Δelta

2 in1 Handheld TENS + Ultrasound Device
Instruction Manual

手提式2合1止痛 + 超聲波治療儀
使用說明書
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1. 結構組成，預期治療效果

1.1 結構組成
手提式2合1止痛 + 超聲波治療儀主要由主機、電極線、電極片及變壓器組成。

1.2 預期治療效果
Delta是可攜式的超聲波及電刺激治療儀, 可用於治療慢性疼痛、創傷後疼痛、手術後疼痛、肌肉痙攣和關節攣縮等症狀。在超聲波和電刺激兩種治療模式下的效果，會比單獨使用超聲波治療的效果更加明顯。

2. 警告及安全

2.1 警告字句定義
此使用說明書內之警告及安全字句由特定標籤指示。請於使用前先瞭解這些標籤定義。標籤定義如下：

⚠ 注意：”注意”標籤指可能存在之安全風險，若不遵守有可能導致輕度至中等人身受傷或儀器損毀。

⚠ 警告：”警告”標籤指若不遵守該指示有可能導致嚴重之人身受傷或儀器損毀。

⚡ 危險：”危險”標籤指若不遵守該指示有可能導致死亡或嚴重受傷之緊急危害。

2.2 注意
⚠ 注意
1. 請細閱及瞭解此使用說明。請瞭解並使用超聲波儀器的相關限制及危險。請查看儀器機身上的警告及安全資料。
2. 請注意相關禁忌症。
3. 請勿於已連接其他醫療儀器/設備的情況下使用此儀器。
4. 為避免電磁干擾而影響儀器的正常工作，請不要在電磁阻隔的環境附近操作本儀器，並應與干擾源保持足夠的安全距離；
5. 使用前需檢查超聲波儀所有操作正常。
   ➤ 檢查強度控制 – 確保超聲波輸出能穩定及正確地調校。
   ➤ 檢查治療時間控制 – 確保超聲波在設定時間完結時停止輸出。
6. 請勿使用尖物如鉛筆或原子筆按鍵，以免損壞。
7. 使用或移動此儀器時請加倍小心。不小心處理或有可能影響儀器功能。
8. 使用前請檢查治療頭是否有破損或導電液滲漏。
9. 請檢查導線及其接駁是否完整。
10. 儀器設計並非防水。任何水分或液體滲入均有機會儀器內部元件損壞，或
會引致用者受傷。

11. 以下用者需特別注意：
   ◀ 用者懷疑有或確診癲癇
   ◀ 用者懷疑或確診心臟疾病

12. 有以下情況用者需特別注意：
   ◀ 於急性創傷或骨折後並有出血傾向
   ◀ 最近曾接受手術，以免妨礙復原
   ◀ 月經時或懷孕子宮
   ◀ 有感知障礙之皮膚部位

13. 部分患者或會因電刺激或導電介質而出現皮膚敏感或過敏反應。這些反應
    通常可透過更換導電介質或電極貼而減輕。

14. 電極位置及電刺激設定應依照治療師的建議。

15. 請勿將電極貼在發炎或破損皮膚上。

16. 儀器應放在小童難以觸及的地方。

17. 請使用製造商指定的電極導線及電極。

18. 請勿於洗澡或浸浴時使用。儀器不可浸於水中或其他液體中，否則有可能
    損壞儀器及危及用者

19. 使用可產生冷或熱的儀器/產品，如電熱墊、熱敷墊或冷敷墊，有可能令電
    極失靈或影響用者血液循環，以致受傷。

20. 駕駛、操作機器或進行牽涉肌肉收縮之運動時請勿使用，以免用者受傷。

2.3 警告

⚠️ 警告

1. 於附近有其他儀器時使用應加倍小心。

2. 為免受電磁場或其他干擾而影響儀器之間的操作，請盡量避免同時使用其
   他儀器。

3. 不要在本儀器附近(2米以內)使用短波治療設備，這將導致儀器輸出不穩定。

4. 盡量避免儀器接觸陽光、雨、塵多或溼度高地方或振動等。

5. 此儀器不可於水療室(hydrotherapy rooms)內使用。

6. 在開始任何治療前，閣下應詳解各治療程式的方法及相關適應症，禁忌
    症、警告及注意事項。請從其他途徑獲得更多關於電療及超聲波的資訊。

7. 請勿使用溶劑清潔此儀器。

8. 儀器如有損壞，請勿繼續使用。

9. 此儀器只可由製造商或授權維修代表進行維修和維護。

10. 遵從所在地適用的規定和法規棄置主機、配件、儲存箱和包裝材料。請將
    此使用說明書同設儀器一併保存於包裝內。

11. 孕婦或餵哺中婦女應小心使用儀器。

12. 請勿用於生長中骨骼上或附近位置，直至骨骼完全生長方可使用。
13. 治療時間每天不應超過30分鐘。
14. 操作儀器時請勿使用電話。
15. 如患者對導電啫喱有過敏傾向，使用前應加倍留意。
16. 電極片不可置於頸動脈實神經，尤其是已知有頸動脈實反射過敏人士。
17. 切勿於頸及口部進行電刺激，否則或會造成嚴重的咽喉肌肉抽搐，其收縮或會阻塞呼吸道，造成呼吸困難。
18. 切勿於頭部、頸動脈(頸與頸部交點)、金屬植入器上、已接駁心臟檢測儀器或睡眠阻塞性症患者身上進行電刺激。
19. 電刺激不可跨越胸部。電流通過心臟或會導致心率不正。
20. 吞噬部位、受感染或發炎、出疹(如靜脈炎、血栓性靜脈炎或靜脈曲張等)。
21. 切勿於惡性傷口上或附位進行電刺激。
22. 治療時超聲波頭應持續移動。
23. 請於治療頭塗上足夠的導電啫喱，以確保治療過程中接觸良好。如有需要，可於調校電流強度時再補塗一些。
24. 如對使用有任何疑問，請向您的醫生諮詢。

2.4 危險

有植入神經刺激器之患者切勿在身上任何部位接受或靠近短波電療、微波電療、超聲波治療或激光治療。電療(短波、微波、超聲波治療或激光)之能量會通過植入神經刺激器，或對組織造成傷害及導致嚴重受傷或死亡。即使植入神經刺激器已關閉，仍有機會在治療期間發生上述危險。

生命危險品

在處理、清潔及棄置曾與體液接觸的部件及配件時，請依照當地規約、條例及程序。

2.5 副作用

- 副作用包括皮膚過敏，發炎及電極下皮膚灼傷。
- 依照以下方法避免出現超聲波治療的副作用。

移動超聲波頭

如超聲波頭移動過慢，患者或會感到骨膜疼痛(深層疼痛)。如移動過快，或超聲波頭沒有與皮膚保持良好接觸，則超聲波治療的效果會被減弱並使治療頭過熱。
患者感受性

某些患者對超聲波的輸出會較為敏感並會出現類似熱癬的反應。於使用期間或治療後應小心檢查皮膚反應，如出現副作用應立即停止使用。

接觸

治療部位與探頭的接觸可透過媒質幫助，如啫喱及乳液。任何媒質都應為高度導電。空氣並非超聲波的良好媒質。

3. 預期用途

Delta是集超聲波與TENS的二合一手提設備，能對人體產生超聲波及深層TENS（經皮神經電刺激）。它設計用於治療指定之症狀如紓緩棘手的慢性疼痛、創傷後疼痛及手術後疼痛症狀、肌肉酸痛及關節變形等。不適用於治療惡性疾病。

4. 禁忌症

1. 請勿用於生長中骨骼上或附近位置，直至骨骼完全生長方可使用。
2. 請勿用於骨折後癒合期使用。
3. 請勿於眼睛及周圍使用。
4. 請勿於心臟及周圍使用。
5. 請勿於腦組織及周圍使用。
6. 請勿用於戴有需求型心臟起搏器的患者。
7. 孕婦請勿使用。
8. 請勿用於睾丸。
9. 接受椎板切除術後患者請勿使用。
10. 請勿用於感覺較差的身體部位。
11. 請勿用於創傷後之身體部位。
12. 身體有植入金屬/人工關節者請勿使用。
13. 身體有植入神經刺激器患者請勿使用。
14. 請勿用於治療惡性腫瘤或用於腫瘤/惡性腫瘤上。
15. 血栓性靜脈炎或/及靜脈曲張患者請勿使用。
16. 有化膿性發炎患者請勿使用。
17. 糖尿病患者請勿使用。
18. 骨質疏鬆患者請勿使用。
19. 血管性疾病患者請勿用於缺血性組織，其血液供應或不足夠新陳代謝需求。
20. 請勿用於頸動脈竇神經、動脈、咽喉及咽喉及喉部肌肉。
21. 出血體質(過度出血疾病)患者切勿使用。
22. 接受椎板切除術後，不可用於脊椎上。
23. 請勿用於已接受麻醉之部位。
24. 急性受傷請勿使用。
25. 請勿用於開放式傷口。
26. 發燒患者請勿使用。
27. 結核病患者請勿使用。
28. 局部發炎患者請勿使用。

5. 產品結構及解釋說明

5.1 按鍵功能定義

1) 時間指示燈
2) 治療模式指示燈
3) “Time” 鍵，用於選擇治療時間
4) “Mode” 鍵，用於選擇超聲波治療強度（L-低，M-中，H-高）
5) “+” 鍵，用於增加電刺激治療強度
6) “-” 鍵，用於減少電刺激治療強度
7) 電刺激指示燈，用於指示電刺激輸出狀態（亮-有電刺激輸出）
8) 電源指示燈，用於指示電源狀態
9) 電源開關，“ON” - 接通電源，“OFF” - 關閉電源
10) 連接變壓器
11) 連接電極線
12) 超聲波治療頭
13) 主機

5.2 圖示、標識解釋說明

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<td>保持乾燥</td>
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<td>聲頭）</td>
<td>水時水的侵入</td>
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<td>□</td>
<td>安全分類，漏電防</td>
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<td>標識設備漏電防</td>
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<td>電子廢棄物的處理</td>
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5.3 配件
包裝箱中含如下物品

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<td>1</td>
<td>Delta治療儀</td>
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<td>2</td>
<td>電源變壓器</td>
<td>1PC</td>
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<tr>
<td>3</td>
<td>超聲波導電凝膠（85g）</td>
<td>1PC</td>
</tr>
<tr>
<td>4</td>
<td>電極貼（50x100mm）</td>
<td>1PC</td>
</tr>
<tr>
<td>5</td>
<td>電極線</td>
<td>1PC</td>
</tr>
<tr>
<td>6</td>
<td>說明書</td>
<td>1PC</td>
</tr>
</tbody>
</table>
6. 治療注意事項

治療前
1）確保沒有治療的禁忌症。用肥皂或酒精（70%）清潔治療部位的皮膚。
2）如果皮膚有過多的毛髮，修剪或刮去毛髮以取得最佳的治療效果。
3）塗抹適量的超聲波導電凝膠在治療部位上。
4）超聲波功能測試:
水平放置治療頭，然後倒些水滴到治療頭的表面，打開儀器並按“Time”鍵。
如超聲波運作正常，你將能夠觀察水滴在超聲頭上晃動，並看到輕微的“蒸氣”，
探頭上的水滴以每秒一百萬次振動並霧化的現象。

治療中
1）移動超聲波治療頭作圓周運動。治療部位應該是治療頭直徑的兩倍。
2）如果超聲波能量的傳播微弱，需要添加更多的導電凝膠或重新放置治療頭。
注意:
1）應以治療頭在治療位置的皮膚表面緩慢並平坦地打圈。應以適中的速度在治
療位置上移動探頭: 不宜過慢，否則可能造成過熱；亦不宜過快，否則可能
減低治療效果。

治療後
1）每次治療後立即清潔接觸表面，確保沒有導電凝膠留在治療頭。建議使用沾
有約70%濃度酒精的軟布清潔超聲頭，不要把儀器浸泡在水裡。
2）檢查是否有任何改善的跡象（如疼痛）。

7. 安裝及說明

7.1 連接電源

ecSTIM Delta屬於手提式醫療設備，無需安裝，僅需連接電源及
附件即可使用。具體操作步驟及相關注意事項請見下文:
1. 把這個治療儀連接到電源之前，確認標籤上規定的電壓和頻率與可用的電
源匹配。
2. 連接電源變壓器

連接電源變壓器與設備的電源線，並把電源變壓器連接到電源插座，
將電源開關至“ON”。
3. Delta提供2種治療模式:
   ➤ 組合治療: 超聲波 + 電刺激治療
   ➤ 超聲波: 單獨超聲波治療
4. 切斷電源變壓器
將電源開關撥到“OFF”位置，關閉設備，從電源插座拔出電源變壓器。

注意:
➢ 連接非製造商規定的附件可能會影響病人安全和設備功能。

7.2 使用超聲波模式

<table>
<thead>
<tr>
<th>1. 連接電源</th>
<th>按照3.1 連接電源的操作，連接好變壓器和主機</th>
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<tbody>
<tr>
<td>2. 塗超聲波導電凝膠</td>
<td>將適量聲波導電凝膠塗在治療部位，塗電凝膠的面積至少是超聲治療頭面積的兩倍。注意：切勿把超聲波導電凝膠直接塗抹於治療頭上，否則機器會誤把導電凝膠當作接觸面並釋出超聲波，有機會對治療頭造成損害。</td>
</tr>
<tr>
<td>3. 打開電源</td>
<td>將電源開關撥至“ON”位置，接通電源。</td>
</tr>
<tr>
<td>4. 選擇強度</td>
<td>按“Mode”鍵選擇超聲波治療強度，強度有三個等級，L-低、M-中、H-高。每個級別對應一個指示燈。</td>
</tr>
</tbody>
</table>
5. 選擇時間
按“Time”鍵選擇治療時間 (5、10和15分鐘), 當選擇時間後, 系統將開始運作。
備註：在運作期間, 用戶可以按“Time”鍵來調整治療時間。

6. 開始治療
將超聲治療頭放置在塗有聲波導電凝膠的皮膚表面，緩慢、循環移動。
注意:
1) Delta具有負載檢測功能，當儀器檢測到超聲頭與皮膚沒有充分接觸時，“Time”指示燈會閃爍 (1Hz)，設備會自動停止超聲輸出；當檢測到與皮膚接觸良好時，重新恢復輸出。
2) Delta有溫度保護功能，當檢測到超聲手柄溫度超過42 (±2) °C時，機器會自動停止超聲輸出，進入保護狀態，超聲手柄LED指示燈閃爍 (2Hz)；當超聲手柄溫度回落到41 (±2) °C時，機器將恢復超聲功率輸出，退出保護狀態。

7. 關掉電源
當治療時間完成後，儀器會自動返回到待機狀態。向下滑動電源開關（“ON”到“OFF”）關閉電源。

7.3 使用超聲波+電刺激模式

1. 連接電源
按照3.1 連接電源的操作，連接好變壓器和主機

2. 連接電極線
將白色電極線插入主機，如左邊的圖片所示。
注意：在連接導線到設備前必須關閉設備。
3. 連接電極片
連接電極貼和電極線，如左邊的圖片所示。

4. 皮膚清潔乾燥後，將電極貼放置在治療部位附近。
注意：
1) 確保電極貼和皮膚充分接觸；
2) 關於電極貼的黏貼部位，可以參考說明書第9章常見治療部位圖示

5. 塗超聲波凝膠
將適量超聲波凝膠塗在治療部位，塗的面積至少是超聲治療頭面積的兩倍。
注意：切勿把超聲波導電凝膠直接塗抹於治療頭上，否則機器會誤把導電凝膠當作接觸面並釋出超聲波，有可能對治療頭造成損害。

6. 打開電源
將電源開關撥至“ON”位置，接通電源。

7. 選擇強度
按“Mode”鍵選擇超聲波治療強度，強度有三個等級：L-低，M-中，H-高，每個等級對應一個指示燈。
a) 如沒有超聲波輸出，電刺激將不能使用。因此用家應先確保超聲波正常運作，再去調校電刺激強度。
b) 如使用過程中感到任何不適，請將輸出強度調低至舒適的程度。如不適情況持續，請諮詢醫生意見。
c) 調節輸出強度時，請先移開超聲波治療頭，以免皮膚的溫度變得過高或灼傷皮膚。
d) 調節輸出強度時，如強度低於5V，則每次的調校幅度為1V；如強度高於5V，則每次的調校幅度為0.5V。
<table>
<thead>
<tr>
<th>8. 選擇時間</th>
</tr>
</thead>
<tbody>
<tr>
<td>按“Time”鍵選擇治療時間(5、10和15分鐘), 當選擇時間後, 系統將開始運作。</td>
</tr>
<tr>
<td>備註: 在運作期間, 用戶可以按“Time”鍵來調整治療時間。</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. 開始治療</th>
</tr>
</thead>
<tbody>
<tr>
<td>將超聲治療頭放置在塗有超聲波凝膠的皮膚表面，緩慢、循環移動。</td>
</tr>
<tr>
<td>注意：</td>
</tr>
<tr>
<td>1) Delta不良接觸提示功能, 當儀器檢測到超聲頭或電極片與皮膚沒有充分接觸時, “Time”指示燈會閃爍 (1Hz), 儀器會自動停止超聲輸出; 當檢測到與皮膚接觸良好時, 重新恢復輸出。</td>
</tr>
<tr>
<td>2) Delta有溫度保護功能, 當檢測到超聲手柄溫度超過42(±2)℃時, 儀器會自動停止超聲輸出, 進入保護狀態, 超聲手柄LED指示燈閃爍(2Hz); 當超聲手柄溫度回落到41(±2)℃時, 儀器將恢復超聲波輸出, 退出保護狀態。</td>
</tr>
<tr>
<td>3) 本儀器沒有震動亦能正常運作。應以治療頭在治療位置及其周邊位置緩慢、慎重且平坦地打圈。完成治療後, 儀器會進入待機狀態。我們不建議用家在療程結束後再次進行治療。</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10. 關掉電源</th>
</tr>
</thead>
<tbody>
<tr>
<td>當持續時間已經完成後, 儀器會自動恢復待機狀態, 向下滑動電源開關 “ON”到“OFF”的位置以關閉電源。</td>
</tr>
</tbody>
</table>
8. 技術規格

超聲波規格參數

<table>
<thead>
<tr>
<th>操作頻率</th>
<th>1MHz±10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>最大功率</td>
<td>10W±20%（占空比：100%）</td>
</tr>
<tr>
<td>脈衝重複頻率</td>
<td>100Hz±10%</td>
</tr>
<tr>
<td>工作週期</td>
<td>30%，40%，50%</td>
</tr>
<tr>
<td>輸出功率</td>
<td>3W（L），4W（M），5W（H）</td>
</tr>
<tr>
<td>有效輻射面積</td>
<td>4cm²±20%</td>
</tr>
<tr>
<td>超聲波最大能量</td>
<td>2.5W/cm²</td>
</tr>
<tr>
<td>波束不均勻係數</td>
<td>5.0</td>
</tr>
<tr>
<td>波束類型</td>
<td>準直型</td>
</tr>
<tr>
<td>波形</td>
<td>脈衝波</td>
</tr>
<tr>
<td>治療時間</td>
<td>5, 10, 15分鐘</td>
</tr>
<tr>
<td>超聲波治療頭物料</td>
<td>鋁</td>
</tr>
</tbody>
</table>

電刺激規格參數

<table>
<thead>
<tr>
<th>輸出特性</th>
<th>持續電壓</th>
</tr>
</thead>
<tbody>
<tr>
<td>治療時間</td>
<td>5, 10, 15分鐘</td>
</tr>
<tr>
<td>輸出波形</td>
<td>雙相向型脈衝</td>
</tr>
<tr>
<td>載波頻率</td>
<td>2.5KHz</td>
</tr>
<tr>
<td>差頻值</td>
<td>1Hz - 120Hz</td>
</tr>
<tr>
<td>最大輸出</td>
<td>0~15V（500Ω負載）</td>
</tr>
</tbody>
</table>

**Delta**的主要設備規格參數

<table>
<thead>
<tr>
<th>安全分類</th>
<th>II類BF型應用部分設備</th>
</tr>
</thead>
<tbody>
<tr>
<td>外形尺寸</td>
<td>209mm（長）x53mm（寬）x89mm（高）</td>
</tr>
<tr>
<td>重量</td>
<td>235g</td>
</tr>
</tbody>
</table>
電源規格參數

<table>
<thead>
<tr>
<th>電源電壓</th>
<th>100V~240V</th>
</tr>
</thead>
<tbody>
<tr>
<td>工作頻率</td>
<td>50Hz~60Hz</td>
</tr>
<tr>
<td>輸出電壓</td>
<td>15V DC</td>
</tr>
<tr>
<td>輸出電流</td>
<td>1.2A</td>
</tr>
<tr>
<td>功率</td>
<td>18W</td>
</tr>
<tr>
<td>外形尺寸</td>
<td>64mm(長) x 50mm(寬) x 26.5mm(高)</td>
</tr>
<tr>
<td>重量</td>
<td>120g</td>
</tr>
</tbody>
</table>

環境條件

<table>
<thead>
<tr>
<th>工作條件</th>
<th>溫度：5℃～40℃</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>濕度：30%～75%</td>
</tr>
<tr>
<td></td>
<td>大氣壓力：700～1060hpa</td>
</tr>
<tr>
<td>儲存、運輸條件</td>
<td>溫度：-10℃～50℃</td>
</tr>
<tr>
<td></td>
<td>濕度：10%～90%</td>
</tr>
<tr>
<td></td>
<td>大氣壓力：700～1060 hPa</td>
</tr>
</tbody>
</table>

9. 常見治療部位圖示

治療效果是否明顯，與正確的放置電極貼有很大關係。以下是常見治療部位圖示，適用於超聲波+電刺激模式下電極貼的黏貼和超聲波治療頭的放置。遇到不清楚電極片黏貼部位或超聲波治療頭放置位置的情況，請諮詢醫生的意見。
### 10. 常见故障及解决方法

<table>
<thead>
<tr>
<th>序号</th>
<th>故障</th>
<th>原因</th>
<th>解决方法</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>LCD显示器不能正常显示</td>
<td>變壓器連接不正確</td>
<td>重新連接變壓器及電源，確保連接正確</td>
</tr>
<tr>
<td></td>
<td></td>
<td>檢查變壓器有損壞</td>
<td>更換新的變壓器</td>
</tr>
<tr>
<td>2</td>
<td>感覺刺激微弱或不能感覺刺激</td>
<td>電極太乾燥或被污染</td>
<td>更換新的電極</td>
</tr>
<tr>
<td></td>
<td></td>
<td>電極沒有很好地黏在皮膚上</td>
<td>重新連接電極</td>
</tr>
<tr>
<td></td>
<td></td>
<td>電極線、電極有損壞</td>
<td>更換新的電極線、電極</td>
</tr>
<tr>
<td></td>
<td></td>
<td>輸出強度太低</td>
<td>增大輸出強度</td>
</tr>
<tr>
<td>3</td>
<td>患者感覺不適</td>
<td>輸出強度太大</td>
<td>降低輸出強度</td>
</tr>
<tr>
<td></td>
<td></td>
<td>電極片尺寸太小</td>
<td>只能使用尺寸為50mm×100mm的電極</td>
</tr>
<tr>
<td></td>
<td></td>
<td>電極有損壞，導致與皮膚接觸面積減小</td>
<td>更換新的電極</td>
</tr>
<tr>
<td></td>
<td></td>
<td>沒有根據說明書來操作設備</td>
<td>在使用之前請查閱說明書</td>
</tr>
<tr>
<td>4</td>
<td>輸出停止</td>
<td>電極片脫落或與皮膚沒有接觸好</td>
<td>重新連接電極貼</td>
</tr>
<tr>
<td></td>
<td></td>
<td>電極、電極線被損壞</td>
<td>重新放置新的電極、電極線</td>
</tr>
<tr>
<td></td>
<td></td>
<td>超聲波治療頭與皮膚接觸不好</td>
<td>塗抹超聲波導電凝膠後，重新放置超聲頭到皮膚上</td>
</tr>
<tr>
<td></td>
<td></td>
<td>超聲波頭表面溫度高於42℃</td>
<td>需暫停使用，直到溫度下降至42℃以下</td>
</tr>
<tr>
<td>5</td>
<td>治療效果不佳或無效</td>
<td>電極放置位置不正確</td>
<td>重新放置電極</td>
</tr>
<tr>
<td></td>
<td></td>
<td>不明原因</td>
<td>請諮詢醫生</td>
</tr>
</tbody>
</table>

備註：如發現其他故障，無法解決，請聯繫製造商或當地授權銷售商維修。
11. 清潔、儲存、運輸

11.1 清潔主機和電線
清潔主機和電線時，請用軟布沾少許消毒液進行擦拭。
1）清潔前，請注意關閉電源，並關閉電源連接。
2）清潔電極線時，需將電極線從主機拔下。
3）清潔時，請勿讓液體滲入儀器內部，否則可能導致損壞。
注意：切勿把儀器浸泡在液體裡。如儀器意外落入液體中，立刻聯絡銷售商或
經授權的客戶服務中心。在儀器經過檢查和測試之前（必須由經授權的客戶服
務中心認證的技術員進行），切勿使用曾浸泡於液體中的儀器。切勿讓液體進
入通風孔洞。

11.2 清潔超聲波治療頭
每次治療後，立即清潔接觸表面，確保沒有導電凝膠殘留在探頭上，可用沾
70%酒精的軟布進行清潔、消毒。應該定期檢查超聲波治療頭是否損壞，如可
以使液體滲透進去的細小的裂縫。

11.3 清潔電極片
- 電極片膠貼面應保持清潔，避免粘上灰塵、油性物、黏性物等，否則會
黏性下降。
- 電極片使用後黏貼在透明薄膜上進行保存，不要任意黏貼在其他物品上，
避免損壞電極片
注意：
1）請不要用紙巾、布等擦電極片黏貼面；
2）請不要用指甲、刷子等刮傷黏貼面。

注意：
1. 電極貼的使用壽命會根據清洗次數、皮膚狀態以及保存狀況而有所改變。
2. 如電極貼未能貼於皮膚上或出現破損，應立刻更換新的電極貼。
3. 建議先沖洗皮膚及洗走多餘油脂，並待皮膚完全風乾後才使用電極貼。
4. 當電極貼並非黏貼在人體之上時，切勿開啟儀器。
5. 儀器處於開啟狀態時，切勿從皮膚移除電極貼。
6. 如需更換電極貼，請確保其尺寸與Delta型號隨附的電極貼一樣，亦即
2吋x4吋（50*100mm）。
7. 如電極貼尺寸過大（較Delta型號隨附的電極貼大），有可能減低電刺激
的效果；如電極貼尺寸過細（較Delta型號隨附的電極貼細），則有可能
增加皮膚敏感或被電極貼灼傷的機率。
8. 請只使用CE認證的電極貼。
11.4 儲存、運輸

1) 在儲存、運輸儀器的過程中，請勿將儀器放置在溫、濕度過高或過低或灰塵大的地方，應符合儀器規定的儲存、運輸條件。同時遠離易燃易爆氣體源。運輸時請小心搬運，勿撞擊或震動。

2) 電子廢棄物降解或釋放出來的物質會污染環境，請勿隨便丟棄，關於超聲電刺激複合治療儀的廢棄物如廢棄電極、包裝材料的丟棄，請按照國家相關的環境保護法和當地政府的環保規定進行處理。

3) 推薦進行儀器年檢。檢查項目如下：
   - 由合格技術人員每年進行超聲波校正。
   - 所有輸出口的輸出電壓和電流。
12. 電磁相容性信息(EMC)

・ 產品需要特別注意電磁相容性，並且必須根據本操作手冊提供的電磁相容性資訊安装和使用產品。
・ 此設備與其他附近/堆積的設備同時請加倍留意。潜在電磁及其他干擾或會出現並影響此或其他設備。盡量避免與其他設備同時使用，以減低干擾。
・ 規格上之表現為設備的實際表現。此設備已經徹底測試以確保其正確操作及輸出。

（表1）

table

<table>
<thead>
<tr>
<th>放射試驗</th>
<th>合規性</th>
<th>電磁環境 - 指南</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF 放射 CISPR 11</td>
<td>第1組</td>
<td>產品僅為其內部功能使用RF能量。因此，它的RF放射很低，並且對附近電子產品產生干擾的可能性很小。</td>
</tr>
<tr>
<td>RF 放射 CISPR 11</td>
<td>B類</td>
<td>產品適合在所有電路設施中使用，包括本地電路設施和直接連接到公共低壓供電網（為本地建築物民用用途供電）的電路設施。</td>
</tr>
<tr>
<td>諧波放射 IEC 61000-3-2</td>
<td>A類</td>
<td></td>
</tr>
<tr>
<td>電壓波動/閃爍放射 IEC 61000-3-3</td>
<td>適用</td>
<td></td>
</tr>
</tbody>
</table>
## 指引及製造商聲明 - 電磁耐受性

產品預期用於下述特定的電磁環境。使用者必須確定產品用於這樣的電磁環境中。

<table>
<thead>
<tr>
<th>耐受性試驗</th>
<th>IEC 60601 試驗水平</th>
<th>合規水平</th>
<th>電磁環境 - 指南</th>
</tr>
</thead>
</table>
| 靜電放電 (ESD) | ±6 kV 接觸放電 | ±6 kV 接觸放電 | 地板材質應為木、混凝土或陶瓷。若板材質為合成材料，則相對濕度應至少達到 30%。
IC 61000-4-2 | ±8 kV 空氣放電 | ±8 kV 空氣放電 |
| 電快速瞬變脈衝群 | ±2kV 電源線 | ±2kV 電源線 | 所用主電源應為普通商用或醫用電源。
IC 61000-4-4 |
| 浪涌 | ±1kV 線對線 | ±1kV 線對線 | 所用主電源應為普通商用或醫用電源。
IC 61000-4-5 |
| 電源輸入線電壓暫降、短時中斷和電壓變化 | <5% UT（在UT上，>95%暫降），持續0.5個週期 | <5% UT（在UT上，>95%暫降），持續0.5個週期 | 所用主電源應為普通商用或醫用電源。如果產品的使用者需要在電源中斷期間繼續操作，建議配備一個不斷電供應系統或電池，以便為產品持續供電。
IC 61000-4-11 | 40% UT（在UT上，60%暫降），持續5個週期 | 40% UT（在UT上，60%暫降），持續5個週期 |
| 70% UT（在UT上，30%暫降），持續25週期 | 70% UT（在UT上，30%暫降），持續25週期 |
| <5% UT（在UT上，>95%暫降），持續5秒 | <5% UT（在UT上，>95%暫降），持續5秒 |
| 工頻磁場 (50/60Hz) | 3A/m | 3 A/m | 工頻磁場應處於一個普通商用或醫用環境應有的水平。
IC 61000-4-8 |

備註：\( U_t \)是指施加試驗電壓之前的交流網電壓。
<table>
<thead>
<tr>
<th>耐受性試驗</th>
<th>IEC 60601試驗水準</th>
<th>合規水準</th>
<th>電磁環境 - 指南</th>
</tr>
</thead>
<tbody>
<tr>
<td>射頻傳導</td>
<td>IEC 61000-4-6</td>
<td>3V（有效值）150 kHz至80 MHz</td>
<td>3 V（有效值）</td>
</tr>
<tr>
<td>射頻輻射</td>
<td>IEC 61000-4-3</td>
<td>3 V/m 80 MHz至2.5 GHz</td>
<td>3 V/m</td>
</tr>
</tbody>
</table>

建議間隔距離

- d=1.2√P
- d=1.2√P, 80MHz to 800MHz
- d=2.3√P, 800MHz to 2.5GHz

其中，P 是發射器製造商規
定的以瓦 (W) 為單位的發射
器額定最大輸出功率，而 d
是米 (m) 為單位的建議間
隔距離。H

根據電磁現
場測量 a 確定的
固定射頻發射器的場強應低
於每個頻率範圍 b 的合規性
水準。

在標有以下符號的產品附近
可能存在干擾：

注1：在80MHz至800MHz頻率下，適用較高的頻率範圍。
注2：這些適用指南可能並不適用於所有情況。電磁傳播受設施結構、物件和人員的吸收和
反射等特性的影響。

a 固定發射機的磁場強度，例如無線電基站（手機/無線電話）和陸地移動無線電、非專業無
線電、AM和FM無線電廣播級電視廣播在理論上都無法精確預測，要評價固定射頻輻射所造
成的電磁環境，應考慮進行電磁場現場調查。如果在使用 Delta 的位置測得的磁場強度超出
以上適用的 RF 頻率範圍，則應觀察產品以驗證其是否正常操作。如果觀察不到正常性能，
則可能需要採取其他措施，例如重新定向或重新放置 Delta。

b 在150kHz至80kHz頻率範圍內，磁場強度應小於3V/m。
Delta與可攜式和及移動式射頻通信設備之建議隔間距離

Delta預期用於輻射頻率騷擾受控的電磁環境。使用者可用於保持通訊產品和Delta的最小隔間距離，來預防電磁干擾。下表為根據通訊產品最大輸出功率確定的最小隔間距離。

<table>
<thead>
<tr>
<th>發射器的額定最大輸出功率（W）</th>
<th>對應發射機不同頻率的隔間距離（m）</th>
<th>150 kHz至80 MHz d = 1.2√P</th>
<th>80 MHz至800 MHz d = 1.2√P</th>
<th>800 MHz至2.5 GHz d = 2.3√P</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.12</td>
<td>0.12</td>
<td>0.23</td>
<td></td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
<td>0.37</td>
<td>0.74</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
<td>1.17</td>
<td>2.33</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>3.69</td>
<td>3.69</td>
<td>7.38</td>
<td></td>
</tr>
<tr>
<td>100</td>
<td>11.67</td>
<td>11.67</td>
<td>23.33</td>
<td></td>
</tr>
</tbody>
</table>

對於最大輸出功率不在上述表格的產品，建議的隔間距離（以“米”為單位）可以用與產品相適應的公式進行計算得出，P是產品的最大額定輸出功率，單位為瓦特（W）。

注1：在80MHz至800MHz頻率下，適用較高的頻率範圍
注2：這些適用指南可能並不適用於所有情況。電磁傳播受設施結構、物件和人員的吸收和反射等特性的影響。

13. 保養及維修

1）儀器出廠前已經過嚴格的測試，請勿私自修理或調節、分解儀器，否則可能引發事故或故障。
2）設備故障時，請聯繫聯繫製造商，將設備送交被授權的專業人員維修，並詳細說明故障問題。
3）請勿嘗試修改裝本儀器。
4）請使用製造商提供的配件，如超聲波治療頭和變壓器，否則可能損壞儀器或影響治療效果。
5）請勿打開主機及配件外殼，否則可能損壞儀器或傷害人體。
6）每次使用該儀器前，請先檢查設備是否安全有效，如外觀是否有損傷，電極線是否損壞，超聲波治療頭是否有裂縫等。
7）若長時間不使用該儀器，請將該儀器進行徹底清潔，拆下所有附件，並包裝好儲存在乾燥通風的地方。

保修說明：

本產品自購買之日起，主機提供免費保養期1年。其他配件如電極貼、電極線屬於消耗品，不提供保修。但由於人為損壞，如自行拆卸、維修、連接不適用的附件、未按說明使用、儀器內部進水等不屬於保養範圍。

產品在送回維修的途中，由於運輸、裝卸所導致的產品故障或損壞及由於意外事件或自然災害導致的故障或損壞不在保養範圍內，照常收取維修費用。如果產品有任何品質問題，請與銷售商或製造商聯繫，我們將為您提供全面優質服務。請妥善保管銷售單據，以便我們及時為您做好售後服務。
Declaration of conformity:
Shenzhen Dongdixin Technology Co., Ltd. declare that the Delta complies with the following normative documents:


Complies with MDD 93/42/EEC and Amended by directive 2007/47/EC requirements
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1.1 General

This manual has been written for the users of Delta. It contains general information on the operation, precautionary practices, and maintenance information of the device. In order to maximize the use, efficiency, and life of the device, please read the manual thoroughly and become familiar with the controls, as well as the accessories before operating the device.

Pay attention to the following before using the Delta:
1. Keep yourself informed of the contraindications (see chapter 4).
2. The device may not be used in close proximity (i.e. less than 2 meters) to shortwave equipment.
3. The device may not be used in so-called “wet rooms” (hydrotherapy rooms).

The manufacturer cannot be held responsible for the results of using this apparatus for any purposes other than those described in these operating instructions.

1.2 Therapy possibilities

Delta is a therapy apparatus that offers both ultrasound therapy and electrotherapy in combination. Pain affects the quality and enjoyment of life, especially for those who suffer chronic pain. Delta is an ultrasound and electrotherapy therapy device for the treatment of chronic and acute muscular pain. The applicator has a radiant surface of 4.0cm² and frequency of 1MHz. Combination therapy of ultrasound and electrotherapy, ideal to localize trigger points and or pain points.

1.3 Applicator

The ultrasound applicator for Delta has one-frequency head. This applicator can now supply 1 MHz ultrasound. The head has excellent beam characteristics, fully meeting the requirements of the existing standards. The excellent beam characteristics, ergonomic design and effective contact control of the single-frequency applicator make optimal treatment possible.
2. SAFETY PRECAUTIONS

2.1 PRECAUTIONARY DEFINITIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definitions of these symbols are as follows:

⚠️ Caution: Text with a “CAUTION” indicator symbol will explain possible safety infractions that could have the potential to cause minor to moderate injury to an individual or damage to equipment.

⚠️ Warning: Text with a “WARNING” indicator will explain possible safety infractions that will potentially cause serious injury to an individual and/or equipment damage.

❗️ Danger: Text with a “DANGER” indicator will explain possible safety infractions that are imminently hazardous situations that could result in death or serious injury.

2.2 Caution

⚠️ Caution

1. Read, understand, and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any ultrasound device. Observe the precautionary and operational decals placed on the unit.

2. Keep informed of the contraindications.

3. DO NOT operate the device when connected to any other medical device.

4. DO NOT operate this device in an environment where other devices used intentionally radiate electromagnetic energy in an unshielded manner.

5. Ultrasound should be routinely checked before each use to ensure that all controls function normally.
   ➤ Check intensity control – make sure it properly adjusts the intensity of the ultrasonic power output in a stable manner.
   ➤ Check treatment time control – make sure it terminates ultrasonic power output when the timer reaches zero.

6. DO NOT use sharp objects such as pencil point or ballpoint pen to operate the buttons on the control panel.

7. Handle the ultrasound applicator with care. Inappropriate handling of the Ultrasound applicator may adversely affect its characteristics.
8. Before each use, inspect the Ultrasound Applicator for cracks to avoid the ingress of conductive fluid.
9. Inspect Applicator cables and associated connectors before each use.
10. The ultrasound therapy control unit is not designed to prevent the ingress of water or liquids. Ingress of water or liquids may cause malfunction of internal components of the device and therefore create risk of injury to the patient.
11. Caution should be used:
   ▶️ With patients suspected or diagnosed with epilepsy.
   ▶️ With patients suspected or diagnosed with heart problems.
12. Caution should be used in the presence of the following:
   ▶️ When there is a tendency to hemorrhage following acute trauma or fracture.
   ▶️ Following recent surgical procedures when muscle contraction may disrupt the healing process.
   ▶️ Over the menstruating or pregnant uterus.
   ▶️ Over areas of the skin which lack normal sensation.
13. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium or alternate electrode placement.
14. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
15. Never apply electrodes over irritated or broken skin.
16. The device should be kept out of the reach of children.
17. The device should be used only with the leads and electrodes recommended for use by the manufacturer.
18. Do not use in the bath or shower. The device should not be submerged in water or other liquids as this will possibly damage the device and startle the patient.
19. The use of heat and cold producing devices, such as electric heating blankets, heating pads or ice packs, may impair the performance of the electrodes or alter the patient’s circulation and increase the risk of injury to the patient.
20. The Delta should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk for injury.

2.3 Warning

⚠️ Warning

1. Care must be taken when operating this equipment around other equipment.
2. Potential electromagnetic or other interference may occur to either this device or to the other equipment, or both. Minimize this interference by not using this device in conjunction with the other equipment.
3. This device may not be used in close proximity (i.e. less than 2 meters) to short-wave equipment.
4. Avoid exposure to direct sunlight, rain, excessive dust, moisture, mechanical vibrations and shocks.
5. This device may not be used in so-called “wet rooms” (hydrotherapy rooms).
6. Before administering any treatment, you should become acquainted with the operating procedures for each program of treatment, as well as the indications, contraindications, warnings, and precautions. Consult other resources for additional information regarding the application of electrotherapy and ultrasound.
7. Do not use solvents to clean this device.
8. Do not use this device if it is damaged in any way.
9. This device must only be serviced, repaired and opened by individuals at authorized sales centers.
10. Dispose of this device in accordance with local regulations. Keep the operating instructions with the device.
11. Pregnant and nursing women should use caution when using the device.
12. Avoid use over or near bone growth centers until bone growth is complete.
13. Treatment time should not exceed 30 minutes a day.
14. Do not use a cell phone while operating the device.
15. Patients with sensitivity to the coupling gel should use caution when using the device.
16. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
17. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
18. Stimulation should not be applied trans-cerebrally (across the head), over the carotid sinus (where the jaw meets the neck), over metal implants or in conjunction with sleep apnea or heart monitors.
19. Stimulation should not be applied transthoracically. Since the introduction of electrical current into the heart may cause cardiac arrhythmias.
20. Stimulation should not be applied to swollen, infected or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
21. Stimulation should not be applied over, or in proximity to, cancerous lesions.
22. Always keep the ultrasound head in constant motion.
23. Use ample conductive gel with the ultrasound head to ensure good coupling throughout the treatment. If needed, apply more when setting intensity.
24. Consult your doctor or physiotherapist if you are in any doubt whatsoever.
2.4 Danger

Danger

Patients with an implanted neurostimulation device must not be treated with or be in close proximity to any shortwave diathermy, microwave diathermy, therapeutic ultrasound diathermy, or laser diathermy anywhere on their body. Energy from diathermy (shortwave, microwave, ultrasound, and laser) can be transferred through the implanted neurostimulation system, can cause tissue damage, and can result in severe injury or death. Injury, damage, or death can occur during diathermy therapy even if the implanted neurostimulation system is turned “off.”

Biohazardous materials

Handle, clean, and dispose of components and accessories that have come in contact with bodily fluids according to national, local, and facility rules, regulations, and procedures.

2.5 Adverse reaction

- Skin irritation, inflammation, and electrode burns beneath the electrodes are potential adverse reactions.
- Perform the following procedures to avoid the negative effects of ultrasound therapy.

Applicator Movement

If movement of the applicator is too slow, the patient may feel periosteal pain characterized by a deep ache or pain. If motion is too fast, or if the applicator does not maintain good contact with the skin, the therapeutic effect of the sound waves will be reduced and the applicator may overheat.

Patient Susceptibility

Some patients are more sensitive to ultrasound output and may experience a reaction similar to a heat rash. Be sure to inspect the treatment area during and following treatment, and discontinue if an adverse reaction occurs.

Coupling

Coupling is described as contact between the applicator and the treatment site and may be accomplished through the use of a coupling agent, such as gel or lotion. Anything used as a coupling agent must be highly conductive. Air is a very poor conductor of ultrasonic waves.
3. INTENDED USE

Delta is a Portable Ultrasound and TENS combo device that generates ultrasound waves and deep TENS (transcutaneous electrical nerve stimulation) within body tissues, it is designed for the treatment of selected medical conditions such as symptomatic relief of chronic intractable pain, post-traumatic pain and post-surgical pain, muscle spasms, and joint contractures. Not recommended for the treatment of malignancies.

4. CONTRAINDICATIONS

1. Do not use over or near bone growth centers (epiphyseal discs) until bone growth is complete.
2. Do not use over a healing fracture.
3. Do not use over the eyes.
4. Do not use over the heart.
5. Do not use over brain tissue.
6. Do not use on patients with demand type cardiac pacemakers.
7. Do not use on someone who is pregnant.
8. Do not use on testicles.
9. Do not use on patients post laminectomy.
10. Do not use on areas of the body that lack sensation.
11. Do not use on areas of post-traumatic sequelae.
12. Do not use if the patient has an endoprosthesis / metal implants.
13. Do not use on patients with implanted neurostimulation systems.
14. Do not use to treat malignancies nor in the region where tumors or malignant tumors are present.
15. Do not use on patients who have thrombophlebitis and/or varices.
16. Do not use on patients experiencing septic inflammation.
17. Do not use on patients who have diabetes mellitus.
18. Do not use on patients who have osteoporosis.
19. Do not use over ischemic tissues in patients with vascular disease where the blood supply would be unable to follow the increase in metabolic demand.
20. Do not use over the carotid sinus nerves or arteries, laryngeal or pharyngeal muscles.
21. Do not use on patients with hemorrhagic diatheses (excessive bleeding disorders).
22. Do not use over an area of the spinal cord following a laminectomy.
23. Do not use over areas that are under anesthesia.
24. Do not use on acute injuries
25. Do not use on open wounds.
26. Do not use if patient is feverish (pyrexia).
27. Do not use on patient with tuberculosis.
28. Do not use on patients who have localized inflammation.

5. PRESENTATION

![Diagram of device with labels](image)

1. TIME LED: indicates treatment times of 5 minutes, 10 minutes and 15 minutes
2. MODE LED: indicates intensity of the ultrasound Low (L), Medium (M) and High (H)
3. TIME button: Adjusts treatment times to either 5 minutes, 10 minutes and 15 minutes
4. MODE button: Adjusts the ultrasound intensity: Low, Medium and High
5. “+” button: Increases the intensity of stimulation
6. “−” button: Decreases the intensity of the stimulation
7. STIM LED: indicates the stimulation output state – when illuminate the stimulation is on.
8. PWR LED: indicates power state
9. On/Off switch: Power on by shifting up or power off by shifting down
6. INSTALLATION

6.1 Before Use

Remove the device and all accessories from box. Inspect the device for damages or missing parts and/or accessories. Report any damage or missing parts or accessories to your local dealer or retailer from which you purchased this device. The case contains the following accessories.

<table>
<thead>
<tr>
<th>Part</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Us Delta</td>
<td>1 PC</td>
</tr>
<tr>
<td>Operating instruction</td>
<td>1 PC</td>
</tr>
<tr>
<td>Electrode 50 x 100mm</td>
<td>1PC</td>
</tr>
<tr>
<td>Lead wire</td>
<td>1 PC</td>
</tr>
<tr>
<td>Adapter 100-240V 50/60 Hz, 1.2A</td>
<td>1 PC</td>
</tr>
<tr>
<td>Ultrasound transmission gel (85g)</td>
<td>1 PC</td>
</tr>
<tr>
<td>Quick Start Guide</td>
<td>1 PC</td>
</tr>
</tbody>
</table>

6.2 Connection

- Prior to connecting this device to the power supply, verify that the voltage and frequency stated on the rating label match the available power supply.
- The power adapter is a part of the supply circuit on which the device’s safety depends on. The approvals for the Delta are only valid if used in combination with this type of adapter we provide.

⚠️ Caution It is not permitted to connect Delta to any other type of adapter other than adapter we provide.

⚠️ Caution: Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and the proper function of the equipment; therefore, it is not permitted.
6.3 Connection of the power adapter

- Connect the power adapter to the device’s power cord.
- Connect the power adapter to the wall outlet.

6.4 Therapy modes

Delta offers 2 treatment modes:
- Combination: Ultrasound + Electrical Stimulation therapy
- Ultrasound: Ultrasound therapy

6.5 Disconnect from power adapter

- Power off the unit by switching power on/off switch from “ON” to “OFF” position.
- Remove the power adapter from the wall outlet.

7. OPERATION

7.1 Measures with regards to treatments

**Before treatment**
- Ensure there are no contraindications to treatment.
  - Clean the skin of the treatment area with soap or alcohol (70%).
- If the skin has excess hair, trim or shave hair for optimal treatment.
- Apply a liberal amount of ultrasound transmission/conductive gel to the treatment area. Use only the ultrasound gel with CE mark.
- Ultrasonic Action Function Test:
  Place the probe horizontally, then apply several water drops on the surface of the probe, turn the device on and press the time button to activate the ultrasound device. You will be able to observe the ultrasonic action as the water droplets will appear to be dancing on the sound head and you may notice a slight “steam” being released. The water droplets on the probe start to perform one million vibrations per second showing the atomization phenomenon.

**During treatment**
- Move the ultrasound-head in a circular motion. The area treated should be two times the diameter of the applicator.
1. Apply Transmission Gel
Apply a layer of ultrasound transmission gel on the treatment area. The gel acts as a coupling substance and ensures effectiveness. The area treated should be two times the diameter of the treatment head.

**Caution**
The ultrasound-head should be moved in a slow, flat, circular motion over the skin surface of the treatment area. Apply the sound head evenly (in time) over the treatment area - not too slow to avoid inducing heat; not too fast to prevent bad contact which would reduce the effectiveness of the treatment.

**After treatment**
- Clean the contact surface immediately after each treatment. Make sure that no ultrasound gel remains on the treatment head. We recommend cleaning the head and cable daily, using lukewarm water – do not immerse the device in water.
- The treatment heads can be disinfected using a cloth moistened with 70% alcohol.
- Check if there are any signs of improvement (e.g. pain, circulation or mobility).

7.2 Operating the device

7.2.1 Ultrasound therapy

1. Apply Transmission Gel
Apply a layer of ultrasound transmission gel on the treatment area. The gel acts as a coupling substance and ensures effectiveness. The area treated should be two times the diameter of the treatment head.

**Caution:** Never apply the gel to the applicator. The applicator will register this as contact and may emit ultrasound energy, which could damage the applicator.

2. Switch on the device
Connect the power adapter according to section 6.3. Switch on the device, using power on/off switch by switching from “OFF” to “ON” position. The LED of power will be light.
3. Adjusting intensity
Press the “MODE” button to select the ultrasound intensity. The intensity has three levels, Low (L), Medium (M) and High (H), each level corresponds to a light indicator.

4. Adjusting treatment time
Press the “TIME” button to cycle through the treatment time (5, 10 and 15 minutes), as shown by the “TIME” indicators. When the time is chosen, the system will start working. During working time, the user can press the “TIME” button to adjust the treatment time.

5. Start treatment
Move the treatment head in a flat, slow, circular motion over the skin surface treatment area that is covered with a layer of ultrasound transmission gel. Apply the sound head evenly (in time) over the treatment area.

Caution:
• The device has a load detection system for safety. When the treatment head does not have good contact with the skin, the device will stop treatment automatically. During this time, the TIME LED will flash slowly (1Hz). The device will not restore treatment until the contact is good.
• The device has a temperature protection function. When the temperature of the treatment head exceeds 107 °F (42 °C) the treatment will automatically stop and the TIME LED will flash quickly (2Hz). The device will not restore treatment until the temperature is below 104 °F (40 °C).

6. Turn off the device
After the time duration has been completed, the device will automatically revert back to standby state. Once your therapy session has been completed, turn off the product by sliding the Power switch downwards from “ON” to the “OFF” position.
7.2.2 Combination therapy

1. Connect the lead wire and electrode pad to the unit as shown by the pictures at the right.
   - Plug the lead wire into the connection point attached to the device,
   - Connect the electrode pad with the lead wire.
   - Make sure all connections are securely in place.

⚠️ Caution: The device must be turned off before connecting the lead wires to the device.

2. Place electrode firmly on the skin after cleaning and drying the treatment area.
   - Place the electrode pad on the area of the body indicated by your physician or therapist.
   - Make sure the electrode pad is placed firmly to the skin and has made good contact between the skin and the pad.

3. Apply Transmission Gel
   Apply a layer of ultrasound transmission gel on the treatment area. The gel acts as a coupling substance and ensures treatment effectiveness. The area treated should be two times the diameter of the treatment head.

⚠️ Caution: Never apply the gel to the applicator. The applicator will register this as contact and may emit ultrasound energy, which could damage the applicator.

4. Switch on the device
   Connect the power adapter according to section 6.3.
   Switch on the device, using power on/off switch by switching from “OFF” to “ON” position. The LED of power will be light.
5. Adjust ultrasound intensity
Press “MODE” button to select ultrasound intensity within low, middle and high. The LED will be lighted to indicate the intensity which you selected.

6. Adjust treatment time
Press the “TIME” button to cycle through the treatment time (5, 10 and 15 minutes), as shown by the “TIME” indicators. When the time is chosen, the system will start working. During working time, the user can press the “TIME” button to adjust the treatment time.

7. Adjust stimulation intensity
Press the “+” button to increase the intensity of the stimulation. Press the “-” button to decrease the intensity of the stimulation. The STIM LED will flash every time the “+” or “-” button is pressed.

**Remark:** There are two colors of Stim LED for indicate the output intensity of stimulation.
Green light: Output intensity < 10V;
Orange light: Output intensity ≥ 10V.

⚠️ **Caution:**
- a) The electrical stimulation cannot work without the ultrasound output. So users can only adjust the stimulation intensity after the ultrasound works properly.
- b) If the stimulation level is uncomfortable or becomes uncomfortable, reduce the stimulation intensity to a comfortable level and contact your medical practitioner if problems persist.
- c) Move the ultrasound treatment head while you are adjusting the stimulation intensity to prevent the local skin temperature from becoming too high or burning.
- d) Each step of increase output intensity is 1V when the output intensity less than 5V; 0.5V/step when the output intensity over 5V.
8. Start treatment

Move the treatment head in a flat, slow, circular motion over the skin surface treatment area that is covered with a layer of ultrasound transmission gel. Apply the sound head evenly (in time) over the treatment area.

⚠️ Caution:

- The device has a load detection system for safety. If the electrode pad or the ultrasound treatment head do not have good contact with the skin, the STIM LED and TIME LED will flash and stop treatment after the output intensity of stimulation surpasses 5V. The intensity will automatically but slowly increase to setting level after the pad and treatment head have made good contact with the skin.
- The device has a temperature protection function. When the temperature of the treatment head exceeds 107°F (42°C) the treatment will automatically stop and the TIME LED will flash quickly (2Hz). The device will not restore treatment until the temperature is below 104°F (40°C).
- The device works without vibration. You must move the applicator with a slow but deliberate speed, flat against the treatment area and in a circular motion around the treatment area. After finishing the treatment, the device will enter the waiting state. It is not recommended that the user restart treatment upon completion of therapy.

9. Turn off the device

After the time duration has been completed, the device will automatically revert back to standby state. Once your therapy session has been completed, turn off the product by sliding the Power switch downwards from “ON” to the “OFF” position.

7.3 The applicator

The applicator is a precision instrument. Great care is taken in the development and production in order to obtain the best possible beam characteristics. Rough treatment (jarring or dropping) can adversely affect these characteristics, and must therefore be avoided.
8. MAINTENANCE

8.1 Cleaning of the device

Switch off the device and disconnect it from the power supply. The device can be cleaned with a damp cloth. Use lukewarm water and a non-abrasive liquid household cleaner (no abrasive, no alcohol content solution). If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.

⚠️ Caution: Do not submerse the device in liquids. Should the unit accidentally become submersed, contact the dealer or Authorized Service center immediately. Do not attempt to use the device that has been submersed in any liquid substrate until inspected and tested by a Service Technician Certified by an Authorized Service center. Do not allow liquids to enter the ventilation holes.

8.2 Cleaning of the applicator

The applicator should be regularly inspected for damage, e.g. hairline cracks, which could allow the penetration of liquids. Clean the contact surface immediately after each treatment. Make sure that no ultrasound gel remains on the applicator. We further recommend cleaning the head and cable daily, using lukewarm water. The applicator can be disinfected using a cloth moistened with 70% alcohol.

8.3 Cleaning the lead wire and adapter

Periodically wipe the lead wire and adapter clean with a cloth dampened with a mild soap solution, and then gently wipe them dry. Use of rubbing alcohol on the lead wire will damage the insulation and dramatically shorten their life.

8.4 Cleaning the electrode pad

1. Switch the power off and remove the pad from the skin and the lead wire.
2. Wash the pad when the adhesive surface becomes dirty and/or the pad is difficult to attach to the skin.
   • Wash the pad softly with your fingertips under slow running cold water for several seconds (do not use a sponge/cloth/sharp object like a nail on adhesive side, do not use detergents, chemicals or soap).
3. Dry the pads and let the adhesive surface air-dry completely (do not wipe with a tissue paper or cloth).
4. Replace the pad on the clear plastic film and store in plastic bag.
CAUTION:

1. The life of the electrode pad may vary by the frequency of washing, skin condition, and storage state.
2. If the electrode pad no longer sticks to your skin or the electrode pad is broken, you should replace with a new electrode pad.
3. Before applying the electrode pad, it is recommended to wash and degrease the skin, and then completely dry the area.
4. Do not turn on the device when the electrode pad is not positioned on the body.
5. Never remove the electrode pad from the skin while the device is still powered on.
6. If replacement electrode is necessary, use only electrode pads that are 2 inch x 4 inch (50*100mm), the same as the electrode pad provided with the Delta device.
7. Use of electrode pads larger than provided may reduce the effect of the stimulation. Use of an electrode pad that is much smaller than the electrode pad provided with Delta device may increase the chance of skin irritation or electrode burns occurring under the electrode pad.
8. Always use electrode pads that CE marked.

### 9. TROUBLESHOOTING

NOTE: If the following measures fail to alleviate the problem, please call your authorized agency or supplier.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible causes</th>
<th>Possible solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>LED fails to light up</td>
<td>Adapter contact failure</td>
<td>Ensure adapter is connected. Check the following contacts: • All contacts are in place. • All contacts are not broken.</td>
</tr>
<tr>
<td>Electrical stimulation weak or cannot feel any stimulation</td>
<td>Electrode pad dried out or is contaminated</td>
<td>Replace with new electrode pad</td>
</tr>
<tr>
<td></td>
<td>Electrode pad does not stick to skin well</td>
<td>Reconnect the electrode pad</td>
</tr>
<tr>
<td></td>
<td>Lead wire Old/worn/damaged</td>
<td>Replace new lead wire</td>
</tr>
<tr>
<td></td>
<td>Electrical stimulation intensity is low</td>
<td>Increase the output intensity</td>
</tr>
<tr>
<td></td>
<td>Intensity is too high</td>
<td>Decrease intensity</td>
</tr>
</tbody>
</table>
## 10. SPecifications and Technical Data

### 10.1 Technical data of Ultrasound

- **Frequency:** 1MHz ± 10%
- **Ultrasound power control (MODE):** 3 intensity levels (L, M, H)
- **Output power:** 3W(L), 4W(M), 5W(H)
- **Pulse repetition rate:** 100Hz ± 10%
- **Duty factor:** 30%, 40%, 50%
- **Effective radiating area (A_{ER}):** 4.0cm²
- **R_{BN} (Max.):** 5.0
- **Beam type:** Collimated
- **Waveform:** Pulsed
- **Treatment time:** 5min, 10min, 15min
- **Material of treatment head:** Aluminum

### 10.2 Technical data of Electrical Stimulation

- **Treatment time:** 5min, 10min, 15min
- **Carrier Frequency (C.F.):** 2.5kHz
- **Beat Frequency:** 1-120Hz
- **Output voltage:** 0~1.5V (500 Ω Load)
- **Stim power control:** 25 intensity levels
10.3 Technical data of Delta main device

Safety class: Class II, BF-type
Dimension: 209mm(L)x53mm(W)x89mm(H)
Weigh: 235g

10.4 Technical data of power supply

Supply voltage: 100V~240V
Frequency: 50Hz~60Hz
Output voltage: 15V DC
Output current: 1.2A
Dimensions: 64mm(L)x50mm(W)x26.5mm(H)
Weight: 120g

10.5 Environmental conditions

Operating conditions:
Temperature: 5~40 °C
Relative humidity: 30%~75%
Atmospheric pressure: 700~1060hPa

Storage and transportation conditions:
Temperature: -10~50 °C
Relative humidity: 10%~90%
Atmospheric pressure: 700~1060hPa
11. STORAGE

For a prolonged pause in treatment, place the unit with the adapter, lead wire, electrode pad and manual back in the case. Store it in a dry room and protect it against heat, sunshine and moisture. Store the machine in a cool, well-ventilated place according to the storage condition on page 21. Never place any heavy objects on the machine.

12. DISPOSAL

Fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose of batteries correctly.

Please dispose of the device in accordance with the legal obligation in your area.

13. IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

1. The device needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information supplied in this manual.
2. Care must be taken when operating this device adjacent to or stacked with other equipment. Potential electromagnetic or other interference could occur to this or other equipment. Try to minimize this interference by not using other equipment in conjunction with it.
3. The performance of the device was determined to be essential performance. This device has been thoroughly tested according to tested and inspected to assure proper performance and operation!
### Guidance and manufacturer’s declaration - electromagnetic emissions

The Delta device is intended for use in the electromagnetic environment specified below. The customer or the user of the Delta should assures that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The Delta device 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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td>The Delta device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Applicable</td>
<td></td>
</tr>
</tbody>
</table>

### Guidance and manufacturer’s declaration — electromagnetic immunity

The Delta device is intended for use in the electromagnetic environment specified below. The customer or the user of the Delta should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV contact ±8 kV air</td>
<td>±6 kV contact ±8 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td>
</tr>
<tr>
<td>Electrical fast transient/burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV line (s) to line (s)</td>
<td>±1 kV line (s) to line (s)</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</td>
<td>&lt;5% U_I (&gt; 95% dip in U_I) for 0.5 cycle 40% U_I (60% dip in U_I) for 5 cycles 70% U_I (30% dip in U_I) for 25 cycles</td>
<td>&lt;5% U_I (&gt; 95% dip in U_I) for 0.5 cycle 40% U_I (60% dip in U_I) for 5 cycles 70% U_I (30% dip in U_I) for 25 cycles</td>
<td>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 needed that the device be powered from an uninterruptible power supply.</td>
</tr>
</tbody>
</table>
\[ d = 1.2\sqrt{P}, \text{80MHz to 800MHz} \]
\[ d = 2.3\sqrt{P}, \text{800MHz to 2,5GHz} \]
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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 V rms 150 kHz to 80 MHz</td>
<td>3 V rms</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Delta device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td></td>
</tr>
</tbody>
</table>

\[ d = 1.2\sqrt{P} \]
\[ d = 2.3\sqrt{P}, \text{800MHz to 2,5GHz} \]
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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

- **NOTE 1**: At 80 MHz ends 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.
- Field strengths from fixed 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...

<table>
<thead>
<tr>
<th>Table 3</th>
</tr>
</thead>
</table>

**Guidance and manufacturer’s declaration. Electromagnetic immunity**

The Delta device is intended for use in the electromagnetic environment specified below. The customer or the user of the Delta should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
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<td>3 V/m</td>
<td></td>
</tr>
</tbody>
</table>

\[ d = 1.2\sqrt{P} \]
\[ d = 2.3\sqrt{P}, \text{800MHz to 2,5GHz} \]
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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

- **NOTE 1**: At 80 MHz ends 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.
- Field strengths from fixed 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...

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environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Delta device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Delta.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

<table>
<thead>
<tr>
<th>Separation distance according to frequency of transmitter m</th>
<th>Rated maximum output power of transmitter W</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>d=1.2√P</td>
<td>d=1.2√P</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
</tr>
<tr>
<td>10</td>
<td>3.69</td>
</tr>
<tr>
<td>100</td>
<td>11.67</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.
14. WARRANTY

Please contact your dealer or the device center in case of a claim under the warranty. If you have to send in the unit, enclose a copy of your receipt and state what the defect is.

The following warranty terms apply:

1. The warranty period for Delta products is one year from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Defects in material or workmanship will be removed free of change within the warranty period.
3. Repairs completed under warranty do not extend the warranty period either for the unit or for the replacement parts.
4. The following is excluded from the warranty:
   • All damage which has arisen due to improper treatment, e.g. non-observance of the user instruction.
   • All damage which is due to repairing or tampering by customer or unauthorized third parties.
   • Damage which has arisen during transportation from the manufacturer to the consumer or to the service center.

15. DESCRIPTION OF SYMBOLS

Complies with the European Medical Device Directive (93/42/EEC) and amended by directive 2007/47/EC requirements. Notified body TÜV Rheinland (CE0197)

Only for Ultrasonic head: Protected against the effects of temporary immersion in water

Keep dry

Class II symbol
Symbol for protection against electric shock: Type BF

Please refer to instruction manual because of the higher levels of output.

Disposal in accordance with Directive 2012/19/EU (WEEE)

Date of manufacture

Batch code and series number

The name and the address of the manufacturer

The name and the address of the Authorized EC-representative in Europe