



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

Model number: UT1033

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What is inside the box?

Parts and Controls

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.





Introduction to Revitive

Important Safeguards

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.

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
- 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
- If you have a metallic implant, you may experience pain or discomfort near the implant when applying ultrasound stimulation. If this should occur discontinue use and seek advice from your doctor
- The ultrasound stimulation may feel more intense close to a metallic implant. It is safe to continue use provided no pain is experienced. You may need to adjust the power to a comfortable level
- 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
- Do not modify this equipment without authorisation of the manufacturer
- Do not service and maintain the device while it is in use
- The patient may be the intended operator
- The device must only be serviced, repaired and opened by service staff (authorised dealers)

- Do not use the device if it is damaged. The continuous use of a damaged device may cause injury, improper results, or serious danger
- Do not store the device at an extreme temperature (below -10°C or over 50°C) or humidity extremes (below 20%RH or over 93%RH). Doing so may affect the performance of the device
- Store the device in the dry, clean place. Keep the device away from pets and pests
- Do not expose the product to any chemical solvent, water, lint, dust, direct sun or high temperature
- Keep power cords and cables out of the reach of children to prevent risk of strangulation
- Keep the device out of the reach of children to avoid inhalation or swallowing of small parts
- Do not operate the device when connected to any other medical device
- Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

Important Safeguards

Instructions for use

Warnings & Cautions

- When the operating environment is relatively dry, strong electromagnetic interference usually occurs. At this time, the device may be affected as follows:
 - the device stops output;
 - the device turns off;
 - the device restarts;

The above phenomenon does not affect the basic safety and essential performance of the device, and the user can use it according to the instructions. If you want to avoid the above phenomenon, please use it according to the environment specified in the manual

- Ultrasound should be routinely checked before each use to determine that all controls function normally, especially that the intensity control properly adjusts the intensity of the ultrasound power output in stable manner. Also, determine that the treatment time control does actually terminate ultrasound power output when the timer reaches zero
- Before each use, inspect the Treatment Head for cracks, which may allow the ingress of conductive fluid
- You may experience skin irritation due to the gel. Discontinue use if any signs of allergy occur
- Use the Treatment Head with care. Inappropriate handling of the Treatment Head may adversely affect its characteristics

Save these Instructions

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 14-15 for details).



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



Press the Mode Button (1) to scroll through the Mode levels. This will cycle through the Mode levels (Low, Medium and High), as shown by the Mode Indicators.





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 19).





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 18).



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 17 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.

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	

The selection of treatment time also depends on the size of the treatment area. If the treatment area is larger, the treatment time will be longer. For example, if the treatment area is 8 cm^2 (double the area of the ultrasound head, 4 cm^2) and the treatment symptom is ACUTE (New Injury), and DEPTH OF INJURY is 2CM [0.8 INCH], according to the table above, the treatment time should be 9 minutes (2 x 4.5 minutes).

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	

The selection of treatment time also depends on the size of the treatment area. If the treatment area is larger, the treatment time will be longer. For example, if the treatment area is 8 cm^2 (double the area of the ultrasound head, 4 cm^2) and the treatment symptom is CHRONIC (Old Injury), and DEPTH OF INJURY is 2CM [0.8 INCH], according to the table above, the treatment time should be 3 minutes (2 x 1.5 minutes).

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.





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.



Lightly | The wat Treatme Importa conduct

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.

Troubleshooting

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:

700 hPa 20 % -10 °C 50 °C

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 16 for details).	
	The temperature safety switch has tripped and the unit has switched off.	Allow the unit to cool down.	
No vibration or The product has failed. indicators		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	REF UT1033
Classification electrical Device: Type BF	<u>خ</u>
Serial number is on the underside of the device	SN XXXXXXXXXXXXXXXX
Lot Number including year (YY) and Month (MM) of manufacture	LOT YYMMXXXX
Center Positive Polarity	$\ominus \bullet \bullet$
DANGER Electric shock risk	<u>Å</u>
Energy Efficiency Grade	IV
Indoor use only	公
Legal manufacturer of device	
EU/EC European Authorised Representative	EC REP
Air pressure, humidity and temperature limits for storage	700 hPa 700 hPa 20 % ^{93 %} -10°C 50 °C

Disposal In accordance with Directive 2012/19/EU(WEEE)	X
Type of protection against electric shock Class II Equipment	
Only for treatment head: Protected against the effects of temporary water immersion	IPX7
Only for main body: The first number 2: Protected against solid foreign objects of 12.5 mm and greater. The second number: Protected against vertically falling water drops when enclosure tilted up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15°, on either side of the vertical.	IP22
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)	
Consult instructions for use	E
Mode	
Time	

Technical Specifications

- Power Supply:
- Input: AC 100-240V, 50/60 Hz, 18W
- Frequency: 1MHz (±10%)
- Mode: 3 levels (Low, Medium, High)
- Time: 5, 10 or 15 minutes with auto turn off
- Power Output: (0.5W/cm² (Low), 0.8W/cm² (Medium), 1.2W/cm² (High)

Output: DC 15V, 1.2A

- Duty Factor: 20% (Low), 33% (Medium), 50% (High)
- RBN:≤8.0
- Rated Output Power: 9.6W (±20%)
- Effective Intensity: 2.4W/cm² (±20%)
- AER: 4 cm²
- Beam Type: Collimated
- Modulation Wave Shape: Pulsed
- Operating Conditions:
- Temperature: 5-40°C Humidity: 30-75%RH Air Pressure: 700-1060hPa
- Service Life of Device: 3 Years*
- Applied Part: Treatment Head
- IP Classification System: IP22

* Period of time specified by the manufacturer during which the device is expected to remain safe for use.

Table 1 Declaration - Electromagnetic Emission

Revitive Ultrasound is intended for use in the electromagnetic environment specified below. The customer or the user of Revitive Ultrasound should ensure 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
Harmonic emissions IEC 61000-3-3	Class A	domestic establishments and in establishments directly connected to the public low-voltage power supply network
Voltage fluctuations/flicker emis- sions IEC 61000-3-3	Complies	that supplies buildings used for domestic purposes.

Table 2 Declaration - Electromagnetic Immunity

Revitive Ultrasound is intended for use in the electromagnetic environment specified below. The customer or the user of Revitive Ultrasound should ensure that it is used in such an environment.

IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
±2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	\pm 0.5kV, \pm 1 kV line(s) to lines \pm 0.5kV, \pm 1 kV, \pm 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
	 ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air ± 2 kV for power supply lines ± 1 kV for input/output lines ± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth 0 % UT; 0.5 cycle At 0 % UT; 0.5 cycle At 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles 	±8 kV contact±2 kV, ±4 kV, ±8 kV, ±15kV air±2 kV, ±4 kV, ±8 kV, ±15kV air±2 kV for powersupply lines±1 kV for input/outputlines±0.5kV, ±1 kV line(s)to lines±0.5kV, ±1 kV, ±2 kVline(s) to earth0% UT; 0.5 cycle At0% UT; 0.5 cycle At0% UT; 1 cycle and70% UT; 25/30 cyclesSingle phase: at 0°0% UT; 250/300 cycles0% UT; 250/300 cycles

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Technical Specifications

Table 3 Declaration - Electromagnetic Immunity

Revitive Ultrasound is intended for use in the electromagnetic environment specified below. The customer or the user of Revitive Ultrasound should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM and ama- teur radio bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of device, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150 KHz to 80 MHz $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz	
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m	$d = 0.7\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: $((\bullet))$	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				
a Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured				

field strength in the location in which device is used exceeds the applicable RF compliance level above, device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating device.

Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and Device

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

Rated maximum	Separation distance according to frequency of transmitter (m)			
output power of transmitter (W)	0.15 MHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.7 GHz $d = 0.7\sqrt{P}$	
0.01	0.12	0.04	0.07	
0.1	0.38	0.11	0.22	
1	1.2	0.35	0.7	
10	3.8	1.1	2.2	
100	12	3.5	7.0	

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.

b

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 free 2-year warranty please register your device at: www.revitive.com/myrevitive

REVITIVE



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Regulatory Certification

UK/Europe Class IIa medical device

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

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