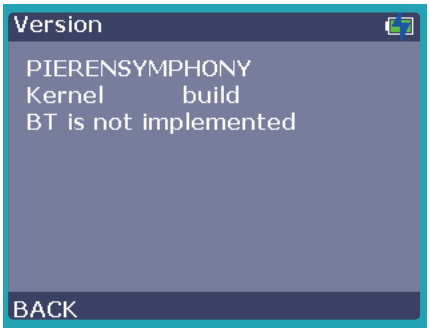
Using the ▲ ▼ buttons, you can scroll through the entries and select the desired entry using the OK button for further information on the program and the treatment duration of the respective application. Use button 1 ⊙ "Back" to return to the previous screen.

If necessary, you can also delete the treatment memory by pressing button 2 ⊙ "Delete". When a new treatment is started, an entry is automatically made by the device.

7.2.5 Version display

In this submenu, you can view the software version of the device. You can also see whether your device supports Bluetooth.

To exit, use button 1 ⊙ "Back".



7.3 Paresis

In the main menu, use the ▲ and ▼ buttons to select the function Paresis and confirm this selection with the OK button. You will now be taken to the stimulation function of the device and you will see the screen on the left.

7.3.1 The following stimulation programs are available (Chapter 5.2)

Programs

Program 1
Program 2
Program 3
Program 4
Program 5
Program 6

7.4 User programs

You can enter parameters yourself to create trapezoidal, triangular or rectangular pulses by freely selecting and setting the ramp, work, and pause times.

The maximum pulse width is generally 6 seconds and the 2-channel stimulation-related pause time between the pulses is at least 5 times the pulse width previously entered.

Example of trapezoidal stimulation:

Rising time 1 s
Working time 1 s } = 3 s pulse width
Falling time 1 s

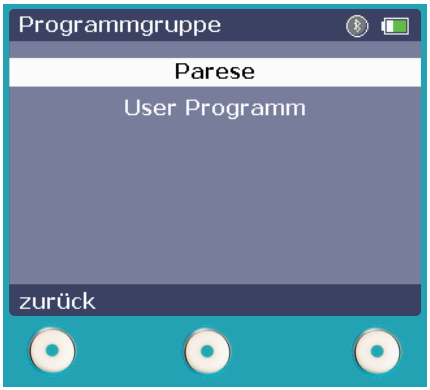
=> 15 s pause until the next pulse

The entire stimulation sequence times are limited to 20 minutes by the manufacturer.

The delete function in the settings user program always only deletes the last sequence/ program setting that was entered!

7.5 Examples

Paresis program



Program 2 started

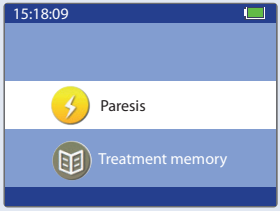
Program 2 stopped

Program 3 started

Program 3 stopped

8. Quick guide

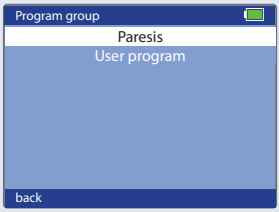
1



OK

Select the "Paresis" menu item shown with a white background with **OK**

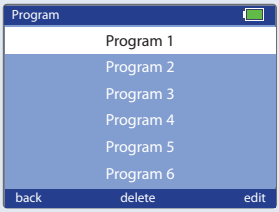
2A



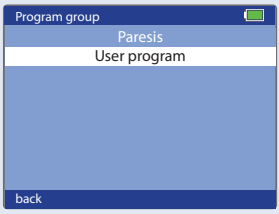
OK

Select the "Paresis" program group shown with a white background with **OK**

2B

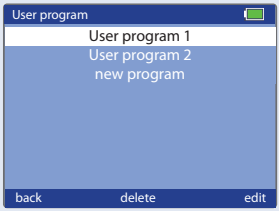


3A

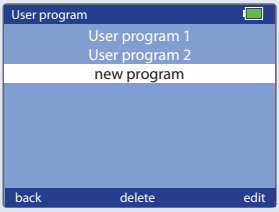


Select the "User program" program group shown with a white background with **OK**

3B

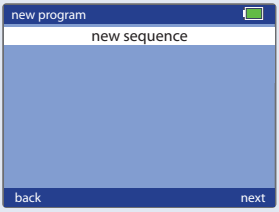


4A



Select the "new program" menu item shown with a white background with **OK** or button 3 ◉ "Edit"

4B



Select the desired program with ▲▼ and select with **OK**

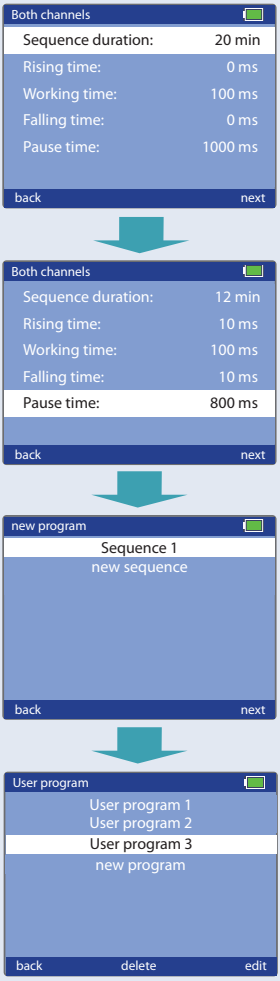
Stimulate with the selected program

Select the desired user program with ▲▼ and select with **OK**

Stimulate with the selected user program

Select the "new sequence" menu item shown with a white background with **OK** or button 1 ⦿ "Next"

4C



The following parameters are preset and can be selected with ▲▼ and changed with **+ –**

Example of changed parameters

with button 1 ⦿ "Back" to the previous menu item

Create another sequence with ▼ or press button 1 ⦿ "Back" to return to the previous menu item

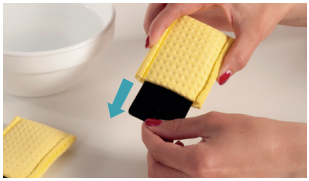
Select the newly created program with **OK** and start the stimulation with button 3 ⦿ "Start"

Modify created user programs with button 3 ⦿ "Edit" or delete them with button 2 ⦿ "Delete".

9. Electrode placement

Due to denervation, the muscle cell needs to be stimulated directly. The electrodes should cover the muscle to be stimulated as completely as possible. The sponge bags must be moistened evenly.

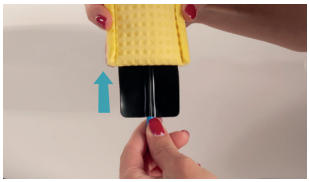
A Remove the silicone rubber electrodes from the sponge bag.



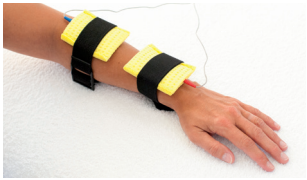
B Moisten sponge bags well and evenly with water.

C Connect the silicone rubber electrodes to the electrode cables.

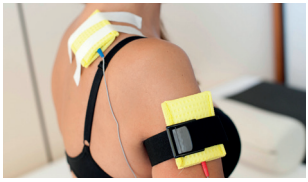
D Insert the silicone rubber electrodes fully into the damp sponge bags.



E Attach the surface electrodes that have been created in this way to the desired areas of the body with the belt straps. **Do not apply to unclean, oily, diseased skin or wounds!**



F Silk tape is recommended for attachment in areas that are difficult for the fastening straps to access. (Not included in the set)



G Now connect the device to the electrode cables.

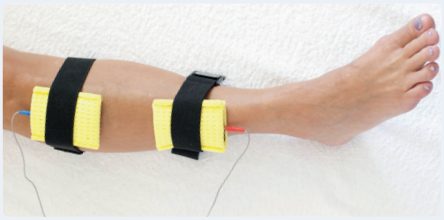
The sponge bags and silicone rubber electrodes are intended for multiple use. However, with correct use and care, they still need to be replaced after around 60 applications.

Note: Do not continue to use surface electrodes that discolour or alter in their structure to avoid any current-related skin damage due to poor conductivity. This can affect both the sponge bag and the silicone rubber electrode and may, if necessary, be before reaching the maximum number of 60 applications. Affected surface electrodes must be replaced.

9.1 Examples of electrode placement in cases of paralysis

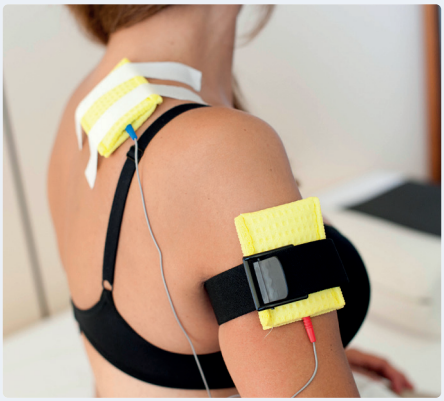
The illustrations are a guide for frequent electrode placements. The attachment points shown are only one of several possibilities and may need to be customised. The red electrode represents the positive pole (anode), visible by the red end of the cable; the blue electrode represents the negative pole (cathode), visible by the blue cable end.

LOWER LEG, PERONEUS



FOREARM, RADIALIS

SHOULDER, AXILLARIS



10. Technical information

The PIERENSYMPHONY P is a portable, transcutaneous, electrical stimulator for muscles and nerves that delivers electrical energy to the body in the form of pulses via cables and electrodes. The device has a TFT display and is operated via a keypad with 13 buttons. The PIERENSYMPHONY P is powered by an internal power supply (3.8 V Li-ion battery) and is protected by a fuse located in the device.

10.1 Technical data

Voltage supply	Internal Li-ion battery 3.8 V, 1700 mAh
Power consumption max.	1200 mA
Max. output voltage	75 Vss (+/- 8 Vss) to 500 Ω real
Max. output current	75 mA
Pulse shape	Time-delayed direct current pulses of alternating polarity
Pulse width	0-6000 ms, adjustable in 10 ms increments
Intensity	75 levels (at load RL = 500 Ω, 1 stage/step corresponds to 1 mA)
Max. pause	30 s
Dimensions	140x83x20 mm
Weight	Approx. 350 g
IP class	IP22
Working conditions	Temperature range: 5-35°C, relative humidity: 30-75%, air pressure: 70–106 kPa
Storage conditions	Temperature range: 5-35°C, relative humidity: 10-90%, air pressure: 50–106 kPa
Max. power consumption	4.5 W
Standby power consumption	0.004 W
Charging time	2 h
Li-ion battery life	2 years or 300 charging cycles
Channels	2 channels

The information on the initial parameters has a tolerance of +/- 15%.

10.2 Explanation of the pulse shape icons on the display

	Rectangular pulse current
	Trapezoidal pulse current
	Triangular pulse current

10.3 Description of the symbols

SN Serial number

REF Article number

Attention! It is necessary to follow the instructions for use in order to use the product safely.

Attention! The product has some non-apparent risks. Please comply with the safety precautions contained in the user instructions!

IP22 The device provides protection against the ingress of solid foreign material with a diameter ≥ 12.5 mm and protection against vertically dripping water (when the device is tilted by up to 15°).

Application part of the BF model
Galvanically isolated application part with a higher level of protection against an electric shock to the body **but not directly to the heart!**

Manufacturer

Date of production

Energy/signal output

Protect from moisture / keep dry

Environmental protection
Do not dispose of the product in normal domestic waste. Take it to an authorised collection site for recycling. By doing this, you will help to protect the environment.

MD Medical device

CE0483 The manufacturer affixes the CE marking to declare that the product fulfils all of the applicable requirements of the relevant EC directives and that a conformity assessment procedure stipulated for the same product has been successfully completed. The CE marking must be followed by the identification number of the notified body responsible for conducting the conformity assessment procedure.

10.4 Classification

The PIERENSYMPHONY P is classed as Class II a according to Annex IX (Rule 9) of the EC directive 93/42/EEC on medical devices.

10.5 Reporting Obligation

Any serious incident that occurs in conjunction with this project must be reported to the manufacturer and the responsible authority in the member state where the user is located.

10.6 Care and cleaning

No special care or cleaning products are required for the PIERENSYMPHONY P. If the device and/or the cables are dirty, clean them using a soft, lint-free cloth. See the "Accessories" chapter for maintenance of the electrodes.

10.7 Combining

The PIERENSYMPHONY P is only to be combined with the articles listed in the scope of delivery and under "Accessories".

10.8 Maintenance/safety controls

The technical safety controls include:

1. Inspection of accompanying documents for the presence of the instructions for use and the medical devices book
2. Check of equipment for completeness
3. Visual inspection:
   - for mechanical damage
   - all cables and connectors for damage
4. Functional safety
   - Testing the output signals at a load resistance of 1 kΩ (current and voltage)
   - Testing the output signals at an ANSI load resistance (current and voltage)
   - Testing the frequency
   - Pulse width test

On request, we will gladly carry out technical safety controls for you for a fee.

11. Accessories

Therapeutic use of the PIERENSYMPHONY P on the patient is only permitted with the accessories described in the instructions for use. Otherwise, we cannot be responsible for the safety of the patient and for the warranty of the device.

11.1 Charging/ energy management

Art.-Nr	REF	Article	Quantity
10003563	106370	Charger cradle	1 pcs.
10005868	104796	Power supply unit (USB charger 5V 2000mA)	1 pcs.
10005866	104795	USB charger cable for power supply	1 pcs.
10002245	106351	Type 5.15 electrode cable	1 pair

11.2 Surface electrodes

Clean the skin in the area of application, remove ointments and creams.

Do not apply to unclean, oily, diseased skin or wounds!

See also chapter 3. The silicone rubber electrode must be fully inserted into the sponge bag to avoid any electrical damage to the skin. Electrode conductivity decreases slowly over time. Replace them after approx. 60 uses at the latest. After each use, please clean the electrodes according to the instructions in the "Important notes on the sponge electrode".

Art.-Nr.	REF	Article	Quantity
10003976	462042	Surface electrode = (Sponge patch 50 x 70 mm, silicone rubber electrode 48 x 68 mm). 2 surface electrodes are required per channel)	1 pc. 

11.3 Other accessories

Art.-Nr.	REF	Article	Quantity
10002362	104781	Belt strap (400x50 mm)	2 pcs. 
10002363	104782	Belt strap (600x50 mm)	2 pcs. 

12. Disposal and return

12.1 Battery return and disposal

Caution: If the batteries are disposed of along with residual waste and later incinerated in a waste incineration plant, toxic pollutants (including mercury, cadmium and lead) can be released into the air. If the pollutants from the batteries find their way into the food chain, they can have serious **health-endangering effects** on humans!

Therefore, please note the following information: In connection with the sale of products containing batteries, which also include rechargeable batteries, we are legally obliged in accordance with § 18 para. 1 of the German Battery Act (BattG), to inform you of the following: The dustbin symbol () indicates batteries containing harmful substances and the fact that batteries must not be disposed of with household waste, but must be disposed of properly. The chemical name of the pollutant is indicated under the dustbin symbol. You are legally obliged to return used batteries. You can return used batteries to a municipal collection point or to your local retailer. As a distributor of batteries, we are also obliged to take back used batteries, although our take-back obligation is limited to used batteries of the type that we carry or have carried in our range as new batteries. Used batteries of the aforementioned type can therefore either be returned to us with sufficient postage or handed in directly to our dispatch warehouse free of charge at the following address: schwa-medico GmbH, Dreieiche 7, 35630 Ehringshausen. Please refer to the following illustration for the symbols used to identify batteries containing harmful substances:

Battery contains more than 0.002 percent by weight of cadmium

Battery contains more than 0.0005 percent by weight of mercury

Battery contains more than 0.004 percent by weight of lead

12.2 Disposal of the Device

In the European Union applies: It is prohibited to dispose of the appliance with household waste. You are obliged to bring the product to public collection points. The manufacturer undertakes vis-à-vis non-consumers to take back the product at his site (address: Dreieiche 7, 35360 Ehringshausen) and to dispose of it properly. On request the dealer undertakes to accept an essentially functionally identical old product from the end user free of charge when this device is handed over to the end user. This only applies if the end user has notified the dealer of his wish to hand in an old device prior to the drop-off date. In addition, the dealer will accept up to 5 other electrical devices free of charge in its sales area (address: Dreieiche 7, 35360 Ehringshausen), which are no larger than 25cm each in height, width and length. Please also observe the applicable regulations in your country.

13. Manufacturer's declaration

Manufacturer's declaration for the medical device PIEREN**SYMPHONY**

Guidelines and manufacturer's declaration - Electromagnetic emission		
The product is intended for operation in an environment as specified below. The customer or the user of the product should ensure that it is operated in such an environment.		
Interference emission measurement	**Concordance**	**Electromagnetic environment - Guideline**
RF emissions according to EN 55011	Group 1	The product uses RF energy exclusively for its internal function. Therefore, its RF emission is very low and it is unlikely to interfere with neighboring electronic devices.
RF emissions according to EN 55011	Class B	The product is suitable for use in all establishments, including residential establishments and those directly connected to a public power supply network that also supplies buildings used for residential purposes.
Emission of harmonics according to IEC 61000-3-2	Not applicable	
Emission of voltage fluctuations/flicker according to IEC 61000-3-3	Not applicable	

Guidelines and manufacturer's declaration - Electromagnetic immunity			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should ensure that it is used in such an environment.			
Interference immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidelines**
Static electricity discharge (ESD) according to IEC 61000-4-2	± 8 kV Contact discharging ± 15 kV Air discharging	± 8 kV Contact discharging ± 15 kV Air discharging	Floors should be wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency should correspond to the typical values found in the business and hospital environment.

Guidelines and manufacturer's declaration - Electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should ensure that it is used in such an environment.

Interference immunity test	IEC 60601-Test level	Matching level	Electromagnetic environment - Guidelines
Conducted RF disturbance variables according to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz, 6 V eff in ISM- and amateur radio frequency bands between 150 kHz and 80 MHz	3 V_{eff} 150 kHz to 80 MHz, 6 V eff in ISM- and amateur radio frequency bands between 150 kHz and 80 MHz	Portable and mobile radios should not be used at a distance from the product, including the lines, less than the recommended separation distance calculated from the equation applicable to the frequency of the transmission. **Recommended protective distance:** $d = 1{,}2\sqrt{P}$, in ISM bands $d = 0{,}58\sqrt{P}$ $d = 0{,}35\sqrt{P}$ for 80 MHz to 800 MHz $d = 0{,}7\sqrt{P}$ for 800 MHz to 2,7 GHz with P as the nominal power of the transmitter in watts according to the transmitter manufacturer's specifications and d as the recommended protective distance in meters [m]. The field strength of stationary radio transmitters should be less than the compliance level at all frequencies[b] according to an on-site[a] survey. Interference is possible in the vicinity of equipment bearing the following symbol.
---------- Gestrahlte HF-Störgrößen nach IEC 61000-4-3	---------- 10V/m 80 MHz bis 2,7 GHz 80% AM bei 1 kHz	---------- 10V/m 80 MHz bis 2,7 GHz 80% AM bei 1 kHz	

NOTE 1 For 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is affected by absorptions and reflections from buildings, objects, and people

a. The field strength of stationary transmitters, such as base stations of radiotelephones and land mobile radios, amateur radio stations, AM and FM radio and television transmitters, cannot theoretically be accurately predicted. To determine the electromagnetic environment with respect to stationary transmitters, a site study should be considered. If the measured field strength at the site where the product is used exceeds the compliance levels above, the product should be observed to demonstrate proper operation. If unusual performance characteristics are observed, additional measures may be required, such as changing the orientation or location of the product.

b. Over the frequency range 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Recommended protective distances between portable and mobile - RF telecommunication equipment and the product

The product is intended for use in an electromagnetic environment in which RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the product, depending on the output power of the communication device, as indicated below.

Rated power of the Transmitter W	**Protective distance depending on transmission frequency in m**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$ (*in ISM bands* $d = 0{,}58\sqrt{P}$)	**80 MHz to 800 MHz** $d = 0{,}35\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 0{,}7\sqrt{P}$
0,01	0,12 *(0,06)*	0,04	0,07
0,1	0,37 *(0,18)*	0,11	0,22
1	1,2 *(0,58)*	0,35	0,7
10	3,7 *(1,85)*	1,1	2,2
100	12 *(5,8)*	3,5	7

For transmitters whose maximum power rating is not specified in the above table, the recommended guard distance d in meters (m) can be determined using the equation associated with the respective column, where P is the maximum power rating of the transmitter in watts (W) as specified by the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is affected by absorption and reflection from buildings, objects, and people.

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