

Innovative
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Classic4

Combination of Electro-acupuncture & TENS/EMS

User's manual

English version 2.3.1

2013

Please read this document first before operating the unit.
Always keep this manual with your Classic4 device.

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Foreword

Thank you for your trust in us in acquiring this Classic4.

Your Classic4 is a high performance electrical stimulator allowing you to set up and control each of its channels independently, in pairs of 2 channels, or in synchronization of all 4 channels. The Classic4 also enables you to run your own sequence of programmes from pre-set.

In order to discover all of its functionalities and operate the Classic4 to its best performance, please read this user manual prior to using the stimulator. Areas covered here include maintenance and troubleshooting information, so please keep it together with the Classic4 unit and refer to its contents regularly.

HMD Europe can only be held responsible for the safety, reliability and performance of the device if:

- The adjustment, modifications and repairs to the device have been carried out by a person approved by HMD Europe.
- The accessories used display the parts numbers shown in the user manual.
- The device is used as described in the user manual.

Important safety instructions

- Do read this instruction manual first to ensure proper operation
- Do keep this manual in a safe place for future reference
- Do not drop this device, and keep it away from water or fluids
- Never use the Classic4 when it is not functioning properly or when it is damaged

WARNING: No modification of this equipment is allowed

Requirements & safety warning

Before using the Classic4 with patients you should have received some training in EA and/or TENS/EMS, know how to set up and use equipment correctly, and feel competent in its use. You should also have familiarised yourself with the Classic4 and this instruction manual.

Your equipment should be thoroughly and regularly checked (at least once each year) to ensure it is performing correctly, and if a device-related adverse incident occurs, you should report this immediately to HMD Europe Ltd.

Finally, ensure that the practice of EA and/or TENS/EMS is covered in your current malpractice and public/products liability insurance policy. If not, you must check with your insurers that additional cover can be provided for these as adjunctive therapy under your policy.

This equipment may be affected by electro-magnetic interference. Also the Classic4 may affect other electrical equipment in the close vicinity. If such effects are suspected either switch off the offending equipment or increase the distance between the affected equipment and that suspected of causing the interference. The device may be sensitive to static discharge, to avoid risks or damage to the unit, do connect to patient before turning it on. Simultaneous connection to high frequency (HF) surgical equipment operation in close proximity to a shortwave or microwave therapy equipment should not be allowed due to unforeseeable hazards.

Intended purpose

The Classic4 stimulator is intended to be used for the alleviation of pain by professionals in the disciplines of physiotherapy, acupuncture, sports medicine or related. It is classified as for continuous use as timers can be reset for a new session at any time. The device is used for electrical stimulation in a TENS/EMS (transcutaneous nerve and muscle electro-stimulation) or electro-acupuncture protocol, in conjunction with usage of electrodes or acupuncture needles. There could be scope for its use by patients after having been instructed by their practitioner/ doctor, who should be satisfied of the appropriateness of this decision.

Contra-indications

Electro-Stimulation Therapy, TENS/EMS or Electro-Acupuncture should not be used by anyone with a cardiac pacemaker. It should not be used in pregnancy or by people with serious disease unless it is part of an intended treatment protocol.

Contra-indications > EA and TENS: *a brief checklist*

- Undiagnosed pain
- Cancer
- Epilepsy
- Pregnancy
- Patient fitted with a pacemaker or other implanted electronic device

All patients should be advised NOT to use TENS while driving or operating hazardous equipment.

Where not to stimulate

- Over the front of the neck or the carotid sinus (at the side of the neck)
- So that current flows through the brain or heart
- Where there are skin conditions such as eczema
- Where there is abnormal skin (or muscle) sensation. In this case, electrodes (or needles) should be positioned elsewhere to ensure effective stimulation
- At contraindicated acupuncture points.
- When using the Classic4 for EA, ensure that you do not apply currents of more than 20 mA, and that you use the 'B' (biphasic) and not the 'M' (monophasic) waveform. Never attempt to use a device designed solely for TENS for EA.
- Please refer to your prior training notes for details. If in doubt, do not treat in these circumstances, and always liaise with a patient's medical practitioner or consultant.

Parameters to use

For low-frequency, 'acupuncture like' stimulation (ALS, 2-10 Hz), it is generally thought that amplitude should be strong, but not painful. For high-frequency, 'TENS-like' stimulation (TLS, 80-175 Hz), stimulation should be definitely feel able, but not uncomfortable.

There is some agreement in the literature that ALS is more appropriate for chronic pain and flaccid paralysis, with TLS more often recommended for acute pain and spasticity.

However, individuals vary in their response to electrical stimulation. Sometimes it is a matter of trial and error to find which particular combination of parameters is most effective for a particular patient. Adjusting the pulse duration may improve results in some circumstances, as may the use of 'dense-disperse' stimulation (alternating low and high frequencies), or simultaneous application of different parameter combinations at different locations. The Classic4 gives much scope for exploring such variation.

Where to position needles & surface electrodes

EA: Points may be selected from local (*ashi* or trigger) and distal points, *huatuoji* and auricular points, and also from most of the points that you would normally use as an acupuncturist for systemic or syndrome-based treatment.

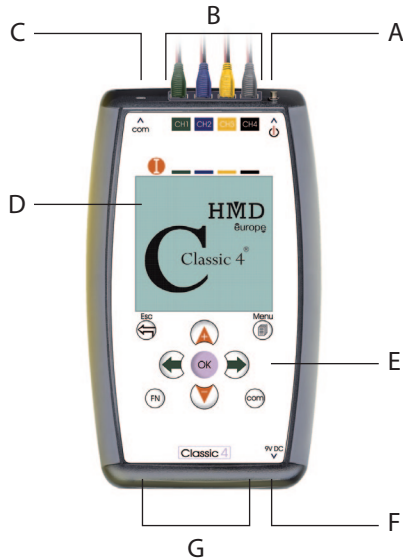
TENS: Useful illustrations of electrode placements can be found at www.harmonymedical.co.uk. It is advised not to apply current densities of more than 4mA/cm² or 25mA with an electrode 2.5x2.5cm

- Note that TLS is more effective when used locally or in an area segmentally related to where the condition is focused, but that ALS may be effective when applied elsewhere as well.

Features

- Versatile electro-therapy for treatment of a wide spectrum of TCM patterns or physical conditions.
- The facility to use different output parameters within the same treatment session.
- The ability to use concurrently as an electroacupuncture stimulator and a TENS/EMS unit.
- 4 Output Modes (Single, Paired, Sync, Sequential)
- 4 Output Channels
- 24 pre-set frequency settings
- 0.5 Hz–200 Hz
- 20mA capped, can be raised to maximum of 60mA output current
- 28 pre-set programmes
- 8 user-defined programmes

Unit layout



- A. On/Off switch
- B. Output channel sockets
- C. Communication port
- D. Screen
- E. Control keys
- F. Adaptor socket
- G. Battery compartment

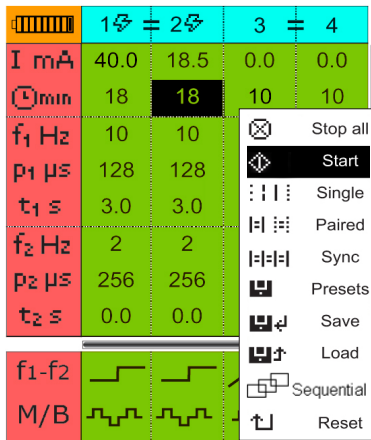
Screen layout (1)

- The screen of Classic4 is divided into a table with 5 columns and 11 rows
- Each entry in the first column shows which parameters are used for that row in the other four columns of the table
- The top row shows the channel number










	1	2	3	4
I mA	8.2	0.0	0.0	0.0
t _{min}	10	5	15	20
f ₁ Hz	10	2	80	200
p ₁ μs	128	256	192	64
t ₁ s	3.0	3.0	2.0	2.0
f ₂ Hz	10	3	2	150
p ₂ μs	128	256	192	64
t ₂ s	0.0	2.0	3.0	1.0
f ₁ -f ₂				
M/B				

Screen layout (2)

- Number of output channel
- Electrical parameters
- Low battery indicator
- Working area
- Pop-up menu








Control keys

	Escape key: Cancel action or selection, return to previous action.
	Menu key: Choose from a list of actions. The main menu includes start/stop options, a selection of output modes, load and save programmes and reset.
	OK key: To confirm and accept a selected/changed value.
	Up key: Press to move the cursor up or click to increase the value inside an active cell. (Keep this key depressed for rapid increase).
	Down key: Press to move the cursor down or click to decrease the value inside an active cell. (Keep this key depressed for rapid decrease).
	Left key: Move left to the previous channel from the current cursor position.
	Right key: move right to the next channel from the current cursor position.
	FN key: The function key may be used in combination with other control keys for rapid action.
	Com key: The com key may be used in combination with other control keys for external communication and applications. (Note: the function of this key is currently under development and is not available to the user with this version).

Channels & cursor



	Channel is active	When the Channel active sign is turned on, it indicates that the channel is ready for treatment use.
	Active in high current	When an active channel is operated beyond 20mA, the icon is changed from a hollow to a solid lightning symbol.
	Channel is faulty	When the Channel faulty sign is turned on, the channel is automatically shut down or the amplitude is reset to zero.
	Cursor cell	The highlighted cell is the current position of your cursor.
	Active cell	An active cell is indicated with an up/down arrow sign inside the cell. Users may change the value in the cell by using the up/down control keys.

Select output channel



- The output sockets are located at the top of your unit. When the unit is turned on, the screen presents a table with 5 columns. The left column lists all available parameters. The remaining 4 columns, with headings numbered 1 to 4, correspond to output channel sockets 1 to 4.
- When the cursor is within the chosen Channel (column), press the **Menu Key** to apply an option or to activate the output channel with the **Start** command.



Activated channel

When the **Start key** is selected, the activated channel(s) will be identified by a small lightning icon next to the channel number(s) and the treatment time count will start counting down. Each channel is capped at 20mA for safety operation in electro-acupuncture. To operate a channel beyond 20mA, press the **FN key** when the intensity reaches 20mA, the lightning icon is changed from hollow to solid.



Faulty channel

- When the X sign appears next to a channel accompanied by a sound (bleep) this indicates that there is an error on the channel.
- The output of that channel is automatically cut off.
- Read the "Trouble shooting" section of this manual to rectify the problem.



The main menu

- When the Menu Key is pressed, the Main Menu appears if the cursor is on a channel that is not activated.
- The Main Menu presents all the options for operating your device.
- Use the Up/Down keys to scroll to desired option, press the OK key to confirm.

	1	2	3	4
I mA	5.5	0.0	Stop all	
min	10	5	Start	
f ₁ Hz	10	2	Single	
p ₁ μs	128	256	Paired	
t ₁ s	3.0	3.0	Sync	
f ₂ Hz	10	3	Presets	
p ₂ μs	128	256	Save	
t ₂ s	0.0	2.0	Load	
			Sequential	
			Reset	



Single mode

Selecting this option allows you to set any parameter for any for a single channel independently of those chosen for the other three. With the cursor on the chosen channel, it can be activated by selecting the **Start** option.

Note: no connecting bars between the channel numbers.

	1	2	3	4
I mA	8.2	0.0	0.0	0.0
min	10	5	15	20
f ₁ Hz	10	2	80	200
p ₁ μs	128	256	192	64
t ₁ s	3.0	3.0	2.0	2.0
f ₂ Hz	10	3	2	150
p ₂ μs	128	256	192	64
t ₂ s	0.0	2.0	3.0	1.0
f ₁ -f ₂				
M/B				



Paired mode

- Selecting this option will set the parameters for channels 1 and 2 as a pair, and those for channels 3 and 4 as a second pair.
- In this mode, the parameters set for either member of a pair of channels will automatically be copied to the other one (except for the Timer duration, and amplitude once the channels have been started). The pulses from the two paired channels will be synchronised.

	1 ↔ 2 ↔	3 = 4		
I mA	40.0	18.5	0.0	0.0
⊖ _{min}	18	18	10	10
f ₁ Hz	10	10	80	80
p ₁ μs	128	128	128	128
t ₁ s	3.0	3.0	1.0	1.0
f ₂ Hz	2	2	10	10
p ₂ μs	256	256	128	128
t ₂ s	0.0	0.0	0.5	0.5

	1 ↔ 2 ↔	3 = 4		
f ₁ -f ₂				
M/B				

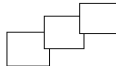


Sync mode

- Selecting this option will set channels 1, 2, 3 and 4 to run in sequence.
- In this mode, the parameters set for channel #1 will be automatically copied to the other three (except for the Timer duration, and amplitude once the channels have been started). The pulses from the four channels will be synchronised.

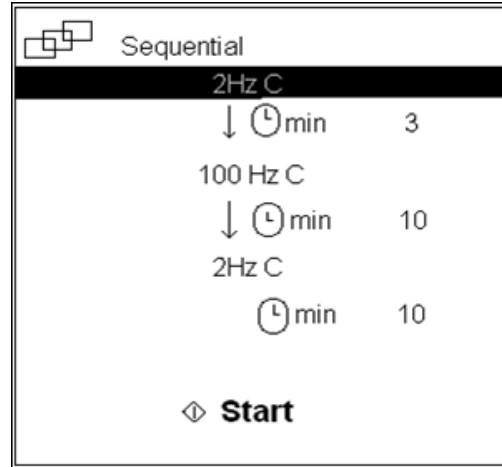
	1 ↔ 2 ↔ 3 ↔ 4 ↔			
I mA	2.0 ↕	0.0	60.0	1.0
⊖ _{min}	10	5	40	30
f ₁ Hz	10	10	10	10
p ₁ μs	128	128	128	128
t ₁ s	3.0	3.0	3.0	3.0
f ₂ Hz	10	10	10	10
p ₂ μs	128	128	128	128
t ₂ s	0.0	0.0	0.0	0.0

	1 ↔ 2 ↔ 3 ↔ 4 ↔				
f ₁ -f ₂					
M/B					



Sequential mode

- Selecting this option will set the unit to run in Sync mode
- Using Up/Down keys to select from pre-sets for first sequence
- Use Right key to down to “min” to set treatment time for the first sequence
- Use Up/Down keys to increase/decrease the treatment time.
- Repeat the steps for second and third treatment sequences.
- Press OK key when Cursor key reaches the Start.
- To suspend a sequence, set time to 0 (zero).





Start

- Start – to start the selected channel after locating the cursor on its column. The activated channel(s) will be identified by a small lightning icon next to the channel number(s) and the treatment time count will start counting down.

	1	2	3	4
I mA	5.5	0.0	Stop all	
min	10	5	Start	
f ₁ Hz	10	2	Single	
p ₁ μs	128	256	Paired	
t ₁ s	3.0	3.0	Sync	
f ₂ Hz	10	3	Presets	
p ₂ μs	128	256	Save	
t ₂ s	0.0	2.0	Load	
			Sequential	
			Reset	



Stop/stop all menu

- When the **Menu Key** is pressed, and the cursor is on a channel that is activated, the Stop/Stop All menu appears on-screen.
- Use the **Up/Down keys** to scroll options, and press the **OK key** to confirm.
- **Stop** – to stop output to the selected channel.
- **Stop All** – to stop output to all active channels.

	1	2	3	4
I mA	40.0	18.5	0.0	0.0
min	18	18	10	10
f ₁ Hz	10	10	80	80
p ₁ μs	128	128	Stop	
t ₁ s	3.0	3.0	Stop All	
f ₂ Hz	2	2	10	10
p ₂ μs	256	256	128	128
t ₂ s	0.0	0.0	0.5	0.5
f ₁ -f ₂				
M/B				



Reset parameters

Reset Values — when this option is highlighted and the **OK key** is pressed, the parameters will be reset to the values previously installed for the selected Channel.



Setting the parameters

The Classic4 is a versatile and powerful stimulator. You can set the frequency, pulse waveform, pulse duration, and timing of each set of pulses and channel according to your clinical needs. You can fine-tune and modify your settings rapidly in various ways. The basic methods are:

- Load preset parameters
- Load saved parameters
- Set your own parameters



Parameters

I mA	Output current amplitude in mA
⌚ min	Treatment duration timer (0-90 mins)
f₁ Hz	Repetition frequency of first set of pulses
p₁ μs	Width of pulses in the first set in microseconds
t₁ s	Burst duration for first set of pulses in seconds
f₂ Hz	Repetition frequency of second set of pulses
p₂ μs	Width of pulses in the second set in microseconds
t₂ s	Burst duration for second set of pulses in seconds
f₁-f₂	The types of change from first pulses to second pulses. Ramped or step.
M/B	Waveform: symmetrical bi-phasic or monophasic

Setting your own parameters

The parameters f₁ (frequency #1), p₁ (pulse width #1) and t₁ (duration of 'on' time #1) refer to an interval of duration t₁ during which pulses are emitted at a repetition frequency f₁ and with a pulse width p₁.

The parameters f₂ (frequency #2), p₂ (pulse width #1) and t₂ (duration of 'on' time #2) refer to an interval of duration t₂ during which pulses are issued at a repetition frequency f₂ and with a pulse width p₂.

At the end of time t₁, the characteristics of the pulses (f₁, p₁, t₁) will change to those of the second set of pulses (f₂, p₂, t₂). Subsequently, at the end of this second interval (t₂) the parameters will revert to those of the first set for the duration of t₁, and so on.

If t₂ is set to zero, the pulses will run continuously with the settings for the first set of pulses (f₁, p₁, t₁).

To change any of these parameters, position the cursor on the desired one, and then press the OK key. A small window will open and the value inside the window can be changed up or down by pressing the Up key or the Down key. A quick press will change the value to the next one, whereas keeping the button pressed will scan through the available values.



List of presets (1)

Preset name	f1 Hz	p1 μ s	t1s	f2 Hz	p2 μ s	t2s	f1-f2	M/B
2 Hz C	2	256	3	2	256	0	Stepped	Bipolar
5 Hz C	5	256	3	5	256	0	Stepped	Bipolar
10 Hz C (default)	10	128	3	10	128	0	Stepped	Bipolar
10 Hz (short pulses)	10	64	3	10	64	0	Stepped	Bipolar
80 Hz C (gate control)	80	128	3	80	128	0	Stepped	Bipolar
100 Hz C	100	128	3	100	128	0	Stepped	Bipolar
150 Hz C	150	64	3	150	64	0	Stepped	Bipolar
0.5/1 Hz (min setting)	0.5	64	3	1	64	3	Stepped	Bipolar
0.5/10 Hz (unequal pulses)	10	192	5	0.5	192	3	Stepped	Bipolar
0.5/80 Hz (equal pulses)	0.5	128	6	80	128	6	Stepped	Bipolar
2/15 Hz (equal pulses)	15	192	3	2	192	3	Stepped	Bipolar
2/80 Hz (equal pulses)	2	192	3	80	192	3	Stepped	Bipolar
2/80 Hz (short pulses)	2	64	3	80	64	3	Stepped	Bipolar
2/100 Hz (unequal pulses)	100	128	3	2	128	3	Stepped	Bipolar



List of presets (2)

Preset name	f1 Hz	p1 μ s	t1s	f2 Hz	p2 μ s	t2s	f1-f2	M/B
60/80 Hz stepped	60	64	10	80	64	10	Stepped	Bipolar
2 Hz (pulse modulated)	2	256	2	2	64	2	Stepped	Bipolar
80 Hz C (pulse modulated)	80	192	2	80	64	2	Stepped	Bipolar
20 Hz (burst)	20	192	5	20	0	3	Ramping	Bipolar
100 Hz (burst)	100	128	3	100	0	3	Ramping	Bipolar
10 Hz short pulse (R)	10	64	3	10	64	0	Ramping	Bipolar
200 Hz C (R)	200	64	2	200	64	0	Ramping	Bipolar
0.5/10 Hz (R)	0.5	256	3	10	192	5	Ramping	Bipolar
2/80 Hz (R)	80	64	3	2	192	3	Ramping	Bipolar
60/80 Hz (R)	60	64	10	80	64	10	Ramping	Bipolar
80 Hz (pulse ramp)	80	192	3	80	64	3	Ramping	Bipolar
50 Hz burst (R)	50	128	4	50	0	6	Stepped	Bipolar
80 Hz long burst (R)	80	64	6	80	0	2	Ramping	Bipolar
200 Hz short burst (R)	200	64	2	200	0	1	Ramping	Bipolar



Loading presets

1. Select the channel(s), press the **Menu key**, move the **Up/Down keys** to select **Presets**.
2. This option will lead to a new screen opening, as shown below. Use the **Up/Down keys** to scroll through the list of presets. The preset parameters are shown in the right column. Press the **OK key** on the desired set.
3. This will load the relevant parameters and copy them over into your selected channel(s) in the left column.

Preset	
10 Hz C (Default)	
f ₁ Hz	3
P ₁ μs	64
t ₁ s	30
f ₂ Hz	18
p ₂ μs	64
t ₂ s	30
f ₁ f ₂	
M/B	



Loading your favourite

1. Select the channel where you want your favourite to be loaded.
2. Press the **Menu key**, move the **Up/Down keys** to select **Load**. A new window opens, as shown below.
3. Use **Up/Down keys** to flick through your saved favourite as in User P1 to P8, click **OK key** to confirm.
4. The left column shows values of your existing channel, the right column shows the stored values.

Load	
User P2	
f ₁ Hz	200
P ₁ μs	64
t ₁ s	1
f ₂ Hz	0
p ₂ μs	0
t ₂ s	0
f ₁ f ₂	
M/B	



Saving your favourite

1. This option will lead to a second screen as shown on the left. Eight User slots are available.
2. Use the **Up/Down keys** to select which slot you want to save your parameters. Existing parameters in the slot will be over-written with your new values.
3. The values saved are taken from the single chosen channel only.

Save	
User P 8	
f ₁ Hz	200
P ₁ μs	64
t ₁ s	1
f ₂ Hz	0
p ₂ μs	0
t ₂ s	0
f ₁ f ₂	
M/EI	

Starting the treatment

Preparation

- Prepare your patient for treatment – keep your patient calm and relaxed.
- Switch ON the Classic4 stimulator. Check that the screen lights up showing all channels and the low battery indicator is not on.
- Switch OFF the Classic4.
- Insert output cables in channel sockets.
- Connect output cable(s) to your patient.
- Turn ON the Classic4 again. The unit is ready to use.

Instructions for use with acupuncture needles

1. Determine the Output mode for your unit.
2. Populate parameters for each channel you want to use.
3. Set the treatment timer for each output channel.
4. Connect output wires to needles/electrodes.
5. Move cursor to highlight the channel you want to begin, press **Menu key**, use **Up/Down keys** to highlight **Start** option, press the **OK key**. The channel is now active.
6. An Active cell opens. Use the **Up/Down keys** to increase the intensity as appropriate, pressing the **OK key** to lock the current intensity.
7. Repeat steps 5 to 6 for the other channels you wish to use. The treatment timer counts down automatically once the channel is set to **Start**, and turns the channel off at this point when it reaches zero. An audio sound is also emitted.

Making adjustments during treatment

1. To adjust the current intensity, go to that channel, press the **OK key** so that the cell is **Active**, use the **Up/Down keys** to make your adjustment, and confirm with **OK key** again.
2. To increase/decrease duration of the treatment session, move the cursor to where the channel and treatment timer (row) meet, press the **OK key** so that the cell is **Active**, use the **Up/Down keys** to increase/decrease the timer setting, and press the **OK key** again to confirm.
3. Each channel is capped at 20mA for safety in electroacupuncture, to increase beyond 20mA, press the **FN key**, and use the **Up key** to increase, and confirm with **OK key** again.

For safety and the patient's comfort, in both Sync and Paired Output modes only the output current intensity and treatment timer are adjustable during a treatment session without resetting the channel. In the more advanced Single Output mode, you can make adjustments to all parameters. However, there will be a timed delay before these changes take place.

Stop & resume a treatment

1. To stop or pause a channel or pair of channels, move your cursor to the channel you wish to pause or stop, press the **Menu key** to open the **Stop sub-menu**, select **Stop** to stop the highlight channel, or **Stop All** channels. This sets the current of selected channel gently to zero, and the treatment timer is set to pause.
2. To resume treatment, press the **Menu key**, select **Start** and adjust the output current again.

Treatment completed

- When a treatment session is completed, turn off the power.
- Disconnect cables from acupuncture needles or electrodes. Then remove plugs from output sockets.

After treatment

- Check for signs of reddening on the skin, for possible patient sensitivity to the small DC residual offset. If present, seek medical advice.
- Replace battery if the Low Battery sign appears during a treatment session.
- Remove the battery from the battery compartment if the unit is not required for more than a few days.
- Remove the AC/DC adaptor if an external adaptor has been used.

Storage & transportation

- Store unit in a dry location free from dust and contamination, where the temperature remains constant and within the range of 16°C to 40°C (61°F to 104°F), humidity between 15% and 95%.
- Do not drop or mishandle. During transportation, always secure the unit in its original case or in a protective container.

Care & maintenance

- Maintenance of the stimulator is limited to periodically wiping clean the unit using a clean, soft, damp cloth with mild soap solution or water. Using other cleaning solutions may damage the unit.
- Cables should also be wiped clean with a mild disinfectant in order to prevent the transmission of skin-borne contamination.
- **DO NOT IMMERSE STIMULATOR IN ANY CLEANING SOLUTION.**
- The output leads should be wiped clean with a cloth dampened with mild soap solution and then wiped dry.
- The unit can be used life-long, unless it develops a malfunction. It does not have a limited shelf life or a restricted 'use by' date. To have your unit serviced or repaired contact an authorized dealer.
- A yearly recalibration service is offered to ensure that the unit is working according to specifications.

Changing battery



- Switch off the unit.
- To change a battery, push open the battery compartment at the back of the unit.
- Remove the used battery from the battery compartment.
- Insert a new battery according to the diagram. The device is protected from damage if the battery is inserted incorrectly, but the device shall not function correctly. Always check the polarity.

Low battery indicator



- The low battery indicator will begin to flash when the battery becomes low. You may continue to use the unit for your current treatment session and replace the battery for your next session. When the low battery indicator flashes, please do not start your treatment session, but replace with a new battery immediately.

AC/DC adaptor

9V DC



- Only use an AC/DC adaptor which is supplied or approved by the manufacturer (FRIWO FW7333M/09) or a medically certified equivalent
- Switch off your Classic4 and disconnect any connected channel.
- Remove battery from battery compartment. Switch off the power supply of your AC/DC adaptor before connecting the plug into Classic4's AC/DC socket.
- Turn on the power supply first, before switching on your Classic4.
- An adaptor is only supplied as an optional item.

Communication port









com

- DO NOT connect to the Communication Port.
- In the current version of Classic4, the Communication Port is used by the manufacturer for programming and diagnostic of the device, and is not designed to be used by users.
- The communication port will become available for users as add-on devices and applications are developed.

Trouble shooting

- If an X sign flashes in the display on a channel, accompanied by an audio sound (beep), the channel is automatically shut down. This may indicate that the connection to the patient is faulty, or a cable is disconnected or broken.
- If the X sign appears, please investigate the cause(s) of the problem before the channel is re-activated.
- When your unit does not respond to any action on your keypad and your screen freezes, turn off the unit by switching off the power. Remove all cables from your unit before turning it on again. Check that the unit operates correctly before re-connecting the cables. Start your treatment again.
- Check and replace battery if the screen does not turn on after the unit is switched on.
- If the problem still cannot be resolved, the unit should be returned for repair. Do not attempt to repair the unit yourself, but return it to your local authorized dealer, or contact the manufacturer for repair or service.

Explanation of symbols

	CE mark of conformity. The device confirms with the Essential Requirements for Medical Devices Directive 93/42/EEC + 2007/47/EC as supervised by SGS United Kingdom Limited, Notified Body Number 0120
	The manufacturer of the medical device
	Read the instructions for use
	TYPE BF APPLIED PART
	The device is manufactured in the year shown next to this symbol
	Contains electronic parts subject to local/national disposal/recycle requirements
IP10	Specification for degrees of protection provided by enclosures (IP code) according to EN 60529

Technical specifications

Frequencies (in Hz): 0.5, 1, 1.5, 2, 2.5, 3, 5, 7, 8, 10, 15, 18, 20, 25, 30, 40, 50, 60, 80, 100, 125, 150, 175, 200

Pulse duration: 0, 64, 128, 192, 256 μ s

Timer (t1 / t2): in seconds: 0, 1, 2, 3, 5, 10, 30, 60, 120, 240, 600, 900

Waveforms:

Biphasic - symmetrical alternating rectangular pulses (charge balanced)

Monophasic - rectangular pulses of a single polarity

Maximum output current: 60mA across 1 Kohm resistive load, 7.5 mA across 10Kohm

Residual DC component: <5mV @ 200 Hz, 60mA

Output modes:

Constant, burst, ramped and user-defined programmes

Size: 145x88x20mm

Power: 1x9V battery/ adaptor

Weight: 260 gms (inc.battery)

Output channels: 4

Treatment timer: 5-90 minutes

Main unit and accessories

Main treatment unit	1 pc	Art No. MA304
Connecting cable to electrodes	4 pcs	Art No. MB113 (in 4 colours – GBYB)
Alligator pins to jacks on electrode cords	4 pcs	Art No. MB160A
User's Manual	1 pc	Art No. MA3042

Optional accessories

Carrying Case	Art No. MB1084
AC/DC adaptor	Art No. MB605
Pin Lead Extension Wire 36"	Art No. MB140
Grasp type to 2mm. PIN lead (5') 1 pair	Art No. MB120
Pen Electrode with Grounding Rod to 2mm pin (female)	Art No. MB4002
PP3 9 Volts battery	Art No. MB902

Standards

- Classic4 Stimulator – complies with: 93/42/EEC and 2007/47/EC.
- EN60601-1: 2006 EN60601-1-2: 2007EMC TESTING compliance: Electric Field Radiated Emission – Vertical Polarisation EN55022 Class A Electric Field Radiated Emission – Horizontal Polarisation EN55022 Class A.

Declaration of conformity

HMD Europe Limited declares that the medical device describes as Classic4 has been classified as Class IIa and is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC and 2007/47/EC and in conformity with the national standard transposing harmonised standard EN60601-1:2006, EN60601-1-2:2007, EN60601-2-10:2001 and is subject to the procedures set out in Annex V of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd.

London, 24 December 2011.

P. Choy

P.Choy
Director
on behalf of HMD Europe Limited

CE
0120

Manufacturer's recommendations and declaration – electromagnetic emissions

The Classic4 is designed to be used in the electromagnetic environments described below. The user should ensure that it is used in such an environment

Emission tests	Compliance	Electromagnetic environment – recommendations
RF Emissions CISPR 11	Group 1	The Classic4 only uses RF energy for internal functioning. As a result its emissions are extremely low and not liable to cause interference in nearby electronic instrumentation. The Classic4 is suitable for use in all establishments, including domestic premises and those connected to the low voltage mains electricity supply supplying domestic buildings.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/oscillating emissions	N/A	

Recommended separation distances between portable RF communication equipment and the device

The Classic4 is designed to be used in an electromagnetic environment in which RF interference is controlled. The user can prevent electromagnetic interferences by keeping a minimum distance between portable RF communication equipment and the Classic4 as recommended below depending on the maximum power emitted from the equipment in question.

Maximum emitter output power (W)	Separation distance depending on emitter frequencies (m)		
	150kHz to 80MHz $d=1.2 \cdot P^{1/2}$	80MHz to 800 MHz $d=1.2 \cdot P^{1/2}$	800MHz to 2.5 GHz $d=2.3 \cdot P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For emitters with a maximum power which is not listed above, the recommended separation distance d in meters (m) can be estimated using the equation which applies to the emitter frequency in which P is the maximum power emitted in watts (W) from the emitter's manufacturing data.

NOTE 1 – At 80 MHz and 800 MHz the separation distance for the highest frequency applies.

NOTE 2 – This guide does not apply to all situations. Electromagnetic propagation is influenced by absorption by and reflection from surfaces, objects and people

Manufacturer's recommendations and declaration – electromagnetic immunity (1)

The Classic4 is designed to be used in the electromagnetic environments described below. The user should ensure that it is used in such environments

Immunity Test	Compliance with IEC 60601	Compliance level	Electromagnetic environment – recommendations
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV on contact ±8kV in air	±6kV on contact	Flooring should be wood or tiled. If floors are covered by synthetic material, relative humidity should be at least 30%.
Transient electrical interferences IEC 61000-4-4	± 2kV for supply voltage ± 1kV for input/output lines	N/A	The power supply quality must be the same as commercial or hospital environment.
Shock wave IEC 61000-4-5	± 1kV differential mode ± 2kV normal mode	N/A	The power supply quality must be the same as commercial or hospital environment.
Fall in voltages, short circuits and changes in supply voltage. IEC 61000-4-11	<5% Ut (>95% fall on Ut) for 0.5 cycle 40% Ut (60% fall on Ut) for 5 cycles 70% Ut (30% fall of Ut) for <5% Ut (95% fall of t) for 5sec.	N/A	The power supply quality must be the same as commercial or hospital environment. If the user requires that the product functions continuously during mains power cuts use with a battery.
Mains frequency (50/60Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields de to the mains frequency should be typical of those found in a commercial or hospital environment.

NOTE 1 – Ut is the main alternative current supply voltage before the test is run

NOTE 2 – Loss of information about the length of stimulation in tests performed according to IEC 61000-4-11 is not hazardous. If the user requires continuous function during mains power cuts, the Classic should be used with a backup power supply or a battery.

Manufacturer's recommendations and declaration – electromagnetic immunity (2)

The Classic4 is designed to be used in the electromagnetic environments described below. The user should ensure that it is used in such environments.

Immunity Test	Compliance with IEC 60601	Compliance level	Electromagnetic environment – recommendations
Conducted RF IEC 61000-4-6	3Veff 150KHz at 80MHz	3Veff	<p>Portable telecommunications or mobile RF equipment should not be used close to the Classic4, either the main box or cables within the recommended separation distance calculated from the emitter frequency equation.</p> <p>Recommended separation distance – $D = 1.2 * P^{1/2}$</p> <p>$D = 1.2 * P^{1/2}$ 80 MHz to 800MHz $d = 2.3 * P^{1/2}$ 800 MHz to 2.5 GHz</p> <p>Where P is the maximum nominal output power in watts (W) according to the manufacturer's data for the emitter and d is the recommended separation distance in meters (m). The field power from fixed RF emitters determined by the place of the electromagnetic tests should be less than the compliance level for each frequency range.</p> <p>Interference may occur close to equipment bearing this symbol:</p>
Dispersed RF IEC 61000-4-3	3 V/m 80 MHz at 2.5 GHz	3V/m	

declaration – electromagnetic immunity (3)

- NOTE 1 – From 80 MHz and 800 MHz, the upper frequency range applies
- NOTE 2 – These recommendations do not apply in all situations. Electromagnetic propagation is influenced by absorption by and reflection from surfaces, objects and people
- NOTE 3 – The field power of fixed emitters such as radiotelephone base stations (cell phones/ wireless) and mobile radios, radio emitter, AM and FM radio emissions and TV emissions cannot be accurately defined theoretically.
- To assess the electromagnetic environment from fixed RF emitters an overview should be made of the whole electromagnetic site.
- If the force fields measured in the place where the Classic4 is used exceeds the RF compliance level which applies above, the Classic4 should be checked to ensure it operates normally.
- If it is found to perform incorrectly, additional measures may be required such as re-orientating or changing the position of the Classic4.
- NOTE 4 – Above the frequency range 150 kHz to 80 MHz, field powers should be less than 3V/m

Resources

The following books provide further information:

Johnson MI (2008). Transcutaneous electrical nerve stimulation (TENS). In Watson T (Ed.), *Electrotherapy: Evidence-based practice* (pp. 253-296). Edinburgh: Churchill Livingstone

Mayor DF (Ed.). (2007). *Electroacupuncture: A practical manual and resource*. Edinburgh: Churchill Livingstone.

For training in the use of EA or TENS, contact your own professional organisation. If you are an acupuncture practitioner in the UK, the Acupuncture Association of Chartered Physiotherapists (AACP) and British Medical Acupuncture Society (BMAS) run courses on EA. For British Acupuncture Council (BAC) members or other qualified acupuncturists, courses can be arranged with David Mayor.

Useful websites

- www.electroacupunctureknowledge.com (for information on EA studies)
- www.electrotherapy.org (for general information on TENS and electrotherapy)
- www.harmonymedical.co.uk (for supply of medical devices, accessories and general reference)
- www.aacp.uk.com (for the AACP)
- www.acupuncture.org.uk (for the BAC)
- www.medical-acupuncture.co.uk (for the BMAS)
- www.welwynacupuncture.co.uk (for David Mayor)

Warranty

This Classic4 electrical stimulator is warranted to the initial purchaser against any defects in material and workmanship for a period of twelve months from the date of purchase. If the stimulator is found to be defective within the warranty period, it will be repaired or replaced if returned prepaid to an authorized dealer. This warranty does not cover damage caused by rental, misuse, negligence, accidents and abuse, or alteration or modification of the unit. No liability is held in either tort or contract for any loss or damage, direct, consequential, or incidental arising out of the use, misuse or inability to use this product.

User's service logs

Visual examination

Date	Performed by	Comments

Operational test according to user guide

Date	Performed by	Comments

Persistent breakdown or operational errors

Date	Description of problem and consequences

Energy emission test

Date	Performed by	Result	Comments

Technical safety test

Date	Performed by	Comments

Calibration test

Date	Performed by	Comments

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