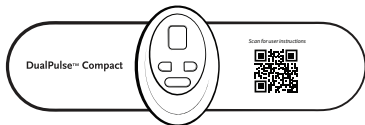




# DualPulse™ Compact

## Model: DPC

**Manufactured by: ManaMed LLC**  
**Distributed by: Össur Americas, Inc**



# Instructions for Use

(Version: V1.1)

*Össur Americas, Inc*



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## 1. SAFETY GUIDE

### 1.1 Warnings

#### **DO NOT USE THIS DEVICE UNDER THESE CONDITIONS**

- You should consult your physician when starting any new treatment, including the use of this device.
- This device must not be used on persons with cardiac pacemakers, implanted defibrillators, other implanted metallic or electronic devices. Such use could cause electric shock, burns, electrical interference, or death.
- The long-term effects of chronic electrical stimulation are unknown.
- MR Unsafe – keep away from magnetic resonance imaging (MRI) equipment.
- Implanted with a life-supporting medical electronic device such as an artificial heart or lung or respirator.
- In the presence of electronic monitoring equipment (e. g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- Do not use on open wounds, rashes, swollen, red, infected or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); On top of, or in proximity to, cancerous lesions.
- Over areas of damaged skin, scratched areas or blisters.
- Do not apply the electrode to your head, face, the front and sides of the neck, the throat, or on both sides of the thorax at the same time.
- Stimulation over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Do not directly stimulate over the front of your neck or mouth. This could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

## 1. SAFETY GUIDE

### 1.1 Warnings (continued)

- Do not place electrode directly over the heart. Electrical current into the heart may cause cardiac arrhythmias.
- TENS is not a substitute for pain medications and other pain management therapies.
- TENS devices have no curative value.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.

### **DO NOT USE ON THESE INDIVIDUALS**

- Adolescent, children or infants, because the device has not been evaluated for pediatric use.
- Persons incapable of expressing their thoughts or intentions.

### **DO NOT USE THIS DEVICE DURING THESE ACTIVITIES**

- When in the bath or shower;
- Before sleep, always set timer so the device will turn off when treatment is over.

### **WARNINGS / PRECAUTIONS REGARDING THE ELECTRODE**

- Apply electrode to normal, healthy, dry clean skin only. Do not apply electrode onto wound or damaged skin because it will be painful and may disrupt the healing process.
- If you experience any skin irritation or redness after using this device, do not continue stimulating in that area until skin has returned to normal.

# 1. SAFETY GUIDE

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## 1.2 Precautions

- Caution: Federal law restricts this device to sale by or on the order of a doctor.
- If you feel abnormal symptoms during the treatment, please stop using the unit and consult a doctor before resuming treatment.
- During the treatment, if you wish to move the electrodes to another part of your body, switch OFF the unit first, and then move the electrodes before resuming treatment.
- If you have any problems on setting, maintaining or using this device, please contact Össur Americas, Inc or customer service. Please report to Össur Americas, Inc if the device malfunctions. Don't open or repair the device by yourself.
- Dust may affect the performance of the unit, please use a soft cloth to clean the device as needed.
- Please use the device according to the requirement of the User's manual, otherwise the effectiveness of the device will be affected.
- Please keep the device from the reach of infants, children or pets, inhalation or swallowing of small parts is dangerous and can be potentially fatal.
- Please use accessories that are specified/authorized by manufacturer only. The use of unauthorized accessories may cause damage to the unit or danger to the operator/patient.
- If you are allergic to plastic, please don't use this device.
- Long cables have the potential to strangulate, therefore, please be careful when using cables around the neck and shoulder areas.
- Do not fold the electrode, this may cause the electrode to not function properly. Store the electrode on the plastic pad holder or on the protective clear plastic sheet when not in use.

## 1. SAFETY GUIDE

### 1.2 Precautions (continued)

- Do not apply ointment or any solvent to the electrode or to your skin because it will cause the electrode to not stick and function properly. The electrode are already pre-gelled and will adhere to your skin when moist.
- Do not use the unit in areas of high humidity, such as the bathroom or in the shower as this may cause damage to the unit.
- During treatment ensure that metallic items with conductive capabilities such as necklaces, belts, rings etc. are kept away from the electrodes.
- Make sure the electrode are stuck tightly on the skin area where you wish to treat to ensure effective therapy. Loose electrodes on the skin can cause uncomfortable pins and needle sensations.
- Simultaneous connection of a patient to this device and a high frequency surgical equipment may result in burns at the site of electrodes and possible damage to the device.
- Do not share electrode with another person. This may cause a skin irritation or skin infection. Individuals should have their own set of electrodes for personal use.
- Do not leave electrode attached to the skin after treatment.
- Do not use the unit in the presence of a flammable anesthetic gas mixture, compressed Oxygen or Nitrous Oxide.
- If the unit is not working properly or you feel uncomfortable during use, stop the treatment.
- Do not use for any other purpose other than the intended use.
- Do not use the device while wearing other electronic devices.
- Do not use while operating a vehicle.
- Dispose of the device and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.

## 1. SAFETY GUIDE

### 1.2 Precautions (continued)

- If you have diagnosed heart disease or have any heart problem, you should follow precautions recommended by your physician.
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Do not use the device in the presence of the following:
  - a. When there is a tendency to hemorrhage following acute trauma or fracture.
  - b. After surgery because stimulation may disrupt the healing process.
  - c. Over areas of the skin that are damaged, cut, with rash or blistered;
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrically conductive medium (gel).
- The stimulation settings should be based on your needs and comfort level.
- Should be used only with the leads and electrodes recommended for use by the manufacturer. Always follow instructions on electrode placement.
- Caution should be used in the presence of the following:
  - Over the menstruating or pregnant uterus; and
  - Over areas of the skin which lack normal sensation.

### 1.3 Contraindications

For the following patients, they should not use this device:

- Patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.
- Patients whose pain syndromes are undiagnosed.

## 1. SAFETY GUIDE

### 1.4 Adverse Reactions

- Person with highly sensitive skin may experience skin irritation with the electrodes.
- You may experience uncomfortable pins and needle sensations during the treatment if the electrode is sticking loosely on the skin, or if the electrodes lack moisture and does not stick properly to the skin. If you experience any unexpected negative reactions with the treatments, stop using the device and consult with your physician first before resuming treatments.

### 1.5 Intended Use / Indications for Use

#### **Mode 2: TENS (Transcutaneous Electrical Nerve Stimulation):**

DualPulse™ Compact is intended for the following use:

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

#### **Mode 1: PMS/NMES (Neuromuscular Electrical Stimulation):**

DualPulse™ Compact is intended for the following use:

- Temporary relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Muscle re-education
- Maintaining or increasing range of motion
- Increase of local blood flow in the treatment area
- Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles

## 2. DEVICE DESCRIPTION

### 2.1 General Description

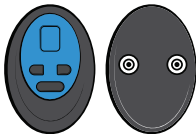
DualPulse™ Compact delivers electric pulse generated to the user's body areas through the electrodes. The device has multiple program modes of different pulse frequencies, covering TENS and PMS/NMES. The main unit is egg shape, includes operating elements, such as the ON/OFF button, intensity increase button and intensity decrease button, and there are two snap connectors on the rear of the device which are for connecting with the electrode. The device could be easily operated through its buttons to manually realize its functions, such as turning on/off and increasing/decreasing intensity, and there is a LED screen to display the selected mode, intensity level, and charging status.

The electrode is a long strip shape with a size of 21 cm x 5.3 cm, its conductive part is black color, and there is white non-conductive area with a width of 1 cm in the middle, which divides the electrode into two parts: positive and negative. There are 2 snap connectors on the white area of the electrode used for connection with the main unit and 2 snap connector receivers on the main unit. The conductive part consists of conductive hydrogel and connecting wire, it contacts with skin directly and delivers electrical stimulation signal generated by main unit to the skin. The model DPC is for RX use.

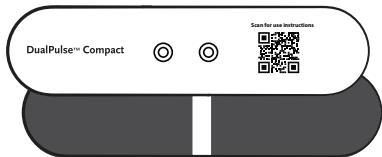
## 2. DEVICE DESCRIPTION

### 2.2 Device Drawing

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*DualPulse™ Compact Main Unit (Qty: 1)*



*Electrode (Qty: 1)*



*USB Cable (Qty: 1)*

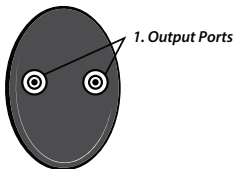


*Adaptor (Qty: 1)*

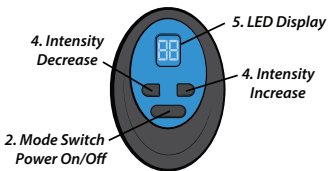
## 2. DEVICE DESCRIPTION

### 2.3 Device Components

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*2.3 1 Rear view of the main unit*



*2.3 2 Front view of the main unit*

## 2. DEVICE DESCRIPTION

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### 2.4 Specifications

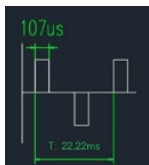
Basic Specifications	
Power Source	DC3.7V, 120mAh rechargeable lithium battery
Method of Line Current Isolation	Type BF Applied Part
Patient leakage current	Comply with IEC 60601-1 and IEC 60601-2-10
- Normal Condition	< 10 $\mu$ A
- Single Fault Condition	< 50 $\mu$ A
Average DC current through electrodes when device is on but no pulses are being applied	< 0.01 $\mu$ A
Dimensions	Main unit:59.8* 40*14.4mm Electrode: 210mm*53mm
Weight	Main Unit: 17.8g Electrode Pad: 16.8g
Patient contacting material	ABS plastic Conductive hydrogel
Indicator Display	Intensity level, mode
Specification of Main Unit	
Number of channels	1
Number of modes	2
Output Intensity Level	19 steps
Time Range (minutes)	30 mins
Waveform and Shape	Pulsed, symmetric biphasic, rectangular
Maximum Output Voltage	45V $\pm$ 10% @ 500 $\Omega$ , 80V $\pm$ 10% @ 2K $\Omega$ , 130V $\pm$ 10% @ 10K $\Omega$
Maximum Output Current	90 mA $\pm$ 10% @ 500 $\Omega$ , 40mA $\pm$ 10% @ 2K $\Omega$ , 13mA $\pm$ 10% @ 10K $\Omega$
Net Charge (per pulse) @ 500 $\Omega$	0 $\mu$ C @ 500 $\Omega$ , Method: Balanced waveform
Maximum Phase Charge	9.6 $\mu$ C @ 500 $\Omega$
Average Current	1.93 mA @ 500 $\Omega$
Maximum Current Density	0.036 mA/cm <sup>2</sup> @ 500 $\Omega$
Maximum Average Power Density	0.035 mW/cm <sup>2</sup> @ 500 $\Omega$
Pulse Duration	107 $\mu$ s
Pulse Cycle	10~28.57ms
Frequency	35~100Hz
Additional Features	
Environment for operation	Temperature: 5°C ~ 40°C, Humidity: $\leq$ 70%, Atmospheric pressure: 86 kPa~106 kPa
Environment for storage	Temperature: -20°C~+55°C, Humidity: $\leq$ 80%, Atmospheric pressure: 50 kPa~106 kPa

## 2. DEVICE DESCRIPTION

### 2.4 Specifications (continued)

#### Treatment Mode Specifications

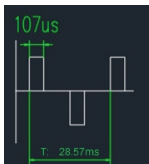
##### Mode 1 Pulse Duration and Pulse Cycle 1



$$f=45\text{Hz}, T1=22.22\text{ms}$$

Note: "T" means Pulse Cycle

##### Mode 1 Pulse Duration and Pulse Cycle 2



$$f=35\text{Hz}, T2=28.57\text{ms}$$

Note: "T" means Pulse Cycle

##### Cycle of Mode 1

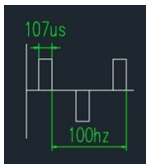


## 2. DEVICE DESCRIPTION

### 2.4 Specifications (continued)

#### Treatment Mode Specifications

##### Mode 2 Pulse Duration and Pulse Cycle



$$T1 = 1/f = 1/100 = 10\text{ms}$$

Note: "T" means Pulse Cycle

##### Cycle of Mode 2

50T1





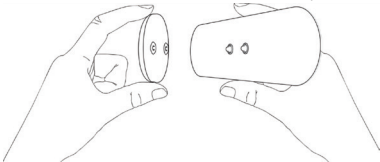
Scan with phone camera for user instructions or continue below with Step 1.

#### **Step 1: Charging**

Charge the main unit with the included adaptor. It takes about 1.5 hours to charge the main unit from low battery to fully charged. After it is fully charged, the device can be used for approximately 2 - 2.5 hours. The device cannot be turned on when charging.

#### **Step 2: Connect electrode to the unit**

Connect the electrode to the main unit with the snap connector.



#### **Step 3: Electrode placement**

Remove the protective film on the electrode and place electrode on clean, dry and healthy skin near the area with pain. Placement locations of the electrode include: shoulder, back, waist, arm, leg, abdomen and buttocks. Contact your medical provider for optimal electrode placement to find which placement best fits your needs.

### 3. USER INSTRUCTIONS

#### Step 4: Operation (continued)

##### 1. Turn on

Briefly press the power button to turn on the device. When booting, the character "1" is displayed, indicating the current mode is Mode 1 (NMES), and the character "0" is displayed after 1 second, indicating that the intensity is 0.

##### 2. Selection for treatment mode

After the device is turned on, briefly press the power button to switch between Mode 1 (NMES) and Mode 2 (TENS).

When switching modes, the corresponding mode "2" will be displayed, and the intensity "0" will be displayed after 1 second. If the mode is switched again, the mode "1" will be displayed, and the intensity "0" will be displayed after 1 second. If there is no key operation, the intensity "0" will always be displayed.

##### 3. Intensity adjustment

Press the "+" button to increase the intensity level from 0 to 19. Press the "-" button to decrease the intensity level from 19 to 0. When changing the intensity, the LED will display the number of intensity level 0-19.

##### 4. Turn off

The treatment time is 30min, after 30min, the device will turn off automatically. You can also turn off the device by long pressing the power button for 1.5 seconds.

### 3. USER INSTRUCTIONS

#### Step 4: Operation (continued)

##### Note:

1. The default working time of 30 minutes is not adjustable, and switching modes does not change the time.
2. The device will automatically shutdown when no load is detected and there is no output after 3 minutes.
3. Select the intensity level that feels right for you. If you want to change the position of the electrode during treatment, turn off the device first before changing the pad position. After you place the electrode onto the new area, then you can turn on the device to start treatment. This procedure helps to avoid potential shock and discomfort.
4. If you want to stop the treatment at any time before the time is up, turn off the device first and then remove the electrode from your skin.
5. The electrode can be reused for 25 times, depending on your skin type and other conditions. Whenever you notice the electrode is not sticking well to your skin, pat the electrode gel with small amount of water by hand (do not wash them with water directly). Pat lightly or shake off excess water, then apply. This will help to restore the stickiness and conductivity of the electrode. If moistening the electrode fails to bring back the stickiness to the electrode, this indicates the electrode needs to be replaced.

#### 3.3 Electrode Guidelines

1. Only use the electrode supplied by the manufacturer; other electrodes may pose a risk of unsuitable electrical characteristics with your DualPulse™ Compact.
2. Do not use the electrode on different individuals, otherwise, skin reaction or cross infection may occur.
3. Always turn power off before removing or repositioning the electrodes.

### 3. USER INSTRUCTIONS

#### 3.3 Electrode Guidelines

4. Make sure the skin has been washed thoroughly before applying the electrodes. Do not clean the skin with alcohol.
5. For better conduction moisten your skin with water before putting the electrode on. Pat lightly or shake off excess water.
6. Apply the whole surface of the electrode firmly to the skin. Do not use electrodes that do not stick properly to the skin or only partially stick to the skin.
7. In case of skin redness under the electrode after stimulation, do not stimulate in the same place until the skin returns to its normal condition.
8. If you need to re-order the electrode, please contact your medical provider or call Össur Americas, Inc at 800-233-6263.

#### 4. CLEANING AND MAINTENANCE

##### 4.1 For Main Unit

Dirt and grime on the device should be wiped with a damp cloth. Use water only, do not use alcohol or other cleaners because they can cause damage to the device.

##### 4.2 For Electrode

To clean the sticky surface of the electrode, spray rubbing alcohol or water lightly on the surface of the electrode. Each person should use their own set of electrodes for best hygiene.

Note:

- Never stick two sections of electrode to each other.
- Keep the electrode clean, and never put them under high temperature and direct sunshine.
- Keep the electrode in the environmental condition:  $5\sim 40^{\circ}\text{C}$ ,  $\leq 95\%\text{RH}$ , when the electrode pad is out of its individual package.

## **4. CLEANING AND MAINTENANCE**

### **4.1 For Electrode (continued)**

- Gently clean the electrode with a moist cloth or use a rubber to remove dust.
- Do not clean the electrode with hot water or any chemical other than rubbing alcohol.
- Do not touch the gel of the electrode with your fingers- it may reduce gel adhesion.
- Place the clear plastic protective film over the sticky surface of the electrode when not in use.

## **5. STORAGE**

Please keep the device out of reach of infants, children or pets. Inhalation or swallowing of small parts is dangerous or even fatal.

Problem	Possible causes	Try this Solution
The stimulation is not felt or the intensity is very weak.	Are both two sections of electrode attached to the body?	Attach both two sections of electrode to the body and make sure the electrode are not touching each other.
	Are the snap connector of the electrode and main unit connect well?	Make sure the snap connectors of electrode and main unit are connected to each other.
	Is the intensity getting weak?	Charge the device, or replace the electrode.
	Is the device low on battery?	Charge the device.
	Whether the gel surface of the electrode is dry or contaminated?	Moisten the gel electrode with a little water. Replace with new electrodes.
	Does your skin have oil or lotion that's preventing the electrode to stick?	Wash your skin with water and try putting the electrode on again.
During the treatment, the unit stops output before the end time.	Check if the batteries have full power. Check to see if the connection between electrode and main unit is loose.	Charge the device. Reconnect the electrode and main unit.
The skin under where places the electrode has turned red and/ or itches or prickles	Check to see whether you are allergic to the electrodes. Do you have any small cut or acne on the skin surface?	Stop using the machine until you ascertain the cause of the skin irritation. Do not put electrodes on recently shaved skin, areas of insect bites, scrapes, acne or any open wounds.
	Is the adhesive surface of electrode dirty or too dry?	Wash adhesive surface of electrode softly with your fingertips for about 3 seconds under slow running water.

## 7. DISPOSAL

1. Dispose of the device in accordance with the laws in your area.
2. The expected service life for the main unit is one year.
3. The electrode can be reused for about 25 times, depending on your skin type and use conditions. Please replace a new electrode when it is not sticky.

## 8. SYMBOL GLOSSARY

For an explanation of symbols, please refer to <https://go.ossur.com/symbols>

## 9. ELECTROMAGNETIC COMPATIBILITY

The DualPulse™ Compact has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

### CAUTION:

Do not use this device simultaneously with devices that have high EMI levels. This device should not be used in environments known for electromagnetic disturbances, strong electric fields, or electromagnetic fields, such as MRI scan rooms, diathermy, electrocautery testing, RFID, and security systems (e.g., electromagnetic anti-theft systems, and metal detectors), and mobile wireless communication devices. The recommendations in the manual should be followed as required in the Electromagnetic Compatibility table. If the device is used carelessly in an unintended environment, turn it off immediately to avoid injury or damage to the device.

## 9. ELECTROMAGNETIC COMPATIBILITY (continued)

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### Manufacturer's declaration - electromagnetic emissions

The DualPulse™ Compact is intended for use in the electromagnetic environments specified below. The customer or the user of the DualPulse™ Compact should assume that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The DualPulse™ Compact uses electric 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	The DualPulse™ Compact 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 61000-3-2	Class A	
Voltage fluctuation / flicker emissions IEC 61000-3-2	$P_{st} \leq 1.0$ ; $P_{it} \leq 0.65$ ; $d_{(t)sec} \leq 0.5$ ; $d_{max} \leq 4\%$ $d_c \leq 3.3\%$	

## 9. ELECTROMAGNETIC COMPATIBILITY (continued)

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### Manufacturer's declaration - electromagnetic emissions

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000 -4-2	± 8 kV for contact discharges ± 2 kV, ± 4 kV ± 8 kV and 15 kV for air discharges	± 8 kV for contact discharges ± 2 kV, ± 4 kV ± 8 kV and 15 kV for air discharges	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000 -4-4	±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.
Surge IEC 61000 -4-5	+0.5kV, +1kV line to line	+0.5kV, +1kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000 -4-11	0%UT 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0%UT 1cycle 70%UT 25/30cycle Signal phase at 0° 0%UT 250/300cycle	0%UT 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0%UT 1cycle 70%UT 25/30cycle Signal phase at 0° 0%UT 250/300cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DualPulse™ Compact requires continued operation during power mains interruptions, it is recommended that the DualPulse™ Compact be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000 -4-8	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.


NOTE  $U_0$  is the a.c. mains voltage prior to application of the test level.

## 9. ELECTROMAGNETIC COMPATIBILITY (continued)

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### Manufacturer's declaration - electromagnetic emissions

The DualPulse™ Compact is intended for use in the electromagnetic environment specified below. The customer or the user of the DualPulse™ should assure 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 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the DualPulse™ Compact, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter.
	6 Vrms in ISM bands between 0,15 MHz and 80 MHz	6 Vrms in ISM bands between 0,15 MHz and 80 MHz	Recommended separation distance
	80 % AM at 1 kHz	80 % AM at 1 kHz	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 meter (m). <sup>b</sup>
Radiated RF	10V/m 80 MHz - 2,7 GHz	10V/m 80 MHz - 2,7 GHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>
IEC 61000 -4-3	80 % AM at 1 kHz 3V/m 80 MHz - 2,7 GHz	80 % AM at 1 kHz 3V/m 80 MHz - 2,7 GHz	Interference may occur in the vicinity of equipment marked with the following symbol:
	80 % AM at 1 kHz	80 % AM at 1 kHz	

## 9. ELECTROMAGNETIC COMPATIBILITY (continued)

### Manufacturer's declaration - electromagnetic emissions

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NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

- a. Field strengths from 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 the DualPulse™ Compact is used exceeds the applicable RF compliance level above, the DualPulse™ Compact should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DualPulse™ Compact.
  
- b. Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3V/m.

## 9. ELECTROMAGNETIC COMPATIBILITY (continued)

### Table: Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	27
450	430-470	GMRS 460, FRS 460	FM $\pm 5$ KHz deviation 1KHz sine	28
710	704-787	LTE 13, 17 Band	Pulse modulation 217 Hz	9
745				
780				
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE 5 Band	Pulse modulation 18 Hz	28
870				
930				
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE 1, 3, 4, 25 Band, UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE 7 Band	Pulse modulation 217 Hz	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

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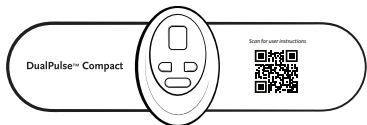


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# DualPulse™ Compact

## Model: DPC

**Manufactured by: ManaMed LLC**  
**Distributed by: Össur Americas, Inc**

*Össur Americas, Inc*