Zimmer
MedizinSysteme

Instructions for Use

emField*Pro*

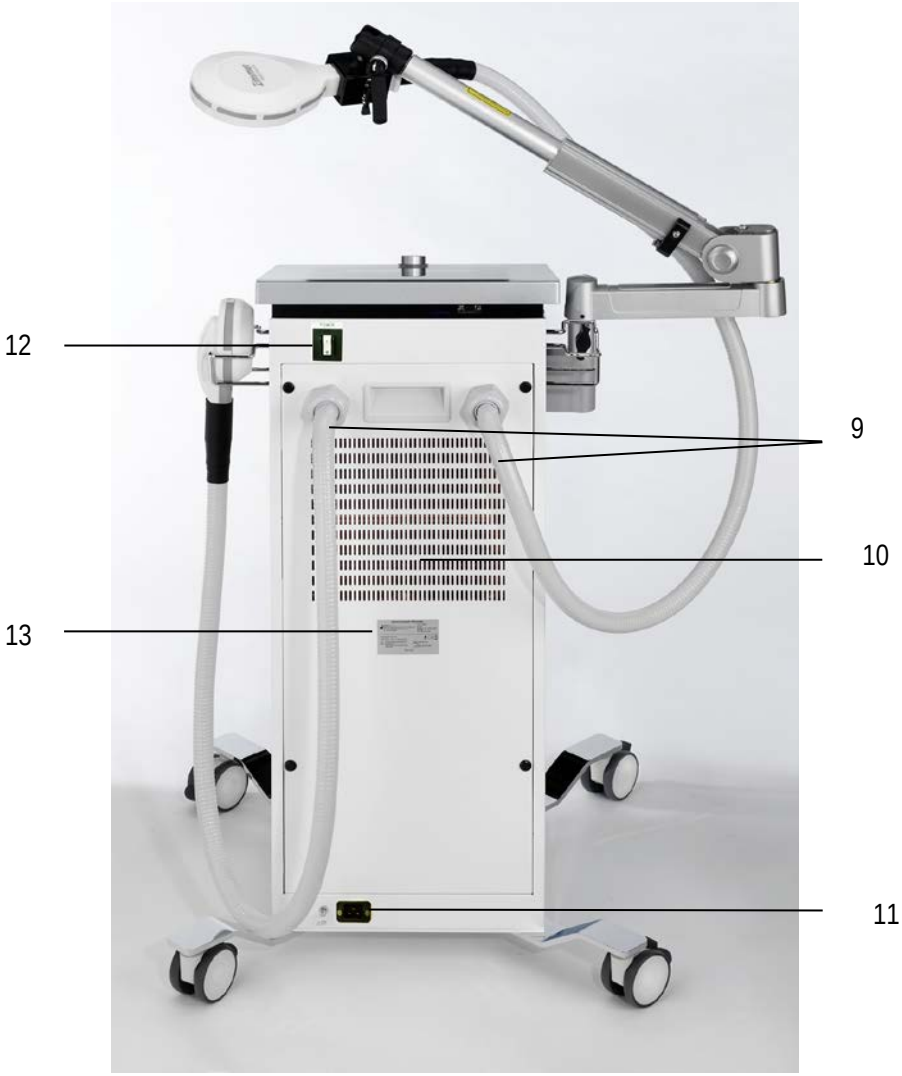
Illustrations

Front of the Device

Fig. 1 Front of the device

1 Applicator (large)
2 Applicator quick-connector
3 Applicator arm
4 Applicator (medium)
5 Display
6 Central control knob
7 Control unit
8 Swiveling wheels

Fig. 2 Rear of the device

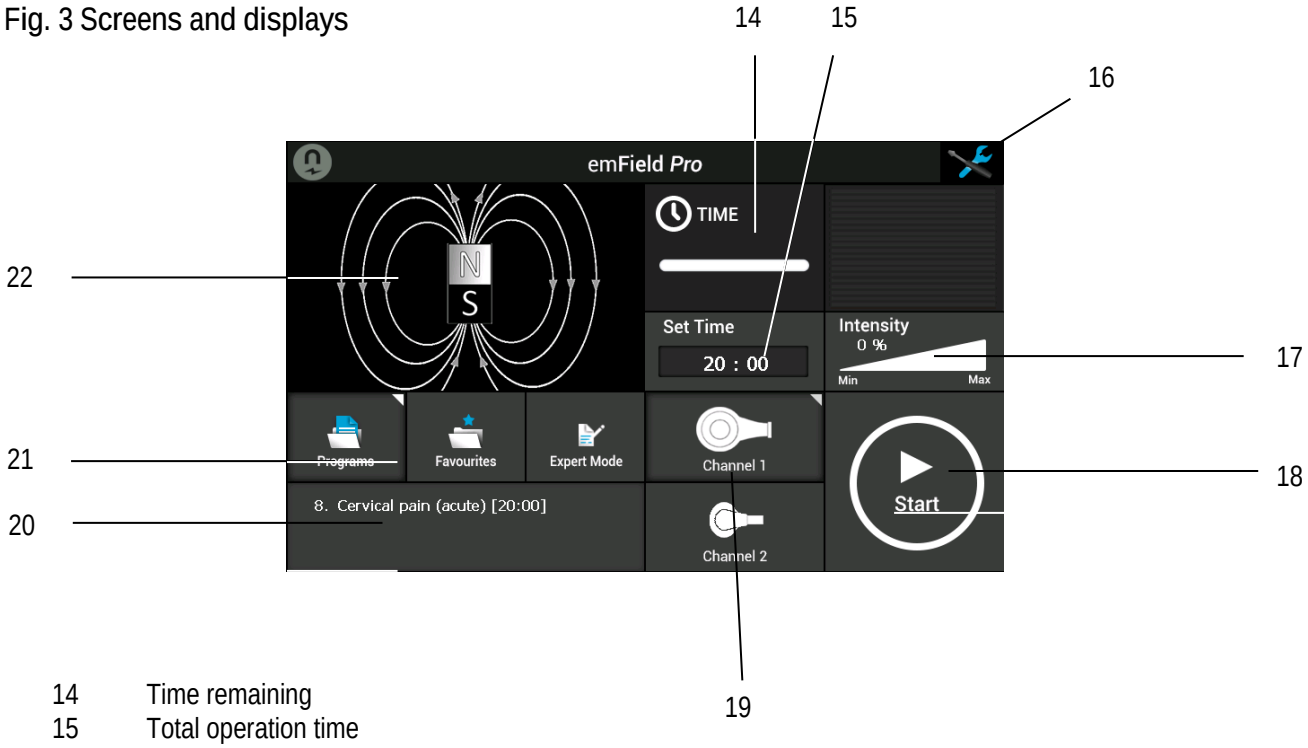


9	Connectors for applicator tube
10	Cooling
11	Power connector
12	Power switch
13	Serial no / Identification plate

Illustrations

Screens and Displays

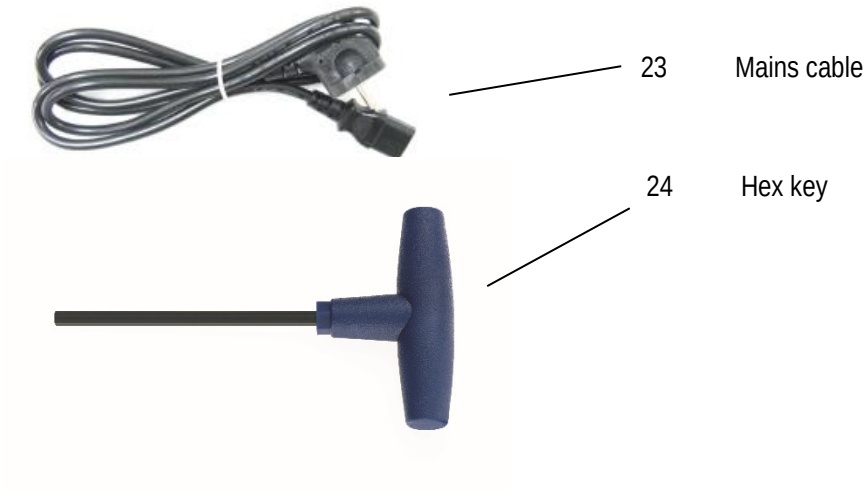
Fig. 3 Screens and displays



14	Time remaining
15	Total operation time
16	Configuration icon
17	Intensity in %
18	Start/Stop
19	Channel selector (CH1 Large or CH2 Medium)
20	Applied program
21	Mode selector (Programs / Favourites / Expert mode)
22	Program information screen

Illustrations

Accessories



23 Mains cable

24 Hex key

Explanation of Symbols

This symbol indicates “Danger” with regard to possible risks to people.

This symbol indicates “Caution” with regard to possible material damage.

Applied part BF type emField*Pro*

Operation instructions

Follow instructions for use

No access for people with pacemakers

Serial number

Article number

Manufacturer

Date of manufacture

Disposal of electrical and electronic equipment as well as used batteries and accumulators.

This product must not be disposed of with household waste.

Explanation of Symbols

Do not push

No sitting on device

The device emits energy in the form of non-ionizing electromagnetic radiation

Warning, magnetic field

Warning, electricity

Protective earth

Equipotentiality, to identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.

Keep dry

Disposable packaging materials

Fragile, handle with care

This way up

Temperature limit

Explanation of Symbols

Do not stack

CE marking with the number of the notified body

Contents

Contents

Contents

Valid for emField *Pro* devices.

This instructions for use is an integral part of the device. It must be stored with the device and kept accessible at all times for anyone authorized to operate this device.
The instructions for use is valid as of December 2021.

If the instructions for use have become illegible, damaged, or are not accessible for the user for other reasons, a replacement is to be requested from the manufacturer for the safe use of emField *Pro* and made available to the user. This also includes the information on the labels on the device. The instructions for use can also be downloaded from our website.

We reserve the right to revise this document at any time or change product specifications described. There is no obligation to provide information about the changes to the customer.

Indications / Contraindications

1

Indications

- Stimulation of muscular tissue
- Nerve regeneration
- General pain control
- Improvement blood circulation
- Urinary incontinence

Contraindications

Absolute contraindications for use of the emField*Pro* are placing an active applicator over metal or electronic implants like cardiac pacemakers, cochlear implants, intrathecal pumps, hearing aids etc.

Be ensured that magnetic stimulation doesn't penetrate the heart region.

The emField*Pro* should be used with caution in persons with Grave's disease, active bleeding disorders or seizure disorders.

Patients in the following categories cannot be treated, prior to permission of the doctor in charge:

- Fever
- Application over menstruating uterus
- Pregnancy
- Application over areas of the skin with sensitivity disorder
- Elderly and childrenPatients with suspected status of epilepsy on the basis of electroencephalograph
- Patients with evidence of external wound at brain and neck
- Patients with cranial implants
- Implanted defibrillators
- Implanted neurostimulators
- Malignant tumor
- Hemorrhagic conditions
- Epilepsy
- Recent surgical procedure
- Pulmonary insufficiency

Side Effects

2

Side effects

Common side effects reported after treatment generally mild in nature. They may include but are not limited to:

- Skin damage, for instance:
  - Local erythema
  - Skin redness
- Abdominal discomfort, such as
  - Menstrual irregularities and abdominal cramping
  - Constipation, diarrhea, or abdominal bloating
- Aches and pain, such as
  - Muscular pain, myalgia
  - Temporary pain, e.g in back, extremities, joints, tendons
- Systemic symptoms, such as
  - Lightheadedness, nausea, headache or migraine
  - Muscle weakness, asthenia, malaise, or somnolence

Adverse events that are seldom seen are

- Dyspigmentation (hyper / hypopigmentation)
- Hair growth
- Infection
- Scarring
- Nerve pain, pinching

If the patient experiences any symptoms, the operator must stop treatment immediately and contact the appropriate physician.

Residual risks

If the device is used within its intended purpose, no other unacceptable residual risks are known besides the side effects and the warnings already mentioned.

Before using the emField*Pro* on a patient, the user should become acquainted with the operating instructions and individual treatment methods as well as the indications / contraindications, warnings and application information. Additional sources of information about types of therapy should be consulted.

Before use, ensure that the device is powered via a properly earthed plug with a grounded outlet (electrical installation according to DIN VDE 0100 Part 710). The device must only be operated with the supplied power cord. The power cord must be protected against mechanical stress.

Operation of this equipment in the vicinity of strong electromagnetic fields (e.g. tomographs, x-ray or diathermy equipment) may interfere with the operation of the device. Please keep a safe distance of several meters.

During use, the device is to be located in a position allowing direct access to the device´s central mains supply so that it can be disconnected for the mains at any time.

To avoid the risk of electric shock; the device´s main plug must be disconnected from the mains supply before performing any maintenance or cleaning activities.

The emField*Pro* is not suitable for use in areas with an explosive, flammable or combustive environment.

Inspect the device before to use. If there is any damage, it must not be used.

Only accessories provided by Zimmer MedizinSysteme GmbH must be used.

This therapy may only be performed on undamaged skin.

Warnings

emField*Pro* is intended to be used exclusively for medical professionals, such as authorised physicians, therapists, and medical paraprofessionals. Magnetic therapy devices are not intended for use by laypersons or in home care

The patient must not be left unattended during therapy.

The device is intended to be used exclusively by medical professionals.

Any treatment instructions regarding treatment location, duration and intensity require medical knowledge and should be given by authorised physicians, therapists and health paraprofessionals. It is imperative that these instructions are followed.

The use in wet areas is not permitted and may in case of non-compliance lead to considerable damage to the device and endanger both the patient and the user.

Dispose packaging materials properly. Make sure that it is not accessible to children.

It is forbidden to push the device if castors are not in transport position.

Sitting on the device prohibited.

What is the emField*Pro*?	emField*Pro* is a most reliable and powerful pulsed inductive therapy device.
What does the emField*Pro* do?	emField*Pro* generates max. 3 Tesla electromagnetic field to treat acute and chronic pains.
What are the advantages of emField*Pro*?	• Non-invasive treatment • Deep penetrating by 3 Tesla pulsed electromagnetic field • Unique oil circulation cooling transducer • Touch screen display for easy operation • Wide range of applications
What are other advantages of emField*Pro*?	Two types of transducer for wider application
Intended use	The emField*Pro* is an electrically powered device intended for medical purposes that repeatedly contracts muscle tissue by passing electrical currents through electrodes non-contacting the affected body area. In addition, the device is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence in humans.
Patient Population	Patients with acute / chronic pain (aged over 18 recommended). No limitations regarding gender or anatomy difference.
Note:	*The device is intended to be used exclusively by medical professionals (e.g. physicians, therapists, medical paraprofessionals).*

After the transport and before switching on the device, make sure that the swiveling wheels are in the ‘locked’ position.

Note:

Make sure that the emField*Pro is placed on a stable and flat surface*

Connect mains cable

Connect the mains cable (23) to the socket on the device (11) and connect it to the mains.

The device may only be connected to earthed sockets

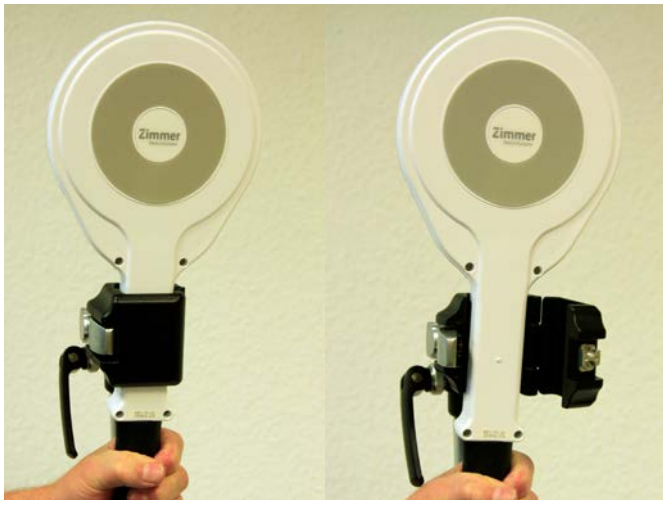
Switching the device on

Switch on the device with the power switch (12)

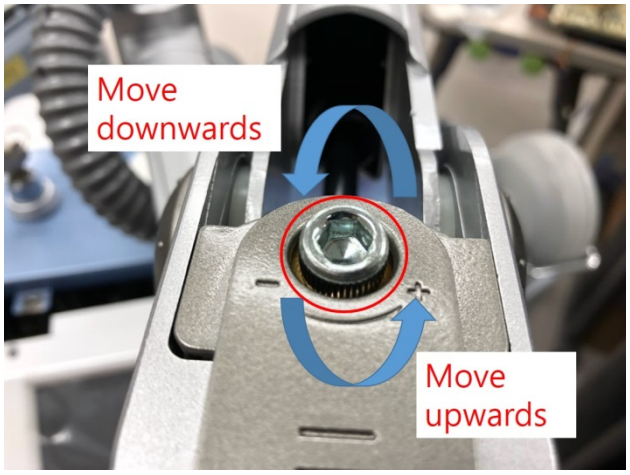
Be aware that connecting the power cable with the power switch turned on may cause malfunction.

If the transducer is used while in a tilted position, the cooling oil will not reach all sections of the transducer and damage the transducer due to overheating. For this reason, it is recommended to place the transducer in a horizontal position as much as possible.

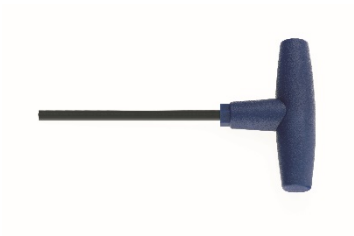
When separating the transducer from the transducer arm supporter, the pressure of the gas spring may cause the arm to jump up and the transducer may fall off. Be sure to hold the transducer with one hand while holding the arm supporter vertically. When replacing the transducer, be sure to mount the arm support vertically as well.



After using the emField*Pro* for a long time, the transducer arm may be stuck down or up. In this case, the position of the transducer arm can be changed by adjusting the gas spring pressure. To lower the arm supporter, turn the hexagonal wrench bolt in the (–) direction as shown in the figure below, and turn it in the (+) direction to lift it upwards.



To adjust the transducer arm use only the supplied hex key (24).



Switching the device off

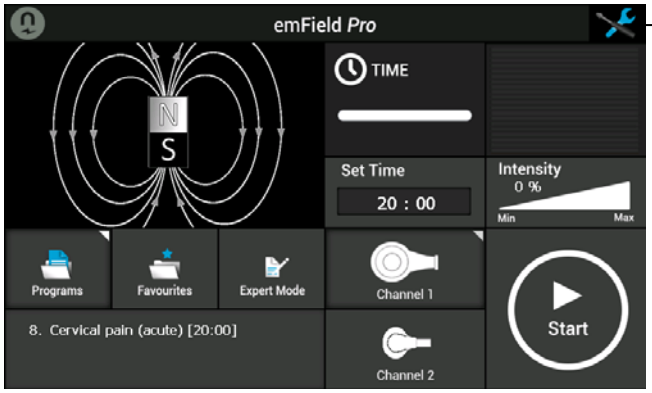
The device is switched off using the power switch (12).
In order to completely disconnect the device (all-phase) from the mains, remove the mains cable.

Start-up screen

Once the device has been switched on and the self-test performed, the start-up screen opens.

Standard screen

After the self-test has been performed, the emField*Pro* goes automatically in the standard screen.

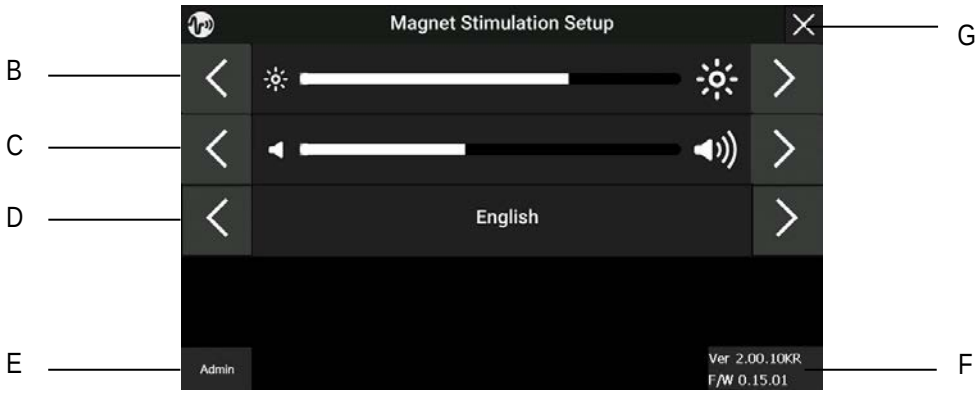


A

Selecting configuration

Pressing the Configuration button (A) immediately switches to the configuration menu.

Configuration menu



(B)	Brightness	Adjust the brightness by using the left and right arrows.
(C)	Volume	Adjust the volume by using left and right arrows.
(D)	Language	Selection of the language by using the left and right arrows.
(E)	Admin	Only for service partners
(F)	Version	Shows information about the current software version
(G)	Close	Closes and stores the configuration menu

Device description

The emField*Pro* consists of a main body and 2 transducers connected to it. It relieves the muscular pain using electromagnetic fields. The transducer is generally placed on the area of the pain with some distance to the skin.

The rated power for this equipment is AC 230V

Repair, expansion, and installation of equipment shall not be performed by anyone other than the specialized personnel authorized by the manufacturer. Arbitrary disassembling/assembling of equipment by the user is absolutely prohibited

As a strong magnetic field is generated around the magnetic field generating section, equipment operation technicians, assistants, and patients must not hold any items which can be affected by the magnetic field.

Note *When equipment is operated, do not use any items as wristwatches, mobile phones, radio sets, transmitters or wireless toys as the may be damaged by magnetic fields. So please be careful and keep them separately.*

Note *To avoid electrical noise during use, the equipment shall be installed at a significant distance from any generator, X-ray equipment, broadcasting device, mobile electric wire, and so on.*

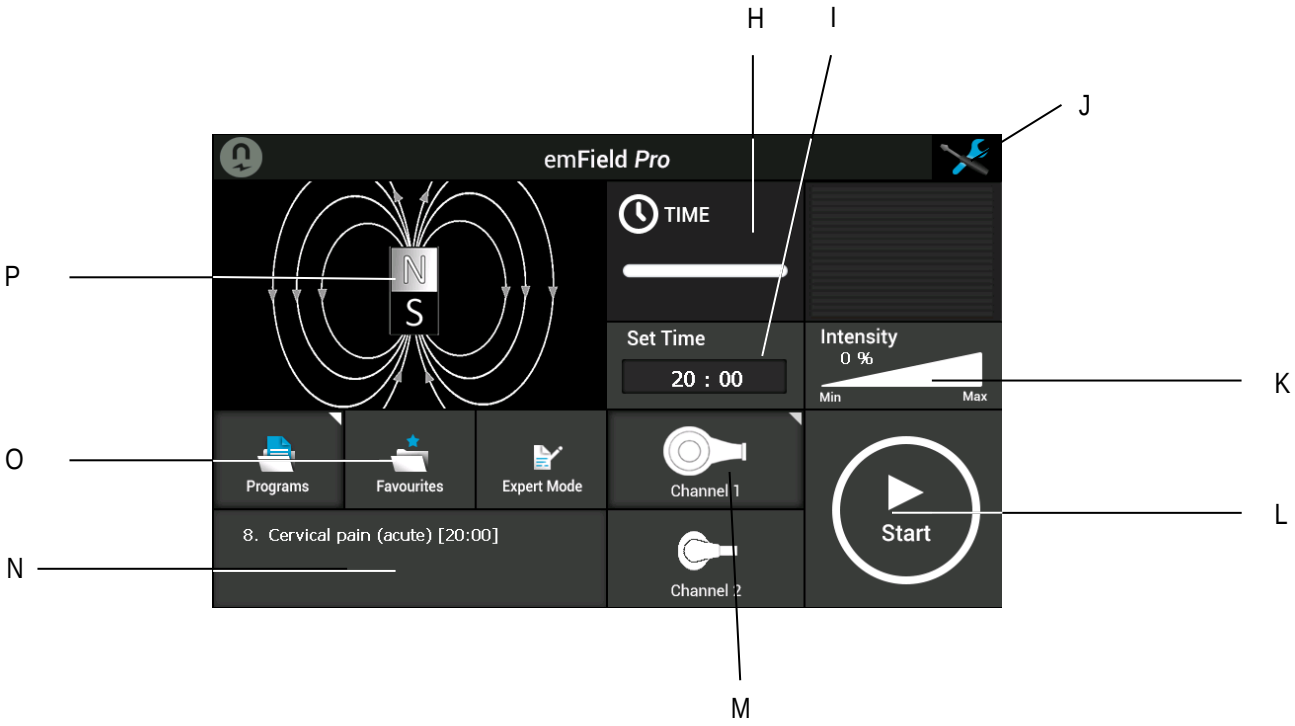
Note *During the operation of the equipment, the patient shall not take drinks, water, etc which can influence the equipment*

The emField*Pro* monitors the temperature of the applicator. Besides that the device will check with regular intervals the connection between applicator and main device. Please refer to Chapter 17 in case any error message should pop-up.

Transducer placement

You can adjust the position and angle of the CH1 transducer according to the patient and the stimulation area. The CH1 transducer arm can be moved up and down and left and right. The angle of the CH1 transducer can be adjusted using the transducer holder. The height of the CH1 transducer arm is adjusted by the weight of the CH1 transducer using gas spring pressure. To adjust the angle of the CH1 transducer, hold the CH1 transducer holder in the unlocked position and adjust the angle. The holder must be locked after adjustment is complete. Please refer the figure below.

Do not use the CH1 transducer of which hose is bent.



(H) Time remaining
(I) Total operation time
(J) Configuration icon
(K) Intensity in %
(L) Start/Stop
(M) Channel selector (CH1 Large or CH2 Medium)
(N) Applied program
(O) Mode selector (Programs / Favourites / Expert mode)
(P) Program information screen

(H) Time remaining	Shows graphical the course of the treatment time.
(I) Total operation time	At start: shows the total treatment time. During operation: count down the treatment time. Set (change) the time: click on button (2) and use the central control knob (6) to set (change) the total operation time.
(J) Configuration menu	Refer to Chapter 7, Settings for setting possibilities.
(K) Intensity	After pressing the start button: shows graphical and in percentage (0 – 100%) the applied intensity. Set (change) the intensity by using the central control knob (6). Turn to the right to increase intensity and/or turn to the left to decrease the intensity.
(L) Start / Stop	After pressing the Start button the applied program starts. The total treatment time will count down to 0. The text on the Start button changes into STOP. Pressing this button again stops the treatment, and reset the treatment time and applied energy.

(M) Channel Selector

Select either CH1 (Large transducer) or CH2 (Medium/Hand-held transducer). The color of the button indicates that the channel has been darkened as active.

(N) Applied program

By using one of the buttons (0) followed by selecting one of the stored programs by using the central control knob (6), the selected mode is displayed in the mode selection window located at the lower left part of the display.

(O) Mode Selector

The Programs mode is preset with parameter values while the Favourites and Expert modes are using configurable programs.

Programs Mode

Programs mode provides the user with a number of pre-programmed treatment recommendations. A more detailed description can be found in the treatment guide.

Every recommendation can be further specified by selecting 'Chronic' or 'Acute'

Favourites Mode

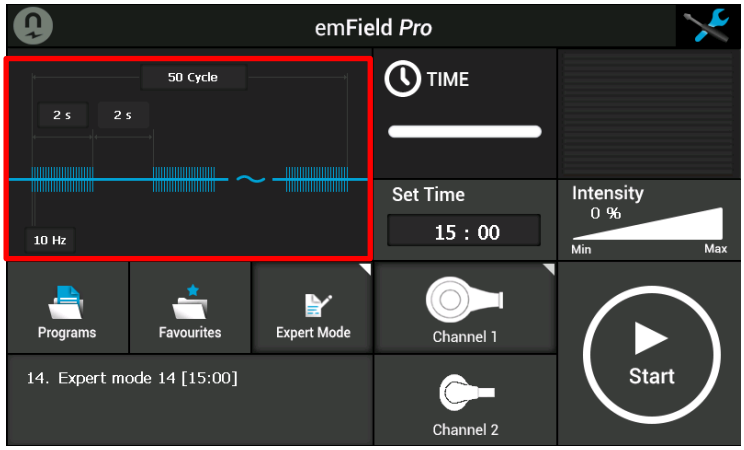
The Favourites Mode has 20 'free to store' programs. Frequency of the magnetic field, continuous output time and pause time are set in advance. The waveform of the selected mode is applied repeatedly during the operating time, set by the user.

The parameter setting ranges are as follows

- F1: 1 ~ 100 Hz
- F2: 1 ~ 100 Hz
- Ton: 1 ~ 4s (The setting ranges are different according to the value of F1 and F2)
- Toff: 0 ~ 10s (The setting ranges are different according to the value of F1 and F2.)

(P) Program Information Screen

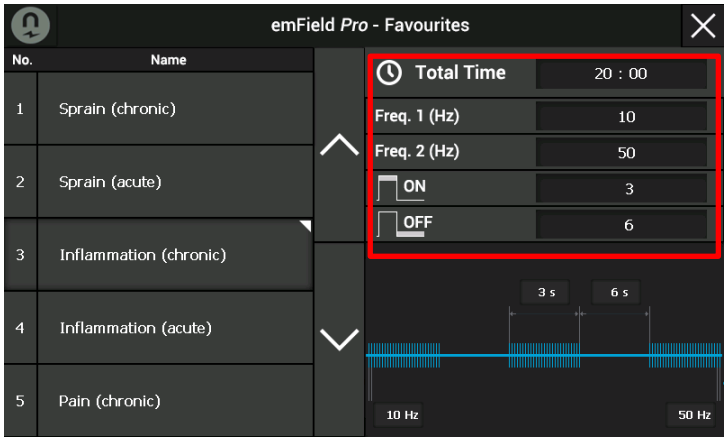
If Program is selected: this screen shows an animation.
If Favourites or Expert Mode is selected: this screen shows a graphic, representing the chosen parameters.



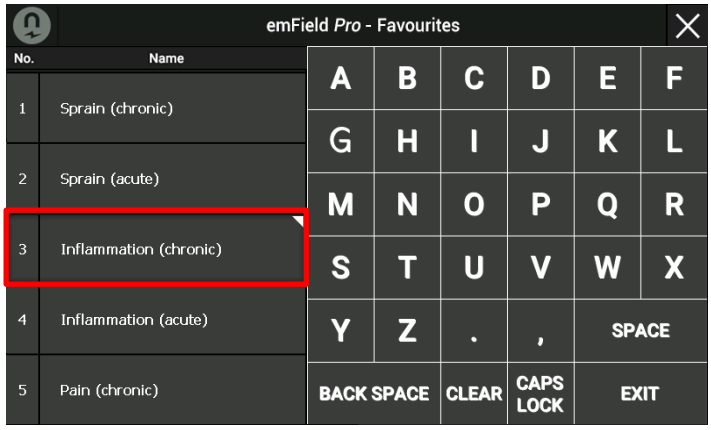
Change settings of the Favourites mode like following:

Press the Favourites button for 2 ~ 3 seconds to set the parameters on touch screen.

The user is able to set the parameter values after appearance of the parameter setting screen



Choose the parameter to change. Freq1, Freq2, On Time, Off Time can be set in this mode. By using the central control knob (6), parameter values are set. After finishing all the settings, close the parameter setting screen by pressing a closing window (X) at the upper right corner.

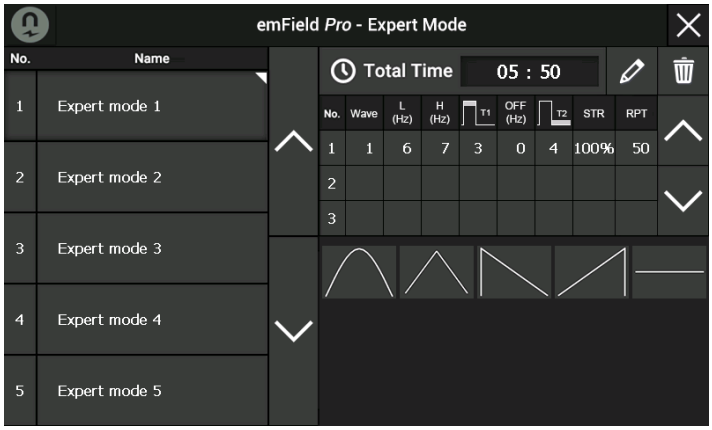


After pressing about 2 seconds on one of the Favourites a screen will appear in which a name of the region can be changed. After changing the name, press Exit to close the screen.

Expert Mode

The Expert Mode has 20 free to store modes; the user can set the parameter values directly.

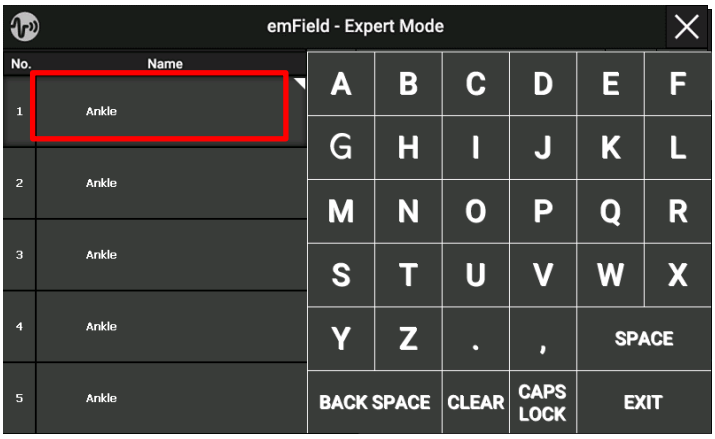
To change settings press Expert Mode on the touch screen for 2 ~ 3 seconds to set the parameter values.



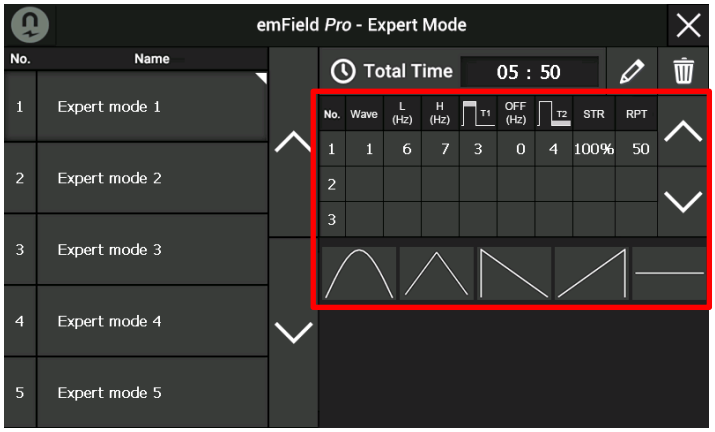
The parameter settings are:

- Wave : Select one of the following waves:
  Sinus; Triangle; Downward Triangle; Upward Triangle or Continues by selecting the according symbol.
- L (Hz) : L(ow) limit of waveform (6-149 Hz). This frequency has to be lower than H (Hz).
- H (Hz) : H(igh) limit of waveform (7-150 Hz). This frequency has to be higher than L (Hz).
- T1 : Duration of the stimulation phase (1 – 10 seconds).
  The setting ranges are different according to the value of the frequencies.
- OFF (Hz) : Frequency during the Off phase (0 – 4 Hz).
- T2 : Duration of the Off phase. (4 – 10 seconds).
  The setting ranges are different according to the value of the frequencies.
- STR : 1 – 100% (multiplying factor for the main magnetic field intensity)
- Repetition : Number of repetitions, 1 ~ 60 cycles.

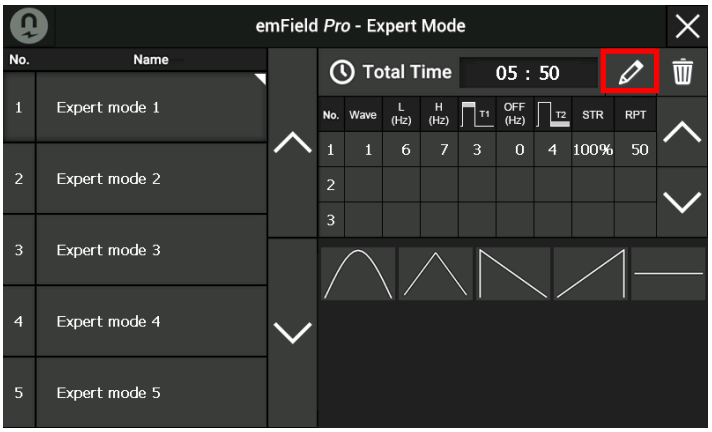
By pressing on the Name for about 2 seconds, an alphabet screen appears and the pre-programmed name can be changed.



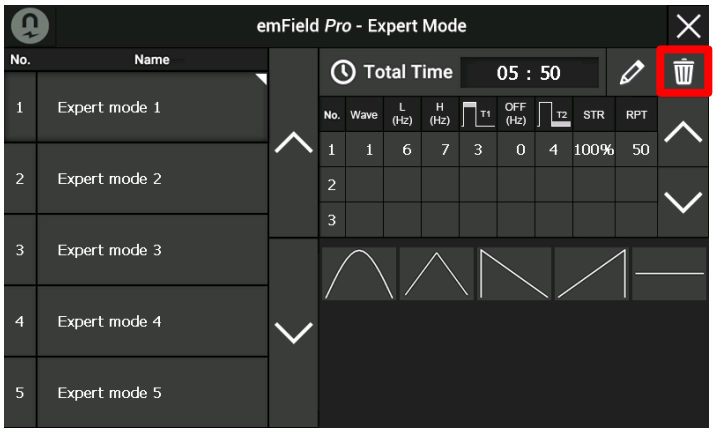
By pressing the Parameter section, setting screen appears and the parameter values change.



Choose the parameter to change. Wave, L (Hz), H (Hz), T1, Off, T2,, Strength, Repetition can be set in this mode by using the central control knob (6) which changes the parameter values.



Each mode has 9 sub-modes with different parameter sets. The Expert mode operates sequentially from sub mode 1.
A sub-mode is added by pressing a pencil figure at the end of the top right parameter setting screen.



To remove a sub-mode, press the bin figure in the right top corner after choosing the specific sub-mode.

After specifying the name and parameter values for the Expert Mode Program, click close window (X) at the top right to close the parameter setting screen.

Technical Information

9

Power supply	Input power: 220-240 V 50/60Hz Power consumption: max 2200VA
Mains fuse	T12,5 AL / 250Vac
Protection class	Class 1
Applied part (Applicator)	Type BF
Dimensions	542 (L) × 501 (W) × 993 (H) mm
Weight	Approx. 60 kg
Operation	Magnetic field strength: - CH1: 3.0 T – pp (±20%) - CH2: 3.0 T – pp (±20%) Modes: - Programs Mode : A1 ~ A20 - Favorites Mode: M1 ~ M20 - Expert Mode: U1 ~ U20
Transport	Transport with the device in a vertical position 1 Packaging 1 device
Operation	Operation environment - Temperature: +10 °C to +30 °C - Humidity: 30 % to 85 % RH - Air Pressure: 700 to 1060 hPa
Storage and Transport	Storage and transport environment - Temperature: 0 °C to 60°C - Humidity: 10% to 90% RH - Air Pressure: 700 to 1060 hPa
Sound Power Level	<70 dB(A)
Notice:	*Storage and transport only in original packaging.*

Subject to technical modifications.

Cleaning
Disinfection

10

We recommend disinfecting at a minimum after each patient and at the end of the day and whenever there is evidence of possible contamination. Contact your health expert on this topic. Always perform cleaning prior to disinfection.

Before starting any maintenance and cleaning measures the device must always be switched off at the main switch and the mains cable unplugged.

Make sure that during cleaning and disinfection no liquids penetrate the device. Do not use sprays.

If during cleaning or disinfecting liquid penetrates the device, please put the unit out of service, protect it from being used again and contact your service representative.

Make sure that when cleaning and disinfecting the labels of the device (such as warnings, labels of control devices, identification plate) are not damaged.

The device and its applied part are considered 'non- critical' in relation to hygiene when used on non-injured and healthy skin.

Housing / Applicator

Cleaning: In the event of visible contamination, the housing, the applicator and all cables can be cleaned using commercially available alcohol-free plastic cleaners. Wipe the surface until the dirt is removed, using a soft cloth soaked according to the specifications of the manufacturer of the cleaning agent but not dripping wet.

Disinfection: We recommend that disinfection to be carried out at least once a week, as well as in the event of evidence of possible contamination. Consult with your health professional when doing so. Always perform cleaning prior to disinfection.

Housing and applicator can be disinfected using disinfectant wipes. Use a commercially available alcohol-free disinfectant for metal and plastic, with bactericidal, veridical and fungicidal properties. Observe the application instructions of the manufacturer. Wipe all surfaces using a cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or with cloth pre-impregnated with disinfectant (wipes).
If applicable, also observe requirements for drying or post-cleaning.

Caution: If flammable solutions are used for cleaning and disinfection, sufficient time must be allowed for the solutions to evaporate before using the device. Otherwise, it may lead to inflammation!

Notice:

Only use the device in a hygienic environment.

CE-Mark

11

The product bears the CE-mark

CE 0123

in accordance with the EC Directive on Medical Devices 93/42/EWG.

Manufacturer

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm, Germany
www.zimmer.de

Scope of Delivery and Accessories

12

Scope of delivery
Art. no. 5030

1 emField*Pro* including
2 transducers
1 applicator arm
1 Instructions for use
1 Mains cable
1 Hex Key

Accessories
Art. no.

54209200	1 Applicator arm
67300124*	1 Mains cable type
10102817	1 Instruction for use

Subject to change!

* Individual mains cable available. Please contact your distributor.

Note: *The device may be operated only with original parts from Zimmer MedizinSysteme GmbH. Otherwise, the function and safety of the patient, user and third parties cannot be guaranteed.*

Device Combinations

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For emField*Pro* no combination devices are provided by the manufacturer.
Anyone who, acting contrary to these specifications combines devices and thus operates a medical system does so at its own risk.

The emField*Pro* is manufactured according to the safety regulations of IEC 60601-1.

As manufacturer, Zimmer MedizinSysteme GmbH can only be considered responsible for the safety and reliability if:

- the device is operated using a proper power outlet that is properly grounded and the electrical installation complies with DIN VDE 0100 part 710,
- the equipment is operated in accordance with the instructions for use,
- extensions, readjustments or modifications are carried out only by persons authorized by Zimmer MedizinSysteme GmbH
- the user is satisfied regarding the functional safety, the proper condition and mechanical integrity prior to using of the device,
- the device is operated only by properly trained personnel,
- the device is not operated in hazardous areas and / or a combustive atmosphere,
- the device is immediately disconnected from the mains in the event of the penetration of liquids. The device does not contain any parts that can be serviced by the operator.

The device does not contain any parts that can be repaired by the operator.

Modification of this device is not permitted.
Service and replacement of components may only be performed by certified service technicians from Zimmer MedizinSystems GmbH.

Reporting

All serious incidents associated with the product are to be reported to the manufacturer and the competent authority of the state in which the user and/or the patient is located.

Routine inspection of equipment

The covering of power line of equipment, transducer connecting line, etc. shall not be peeled off and internal lines shall not be exposed, and shall not be damaged by impact from outside.

There shall be no trace of oil leakage from transducer.

Wash the outside of equipment so that there is no foreign material.

The button for equipment operation, etc. must not shake.

The various parts attached to the device must not shake.

If any of the above occurs, contact your servicepartner for help.

Safety inspection

In order to ensure safe use, internal cleaning should be performed once per year by a person authorized by Zimmer MedizinSysteme GmbH

In order to ensure safe use, be sure to check the equipment including internal components and output voltage from the person who has been given authorization from the company once per year.

Please clean the transducer before storing

After storing the device for a long period of time, be sure to check the device before using it.

Please note the following regarding storage conditions:

- Keep out of water
- Keep away from direct sunlight
- Do not store near heaters
- Avoid locations subject to excessive shock or vibration, exposure to chemicals or explosive gases.

Troubleshooting

If the equipment does not operate normally during use, please check the items listed in the table before requesting service. If none of the following problems apply, or if the following remedies do not help, turn off the power to the equipment and contact your servicepartner.

Self-troubleshooting

Symptom	What to do	References in the User Guide
Equipment does not turn on.	Check if the power connector of the equipment is properly connected.	• Chapter 6; device set up
	Check if the power switch of equipment is turned on.	• Figure 2; Rear of the device
Magnetic field is not generated from equipment.	Confirm if the LCD displays an ERROR message.	• 17. Error Messages and Troubleshooting
	Check if the output strength is set by turning the Turning Knob after pressing the Start button.	• 8. Operation Instructions
Over Temperature message is displayed.	If transducer is in an upright position, it is easy for the transducer to overheat. Maintain a horizontal position as much as possible.	• 17. Error Messages and Troubleshooting
	If the room temperature is too high, disorder can be caused in the cooling. Maintain the room temperature at less than 25℃ as much as possible.	• 17. Error messages and Troubleshooting

In the following cases, stop the operation by cutting off the power to the equipment, and contact the service center.

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- The main power switch spontaneously turns off.
- The LCD screen of operation panel does not illuminate when power is turned off and then turned on again.
- When stimulation is not generated by transducer, even after intensity is increased.
- The temperature icon on the screen blinks and the equipment is not operated.

Regular inspection for performance maintenance

In order to ensure safe use, be sure to have a regular, and at least early inspection by an authorized person.

The emField*Pro* is listed in attachment 1 of the MPBetreibV (Medical Device Operator Ordinance).
Please observe the measures which are necessary as a result.

In Germany, the German Social Accident Insurance (DGUV) (Regulation 3 – Electrical systems and equipment), as amended, must also be observed.

Note: *These requirements apply to the operation of the device in Germany. Divergent regulations may apply in your country.*

Error Messages

Messages:

Over Temperature

The emField*Pro* is an equipment that generates a magnetic field by applying a high current to a transducer. As heat is generated from the transducer using the high current used to create the magnetic field, cooling is performed by circulating the cooling oil inside the emField*Pro* transducer. If the transducer is used in a tilted position, the cooling oil will not reach all sections of the transducer, and injury or stoppage of operation can occur. Because of this, it is recommended to place the transducer in a horizontal position. When transducer is overheated, the operation is temporarily suspended and the “Over Temperature” message as shown in figure 25 is displayed. When this message is displayed, put the transducer away from the patient for a while (Do not turn off the equipment) until the message disappears and the equipment returns to a normal state.

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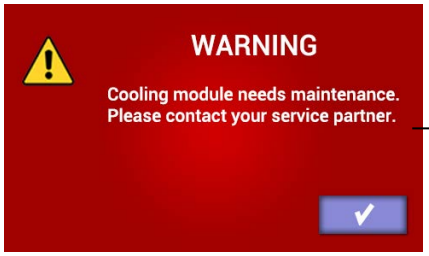
It is highly recommended to use the transducer in a horizontal position.

Cooling module lifetime

The emField*Pro* uses an oil pump for cooling. This component is a consumable component, with 5000 hours of warranty. After 5000 hours ‘cooling Module’ message as shown in the figure 26 is displayed. This is not a failure, but a notification of maintenance. Touch the panel and the device will be back to normal state.
Replacing the component to prevent unexpected failures.



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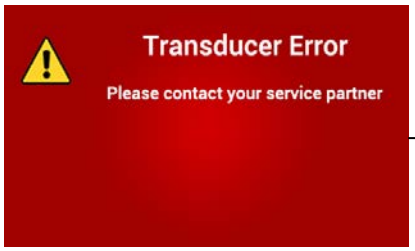
Transducer Error

The emField*Pro* always checks the connection of the transducer cable. If the cable is disconnected or damaged, the message is shown as in figure 27. In this case, equipment cannot be used anymore, and the user must contact authorized personnel of our local distributor maintenance.



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Note: *The* emField*Pro always checks the connection state of the cable connected to the transducer.*

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Disposal

The device may only be returned to the factory in the original packaging.
It must be disposed by Zimmer MedizinSysteme GmbH.

In foreign (European) countries, please refer to national regulations for disposal.
Contact your distributor if necessary.

With regards to the EMC (electromagnetic compatibility) 4th Edition, medical electrical devices such - as the emField*Pro* are subject to special safety measures and must be installed and commissioned in accordance with the EMC instructions in the operating instructions or accompanying documents.

Portable and mobile HF communications equipment (e.g mobile telephones, cell phones) can impact medical electrical devices.

The emField may only be operated using the original power cable indicated in the scope of delivery list.Operating the device with another power cable can lead to increased emissions or reduced interference resistance of the device.

The emField*Pro* is developed according to the recognized standards of technology; the information on the intended use of the components is taken into account.

The emField*Pro* must not be operated near active HF surgery devices or magnetic resonance tomography that can cause high levels of electromagnetic interference.

The emField*Pro* is exclusively for professional health care facilities such as hospitals provided and tested.

The emField*Pro* has an essential performance of supplying 2.0 T +/-20% which is not influenced by electromagnetic interference.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The electromagnetic compatibility of the emField*Pro* device has been tested on the original device with handpiece.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.

The device emField*Pro* contains no interchangeable components, cables or other that leads to a deterioration of the EMC.

WARNING: Portable RF communication equipment (including peripherals such as antennas) should be used no closer than 30 cm (12 inches) to any part of the device emField*Pro* including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The device was tested for RF immunity only at selected frequencies. Nearby transients at other frequencies may result in degraded operation. The frequencies tested are listed in Table 4.

The emField*Pro* is developed according to the recognized standards of technology; the information on the intended use of the components is taken into account.

The device emField*Pro* does not contain any components which age over the course of the device life time and could lead to a deterioration of the electromagnetic compatibility. Thus, no maintenance is required during the life of the device to ensure basic safety. All tests according to standard IEC 60601-1-2 Ed. 4.0 were performed. No other standards and regulations for electromagnetic compatibility have been applied.

Table 1

Guidance and Manufacturer's Declaration- Electromagnetic Emissions		
The device emField*Pro* is intended for use in the electromagnetic environment specified below. The customer or user of the device emField should ensure that it is used in such environment.		
Emission Measurement	Compliance	Electromagnetic Environment-Guidelines
RF Emissions in accordance with CISPR 11	Group 1	The device emField*Pro* must emit electromagnetic energy in order to ensure its intended function. Nearby electronic equipment may be affected.
RF Emissions in accordance with CISPR 11	Class A	The device emField*Pro* is suitable for use in all establishments, including domestic establishments and those directly connected to the public supply network that also supplies buildings used for domestic purpose.
Emissions of Harmonics in accordance with IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/ flickers in accordance with IEC 61000-3-3	Compliant	

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

Table 2

Guidance and Manufacturer's Declaration- Electromagnetic Immunity			
The device emFieldPro is intended for use in the electromagnetic environment specified below. The customer or user of the device emField should ensure that it is used in such environment.			
Immunity Tests	IEC 60601- Test Level	Compliance Level	Electromagnetic Environment - Guidelines
Electrostatic Discharge (ESD) in accordance with IEC 61000-4-2	± 8 kV Contact Discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air Discharge	± 8 kV Contact Discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air Discharge	Floors should be made from wood, concrete or ceramic tiles. If floor are covered with synthetic material, the relative humidity must be at least 30 %
Electrical fast transient/ burst in accordance with IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	The supply voltage quality must correspond to that of a typical commercial or hospital environment.
Surges in accordance with IEC 6100-4-5 -Line-to-Line-	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV	
Surges in accordance with IEC 6100-4-5 -Line-to-ground	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV	
Voltage dips in accordance with IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The supply voltage quality must correspond to that of a typical commercial or hospital environment. If the user of the device emField requires continued operation, even in the case of interruptions in the power supply, it is recommended that the device emField be powered from an uninterrupted power supply or a battery.
	0 % U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	0 % U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	
Voltage interruptions in accordance with IEC 61000-4-11	0% U_T; 250/300 cycle	0% U_T; 250/300 cycle	
Magnetic field of supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz	Magnetic fields at mains frequency should have the typical values found in a business or hospital environment.
Note: U_T is the mains AC Voltage before application of the test level			

Table 3

Guidance and Manufacturer's Declaration- Electromagnetic Immunity			
The device emFieldPro is intended for use in the electromagnetic environment specified below. The customer or user of the device emField should ensure that it is used in such environment.			
Immunity Test	IEC 60601-Test Level	Compliance Level	Electromagnetic Environment - Guideline
Conducted Disturbances induced by RF fields according IEC 61000-4-6	3 V 0,15 MHz to 80 MHz 6 V in ISM Band between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz to 80 MHz 6 V in ISM Band between 0,15 MHz and 80 MHz 80% AM at 1 kHz	In the vicinity of devices, bearing the following symbol, interference is possible: 
Radiated RF EM fields according IEC 61000-4-3	3 V/m 80 MHz-2,7 GHz 80% AM at 1 kHz	3 V/m 80 MHz-2,7 GHz 80% AM at 1 kHz	

Table 4

Electromagnetic immunity to HF radio communication equipment						
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Energy (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ± 5kHz Derivation 1kHz Sine	2	0,3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0,3	28

Electromagnetic immunity to HF radio communication equipment						
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Energy (W)	Distance (m)	Immunity Test Level (V/m)
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0,2	0,3	9
5500						
5785						

emField*Pro*

Instructions for Use

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