

User Manual
emField



Zimmer

Basic features of the device

The emField is a non-invasive therapeutic device. The device produces a magnetic field that interacts with the tissues of the human body. By muscle stimulation, the emField is indicated for bulk muscle excitation in the legs or arms for rehabilitative purposes.

Illustrations

Front of the device

Fig. 1 Front of the device

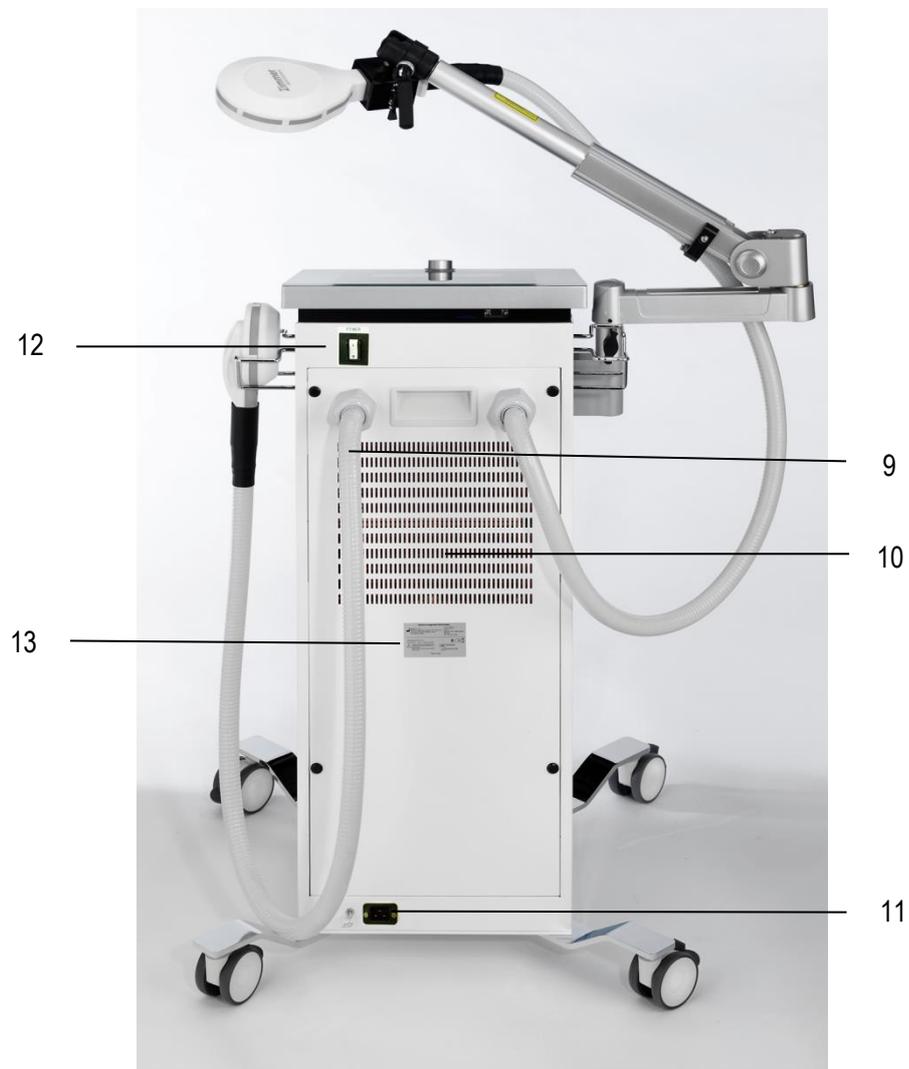


- 1 Applicator (large)
- 2 Applicator holder
- 3 Applicator arm
- 4 Applicator (small)
- 5 Display
- 6 Central control knob
- 7 Control unit
- 8 Swiveling wheels

Illustrations

Rear of the Device

Fig. 2 Rear of the device

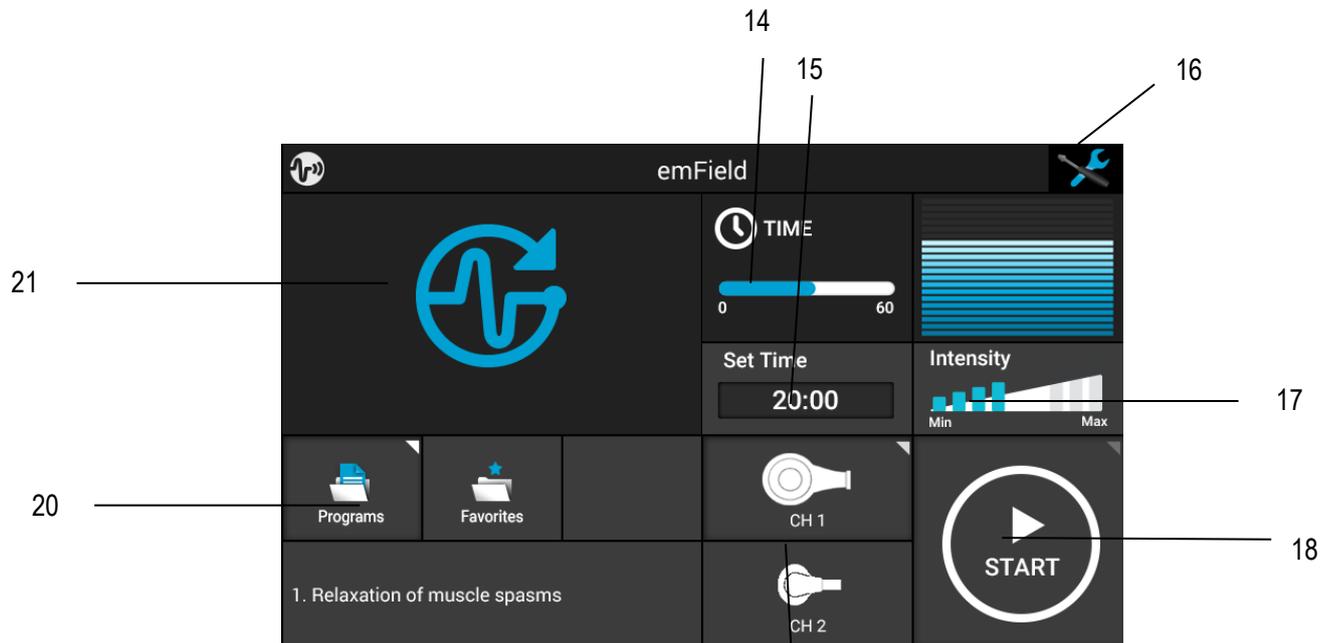


- 9 Outlet for applicator tube
- 10 Ventilation grid
- 11 Power connector
- 12 Power switch
- 13 Serial no / Identification plate

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 or CH2)
- 20 Mode selector (Programs / Favorites)
- 21 Program information screen

Illustrations

Accessories



22 Mains cable



23 Hex key

Explanation of Symbols



In the instructions for use this symbol indicates “**Generic Caution**” with regard to indicate a hazardous situation.

Caution!

In the instructions for use this symbol indicates “**Caution**” with regard to possible damage of the device.



This symbol indicates in the instructions for use for **dangers** to patient, user or third.



Applied part BF



Consult Instructions for Use



Follow instructions for use



No access for persons with pacemakers



No pushing



No sitting



Warning, magnetic field



Protective earth (ground)



Keep packaging dry

Explanation of Symbols



Fragile; handle with care



Serial number



Catalog 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.



R_x ONLY

In the United States of America, federal law restricts this device to sale by or on the order of a physician.



Potential for Electromagnetic Interference



Temperature limit



This way up

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Valid for the device MFG-01 further in this manual called emField.

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 June 2021

R_x ONLY

U.S.A Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner licensed by the law of the State in which he/she practices to use or order of the Device

Indications for use:

The emField is indicated for:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

Contraindications:

- Active applicator should never be placed over implanted electrical devices like cardiac pacemakers, cochlear implants, intrathecal pumps, hearing aids etc.
- Be ensured that magnetic stimulation doesn't penetrate the heart region.
- The emField should be used with caution in persons with Graves' disease, active bleeding disorders or seizure disorders.
- Women who are close to menstruation may find that it comes sooner, or cramping is increased / intensified with emField treatments. Therefore, it is recommended to not undergo treatment during this time of the month.

Other**Contraindications:**

- Fever
- Application over menstruating uterus
- Application over areas of the skin that lack normal sensation
- Metal or electronic implants in the treatment area
- Implanted defibrillators
- Implanted neurostimulators
- Drug pumps
- Malignant tumor
- Hemorrhagic conditions
- Epilepsy
- Recent surgical procedure
- Pulmonary insufficiency
- Pregnancy
- Cardiac pacemakers
- Application in the area of growth plate
- Application in the head area

The adverse effects may include, but are not limited to:

- Muscular pain
- Temporary muscle spasm
- Temporary joint or tendon pain
- Local erythema or skin redness

Precautions

- The system is intended for use by a trained physician or by a physician-designated medical professional.
- If the operator observes a potential safety issue or operational abnormality during use, the operator should stop the treatment immediately.
- The use of other equipment and supplies with the system has not been tested and may cause unexpected results.



Before using the emField 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 mains outlet. The device must only be operated with the supplied power cord. The power cord must be protected against mechanical stress.



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.



The emField is not suitable for use in areas with an oxygen rich, explosive, flammable or combustible 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.



The maximum treatment time is 30 minutes per treatment cycle. Allow a cool down period after each treatment.



Maximum surface temperature of the applicator is 43°C. If the maximum temperature is reached allow the system to cool down. Place the applicators as defined in the chapter about applicator placement.



During treatment the applicator will warm up, this is normal, If the patient experiences any discomfort due to excessive heat from the applicator (>43°C) then discontinue treatment.



The small applicator should be placed above 1 cm from skin surface to reduce potential tissue burn.



Users of the emField must be trained in how to use the device properly and have the appropriate skills.



During treatment, do not place any ferromagnetic or metallic materials (such as metal buttons, clasps, piercings, zippers, coins, keys, metallic fibers in the fabrics, etc.), data carriers (credit cards, USB flash drives etc.) or electronic devices (mobile phones, tablets, watches, PCs etc.) and other medical device applicators or accessories in the direct vicinity (less than 30 cm / 1 foot) of the applicator(s). Do not place the device near other devices that produce strong electromagnetic field (diathermy, X-Ray, cell phones, radiofrequency) in order to prevent mutual functionality influence. If this happens, move the device further away from the source of interference or contact an authorized service personnel.



Ensure that persons with pacemakers are not present in vicinity of the device in operation less than 1.2 meters or approx. 4 feet.



Pushing of the device is prohibited if the arm is not in an upright position.



Sitting on the device is prohibited.



The patient must not be left unattended during therapy.



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



To avoid the risk of electric shock, the mains plug of the device must be disconnected from the mains before maintenance and cleaning work.



The emField is intended as a standalone device. No other electrical device should be operated on the patient while being treated with the emField.



The device may not be connected to other devices.



Thermal energy may be accumulated in the applicators at the end of the treatment. Allow device to cool down before next treatment or turning off the device.



Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.



Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.



Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.



Maximum surface temperature of the applicator is 43° C.



Caution should be used for patients with suspected or diagnosed heart problems.



For adults use only.



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.

Caution!

1. 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 is placed on a stable and flat surface

Connect mains cable

2. Connect the mains cable (22) 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

3. Switch on the device with the power switch (12).

Caution!

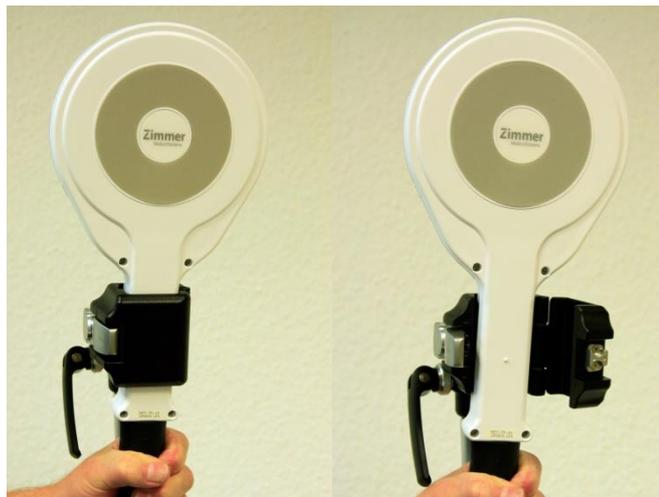
Be aware that connecting the power cable with the power switch turned on may cause malfunction.

Caution!

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



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



5. After using the emField for a long time, the applicator arm may be stuck down or up. In this case, the position of the applicator 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.

Caution!



Caution!

6. To adjust the applicator arm use only the supplied hex key (23).



Switching the device off

7. Do not switch off system when it is cooling down post treatment. 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

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

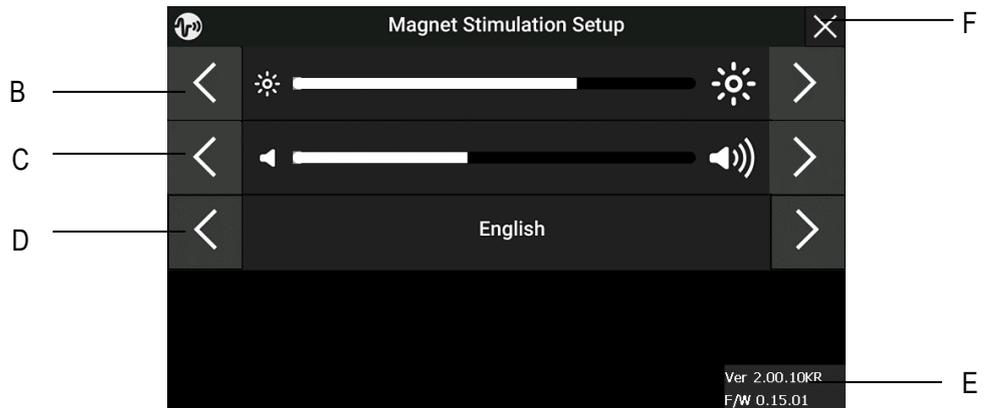
**Standard screen**

2. After the self-test has been performed, the emField turns automatically in the standard screen.

**Selecting configuration**

3. Pressing the Configuration button (See 'A' on image above) the software switches to the configuration menu.

Configuration menu



(B) Brightness

Adjust the brightness of the display by using the left and right arrows.

(C) Volume

Adjust the volume of the audible signal by using the left and right arrows.

(D) Language

Selection of the language by using the left and right arrows

(E) Version

Shows information about the current software version

(F) Close

Closes and stores the configuration menu

Device description: The emField consist of a main body and 2 applicators connected to it.



The rated power for this equipment is 220 - 240V AC



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 they may be damaged by magnetic fields. So please be careful and keep them separately.

Note

To avoid electromagnetic disturbance during use, the equipment shall be installed at a significant distance from any generator, X-ray equipment, broadcasting device, mobile electric wire, and other electromagnetic radiation emitting devices.

Note

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

The emField 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 14 in case any error message should pop-up.

Applicator placement

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

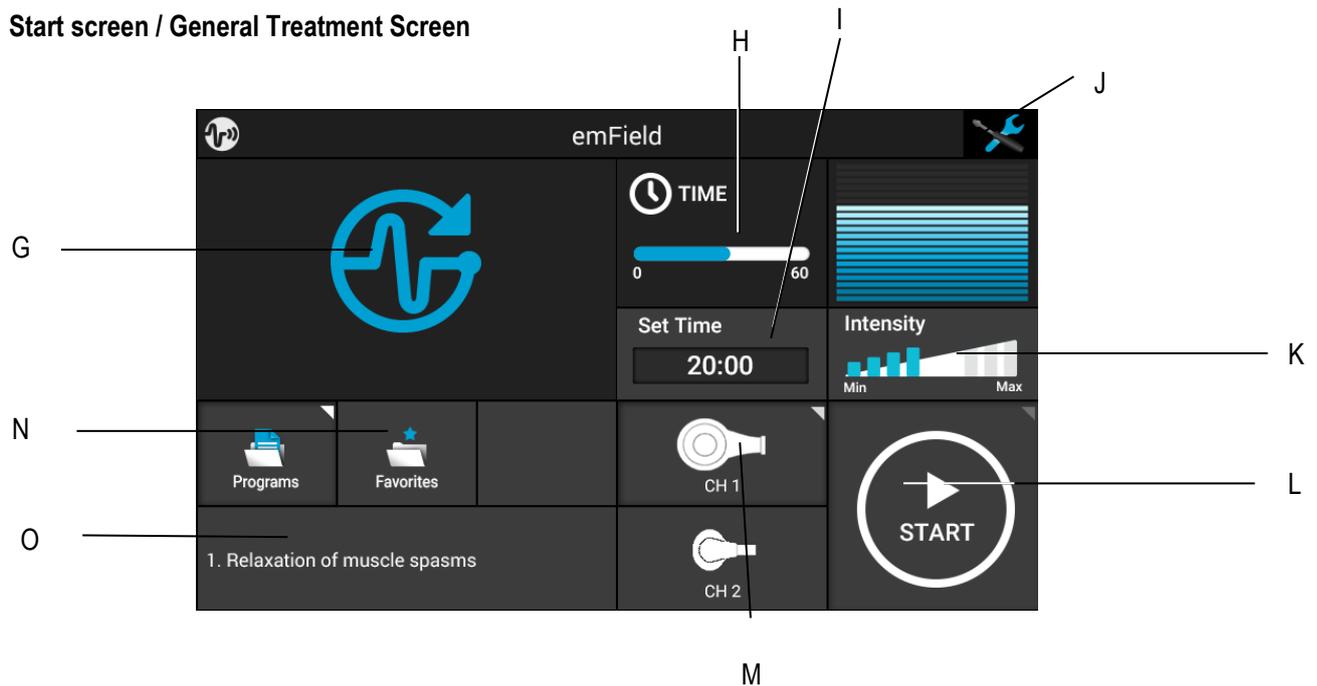


Do not use the applicator when the hose is bent.



The applicator may not touch the patient's skin. Ensure that there is always a layer of clothing between the applicator and skin.

Start screen / General Treatment Screen



- (G) Program information screen
- (H) Time remaining
- (I) Total operation time
- (J) Configuration button
- (K) Intensity in %
- (L) Start / Stop
- (M) Channel selector (CH1 or CH2)
- (N) Mode Selector (Programs / Favorites)
- (O) Selected Program

- (G) Information Screen**

If Program is selected: this screen shows an animation.
 If Favorites is selected: this screen shows a graphic, representing the chosen parameters.
- (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 (I) and use the central control knob (6) to set (change) the total operation time.
- (J) Configuration menu**

Refer to Chapter 6; 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 applicator) or CH2 (Small applicator).
The color of the button indicates that the channel has been darkened as active.

(N) Mode Selector

The Programs mode is preset with parameter values while the Favorites are using configurable programs.

(O) Programs

Program mode provides the user with a number of 6 programs. Press the Programs button for 2 ~ 3 seconds.

Favorites

The Favorites 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. Press the Favorites button for 2 ~ 3 seconds.

The parameter setting ranges are as follows:

F1: 1 – 150 Hz

F2: 1 – 150 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)

Program Screen

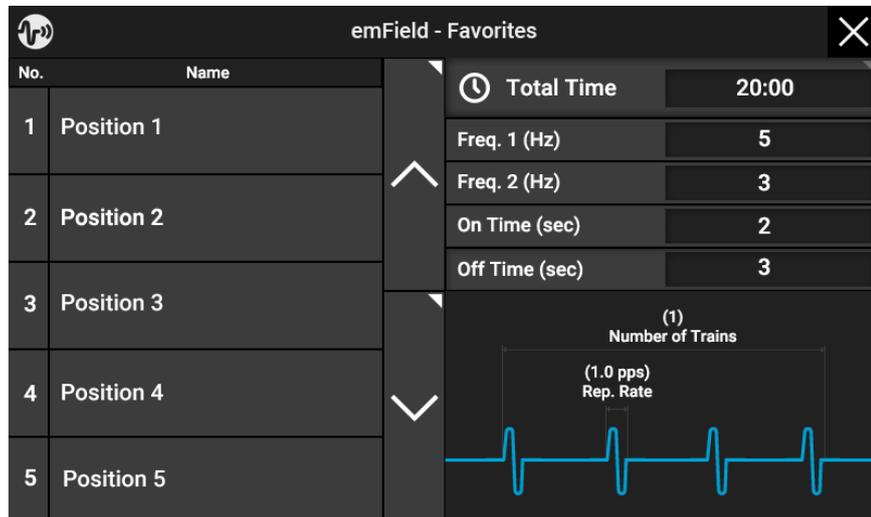
When the user presses the program button the user can select one of the 6 programs by moving the rotary knob. The selected program is shown in the display.



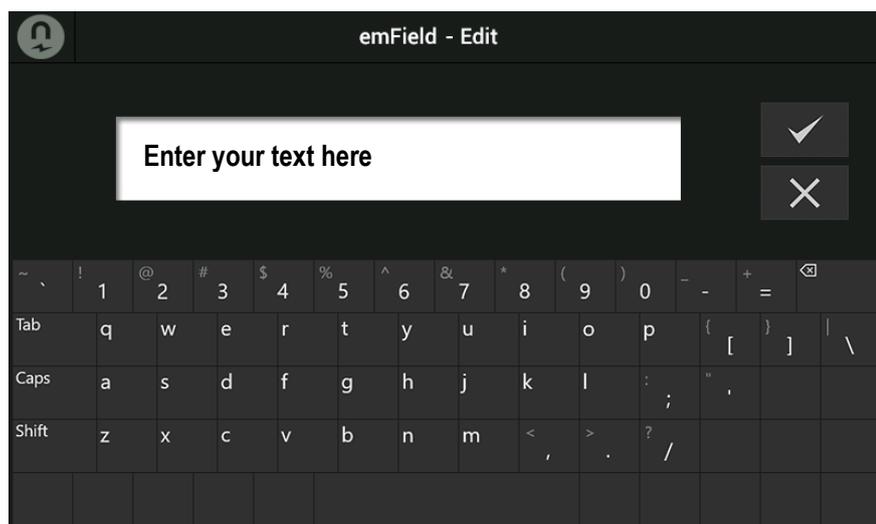
1. Select the program
2. Selected program is shown in the display

Favorites Screen

When entering the favourite screen the screen below appears. In this screen the user can adjust the parameters (defined below) and create a user-defined favorite program. Frequency one will be the starting frequency and will alternate with frequency two for the total user-defined therapy time. T_{ON} and T_{OFF} will stay the same for both frequencies.



1. The user is able to set the parameter values after appearance of the parameter setting screen
2. 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.
3. Press the button on the left side to enter the Favorites name. After entering the name close the screen by pressing the exit button.



Power supply	Input power: 220 - 240V AC, 50/60Hz Power consumption: max. 2,2KVA
Mains fuse	12,5 AT
Protection class	Class I
Applied class	Type BF
Dimensions	542 (L) x 501 (W) x 993 (H) mm
Weight	Approx. 60 kg
Operation	Magnetic field strength: CH1 0.5 – 1.5T ± 20% CH2 0.5 – 2.0T ± 20% Modes: Programs Mode Favorites Mode
Transport	Transport the device in a vertical position 1 Packaging 1 device
Operation	Operation environment Temperature: 50 - 86 F (10°C to 30°C) Humidity: 30 ~ 85% RH Air Pressure: 700 - 1060 hPa
Storage and Transport	Storage and transport environment: Temperature: 32 - 140 F (0°C to 60°C) Humidity: 10 ~ 90% RH Air Pressure: 700 - 1060 hPa

Notice: *Storage and transport only in original packaging.*



The device always has to be turned off before any cleaning and disinfecting activity.

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 soft 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 before every treatment and at the end of every day 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

Scope of delivery
Art. no. 5038

1 emField including:
2 applicators
1 applicator arm
1 Instructions for use
1 Mains cable
1 Hex Key

Accessories

67300124*
10102981
54209200

1 Mains cable
1 Instructions for use
1 Applicator arm

Subject to change!

* Individual mains cable available. Please contact your distributor.



The emField is intended as a standalone device. No other electrical device should be operated on the patient while being treated with the emField.

The device may not be connected to other devices!

The emField is manufactured according to the safety regulations of IEC 60601-1, Rev 3.1.

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 the National safety requirements,
- 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 skilled personnel,
- the device is not operated in hazardous areas and / or a combustive atmosphere,
- the fuses can changed by qualified personal only.
- 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 or serviced 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 MedizinSysteme GmbH.

Routine inspection of equipment

The covering of power line of equipment, applicator 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 applicator.

Assure there is no foreign material on the outside of the equipment.

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 service partner for assistance.

Safety inspection

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 applicator 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 service partner.

Error messages

Messages

Over Temperature

The emField is an equipment that generates a magnetic field by applying a high current to an applicator. As heat is generated from the applicator using the high current used to create the magnetic field, cooling is performed by circulating the cooling oil inside the emField applicator. If the applicator is used in a tilted position, the cooling oil will not reach all sections of the applicator, and injury or stoppage of operation can occur. Because of this, it is recommended to place the applicator in a horizontal position. When applicator is overheated, the operation is temporarily suspended and the "Over Temperature" message as shown in figure below is displayed. When this message is displayed, put the applicator 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.



Caution!

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

Cooling module lifetime

The emField 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 below 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.



Applicator Error

The emField always checks the connection of the applicator cable. If the cable is disconnected or damaged, a message appears. In this case, the equipment cannot be used anymore, and the user must contact authorized personnel of our local distributor maintenance.



Note

The emField always checks the connection state of the cable connected to the applicator.

Self-troubleshooting

Symptom	What to do	References in the Instructions for Use
Equipment does not turn on.	Check if the power connector of the equipment is properly connected.	• Chapter 5; 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.	• 14 Error Messages and Troubleshooting
	Check if the output strength is set by turning the Turning Knob after pressing the Start button.	• 7 Operation Instructions
Over Temperature message is displayed.	If applicator is in an upright position, it is easy for the applicator to overheat. Maintain a horizontal position as much as possible.	• 14 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°C as much as possible.	• 14 Error messages and Troubleshooting

In the following cases, stop the operation by cutting of the power to the

equipment, and contact the service center.

- 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 applicator, even after intensity is increased.
- The temperature icon on the screen blinks and the equipment is not operated.

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With regards to the EMC (electromagnetic compatibility) 4th Edition, medical electrical devices such - as the emField 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** is developed according to the recognized standards of technology; the information on the intended use of the components is taken into account.

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

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

The **emField** 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** 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** 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** 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** 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** 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 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 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 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 emField 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	

Guidance and Manufacturer's Declaration- Electromagnetic Immunity			
The device emField 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
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 emField 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 \pm 5kHz Derivation 1kHz Sine	2	0,3	28
710	704-787	LTE Band 13, 17	Pulse Modulation	0,2	0,3	9
745						

Electromagnetic immunity to HF radio communication equipment						
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Energy (W)	Distance (m)	Immunity Test Level (V/m)
780			217Hz			
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
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0,2	0,3	9
5500						
5785						

emField

User Manual

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