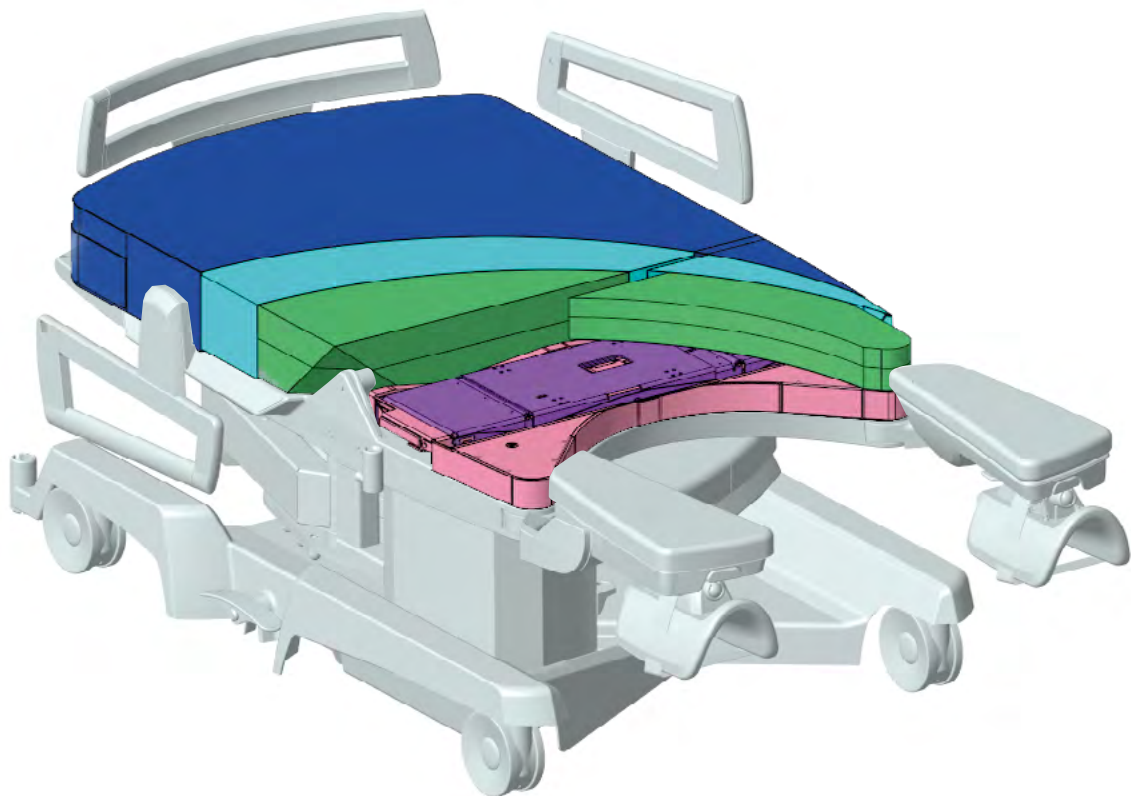


Instructions for Use and Technical Description



Vibwife Moving Mattress



D9U001VBB-0101

Version: 03

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LINET

Vibwife

Moving mattress

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Related links: www.linnet.com

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1 Symbols and definitions

1.1 Warnings

1.1.1 Types of Warning Notices

Warning notices are differentiated by the type of danger using the following key words:

- ▶ **CAUTION** warns about the risk of material damage
- ▶ **WARNING** warns about the risk of physical injury
- ▶ **DANGER** warns about the risk of fatal injury

1.1.2 Structure of Warning Notices



DANGER!
Warning; Electricity!
▶ Measures to avoid the risk.



WARNING!
Type and source of risk!
▶ Measures to avoid the risk, if necessary.



CAUTION!
Type and source of risk!
▶ Measures to avoid the risk, if necessary.


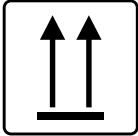


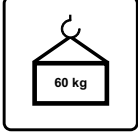
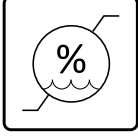
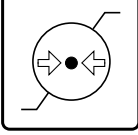


1.2 Instructions

Structure of instructions:











- ▶ Perform this step


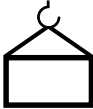







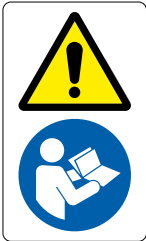

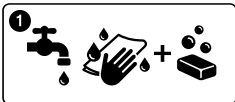

Results, if necessary.





1.3 Symbols on the Package

	FRAGILE!
	THIS SIDE UP
	KEEP DRY (PROTECT FROM MOISTURE)
	STACKING LIMIT BY MASS
	MAXIMUM WEIGHT OF PACKED PRODUCT (INCLUDING PALLET)
	RELATIVE AIR HUMIDITY
	AIR PRESSURE
	PAPER RECYCLING SYMBOL
	DO NOT POLLUTE THE ENVIRONMENT

1.4 Symbols and labels on the mattress

	SERIAL NUMBER
	REFERENCE NUMBER (PRODUCT TYPE DEPENDING ON THE CONFIGURATION)
	UNIQUE DEVICE IDENTIFIER
	MEDICAL DEVICE (COMPATIBLE WITH MEDICAL DEVICE REGULATION)
	EU LEGISLATION COMPLIANT PRODUCT
	EAC MARKING
	AUTHORIZED REPRESENTATIVE IN GREAT BRITAIN
	AUTHORIZED REPRESENTATIVE IN SWITZERLAND
	MANUFACTURER
	DATE OF MANUFACTURE
INT.: x/y	INTERMITTENT RUN MARK (DUTY CYCLE) - THIS MEANS THAT IF THE PRODUCT IS USED CONTINUOUSLY FOR "X" PERIOD OF TIME, THEN IT MUST NOT BE USED FOR "Y" PERIOD OF TIME. FOR EXAMPLE, INT.: 10/20 MEANS THAT AFTER 10 MINUTES OF USE/ CONTINUOUS POSITIONING, THE PRODUCT MUST NOT BE USED/ POSITIONED FOR 20 MINUTES
IP X	STRUCTURAL PROTECTION AGAINST WATER PENETRATION, HAZARDOUS CONTACT AND RESISTANCE AGAINST FOREIGN OBJECTS
~	ALTERNATING CURRENT

	MAXIMUM WEIGHT OF A WOMAN IN LABOUR/USER
	OVERALL PRODUCT WEIGHT
	APPLIED PARTS TYPE B
	APPLIED PARTS TYPE BF
	SUITABLE FOR INTERIOR USE ONLY
	MARKING ACCORDING TO THE DIRECTIVE EC 2002/96/EC (DIRECTIVE ON DISPOSAL OF OLD ELECTRIC AND ELECTRONIC APPLIANCES). SYMBOL FOR: "DO NOT DISPOSE OF THE PRODUCT INTO COMMUNAL WASTE. USE SPECIAL COLLECTION POINTS FOR OLD ELECTRONIC APPLIANCES."
	DANGEROUS ELECTRICITY!
	GENERAL WARNING SIGN
	CAUTION SIGN
	WARNING, READ INSTRUCTIONS FOR USE
	MANUAL WASHING, MANUAL MAINTENANCE
	WIPE WITH SOFT CLOTH WITH UNIVERSAL CLEANING SAPONATE SOLUTION
	DISINFECT WITH SOLUTION CONTAINING less then 5 000 ppm SODIUM HYPOCHLORITE (REFER TO INSTRUCTIONS FOR USE)

	RINSE WITH WATER
	DO NOT USE PHENOL!
	<p>THE UPHOLSTERY MEETS THE REQUIREMENTS ON RESISTANCE TO IGNITION ACCORDING TO BS 7177 IN THE MEDIUM HAZARD CATEGORY.</p> <p>THE UPHOLSTERY MEETS THE REQUIREMENTS OF EN 597-1; EN 597-2; BS 6807 – RESISTANCE TO IGNITION SOURCES 5</p>
	<p>THE SYMBOL OF THE CERTIFICATION AUTHORITY FOR QUALITY MANAGEMENT SYSTEMS</p>
<p>Contains FCC ID: 2AJYU-8PYA008 Contains IC: 23761-8PYA009 This device complies with Part 15 of the FCC Rules. Operation is subject to the conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.</p>	DESIGNATION OF COMMUNICATION MODULE
<div> <div>Vibwife 100-240 V AC, 50/60 Hz</div> <div>Vibwife 100-240 V AC, 50/60 Hz</div> </div>	MAINS CABLE LABEL

2 Safety Instructions



WARNING!

Never use the motion and positioning functions of the Vibwife in situations where manual mobilization or positioning techniques are considered inappropriate! The device must be disconnected from the mains.



WARNING!

Never use the motion and positioning functions of the Vibwife on women in labour/users with pre-eclampsia. The device must be disconnected from the mains.



WARNING!

Never use the motion and positioning functions of the Vibwife during surgical procedures (e.g. suturing, caesarean section, episiotomy)! The device must be disconnected from the mains.



WARNING!

Never perform maintenance or service work during use!



WARNING!

Never clean in automatic dishwashers!



DANGER!

Never place the power supply in the moving parts of the birthing bed.



DANGER!

Inappropriate handling of the power supply cord, e. g. by kinking, shearing or other mechanical damages is hazardous!



DANGER!

An additional multiple socket-outlet or extension cord shall not be connected to the medical electrical system.



DANGER!

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



WARNING!

This medical device is not intended for oxygen enriched environment!



WARNING!

This medical device is not intended for use with flammable substances!



WARNING!

Using, handling or servicing the product in a manner not in accordance with this manual is not permitted and may cause damage to the user for which the manufacturer is not responsible!



WARNING!

If the operation and parameters of the product are not as described in this user manual, do not use the product and report the problem to the manufacturer immediately!



WARNING!

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established!



WARNING!

Any repairs to the medical device must only be carried out by an authorized service provider!



DANGER!

Disconnect the device from the power supply before any repair.



WARNING!

No modifications may be made to the product without the manufacturer's permission!



WARNING!

In case of modification of this product, appropriate checks and tests must be carried out to ensure its permanent safe use.



WARNING!

After the expiry date of the product, it is permissible to continue its operation after obtaining a positive result of the technical inspection carried out by an authorized service provider.



CAUTION!

The manufacturer reserves the right to introduce changes to the product and changes to the instructions for use that result from technical progress.



CAUTION!

The manufacturer states that all parameters and equipment can be adjusted and changed. In particular, the design, technology and materials are subject to change without affecting the technical and operational parameters and the safety of the product.



CAUTION!

The design of the product guarantees safe use if the instructions given in this manual are followed.



CAUTION!

The Vibwife is only installed by an authorized manufacturer or an authorized service provider.

Additional instructions for correct use:

- ▶ Carefully follow the instructions for use
- ▶ Ensure that each user has read and fully understood these instructions before using the product
- ▶ Only use the Vibwife as specified in these instructions for use and only when it is in perfect condition
- ▶ If necessary, check the function of the Vibwife daily or at each shift change.
- ▶ Only use the Vibwife with the correct power supply
- ▶ Ensure that the Vibwife is only operated by qualified personnel who have been trained in the use of the mattress in accordance with the instructions for use by the manufacturer or a person approved by the manufacturer or an authorized representative or a person approved by an authorized representative
- ▶ Ensure that women in labour/users are informed about how to use the Vibwife and all relevant safety instructions
- ▶ Use original spare parts as replacements for any damaged parts and request them from the manufacturer's service department
- ▶ Ensure that maintenance and installation is carried out only by qualified personnel who have been trained by the manufacturer
- ▶ Ensure that the specified duty cycle of the Vibwife is not exceeded
- ▶ To avoid malfunctions, use only original manufacturer's accessories
- ▶ Ensure that the specified safe working load is not exceeded
- ▶ Do not exceed the maximum weight limit of the woman in labour/user for both the birthing bed and the Vibwife
- ▶ For basic cleaning, use a soft cloth and only a solution of all-purpose neutral detergent cleaning solution
- ▶ For disinfection, we recommend using standard surface disinfection products, e.g. quaternary ammonium-based, peroxide-based solutions. Always follow the concentration recommended by the product manufacturer for the type of surface!
- ▶ Do not use any abrasive substances or organic solvents
- ▶ Do not use large quantities of cleaning solution, there is a risk that water may enter the motor drive and damage the electrical installation, so that the product will not function properly
- ▶ In case of improper cleaning and disinfection, there is a risk of nosocomial infection
- ▶ Only place the upholstery on a dry bed surface

3 Intended use

- ▶ The Vibwife is an electrically powered moving mattress intended to be used on compatible birthing beds to support physiological childbirth

3.1 Indication

- ▶ For women during ambulant and stationary pregnancy check-ups and/or in all labor stages and during postpartum period

3.2 Contraindications

Vibwife movements can't be used for:

- ▶ any medical invasive procedure such as unplanned Caesarean sections
- ▶ during placement of Epidural Anesthesia
- ▶ episiotomy
- ▶ vacuum or forceps birth
- ▶ not on pregnant women with risk of unwanted preterm birth

In these cases, the device must always be disconnected from the mains!

3.3 Patient population

- ▶ Women, who are pregnant or in postpartum period. Application Environment 5 (Ambulatory), as in IEC 60601-2-52, such as Gynecology and Obstetrics departments in health care facilities

3.4 Intended user

- ▶ Caregivers (nurses, doctors)
- ▶ Women, who are pregnant or in postpartum period are allowed to safely use all functions of the Vibwife device except in cases that are mentioned as contraindications mentioned in the chapter "3.2 Contraindications" (based on the individual assessment of the woman's condition by the caregiver)
- ▶ Technical personal – maintenance and cleaning

4 Product Description

- ▶ The Vibwife imitates manual mobilization and position techniques. It is intended for use by professional birthing professionals and the woman in labour/user herself. The range and speed of movements are physically limited. The limits have been chosen to be sufficiently low to ensure that even incorrect or unintentional pressing of any of the controls will not cause any harm to the woman in labour/user.
- ▶ The basic function is the mattress function. The consequence of a failure of the motion and positioning functions of the Vibwife is simultaneous “standard care”, which poses no risk to the user.
- ▶ The Vibwife mattress motion module, which provides movement in the pelvic area, is located in the seating area of the mattress.
- ▶ The outer cover is cleanable (see chapter “11 Cleaning and disinfection”). If the outer cover is damaged, contact the service department for replacement.
- ▶ Vibwife is available in two variants - Vibwife and Vibwife Premium, which differ in the stiffness of the foam filling of the backrest.

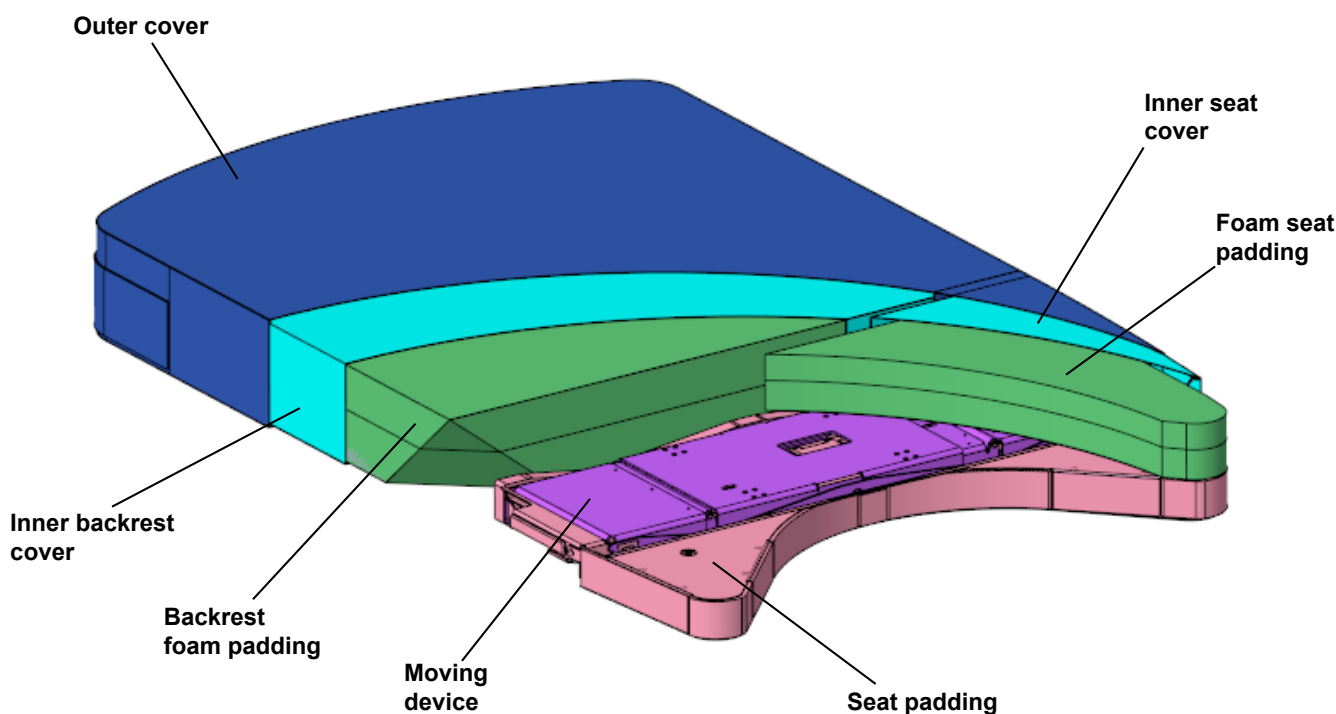


Fig. 1 Description of the Vibwife

4.1 FIRMWARE



CAUTION!

Risk of property damage due to improper use of Vibwife!

- ▶ After installing the new firmware, the medical personnel must be informed about the changes in the use of the medical device and then trained properly!

The product contains firmware that may only be updated by an authorized service technician or authorized representative. An authorized representative is a person who has successfully completed the LINET AR online training, and is then included in the LINET AR global list. At the same time, he or she receives the exact procedure for installing the firmware and for its verification.

NOTE The handset may display a black screen during the firmware update, after the update the display will light up again and the start menu will be displayed.

5 Technical Specification

All specifications are nominal and are subject to design and manufacturing tolerances.



WARNING!

Use the Vibwife exclusively with the AVE2 birthing bed, respect both mechanical and electrical specification values to avoid damage to either component!

5.1 Identification of type B applied parts

This part of the Vibwife Moving mattress is type B Applied Part:

- Moving Mattress

5.2 Identification of type BF applied parts

This part of the Vibwife Moving mattress is type BF Applied Part:

- Handset

5.3 Mechanical specification

Parameter	Value
Dimensions (length x width x height)	144 cm x 85,5 cm x 13,5 cm
Mattress weight (without power supply and handset)	26 kg
Maximum weight of a woman in labour/user	220 kg
The maximum load of the seat part (this weight corresponds to the recommended kneeling and sitting position for a birthing woman weighing 220 kg, i.e. the permitted SWL)	155 kg
Power supply weight	1,5 kg
Handset weight	0,3 kg
Maximum shift	± 2,3 cm
Maximum tilt	± 5,5°

	VIBWIFE	VIBWIFE PREMIUM
Foam material	Polyurethane foam	Polyurethane and memory foam
Cover material Base Coating	100% polyester 100% polyurethane	100% polyester 100% polyurethane
Cover	Waterproof	Waterproof
Water column height	>200 cm	>200 cm
Fire Resistance of the cover	According to BS7175 - ignition source 5	According to BS7175 - ignition source 5
Fire Resistance of the whole mattress	According to BS7177 - ignition source 5	According to BS7177 - ignition source 5
Biocompatibility of the Top Cover	According to ISO 10993-5 (cytotoxicity) and ISO 10993-10 (skin sensation and irritation)	According to ISO 10993-5 (cytotoxicity) and ISO 10993-10 (skin sensation and irritation)
Mattress type	Single sided	Single sided
Mattress shape	Shape of the back and seat section of the bed	Shape of the back and seat section of the bed

5.4 Electrical Specifications

Parameter	Value
Power adapter	48 V DC; 4,6 A (type MEAN WELL GSM220A48-R7B)
Voltage input, frequency	100 - 240 V AC, 50/60 Hz
Maximum input	312 VA
Ingress protection (EN 60529)	IPX4 (Vibwife used on AVE2 bed)
Protection class - Product	Class I

The device contains a non-removable battery that is part of the main PCB (vanadium pent-oxide lithium rechargeable battery type VL 2020).

The device contains overcurrent protection elements that are not user replaceable and are not intended to be replaced during routine service intervention.

5.5 Communication module

- ▶ The device contains an LTE modem with automatic communication
- ▶ The LTE modem is intended exclusively for transmission of operational data and software updates, it does not transmit any patient or staff data
- ▶ These devices produce a log file every time there is a session
- ▶ This log file is uploaded over the GSM/LTE module to the cloud server
- ▶ After the log file is uploaded, it is processed and valid information is imported to the database of the cloud application
- ▶ The database stores insights, analyses and detailed information about device association, usage of devices and report on these parameters
- ▶ Only the employees of L I N E T spol. s r.o. have access to the data
- ▶ Data can be managed in Power apps and they are visualized in Power BI application available online
- ▶ The modem is located under a cover and is not accessible to staff and patient
- ▶ The modem is equipped with two antennas
- ▶ The modem is compatible with 2G/3G/4G networks with global support, with very low power consumption

5.6 Environmental conditions

Use Conditions	
Ambient Temperature	10°C to 40°C
Relative Humidity	30% - 75 %
Atmospheric Pressure	795 - 1060 hPa
Storage and Transport Conditions	
Ambient Temperature	-40°C to 70°C
Relative Humidity	10 - 100 % (non-condensing)
Atmospheric Pressure	795 - 1060 hPa

5.7 Electromagnetic compatibility

The Vibwife is intended for hospitals except for near active HF surgical equipment and the RF shielded room of a medical system for magnetic resonance imaging, where the intensity of EM disturbances is high.

List of used cables

- Mains cable, maximum length 6 m



WARNING!

Use of the accessories, converters and other cables, than specified and provided by manufacturer of the Vibwife leads to increase of electromagnetic emission or lower the electromagnetic immunity of the Vibwife and leads to improper operation.



WARNING!

Mobile RF communication device (including end use devices like antenna cables and external antenna) should not be used closer than 30 cm (12 inches) from any part of the Vibwife including cables specified by manufacturer. Otherwise this could lead to deterioration of functionality of Vibwife.



WARNING!

Do not overload the Vibwife (SWL - Safe working load), respect the duty cycle (INT.) And take into consideration chapter “13 Maintenance” in order to maintain the basic safety with regard to electromagnetic disturbances for the expected service life.



WARNING!

The power supply “GSM220B48-R7B” is an integral part of the medical device, the Vibwife. To prevent liquids from coming into contact with the power supply, the power supply must be fixed above the floor. The use of another model of power supply must be approved by the manufacturer. Use of another power supply may lead to increased levels of interfering electromagnetic radiation and reduced the woman in labour/user and operator safety.

5.7.1 Manufacturer Instructions - Electromagnetic Emissions

Emission Test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies

5.7.2 Manufacturer Instructions - Electromagnetic Susceptibility

Immunity Tests	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV for contact discharge ± 15 kV for contact discharge
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	see “TABLE 1” on page 18
Fast electrical transients / burst IEC 61000-4-4	±2 kV for power line repetition frequency 100 kHz

Immunity Tests	Compliance level
Surge IEC 61000-4-5	± 1 kV Line-to-line ± 2 kV Line-to-ground
Conducted RF IEC 61000-4-6	3 V (0,15 MHz – 80 MHz) 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m
Voltage dips, short interruptions on power supply input lines IEC 61000-4-11	0 % U_T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° a 315° 0 % U_T ; 1 cycle and 70 % UT; 25/30 cycle Single phase: at 0° 0 % U_T ; 250/300 cycle

TABLE 1 - IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test Level V/m
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28
710 745 780	704 - 787	LTE band 13, 17	Pulse modulation 217 Hz	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	28
1 720 1 845 1 970	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation 217 Hz	28
5 240 5 500 5 785	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9

NOTE There are applied no deviations to requirements of IEC 60601-1-2 ed. 4.

NOTE There are no known other measures for keeping the basic safety based on EMC phenomena.

6 Terms of use and storage



DANGER!

Risk of death due to electric shock!

To ensure the Vibwife's Class I protection against electric shocks:

- Use only hospital outlets to connect the power supply



DANGER!

Risk of death due to electric shock!

- Do not plug the Vibwife into the mains without the power cable of the bed plugged in and disconnect the power cable of the Vibwife before disconnecting the power cable of the bed!

6.1 Terms of use



CAUTION!

Risk of property damage

- Improper use of the Vibwife may result in damage to the equipment
- **The maximum load of the seat part is 155 kg.** This weight corresponds to the recommended kneeling



and sitting



position for a birthing woman weighing 220 kg, i.e. the permitted SWL)

The device automatically stops after a maximum of 6 hours of operation. In case of overload, which could occur at any time after an **ON period** and within 6 hours of operation, the device may stop itself. In this case, the Vibwife can be manually switched ON again after a while.

Duty cycle (INT.):

The Vibwife is not designed for continuous operation - the seating area can be loaded up to a maximum of 155 kg, i.e. the worst case is for Vibrations & Jiggle mode - 10 minutes of operation followed by 33 minutes of OFF period (Vibwife was tested for 10 minutes with maximum load and at maximum speed. After a cool down cycle it can be used further. Exceeding the duty cycle can lead to increased motors heating and subsequent activation of the integrated thermal protection, which stops the motors when it exceeds 80 °C. Once the temperature has been reduced to a safe operating temperature for the motors (after the OFF period has been reached), it can be switched ON again manually.).

Values of the duty cycle (INT.) for individual modes:

Function	INT.
Vibrations & Jiggle	10 min ON / 33 min OFF
Rocking Baby	50 min ON / 15 min OFF
Sleeping Beauty	without limitation
Infinite Harmony	40 min ON / 15 min OFF

NOTE Measured at max. seat load 155 kg, max. ambient temperature 40 °C, mode setting 5/5.

The Vibwife is intended for use in rooms for medical purposes. For this reason, the wiring must comply with local standards that specify the conditions necessary for electrical wiring

- In exceptional circumstances (i.e. in the event of a storm or earthquake), disconnect the mattress from the mains

6.2 Storage



CAUTION!

- When storing, do not leave the seat cushion lying on the fixing pins - there is a risk of damaging the mattress



CAUTION!

- Do not place any sharp, heavy, or small objects on the mattress during storage - there is a risk of damage to the cover and foam core

When not using the Vibwife:

- Disconnect the power cable
- Make sure the mattress is cleaned and completely dry (see chapter "11 Cleaning and disinfection")
- Store the mattress in a dry and safe place, away from sharp objects

7 Scope of Delivery and Product Variants

7.1 Delivery

- ▶ Upon receipt, check that the delivery is complete as stated on the delivery document
- ▶ Notify the carrier and supplier immediately of any shortages or damage, either in writing or by noting it on the delivery note

7.2 Scope of delivery

- Vibwife:
 - The moving mattress is only compatible with the LINET® AVE2 birthing bed
- Handset
- Adapter
- Adapter holder
- Power cable
- Power cable holder
- Extension cable
- Extension cable holder
- Instructions for use

8 Putting into Service

Vibwife replaces the original mattresses exclusively intended for and compatible with the AVE2 birthing bed.



DANGER!

Risk of death due to electric shock!

- ▶ Do not plug the Vibwife into the mains without the power cable of the bed plugged in and disconnect the power cable of the Vibwife before disconnecting the power cable of the bed!



WARNING!

Danger of injury when working with the Vibwife

- ▶ Make sure that the Vibwife is disconnected from the mains before commissioning, decommissioning and maintaining it



CAUTION!

Risk of material damage due to incorrect commissioning!

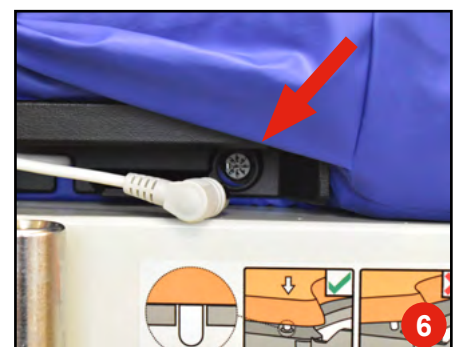
- ▶ Before installation, make sure the Vibwife is compatible with your birthing bed
- ▶ Ensure that putting into service is performed exclusively by manufacturer's customer service
- ▶ Due to the higher weight of the seating part of the Vibwife (moving mattress) than a normal mattress, take extra care when handling it. When manipulating the seating part, use only the plastic handles on the sides, do not use the flaps of the top cover!
- ▶ **Do not use the flap of the top cover to handle the backrest!**
- ▶ Each compatible birthing bed has separate technical installation/de-installation instructions. Instructions can be requested from the manufacturer at any time. Installation/de-installation may only be carried out by the manufacturer's customer service or by trained hospital personnel. The manufacturer will provide the technical personnel with the necessary installation/de-installation instructions.

8.1 Installation of the Vibwife on the AVE2 birthing bed

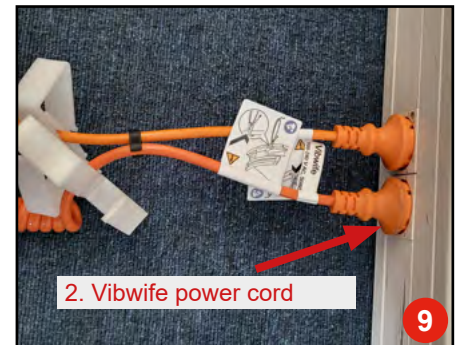
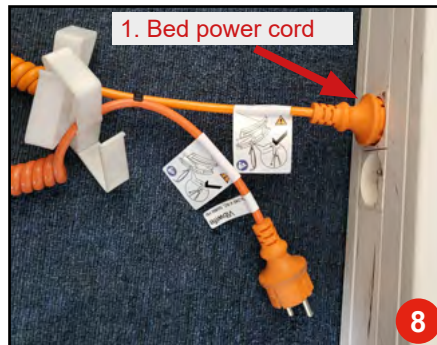
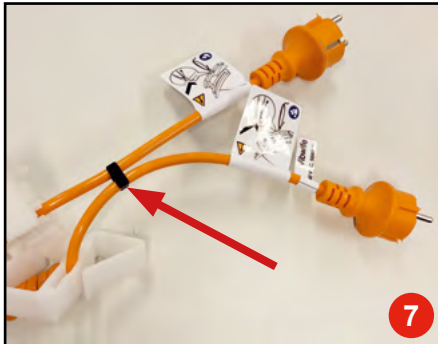
- ▶ Remove the original mattress
- ▶ **Using the plastic handles** place the Vibwife's seat section on the seating part of the bed frame (do not insert the pins in the Vibwife seat part into the holes in the bed frame yet) and thread the connection cable through the gap in the seat section **(1)**
- ▶ Secure the Vibwife seat section on the bed, i.e. insert the pins on the Vibwife seat section into the holes in the bed frame **(2)**
- ▶ Plug the connecting cable into the connector of the extension cable. Ensure that the connecting cable is routed **behind the hand grip! (3)**



- ▶ Insert the inner backrest mattress into the outer cover and fasten the zipper **(4-5)**. Flip the backrest over onto the backrest of the bed
- ▶ Connect the handset **(6)**



- ▶ Ensure that the Vibwife is correctly positioned on the bed.
- ▶ Connect the power cord of the AVE2 birthing bed with the power cord of the Vibwife using a plastic connector (7).
- ▶ **Plug the bed into the mains first! (8)**
- ▶ Plug the Vibwife into the mains (9) - the device automatically starts in Stand-by mode (see chapter “8.2 Stand-by mode”).




De-installation or removing the Vibwife from the bed:

- ▶ Follow the installation steps in reverse order but keep the power cords connected with a plastic connector
- ▶ It is not necessary to remove the inner mattress of the backrest

8.2 Stand-by mode

In Stand-by mode, the device is powered on and communicates up to the LTE module. The motors and power part are inactive, the controller is without power (not active, no backlighting of the display).

- ▶ When Vibwife is plugged into the mains, the device automatically starts in Stand-by mode
- ▶ To switch from Stand-by mode to active mode, any button on the handset must be pressed
- ▶ Stand-by mode is activated automatically after 1 minute of inactivity
- ▶ Stand-by mode can be activated immediately (without a delay of 1 minute) by pressing the STOP  button on the handset twice
- ▶ The Vibwife can be switched off by disconnecting from the mains, otherwise the device is active or in Stand-by mode

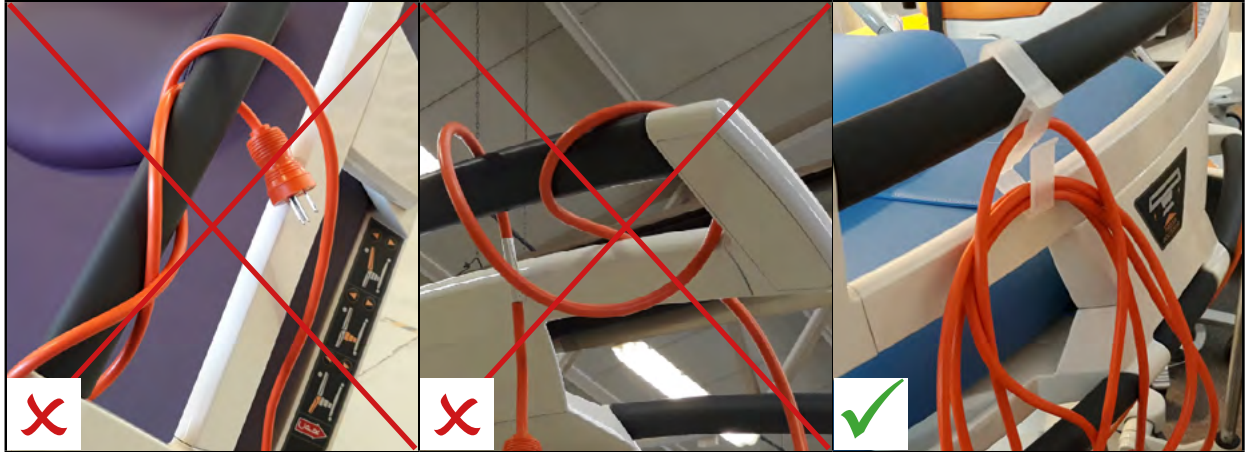
9 Power cord

Attachment plug is means of connecting and disconnecting Vibwife from the mains.



DANGER!

The power cable must be fixed to the bed at the selected point using plastic hook! Never wind up the cable on the bed/its parts, e.g. side handles, front section, handrails and other items!



DANGER!

In case of visible damage of the power cable, do not use the Vibwife and/or the cable! Always call technical service operator!



DANGER!

The power cable may only be replaced by an authorised and trained person using a tool!

10 Control of the Vibwife



WARNING!

Risk of injury when using the Vibwife!

Before connecting the Vibwife to the mains, make sure:

- ▶ that the connecting cable is plugged into the connector on the bed frame, is routed correctly between the mattress and the bed frame and shows no signs of damage. If the connection cable is visibly damaged, do not use the Vibwife and contact the service
- ▶ that there are no signs of damage to the mattress cover. If the top cover of the mattress is damaged, do not use the Vibwife and contact the service department.



WARNING!

Risk of injury when using the Vibwife!

- ▶ The woman in labour/user may only use the controls if the hospital staff has assessed that the patient's physical and psychological condition is compatible with their use, and only if the hospital staff has trained the woman in labour/user in accordance with the instructions for use!



WARNING!

Risk of injury when using the Vibwife!

- ▶ If the woman in labour/user uses the Vibwife on her own, the footrest must be in the unfolded and locked position
- ▶ Woman in labour/user with epidural anaesthesia or lower sensitivity in the lower part of the body may only be left in a safe position on the bed, i.e. the bed is set for the lying position (backrest, seat part and footrest are in one plane)
- ▶ If the woman in labour/user uses the Vibwife on her own, make sure that the Vibwife is always in the optimal position for the selected function



WARNING!

There is a risk of injury when placing the woman in labour/user on the bed!

Before placing the woman in labour/user on the bed

- ▶ Make sure the mattress is properly placed on the bed using the fixing pins



WARNING!

Risk of injury when using the Vibwife

- ▶ When the woman in labour/user gets in or out of bed, all functions of the moving mattress must be switched off



CAUTION!

Risk of property damage due to moisture or contamination!

- ▶ Make sure the mattress cover is cleaned and completely dry (*see chapter "11 Cleaning and disinfection"*)









Preparing the Vibwife for the woman in labour/user placement

- ▶ Ensure that the mattress is correctly positioned on the bed using the fixing pins
- ▶ Place a sheet on the mattress unless otherwise instructed by a qualified person



Placing the woman in labour/user on the bed

- ▶ Place the woman in labour/user on the bed according to the optimal birthing position for the selected mattress function

10.1 Handset

- ▶ The Vibwife is ready when it is installed on the birthing bed according to these instructions for use
- ▶ Once the device is plugged into the mains, the device is in sleep mode
- ▶ The moving positioning functions can be used by pressing any button on the handset
- ▶ If the Vibwife is not used for 60 seconds, it switches off and the motor controllers are completely disconnected from the power supply. They cannot switch themselves back on without the woman in labour/user pressing a button on the handset
- ▶ The operator can use the buttons , ,  or  to choose a mattress movement and using the buttons   and   control its range and speed
- ▶ The buttons that can be used for the selected function **are always illuminated**

NOTE:

- ▶ Pressing the STOP  button once slows down the current movement and returns the Vibwife to the neutral position where it stops. Handset remains active
- ▶ Pressing the STOP  button twice will immediately turn off the Vibwife and the handset
- ▶ All function buttons (1 - 7 in Fig. 2) can be used even if the handset display is not working

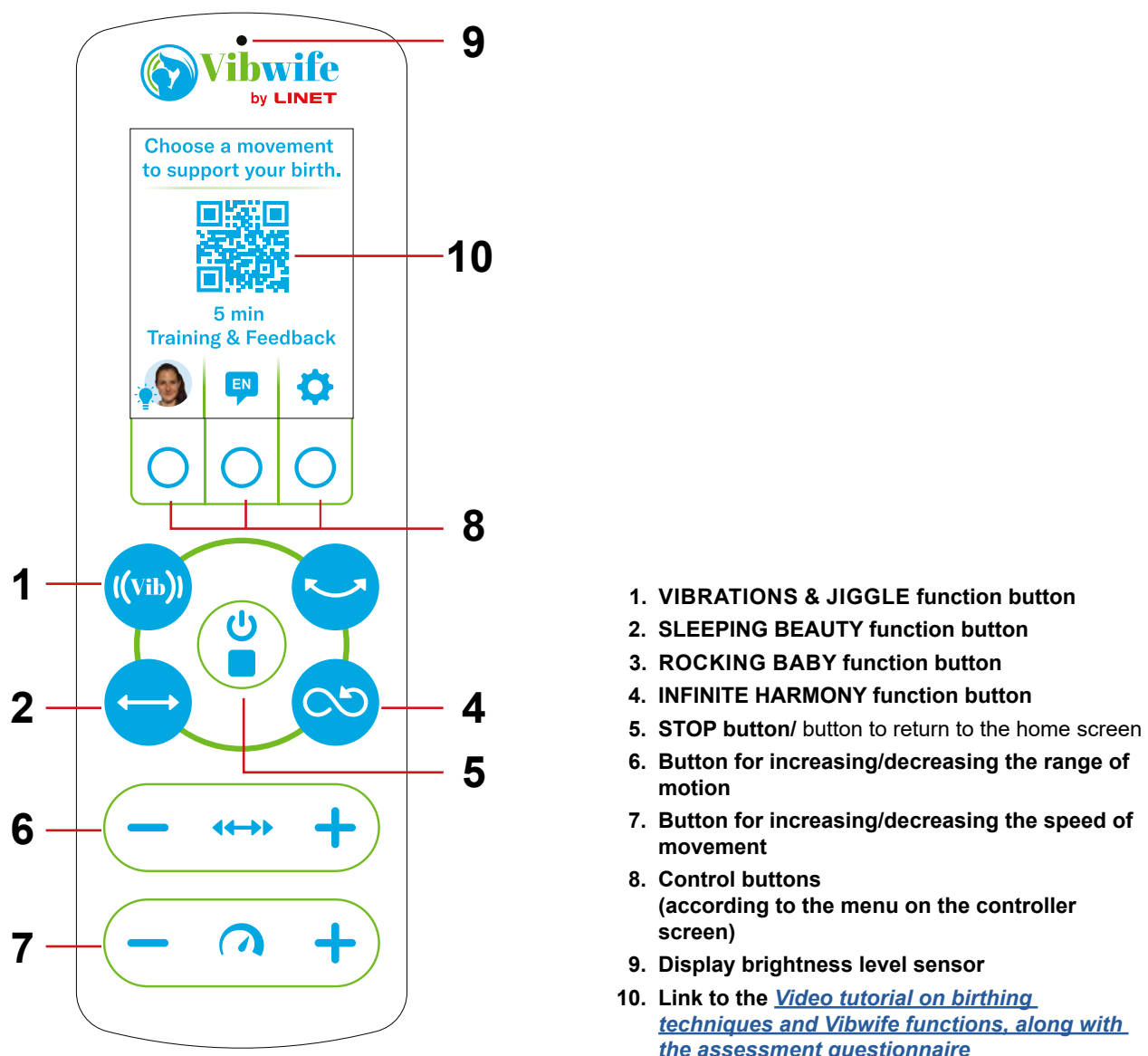


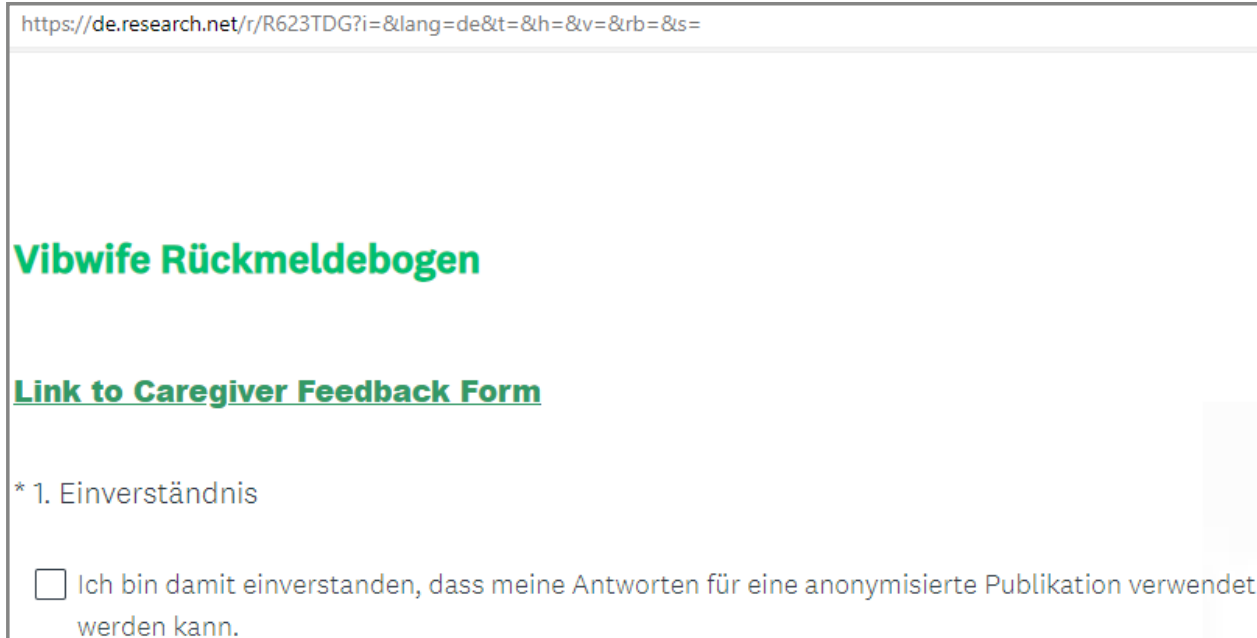
Fig. 2 Vibwife handset

QR code reading device:

- ▶ You can read a QR code using a smartphone or tablet that has a camera and a QR code reader app installed. If they don't have the app on the camera, you can download a QR code reading app from the App Store or Google Play.

How to read a QR code:

- ▶ Open the Camera app or any other suitable app available for reading the QR code and point the camera directly at the QR code. Wait for the reader to focus and scan it.
- ▶ Select the action that the mobile app offers you. In this case, it is a web address that will offer you to open a web page in your mobile's web browser (<https://vibq.ch/> → <https://de.research.net/>).



<https://de.research.net/r/R623TDG?i=&lang=de&t=&h=&v=&rb=&s=>
















Vibwife Rückmeldebogen







[Link to Caregiver Feedback Form](#)

* 1. Einverständnis

☐ Ich bin damit einverstanden, dass meine Antworten für eine anonymisierte Publikation verwendet werden kann.

BUTTONS AND ICONS OF THE HANDSET

BUTTON/SYMBOL	MEANING
	STARTING THE "VIBRATIONS & JIGGLE" FUNCTION
	STARTING THE " SLEEPING BEAUTY" FUNCTION
	STARTING THE "ROCKING BABY" FUNCTION
	STARTING THE "INFINITE HARMONY" FUNCTION
	<p>STOP BUTTON</p> <p>One press = stopping the movement of the Vibwife with reaching the neutral position, handset is active</p> <p>Double press = switching Vibwife to Stand-by mode, handset is off</p> <p>BUTTON TO RETURN TO THE HOME SCREEN</p>
	SETTING THE RANGE OF MOTION
	SETTING THE SPEED OF MOVEMENT
	VIBWIFE FEATURES GUIDE & DEMO FUNCTIONS
	LANGUAGE SELECTION
	<p>SETTINGS</p> <p>(TurnSupport, Angle pelvis, Language, Brightness, Info)</p>
	MOVE DOWN IN THE MENU
	MOVE UP IN THE MENU
	ENTER THE EXTENDED MENU / GO TO THE NEXT MENU PAGE
	EXITING THE DEMO FUNCTION "TIPS FROM ANNA"
	RETURN TO THE PREVIOUSLY SELECTED MENU

BUTTON/SYMBOL	MEANING
	CONFIRMATION OF SELECTION
	PAUSE IN THE PROGRAMME
	RECOMMENDED KNEELING BIRTH POSITION
	RECOMMENDED SEATED BIRTH POSITION
	RECOMMENDED BIRTH POSITION LYING ON THE SIDE
	TIMER

10.1.1 Home screen

- The handset display shows different screens according to the current selection
- On each selected screen, a menu bar is displayed at the bottom
- Using the control buttons on the hand control, you can then select an item from the Vibwife menu and scroll through the corresponding menu

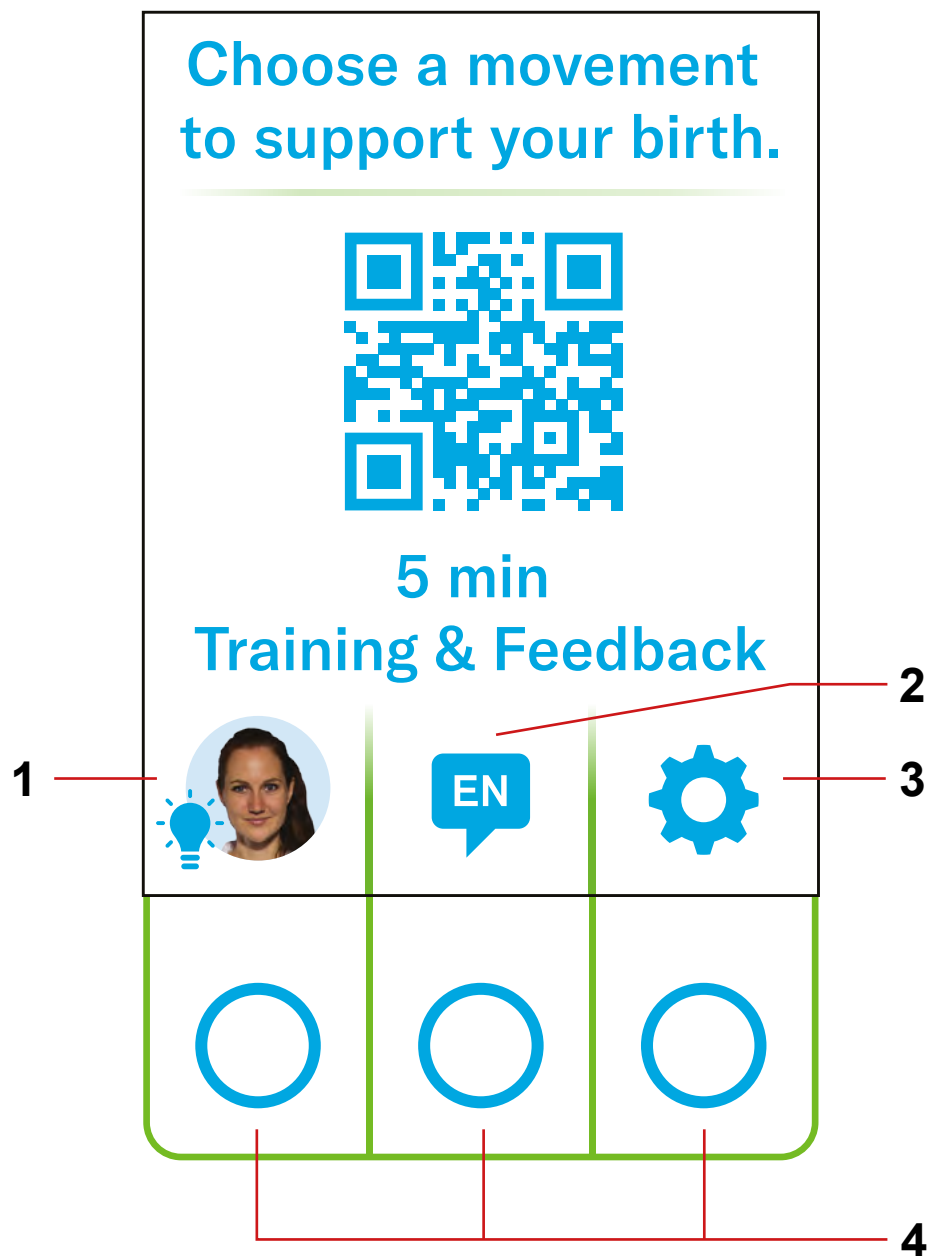


Fig. 3 Home screen

1. Icon for DEMO mode "Tips from Anna"
2. Icon for LANGUAGE SELECTION menu
3. Icon for SETTINGS menu
4. Control buttons for selecting items in the menu bar and scrolling through the menus

DEMO MODE „TIPS FROM ANNA“ - Vibwife functions guide

Inform the woman in labour/user that a Vibwife is installed on the birthing bed. In particular, mention that the Vibwife mimics manual mobilisation and positioning techniques. These techniques could help her to relax and positively influence the birth.

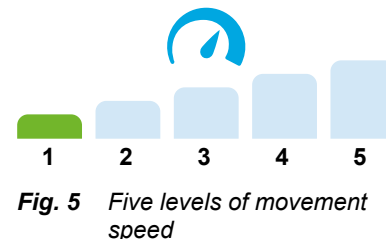
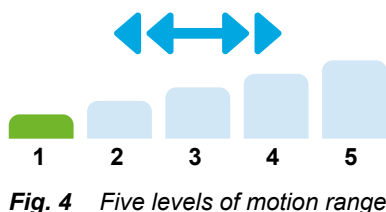
If interested, use the DEMO mode “Tips from Anna”  and demonstrate the functions of the Vibwife in 5 minutes:

- ▶ ROCKING BABY
- ▶ INFINITE HARMONY
- ▶ SLEEPING BEAUTY
- ▶ VIBRATIONS & JIGGLE

For more information, see chapter “Screens shown on the handset display in the DEMO mode” on page 32

The range and speed of movement for the ROCKING BABY, INFINITE HARMONY, SLEEPING BEAUTY and VIBRATIONS & JIGGLE functions have 5 levels

- ▶ Explain to the woman in labour/user that all motor functions start at the lowest range and level of speed
- ▶ Explain to the woman in labour/user that the range of motion and the intensity of the selected function can be independently increased/decreased



Optimal birthing positions


- ▶ Explain to the woman in labour/user that for each function of the motion mattress, the optimal positions - kneeling, sitting or lying on the side - are shown on the handset display.
- ▶ If more than one position is listed for the selected position, **the most optimal position is the one listed on the far left**





Fig. 6 Optimal birthing positions
(the most optimal position is always on the left)


















LISTING IN THE MENU OF THE DEMO MODE “TIPS FROM ANNA”

To start the Vibwife DEMO mode:

- Press the  button on the **home screen** of the display

To choose the requested DEMO function (Rocking baby, Infinite harmony, Sleeping beauty, Vibrations&Jiggle):


- Use the  or  control button

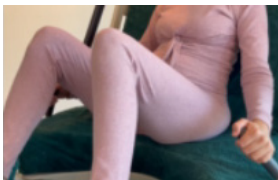










<p>Choose a movement to support your birth.</p>  <p>5 min Training & Feedback</p> <div>    </div>	<p>My name is Anna.</p>  <p>I'm a midwife & mom from Switzerland. I invented Vibwife and will now show you how it works! Push down button to start.</p> <div>   </div>	<p>Rocking Baby</p>  <p>RECOMMENDED POSITIONS</p>  <div>    </div>	<p>Infinite Harmony</p>  <p>RECOMMENDED POSITIONS</p>  <div>    </div>
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For more information on the selected function:



- Press the  button in the menu with the selected function and then use the  or  button

To return to the screen with the selected function

























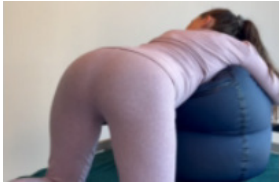






























- Press the  button

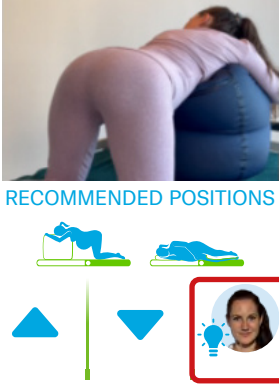

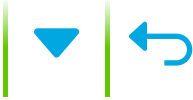






<p>Rocking Baby</p>  <p>RECOMMENDED POSITIONS</p>  <div>    </div>	<p>The Rocking Baby gently rocks your baby in the pelvis. This movement is most effective when you are on the knees (preferred) or sitting:</p>  <div>   </div>	<p>While rocking, asymmetry is created in the pelvis. This gives your baby room to descend in the birth canal. Rocking Baby is based on birth movement techniques using the</p> <div>    </div>
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To return to the Vibwife home screen:

- Press the  button at any time during the DEMO function demonstration or press the  button at the end of the DEMO function presentation

SCREENS SHOWN ON THE HANDSET DISPLAY IN THE DEMO MODE



Initial Information	<p>Choose a movement to support your birth.</p>  <p>5 min Training & Feedback</p>   	<p>My name is Anna.</p>  <p>I'm a midwife & mom from Switzerland. I invented Vibwife and will now show you how it works! Push down button to start.</p>  		
ROCKING BABY	<p>Rocking Baby</p>  <p>RECOMMENDED POSITIONS</p>     	<p>The Rocking Baby gently rocks your baby in the pelvis. This movement is most effective when you are on the knees (preferred) or sitting:</p>     	<p>While rocking, asymmetry is created in the pelvis. This gives your baby room to descend in the birth canal. Rocking Baby is based on birth movement techniques using the</p>   	<p>traditional Mexican rebozo towel. A clinical study performed by Monod et al. (2021) found: 90% of mothers using Vibwife would like to use it again.</p>   
INFINITE HARMONY	<p>Infinite Harmony</p>  <p>RECOMMENDED POSITIONS</p>     	<p>The Infinite Harmony simulates stair walking in the pelvis when you are on your knees:</p>  <p>By fully putting the weight of the upper</p>   	<p>body on a pillow or a birthing ball, the pelvis is the most flexible. The movement can be used in all positions. A clinical study performed by Monod et al. (2021) found:</p>   	<p>The Infinite Harmony is the most often chosen movement.</p>   
SLEEPING BEAUTY	<p>Sleeping Beauty</p>  <p>RECOMMENDED POSITIONS</p>    	<p>The Sleeping Beauty is best when you are lying on your side:</p>  <p>It gently moves the pelvis over hours – even when you relax or sleep.</p>   	<p>The movement changes the angle of the pelvis. This helps your baby to gently move down in the pelvis. A clinical study performed by Monod et al. (2021) found:</p>   	<p>93% of midwives recommend using Vibwife.</p>   

VIBRATIONS & JIGGLE	<p>Vibrations & Jiggle</p>  <p>RECOMMENDED POSITIONS</p>	<p>Vibrations & Jiggle helps to relax all muscles – even those you cannot consciously control. In the knees position, the movement imitates a traditional</p>  	<p>midwife technique called “shaking the apple tree”:</p>  <p>The movement can be used in all position. A clinical study performed by Monod et al. (2021) found:</p> 	<p>90% of mothers using Vibwife felt relaxed after using it.</p> 
More detailed information	<p>Press + and – for RANGE and SPEED and feel the difference.</p> 	<p>Which program did you like most? Now it's your turn to test out what feels best. Don't forget: The more you move, the more you support your baby! Sincerely, Anna</p>  		

LANGUAGE

The LANGUAGE menu allows the user to select the language version in which the menu will be displayed on the controller display.

It is possible to enter the LANGUAGE menu:

- ▶ using the LANGUAGE  control button
- ▶ or using the SETTINGS  control button

ENTERING THE “LANGUAGE” MENU USING THE CONTROL BUTTON

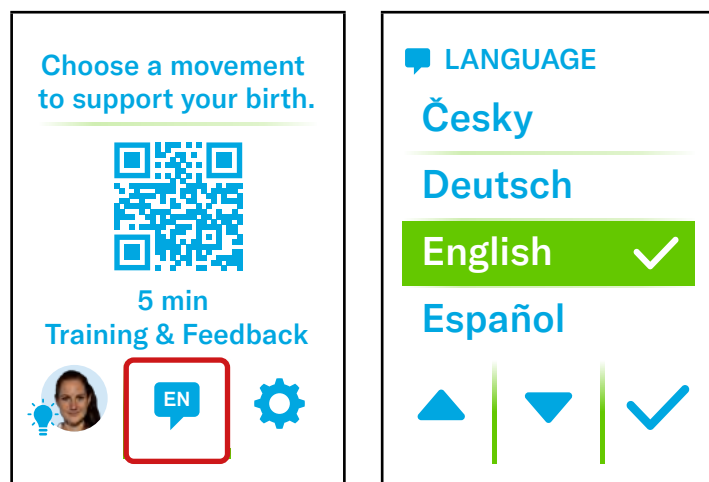









FIG. 7 LANGUAGE menu

To select a requested LANGUAGE:

- ▶ Press the  control button on the home screen of the display
- ▶ Using the  or  control button select the desired language
- ▶ Confirm the selection with the  control button

NOTE: When the  button is pressed briefly, the menu is displayed in the selected language for 14 hours. If Vibwife is then switched off for more than 30 minutes, the menu is displayed in the default language when the device is started. To permanently change the selected language to the default language, press the  button for 5 seconds.

To return to the home screen:

- ▶ Press the STOP button  on the handset

ENTERING THE “LANGUAGE” MENU USING THE CONTROL BUTTON

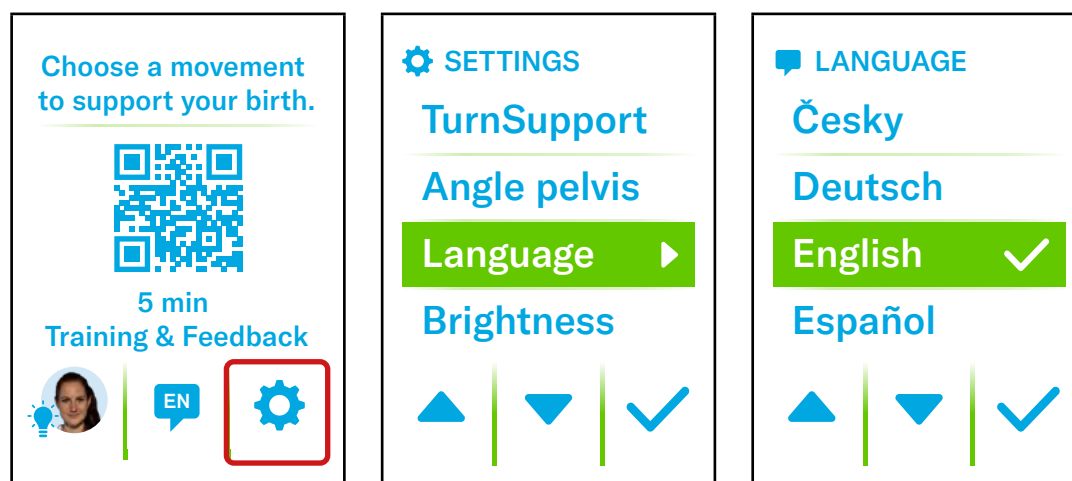











FIG. 8 LANGUAGE menu

To select a requested LANGUAGE:

- ▶ Press the  control button on the home screen of the display
- ▶ Select “Language” using the control button  or 
- ▶ Confirm the selection with the  control button
- ▶ Using the  or  control button select the desired language
- ▶ Confirm the selection with the  control button

NOTE: When the  control button is pressed briefly, the menu is displayed in the selected language for 14 hours. If Vibwife is then switched off for more than 30 minutes, the menu is displayed in the default language when the device is started. To permanently change the selected language to the default language, press the  control button for 5 seconds.

To return to the home screen:

- ▶ Press the STOP button  on the handset

SETTINGS MENU - TurnSupport

The **TurnSupport** function helps the mother to turn from one side to the other. In this case, there is usually no need for manual assistance from medical personnel.



WARNING!

Risk of injury when using the Vibwife!

- ▶ This function may only be **used by properly trained personnel** who will instruct the birthing woman on how to proceed during movements of the Vibwife mattress.

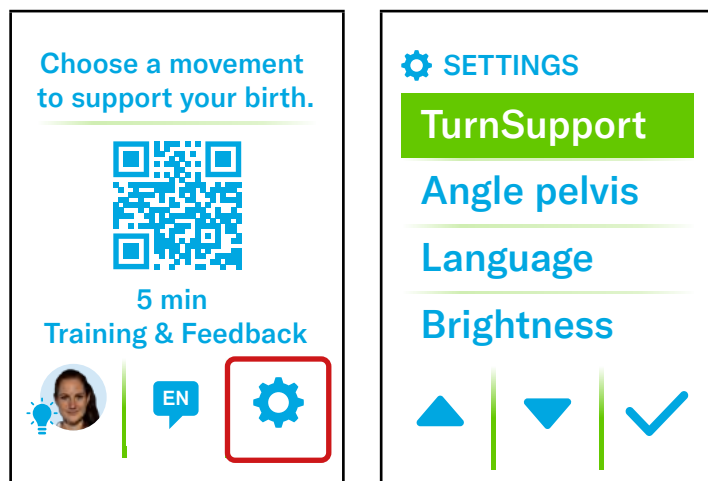


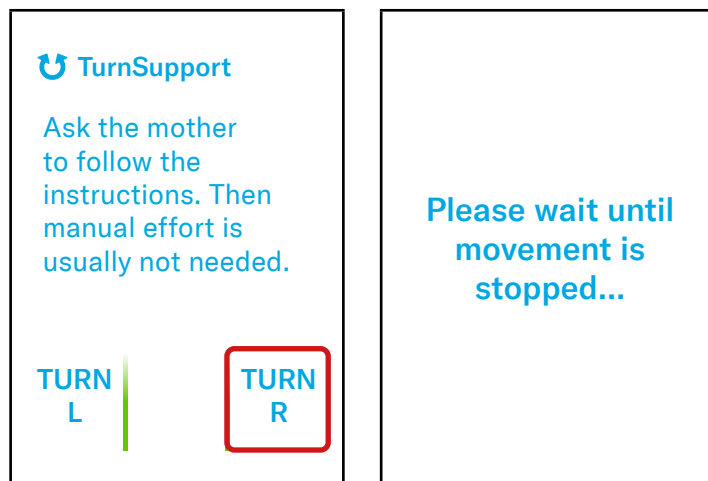


FIG. 9 SETTINGS menu - TurnSupport

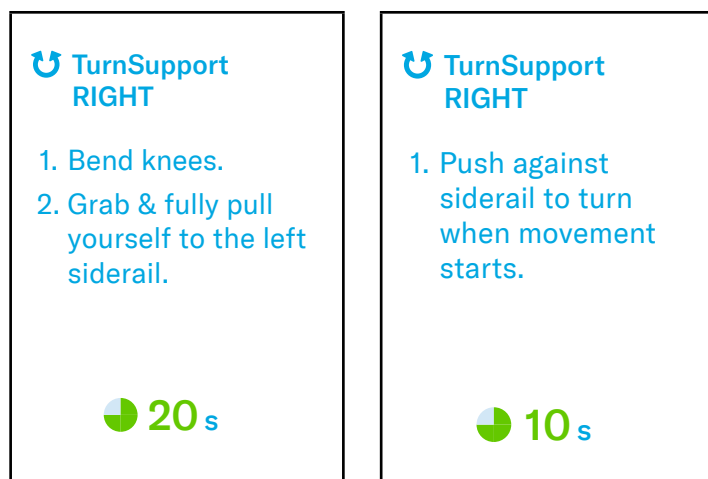
To select the Turn Support function:

- ▶ Press the  control button on the home screen of the display
- ▶ Use the  button to select "TurnSupport"



To start the Turn Support function:

- ▶ Choose a side for the TurnSupport - TURN R (right) or TURN L (left)
- ▶ As soon as the TurnSupport is activated and the first movement starts, the default screen "Please wait until the movement is stopped..." is displayed
- ▶ The device moves to the outermost position according to the selection (in this case **RIGHT**)



- ▶ When the movement stops a screen with instructions „1. Bend knees“ and “2. Grab & fully pull yourself to the left siderail“ displays
- ▶ Instruct the birthing woman to follow the steps
- ▶ The Vibwife will remain in this position for 30 s. After the first 20 s, a screen will appear with the instruction “1. Push against the siderail to turn when movement starts.”
- ▶ Inform the birthing woman that in 10 s the Vibwife will start to tilt to the other side and instruct her on how to proceed thereafter

TurnSupport RIGHT

1. Push against siderail to turn when movement starts.

TurnSupport RIGHT

1. Push against siderail to turn when movement starts.

 20s

- ▶ The "TurnSupport RIGHT (LEFT)" screen without a timer will then be displayed and the tilt to the other side will be indicated. At this point, instruct the birthing woman to push off the siderail and begin the rollover to the other side
- ▶ After the tilt is completed, the Vibwife will remain in this position for 20 seconds. During this time, the "Turn-Support RIGHT (LEFT)" screen with a timer will be displayed

TurnSupport finished

Please wait until
movement is
stopped...

Choose a movement
to support your birth.



5 min
Training & Feedback



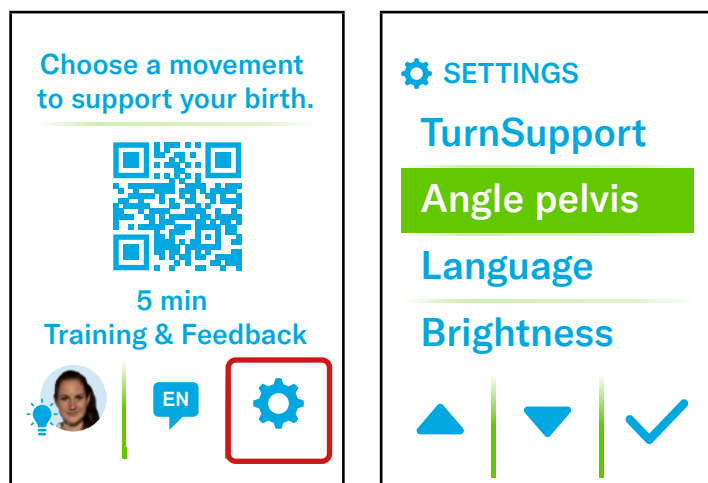
EN



- ▶ The "TurnSupport finished" screen will then be displayed with the instruction *"Please wait until movement is stopped..."* and the device moves to its default position (centred/default)
- ▶ The "TurnSupport" function is stopped

SETTINGS MENU - Angle pelvis

In ANGLE PELVIS menu it is possible to set permanent tilt of the Vibwife (LEFT/RIGHT).



Obr. 10 SETTINGS menu - Angle pelvis

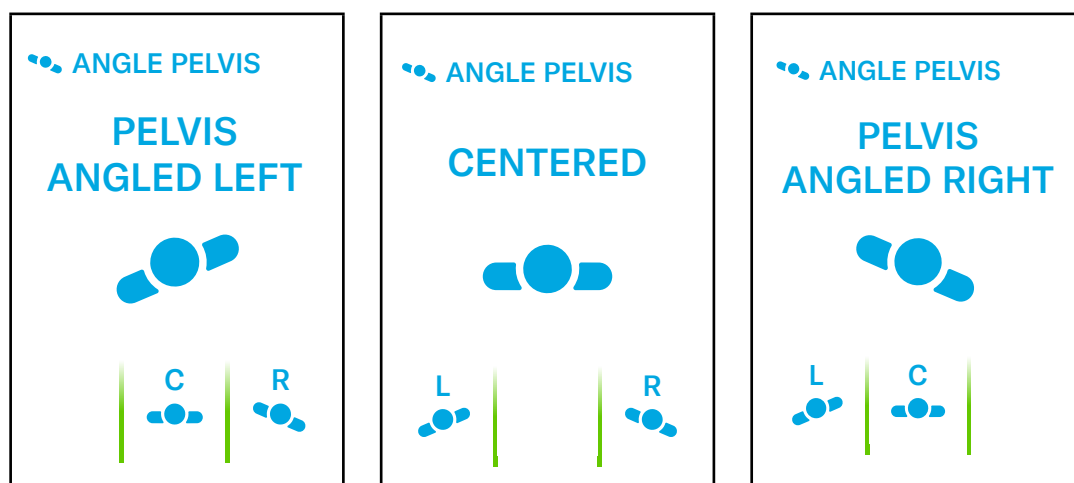











Fig. 11 Angle pelvis options

Selecting the requested tilt:

- ▶ Press the  control button on the home screen of the display
- ▶ Select "Angle pelvis" using the  or  control button
- ▶ Confirm the selection with the  control button
- ▶ Using buttons ,  or  select the requested tilt

Vibwife functions suitable when choosing RIGHT or LEFT tilt:

- ▶ **VIBRATIONS & JIGGLE** function  (see chapter "10.1.2 VIBRATIONS & JIGGLE function ")
- ▶ **SLEEPING BEAUTY** function  (see chapter "10.1.3 SLEEPING BEAUTY function ")

SETTINGS MENU - Brightness

Using the Brightness function, the backlight intensity of the display and the buttons on the handset can be adjusted.

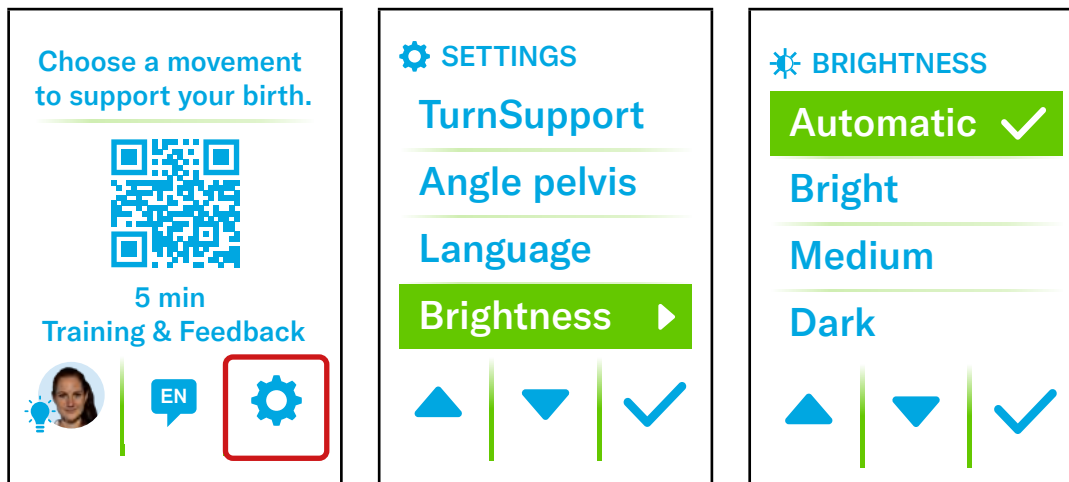








Fig. 12 SETTINGS menu - Brightness

Setting the display brightness level:

- ▶ On the home screen of the display, press the  control button
- ▶ Using the button  select "**Brightness**"
- ▶ Using the button  enter the submenu
- ▶ Using the  or  control button select the desired brightness level (Automatic/Bright/Medium/Dark)
- ▶ Confirm the selection with the  button

Brightness shall reset to "Automatic" after 14 hours of no usage.

Return to the home screen:

- ▶ Press the **STOP** button  on the handset

SETTINGS MENU - Info

The INFO menu displays:

- ▶ Firmware version
- ▶ Serial Number of the device.
- ▶ LTE connection status (shows whether the device is connected to the LTE network)

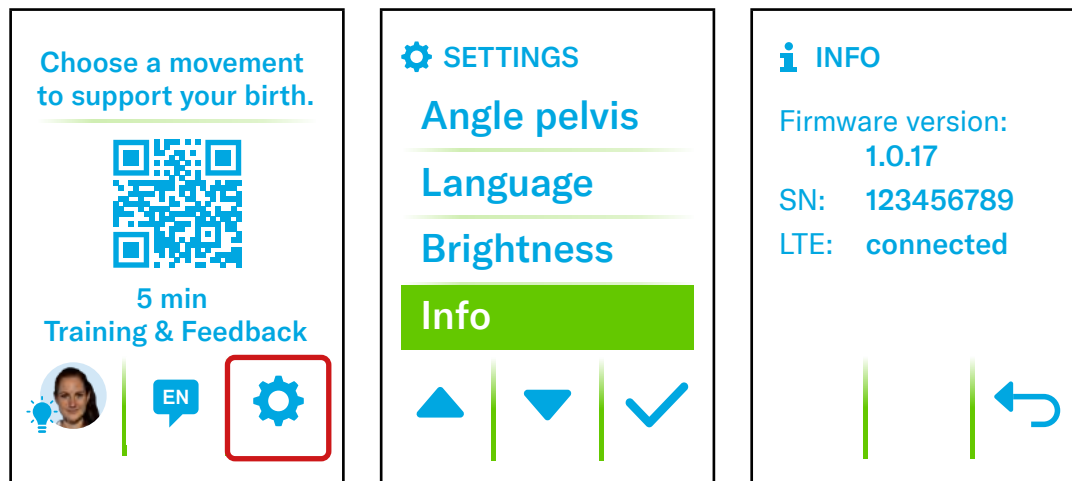





Fig. 13 SETTINGS menu - Info

Firmware version display:

- ▶ On the home screen of the display, press the  control button
- ▶ Using the button  select "Info"
- ▶ Confirm the selection with the  button

Return to the SETTINGS menu:

- ▶ Press the button  on the handset

Return to the home screen:

- ▶ Press the **STOP** button  on the handset

10.1.2 VIBRATIONS & JIGGLE function

The **VIBRATIONS & JIGGLE** function helps to relax muscles, including those that cannot be consciously controlled.

Optimal birthing position:

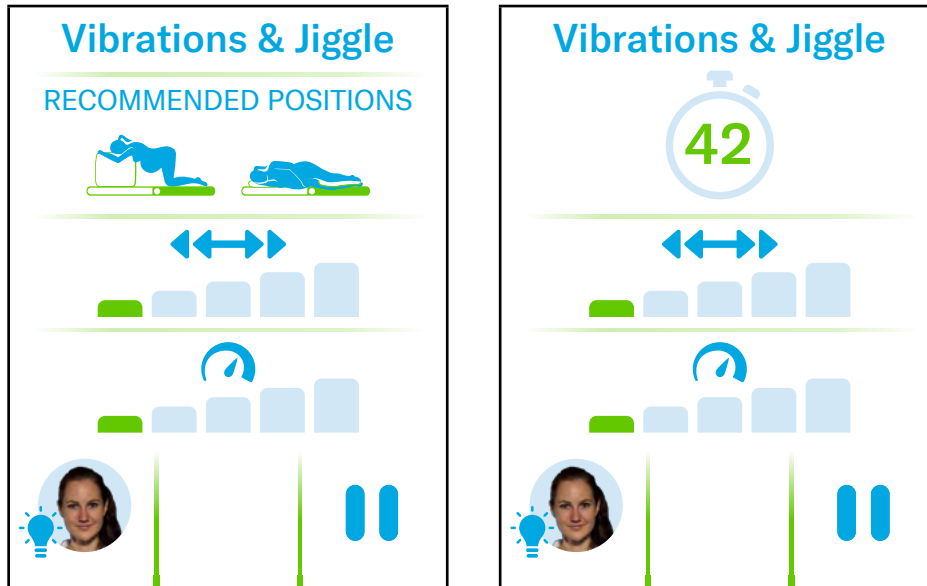






FIG. 14 VIBRATIONS & JIGGLE function


Selecting the VIBRATIONS & JIGGLE function:

- Press the  button on the remote control
- The display will show the optimal birthing position and the movement mode indicator (choice of two types of vibration)
- After 10 minutes of inactivity on the handset, a timer appears on the display, indicating the running time of the motion function
- If the VIBRATIONS & JIGGLE function is not paused using the  button, it will switch off automatically (max. of 6 hours from start-up)
- During the movement it is possible to display "Tips from Anna" using the  button

Setting the range of motion:

- Use the  button on the handset
- To **increase** the range of movement, press "+"
- To **decrease** the range of movement, press "-"

Setting the speed of movement:

- Use the  button on the handset
- To **increase** the speed, press "+"
- To **decrease** the speed, press "-"

Range and speed of movement have 5 levels

- The **VIBRATIONS & JIGGLE** motion function always starts at the lowest range of motion (1) and at the lowest speed level (1)

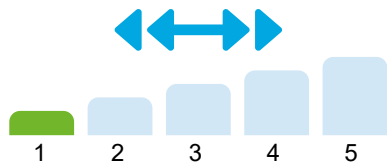




Fig. 15 Five levels of motion range



Fig. 16 Five levels of movement speed

Suspension of the VIBRATIONS & JIGGLE function

- Press the  control button
- The movement stops and the mattress moves to the centre position
- The device remembers the set range of motion and speed level
- The function will be suspended for 5 minutes. During this time, the function can be restarted with the  control button
- If the VIBRATIONS & JIGGLE function is not restarted within five minutes, it will be automatically switched off

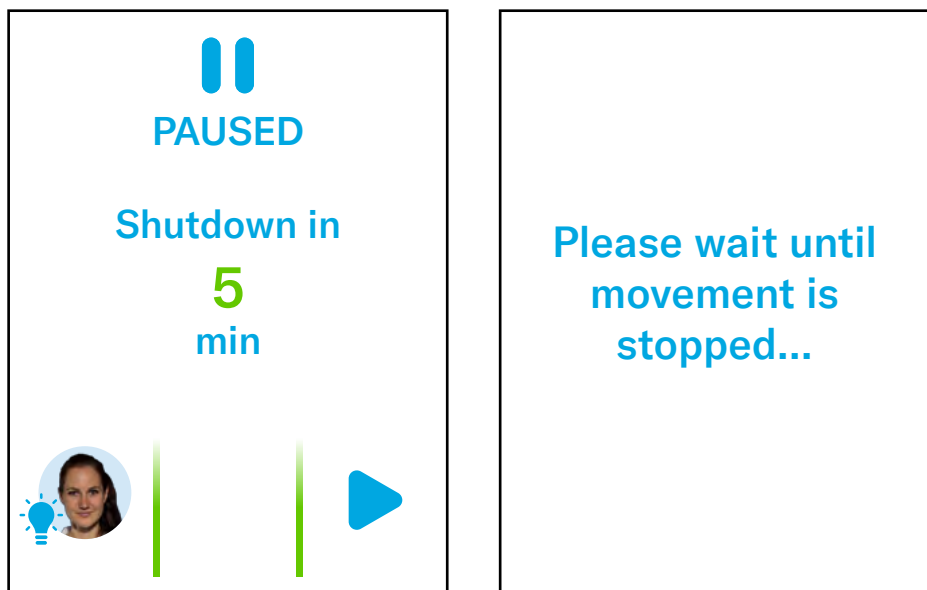




Fig. 17 Suspension of the VIBRATIONS & JIGGLE function


Stopping the VIBRATIONS & JIGGLE function and returning to the home screen:

- Press the **STOP** button  on the handset
- The movement stops and the mattress moves to the base position. During this time, the button  flashes

10.1.3 SLEEPING BEAUTY function

The **SLEEPING BEAUTY** function allows gentle movement of the pelvis. This helps the baby to gently descend in the birth canal.

Optimal birthing position:

- lying on the side 

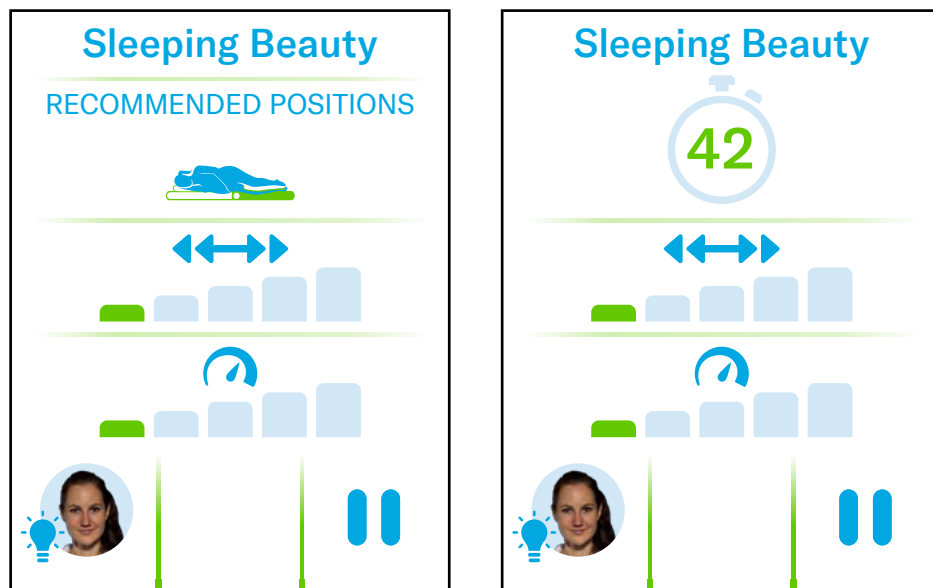






Fig. 18 SLEEPING BEAUTY function


Select the SLEEPING BEAUTY function:

- Press the  button on the remote control
- The display will show the optimal birthing position and the range and speed setting levels
- After 10 minutes of inactivity on the handset, a timer appears on the display, indicating the running time of the motion function
- If the SLEEPING BEAUTY function is not paused using the  button, it will switch off automatically (max. of 6 hours from start-up)
- During the movement it is possible to display "Tips from Anna" using the  button

Setting the range of motion:

- Use the  button on the handset
- To **increase** the range of movement, press "+"
- To **decrease** the range of movement, press "-"

Setting the speed of movement:

- Use the  button on the handset
- To **increase** the speed, press "+"
- To **decrease** the speed, press "-"

Range and speed of movement have 5 levels

- The SLEEPING BEAUTY motion function always starts at the lowest range of motion (1) and at the lowest speed level (1)

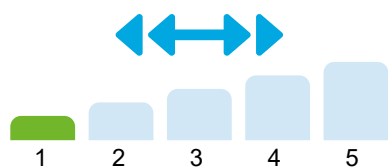


Fig. 19 Five levels of motion range

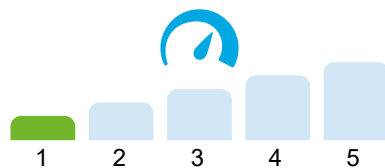




Fig. 20 Five levels of movement speed

Suspension of the SLEEPING BEAUTY function:

- Press the  control button
- The movement stops and the mattress moves to the centre position
- The device remembers the set range of motion and speed level
- The function will be suspended for 5 minutes. During this time, the function can be restarted with the  control button
- If the SLEEPING BEAUTY function is not restarted within five minutes, it will be automatically switched off

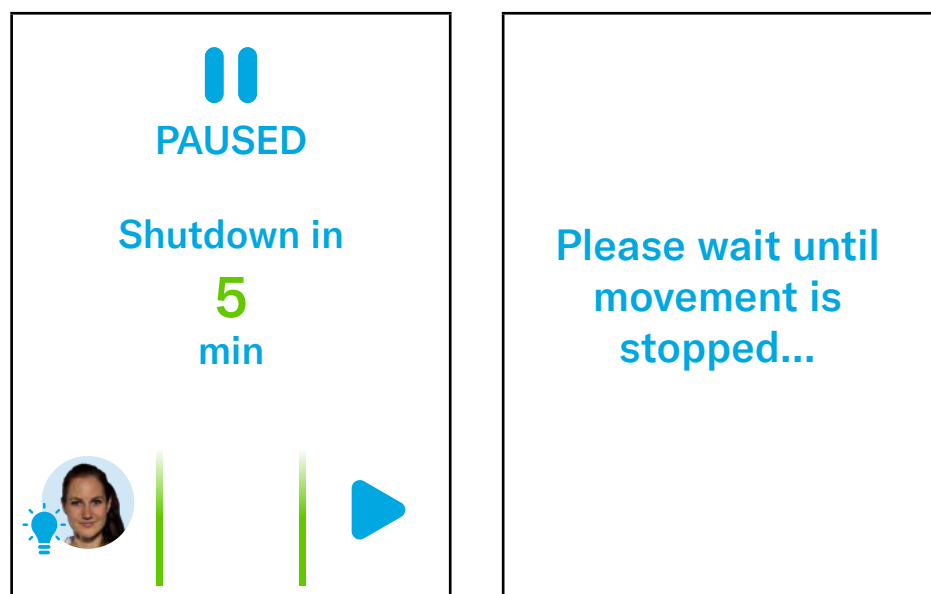




Fig. 21 Suspension of the SLEEPING BEAUTY function

Stop the SLEEPING BEAUTY function and return to the home screen:

- Press the **STOP** button  on the remote control
- The movement stops and the mattress moves to the base position. During this time, the button  flashes

10.1.4 ROCKING BABY function

During the **ROCKING BABY** function, the baby is gently rocked in the pelvis. This movement helps to open the pelvis, making it easier for the baby to move through the birth canal.

Optimal birthing position:

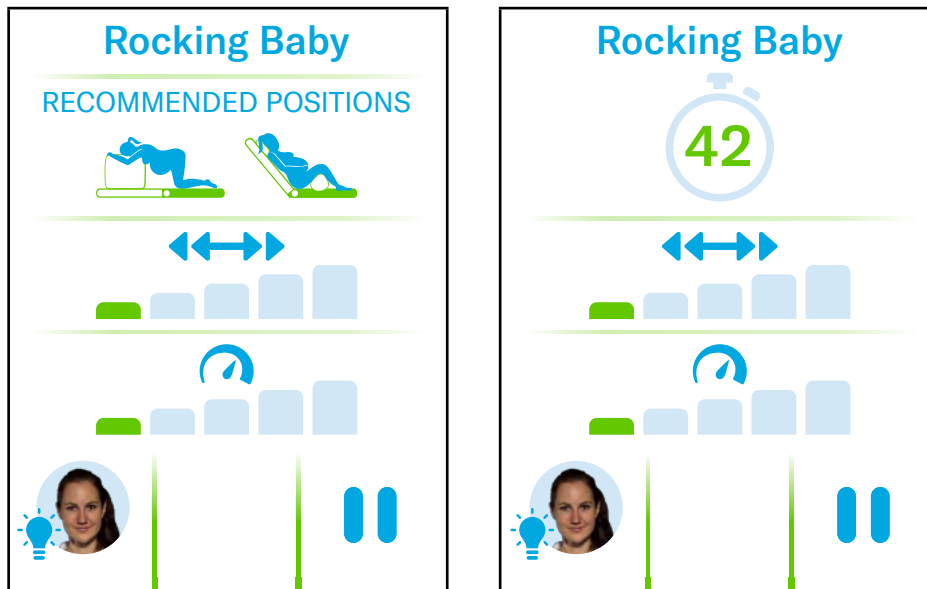






FIG. 22 ROCKING BABY function


Selecting the ROCKING BABY function:

- Press the  button on the hand control
- The display shows the optimal birthing position and the range and speed setting levels
- After 10 minutes of inactivity on the handset, a timer appears on the display, indicating the running time of the motion function
- If the ROCKING BABY function is not suspended using the  button, it will switch off automatically (max. of 6 hours from start-up)
- During the movement it is possible to display "Tips from Anna" using the  button

Setting the range of motion:

- Use the  button on the handset
- To **increase** the range of movement, press "+"
- To **decrease** the range of movement, press "-"

Setting the speed of movement:

- Use the  button on the handset
- To **increase** the speed, press "+"
- To **decrease** the speed, press "-"

Range and speed of movement have 5 levels

- The ROCKING BABY movement feature always starts at the lowest range of movement (1) and the lowest speed level (1)

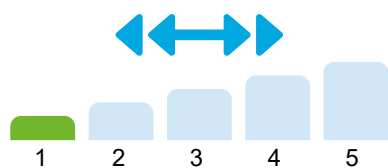


Fig. 23 Five levels of motion range

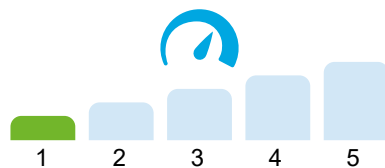




Fig. 24 Five levels of movement speed

Suspension of the ROCKING BABY function:

- Press the  control button
- The movement stops and the mattress moves to the centre position
- The device remembers the set range of motion and speed level
- The function will be suspended for 5 minutes. During this time, the function can be restarted with the  control button
- If the ROCKING BABY function is not restarted within five minutes, it will be automatically switched off

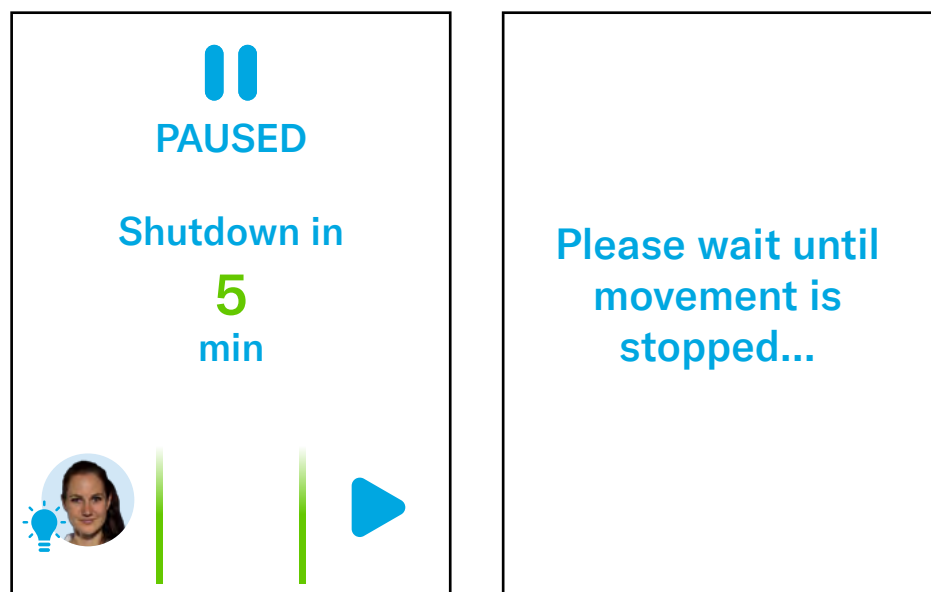




Fig. 25 Suspension of the ROCKING BABY function

To stop the ROCKING BABY function and return to the home screen:

- Press the **STOP** button  on the handset
- The movement stops and the mattress moves to the base position . During this time, the button  flashes

10.1.5 INFINITE HARMONY function

The **INFINITE HARMONY** function simulates the movement of the pelvis when walking up stairs. When rocking, asymmetry is created, which gives the baby room to descend in the birth canal

Optimal birthing position:

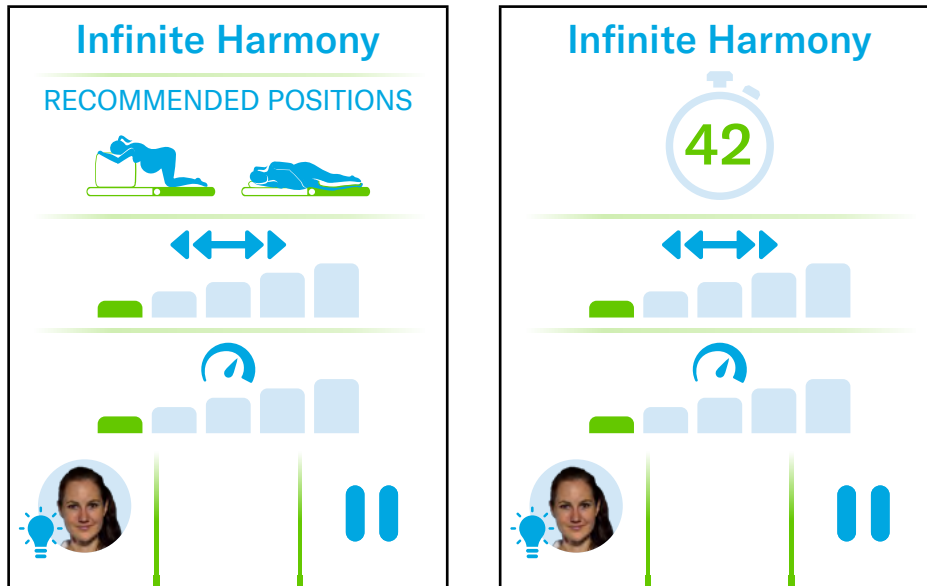






FIG. 26 INFINITE HARMONY function


Selecting the INFINITE HARMONY function

- Press the  button on the remote control
- The display shows the optimal birthing position and the range and speed setting levels
- After 10 minutes of inactivity on the handset, a timer appears on the display, indicating the running time of the motion function
- If the INFINITE HARMONY function is not suspended using the  button, it will switch off automatically (max. of 6 hours from start-up)
- During the movement it is possible to display "Tips from Anna" using the  button

Setting the range of motion:

- Use the  button on the handset
- To **increase** the range of movement, press "+"
- To **decrease** the range of movement, press "-"

Setting the speed of movement:

- Use the  button on the handset
- To **increase** the speed, press "+"
- To **decrease** the speed, press "-"

Range and speed of movement have 5 levels

- The INFINITE HARMONY motion function always starts in the lowest range of motion (1) and at the lowest speed level (1)

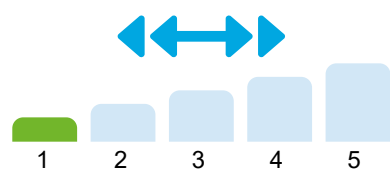


Fig. 27 Five levels of motion range

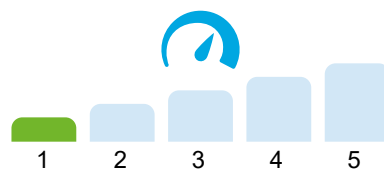




Fig. 28 Five levels of movement speed

Suspension of the INFINITE HARMONY function:

- Press the  control button
- The movement stops and the mattress moves to the centre position
- The device remembers the set range of motion and speed level
- The function will be suspended for 5 minutes. During this time, the function can be restarted with the  control button
- If the INFINITE HARMONY function is not restarted within five minutes, it will be automatically switched off

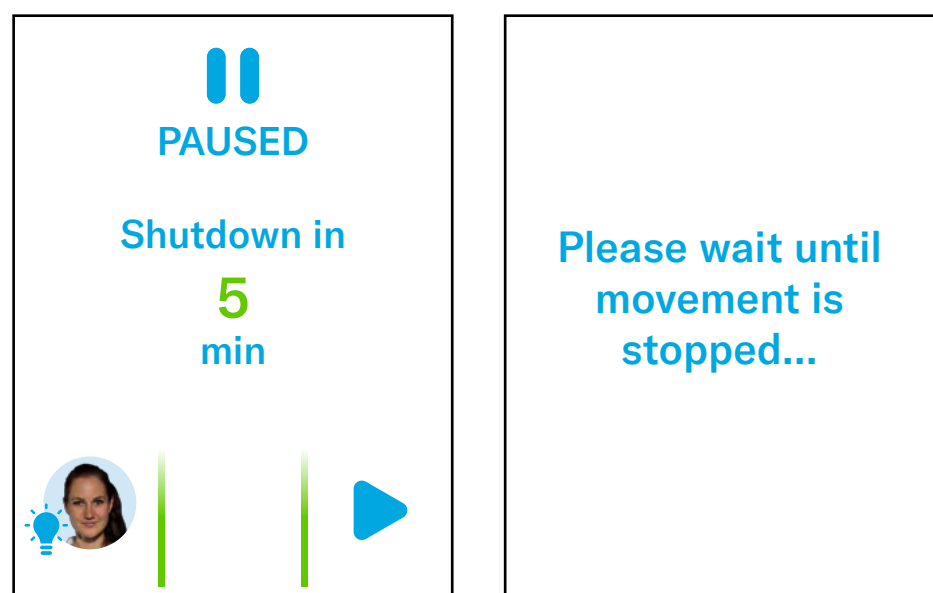












Fig. 29 Suspension of the INFINITE HARMONY function

To stop the INFINITE HARMONY function and return to the home screen:

- Press the **STOP** button  on the handset
- The movement stops and the mattress moves to the base position. During this time, the button  flashes

10.1.6 Error codes

Status (Pop-up)	MEANING
 <p>The device is overheated.</p> <p>Please wait until the device cools itself down.</p> <p>SF 8888ABCD, SC 8888ABCD TF 8888ABCD, TC 8888ABCD</p>	<p>The device is overheated.</p> <p>Wait for the device to cool down.</p>
 <p>The device is overloaded.</p> <p>Lower the load and press . If the problem persists, please call the service.</p> <p>SF 8888ABCD, SC 8888ABCD TF 8888ABCD, TC 8888ABCD</p>	<p>The device is overloaded.</p> <p>Reduce the load and press the STOP  button on the handset. If the problem persists, call for service.</p>
 <p>The device might be damaged.</p> <p>Try power cycling the device. If the problem persists, please call the service.</p> <p>SF 8888ABCD, SC 8888ABCD TF 8888ABCD, TC 8888ABCD</p>	<p>The equipment may be damaged.</p> <p>Try switching the device off and on again. If the problem persists, call for service.</p>
 <p>Safe limits exceeded.</p> <p>Lower the load and press . If the problem persists, please call the service.</p> <p>SF 8888ABCD, SC 8888ABCD TF 8888ABCD, TC 8888ABCD</p>	<p>Exceeding safe limits.</p> <p>Reduce the load and press the STOP  button on the handset. If the problem persists, call for service.</p>

11 Cleaning and disinfection



CAUTION!

Risk of property damage caused by improper cleaning/disinfection

- ▶ Do not use pressure or steam cleaners
- ▶ Follow the instructions and dosage recommended by the manufacturer. Never exceed the recommended concentrations given in this document. Always wipe and dry the mattress before putting it back into service, even if the chemical manufacturer states that its cleaning agent does not need to be rinsed
- ▶ Ensure that disinfectants are selected and used only by qualified professionals in Hygiene

General Guidance

- ▶ Do not use any strong acids or alkalines, (optimum pH range 6 – 8. Do not exceed pH of 9). Some hard surface cleaners have pH values outside this range, these are not suitable for use on coated textiles.
- ▶ Only use detergents that are suitable for cleaning medical equipment and for use on coated textiles.
- ▶ Do not use abrasive powders, steel wool, or other material and cleaning agents that might damage the mattress. Do not scrub mattress surface.
- ▶ Never use any corrosive or caustic detergents.
- ▶ Never use detergents that deposit calcium carbonate.
- ▶ Never use detergents with solvents that might affect the structure and consistency of the plastics (benzene, toluene, acetone, phenol, etc.).
- ▶ Use only hospital-approved cleaners and observe local directives concerning infection control.
- ▶ Always rinse with a cloth soaked in clean water after cleaning and dry thoroughly before use.

Mattress parts to be cleaned	Recommended Cleaning Agents (General cleaning)
Top Cover	For general cleaning and superficial dirt, use a disposable wipe with a solution of warm water and neutral detergent. Do not use abrasive or phenolic-based cleaners. Cleaning by neutral water and soap, followed by rinsing with water, is sufficient to clean this product. Solvent containing alcohol, bleaching or abrasive products can be harmful.
	Decontamination: Blood spills/Clostridium difficile etc.
	Chlorine based disinfectants containing Chlorine: <ul style="list-style-type: none"> ▶ for routine decontamination, use a concentration of 5 000 ppm chlorine ▶ in case of heavy contamination, a concentration of up to 10 000 ppm chlorine can be used Dwell time on surface at 10 000 ppm of 2 minutes, followed by wiping with a wet cloth and thorough drying before use. PU coated fabrics may feel dry to the touch, but still retain moisture. Wait until the surface is no longer cold to the touch before putting PU coated fabrics back into service.
Inner covers (foam core covers)	In case of soiling of the inner covers, do not use the Vibwife and contact the service department.

As stated above, after application of a suitable cleaner, the surface must be wiped with a cloth soaked in clean water and dried before use (even if the cleaner instructions say that this is not required). This prevents a build up of chemicals on the mattress surface which could be reactivated during use and affect biocompatibility and durability.

NOTE Continued use of high concentration, chlorine-based disinfectants may significantly reduce the performance and the working life of a coated material.

11.1 Recommended manual cleaning and disinfection of the top cover



WARNING!

Risk of infection from the inside of the mattress!

- ▶ Check the top cover of the mattress for any signs of damage. If the top cover is damaged, do not use the Vibwife and contact the service department



CAUTION!

Risk of property damage caused by improper cleaning/disinfection

- ▶ When manipulating the seating part, use only the plastic handles on the sides, do not use the flaps of the top cover.
- ▶ After cleaning, check for damage to the connection cable connector and the connector on the bed frame.

To maintain the life of the mattress, we recommend following these cleaning and disinfection steps. These instructions are also given on the mattress print:


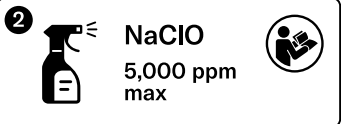

	<p>Step 1. Clean the top and bottom of the mattress with a soft cloth with a solution of universal neutral cleaning detergent</p> <p>NOTE: Before cleaning the bottom of the seat section, first disconnect the connecting cable (1). Insert the cover cap into the connector (2) (see Fig. 30)</p>
	<p>Step 2. Allow the mattress to dry or wipe it dry with a soft cloth</p> <p>Step 3. Disinfect the mattress with sodium hypochlorite solution or the disinfection recommended in chapter "11.2 Recommended chemical concentrations for cleaning the top cover"</p>
	<p>Step 4. Rinse the mattress with a cloth soaked in clean water</p> <p>Step 5. Allow the mattress to dry or wipe it dry with a soft cloth</p> <p>Step 6. Connect the connection cable to the connector on the bed frame (see Fig. 30)</p>



Fig. 30 Disconnecting the connection cable and covering the connector with a cap

11.2 Recommended chemical concentrations for cleaning the top cover



CAUTION!

- Do not use disinfectants with active substance: alcohol over 70 %, active chlorine over 10 000 ppm, iodine, aldehydes and phenols

Active substance	Concentration	pH range	Dwell time	Post application	Recommendations for use
Chlorine and compounds	1 000 - 10 000 ppm	7 - 9	<10 mins Strength and microbial target dependent	Wipe with a wet cloth and dry	Acceptable and recommended 1000ppm is appropriate for day to day cleaning. For routine decontamination, use a concentration of 5 000 ppm chlorine, in case of heavy contamination, a concentration of up to 10 000 ppm chlorine can be used. Must be wiped with a wet cloth and dried with a towel (avoid rough abrasion).
Alcohol	70 %	–	10 mins (max)	Wipe with a wet cloth and dry	Acceptable for use and recommended subject to precautions Coating may swell and be prone to damage. Care must be taken until fully dry (~1hr).
Glutaraldehyde	2 %	7,5 - 8,5	Temperature dependent	Wipe with a wet cloth and dry	Acceptable for use
Ethylene Oxide	3 %	–	>30 mins Temperature dependent	Thoroughly wipe with a wet cloth and dry before use	Acceptable for sterilization only Ensure that appropriate sterilization validation has been completed. Requires cleaning afterwards.
Hydrogen peroxide	3 %	5 - 9	<5 mins	Thoroughly wipe with a wet cloth and dry	Acceptable for use Must be fully rinsed. Highly acidic or alkaline peroxides should be avoided as they will damage the coating.
Quaternary Ammonium Compounds (QAS)	3 - 15 %	7 - 10	Varies Refer to label guidance	Wipe with a wet cloth and dry	Acceptable for use and recommended subject to precautions Some Quaternary Ammonium Compounds are too alkaline. Always check the label first. Quaternary solutions having a pH >10 are not recommended. DO NOT USE QUATs (WIPES) containing sodium hydroxide (NaOH).
Peracetic acid					DO NOT USE
Iodophors					DO NOT USE
Phenolics					DO NOT USE
Steam Sterilization					DO NOT USE
Dry heat					DO NOT USE

11.3 Recommended chemical concentrations for cleaning the inner cover


CAUTION!

- Do not use disinfectants with active substance: alcohol over 30 %, active chlorine over 5 000 ppm, iodine, aldehydes and phenols

Active substance	Concentration
Amine. Alcohol	up to 30 %
Hydrogen Peroxide	3 %
Alcohol	up to 30 %
Glukoprotamine	0,5 %
Amine, QAS	0,5 %
Oxygen, QAS	1 %
Oxygen	1 %
Chlorine and its substances	5 000 ppm

12 Troubleshooting and behaviour of the Vibwife



WARNING!

Risk of injury due to defective mattress system

- Damage and defects found in the product must be reported to the manufacturer immediately. A product that cannot be operated safely (defects and damage have not been rectified) must not be used until it has been repaired.





Non-standard Vibwife behaviour	If Vibwife does not behave as specified, it must be stopped by pressing the STOP  button once (Vibwife slows down and stops in the neutral position, handset remains active) or switched off by pressing the STOP  button twice (immediate stop of movement, the handset is off). If the Vibwife's behaviour does not change after activation, contact the service department
Error shown on the handset display	It is necessary to stop the Vibwife by pressing the STOP  button (Vibwife slows down and stops in the neutral position, handset remains active) or switch off by pressing the STOP  button twice (immediate stop of movement, the handset is off). If the error is still displayed after activating the handset, contact the service department
Disconnecting the plug	When the device is disconnected from the mains during movement, Vibwife stops immediately and self-locking brakes ensure that the device does not move any more
Non-functioning handset	<ul style="list-style-type: none"> • Check the connection of the Vibwife to the mains (<i>Fig. 31</i>) • Check the connection of the handset (<i>Fig. 32</i>) • Check the connection of the Vibwife to the adapter (<i>Fig. 33</i>) <p>If the handset still does not work, contact the service department</p>
Damaged outer cover	Contact the service department



Fig. 31 Vibwife mains cable



Fig. 32 Handset connection



Fig. 33 Adapter connection

13 Maintenance



WARNING!

There is a risk of injury when working on the Vibwife!

- ▶ Make sure the Vibwife is disconnected from the mains before installation, servicing, maintenance and dismantling



WARNING!

Risk of injury due to defective Vibwife!

- ▶ Have the defective Vibwife repaired immediately
- ▶ If the fault cannot be repaired, do not use the Vibwife



CAUTION!

Risk of property damage due to improper maintenance!

- ▶ Ensure that maintenance is carried out exclusively by the manufacturer's customer service or by authorised service personnel certified by the manufacturer
- ▶ If the fault cannot be repaired, do not use the Vibwife

13.1 Regular maintenance

- ▶ Regularly carry out a visual inspection of the product
- ▶ If any parts of the product are missing, ask the manufacturer's service department to supply original spare parts
- ▶ Request original spare parts to replace any damaged parts of the product from the manufacturer's service department
- ▶ Check the mattress externally for signs of mechanical damage or heavy wear
- ▶ Check that the mattress functions properly

13.2 Spare parts

The serial label of the Vibwife device is located on the inner seat cover. The serial label contains information for claims and ordering spare parts.

Information about spare parts is available from:

- ☐ Manufacturer's customer service
- ☐ Sales department

13.3 Safety Technical Checks



WARNING!

Risk of injury due to incorrect safety technical checks!

- ▶ Ensure that safety technical checks are performed exclusively by manufacturer's customer service or by authorised service personnel certified by the manufacturer
- ▶ Ensure that the safety technical checks are recorded in the service and maintenance log

-
- ▶ **Safety technical inspections of the Vibwife must be carried out at least once every 12 months or every 1 825 hours, whichever comes first**
 - ▶ The procedure for carrying out safety technical checks is set out in EN 62353:2014
-

NOTE Upon request, the manufacturer shall provide service documentation (e.g. electrical circuit diagrams, parts and component lists, descriptions, calibration instructions, etc.) to service personnel for the purpose of repairing medical electrical equipment that the manufacturer indicates may be repaired by service personnel

14 Disposal

14.1 Environment Protection

The company LINET® is aware of the importance of environmental protection for future generations. Within this company the environmental management system is applied in accordance with the internationally agreed standard ISO 14001. The compliance with this standard is annually tested by the external audit executed by an authorised company. Based on the **WEEE** - Waste, Electric and Electronic Equipments Directive the company L I N E T spol. s r. o. is registered in the List of Electric and Electronic Equipment Producers (**Seznam výrobců elektrozařízení**) on the Ministry of the Environment of the Czech Republic (Ministerstvo životního prostředí).

Materials used in this product are not environmentally hazardous. LINET® products meet valid requirements of national and European legislation in the areas of **RoHS** and **REACH**, so they do not contain any prohibited substances in excess quantities.

None of the wooden parts is made of tropical wood (such as mahogany, rosewood, ebony, teak etc.) or made of timber from the Amazon region or from similar rainforests. Product noise (sound pressure level) meets requirements of the regulations for the protection of public health against undesirable effects of noise and vibration in protected interior spaces of buildings. Used packaging materials are in accordance with requirements of the Packaging Act (**Zákon o obalech**).

For disposal of packaging materials after installation of products contact your sales representative or manufacturer's customer service about the possibility of a free take-back of packaging through an authorized company (more details on www.linnet.cz)

14.2 Disposal

Materials used in this product burden the environment but at the same time the whole range of these materials can be very effectively reused and recycled. Mechanical disassembly of the product and material sorting into the basic waste types (plastic, metal, wooden materials) should be performed after the end of product life.

The main objective of the obligations arising from the European Directive on Waste, Electric and Electronic Equipments is to increase the re-use, material recovery and recovery of electric and electronic equipment at the required level, thereby avoiding the production of waste and thereby avoiding the possible harmful effects of hazardous substances contained in electric and electronic equipment on human health and the environment. LINET® electric and electronic equipments that have a built-in battery or accumulator are designed so that the used batteries or accumulators can be safely removed by LINET® qualified service technicians. There is an information about its type on the built-in battery or accumulator.

14.2.1 Within Europe

To dispose of the electric and electronic equipment:

- ▶ The electric and electronic equipment must not be disposed of as household waste
- ▶ Dispose of this equipment at designated collection points or take-back points
- ▶ Dispose of the product or its components in accordance with local laws and regulations!
- ▶ Hire an approved waste disposal company for disposal!

To dispose of the other equipment:

- ▶ The equipment must not be disposed of as household waste
- ▶ Dispose of this equipment at designated collection points or take-back points

LINET® participates in a collective system with take-back company REMA System (see www.remasystem.cz/sberna-mista/). By bringing electric and electronic equipment to a take-back point, you participate in recycling and you save primary raw material resources while protecting your environment from effects of unprofessional disposal.

14.2.2 Outside Europe

- ▶ Dispose of the product or its components in accordance with local laws and regulations!
- ▶ Hire an approved waste disposal company for disposal!

15 Warranty

L I N E T spol. s r.o. will only be held responsible for the safety and reliability of products that are regularly serviced, maintained and used in accordance with the safety guidelines

Should a serious defect arise that cannot be repaired during maintenance:

- ▶ Do not use the Vibwife anymore

The warranty on this product and its conditions depend on the agreement between the buyer and the seller, in addition to the legal minimum guarantee provided by law.

The warranty covers all material and manufacturing-related failures and errors. Failures and errors caused by incorrect use and external effects are not covered. Justified complaints will be fixed free of charge during the warranty period. Proof of purchase, with the date of purchase, is required for all warranty service.

16 Standards and Regulations

Applied norms are stated on Declaration of Conformity.

The manufacturer adheres to a certified quality management system in compliance with the following standards:

- ☐ ISO 9001
- ☐ ISO 14001
- ☐ ISO 13485
- ☐ MDSAP (Medical Device Single Audit Program)