SWISS MED TECH

Vibra™ 3.0 A DIFFERENT VIBE

SELECTIVE

VIBRATION MEDICAL DEVICE

Use, installation and maintenance manual

SWISS MADE

CE 0476

GENERAL INTRODUCTION

VIBRA™ 3.0 is an innovative medical device that delivers selective square-wave mechanical-sound vibrations simultaneously on multiple outputs for the treatment of muscular and neuromuscular disorders in specific fields of medicine.

The vibratory function applied to individual muscles has been shown to exert direct, targeted action on selected nerve networks, which play a primary role in controlling and coordinating all our movements. Vibration is a sequence of mechanical signals of extremely low amplitude, which are read by specific nerve sensors located in the muscles and sent to the central nervous system.

What appears to be a small mechanical vibration is in fact a code capable of reprogramming selected areas of the nervous system pertaining to the hundreds of nerve sensors located in the muscles. These 'read' the vibrations and send them to the nerve centers that control the treated muscle. The central nervous system therefore improves the control and coordination of the bands of muscle. The stimulus imparted to the muscle depends on both the frequency and power of the vibration, and hence also on the pressure, in mbar, exerted on the muscle.

In fact the vibration proved capable of generating positive effects in a very wide range of situations, and the high level of construction technology of VIBRA™ 3.0 and the innovative accessories with which it is equipped make it possible to provide treatments with a hitherto unattainable degree of accuracy.

- in neurology;
- in orthopedics/physiotherapy/physiatrics;
- in geriatrics;
- in sports medicine;
- in aesthetic medicine.

Use of the manual: this manual is designed to ensure safety and high standards of performance. Do not use the device before reading this manual and attending the compulsory training course.

The manufacturer accepts no responsibility attributable to improper use of the device. To ensure correct use of VIBRA™ 3.0, we therefore recommend that you read this user manual carefully, as it sets out the technical specifications of the device and the procedures for its use. In particular, before carrying out any operation, it is imperative to read the safety section carefully.

Operational personnel must have a perfect understanding of the correct use of the device.

Maintenance: VIBRA™ 3.0 is a precision device requiring regular maintenance, which must be performed by qualified and authorized technical personnel.

1 SAFETY

1.1 INTENDED USE OF THE VIBRA™ 3.0 MEDICAL DEVICE

Clinical Applications

VIBRA 3.O is a medical device designed for providing physical therapy aimed at treating muscular and neuromuscular pathologies and disorders within the following fields of medicine:

Physical and Rehabilitative Medicine	Physiatric Medicine	Orthopedic and Traumatological Medicine
Neurological Medicine	Geriatric Medicine	Sports Medicine
Aesthetic Medicine	Pain treatment	Physiotherapy

The main indications are:

- NEUROLOGY: Hemiplegia, Stroke, Neuropathy.

- GERIATRICS: Osteoporosis, Sarcopenia.

- PHYSIATRICS: Anterior Cruciate Ligament Injury (phase I and II), Lumbago (Acute and Chronic);

- ORTHOPEDICS and TRAUMATOLOGY: sprained ankle, rehabilitation of the shoulder, patellofemoral pain syndrome, arthrosis of the knee/hip

- TRAINING Performance, prevention, preventive treatments (treatments NOT covered by CE marking with Notified Body because non-therapeutic)
-PAIN: Myofascial

- AESTHETIC MEDICINE: postpartum support treatments (treatments NOT covered by CE marking with Notified Body because non-therapeutic).
Depending on the status of the pathology/problem diagnosed, you can refer to the treatment table shown in figure 1.1 for the status/operating frequency combination.

FREQUENCIES AND OPERATING PHASES				
300				☑
200	☑	☑		
150		☑	☑	☑
100	☑			
80	☑	☑	☑	☑
50	☑	☑	☑	☑
Hz	**ACUTE PHASE**	**SUB-ACUTE PHASE**	**RECOVERY PHASE**	**SPORT PHASE**

Table 1.1

Place of use

The device is designed for use in public or private facilities for rehabilitation, recovery and sports activities

- Public or private hospitals;
- Public or private rehabilitation centers;
- Sports centers with rooms intended for medical use.

1.2 TECHNICAL WARNINGS AND IMPROPER USE

Despite the fact that the system has been designed and manufactured in accordance with the applicable safety regulations, only correct and careful use can ensure full safety. This manual therefore sets out the various precautions to take when using the machine.

1.3 CONTRAINDICATIONS AND APPLICATION WARNINGS

SAFETY PRECAUTIONS

Treatment carried out with VIBRA™ 3.0 does not require the active collaboration of the patient, and is intended for both male and female patients, of all ages and states of health, with the exception of patients whose pathologies meet the criteria for exclusion or are included in the list of contraindications set out below.
This manual describes applications that have already been validated by medical-scientific research. Other applications which are currently being studied at scientific research institutes and universities will be divulged to practitioners as soon as they are validated.

Treatment with VIBRA™ 3.0 is contraindicated in the following cases:

- Neoplasms;
- Obliterative arterial disease;
- Recent muscle injuries in the vicinity of the areas to be treated;
- Infectious diseases of the bones or tendons;
- Acute colitis (applications on abdominal muscles);
- active dysmenorrhea (applications on abdominal muscles);
- Thrombophlebitis or acute varicophlebitis;
- Individual intolerance.

You are advised NOT to apply VIBRA™ 3.0 in the vicinity of the:

- lymph node areas
- apex cordis or diaphragmatic insertions;
- abdominal muscles during the menstrual cycle.

1.4 VIBRA™ 3.0 TECHNICAL DATA SHEET

Environmental operating conditions	TEMPERATURE: 10 ÷ 30°C RELATIVE HUMIDITY: 30 ÷ 70% Atmospheric pressure: 70 ÷ 106 kPa		
Storage and transport conditions	TEMPERATURE: 10 ÷ 50 °C RELATIVE HUMIDITY: 10 - 95% INCLUDING CONDENSATION Atmospheric pressure: 50 ÷ 106 kPa		
Emission type	selective square-wave mechanical-sound vibrations on multiple outputs simultaneously. Flow modulation technology with separate Zero Air Leak (Z.A.L) chambers.		
Available frequencies	30÷900 Hz	**Pressure intensity**	> 600 mbar pp
Dimensions	40 x 40 x 115 cm	**Weight**	50 kg
No. of Outputs	14 extendable to 28 + 1 for the manual transducer		
Type of outputs	on the rear panel, fixing connectors with ***spring-type release system***		
Transducers	with variable-geometry dome-shaped cup, incorporating applied part made of medical rubber and quick coupling for hoses. Qty. 8 per type (large, medium, small, ultra-small): TOT Qty. 32		
Manual transducer	Always operational with a compact, ergonomic profile - dedicated output with Hybrid Push Pull connector - controls replicated on the handpiece for start/stop treatment + pressure intensity increase/decrease - easily interchangeable tips of different shapes and sizes		
Cooling	forced-air ventilation by means of two side fans tilted towards the front.		
User interface	10.1" graphical display with bright, ultra-fast touchscreen predisposed for Wi-Fi connection (monitoring and upgrade) Also available: native guidelines, area for designing new multiphase protocols, transducer positioning guide, patient database and media kit area with in-depth guidance and tutorial		
Controls	system with independent dual microprocessor control for the precision and stability of **emission frequency**		
Accessories port	Logo duffle. Dim. 50 x 30 36 cm.		
Wheels	chromed twin wheels, with brakes at the front		
Power cable	L=2 meters with V-Lock fixing system	**Functional earth cable**	L= 2m with Europlug
Casing	Custom, gloss white ABS exterior and aluminum internal structure		
Mains voltage	230 Vac – 50/60 Hz	**Input power**	< 1200 VA
Fuse	2x8A time-lag 250V 5x20	**Electric Class**	Class I
MDD Classification	Class IIa Medical Device BF type applied parts		

Table 1.2

1.5 SAFETY PRECAUTIONS

SAFETY PRECAUTIONS

THE SAFETY OF THE DEVICE IS GUARANTEED ONLY IF IT IS USED APPROPRIATELY AND IN STRICT ACCORDANCE WITH THE INSTRUCTIONS SET OUT IN THIS MANUAL. IT IS THEREFORE IMPERATIVE TO READ THE ENTIRE MANUAL CAREFULLY, AND KEEP IT FOR FUTURE REFERENCE IN A PLACE THAT IS READILY ACCESSIBLE TO ALL OPERATORS WITH REDUCED PHYSICAL, SENSORY OR MENTAL CAPACITY, OR INSUFFICIENT EXPERIENCE AND KNOWLEDGE, UNLESS THEY HAVE BEEN TRAINED IN THE USE OF THE DEVICE BY AUTHORIZED TECHNICAL PERSONNEL.

IN ADDITION TO THE ESSENTIAL SAFETY PRECAUTIONS FOR THE USE OF AN ELECTRICAL DEVICE, THE FOLLOWING PRECAUTIONS MUST ALSO BE TAKEN

- **READ ALL INSTRUCTIONS**
- BEFORE CONNECTING THE DEVICES TO THE MAINS POWER SUPPLY, MAKE SURE THAT THE MAINS VOLTAGE IS AS SPECIFIED FOR THE DEVICE.
- THE DEVICE MUST BE INSTALLED IN AN APPROPRIATE LOCATION EQUIPPED WITH AN ELECTRICAL SYSTEM IN COMPLIANCE WITH THE APPLICABLE LAWS AND REGULATIONS AND CAPABLE OF SUPPLYING SINGLE-PHASE ALTERNATING CURRENT AND THE CURRENT SPECIFIED ON THE DATA PLATE AND IN THE TECHNICAL SPECIFICATIONS.
- MAKE SURE THE MAINS POWER SOCKET IS EQUIPPED WITH AN ADEQUATE AND EFFICIENT EARTH CONNECTION.
- DO NOT USE POWER CABLES OTHER THAN THE ONE SUPPLIED BY THE MANUFACTURER.
- AVOID USING EXTENSION CABLES FOR THE POWER CABLE AND/OR ADAPTERS FOR POWER SOCKETS.
- NEVER PULL THE POWER CABLES TO MOVE THE DEVICE OR TO REMOVE THE PLUG FROM THE SOCKET.
- ALWAYS SWITCH THE DEVICE OFF BEFORE INSERTING OR REMOVING THE POWER CABLE FROM THE DEVICE**.**
- THE POWER CABLE MUST BE DISCONNECTED IF THE DEVICE IS LEFT UNUSED FOR LONG PERIODS.
- CARRY OUT CLEANING OPERATIONS AS RECOMMENDED IN THE ROUTINE MAINTENANCE CHAPTER OF THIS MANUAL.
- ALL CLEANING AND MAINTENANCE OPERATIONS MUST BE CARRIED OUT WITH THE DEVICE DISCONNECTED FROM THE MAINS POWER SUPPLY.
- DO NOT INSTALL OR USE THE DEVICE NEAR ANY SOURCE OF WATER OR IN ANY CONDITIONS OTHER THAN THOSE DESCRIBED IN THE TECHNICAL DATA SHEET FOR THE DEVICE.
- DO NOT HANDLE CLEANING FLUIDS ABOVE THE DEVICE, AND IN THE EVENT OF SPILLAGE OF EVEN MINIMAL QUANTITIES OF LIQUID ON IT, SUSPEND USE IMMEDIATELY AND GET THE DEVICE FULLY CHECKED.
- DO NOT OPEN THE DEVICE (POINTS IN IT ARE SUBJECT TO DANGEROUS ELECTRIC POTENTIAL).
- DO NOT POSITION THE DEVICE IN DIRECT SUNLIGHT OR AT A DISTANCE OF LESS THAN 2 METERS FROM HEAT SOURCES.
- DO NOT USE THE DEVICE IF THE COVERS OR PANELS ARE NOT CORRECTLY FITTED.
- DO NOT USE THE DEVICE IF THE POWER CABLE SHOWS SIGNS OF WEAR OR AGING.
- DO NOT COVER THE SIDE AIR VENTS.
- USE ONLY THE ACCESSORIES SUPPLIED WITH THE DEVICE AND INDICATED IN THIS MANUAL.
- THE DEVICE AND ACCOMPANYING ACCESSORIES ARE SUPPLIED IN NON-STERILE FORM. IT IS THEREFORE NECESSARY TO CLEAN AND SANITIZE THE EQUIPMENT, WITH PARTICULAR REFERENCE TO THE PARTS APPLIED TO THE PATIENT, AS SPECIFIED IN THE APPROPRIATE SECTION OF THIS MANUAL.
- DO NOT TILT DEVICE BY MORE THAN 10°.
- DO NOT PUSH THE DEVICE AGAINST A STEP HIGHER THAN 1 CM.
- DO NOT CARRY THE DEVICE ON STAIRS WITHOUT OBSERVING THE PROCEDURES GIVEN IN THE INSTRUCTION MANUAL.

- THE HANDLE MUST ONLY BE USED FOR PUSHING THE DEVICE: DO NOT USE IT TO LIFT THE DEVICE OR AS SUPPORT.
- DO NOT BRING YOUR FACE (ESPECIALLY YOUR EYES) NEAR THE AIR OUTLET FROM THE PNEUMATIC HOSES DURING OPERATION OF THE DEVICE.
- THE DEVICE IS DESIGNED NOT TO BECOME DANGEROUS AS A RESULT OF ELECTROMAGNETIC INTERFERENCE FROM THE SURROUNDING ENVIRONMENT (LIMITED TO ENVIRONMENTS THAT ARE COMPATIBLE WITH THE INTENDED USE). IN PARTICULAR, TEMPORARY INTERRUPTION OF THE FUNCTIONS IS TOLERATED AND CAN BE RESET BY AN OPERATOR INPUT.
- THE DEVICE IS EQUIPPED WITH ACCESSORIES THAT COULD CAUSE STRANGULATION DUE TO CABLES AND HOSES OF EXCESSIVE LENGTH.
- THE DEVICE IS EQUIPPED WITH SMALL PARTS THAT COULD BE SWALLOWED.
- THE APPLIED PARTS ARE MADE OF BIOCOMPATIBLE MEDICAL MATERIAL. THERE ARE NO KNOWN ALLERGIC REACTIONS TO THE ACCESSIBLE MATERIALS USED IN THE MEDICAL DEVICE.
- THE APPLIED PARTS HAVE NO ROUGH AREAS OR SHARP EDGES THAT COULD CAUSE INJURY OF ANY KIND.
- DO NOT MODIFY THE MEDICAL DEVICE: NON-COMPLIANCE WITH THIS REQUIREMENT COULD COMPROMISE THE SAFETY OF THE DEVICE OR CAUSE IT TO MALFUNCTION.

WARNINGS relating to the electromagnetic immunity of the device

The DP001 Vibra 3.0 medical device is suitable for use in all professional environments suitable for medical use.

The deterioration of the display quality on the screen without effects on the operation and treatment of the patient and the temporary interruption of the therapy, if and only if this is automatically restored without the intervention of the operator, are the only permitted degradations.

The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this equipment could lead to greater electromagnetic emissions or a decrease in the electromagnetic immunity level of this equipment, resulting in incorrect operation.

Transportable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no less than 30 cm (12 inches) away from any part of the DP001 Vibra 3.0 device, including cables specified by the manufacturer. Otherwise, performance degradation of this unit may occur.

The use of this device near or placed on other devices should be avoided, as this can lead to incorrect operation. In these cases it is necessary that the appliance and other equipment are kept under observation to verify their normal operation.

NOTE The EMISSION characteristics of this device make it suitable for use in industrial and hospital environments (class A of CISPR 11). If used in residential environments (for which class B of CISPR 11 is normally required) this equipment may not offer adequate protection for radio frequency communication services. The user may have to apply noise mitigation measures, such as relocation or reorientation of the equipment.

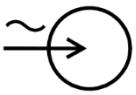
- THE DISTRIBUTOR AND MANUFACTURER ACCEPT RESPONSIBILITY FOR THE SAFETY OF THE PRODUCT ONLY IF:
  - REPAIRS AND MODIFICATIONS
    ARE CARRIED OUT BY PERSONS EXPRESSLY AUTHORIZED BY THEM, AND IF:
  - THE DEVICE IS USED BY QUALIFIED AND AUTHORIZED PERSONNEL IN ACCORDANCE WITH THE INSTRUCTIONS FOR USE.
  - THE ELECTRICAL SYSTEM TO WHICH THE DEVICE IS CONNECTED IS COMPLIANT WITH THE APPLICABLE REGULATIONS.

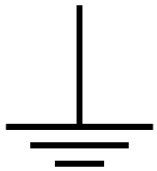
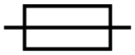
CAUTION

The manufacturer and distributor accept no responsibility for incorrect use of the medical device.

1.6 DATA PLATE LABEL

The system is equipped with a data plate showing the nominal operating values, identification data and general specifications of the device. The table below shows all the labels affixed to the device:

	Indicates the medical device manufacturer.
	Indicates the references of the authorized representative in the European Community Do Well Technologies di Bucci Claudia, located in Italy, in the person of Mrs. Claudia Bucci Company Address: 301a, Cenacchio Str., IT-40018 San Pietro in Casale (BO), Fiscal Code: BCCCLD80C61D077W Vat Number 03527881209 Email address: info@dowelltechnologies.it Mob. +39 348 77 01 021
	Indicates the manufacturer's catalogue number, so that the medical device can be identified.
	Indicates the manufacturer's serial number, so that a specific medical device can be identified
	Indicates the date when the medical device was manufactured.
	To indicate an a.c. rated power input to the medical device (Ref. IEC 60417-6045).
	Warning symbol: please pay particular attention to information marked with this symbol UNI EN ISO 15223-1
	Dispose of electronic waste separately
	*BF TYPE APPLIED PARTS*

	*The device is equipped with a functional earth connection (IEC symbol 60417-5017)*
	**Operating instructions: indicates that you must carefully read the documentation supplied with the device**
	**Identifies the fuses in the medical device.**
	**CE Marking: indicates that the device is certified according to European Directive 93/42/EEC and subsequent amendments by the Notified Body Kiwa CERMET Italia S.p.a. N° 0476**
	**ESD - electrostatic discharge graphic warning symbol (IEC 60417-5134 (2003-04))** **WARNING: The pins of the USB connector must NOT be touched**

2 CONNECTIONS AND INSTALLATION

2.1 TRANSPORT AND UNPACKING

VIBRA™ 3.0 is transported in wooden crates with stabilizer fastenings. At the final distribution center, the packaging is modified according to the most appropriate solution for the delivery to be made. VIBRA™ 3.0 is delivered to the user in easily removable, open-faced packaging. After unpacking, carry out a thorough inspection to ensure that the device and accessories are undamaged. Should you find any damage, notify your dealer immediately. Check the various parts in the package against the packing list, to ensure that no parts are missing.

In extreme weather conditions (heat, cold, humidity), you are advised to wait a few hours between removing the device from its packing and switching it on for the first time. This precaution helps eliminate any condensation that may have formed inside the packaging.

2.2 DISPOSAL

At the end of its useful life, the device, including its removable parts and accessories, must not be disposed of with ordinary household waste but in accordance with European Directive 2012/19/EEC.
Since it must be processed separately from household waste, the device must be taken to a differentiated waste disposal center for electrical and electronic equipment or returned to the dealer upon purchase of an equivalent new device. Severe penalties are applicable in the event of non-compliance.

3 CONNECTIONS AND INSTALLATION

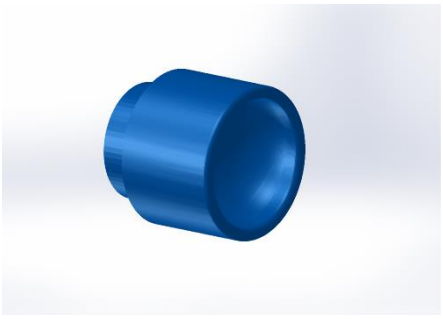
3.1 CONTENTS OF THE SALES UNIT

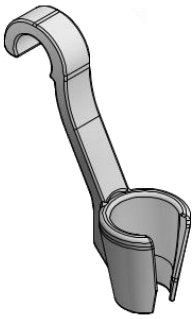
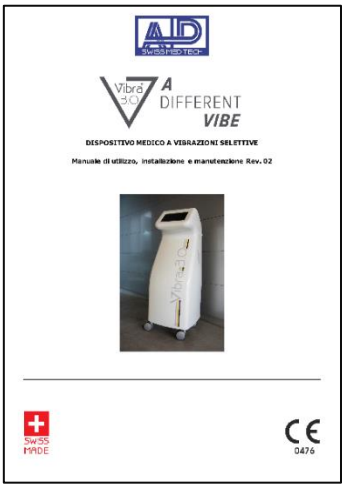
The device consists of:

- a central unit
- the accessories for its use and their bag

The table below provides an itemized list of the contents of the sales unit with the necessary codes for reordering parts.

Qty.	DESCRIPTION	CODE	IMAGE
1	Accessory case	VA000005	
8	Dome-shaped transducer, large	CAL00001	
8	Dome-shaped transducer, medium	CAL00002	
8	Dome-shaped transducer, small	CAL00003	
8	Dome-shaped transducer, ultra-small	CAL00004	
2	Ultra-flat transducers, large	CAL00005	
2	Ultra-flat transducers, small	CAL0006	
1	KIT of 20 elastic bands h 10 cm - Qty. 10 L=60 cm - Qty. 10 L=80 cm	FEAD1060 FEAD1080	
5	Y-fitting	RI000009	

5	T-fitting	RI000010	
7	Custom hoses made of flexible polyether polyurethane with low radius of curvature. L=180cm. With fitting. Col. gray	TUPP0GR5-180	
7	Custom hoses made of flexible polyether polyurethane with low radius of curvature. L=180cm. With fitting. Col. neutral	TUPP0NT5-180	
14	Custom hoses made of flexible polyether polyurethane with low radius of curvature. L=20 cm. Col. Gray	TUPP0GR5-20	
14	Custom hoses made of flexible polyether polyurethane with low radius of curvature. L=20 cm. Col. neutral	TUPP0NT5-20	
1	Manual transducer with integrated keypad, hose and dedicated connector	DM001 15	
1	Cylindrical tip for manual transducer h 17 mm	DM001 28	
1	Conical tip for manual transducer	DM001 20	

1	Extension tip for manual transducer L=100 mm (optional)	DM001 29	
1	Spoon tip for extension (optional)	DM001 55	
1	Holder for manual transducer	DM001 56	
1	Power cable with Europlug and V-Lock fixing system. L02 mt	PCH05001	
1	Functional earth cable with Europlug	CTF00001	
1	Use and maintenance manual	MUM00001	

3.2 DESCRIPTION OF THE MAIN UNIT

Figure 3.1

The front panel consists of a 10.1" touchscreen display.

There are air vents on both sides to vent the air from the cooling system.

Above the air vents there are two hose-holder brackets, which can be used for storing the pneumatic hoses when not in use.

Figure 3.2

The back of the device consists of the technical operating panel.

It includes the following parts, from bottom to top:

BOTTOM SECTION

- mains power socket with illuminated switch and display of on-off symbols | / O
- functional earth socket
- data plate with basic technical specifications

MIDDLE SECTION

- 14 quick connectors with ***spring-type release***. (two vertical rows of 7 connectors) with integrated hose-holder system
- 1 socket for manual transducer (air/signals)

TOP SECTION

- USB 2.0 port
- Handle for moving the device

3.3 INSTALLING THE DEVICE

3.3.1 Connecting the mains power cable

Assemble as follows:

- Plug the power cable into the socket on the back of the device and connect it to a mains power socket

  CAUTION: Before connecting the power cable to the mains power socket, make sure the specifications of the electrical system comply with the specifications shown on the device's data plate, and make sure the socket has an earth connection

- Plug the functional earth cable into the socket on the back of the device and connect it to a mains power socket.

3.3.2 Connecting the pneumatic hoses to the device

Each hose is equipped with an in-line terminal which must be inserted fully home into the respective connector on the panel. When the spring clicks, this indicates that the terminal is correctly connected.

To remove the hose, simply press the metal tab on the connector to release the terminal from the connector.

3.3.3 Connecting pneumatic hoses to the dome-shaped and ultra-flat transducers

The dome-shaped and ultra-flat transducers are equipped with a built-in quick connector that facilitates fitting and removal of the hoses.

For correct connection, make sure the pneumatic hoses are inserted fully home.

To remove a pneumatic hose, simply press the ring-nut at the point of entry with two fingers, and remove the hose.

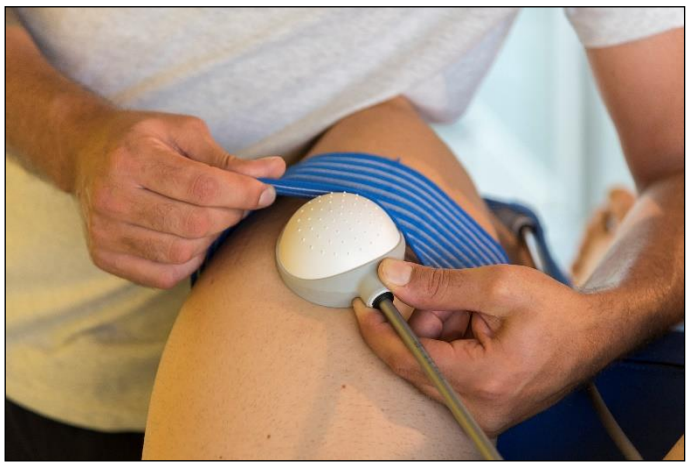


Figure 3.3

3.3.4 Connecting the manual transducer

The manual transducer is equipped with a multi-pole connector for the air and data signals to allow passage of both the vibrations and the commands for the integrated keypad on the handpiece.
The connector is polarized, and can only be connected in one way, by pushing it horizontally into the respective socket on the back of the device. When plugging it in, keep **the arrow facing upwards and DO NOT ROTATE THE CONNECTOR AT ALL.**
To remove it, pull the connector out horizontally, **without rotating it at all.**

Figure 3.4

3.3.5 Locking the wheels

One of the front wheels and one of the rear wheels can be braked.

To engage the brake, press down the tab on the wheel with the tip of your foot until you hear a click, indicating that the wheel is now locked.

To disengage the brake, lift the same tab up with the tip of your foot.

4. OPERATING PROCEDURES

4.1 STARTING THE DEVICE

- Start the device by means of the switch located on the back.
- Connect the necessary pneumatic hoses.
- Instruct your patient to lie down on the bed, then place the transducers on the relevant area of the body. The transducers must be positioned on the muscle belly (POINTS VM) or on the myotendinous junction as per therapeutic indications.

4.2 DESCRIPTION OF CONTROL COMPONENTS

Color touchscreen TFT DISPLAY: shows all the device's operating functions and programs, and makes the VIBRA™ 3.0 extremely simple and intuitive to use.

Immediately after switch-on, VIBRA™ 3.0 displays the welcome screen. Click anywhere on the display to open the main menu.

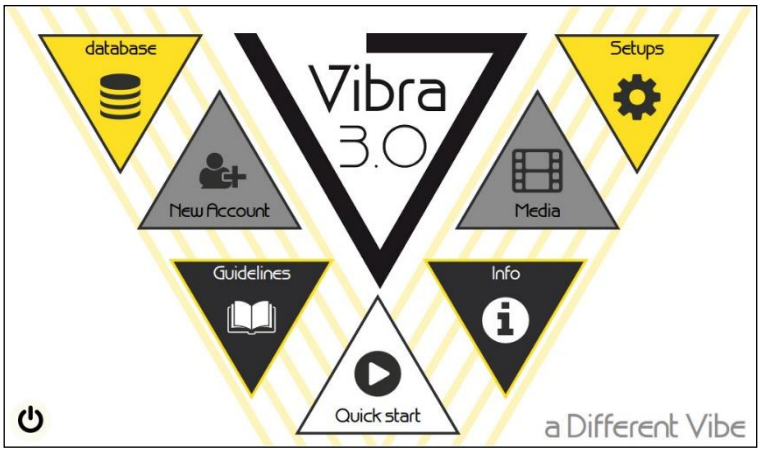


Figure 4.1

The table below shows all the functions of each section:

SCREEN	FUNCTION
DATABASE	Open existing patient files
	Save treatments, including operating parameters and points of application
NEW ACCOUNT	Enter a new patient
	Enter guidelines associated with a new patient
GUIDELINES	Enter new guidelines
	Consult and start existing guidelines
QUICK START	Open and start standard guidelines
CONFIGURATIONS	Change user language
	Open service area

	Activate Wi-Fi connection (if available)
	Check revision date
MEDIA KIT	Consult digital in-depth guidance
INFO	View the contact details of your Technical Support Service

Table 4.1

4.3. QUICK START

From this screen, you can start a treatment directly by selecting one of the 6 available frequency indications:

→ 50 Hz capillarization;

→ 80 Hz decontracting;

→ 100 Hz Neurological;

→ 150 Hz resisting force rehab coordination;

→ 200 Hz pain trigger point;

→ 300 Hz resisting force sport coordination.

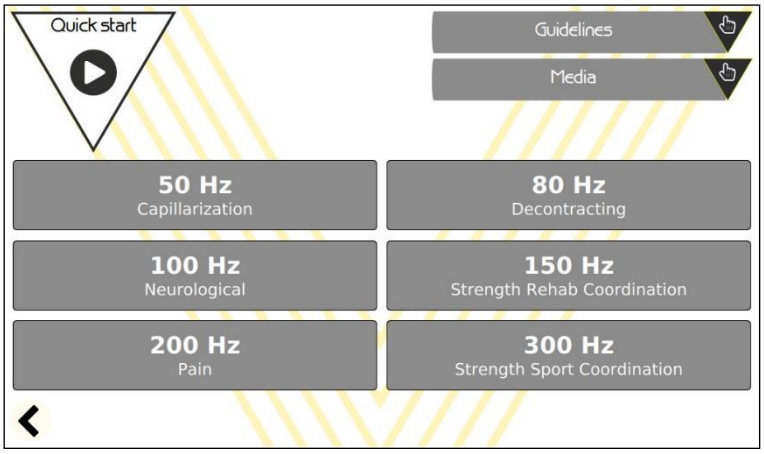


Figure 4.2

Once you have selected the treatment to give, you can view the suggested application points as shown in figure 4.3. In this quick start phase, you cannot save the transducer positions.

FREQUENCIES AND OPERATING PHASES: APPLICATION POINTS		
300	✓	
200		
150	✓	
100		✓
80		✓
50		✓
Hz	**MUSCLE BELLY**	**MYOTENDINOUS JUNCTION**

Figure 4.3

4.4 NEW ACCOUNT

In this menu you can enter new patients and save their treatments.

4.5 GUIDELINES

In this submenu you can manually create a new guideline and then save it, if you wish, for future use.

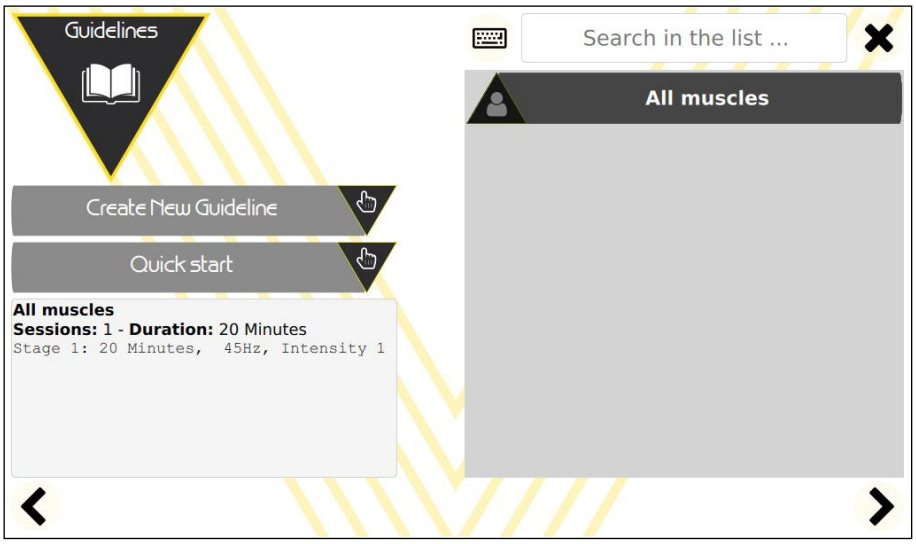


Figure 4.4

From this screen you can:

- change the treatment settings (Duration, Frequency, Pressure Intensity, Pause between two or more phases and Adaptability).
- Add additional phases by clicking "+" to create a new phase or clicking the folder to load an existing guideline. These new phases will also be modifiable and there can be up to 6 phases.
- Define the position of the transducers.
- Save the newly created treatment as a guideline.

POSITIONING THE TRANSDUCERS

Clicking on the area of interest displays the respective enlargement and:

- the points at which it is possible to position the transducers;
- the front/back of the figure;
- the type of transducers available by size;

To insert the transducers, position them on the muscle concerned. To remove the applicator, select the transducer flag.

Figure 4.5

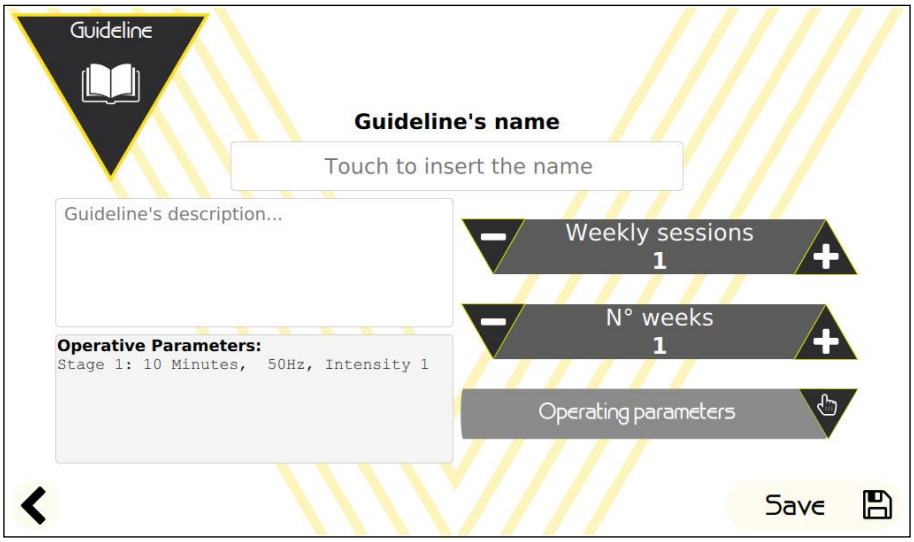


Figure 4.6

Figure 4.7

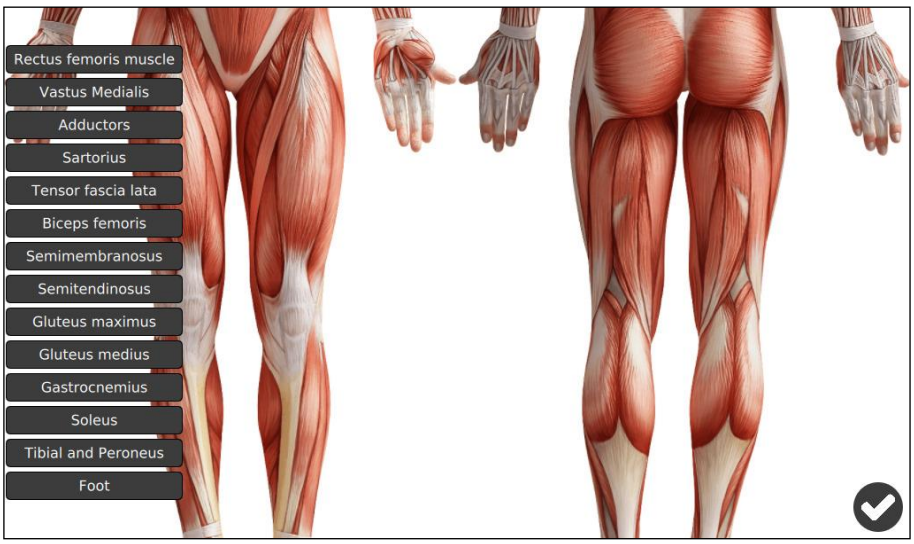


Figure 4.8

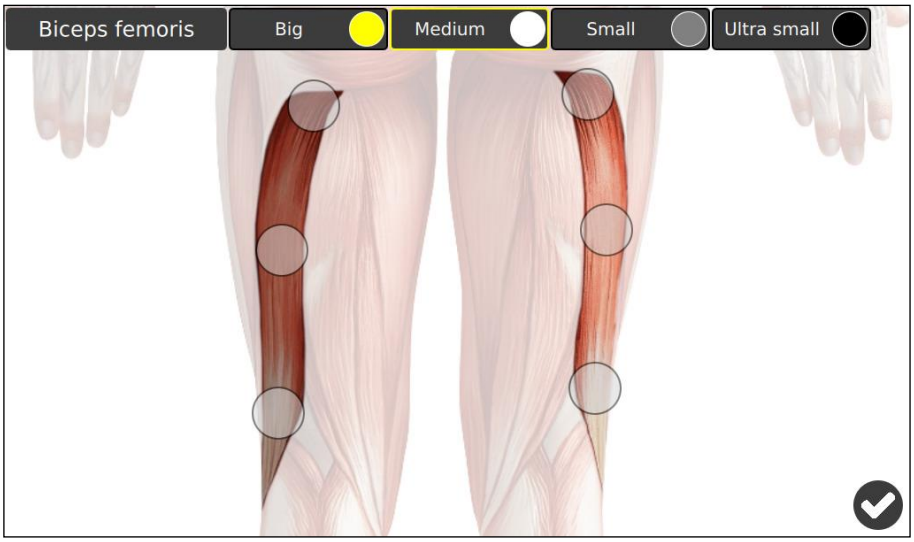


Figure 4.9

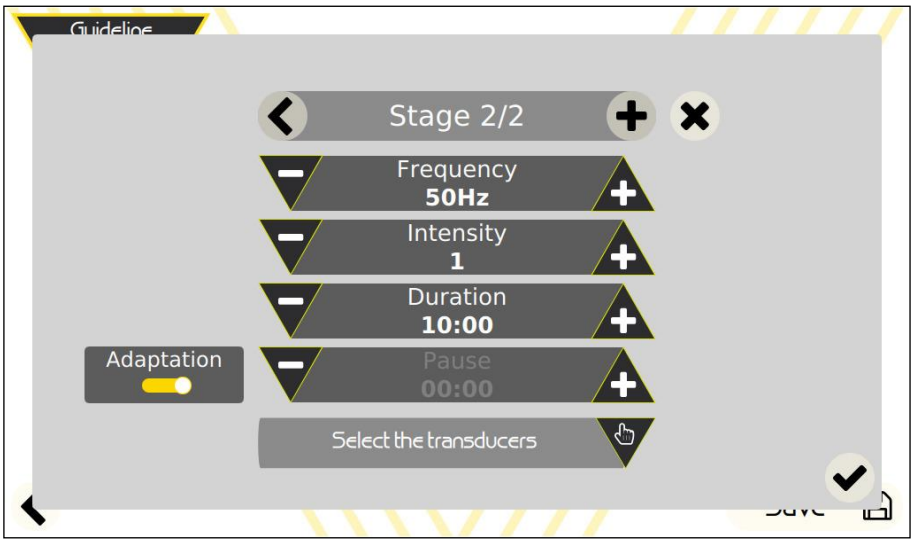


Figure 4.10

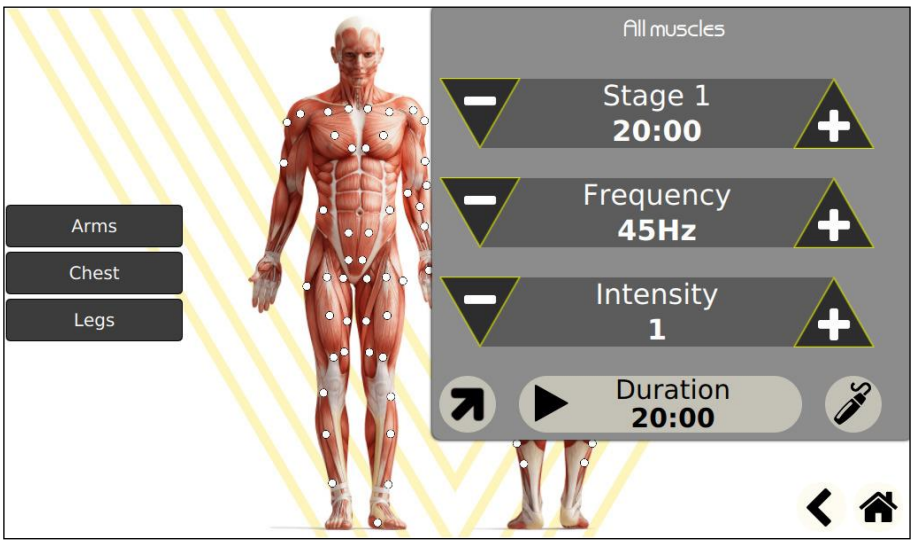


Figure 4.11

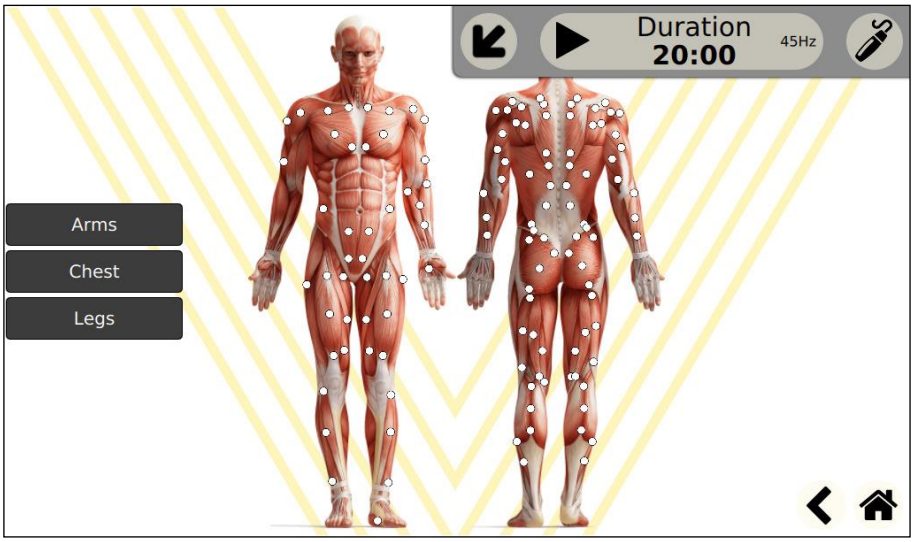


Figure 4.12

TEMPORARY STOPPAGE DURING TREATMENT

If you need to stop the treatment temporarily at any time, click "II" and then click "□" to resume treatment. To stop the treatment definitively, click the "home" icon.

4.6 Using the manual transducer

The manual transducer is equipped with a multi-pole connector for the air and data signals to allow passage of both the vibrations and the commands for the integrated keypad on the handpiece.
The transducer has an integrated keypad for activating and deactivating the treatment and increasing and reducing pressure intensity.

Press  to activate and deactivate the treatment, and press  and  to increase and reduce the pressure intensity respectively.

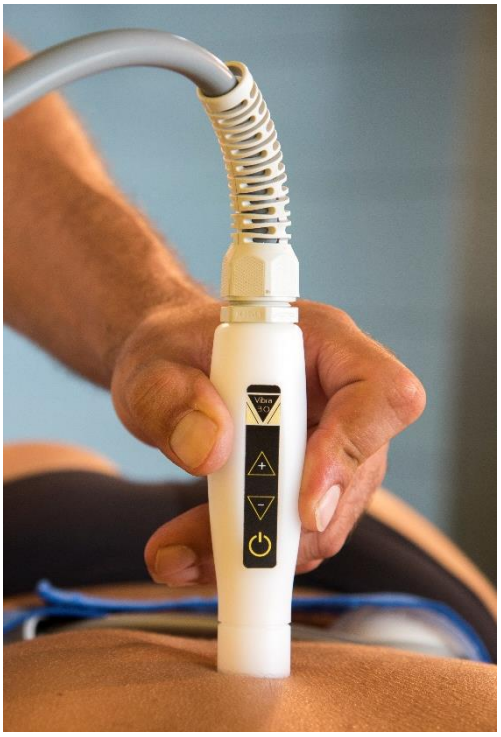


Fig. 4.13

4.7 CONFIGURATIONS

In this section you can configure the main settings

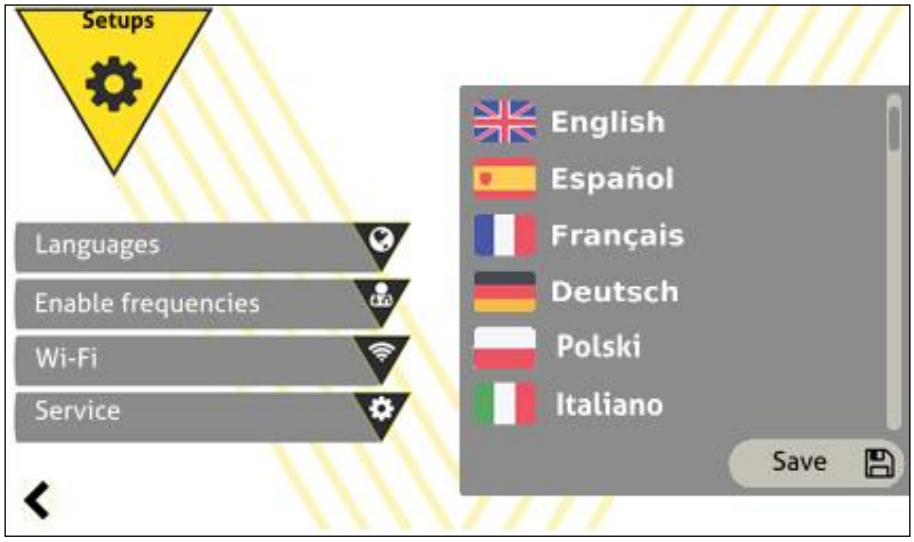


Figure 4.14

4.8 SAFE SHUTDOWN

To shut the device down safely, you are advised to use the software:

go to the "HOME" screen and press and hold the button in the bottom left corner until the screen shown below appears.

Figure 4.15

Press **OK** to continue, and once the screen shown below appears, switch the device off using the switch on the rear panel of the device.

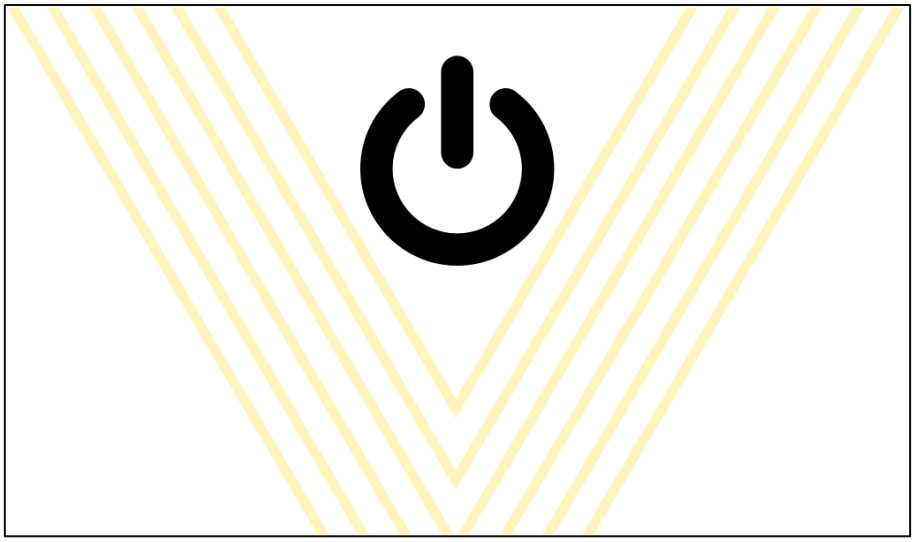


Figure 4.15

5 MAINTENANCE AND SCHEDULED SAFETY CHECKS

THIS SECTION CONCERNS THE MAINTENANCE OF THE DEVICE

READ CAREFULLY

5.1 GENERAL INFORMATION

This section describes the inspections, safety checks and maintenance operations that must be performed by the operator on a routine basis and that fall outside the scope of the normal precautions for use already set down in previous paragraphs. Only those operations that are explicitly specified may be performed by the operator. All others must be carried out exclusively by authorized technical personnel (Technical Support Service). Any unauthorized operation may adversely affect system operation and give rise to dangerous situations.

5.2 SOFTWARE UPDATES

The periodic software updates needed for loading new programs or correcting existing ones in order to keep up to date with the latest technological developments and medical requirements, can only be applied by:

- specialized technicians.
- Yourself after written authorization of the manufacturing or its authorized service.

It is not necessary, however, to withdraw the machine from service for this purpose.

The procedure is facilitated by the use of a USB key which, by means of a confidential code available only to authorized personnel, allows any type of software update to be made very quickly.

5.3 INSPECTION OF APPLIED PARTS

5.3.1 PRELIMINARY CHECKS: tasks to be performed every day

Before the start of each treatment, check that the following are in sound condition:

- **Pneumatic hoses**: check that there are no nicks, cracks or other damage. If appropriate, replace the hoses and order more from your distributor.
- **Dome-shaped transducer:** check that there are no nicks, cracks or other damage. If appropriate, replace the transducer and order more from your distributor.
- **Fixing bands**: check the elasticity of the bands; if they do not ensure correct fixing of the applicator, replace them and order more from your distributor

5.4 SCHEDULED SAFETY CHECKS

Before carrying out any operation, it is good practice to visually inspect the power cable to make sure it is in sound condition.

In particular, check that:

- The cable is in sound condition, i.e. it is free from cuts, surface damage or exposed or twisted conductors;
- The power sockets (both on the VIBRA™ 3.0 side and the electrical system side) are in sound condition, i.e. they are free from any damage, such as nicks, cracks or exposed conductors.

Should the operator detect any fault in the supply system, it is mandatory to refrain from using the VIBRA™ 3.0 system and notify the authorized Technical Support Service immediately.

OUTER CASING

Make sure the outer casing of the device is in sound condition. If it is not, refrain from using the device and contact the Technical Support Service.

HANDLE

make sure the handle is securely connected to the outer casing. If it is not, refrain from using the device and contact the Technical Support Service.

WHEELS

Check that the wheels are screwed in properly by pushing the device along in a straight line, using the handle. Observe the wheels and make sure they follow a straight course. If they do not, refrain from using the device and contact the Technical Support Service.

5.5 ALERT MESSAGES

In the event of a device malfunction for any reason, the system indicates the type of problem so as to speed up diagnosis by the authorized Technical Support Service.

The alert messages that may appear during the use of VIBRA™ 3.0, and the respective solutions, are summarized below:

ALERT	**EXPLANATION AND FIRST SOLUTION**
File not found	File not found in the MD memory, repeat the search or check that the file is located in the Client directory
Patient name already in use	An identical patient name to the one you want to enter is already in use; change the name.
Motor stoppage	The motor that controls the vibration frequency has stopped. Shut down and restart the device. Contact the Technical Support Service if the problem persists.
Service due	Notifies the user that the device needs to be serviced.
Block warning	It warns that the device has reached a useful life of 25,000 operating hours.

5.6 SERVICING

Servicing is carried out every 36 months of use. An alert message indicates when servicing is due.

5.7 Machine lock

Contact authorized assistance to restore the equipment.

5.8 REPLACING FUSES

Before replacing fuses, unplug the device from the mains power supply.

Open the fuse compartment adjacent to the switch and replace with the fuses listed in the device technical specifications table (chap.1)

5.9 CLEANING AND DISINFECTION

CAUTION
Always make sure the device is unplugged from the power supply before carrying out cleaning operations

5.9.1 Cleaning and disinfection of the **dome-shaped transducers**

- **Plastic top side:** treat with a mild disinfectant for surfaces
- **Medical rubber underside: since this part is applied to the** patient, it must be thoroughly cleaned and disinfected after each treatment, using a mild disinfectant for surfaces. You can immerse it in a disinfectant solution taking care not to wet the metal connector above it.

Do not use detergents or disinfectants that contain one or more of the substances listed below:

- aniline
- dimethylformamide
- ethyl acetate
- methylene chloride
- N-methylpyrrolidone
- nitric acid, 20%
- hydrochloric acid, 20%
- sulphuric acid, 20%
- trichloroethylene
- tetrahydrofuran
- toluene

NOTE The ingredients listed in this manual are provided by way of example. The list is not exhaustive.

5.9.2 Cleaning and disinfection of the single transducer and ultra-flat transducers

Clean the external applied part using a cloth moistened slightly with water and non-abrasive neutral liquid detergent or alcohol.

NEVER ALLOW liquids or other products to enter the vibration channel.

5.9.3 Cleaning of the **elastic bands**

The elastic bands can be cleaned with neutral soap and water, including by immersion.

5.9.4 Cleaning the display

The display can be cleaned gently with a dry microfiber cloth.

5.9.5 Cleaning and disinfection of the hoses

The pneumatic hoses can be cleaned with water or mild detergents poured onto a soft damp cloth.
Do not allow any liquid to enter the hoses**.**

5.9.6 Cleaning of the outer casing

The outer casing must be cleaned with water or mild detergents poured onto a soft damp cloth.

Always make sure the device is unplugged from the power supply before carrying out cleaning operations

- Carry out cleaning operations with a soft cloth, either dry or moistened with water or mild detergents dissolved in hot water.

- Do not use volatile agents or unduly aggressive chemicals such as: Acids, Alcohols, Acetones, Solvents in general. Do not expose to direct UV radiation for long periods.

- Make sure no dust or debris has accumulated in the air vents on the sides of the device. If necessary, remove with a soft cloth or vacuum cleaner.

6 TECHNICAL SUPPORT

In the event of a failure or malfunction, contact your nearest dealer.

7 WARRANTY

The manufacturer undertakes to replace free of charge any items manifesting defective materials or workmanship, provided this is proven, for the period defined in the sale documents, and in any case for no less than 12 months from the date of delivery to the end user. The manufacturer shall not, however, bear the shipping costs or accept responsibility for the risks arising from transport. For all other cases, the warranty set down in the general conditions of sale shall apply.

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