

● **User Operation Manual (20180218-revised)**

**Band name: TendonCARE Model: Bio-838**

**Place of manufacturing and development : Hong Kong**

**Manufacturer: TendonCARE Biophysics Co.Ltd.**

**Warranty: 12 months**

(Excluding power adaptor)

**Conditions out of warranty:**

- Water gets into device cavity
- Horn hits with hard materials
- Casing is opened unofficially
- Wrong electrical input

**Owner should be noticed:**

Usage on this high frequency electronic device as ultrasound therapy, you are advised to have manufacturer calibration yearly.

**Serial Number:**




See label stuck on metal horn (SXXX)

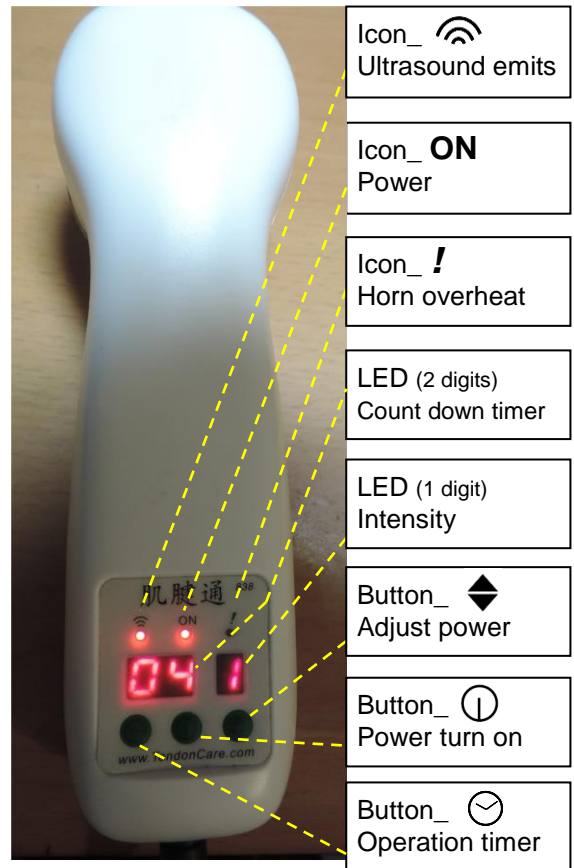
**1. Product Introduction**

Bio-838 with LIPUS program embedded massager, can generate a high frequency (1 MHz) wave signal with various output of ultrasound intensity for various massage therapy.

You are advised to consult medical advice before using the device.

**2. Steps to startup:**




- 2.1: Press button  for turn on the unit
- 2.2: Press button  for adjust the unit output power
- 2.3: Press button  for pre-set operation timer



Ultrasound intensity (SATA)		
1) 100mW/cm2 (LIPUS)	4) 0.8W/cm2 (Cont.)	7) 0.6W/cm2 (Pulse)
2) 0.3W/cm2 (Cont.)	5) 1.0W/cm2 (Cont.)	8) 1.0W/cm2 (Pulse)
3) 0.5W/cm2 (Cont.)	6) 1.2W/cm2 (Cont.)	9) 2.0W/cm2 (Cont.)
有骨裂情況下只可使用第 1 檔 LIPUS (20 分鐘/日)		
第 1~3 檔適用於急性傷患(患處表徵紅腫脹痛)；第 4~9 檔適用於慢性傷患(舊患)		
單一傷患處每次約 10 分鐘；每傷患處治療時間須相隔 6 小時		
Frequency =1Mhz; 1:4 Pulsed Continuous with 100RPF (Fixed)		

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#### 3. Operation procedure:

- 3.1. Plug in AC power adapter (220~110Vac) and connects DC plug (15Vdc) to the device. LED **ON** flashing, shows electric power is connected.
- 3.2. Press the button  for turn on the unit, the timer setting is pre-set to 05 minutes.
- 3.3. The LED is  flashing, indicates ultrasound is generating on the metal horn.
- 3.4. Press the button  for adjusting the ultrasound power.  
"1" (weakest) and "9" (strongest)
- 3.5. Timer can be adjusted from 5 to 30 minutes per 5 minutes step. 2 digit displayed time of count-down to "00", and device will stop operation with 2s buzzer alert to user.
- 3.6. Sufficient ultrasound conduction gel must be applied on treatment area that **do not have open-wound**. User must keep the metal horn slowly, lightly sweeping around and close touching on lesion during treatment.
- 3.7. For optimized biological effects, Bio-838 is designed in restrict of operation temperature 45°C. If metal horn runs higher than preset limits, overheat LED **!** will flash with 2s lasting alert to user before stopping operation.
- 3.8. For safe consideration in high ultrasound intensity setting mode 9, it is restricted to set only 1min. Please consult your medical advice for using longer duration of treatment.

#### Highlights you must know on operation:

- Plenty conductive gel must apply on lesion
- Keeps metal horn surface close touching with skin
- Keeps sweeping around lesion with slowly movement

**Mode Intensity**

Frequency 1MHz P=Pulsed (1:4) C=Continuous  
 Ultrasound Output **ON** Power On **!** Device Over Run

1) LIPUS	4) 0.8 W/cm <sup>2</sup> C	7) 0.6 W/cm <sup>2</sup> P
2) 0.3W/cm <sup>2</sup> C	5) 1.0 W/cm <sup>2</sup> C	8) 1.0 W/cm <sup>2</sup> P
3) 0.5W/cm <sup>2</sup> C	6) 1.2 W/cm <sup>2</sup> C	9) 2.0 W/cm <sup>2</sup> C

Mode 1 (LIPUS) only in case of **Bone Fracture** (20min/day)  
Mode(1-3) Acute Lesion Mode(4-9) Chronic Lesion

#### Warnings:

If any session of ultrasound therapy causes physical discomfort, stop using Immediately. Correct setting of Ultrasound Therapy should not be painful and low temperature raised. Over setting may cause tissue burning due to cavitation.

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### Restrictions on using ultrasound massager

- Over organs (stomach, liver, lungs, spleen, bowels, heart, kidneys, thyroid)
- Over the pelvis, abdomen and lumbar (lower back) region in pregnant or potentially pregnant females.
- On patients with pace-makers on patients with phlebitis, deep venous thromboses or patients with hemophilia.
- Over mucous membranes (mouth, nose, rectum/anus, vagina)
- Over highly ultrasound-sensitive organs (eyes, ears, ovaries, testicles, brain, spinal cord)
- On patients with spinal bifida / bone with active infection / a bone fracture
- Over areas suspected to be cancerous / pre-cancerous
- Over de-sensitized (numb, hypoesthesia) areas of the skin (e.g. diabetic neuropathy)
- Do not apply ultrasound gel on lesion with open wound
- Never use Ultrasound unit on children or under the age of 16 without the recommendation / supervision of a physician or therapist

Mode of Function	
Mode 1 (LIPUS-I) (100mW/cm <sup>2</sup> )	*Protein Synthesis, **Bone fracture healing, ***Nerve tissue repair *(Increased the aggrecan and type II collagen synthesis on the human chondrocytes cultured in 3D agarose gel) **(Transforming growth factor-β (TGF-β) synthesis and adenylyl cyclase activation in osteoblasts) *** (Improving peripheral nerve tissue regeneration glial cells)
Mode 2 (0.3W/cm <sup>2</sup> )	Protein Synthesis, (Increasing the chondrocytes viability isolated from OA patients, PG synthesis and type II collagen synthesis)
Mode 3 (0.5W/cm <sup>2</sup> )	*Acute phase of Tendon or Muscle healing -Stimulates growth factors -Angiogenesis (the growth of new blood vessels) -Reduce inflammation by drug transfer -Phonophoresis (lead in medication by ultrasound)
Mode 3~6 (0.8~1.2W/cm <sup>2</sup> )	**Sub-acute phase of Tendon or Muscle healing --Angiogenesis --Fibroplasia (formation of fibro tissue)
Mode 6~9 (1.2~2W/cm <sup>2</sup> )	***Chronic phase of Tendon or Muscle healing ---Remodeling ---Elevate tissue temperature ---Effects on scar tissue