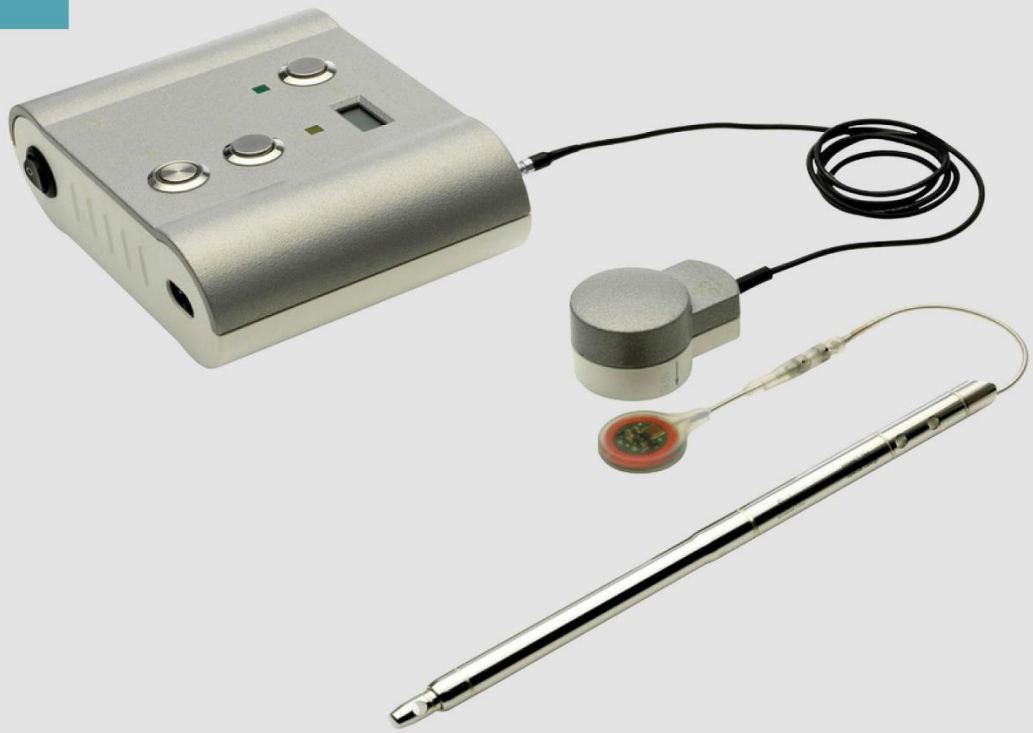
WITTENSTEIN | intens

FITBONE® Control Set

Instructions for Use



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Dear FITBONE® patient,
For the purpose of your planned limb lengthening (limb distraction), a mechatronic system has been implanted in your body, which, following instruction from your treating physician, you must activate several times a day. The limb lengthening process through continuous tension dates back to experiences made up to the beginning of the last century.
While, until a few years ago, only external fixators were available for such procedures, these can today also be performed using fully implantable systems. For this purpose, the bone is surgically severed during a minimally invasive operation and an intramedullary lengthening nail is inserted in the medullary cavity for stabilisation. Following a waiting period of generally 5 to 10 days, operation of this drive externally via the control electronics and the corresponding Transmitter begins. From this point onwards, lengthening at a rate of approx. 1mm / day takes place. The energy required for the distraction procedure is transmitted from outside the body by placing the Transmitter on a Receiver located in the subcutaneous fat tissue. This Receiver can be felt from the outside through the skin. The special feature of this method is that the skin remains completely intact and the energy transmission is not felt by the patient. New bone regenerate forms in the gap created. After completion of the distraction phase, this regenerate matures into fully-functioning highly loadable bone.
You are required to independently perform the energy transmission daily by placing the Transmitter on the skin in accordance with the medical instructions. Please refer to section 4 "Operation" of these Instructions for Use for further details.
The correct chronological sequence is decisive for the success of the treatment. If distraction is performed too slowly, the gap in the bone may be bridged prematurely, preventing further distraction. Excessively rapid distraction can cause lasting damage to blood vessels and nerves and reduce the formation of new bone material to the extent that the resulting gap in the bone can no longer stabilise, even at a later date.
For this reason, your treating physician will determine the distraction rate on an individual basis, taking all influencing factors into account, and will provide you with a log indicating the daily distraction rates, see sections 9 "Distraction log" and 10 "Comments and special notes". The daily distraction rates recommended by the physician must not be exceeded.
In order to benefit from the full functionality of the system, observing the operating instructions outlined below as well as the instructions of your treating physician are of major importance.

Your manufacturer
WITTENSTEIN intens GmbH

1 Introduction

These Instructions for Use contain information on the FITBONE® System, in particular on the function and operation of the FITBONE® Control Set, comprising the control electronics with power cable and Transmitter with coaxial cable.
The original of these Instructions for Use was written in German, all the other language versions are translations from these Instructions.
Keep these Instructions for Use in a safe place, preferably together with the FITBONE® Control Set.
Please read these Instructions for Use thoroughly **before** initial operation so that you are familiar with the characteristics of the intramedullary lengthening nail and of the FITBONE® Control Set and can optimally use its functions.
Ensure that you are thoroughly familiarised with operation of the FITBONE® Control Set during your hospital stay. Do not hesitate to immediately have wordings you do not understand or any other questions explained to you.
Always observe the instructions of your treating physician.
Together with the FITBONE® Control Set, you will receive an Implant ID, which you should always carry with you.
You can find the EC Declaration of Conformity for your implant on our homepage under Downloads (https://intens.wittenstein.de/en-en/downloads/).

1.1 Information symbols

The following information symbols are used:

- Requires you to perform an action
- ➲ Indicates the consequence of an action
- ⓘ Provides additional information on the action

1.2 Signal words and symbols

The following signal words are used to indicate possible hazards, prohibited actions, and important information:

	⚠ DANGER
	This signal word indicates an imminent danger resulting in serious injury or even death.

	⚠ WARNING
	This signal word indicates a potentially imminent danger that may result in serious injury or even death.

	⚠ CAUTION
	This signal word indicates a possible danger that can result in minor to serious injury.

	NOTICE
	This signal word indicates a possible danger that can result in material damage.

	A note without a signal word indicates usage tips or especially important information for using the FITBONE® Control Set.

The following safety symbols are used to indicate possible hazards, prohibited actions, and important information:

	
General danger	Electric voltage

2 System description

2.1 Intended Purpose

FITBONE® TAA is an intramedullary lengthening system for limb lengthening of the femur and tibia.

2.2 Indications for Use

FITBONE® TAA is an intramedullary lengthening system for limb lengthening of the femur and tibia.
FITBONE® TAA intramedullary lengthening system is indicated for adult and pediatric (greater than 12 through 21 years of age) patients.

2.3 Contraindications

- Patients with any open wounds or areas with poor soft tissue coverage near the operative site
- Patients with anatomic deformities which prevent the device from fitting
- Patients with poor bone quality that would prevent adequate fixation of the device
- Patients with compromised capacity for healing
- Patients with metal allergies and sensitivities
- Patients in which the implant would cross open, healthy epiphyseal growth plates
- Blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity
- Insufficient intramedullary space which would lead to cortical weakening or vascular damage during an implantation
- Patients with a body weight of > 100 kg for TAA11/13
- Patients with a body weight of > 50 kg for TAA09
- Differences in leg length of less than 20 mm
- Lack of hip head roofing (hip dysplasia) with femoral extensions
- Lack of stability in the surrounding joints
- No free access for proximal insertion of the intramedullary lengthening nail (e.g. coxa valga)
- No reliable exclusion of bone infection
- Expected non-compliance, mentally ill patient or patient with clouded consciousness
- Pregnancy

2.4 Possible side effects

In addition to the general risks associated with the surgical intervention, the following side effects may occur in some cases despite correct treatment:

- slight tingling to severe pain in the affected limb, particularly during and after distraction
- temporary limited mobility of the affected limb

ⓘ For a list of medical risks please refer to section 2.5 "Medical risks".

2.5 Medical risks

Possible risks related to the surgical intervention are:

- Injury to blood vessels, nerves, muscles or tendons. The consequences can be circulatory disturbances, functional disturbances, sensory disturbances, nerve pain, paralysis of the leg or a loss of the limb. Reconstructive interventions may be necessary.
- Thromboses, Embolism with respiratory distress, lung damage and even death
- Bone, soft tissue or joint infections
- Swelling and possibly bleeding of soft tissue, compartment syndrome
- Severe local circulatory disturbances which can lead to loss of limbs.
- Numbness around the scar
- Hyperreactions of the skin
- Positioning injury to the healthy limbs, buttocks or head
- General infections up to blood poisoning
- Risks related to blood transfusion (e.g. HIV, hepatitis)

Possible risks related to distraction treatment after surgery for leg lengthening are among others:

- Functional limitations of the limbs
- Delayed or absentbone osteotomyhealing.
- Joint injury, subluxations, luxations, joint stiffness, femoral head necrosis
- Allergic reactions to the implant material
- Remaining or re-emerging shortening, remaining axial and torsional misalignment and, if necessary, further surgical correction
- Loosening of the intramedullary lengthening nail
- Iatrogenous fractures
- Fracture of the bone after explantation of the implant
- Too frequent or excessive distraction can lead to overstretching of the nerve fibres, which, in some cases, can result in temporary nerve damage or permanent paralysis.
- Bone fracture at the end of the locking screw
- Contracture of the knee, ankle and hip flexor muscle
- Delayed consolidation
- Valgus deformity
- Possibility of an over- or under-correction

System-related risks:

- Malfunction of the intramedullary lengthening nail or Receiver with necessity of a re-operation to replace the components
- Breakage of the intramedullary lengthening nail

2.6 Safety

	**⚠ WARNING** **Dangers due to non-explantation of the intramedullary lengthening nail and Receiver** • The intramedullary lengthening nail and Receiver must be explanted following completed consolidation. The system is not designed for permanent implantation. Please consult your treating physician to agree a suitable time.
	**During the active phase and the early healing phase, the loadability of the intramedullary lengthening nail is limited to a partial load of 20 kg. A load beyond this can lead to fracture of the intramedullary lengthening nail.** • Observe the instructions of your treating physician.
	**Unanticipated / undesirable overloading, particularly during the active distraction phase and the early healing phase can damage the intramedullary lengthening nail. This can lead to fracture of the extension nail.** • It is essential that you avoid full loading as well as falls or stumbling. • Should such an event nevertheless occur, please make an appropriate note in the distraction log and immediately inform your treating physician.
	**The following symptoms indicate health risks:** **- Suddenly occurring severe pains** **- Sensory disturbances, numbness or other severe abnormal sensations** **- Pronounced cooling of the leg** **- Paleness or bluish colouring of the skin** **- Pronounced warming or reddening of the leg** **- Sudden fever not attributable to another cause** • In such cases, **urgently** (i.e. at any time of the day or night) contact the hospital where the intramedullary lengthening nail was implanted.

	**⚠ CAUTION** **Non-ionising radiation is used for energy and data transmission. Electromagnetic and magnetic impulses can cause interference.** • Note that radio equipment with transmission frequencies below 500 kHz may inadvertently lengthen the intramedullary lengthening nail. Keep away from potential sources of such electromagnetic fields as, for example: - Industrial equipment with wireless energy transmission, including production facilities and logistics centres. Please observe any posted warnings relating to increased electromagnetic radiation. - Radio masts / radio towers used as time-signal transmitters. • Observe the special precautions relating to electromagnetic compatibility (EMC) in accordance with the accompanying documentation (see section 11 "Electromagnetic compatibility") of these instructions.
	**The continuation of distraction should not be interrupted for longer than 2 days at most because the risk of premature bone bridging is otherwise present.**
	**Damage to implanted system components** • If injections are necessary, it must be ensured that no implanted system components (e.g. Receiver) are damaged.

2.6.1 Leg lengthening is not started in the case of a pregnancy

No experience has been made of treatment with FITBONE® during a pregnancy. However, according to the current state of knowledge, no adverse effects can be assumed.

- Should you become pregnant during the course of the lengthening treatment, immediately inform your treating physician.
- Please note that the treatment of your leg cannot be continued without X-ray check-ups, which must be avoided at all cost during a pregnancy.
- According to medical opinion, it is therefore urgently recommended that you should take precautions against becoming pregnant throughout the entire treatment of your leg.

2.6.2 The treating physician must decide on the risks and benefits with regard to the following treatments

All forms of electrical therapy in which a current flows through body of the patient must be avoided at the affected limb; the same applies to therapeutic ultrasound.

- If this cannot be avoided, careful monitoring of the intramedullary lengthening nail function must be performed to ensure that any resulting malfunctions are detected.
- If medical treatments are necessary in which electric current from an external source is passed through the patient's body, switch off the control electronics and carefully monitor operation of the device during distraction over the following 4 to 5 days.

With the exception of diagnostic X-ray radiation, the manufacturer has no experience regarding the response of the intramedullary lengthening nail to high-energy ionising radiation. Treatments of this kind must in all cases be refrained from for the duration of the distraction phase.

- Please discuss this with your treating physician.

The leakage currents to be expected in the patient's body during the use of defibrillators can result in impairment to the intramedullary lengthening nail, potentially to the extent that this fails. Such applications should therefore be avoided whenever possible.

- If such an application is unavoidable, carefully monitor the function of the implant for the following 4 to 5 days during distraction.

2.7 MRI safety information

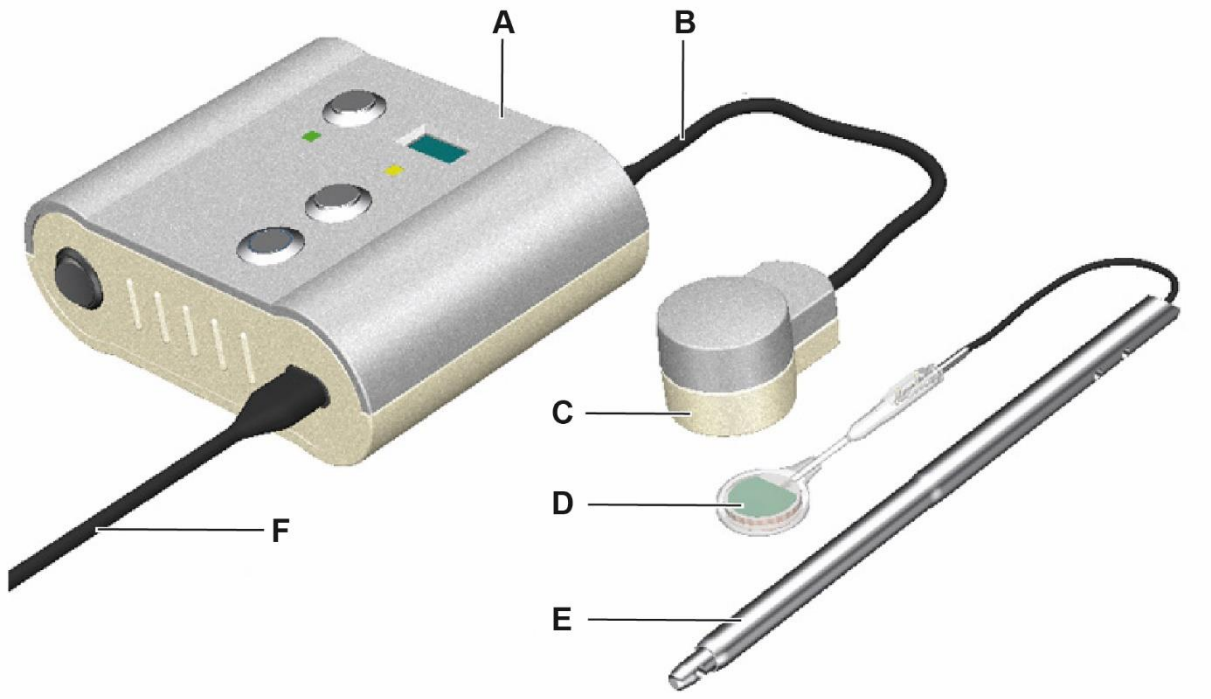
⚠ WARNING

FITBONE® is MR unsafe.

- Keep away from MRI examination rooms.

2.8 System overview

The FITBONE® System comprises the following implantable and non-implantable system components:



A Control electronics
B Coaxial cable
C Transmitter
D Receiver
E Intramedullary lengthening nail
F Power cable

Control electronics (A)
Transmitter (C) with coaxial cable (B)
Power cable (F)

} Non-implantable system components = FITBONE® Control Set

Intramedullary lengthening nail (E)

Receiver (D)

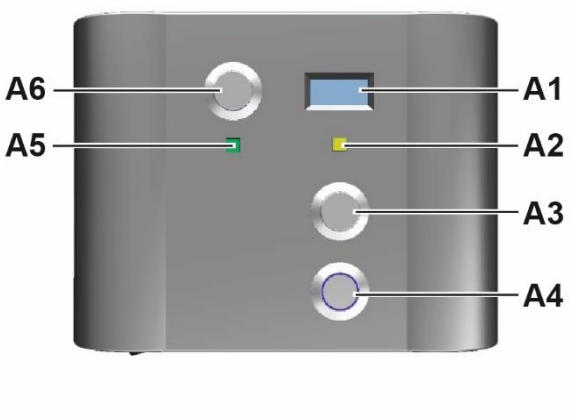
} Implantable system components

Each patient receives a stethoscope for acoustic monitoring of distraction. Instruction for use takes place during the in-patient stay for implantation of the FITBONE® at the hospital.

⚠ WARNING

The supplied system components constitute a treatment system and must not, under any circumstances, be replaced or combined with other devices without written permission by the manufacturer.

The control electronics **components** are shown in the illustration below:



Frontal view

A1 Display
Indicates the number of transmitted impulses.

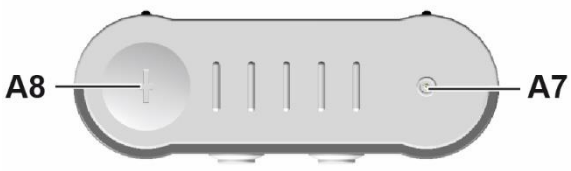
A2 Transmit LED
Indicates energy transmission.

A3 Patient button
Starts energy transmission.

A4 Doctor switch
Lights up blue when activated. It may **only be operated** by the physician.

A5 Power LED
Indicates the presence of mains voltage.

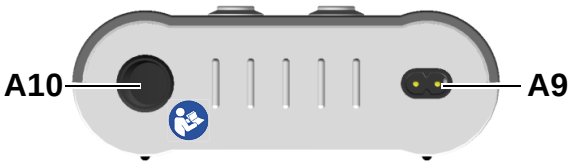
A6 Reset button
For resetting the counter after a day target has been reached or at the end of the lengthening process.



Top view

A7 Connection for the coaxial cable
The Transmitter is connected to this connection.
A8 Housing cover
The area beneath the housing cover is exclusively reserved for the physician.

Any modifications can result in malfunctions and severe health problems.

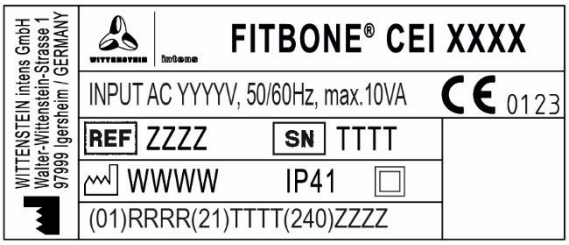


Bottom view

A9 Mains connection
The control electronics are connected to the mains supply via this connection.
A10 On/Off switch
For switching the device on and off.
Switch position 0: The control electronics are switched off.
Switch position I: The control electronics are switched on.

The Instructions for Use **must** be observed.

The type plate, which contains information on the relevant device, is located on the rear of the control electronics. The symbols on the type plate (according to ISO 15223-1) are displayed below:



Manufacturer's name and address

XXXX Type designation of control electronics

YYYY Mains voltage for the control electronics

CE 0123 CE label

REF Article number

ZZZZ Article number of the control electronics in numerals

SN Serial number

TTTT Serial number of the control electronics in numerals

Date of manufacture

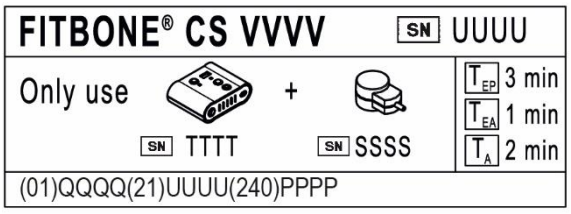
WWWW Date of manufacture of the control electronics in year - month - day

IP 41 The device is protected against ingress of solid foreign bodies greater / equal 1 mm diameter / protected against ingress of drip water.

Device complies with protection class II according to EC 60601-1

RRRR GTIN of the control electronics (**G**lobal **T**rade **I**tem **N**umber)

ZZZZ Article number of the control electronics



VVVV Country-specific article designation
(e.g. 230 V – C, indicates the input voltage and connector type)

SN Serial number

UUUU Serial number of the Control Set in numerals

TTTT Serial number of the control electronics in numerals

SSSS Serial number of the Transmitter in numerals

T_{EP} Maximum on-time in Patient mode

T_{EA} Maximum on-time in Doctor mode

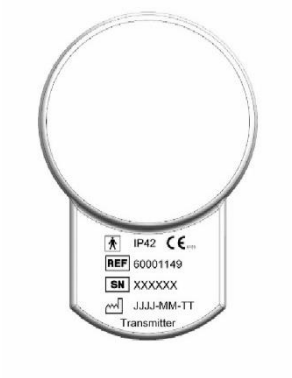
T_{A} Minimum off-time

QQQQ GTIN of the Control Set (**G**lobal **T**rade **I**tem **N**umber)

PPPP Article number of the Control Set

Your FITBONE® Control Set with the serial number UUUU comprises the control electronics with the serial number TTTT and the Transmitter with the serial number SSSS. The serial numbers indicated here must correspond to the serial number on the type plate of the control electronics and the serial number on the Transmitter respectively. Only the combination given here may be used. If the serial numbers do not match, please contact your treating physician.

The type plate, which contains information on the relevant device, is located on the Transmitter. The symbols on the type plate (according to ISO 15223-1) are displayed below:



The Transmitter is a Type BF applied part according to IEC 60601-1.

IP 42 — The device is protected against ingress of solid foreign bodies greater / equal 1 mm diameter / protected against ingress of drip water when the housing is inclined by up to 15°.

CE label

Article number

Serial number

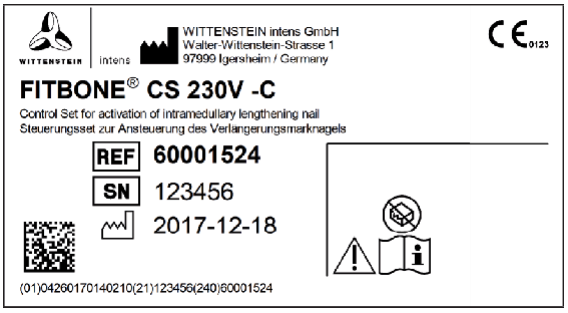
XXXXXX — Serial number of the relevant Transmitter in numerals

Date of manufacture

JJJJ-MM-TT — Date of manufacture of the Transmitter in year - month – day

SKIN — Indicates the surface placed on the skin during energy transmission for distraction.

On the rear of the sales packaging of the FITBONE® Control Set, there is a label that contains information on the relevant device. The symbols on the label (according to ISO 15223-1) are displayed below:



Manufacturer's name and address

CE label

Article number of the Control Set

Serial number of the Control Set

Date of manufacture of the Control Set

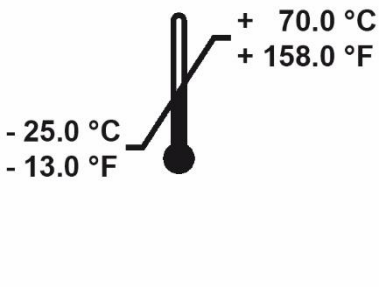
Do not use if the packaging is damaged

Observe the Instructions for Use

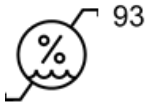
Observe the warnings and precautionary measures in the Instructions for Use

Data matrix code (contains the GTIN, serial number and article number of the Control Set)

The following symbols are additionally located on the back of the sales packaging:



Temperature limit:
indicates the temperature limits to which the medical device can safely be exposed (upper and lower limit).
Lower limit: - 25,0 °C (- 13,0 °F)
Upper limit: + 70,0 °C (+ 158,0 °F)



Humidity max. 93% relative humidity, non condensing

3 Safety with regard to the FITBONE® Control Set

The FITBONE® Control Set must only be used in conjunction with the intramedullary lengthening nail in accordance with the Instructions for Use FITBONE® Control Set.

⚠ CAUTION

The control electronics may only be connected to the mains supply voltage of 230 V indicated on the type plate. It does not contain an internal voltage transformer.

- If you are in a country with a mains supply voltage different to that indicated, you must use a voltage transformer.

A commercially available socket adapter is not sufficient.

During use of the FITBONE® Control Set as intended, any damage to health is excluded.

⚠ CAUTION

The following symptoms indicate a fault of the FITBONE® Control Set:

- **Externally visible damage to the device**
- **The indicator light does not flash as described despite several attempts**
- **No running noise is audible during the distraction procedure**

- In such cases, it is sufficient if you contact the hospital or the treating physician **the following day** or after the weekend.

⚠ DANGER

- Do not place the Transmitter or Retraction Transmitter while energy transmission is activated in a distance of less than 5 cm to other active implants (and any of their components) in your body. Please respect the Instruction for Use of the other active implant(s) regarding EMC.

Electric shock resulting from damage to the FITBONE® Control Set

- Only switch on the control electronics if the device and power cable are undamaged.

Lethal voltages inside the control electronics and the Transmitter

- Ensure that the housings of the two devices are always closed and undamaged so that no internal parts can be touched inadvertently.
- Do not remove the housing of the control electronics or of the Transmitter.
- Only have the devices opened by the manufacturer's specialist personnel.
- Never submerge the control electronics or Transmitter in water and do not use them outdoors. The same principles of electrical safety as for any other commercially available electrical device, e.g. hair dryer, electric shaver, etc. apply here.

⚠ WARNING

Damage through incorrect voltage supply

- Only connect the device to voltage supplies that meet the electrical requirements on the type plate.
- Always use sockets with a protective earthing conductor.
- If you plan to travel abroad, please consult your treating physician.
- Only use the components (e.g. power supply units or cables) provided by the manufacturer.
- Combination with other devices, as described in section 2.8 "System overview", is prohibited.

Non-observance of the instructions jeopardises the therapeutic objective and can result in serious damage to health, including loss of the leg.

- Ensure that you perform the distraction carefully and correctly.

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

Portable RF communications equipment (including their accessories, such as antenna cables and antennae) must not be used at a distance of less than 30 cm from the Control Set during the distraction. Not observing this can lead to a reduction of the performance features of the Control Set.

⚠ CAUTION

Damage to the control electronics through mechanical loading

- Avoid impacts, e.g. dropping of the device, as well as shocks and pressure loads. Store the control electronics in a safe place following each transmission.
- Should the control electronics nevertheless be dropped, check the device for external damage yourself. If you detect any damage, you must no longer use the device. Please contact your treating physician immediately. He or she will promptly ensure a replacement. If no external damage is visible, please check the functions based on the LED indicators and with the aid of the stethoscope:
  - The yellow indicator light must flash during transmission.
  - When listening to the intramedullary lengthening nail function with the stethoscope, the familiar running noise must be audible.
- If one of these functions is absent, please contact your treating physician immediately. He or she will promptly ensure a replacement.

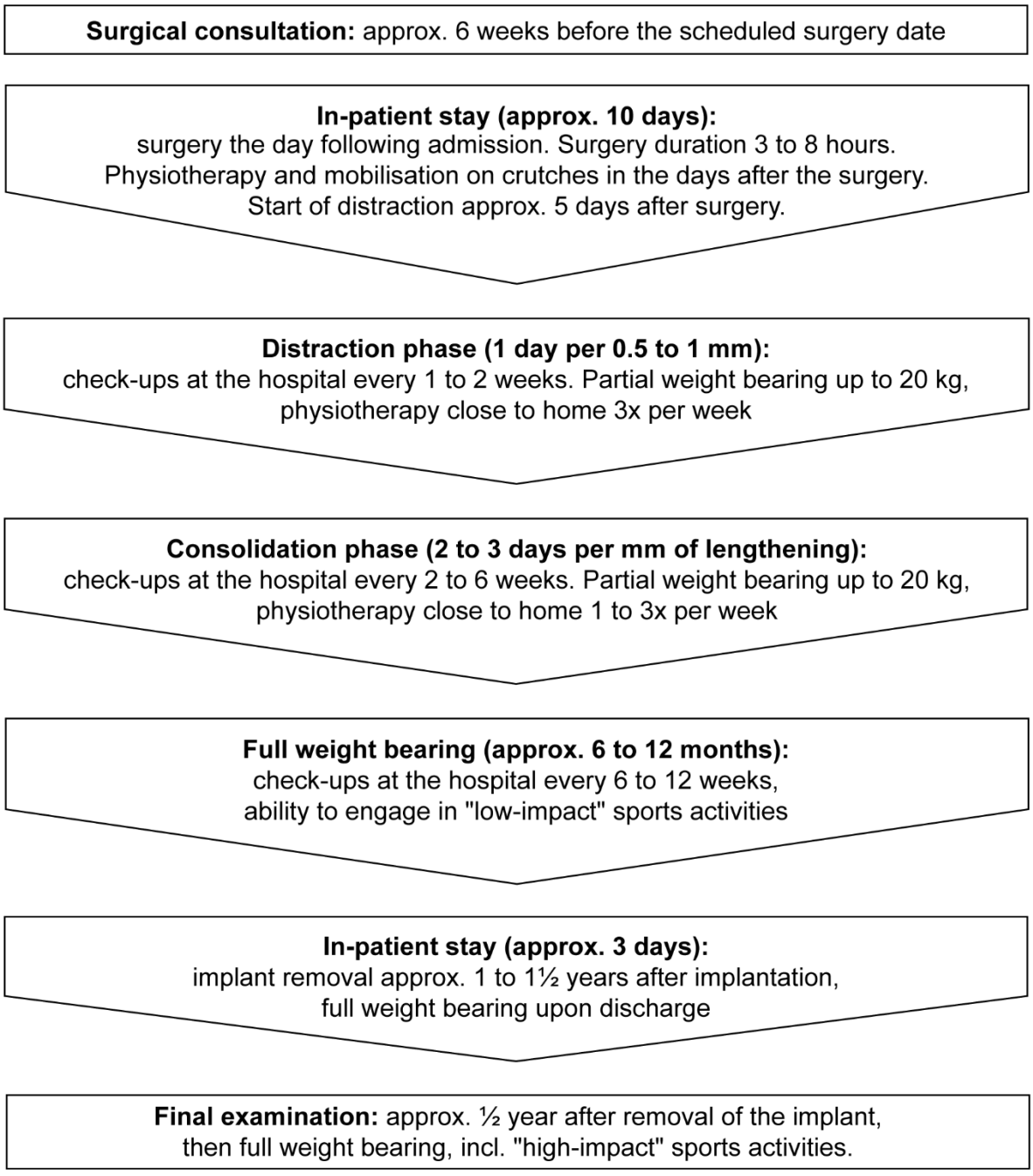
	**⚠ CAUTION**
	Caution when using chemicals • Do not use any chemical agents on the FITBONE® Control Set. These could damage the device. • In the event of soiling, clean the device and accessories using a soft lint- free cloth, slightly dampened with water.
	**Inadequate safety due to missing Instructions for Use** • Should you lose these Instructions for Use, please request a replacement from your treating physician.
	**Inadequate safety due to incorrect storage** • The FITBONE® Control Set must not be stored directly adjacent to or stacked with other electromagnetic, magnetic, ionising, wireless or radio frequency equipment. Should this be unavoidable, carefully monitor correct operation of the device during distraction for the following 4 to 5 days.
	**Damage to the FITBONE® Control Set through extreme temperatures** • Protect the control electronics from excessive heat (not above 70 °C) and cold (not below -25 °C). Avoid direct sunlight, extreme humidity (> 93 %), and, for example, overnight storage in a car.
	**Damage to the FITBONE® Control Set due to ambient conditions** • Do not use the FITBONE® Control Set above an altitude of 4000 m above sea level. • Only use the FITBONE® Control Set in closed and dry rooms.
	**Operating time** • The FITBONE® Control Set is not suitable for continuous operation. Please switch it off immediately once lengthening has been performed (see section 7.3 "Operating time").
	**Connection to other devices** • The FITBONE® Control Set must not be used together with devices that are not described as accessories in these Instructions for Use.
	**Metallic objects** • Do not trigger energy transfer while holding the Transmitter over metallic objects inside or on your body (e.g. other implants or body jewellery such as piercings). This could cause the objects to heat up.

	NOTICE **Disposal** • In the interests of environmental protection, the FITBONE® Control Set must not be disposed of together with domestic waste. • When your treatment has been completed, please return the FITBONE® Control Set to your treating physician.

4 Operation

4.1 Chronological sequence of leg lengthening

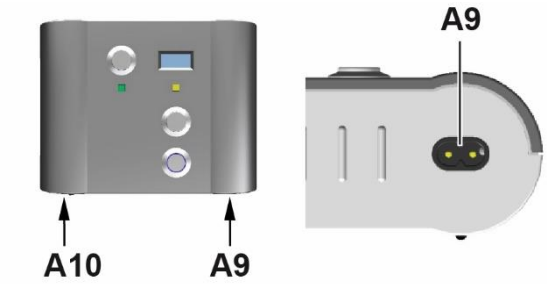
The chronological order of the leg lengthening process corresponds to the following sequence diagram:



Source: ZEM: Limb Lengthening Center Munich / Germany, Prof. Dr. Dr. med. Rainer Baumgart

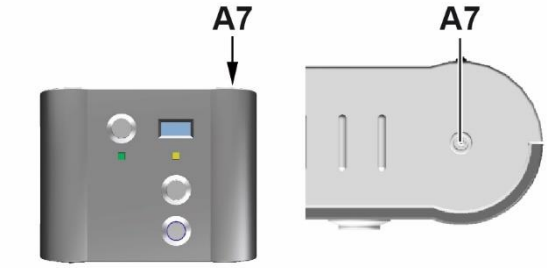
4.2 Preparation for distraction

During your hospital stay, your treating physician will instruct you on operation of the FITBONE® Control Set. You, as the patient, are the operator of the FITBONE® Control Set. You can make notes and write down instructions in section 10 "Comments and special notes" for future reference after you leave the hospital. The preparations for distraction always follow the same sequence.

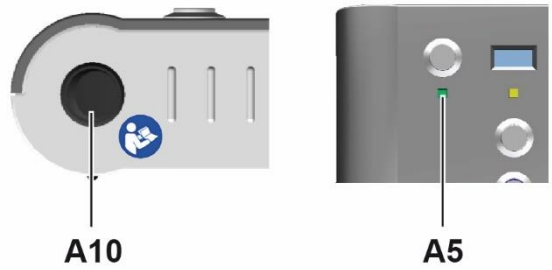


- Connect the control electronics to the socket for the power cable (A9) using the supplied power cable and plug it into the mains outlet.
  Ensure that the correct mains voltage is present.

  ⓘ If you plan to travel abroad, please consult your treating physician.



- Connect the coaxial cable of the Transmitter to the control electronics via the connection for the coaxial cable (A7).



- Switch on the control electronics using the On/ Off switch (A10) (left picture).

➲ The green LED indicator (A5) (right picture) shows that mains voltage is present.

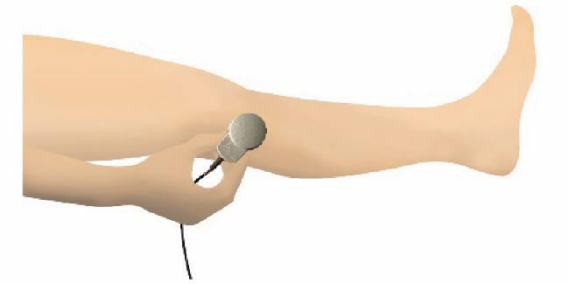
4.3 Performance of distraction

The following sequence diagram provides an overview of operation of the control electronics.

	When positioning the Transmitter, ensure that you adopt the leg position specified by the treating physician.

- Feel for the position of the Receiver which is located under the skin.
- Place the Transmitter at the position of the Receiver, with the white side on your skin.

ⓘ In the case of thigh (femur) lengthening, the Transmitter must be positioned on the thigh.



ⓘ Accordingly, in the case of lower leg (tibia) lengthening, the Transmitter must be positioned on the lower leg.

- Place the stethoscope earbuds in the ears and place the stethoscope head on the patella.
- Initiate energy transmission by pressing the "Patient" button (A3) once.

➲ If placement is correct, the yellow "Transmit" LED (A2) flashes 5 times within one second. This procedure is repeated every 9 seconds and indicates to you that energy is being transmitted.

➲ Meanwhile you hear a short running noise of the drive via the stethoscope which you have placed on the patella.

ⓘ The procedure ends after 9 flashing sequences or a total of 90 seconds.

After each energy transmission, 9 more impulses should be shown on the display (A1) at the start of the respective distraction procedure.

ⓘ This display can be reset to "0" using the reset button (A6).

In the distraction log, your treating physician determines when and how often you should initiate an interval of this kind with 9 impulses.

⚠ CAUTION

If the yellow Transmit LED does not flash or if no running noise is heard during the individual transmissions, please refer to section 5 "Malfunctions".

- Do not interrupt the distraction process for longer than max. 2 days as there is otherwise a risk of bridging of the new bone regenerate, which would jeopardise the further course of treatment, unless your treating physician gives you a differing recommendation.
- Once distraction is complete, please switch off the control electronics (A10) and unplug the power cable.
- Remove the Transmitter from the control electronics. To do this, please hold the metal cable connector at the Transmitter.
- Then place all parts of the FITBONE® Control Set back in the packaging for storage.

Be sure to go to the regular check-up examinations prescribed by your attending physician. The correct distraction progress is checked at defined intervals by way of the standardised ultrasound and X-ray check-ups with visualisation of the distraction path during these visits.
If, after starting the distraction, the power transmission is accidentally interrupted (e.g. due to slipping of the Transmitter or inadvertent switching off of the control electronics), the transmission of the outstanding impulses from the system will continue without error if you restore the power transmission within 10 seconds.
However, if the power transmission is restored after more than 10 seconds, the distraction must be restarted and the remaining pulses transmitted.

4.3.1 Insufficient impulses transmitted

If an insufficient number of impulses is transmitted during a distraction, you must try to perform an additional distraction in order to compensate for the missing impulses.

- For this purpose, start a new distraction as described in section 4.3 "Performance of distraction".
- Perform the remaining missing impulses and end the transmission when the number of impulses specified by your treating physician (generally 9 impulses) has been reached.
- To end the energy transmission, raise the Transmitter from your leg and switch off the device as described in section 4.3 "Performance of distraction".

4.4 Keeping the distraction log

Keeping the distraction log is helpful for monitoring and documenting the therapeutic progress.

- If the number of impulses checked acoustically using the stethoscope does not correspond the specifications of the treating physician, please make a note of this under “Particularities” in section 9 "Distraction log".

4.5 Return of the FITBONE® Control Set

- When your treatment has been completed, please return the FITBONE® Control Set to your treating physician. None of the FITBONE® Control Set components may be disposed of. These components are the property of the manufacturer and are only provided on loan.

5 Malfunctions

Malfunction	Possible cause	Actions
The device cannot be switched on. Power LED (green) does not light up.	No connection to the mains power supply, power cable not plugged in	Insufficient mains voltage: Check connection to the mains power supply, connect to a different socket if necessary.
	Power cable defective	Contact your treating physician.
Transmit LED (yellow) does not flash, counter does not respond and no motor noise is audible.	No connection to the mains power supply, power cable not plugged in	Plug in the power cable.
	Control electronics not switched on	Switch on the control electronics.
	The Doctor switch has been operated instead of the Patient button (now lights up blue).	Release the Doctor switch by operating it again and repeat distraction in accordance with section 4.3 "Performance of distraction".
Transmit LED (yellow) does not flash during energy transmission, but lights up continuously for one second. No transmission impulse is counted on the display. The motor noise may be audible.	Coaxial cable of the Transmitter not connected to the control electronics.	Check the plug connection.
	Distance range of 8 to 12 mm between Transmitter and Receiver, which is required for correct energy transmission, has been exceeded.	Change the Transmitter position or reduce the distance to the Receiver (for example by pressing the Transmitter button) or reposition the Transmitter.
	Transmitter coaxial cable faulty	Contact your treating physician.
No motor running noise audible via the stethoscope during distraction.	Excessive distance between the Transmitter and Receiver	Reduce the distance to the Receiver (for example by pressing on the Transmitter) or reposition the Transmitter.
	Incorrect positioning of the stethoscope	Change the position of the stethoscope.
	Intramedullary lengthening nail temporarily overloaded.	Check the position of the Transmitter and keep trying until distraction takes place.
	Incorrect voltage supply	Check whether you are supplying your device with the correct mains voltage (required mains voltage is indicated on the type plate and on the label next to the socket).
	System failure	Contact your treating physician.
LCD display constantly fails to count correctly.	LCD display faulty	Contact your treating physician.
	Incorrect transmission rate	Reposition the Transmitter.
Insufficient number of impulses during a distraction procedure.	Incorrect positioning of the Transmitter	Please refer to section 4.3.1 "Insufficient impulses transmitted".
	Plug is disconnected during the procedure or Off button is pressed.	

Because a potential malfunction does not constitute an emergency, it is sufficient if you inform your treating physician the following day. He or she will promptly ensure a replacement. In the meantime, you should continue trying to transmit energy. If you are uncertain whether the lengthening procedure has been performed correctly, you should also contact your physician the following day.

ⓘ To prevent damage to the system, the intramedullary lengthening nail is designed not to perform distraction under excessive loads. It is therefore entirely possible that following several unsuccessful attempts to transmit energy, a regular distraction procedure can suddenly again be performed. Physiotherapy exercises benefit the distraction process. Please observe the instructions of your treating physician in this regard.

In the event of faults or malfunctions, switch off the FITBONE® Control Set. Do not perform any interventions yourself and only have repairs carried out by the manufacturer. Non-observance of the above instructions may jeopardise the safety of the device. Should you have any problems during initial operation of the FITBONE® Control Set or require assistance in this regard, please contact the manufacturer.

6 Care instructions

6.1 Safety checks and maintenance

Repair and maintenance of the FITBONE® Control Set may only be performed by the manufacturer's specialist personnel. This maintenance work is performed after each completed treatment.
All warranty and liability on the part of the manufacturer are excluded in the event of modifications and repairs to devices performed by unauthorised persons. Moreover, there is a risk of danger through electric shock if the FITBONE® Control Set is tampered with, see section 3 "Safety with regard to the FITBONE® Control Set".

6.2 Care and cleaning

Clean the FITBONE® Control Set from time to time, or immediately in the case of soiling.

⚠ CAUTION

The FITBONE® Control Set must be switched off and disconnected from the mains supply prior to cleaning.

Use a cloth dampened with water to clean the surfaces of the FITBONE® Control Set by hand. Do not use any cleaning agents.

⚠ CAUTION

Ensure that no water penetrates into the FITBONE® Control Set.

- Do not touch the device with damp hands when it is connected to the mains supply.
- Ensure that no water splashes onto the device.
- The device may only be operated when completely dry.

7 Technical data

7.1 Technical data for the control electronics of the 230 V FITBONE® Control Set

Mains voltage 230 V AC + 10 % / - 15 %, 50/60 Hz (power input from main power supply max. 10 VA); see identification plate.
Mains plug 2-pin in compliance with DIN 49464/VDE, with 1.8-meter power cable 2 x 0.75 mm^2 in compliance with CEE/VDE.
RF transmission power, output max. 1,5 watt (magnetic field)
Frequency 71-85 kHz, load-dependent, physically determined.
Dimensions of transmitter 45 mm diameter x height 36 mm x length 63 mm
Weight of transmitter about 120 grams.
Control electronics and Transmitter are in protection class II construction, i.e. in protective insulated design.
The internal electrical transformer is a safety transformer also in protection class II in compliance with VDE 0551/EN 60742/IEC 742.

7.2 Ambient conditions

Ambient conditions during operation	+5 °C to +40 °C, between 15 % and 93 % rel. humidity, non-condensing; do not use above an altitude of 4000 m above sea level
Ambient conditions during transport and storage when not in use	- 25 °C to + 70 °C; max. 93% rel. humidity, non-condensing

7.3 Operating time

	Duration
Operation in Patient mode	max. 3 minutes
Operation in Doctor mode (continuous operation)	max. 1 minute
Switch-off duration after the transmission of energy is complete (cooling the implant and Control Set)	min. 2 minutes

⚠ CAUTION

In continuous doctor mode operation, the Transmitter can reach a maximum temperature of 47,2 °C.

Operating life of the FITBONE® Control Set: 1 year

8 Implant ID

During your in-patient hospital stay, you will receive an Implant ID containing the identification details of the implanted system components and further important information.

- Please carry this A7-size document with you at all times so that identification of the intramedullary lengthening nail is possible at all times, e.g. during airport security checks.

9 Distraction log

9.1 Description

In the distraction log, you have the opportunity to enter comments regarding false indicator light displays, absence of running noise and pains you experience, for example.

- Please always enter this information so that your treating physician has the details at his disposal in order to optimise the treatment process.

	NOTICE
	Keeping the distraction log is helpful for monitoring and documenting the therapeutic progress. Always observe the instructions of your treating physician.

Distraction log
FITBONE®

Patient (name, birth date) _____

Diagnosis: _____

Operation on: _____

_____

Distraction Target _____ mm

Example of a distraction log

This value is only entered by your physician during X-ray check-ups.

Month: *January*								
Date	**1**	**2**	**3**	**4**	**5**	**Δ tot. mm**	**Pain status***	**Particularities**
1	*9*	*9*	*9*				*0*	
2	*7*	*8*	*7*				*2*	*Slight pulling sensation in leg*
3	*6*	*6*	*6*	*6*			*0*	

Pain on an imaginary scale from 0 (no pain) to 10 (maximum pain)

The number of impulses to be transmitted (= TARGET) is entered here. TARGET is specified by the physician.

Any anomalies noticed should be entered in the „Particularities“ / „Pain status“ column. If necessary, interim check-up information can be added to the log by the physician.

9.2 Form

Month 1

Month _____								
Date	**1**	**2**	**3**	**4**	**5**	**∆L tot. mm**	**Pain status***	**Particularities**
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
23								
24								
25								
26								
27								
28								
29								
30								
31								

* Pain on an imaginary scale from 0 (no pain) to 10 (maximum pain)

Month 2

Month_____								
Date	**1**	**2**	**3**	**4**	**5**	**∆L tot. mm**	**Pain status***	**Particularities**
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
23								
24								
25								
26								
27								
28								
29								
30								
31								

*Pain on an imaginary scale from 0 (no pain) to 10 (maximum pain)

Month 3

Month_____								
Date	**1**	**2**	**3**	**4**	**5**	**∆L tot. mm**	**Pain status***	**Particularities**
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
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30								
31								

*Pain on an imaginary scale from 0 (no pain) to 10 (maximum pain)

10 Comments and special notes

11 Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic emissions

The FITBONE® System is designated for operation in the electromagnetic environment specified below. The user of the FITBONE® System should ensure that it is used in an environment of this type.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The FITBONE® System uses RF energy exclusively for its internal operation. It consequently has very low RF emissions and interference with electronic devices in the vicinity is improbable.
RF emissions CISPR 11	Class B	The FITBONE® System is suitable for use in all types of premises, including residential quarters and those directly connected to a public mains power supply that supplies buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity
The FITBONE® System is designated for operation in the electromagnetic environment specified below. The user of the FITBONE® System should ensure that it is used in an environment of this type.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	**Valid until 31/12/2018 [date of manufacture]:** ± 6 kV contact discharge ± 8 kV air discharge **Valid from 01/01/2019 [date of manufacture]:** ± 8 kV contact discharge ± 15 kV air discharge	**Valid until 31/12/2018 [date of manufacture]:** ± 6 kV contact discharge ± 8 kV air discharge **Valid from 01/01/2019 [date of manufacture]:** ± 8 kV contact discharge ± 15 kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with a synthetic material, the relative humidity must be at least 30%.
Electrical fast transient disturbances/ bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	The quality of the supply voltage should be at levels typical for commercial or hospital environments.
Surges according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode Not applicable	The quality of the supply voltage should be at levels typical for commercial or hospital environments.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	**Valid until 31/12/2018 [date of manufacture]:** < 5% U_T (>95% dip in U_T) for ½ cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds **Valid from 01/01/2019 [date of manufacture]:** < 0% UT for ½ cycle 0% UT for 1 cycle 70% UT for 25 or 30 cycles (at 50 Hz or 60 Hz)	**Valid until 31/12/2018 [date of manufacture]:** < 5% U_T (>95% dip in U_T) for ½ cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds **Valid from 01/01/2019 [date of manufacture]:** < 0% UT for ½ cycle 0% UT for 1 cycle 70% UT for 25 or 30 cycles (at 50 Hz or 60 Hz)	The quality of the supply voltage should be at levels typical for commercial or hospital environments. If the user of the FITBONE® System requires continued operation even in the event of power supply interruptions, it is recommended that the FITBONE® System is powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	**Valid until 31/12/2018 [date of manufacture]:** 3 A/m	**Valid until 31/12/2018 [date of manufacture]:** 10 A/m	Power frequency magnetic fields should be at levels typical for commercial or hospital environments.
	Valid from 01/01/2019 [date of manufacture]: 30 A/m	**Valid from 01/01/2019 [date of manufacture]:** 30 A/m	
NOTE	U_T is the AC mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration – electromagnetic immunity
The FITBONE® System is designated for operation in the electromagnetic environment specified below. The user of the FITBONE® System should ensure that it is used in an environment of this type.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Valid until 31/ 12/2018 [date of manufacture]: Conducted RF disturbances acc. to IEC 61000-4-6	**Valid until 31/ 12/2018 [date of manufacture]:** 3 V 150 kHz to 80 MHz	**Valid until 31/ 12/2018 [date of manufacture]:** 3 V	Portable and mobile RF communications equipment should be used no closer to any part of the FITBONE® System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the Transmitter.
Radiated RF disturbances acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
Valid from 01/ 01/2019 [date of manufacture]: Conducted RF disturbances acc. to IEC 61000-4-6	**Valid from 01/ 01/2019 [date of manufacture]:** 3 V 150 kHz to 80 MHz	**Valid from 01/ 01/2019 [date of manufacture]:** 3 V	Recommended separation distance **Valid until 31/12/2018 [date of manufacture]:** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.34\sqrt{P}$ for 800 MHz to 2.5 GHz
	6 V in ISM and amateur radio frequency bands between 150 kHz and 80 MHz	6 V	Recommended separation distance Valid from 01/01/2019 [date of manufacture]: $d = 0.6 * \sqrt{P}$ Minimum distance: 0.3 m with P as the maximum output power rating of the Transmitter in watts (W) according to the Transmitter manufacturer and d as recommended separation distance in meters (m).
Radiated RF disturbances acc. to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Field strengths from fixed RF Transmitters as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol. 

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FITBONE® System is used exceeds the applicable RF compliance level above, the FITBONE® System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the FITBONE® System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distance between portable and mobile RF communications equipment and the FITBONE® System valid until 31/12/2018 [date of manufacture]			
The FITBONE® System is intended for use in an electromagnetic environment in which RF interference is controlled. The user of the FITBONE® System can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FITBONE® System – depending on the power output of the communications equipment, as stated below.			
Rated output P of transmitter [W]	**Separation distance d depending on the frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17 * \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17 * \sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.34 * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.7	3.7	7.4
100	11.7	11.7	23,4
For transmitters whose maximum output power is not listed above, the recommended safety distance d in metres (m) can be determined using the equation applicable to the respective column, whereby P is the maximum output power rating of the transmitter in watts (W) according to the manufacturer. NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distance between portable and mobile RF communications equipment and the FITBONE® System valid from 01/01/2019 [date of manufacture]		
The FITBONE® System is intended for use in an electromagnetic environment in which RF interference is controlled. The user of the FITBONE® System can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FITBONE® System – depending on the power output of the communications equipment, as stated below.		
Rated output P of transmitter [W]	**Separation distance d depending on the frequency of transmitter [m]**	
	Minimum distance d [m]	**$d = 0.6 * \sqrt{P}$**
0.01	0.3	
0.1	0.3	
1	0.6	
10	1.9	
100	6	
For transmitters whose maximum output power is not listed above, the recommended safety distance d in metres (m) can be determined using the equation applicable to the respective column, whereby P is the maximum output power rating of the transmitter in watts (W) according to the manufacturer. NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

Interference resistance against high-frequency electromagnetic fields in direct proximity to wireless communications equipment valid from 01/01/2019 [date of manufacture]

Band [MHz]	Service	Maximum power [W]	Distance [m]	Immunity test level [V/m]
380 to 390	TETRA 400	1.8	0.3	27
430 to 470	GMRS 460; FRS 460	2	0.3	28
704 to 787	LTE Band 13, 17	0.2	0.3	9
800 to 960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	2	0.3	28
1700 to 1990	GSM 1800; TETRA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	2	0.3	28
2400 to 2570	Bluetooth; WI-FI 802.11 b/g/n; RFID 2450; LTE Band 7	2	0.3	28
5100 to 5800	WI-FI 802.11 a/n	0.2	0.3	9

For technical questions, please contact the manufacturer:

WITTENSTEIN intens GmbH
Walter-Wittenstein-Straße 1
97999 Igersheim
Germany

Tel.: +49 7931 493-0
Fax: +49 7931 493-10906
E-Mail: info@wittenstein-intens.de

CE 0123
2009

WITTENSTEIN intens GmbH · Walter-Wittenstein-Straße 1 · 97999 Igersheim · Germany
Tel. +49 7931 493-0 · info@wittenstein-intens.com

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www.wittenstein-intens.com