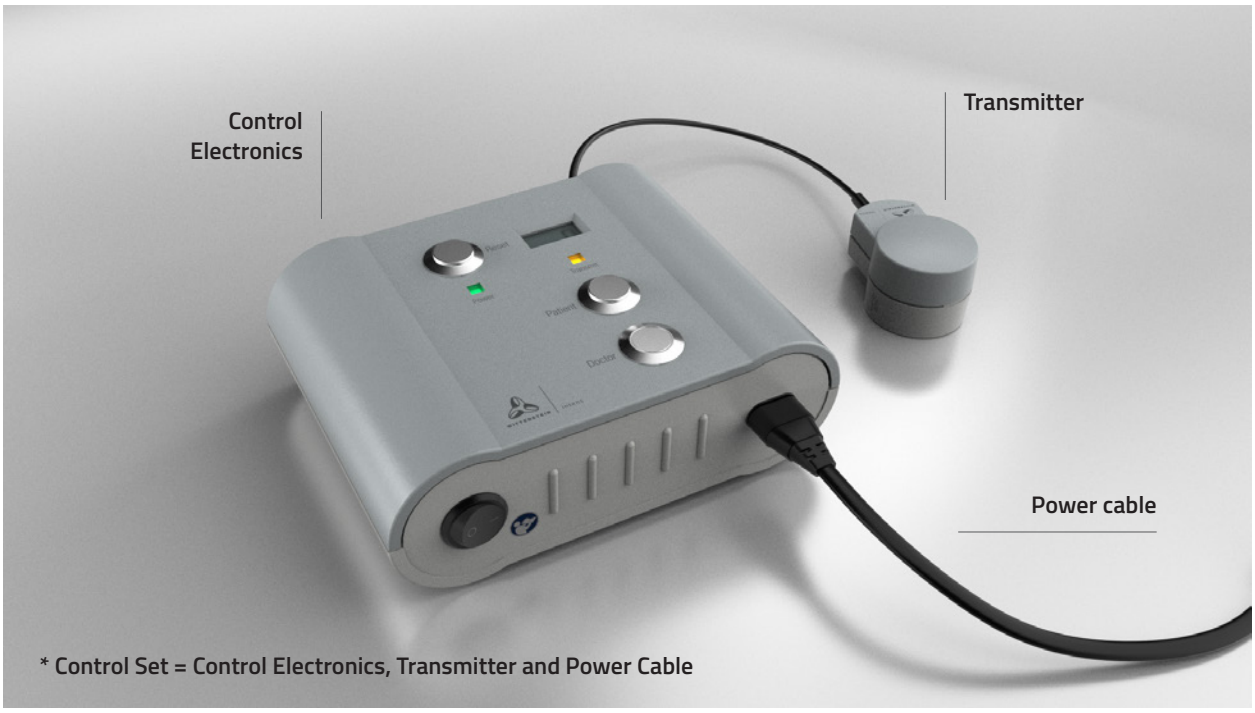
FITBONE®
Powered by ORTHOFIX®

Control Set

A quick guide for **SURGEONS**

Control Set* components



Reset button
Resets the counter

Power LED
Indicates power ON

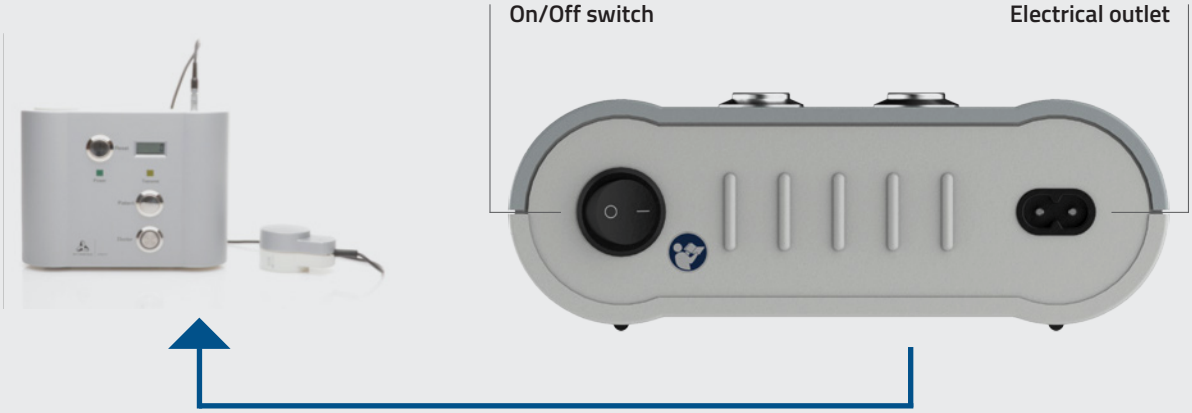
Display
Indicates number of impulses transmitted
27 impulses = 1mm

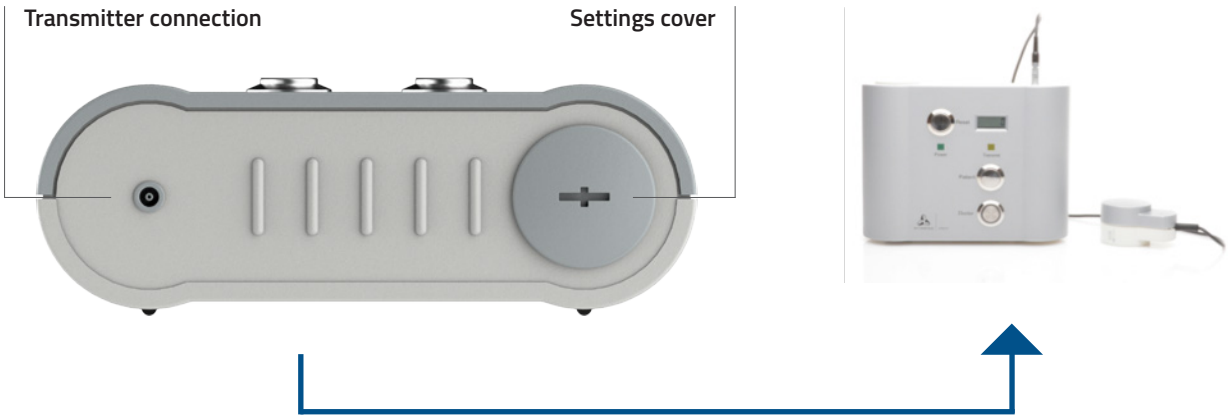
Transmit LED
Indicates energy being transmitted

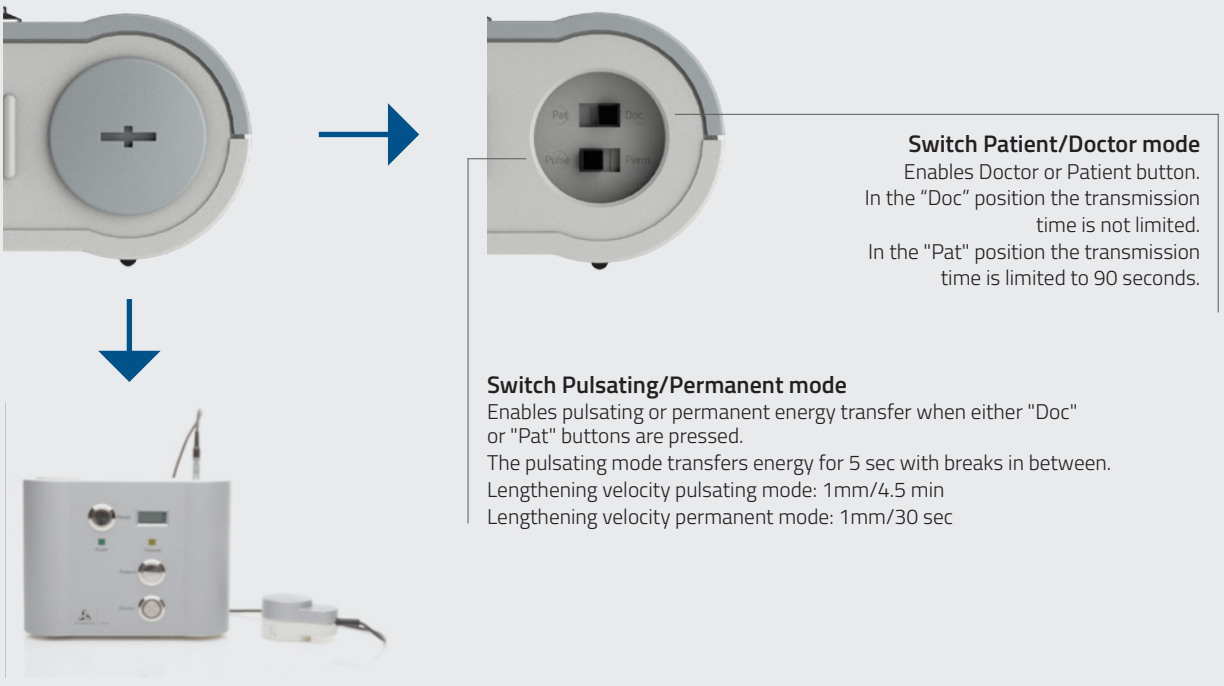
Patient button
Starts energy transmission in *patient mode* (duration 90 seconds = 9 impulses and stops automatically).
Lengthening velocity: 1mm/4.5min

Doctor switch
Starts energy transmission in *doctor mode* (on/off)
Lengthening velocity: 1mm/30sec

ORTHOFIX® | EXTREMITIES







Switch Patient/Doctor mode
Enables Doctor or Patient button.
In the “Doc” position the transmission time is not limited.
In the "Pat" position the transmission time is limited to 90 seconds.

Switch Pulsating/Permanent mode
Enables pulsating or permanent energy transfer when either "Doc" or "Pat" buttons are pressed.
The pulsating mode transfers energy for 5 sec with breaks in between.
Lengthening velocity pulsating mode: 1mm/4.5 min
Lengthening velocity permanent mode: 1mm/30 sec

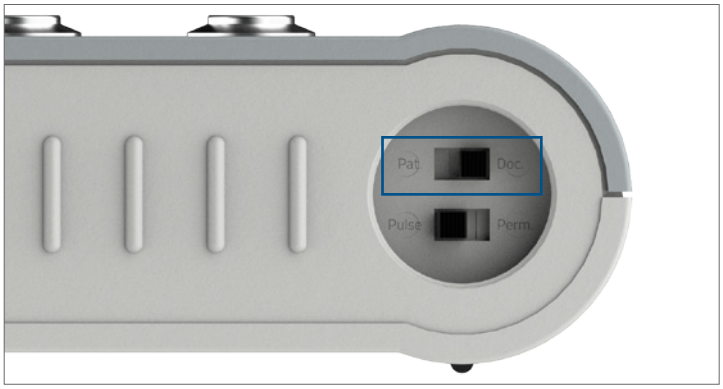
Please notice that the Transmitter and the Control Electronics are electronically paired. Therefore they have the same serial number.

If the Transmitters are changed without being coupled, they won’t work.

Intraoperative lengthening test

Open the Control Set box.

Take out the Control Electronics.



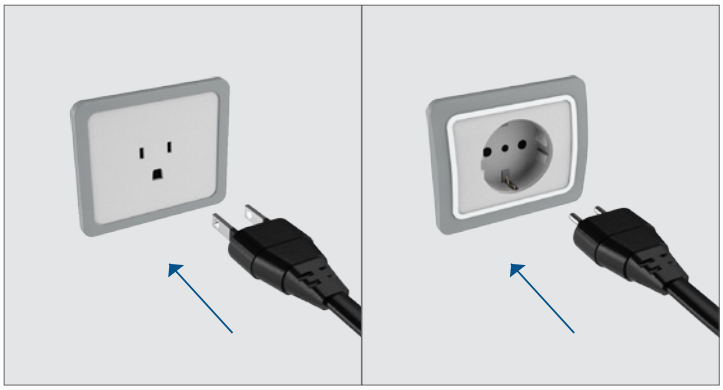
Choose test settings:
- Doctor mode
- Permanent/Pulsating mode

Lengthening velocity in Doctor and Permanent mode is 1mm/30 sec

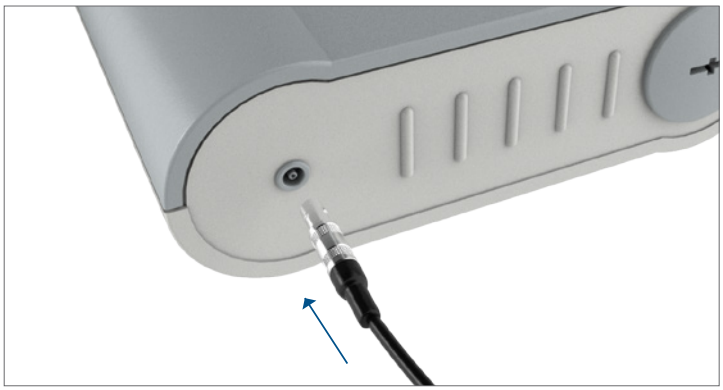
Lengthening velocity in Doctor and Pulsating mode is 1mm/4.5 min

Take out the power cable.

Connect the power cable to the Control Electronics.



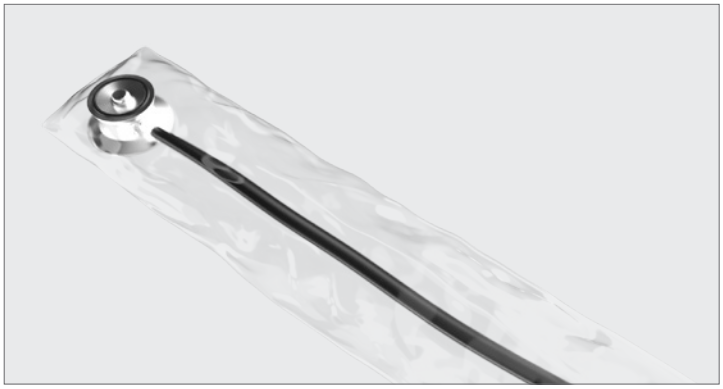
Plug in the power cable.



Plug the Transmitter into the Control Electronics.

Turn on the Control Electronics.

Cover the Transmitter in the delivered sterile Raucoderape® (not currently delivered to US market).



Cover the Stethoscope in the delivered sterile Raucoderape® and place the Stethoscope earbuds in the ears of the operating surgeon (raucodrape not currently delivered to US market).

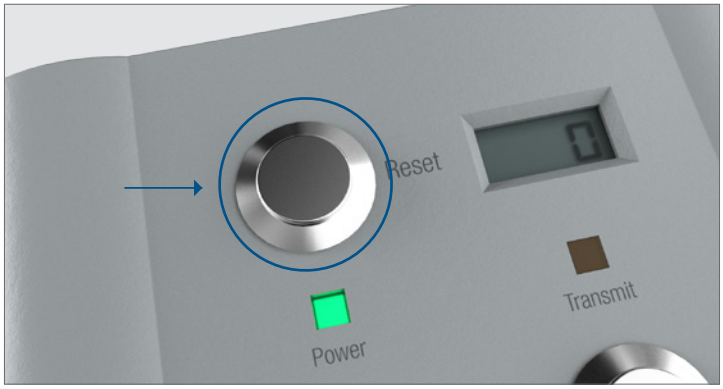
Place the Transmitter at the position of the Receiver, with the white side on the skin.

Place the Stethoscope on the patella (knee cap) and you will hear the motor working.

On the front of the FITBONE® Control Electronics, press the switch labeled "Doctor". The switch lights up blue after being pressed.

> ⚠ Use of continuous operation mode must be interrupted after a maximum of 1 minute for a minimum of 2 minutes to prevent excessive heat in the tissue between the Transmitter and Receiver. In Doctor Mode (continuous operation), the Transmitter can reach a maximum temperature of 47.2 °C.

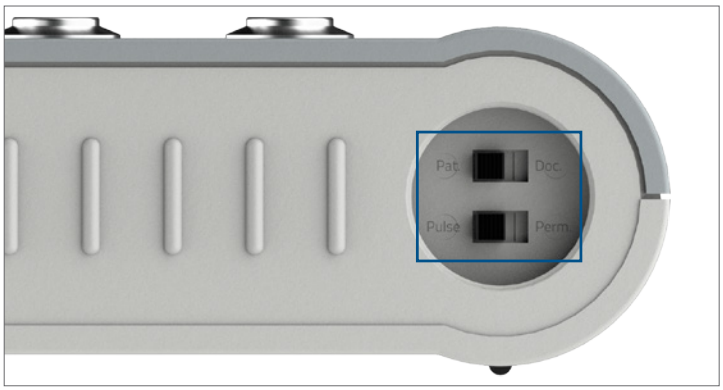
If placement is correct, the yellow "Transmit" LED will flash 5 times within one second. You'll also see the counting on the display.



By pressing the reset button, the counter will return to 0 (zero).

27 impulses is equivalent to 1mm.

Turn off the Control Electronics and disconnect the cables.



Please make sure that the patient gets the Control Electronics with the right settings (Pat + Pulse).

Patients should not use the Doctor Mode or permanent mode.

Avoid pulling on the cable of the Transmitter.

Protect the Transmitter's cable from harm.

Patient instructions for lengthening

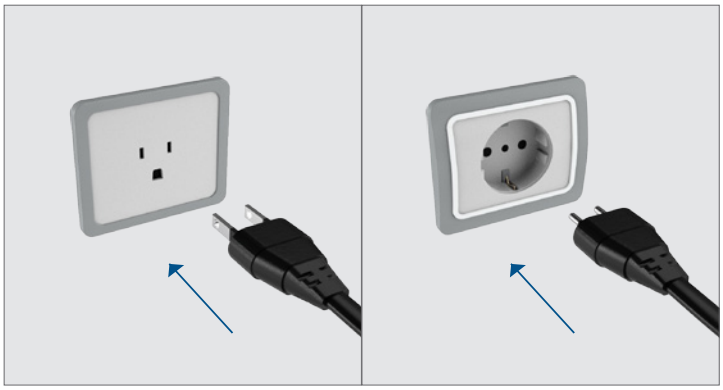
Open the Control Set box.

Take out the Control Electronics.

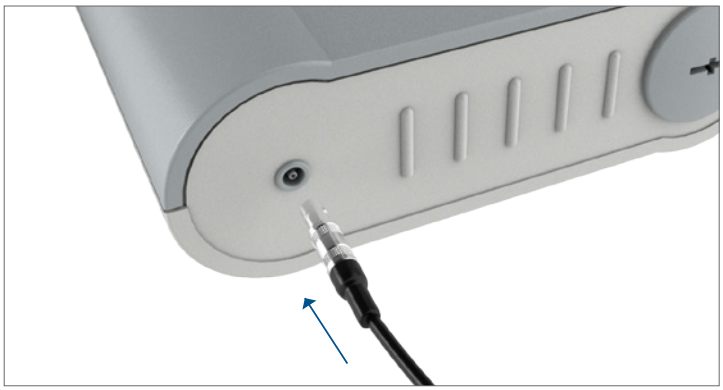
Take out the power cable.

Take out the Transmitter.

Connect the power cable to the Control Electronics.



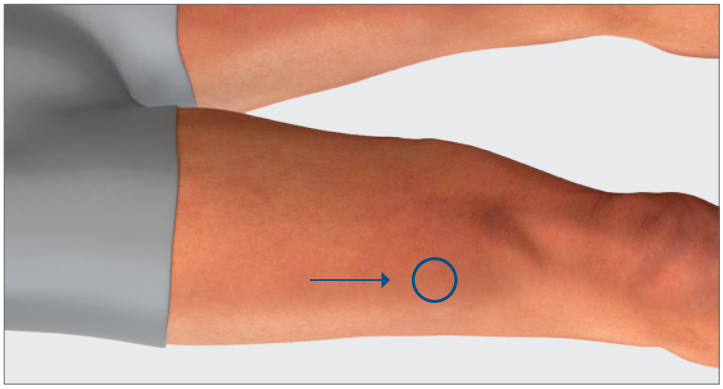
Plug in the power cable.



Plug the Transmitter into the Control Electronics.

Turn on the Control Electronics.

Place the Stethoscope earbuds in the ears.



Locate the Receiver under patient's skin.

Find the marking "SKIN" on the Transmitter indicating the side to be in contact with skin.

Place the Stethoscope on the patella to hear the motor.

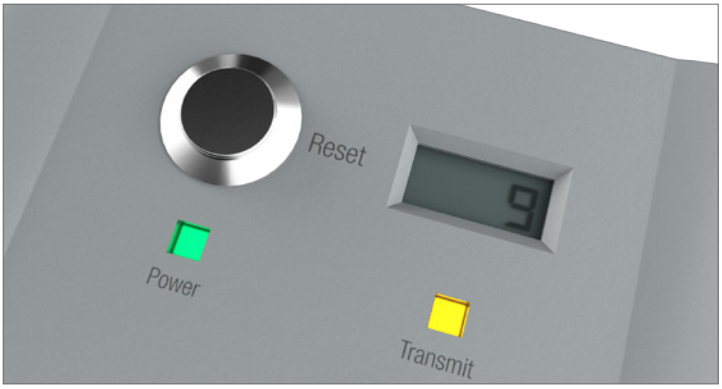
Place the Transmitter at the position of the Receiver, with the white side on the surface of the skin.

Initiate energy transmission by pressing the "Patient" button once.

If placement is correct, the yellow "Transmit" LED will flash 5 times within one second. You'll also see the counting on the display.

This process is repeated every 9 seconds without any need to press the "Patient" button again. The yellow "Transmit" light indicates that energy is being transmitted to the Receiver.

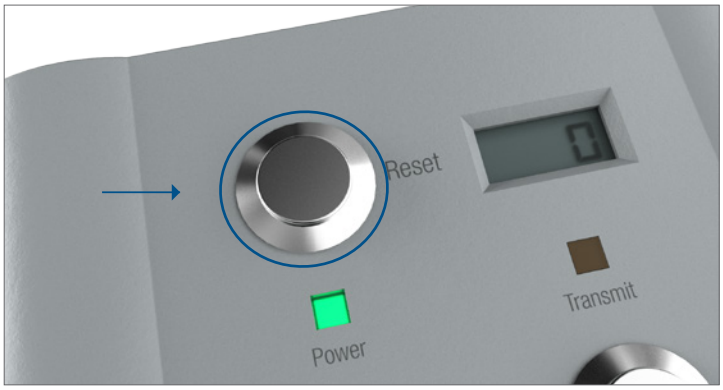
You should hear the motor working through the Stethoscope. If you cannot hear it, try repositioning the Stethoscope.



The process ends after 9 flashing sequences or a total of 90 seconds. You will see the 9 impulses shown on the display. Make sure that you also hear the 9 impulses being transmitted to the motor.

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

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.



By pressing the reset button, the counter will return to 0 (zero).

You can reset every 9 impulses or after you finish the number of impulses, according to the instructions of your treating physician.

27 impulses is equivalent to 1mm.

Turn off the Control Electronics and disconnect the cables.

Avoid pulling on the cable of the Transmitter.

Protect the Transmitter's cable from harm.

Chronological sequence of leg lengthening

1. SURGERY	▪ Hospital stay: approx. 10 days ▪ Start of distraction: approx. 5 days after surgery ▪ Physiotherapy and mobilization on crutches in the days after surgery
2. DISTRACTION PHASE	▪ Lengthening: 0.5-1mm daily ▪ Hospital check-ups: 1-2 weeks ▪ Weight bearing: 20kg ▪ Physiotherapy: 3 times per week
3. FULL WEIGHT BEARING	▪ Approx. 6-12 months ▪ Low-impact activities
4. NAIL EXTRACTION	▪ After approx. 1 to 1.5 years ▪ Hospital stay: approx. 3 days ▪ Full weight bearing upon discharge
5. FINAL EXAMINATION	▪ Approx. 6 months after implant removal ▪ High-impact sport activities

Post-operative care

- The extremity should be fully extended from the first post-operative day.
- Patient mobilization on crutches in the days after surgery.
- Partial weight bearing of not more than 20kg on the operated leg is permitted.
- An ice pack is recommended in the area of the osteotomy.
- An appropriate-sized shoe lift should be used to compensate for differences in leg length.
- Physical therapy is initially limited to the prevention of pulmonary and thromboembolic complications.
- Exercising of the knee joint starts on the fourth post-operative day. The following techniques are recommended:
  - Manual therapy techniques (physiological movement, additional movement),
  - Muscle relaxation techniques in supine position, tilted with healthy leg lifted as support,
  - Posterior/anterior movement of the femur in the prone position and maximum hip extension,
  - Extension movements with gentle traction,
  - Other techniques, which can be used as required, particularly during and after the consolidation phase, include nerve mobilization techniques, strength improvement measures (PNF, MTT), improvement in proprioception and gait training.

Troubleshooting

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 main voltage: check connection to the mains power supply, connect to a different socket if necessary
	Power cable defective	Contact your FITBONE® sales representative
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” in Instructions for Use FITBONE Control Set
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 12mm 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 FITBONE® sales representative
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 FITBONE® sales representative
LCD display constantly fails to count correctly	LCD display faulty	Contact your FITBONE® sales representative
	Incorrect transmission rate	Reposition the Transmitter
Insufficient number of impulses during a distraction procedure	Incorrect positioning of the Transmitter	Please refer to section "Insufficient impulses transmitted" underneath
	Plug is disconnected during the procedure or OFF button is pressed	

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 “Instructions for distraction” above.
- Perform the remaining missing impulses and end the transmission when the number of impulses (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 “Instructions for lengthening”.

Because a potential malfunction does not constitute an emergency, it is sufficient if you inform your FITBONE® sales representative 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 contact your FITBONE sales representative 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.

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 jeopardize 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.

For a full list of warnings and further information, please refer to the Instructions for Use FITBONE® Control Set and the FITBONE TAA Clinician Guide.

Manufactured by:

WITTENSTEIN | intens

WITTENSTEIN intens GmbH
Walter-Wittenstein-Straße 1
97999 Igersheim, Germany
Tel. +49 7931 493-0
Fax +49 7931 493-10906

CE 0123

FB-2027-PL-E0 B 02/21

Distributed by:

ORTHOFIX Srl
Via Delle Nazioni 9
37012 Bussolengo (Verona), Italy
Telephone +39 045 6719000
Fax +39 045 6719380

Local contact:

orthofix.com | ORTHOFIX®