REVITIVE®
MEDIC PAIN RELIEF

ULTRASOUND THERAPY

User's Manual

PLEASE READ THE USER'S MANUAL CAREFULLY BEFORE USING THIS PRODUCT

USE ONLY AS DIRECTED
If symptoms persist, consult your healthcare professional

Model number: UT1033

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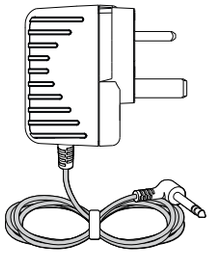
What is inside the box?

On opening the carton, please check that the following components are provided. If you think anything is missing, please contact us using the helpline numbers on the back of this booklet.

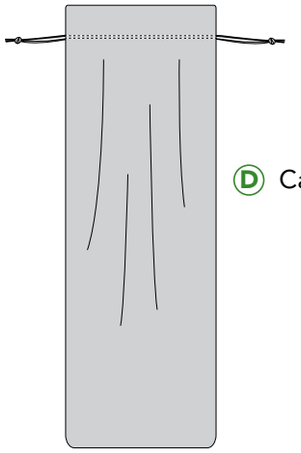
Ⓐ REVITIVE Ultrasound

Ⓑ AC/DC power adaptor

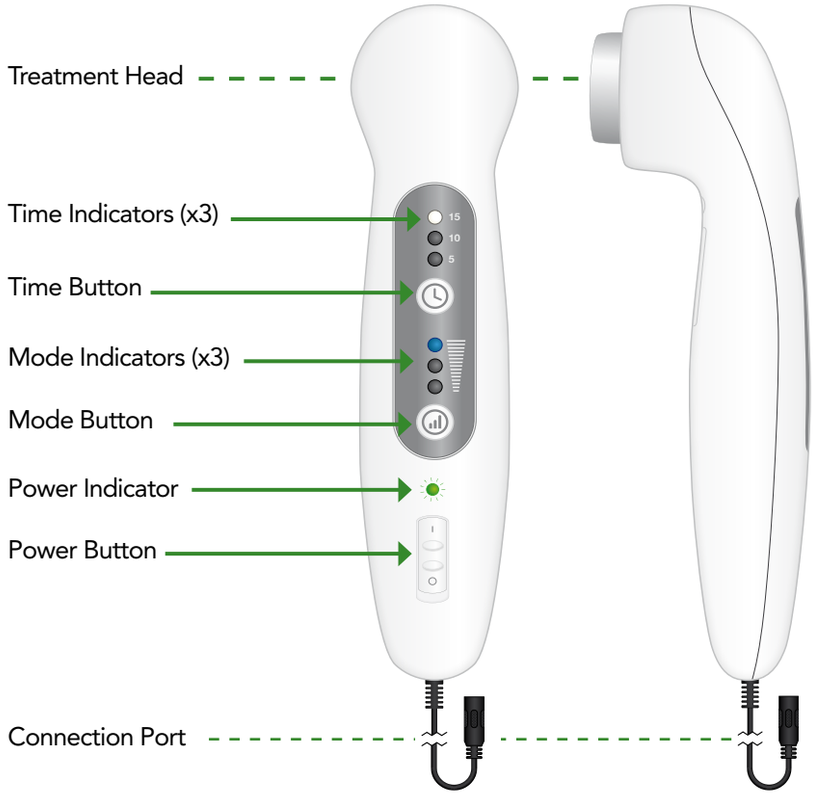


Ⓒ Ultrasound Gel

Ⓓ Carry Case



Parts and Controls



Introduction to REVITIVE

Before operating your REVITIVE Ultrasound device, please read these instructions in full and save this manual for future reference.

INDICATIONS FOR USE

- May help to relieve pain
- May help to aid healing

Suitable for people suffering from muscular injuries, aches, pains and strains. Especially effective on lower back and shoulders.

IMPORTANT SAFEGUARDS

READ ALL INSTRUCTIONS BEFORE USE

CONTRAINDICATIONS

REVITIVE Ultrasound should not be:

- Used for the treatment of malignancy (application over a suspected or confirmed tumour)
- Used on the skin over electronic implants, including pacemakers or defibrillators
- Used on an infected or bleeding area, including tuberculosis
- Used on the skin over vascular (blood vessel) abnormalities (such as haemangioma, capillary, lymphatic, arterial or arterio-venous malformations)
- Used directly on the abdomen or lower back of pregnant women
- Applied directly over active epiphysis regions (growth plates), in the presence of myositis ossificans (bone formed within the muscle) or over the eyes, skull or reproductive organs
- Used over open wounds or fragile or damaged skin eg eczema
- Used on the front of the neck over the carotid sinus
- Used over spinal abnormalities e.g. spina bifida, following laminectomy
- Used over active deep vein thrombosis or thrombophlebitis
- Used on recently irradiated tissue (within 6 months)
- Used on heart, eye, testes, near brain, cervical ganglia, spine, laminectomy sites (can cause spinal cord bleeding).
- Used by individuals who do not comprehend the instructions for application

If you have any doubts about the suitability of REVITIVE Ultrasound, please consult your healthcare professional before using this product

IMPORTANT SAFEGUARDS

WARNINGS & CAUTIONS

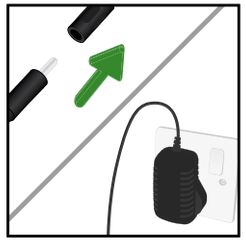
- Clean the Treatment Head completely after use as this will prevent any possible cross-infection to other users
- Keep out of the reach of children
- People with local circulatory insufficiency or bleeding disorder (eg haemophilia) should consult their health care professional before use
- Do not use on de-sensitised (numb, hypoaesthesia) areas of the skin (eg diabetic neuropathy)
- Use caution when treating pain of undiagnosed origin with a history of cancer (within 5 years)
- Use a low intensity setting only over areas containing plastic/ cement implants
- Discontinue use if any signs of inflammation increase (redness, heat, pain, swelling)
- Discontinue use if 'pins and needles' are experienced during treatment and consult your health care professional
- The socket outlet should be installed near the equipment and should be easily accessible
- Use only the accessories supplied by, or purchased from, the manufacturer

SAVE THESE INSTUCTIONS

Instructions for use

HOW TO USE REVITIVE ULTRASOUND

Please read this User's Manual carefully before using this product.

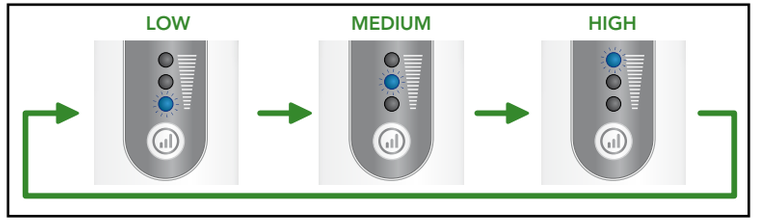


Plug the adaptor to the Connection Port.
Also plug the adaptor into the mains power supply.

Consult the Therapy Application Table to determine the appropriate Mode level and Time duration for the ailment to be treated (see page 12 for details).

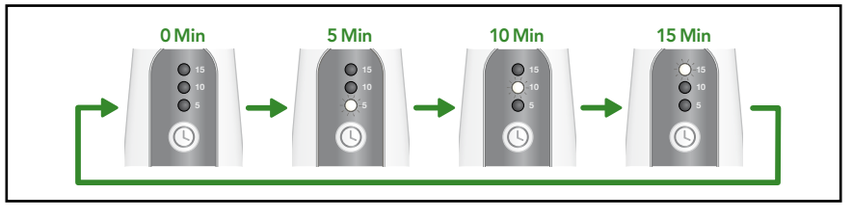
Turn the product on by sliding the Power Button upwards. The Power Indicator will also turn on.

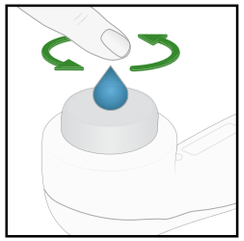
Press the Mode Button to scroll through the Mode levels. This will cycle through the Mode levels (Low, Medium and High), as shown by the Mode Indicators.



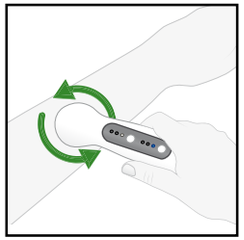
Instructions for use

Press the Time Button to cycle through the Time durations (5,10 and 15 minutes), as shown by the Time Indicators. When in use, the chosen Time Indicator will be on constantly and the treatment will count down for the chosen Time duration. If the Time Indicator is flashing, there is not enough pressure being applied. (See Troubleshooting, page 17).





Hold the device horizontally with the Treatment Head facing upwards. Apply the Ultrasound Gel to the Treatment Head and spread in a circular motion for a few seconds (see page 15 for details).



Move the Treatment Head in a flat, slow, circular motion over the skin surface of the treatment area. You should aim to apply the Treatment Head evenly (in time) over the surface area.

After the Time duration has been completed, the device will automatically turn off (all Time Indicators will turn off and the therapy will stop). Once your therapy session has been completed, turn off the product by sliding the Power Button downwards. The Power Indicator will turn off. The product is off when none of the indicators are lit.

Important: Clean after every use.
(See Cleaning Recommendations page 16).

THERAPY APPLICATION TABLE

There are three considerations when deciding how to treat the injured area:

1. When did the injury occur? If it is in the last seven days, then it is "acute". If the injury has existed for a longer period then treat as "chronic".
2. How deep is the problem area? This refers to the estimated thickness of the tissue where the injury exists in centimetres (or inches).
3. How big is the problem area compared with the size of the Treatment Head of REVITIVE Ultrasound?

Use the Therapy Application Tables to create a therapy.

 Apply the therapy once or twice a day only.

ACUTE (New Injury)		
DEPTH OF INJURY CM [INCH]	POWER	TREATMENT TIME
0.5 [0.2]	LOW	3 minutes per treatment head area
1 [0.4]	LOW	4 minutes per treatment head area
2 [0.8]	LOW	4.5 minutes per treatment head area
3 [1.2]	MEDIUM	2 minutes per treatment head area
4 [1.6]	MEDIUM	2.5 minutes per treatment head area

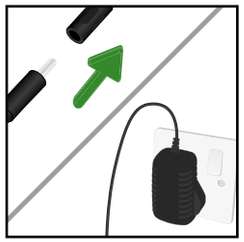
Positive effects should be seen in 6 weeks. If symptoms persist, please consult your healthcare professional. The device is suitable for use for a longer period.

CHRONIC (OLD INJURY)		
DEPTH OF INJURY CM [INCH]	POWER	TREATMENT TIME
0.5 [0.2]	MEDIUM	2 minutes per treatment head area
1 [0.4]	MEDIUM	2 minutes per treatment head area
2 [0.8]	HIGH	1.5 minutes per treatment head area
3 [1.2]	HIGH	2 minutes per treatment head area
4 [1.6]	HIGH	2.5 minutes per treatment head area

Positive effects should be seen in 6 weeks. If symptoms persist, please consult your healthcare professional. The device is suitable for use for a longer period.

TREATMENT HEAD TEST

You will not be able to feel the vibration from REVITIVE Ultrasound because it is operating at an ultrasonic frequency. However, if you are unsure whether the Treatment Head is vibrating, you can do the following test:

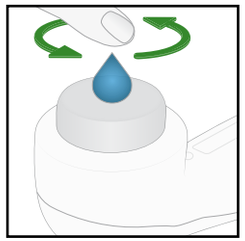


Plug the adaptor to the Connection Port. Also plug the adaptor into the mains power supply.

Turn the product on by sliding the Power Button upwards. The Power Indicator will also turn ON.

Press the Time Button ◷ and scroll through to any Time Duration (see page 10 for details).

Important: The device will not work unless a Time Duration is chosen.



Hold the device horizontally with the Treatment Head facing upwards. Place a large drop of water on the Treatment Head and spread in a circular motion for a few seconds.

⚠ **Do not immerse in water.**

Lightly press one finger onto the Treatment Head. The water will visibly vibrate, demonstrating that the Treatment Head is working correctly.

Important: The Treatment Head only vibrates if the conductive fluid (water or gel) covers the entire surface of the Treatment Head.

HOW TO USE YOUR CONDUCTIVE GEL

⚠ For external use only. Do not use on broken skin. Discontinue use if rash or irritation occurs.

⚠ Always read the label. Use only as directed. If symptoms persist please consult your doctor.

When using REVITIVE Ultrasound it is essential to use a liberal amount of Ultrasound Gel in order to reduce friction and assist in the transmission of the ultrasonic waves deep into the tissue. If the gel is inadequate, the effectiveness of the therapy may be reduced by up to 90%.

Choose the area of skin to be treated and use water or alcohol to clean it. Then liberally spread the conductive gel on the skin or directly onto the Treatment Head of the REVITIVE Ultrasound. During the therapy, the Treatment Head should be kept in constant motion and flat against the surface of the skin.

CLEANING RECOMMENDATIONS

Do not immerse the device in water.

Do not clean with chemicals.

No part of REVITIVE Ultrasound is suitable for dishwasher use.

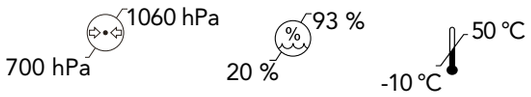
Important: It is recommended to clean the product after every use.

Clean the Treatment Head with a tissue or a soft, damp cloth. This will remove any excess Ultrasound Gel.

STORAGE

REVITIVE Ultrasound:
When not in use, store the device with the adaptor in a dry room and protect it against extreme moisture, heat and direct sunlight.

Air pressure, humidity and temperature limits for storage:



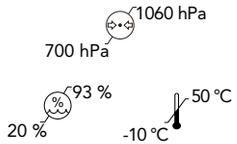
REVITIVE Ultrasound Gel:
Wipe nozzle clean and re-cap after each use. Store in a cool, dry place.

Problem	Possible Cause	Solution
No vibration	Ultrasound waves, with a vibration of 1-million times per second are too fast to see or feel. Therefore, you will not feel any sensation when using REVITIVE Ultrasound.	To confirm your REVITIVE Ultrasound is operating, follow the treatment head test (See page 14 for details).
	The temperature safety switch has tripped and the unit has switched off.	Allow the unit to cool down.
No vibration or indicators	The product has failed.	Contact your dealer.
Unit will not turn on	Temperature is too high.	Allow to cool.
Time indicator flashing	Poor contact between the treatment head and the body, (not enough pressure is being applied).	Apply a generous amount of Ultrasound Gel to create good contact between the Treatment Head and the body. Treatment is automatically restored when good contact is restored.

Symbols

Model or type designation/order number Directive 93/42EEC Annex 1,13,3(a) IEC 60601-1(6.1f) EN ISO 15223-1:2012	REF UT1033
Classification electrical Device: Type BF IEC 60601-1(6.1l)	
Serial number is on the underside of the device and on the packaging Directive 93/42EEC Annex 1,13,3(d) EN 15223-1:2012	SN XXXXXXXX
Lot Number including year (YY) and Month (MM) of manufacture	LOT YYMMXXXX
CONTRAINDICATIONS: This describes situations where you should not use REVITIVE Ultrasound	
CAUTION: This highlights warnings and cautions when using the device. Make sure you understand these before using REVITIVE Ultrasound	
Center Positive Polarity	
DANGER Electric shock risk	
Energy Efficiency Grade	
Indoor use only	
Complies with the European Union Directive 2011/65/EU (Hazardous Substances)	**RoHS**
Legal manufacturer of device	
EU/EC European Authorised Representative	EC REP

Symbols

Air pressure, humidity and temperature limits for storage	
Disposal In accordance with Directive 2012/19/EU(WEEE)	
Type of protection against electric shock Class II Equipment	
Only for treatment head: Protected against the effects of temporary immersion water	IPX7
Complies with the European Medical Device Directive (93/42/EEC), amended by directive 2007/47/EC and 2011/65/EU requirements. Notified body TUV Rheinland (CE0197)	CE 0197
Consult instructions for use	
Mode	
Time	

- Power Supply:
  Input: AC 100-240V, 50/60 Hz, 0.35A Output: DC 15V, 1.2A
- Frequency: 1MHz (±10%)
- Mode: 3 levels (Low, Medium, High)
- Time: 5, 10 or 15 minutes with auto turn off
- Power Output: (0.7W/cm^2 (Low), 1.0W/cm^2 (Medium), 1.2W/cm^2 (High)
- Duty Factor: 30% (Low), 40% (Medium), 50% (High)
- RBN : < 8.0
- Rated Output Power: 9.6W (±20%)
- Effective Intensity: 2.4W/cm^2 (±20%)
- AER : 4 cm^2
- Beam Type: Collimated
- Modulation Wave Shape: Pulsed
- Operating Conditions:
  Temperature: 5-40°C Humidity: 30-75%RH Air Pressure: 700-1060hPa

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS FOR ALL EQUIPMENT AND SYSTEMS

REVITIVE Ultrasound is intended for use in the electromagnetic environment specified below. The user of REVITIVE Ultrasound should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance.
RF emissions CISPR 11	Group 1	REVITIVE Ultrasound uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	REVITIVE Ultrasound is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-3	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Technical Specifications

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND EQUIPMENT OR SYSTEMS THAT ARE NOT LIFE SUPPORTING.

REVITIVE Ultrasound is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of REVITIVE Ultrasound can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and REVITIVE Ultrasound as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance D in metres (M) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Your international 2 year warranty

It is important to retain the retailer's receipt as proof of purchase; we suggest you staple your receipt to this manual for future reference.

In the unlikely event of your product proving to be faulty within 28 days of purchase it should be returned to the place where you bought it. If a fault develops after this period we grant a 2 year limited guarantee on the product commencing on the date of purchase.

Within the guarantee period we will eliminate, free of charge, any defects in the product resulting from faults in materials or workmanship, either by repairing or replacing the complete product as we may choose.

To obtain service within the guarantee period contact your local distributor. You will be asked to return the product (in secure, adequate packaging) together with a copy of proof of purchase. Subject to the exclusions set out below (see Exclusions below) the faulty product will then be repaired or replaced within 7 working days of receipt. The guarantee extends to every country where this product is supplied by Actegy or its appointed distributor.

If, for any reason, the product is replaced during the 2 year guarantee period, the guarantee on the new item will be calculated from the original purchase date.

Exclusions

Actegy Ltd shall not be liable to replace or repair the goods under the terms of the guarantee where:

- Damage or the fault is due to improper use, normal wear or use, accidental use, misuse, negligent use or use contrary to the manufacturer's recommendations or where the fault has been caused by power surges or damage carried out during transit.
- Defects have a negligible effect on the value or operation of the appliance.
- The device has been used on a voltage supply other than that stated on the product or used with a power adapter other than the one supplied with the product.
- Repairs have been attempted or undertaken by a person other than our service staff (or an authorised dealer) or if original REVITIVE parts are not used.
- The device has been used for hire purposes or non-domestic use.
- The device is second hand.

Actegy Ltd are not liable to carry out any type of servicing work under the guarantee.

This guarantee does not confer any rights other than those expressly set out above and does not cover any claims for consequential loss or damage. This guarantee is offered as an additional benefit and does not affect your statutory rights as a consumer.

To activate your warranty please register your device at www.revitive.com
If you prefer you can also post your registration, see warranty/guarantee card

CONTACT INFORMATION

Regulatory Certification

UK/Europe Class IIa medical device
AU/NZ Class IIb medical device

Shenzhen Dongdixin Technology Co Ltd
No3 Building, Xilibaimang Xusheng
Industrial Estate, 518108, Nanshan
Shenzhen, PRC.

EC REP

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537, Hamburg, Germany

ISO 13485 – Manufactured under the international quality management standard for medical devices.
Made in PRC.

Country Contacts:

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AW 3269_IFU02_14269060 PD 07.2017

RoHS

REVITIVE Ultrasound
complies with the WEEE Directive.
Save our green planet.