



## USER INSTRUCTION MANUAL

# OneStim-DUO

## Cardiac Stimulator



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**CAUTION**

US Federal Law restricts this device to sale  
by or on the order of a physician



**User Instruction Manual:**

<https://micropaceep.com/product/onestim/>



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**Regulatory:** [www.micropaceep.com/company/quality-regulatory](http://www.micropaceep.com/company/quality-regulatory)

**Warranty:** [www.micropaceep.com/company/warranty-statement](http://www.micropaceep.com/company/warranty-statement)

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## 1. Introduction

### 1.1 Device Description

OneStim is a portable diagnostic programmable cardiac stimulator and ECG recorder suitable for performing limited cardiac electrophysiological (EP) investigations.

The device has four stimulation channels and electrocardiogram (ECG) recording via diagnostic electrode catheters, pacing leads or trans-esophageal electrodes. Stimulation protocols provide burst, ramping, up to 4 extrastimuli as well as sequenced pacing into two or three chambers, with set current or voltage and impedance measurement.

The device displays up to 14 channels of intra-cardiac and surface 12 lead ECG signals on a 12" touch display with configurable frequency filters. Analysis may be performed on a live or triggered display and a review page with interval and amplitude measurements, sweep speeds up to 400mm/s and print to PDF files to a USB drive.

The OneStim is a diagnostic device not intended for life supporting pacing or ECG monitoring.

### 1.2 Glossary and Terms

Term	Explanation
CM / DM	Common Mode / Differential Mode
Drive Train	Also "S1"; the 6-8 regular pacing stimuli before extra-stimuli are applied
ECG	Generic Electrocardiogram – iECG or sECG or endo-esophageal electrogram
EP	Electrophysiology
EP / CP Mode	Electrophysiological / Conduction System Stimulator mode
EPO	Emergency Pacing Output
HFS	High Frequency Stimulation, for cardiac Ganglionic Plexus stimulation
HR	Heart Rate
iECG	Intra-cardiac ECG
PFA	Pulsed Field Ablation
PSA	Pacemaker System Analyser
QRS	P wave or QRS; also signifies any iECG complex
RA	Right Atrium
RF	Radiofrequency, e.g. RF Ablation
RR	R-R interval on ECG or peak-to-peak interval on iECG.
RV	Right Ventricle
S1	Basic stimulation interval
sECG	Surface ECG
SNRT	Sinus Node Recovery Times
Sx	The name for and the coupling interval of extra-stimuli added after S1 Drive Train called S2, S3, S4
Sync	Synchronization / trigger stimulus to ECG event
TEEP	Trans-esophageal EP
TMP	Temporary Pacemaker

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## 2. ESSENTIAL PRESCRIBING INFORMATION

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### 2.1 *Intended Use / Indications for Use*

The OneStim is an electrophysiology measurement system used to acquire, filter, digitize, amplify, display, and record cardiac electrical signals combined with a programmable diagnostic cardiac stimulator intended to be used for testing of the heart during cardiac electrophysiological studies and related procedures in hospital facilities.

The OneStim indicated for adult and pediatric population in the management of cardiac arrhythmias and conduction disorders.

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### 2.2 *Intended Operating Environment and Users*

The OneStim Cardiac Stimulator is intended for use in hospital cardiac electrophysiology laboratories and hospital procedure and operating rooms equipped and staffed for advanced cardiac resuscitation.

Examples of suitable environments include:

- Cardiac Electrophysiological (EP) or Cardiac Catheterisation laboratory.
- Operating theatres equipped for arrhythmia surgery or ablation.
- Intensive care, coronary care units, emergency departments, surgical procedure rooms.

Device is intended to be used by licensed specialist cardiologist physicians or surgeon's expert in arrhythmia management and trained on OneStim.

The device may be used in the patient environment, but must be protected from ingress of fluids. In sterile environments, OneStim has no sterilisable parts but may be covered by a sterile plastic cover.

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### 2.3 *Contraindications*

Do not use the OneStim for life support pacing; instead, use a temporary external pacemaker.

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### 2.4 *Clinical Benefits*

The OneStim device is a compact portable combined programmable diagnostic cardiac stimulator and limited EP recorder allowing physician users to perform appropriate limited EP studies and arrhythmia procedures in EP laboratories as well as in hospital procedure and operating rooms for management of cardiac arrhythmias.

Over 7,000 Micropace cardiac stimulators have been distributed since 2001 into over 50 countries and are estimated to have been used in 3.5 million EP studies with no reported deaths or significant adverse events caused by the Micropace device. This offers a very high favourable risk-benefit ratio, a characteristic common to the whole class of diagnostic cardiac stimulators.

Risk-benefit of and recommendations for EP Studies and therapies for various indications are documented in relevant ACC/AHA/ESC Consensus Recommendations on management of arrhythmias.

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### 2.5 *Compatible Equipment*

Micropace OneStim Cardiac Stimulator is compatible with the following equipment:

**Diagnostic pacing electrode catheters and Pacing leads**

- Any currently available legally marketed electrophysiological diagnostic pacing and sensing electrode catheters exhibiting a tissue contact impedance of between 200Ω to 2000Ω at nominal stimulation current of 5 mA or 5 Volts, verified prior to use to be able to reliably capture the heart rhythm for diagnostic purposes. This includes diagnostic transvenous electrode catheters and permanent pacing leads manufactured by Cordis Biosense Webster, Daig, Boston Scientific and Medtronic as well as trans-esophageal electrical catheters manufactured by FIAB and CardioCommand.

#### **EP Recording equipment**

- OneStim Stimulator is compatible by design with Computerized EP Recording systems designed to pass cardiac stimulation pulses of up to 25 Volts and 25 mA, for example those manufactured by Boston Scientific (LabSystems Pro™) and GE/Prucka (CardioLab™).

#### **High Energy Medical Devices**

- OneStim is protected from damage by and is suitable for use with external and internal implanted cardiac defibrillators and with cardiac RF ablation devices and general surgical diathermy devices.
- OneStim is suitable for use with Pulsed Field Ablation (PFA) equipped with isolating switches during energy delivery.

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## **2.6 Important Patient Safety Warnings & Precautions**

The OneStim produces standard electrical cardiac stimulation outputs similar to that of Micropace EPS320 family of cardiac stimulators on the market since 2001 and other programmable cardiac stimulators on the market; there are no known adverse effects from short term diagnostic use of such stimulation. Following is a list of potential adverse events from Stimulator device malfunction or human error (in alphabetical order):

- Inadvertent arrhythmia induction due to user error or device malfunction requiring cardioversion/defibrillation
- Failure to pace patient having bradycardia or asystole due to misuse for life-support and technical failure requiring backup pacing with temporary external pacemaker
- Incorrect displayed data leading to incorrect arrhythmia diagnosis and therapy due to user or device error requiring use only by suitably trained staff

OneStim issues user-programmed cardiac stimulation and displays resulting ECG amplified and filtered signals according to user settings. The device utilizes no closed physiological feedback loops and makes no diagnoses. All measurements and interpretations are either made by user or transparently displayed for user verification and adjustment if required.

#### **Warning: OneStim must be used only by or under supervision by a trained cardiologist**

- The OneStim may be used on patients only by or under direct supervision by a physician expert in cardiac electrophysiology and trained on OneStim use in an appropriate hospital facility with advanced cardiac resuscitation.
- The supervising physician must verify all OneStim settings immediately prior to commencement of pacing.

#### **Warning: Use OneStim only in procedure rooms with advanced life support, including**

- Life signs / ECG / Finger Oximetry Monitor.
- Cardiac Defibrillator which is immediately available.
- Temporary pacemaker which is immediately available.
- Staff trained in advanced resuscitation.

#### **Warning: Monitor patient's life signs and heart rate at all times, independently of OneStim**

- Patients undergoing cardiac EP studies may experience unexpected bradycardia, asystole or tachy-arrhythmias during the study spontaneously or due to electrical or mechanical stimulation, ablation and post defibrillation.
- OneStim may unintentionally stimulate the heart due to software, hardware or human error and induce dangerous arrhythmias.
- OneStim heart rate (HR) measurement may not be reliable due to changing configurations, device or operator error.
- OneStim indicated HR may not reflect patient's heart rate in some sensing sites, due to conduction blocks, changing electrogram amplitude and signal quality causing mis-sensing and due to incorrectly configured QRS detection.
- When using Trigger Page, arrhythmia may not be apparent - monitor heart rate independently of triggered display and consider enabling QRS Sense Sound.

**Warning: Disconnect patient's pacing catheters from Stimulator output in case of unexpected OneStim behaviour**

- In case OneStim's screen becomes unresponsive or stimulates unexpectedly or incorrectly, disconnect device from patient; OneStim may be power cycled and if no errors reported, used to complete patient study before being sent for service, with description of event.
- In case of repeated recurrence of unexplained dangerous arrhythmias despite cardioversion / defibrillation during the use of the OneStim, disconnect the OneStim outputs from the patient in case an occult malfunction, electromagnetic interference or leakage currents from attached equipment are causing the arrhythmias by micro-electrocution.

**Warning: Limit maximum stimulation voltage when testing using Permanent Pacing Leads**

- When performing electrophysiological measurements using permanent pacing leads, in order to avoid exposing electrodes to unintended high currents, always use OneStim in PACE Mode, which limits stimulation pulses to the typical pacing limits of 8V and 2 ms.
- When using OneStim for electrophysiological measurements related to permanent pacing leads, to ensure safe pacemaker operation, always verify final pacing lead performance using the implanted pacemaker itself.

**Warning: Do not use OneStim for life support pacing – use an approved temporary pacemaker**

- OneStim is not a life support temporary pacemaker because it may fail to stimulate due to battery depletion, software or hardware failure or erroneous configuration by user.
- If a patient requires life-support pacing, immediately use a temporary pacemaker approved for life support pacing, connected directly to patient's pacing catheter / lead.
- OneStim's Emergency Pace outlets are not for life support and may be used to pace a bradycardic patient to maintain haemodynamic stability for the few seconds while retrieving and connecting the required temporary pacemaker. Emergency stimulation at 100ppm / 8mA starts automatically on connection to intra-cardiac leads (triggered by sensing an impedance < 50kΩ).

**Warning: Do not use OneStim for life signs monitoring – use an approved ECG monitor with appropriate alarms**

- OneStim is not intended for monitoring life signs due to its complex configuration options and diverse operations and consequently lacks Heart Rate Alarms.
- OneStim limits Life Signs monitoring misuse by adopting Sleep Mode after predetermined period of inactivity.

**Warning: Do not modify OneStim**

- To prevent unpredictable and unsafe device operation, do not modify this equipment without authorization of the manufacturer, including attempting to install other software, for example via USB port, or using without the Patient Connection box which contains critical protection circuitry against defibrillation and RF energies. Do not use 3rd party ECG cables which may not contain defibrillation protecting resistors.

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## 2.7 General Precautions in Handling OneStim

The following instructions must be followed to ensure intended performance of OneStim and minimize modest risks.

### Caution: Installation, Connections, Transport, and Storage

- To avoid risk of electric shock and electrical noise, connect only to supply mains with protective earth, otherwise use internal battery power.
- To minimize risk of patient and operator electrocution and avoid introduction of electrical noise, when device is being used on patients, do not connect USB port or HDMI port to mains powered equipment unless they are powered from a medical grade isolation transformer and/or they are IEC60601-1 certified.
- To ensure that backup battery remains fully charged, store OneStim between uses connected to the mains power.
- To avoid damage to the OneStim, avoid exposure to chemical gases, excessive vibration, impact, temperatures above 60°C or ambient air pressures equivalent to above 4,267m altitude during transport and handling.
- To reduce electrical interference in registered electrograms, connect OneStim's Equipotential Ground socket to suitable medical grade ground such as POAG outlet using supplied green cable.

### Caution: Precautions prior to use

- Do not use the OneStim if any component appears damaged or device appears to start up with error messages. If in doubt, contact the Distributor or Micropace directly via contact details on underside of device.
- Do not touch the touch screen during startup of OneStim in order to avoid mis-autocalibration of screen and failure of touch response or spontaneous touch events.
- Do cover Touch Screen with sterile plastic bag if it is to be part of a sterile field to prevent ingress of liquids or body fluids and preserve sterility, while leaving air vents unobstructed. Verify correct operation of the touch screen so covered prior to use on patient.
- After turning on the OneStim, ensure all battery indicators and Emergency Stimulation LEDs illuminate briefly during the Power On Self-Test and no error messages are displayed. Otherwise refer to Troubleshooting section 13 below.
- Prior to use, ensure battery charge is adequate. Otherwise charge battery or use external power supply unit.
- The Operator must be trained on how to use the OneStim and its Emergency stimulation feature.

### Caution: Precautions during use

- Observe the OneStim and patients at all times for abnormal function and rectify any problem promptly or disconnect the patient from the Stimulator by unplugging the green plug from the green Patient Connection Box Socket on the right side of OneStim Console.
- Use of excessive stimulation currents may induce cardiac fibrillation and produce misleading results in ventricular stimulation studies.

- OneStim is protected against splashed liquids from above only; the Operator should protect it from liquids and contamination on the touch screen or entering cooling vents.
- To avoid loss of diagnostic pacing, connect device to mains power supply during continuous use. OneStim operation on battery power is limited to 2 hours of continuous use or an estimated 4 hours of typical intermittent use with power saving sleep states enabled. The Emergency Pacing Outlet operates from a separate long-life battery and may be utilized any time by connecting to patient electrodes.
- To avoid overheating of OneStim, keep air vents on the left side and under the device unobstructed - place device on a hard surface when in use, not on soft surfaces such as a bed.
- OneStim can resist the maximum high energy from defibrillation (up to 5kV) on its surface ECG inputs using the supplied ECG cable. The pacing channels are protected against the lesser intra-corporal defibrillation voltages (5kV common mode, 900V differential mode). ECG readings may be inaccurate for up to 5s after use of defibrillators. Patient connection leads may be damaged and should be functionally checked following defibrillation events.
- OneStim is protected against energies from electrosurgical units, however ECG readings may be inaccurate during and up to 5s after use in electrosurgery. In order to minimize interference and risk of burns, OneStim surface and intra-cardiac electrodes should be kept as far from the ablation site as practicable.
- OneStim may not be protected against the high voltage high frequency energies of Pulsed Field Ablation (PFA) devices. Keep OneStim-connected electrodes at least 20mm away from PFA electrodes.
- Any serious incidents related to this device should be reported to the manufacturer and in the European Union, to the listed Authorised Representative and the competent authority of the Member State in which the serious incident occurred.
- OneStim is not intended for secure storage of patient private and ECG data; for compliance with personal data protection laws, user should not record personal data, including in the review Comment fields, other than patient's MRN. Promptly after procedure, user should delete or export patient data from OneStim to a USB and transfer data to a secure location, such as the Hospital Information System (HIS).

## 3. Device Ratings, Classification and Certification

### 3.1 Medical Device

- Australian TGA MD Classification: **Class IIb** via rule 4.3
- Medical Devices Directives (93/42/EEC), Rule 10 classification: **Class IIb**
- FDA Medical Device Classification: Class II, Product Code DQK, JOQ

### 3.2 Medical Electrical Equipment

- IEC60601-1 Class II ME Equipment
- Power supply mains Input Class I (3<sup>rd</sup> conductor is only functional earth, 2 x MOPP)
- Type CF applied parts: ECG leads, Stimulation channels
- Console: Protected from vertical rain (201.11.6.5 of IEC60601-2-27)
- Patient Box: Protected from saline spill (201.11.6.5 of IEC60601-2-31), suitable for use within Patient Environment.

### 3.3 Compliance Standards

- EN/ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
- EN/ISO 14971:2019 Medical devices — Application of risk management to medical devices
- IEC 60601-1:2005/A2:2020 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance; Including collateral and particular standards:
  - EN/IEC 60601-1-2:2014, FCC Part 15 Subpart B and Canada ICES-003 Issue 7 (EMC)
  - EN/IEC 60601-1-6:2010 (Usability)
  - EN/IEC 60601-2-27:2014 (ECG Monitors), applicable clauses
- EN/IEC 62304:2006 (Medical device software - Software life-cycle processes)
- EN 62133-2:2017 (Lithium Batteries)

### 3.4 Power Rating

- 220-240VAC 50-60Hz, 0.3A max / 110-120VAC 60Hz, 0.6A max

### 3.5 Environmental Conditions

- Operating Temperature Range: +5°C to +35°C
- Operating Relative Humidity Range: 30% to 80% RH

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'Microsoft© Windows© CE trademark and copyright owned by Microsoft Corporation.

## 4. OneStim Description and Connections

### 4.1 Unpacking components, installation and training

Ordering No. (REF)	Description
MP5003-4CO	OneStim-DUO Cardiac Stimulator

OneStim is shipped with following components. Unpack and check for visible damage prior to installation.

Part Number	Part Name	Part Description	Length
MP4011-4BM	OneStim-DUO Console 4CH	OneStim-DUO Console 4 Channel	N/A
MP4075-4B	Patient Connection Box 4CH	Patient Connection Box 4 Channel	1.8 m
MP4105	ECG Cable, 10 lead	ECG Cable, 10 lead Integrated IEC	4.6 m
MP4108	ECG Cable, 5 lead	ECG Cable, 5 lead Integrated IEC	3.5 m
MP4118	Equipotential Grounding Cable	Grounding Cable max 0.5A	5.0 m
MP4002	DC Power Supply	Power Supply, 18V 3.4A, medical grade	1.5 m
MP3059-US	Mains Cable, US	Mains Cable US NEMA 5-15P	2.0 m
MP4006-DUO	User Instruction Manual	User Instruction Manual	N/A

**Table 1: Package Contents**

#### Optional components:

Part Number	Part Name
MP4085	4 Channel Unipolar Reference Adaptor Cable
MP4136	Equipotential (POAG) Grounding Cable 2.5M
MP4170	Equipotential (POAG) Grounding Cable Clamp
MP4009	Carrying Case
MP4003	SIP/SOP Cable Adaptor
MP3058	Circuit Continuity Test Led
MP4138	HDMI Male to HDMI/DVI Male Cable 5M
MP4140	HDMI Male to HDMI/DVI Male Cable 10M
MP4166	MedConnect Adapter Cable, 1.2 m
MP4110	OneLink Splitter Cable, 1.2 m

**Table 2: Optional Components**

Training on OneStim operation use is provided by distributor, and via training materials on Micropace website <https://onestim.io/educational-resources.html>.

4.2 Device Description

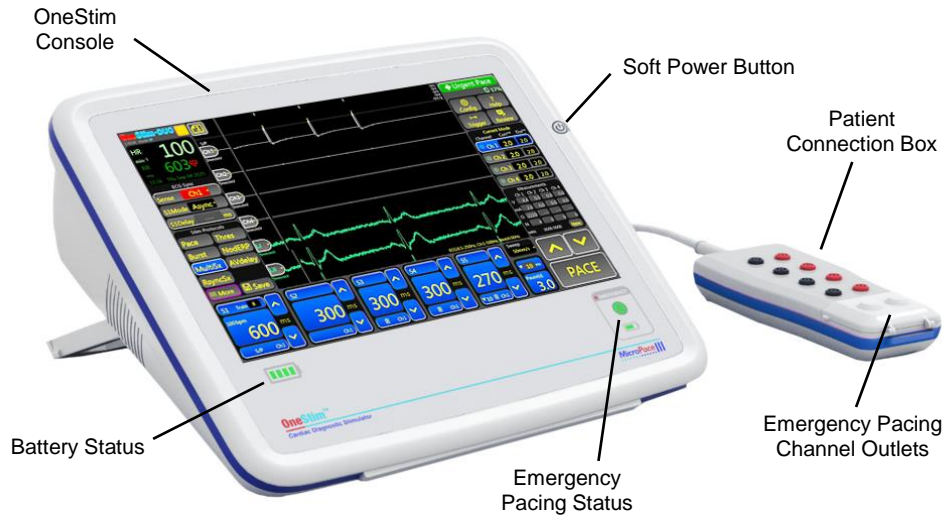


Figure 1: OneStim Product Appearance

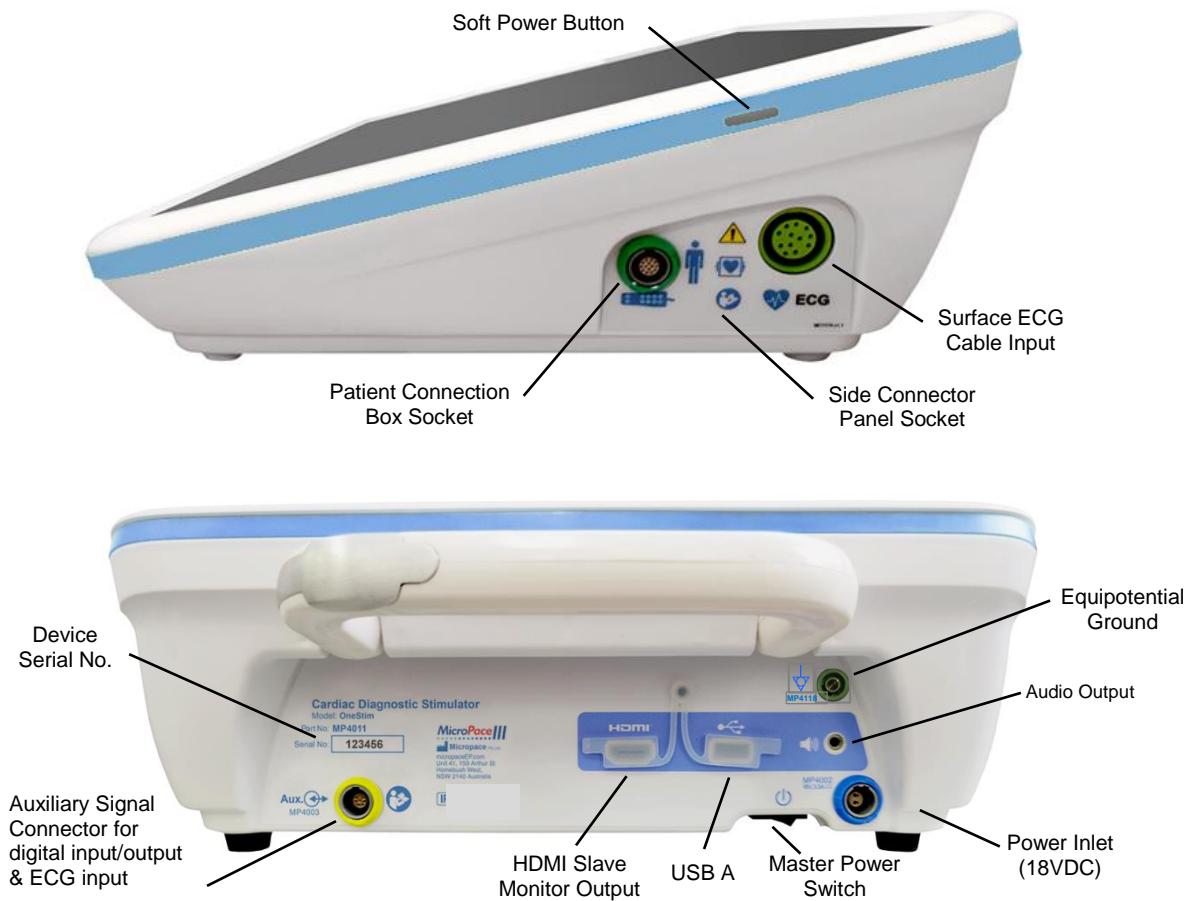
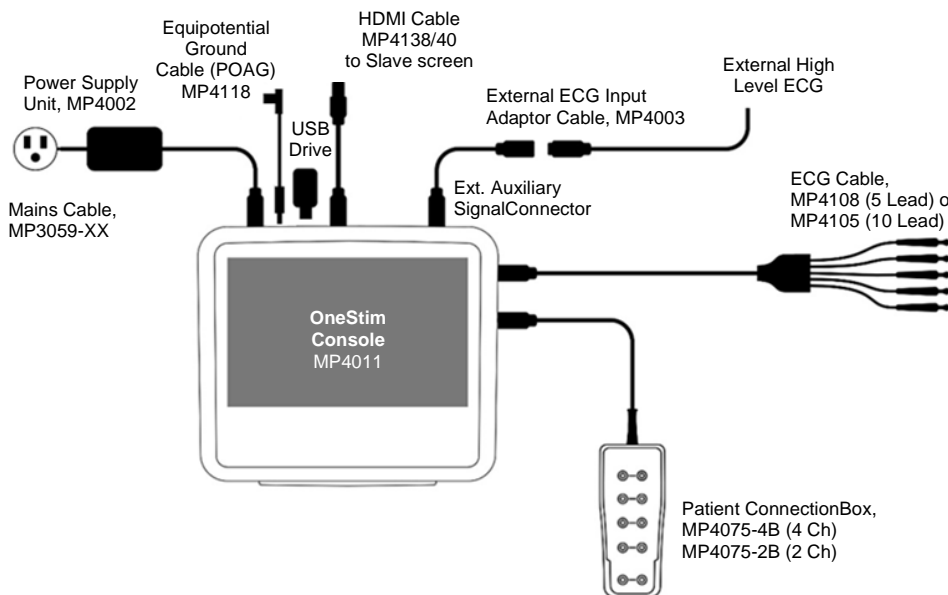


Figure 2: OneStim Product Connection Ports

### 4.3 Assembling / installing the OneStim Stimulator Console

- Connect Power Supply to mains power outlet to operate device and charge battery (4 hours to charge fully), or operate device on battery.
- Connect Patient Connection Box to Patient Connection Box socket on OneStim’s Side Connector Panel.
- If a surface ECG trace is required, connect supplied ECG Cable to the ‘ECG’ socket on OneStim’s Side Connector Panel.
- Alternatively, obtain ECG from a 3<sup>rd</sup> party ECG Monitor signal output via supplied External ECG input Adaptor Cable plugged into the Ext. Auxiliary Signal Connector on the rear.
- The Stimulator is intended to be positioned and operated next to the patient in the Patient Area
- For external slave screen display, connect screen to the HDMI outlet on the rear of OneStim.



**Figure 3: OneStim Components Connection Diagram (Note: Two channels)**

### 4.4 Turning on, verifying and operating device

Switch on the Master Power Switch at rear underside of unit; this should be left permanently On, unless storing or shipping device, so unit can charge when connected to mains.

If all battery indicators and Emergency Stimulation LEDs illuminate briefly during the Power On Self-Test and no error messages are displayed then device is ready for use, otherwise refer to Troubleshooting section below.

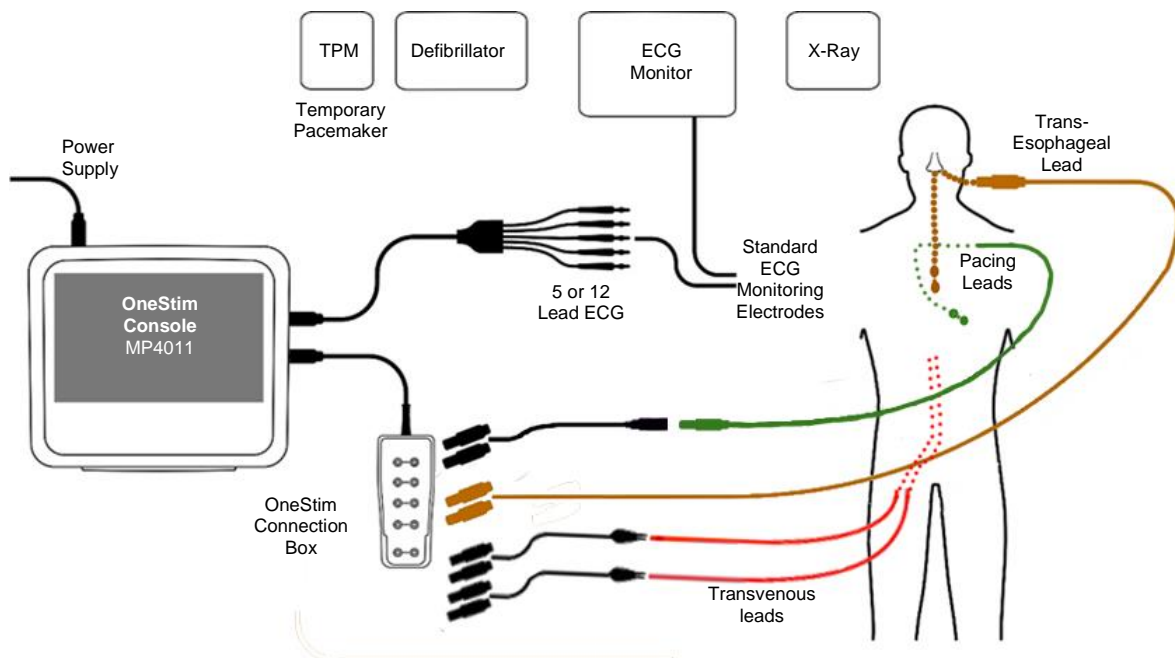
If more than 30 minutes has elapsed since the last use, a Safety Message and a dialog box to confirm Study Number or create New Study Number will appear.

If OneStim enters Sleep Mode, it will turn itself Off after a configurable number of minutes. Restore OneStim from Sleep Mode by touching the screen and from Off Mode by pressing the soft power button on right side of screen.

### 4.5 Connecting OneStim to the Patient

1. Connect cardiac leads to the Patient Connection Box channels 1-4. These may be EP catheters, cardiac pacing leads, trans-oesophageal pacing catheters, post-operative heart wires.
2. Connect ECG Leads as required to skin electrodes at standard positions.

The following Figure 4 illustrates potential connections.



**Figure 4: Patient Connections. OneStim may be used with 3<sup>rd</sup> party equipment such as EP Recorders and Pacing System Analysers with suitable cable connections.**

### 4.6 User Interface Modes

User may select one of three interface modes, EP, Pace and Stim, using Configuration Menu, A.Basic Settings, Parameter: "12. Device Mode".

#### 4.6.1 EP Interface Mode

Interface is optimized for stimulation and analysis of cardiac electrograms during simple EP Procedures using up to 4 diagnostic catheters / bipoles including during trans-esophageal EP studies. It provides all available stimulation protocols and displays 8 ECG traces. Select "EP" to enable this interface mode.

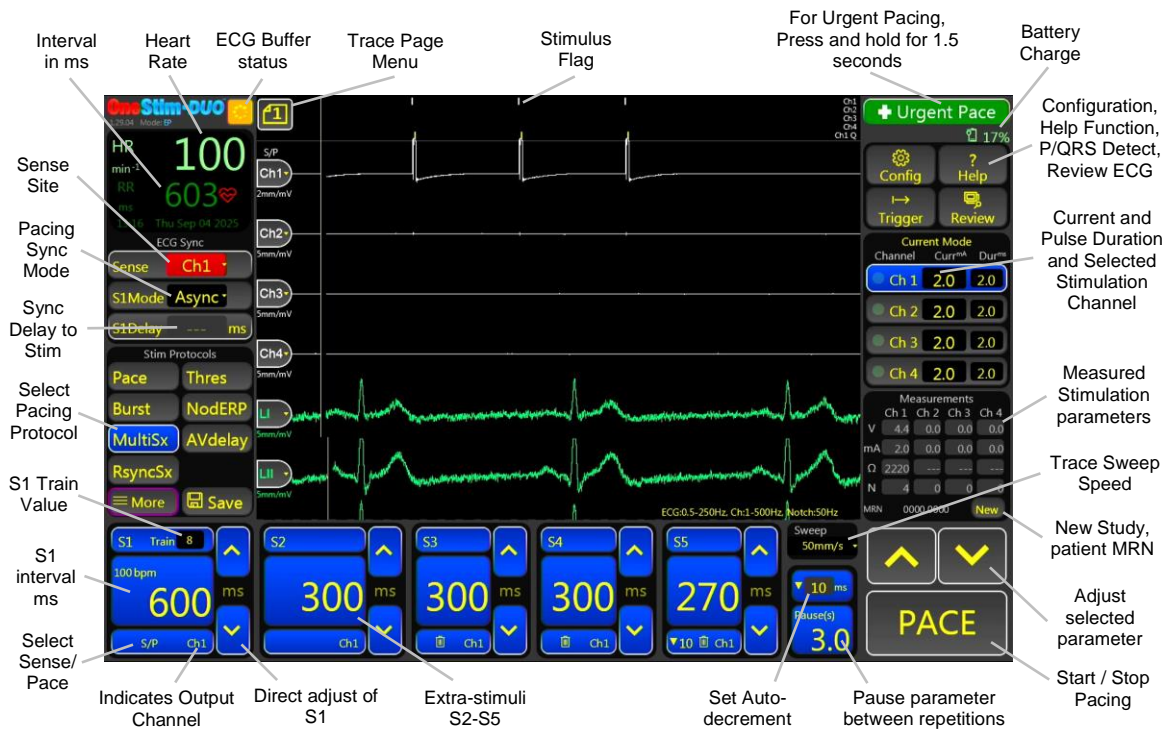


Figure 5: OneStim Main Screen in EP Mode, configured with four channels.

### 4.6.2 PACE Interface Mode

Pace Interface is optimized for stimulation and analysis of cardiac conduction parameters during physiological pacemaker lead positioning. It provides an interface with stimulation limited to 8 Volts, display of 14 ECG traces, (12 surface ECG leads and 2 intra-cardiac electrograms (EGM's)) with more limited stimulation protocols listed in Section 7.1.

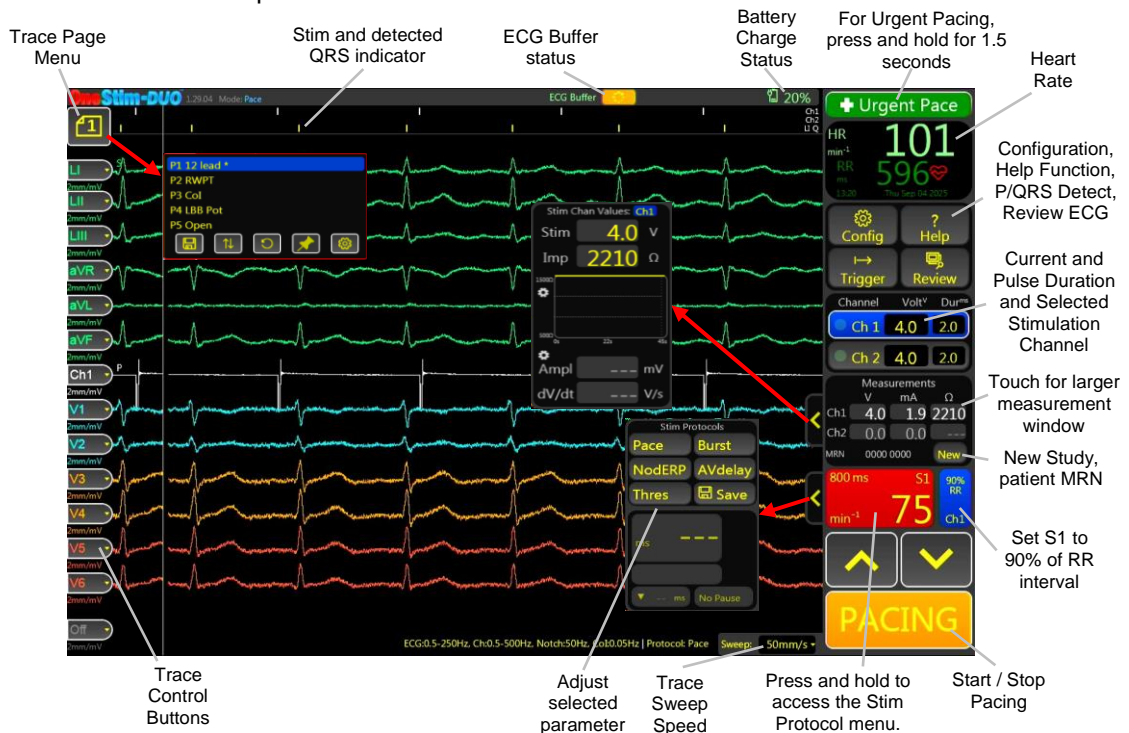


Figure 6: OneStim Main Screen in PACE Mode.

### 4.6.3 STIM Interface Mode

Optimized for Stimulation when used with EP Recorders in EP Laboratories. Device configuration is similar to EP Mode but with more pacing protocols and one or two EGM display traces.

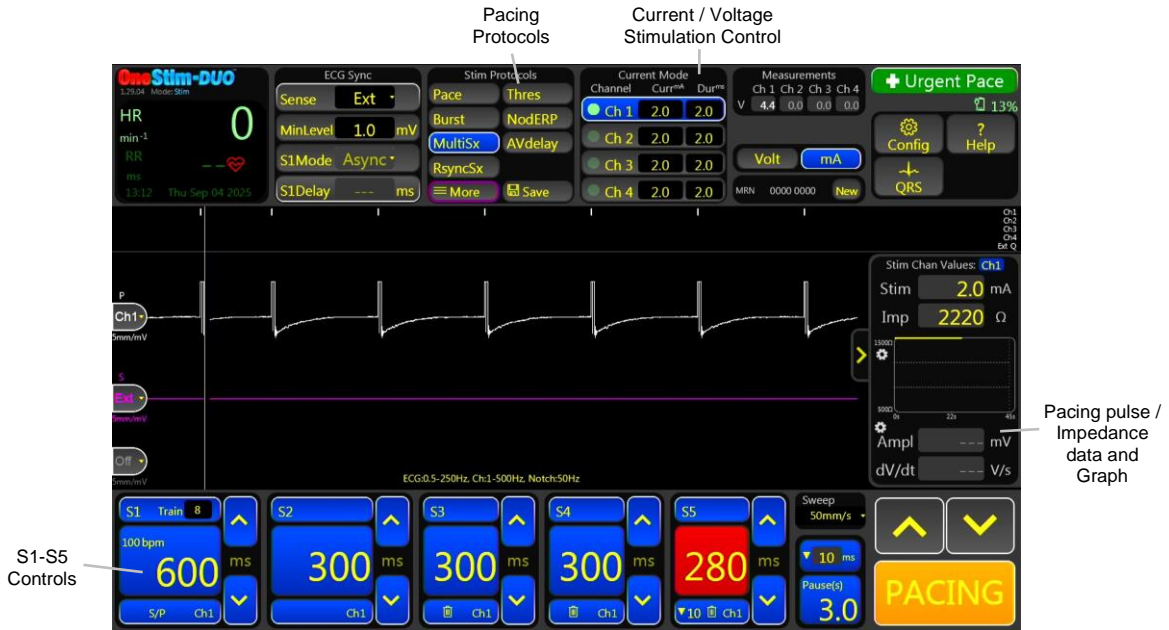
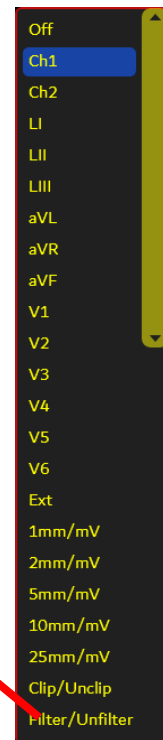
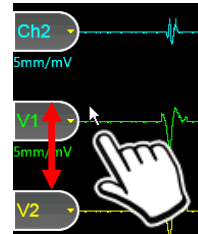


Figure 7: OneStim Main Screen in STIM Mode.

## 5. ECG Signals

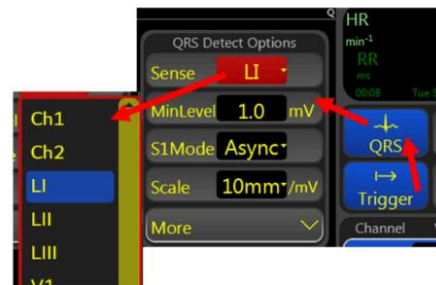
### 5.1 Setting up ECG Sources for display

1. Single-tap the Trace Control Tab to show its menu to select source of ECG and the vertical scale (only one item may be selected from menu at a time).
2. ECG signal may be from:
  - Surface leads (sECG): 5 or 12 Leads if enabled
  - Stimulation channels iECG
  - External High Level ECG input: Ext
3. For External High Level ECG input (e.g. from a bedside ECG Monitor), set Configuration parameter 'Amplifier gain External ECG' to the ECG monitor's gain. (For example, an ECG monitor outputting  $\pm 1V$  signal representing  $\pm 1mV$  ECG, has a gain of 1000x).
4. Touch and drag ECG handle to move trace up and down.
5. Select Off to turn off ECG trace to reduce screen clutter.
6. ECG Trace colors can be modified in Config H. Trace Colors



## 5.2 Selecting Sensed ECG source

1. Press Trigger and the QRS buttons.
2. Select ECG channel for stimulation synchronization (Sync) by tapping the Sense Parameter and selecting channel from menu.
3. The Sensed Display Channel is indicated by an 'S' symbol above the channel handle.
4. Note: augmented leads aVL, aVF and aVR can be displayed on screen but cannot be used for sensing.

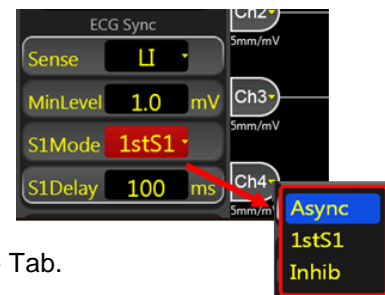


### 5.2.1 Setting Stimulation Sync to ECG

Stimulation S1 train may be synchronized to a selected ECG Sense channel with a set delay. Synchronization source Channel is set as follows:

**Sense:** Source of Sync ECG:

1. Select ECG for sync source: Ch1-Ch4, sECG and EXT.
2. An 's' symbol is shown above the sensed ECG Trace Tab.



**S1Mode:** Mode of Stimulation

Select from:

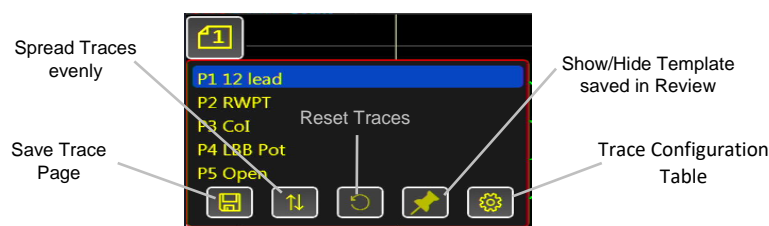
1. **Async:** asynchronous pacing, pacing starts immediately and regardless of patient's intrinsic ECG activity.
2. **1stS1:** synchronizes onset of pacing (1st S1) to be a set delay after first sensed QRS, following which stimulation is asynchronous (VOO/AOO).
3. **Inhibited:** each S1 is inhibited if earlier QRS is sensed in ECG indicated by Flash "Inhibited". When inhibited pacing, checks for noise i.e. moving average of HR in last 2 seconds is more than set reversion rate, displays a flash message & reverts to Async. Note 1: The term 'QRS' is used generically to represent any triggering electrogram complex, e.g. in atrial electrogram it would be the 'A' wave.

**S1Delay:** In S1Mode 1stS1, sets the delay from electrogram trigger to onset of first S1stimulation.

1. Delay between detected Sync trigger and onset stimulation, i.e. from sensed QRS to the delivery of the first S1 stimulus. ('S1Delay' is ignored in Async Mode).
2. Range 10-2000ms; Special value 0 sets delay to '=S1'.

## 5.3 ECG Page Menu

The ECG Trace Page menu allows you to select and save different trace pages. ECG pages allow the user to customise the displayed waveforms, their scale and positions. You can modify, rename and save each of the 5 trace pages.



ECG traces and pacing events are continuously being stored to a buffer whose length is programmable from 10 to 90 seconds.

## 6. Stimulating

### 6.1 Selecting Stimulation Channel

Touch Stimulation channel to select it.

The Channel buttons have Pace indicator LED's at their left border which flash Green when stim delivered, and flash Red when Stim current failed to be delivered, usually due to open pacing circuit.



### 6.2 Pace On / Off

Press the PACE button briefly to toggle pacing on and off, with button turning orange while pacing. A prolonged press, >300ms, will perform as Push to pace, pacing only for the duration of the press.



### 6.3 Setting Stimulation Amplitude and Duration

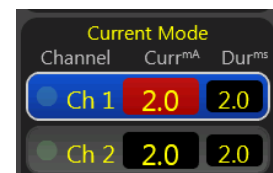
In EP Mode, OneStim is a controlled current stimulator – it varies the output voltage to deliver set current regardless of load impedance, up to the available Compliance Voltage. If stimulation impedance is too high (or circuit is broken) for stimulator to deliver the set current a Flash Message “High Impedance” is displayed.

For EP Study intra-cardiac stimulation, typical amplitude is 2 – 5 mA and duration 2ms.

Trans-esophageal cardiac pacing exhibits higher pacing impedance (1000-2000 Ω, compared to 500-1000 Ω for intra-cardiac). Capture may be achieved by using longer pulse duration, up to the maximum 10ms.

In PACE Mode, stimulator provides Voltage controlled stimulation.

In STIM Mode, both Current and voltage control are available.



**Warning: Limit maximum stimulation voltage when testing using Permanent Pacing Leads.**

When performing electrophysiological measurements using permanent pacing leads, in order to avoid exposing electrodes to unintended high currents, always use OneStim in PACE Mode, which limits stimulation pulses to the typical pacing limits of 8V and 2 ms.

A panel under the Stimulation Control panel displays delivered Voltage, Current, and calculated pacing impedance. In Pace mode, touching this measurements Panel opens a detail panel with more measurements and a continuous Impedance graph.



## 7. Performing Diagnostic Stimulation

### 7.1 Limited Pacing Protocols in Pace Mode

Pacing Protocol menu may be displayed by pressing the '<' Tab next to the S1 button, and contains the following protocols:

**Pace:** default regular pacing also performed when no Pacing Protocol Menu is displayed, with default S1 lower limit of 300 ms, configurable down to 280ms.

**Burst Pace:** Rapid Pacing with default lower limit of 240 ms, configurable down to 100ms.

**NodERP :** 'NodalERP ' one extra-stimulus protocol. Set Train for number of S1 in train and set Pause to required pause in seconds between Train repetitions; set Pause to 0 for no repetition. The down arrow sets the automatic decrementation of S2 between train repetitions, default 10ms. Icons: = Pause, = S2 Decrement.

**AVDelay:** A-V pacing with S2 A-V delay. If S1Mode is set to Inhibited, then sensing is automatically set to Atrium only and cannot be changed.

**Thres:** The 'Threshold' protocol aids in establishing the pacing threshold for all protocols by initiating pacing and then gradually reducing the pacing amplitude. The operator needs to halt pacing when capture is lost after which it may be fine tuned manually. Adjust Train parameter to adjust speed of reducing current



### 7.2 Pacing Protocols in EP and STIM Modes

Select required pacing protocol from Protocol Menu:

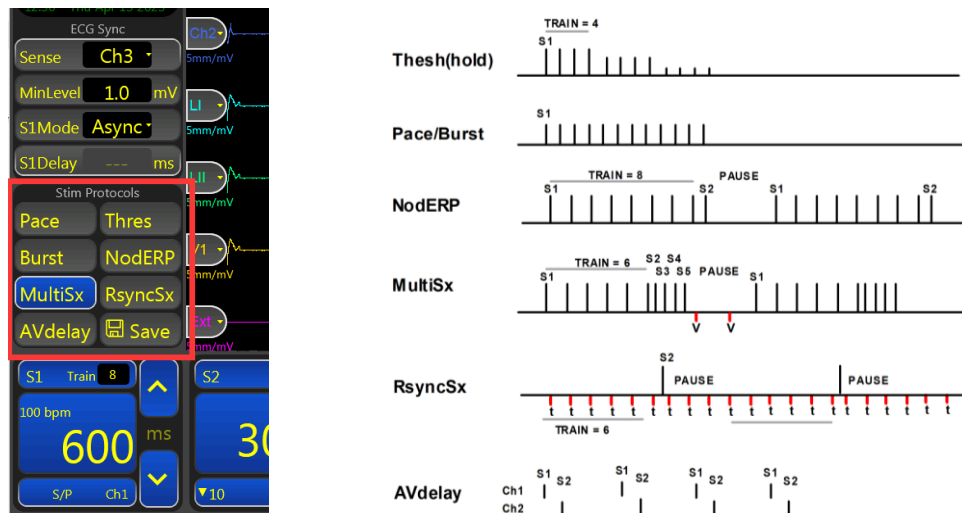


Figure 8: Main Pacing Protocols

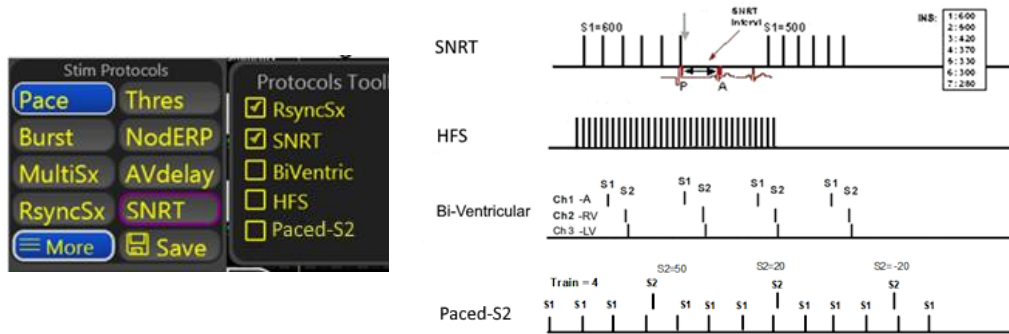
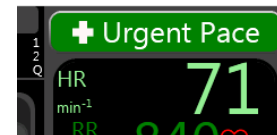


Figure 9: Additional Pacing Protocols

### 7.3 Urgent Pace

For urgent physiological pacing, no matter which protocol and what parameters are set at the time, press and hold ‘Urgent Pace’ for 1.5 seconds – OneStim will enter Urgent Pace Protocol, stimulating at 600ms into all channels at a higher current. Press same button renamed “Cancel” to exit this mode.



Note: This function is distinct from Emergency Pace Output (EPO) which is module powered by an independent battery described below.

**Warning: OneStim Urgent Pacing is not intended or approved for life support pacing.**

It is intended only for brief pacing to support blood pressure while a temporary pacemaker is retrieved and connected to the patient requiring life supporting pacing.

## 8. Trigger Page

This menu provides navigation to Triggered Page and QRS Detetion Settings Page.



### 8.1 Trigger Page

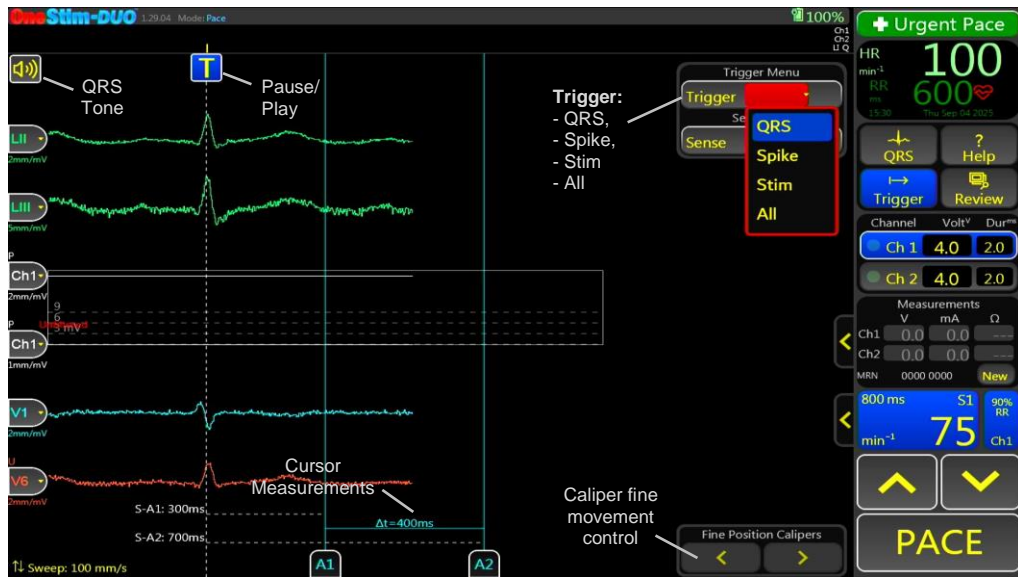
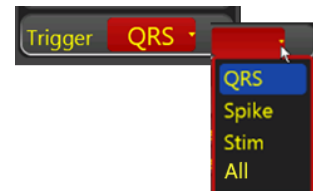


Figure 10: Triggered Sweep page

The QRS may be examined during intrinsic or paced rhythm in this mode, triggering the sweep on one of three triggers:

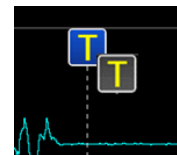
1. **QRS**: Detected QRS (first peak)
2. **Spike**: Pacemaker Spike (External PPM or PSA)
3. **Stim**: OneStim pacing stimulus
4. **All**: Any above events will trigger



#### Pause / Go button

This control "T" pauses and restart the triggering of display. The Page allows measurement of three intervals in milliseconds, indicated by Cursors A1 and A2 in Figure 10:

1. **S-A1**: From Trigger (Spike or Stim) to A1 Cursor
2. **S-A2**: From Trigger (Spike or Stim) to A2 Cursor
3. **Δt**: Time difference between A1 and A2 cursors



## 8.2 QRS Detection Page

QRS Detection Page shows magnified ECG with indication of the ECG Complex detection algorithm (generically referred to as 'QRS').

QRS detection threshold is dynamic, as in permanent pacemakers, and performance may be adjusted by MinLevel threshold, Polarity, Blanking period, Post Blank threshold reduction by % and inter-complex Decay of Threshold value.

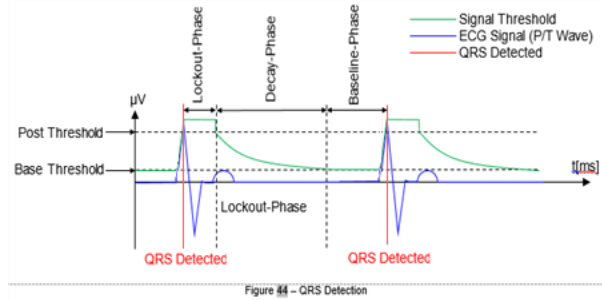
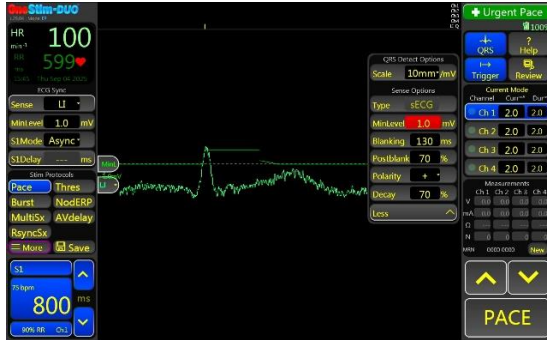


Figure 11: QRS Detect Menu (MinLevel = Minimum Threshold)

## 9. Help Menu

To obtain help information on parameters, press the 'Help' icon and then click the element for which help is required. For example, to get help on Ch1 Amplitude parameter, press 'Help' Then touch the Ch1 Voltage/Current field:



You can also press the Book and World Icon at the top for multi-lingual User Instruction manual.

## 10. Reviewing and Saving ECG

The Review Page selected by 'Review' button is used to review and export events of interest from the study.

### 10.1 Signal Review Page

Captured ECG may now be reviewed and analysed. Position and size of traces on the screen may be adjusted by:

- Dragging left or right on the trace to pan sideways.
- Quick swiping left / right to align cursor A1 to next / previous stim flag (if present).
- Swiping up or down to change sweep speed.
- Slowly sliding the trace control buttons on the left side of the screen upwards or downwards.
- Tapping on the trace control button and choosing the channel or scale you wish to display.

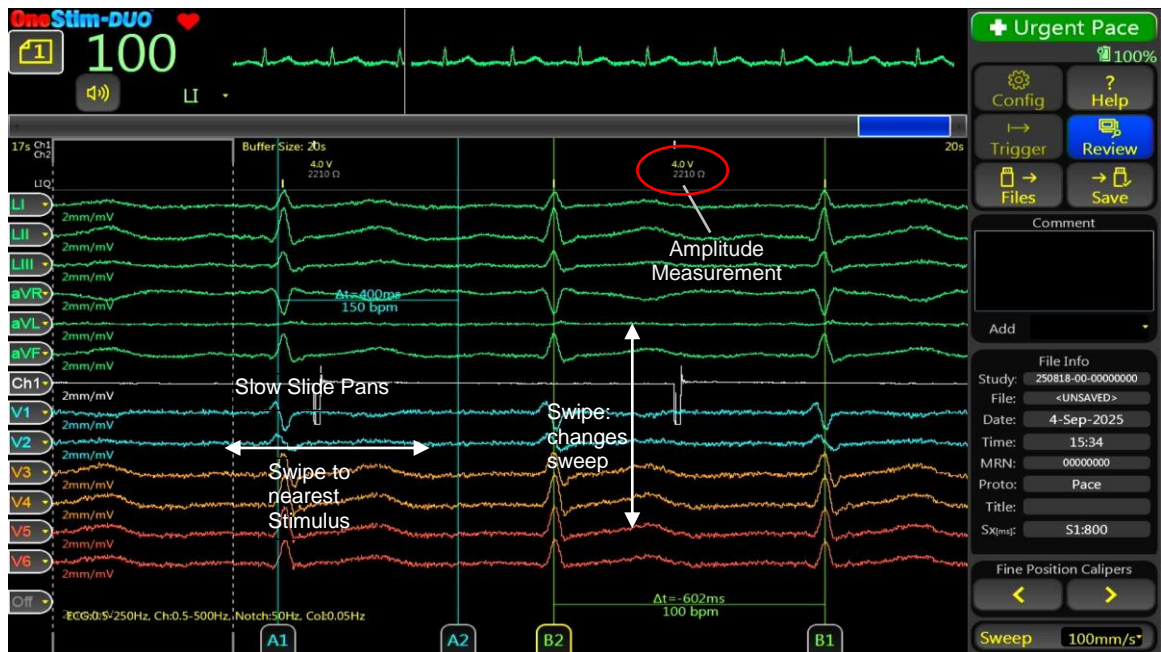
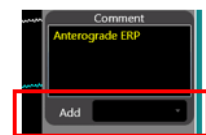


Figure 12: Review Screen with Time callipers and amplitude (circled).

Electrogram size and timing may be measured as follows:

- Touching the electrogram feature will show the amplitude (red circled - Figure 12).
- Sliding time Calliper pairs A1 & A2 and B1 & B2 will measure time intervals; use and buttons for fine adjustment.

A legend or comments may be added to the file via the Comment box and will appear on top of the PDF printout.



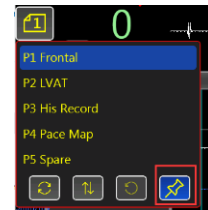
## 10.2 Review Template / Freeze column

On the review page, OneStim allows users to save the leftmost traces as a template.



Figure 13: Review Template/Freeze column

- Pressing the 'PIN' icon in the Trace Page menu freezes the leftmost area of ECG indicated by dashed line as a Template. Press icon again to delete template.
- The saved Template may be displayed in the Live Screen by the 'PIN' icon in its Trace Page menu. Press icon again to hide template.
- ECG Leads and sweep speed may be changed in the Template.
- Frozen 'Template' will automatically follow any changes made to trace lead selection, trace position, scale and page on the Review Screen and Main Screen.



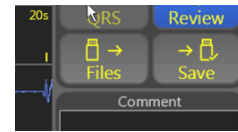
On the Main Page, users can load/hide the last saved 'freeze column' from trace page menu.



Figure 14: Load Frozen Column on the main page

### 10.3 Saving and Recalling Data

The SAVE button will save review data to an inserted USB Drive (format must be FAT32), or if absent, then to internal storage. The complete ECG buffer data along with Date/Time, the last Stimulation protocol and entered Comments are saved and the visible screen is also saved as a printable PDF file.



A Study is auto-created from the current Study Number and files numbered sequentially and with last Protocol name and first few characters of any Comment.

The File Manager shows content of OneStim internal storage or inserted USB drive with studies on the left panel and their files on the right.

Individual files may be loaded for review.

Single or multiple studies or files may be exported to USB drive, loaded from USB Drive or deleted.

Note: 'Sandisk' brand USB drives are recommended for compatibility, e.g. Cruiser Blade. Some other brands may fail to be detected. Format must be FAT32.

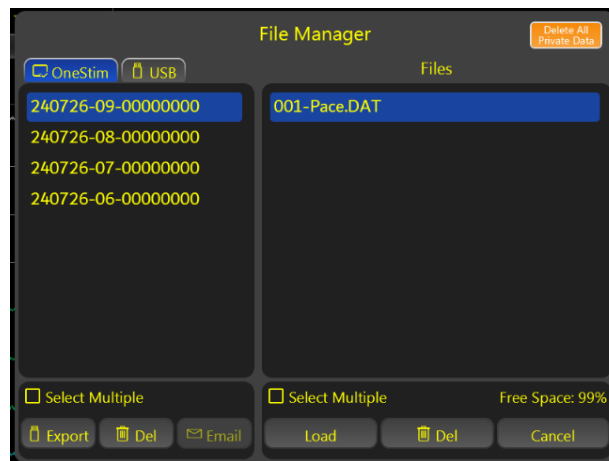


Figure 15: Study and File recall and management

### 10.4 Printing

PDF files saved on the USB drive may be printed Full 1:1 scale to A4 or Letter format paper from any computer with suitable PDF software.

Retained records should be suitably and securely identified to the patient, such in the Hospital Information System or with an applied 'Hospital ID sticker' if printed.

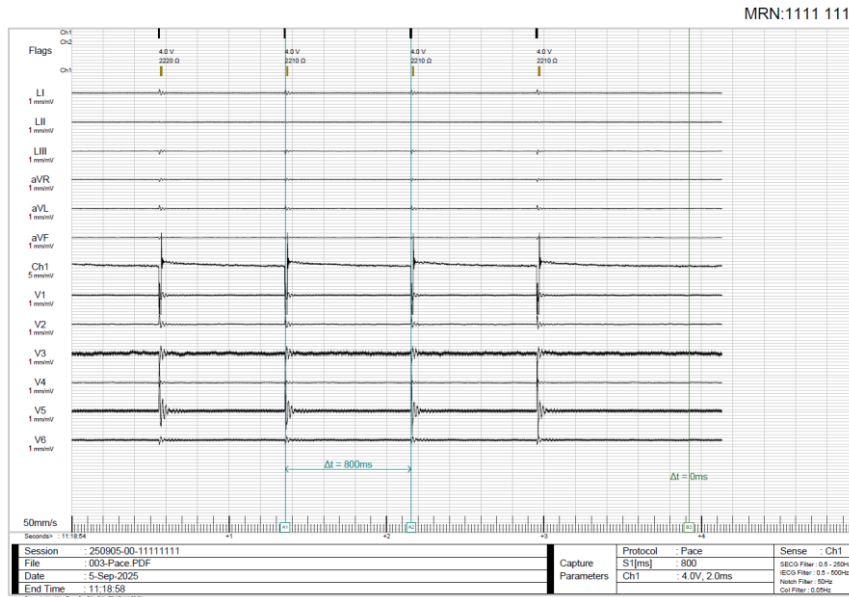


Figure 16: Example of ECG PDF Printout

## 11. Using the Emergency Pacing Output (EPO)

Emergency Pacing Output (EPO) is an independently battery powered emergency pacing output which remains available even if OneStim becomes inoperable due to device failure or depleted battery. On connection of pacing output to intra-cardiac pacing lead, EPO detects connection and immediately starts pacing at a fixed 100ppm / 8mA / 2ms.

**Warning: The Stimulator’s Emergency Pace outlet is not for life support.**

It may be used to pace a bradycardic or asystolic patient to maintain haemodynamic stability for the few seconds while retrieving and connecting a temporary external pacemaker. Emergency stimulation at 100ppm / 8mA starts automatically on connection to intra-cardiac leads (impedance < 50kΩ).



3. Pacing starts automatically, orange light flashes
2. Move pacing leads to Emergency Channel
1. Forcefully open cover

Figure 17: Emergency Stimulation Channel connection.

To use, open the clear cover on the Patient Connection Box and connect to patient’s ventricular pacing lead. Stimulation commences immediately on connection and will be indicated by flashing orange pulse between the Emergency Channel connectors and also at the OneStim Console at the right lower area titled Emergency. Use EPO only until the pacing can be changed to an approved temporary external pacemaker. The EPO battery has a shelf life of 10 years and provides more than 8 hours of pacing. Battery charge adequacy is verified at device power on tests; battery depletion while pacing is signalled pacing at half rate, i.e. 50 min<sup>-1</sup>.

## 12. Device Configuration

The device may be configured in the Configuration Menu. Refer to the Help Menu. Allows configuration of Background Parameters related to Basic Operation, including idle and sleep timeouts, ECG Settings, Stimulation Settings and Advanced Settings. Config menu can be protected by enabling password (fixed to 7845) in Localisation Setup menu.



## 13. Troubleshooting

Problem	Solution
OneStim is unresponsive when I press the ON (Sleep/Wake) button on the right hand side.	1. Ensure that device is switched ON at the Power Switch on the rear–underside of device.
	2. Battery may be depleted - connect to external power supply and try again.
OneStim is stimulating, but the patient's heart is not capturing.	1. Verify that the correct channel is being paced.
	2. Verify that the pacing circuit is complete.
	3. The LED next to the Pace Channel Current Setting button should flash green, if it flashes red, then the circuit is incomplete and all connections to the patient need to be checked.
	4. Check the Pacing impedance – in the Measurements section, indicated next to the Ohm ( $\Omega$ ) symbol for the paced channel. It should be between 300 and 1200 $\Omega$ for the intra-cardiac and between 500 and 2500 $\Omega$ for the esophageal pacing route.
	5. Check the position of the pacing lead in relation to the heart – preferably on an X-ray.
OneStim's display is frozen or OneStim starts beeping irregularly on start-up and responds erratically to touch	1. Restart the device by switching the Power Switch on the rear-underside of the device to Off and On, while making sure that nothing is touching the screen during start-up, as this will interfere with self-calibration of the touch screen.
The Emergency Stimulation does not work.	1. The Emergency Stimulation starts pacing automatically when it senses a conduction path of an intra-cardiac pacing catheter connected to its outputs (<50 k $\Omega$ )
	2. Test Emergency Stimulation by inserting the Micropace Test LED, MP3058, or by shorting outputs with a conductor (paper clip will do) – expect a tone and Pulse light on the Patients Connection Box to flash at 100ppm.
The On-screen Battery Indicator has a small cross on it or has incorrect charge indication, e.g. the device powers off at 20% charge.	1. This normally occurs for several charge & discharge cycles after replacement of a battery, until the fuel gauge 'learns' the new battery. If the issue persists contact service.
	2. If the battery has not been changed recently, this may indicate the End of Life or a faulty battery.
While pacing, pacing sounds are irregular and ECG display sweep pauses for a second.	1. Occasional delays in display are normal and do not interfere with pacing, which remains regular and accurate within $\pm 1$ ms.

**Table 3: Troubleshooting**

## 14. Software Warning / Error Messages

### 14.1 Flash Messages

OneStim issues brief 5 second advisory 'Flash Messages' in the middle of the screen.



These messages are self-explanatory, examples include:

Flash Message	Meaning & Action
F12: Cannot change config settings while pacing!	You must stop pacing before changing some parameters, such as those in the Configuration Menu.
F17: Cannot change protocol while pacing!	Stop pacing before changing stimulation protocol.
F18: Lower Limit : [number]	Enter a value within stated limits.
F35: Waiting for QRS Sync...	Start of stimulation is synchronized to ECG (Mode: 1stS1); waiting for ECG trigger to start pacing.
F37: Open Circuit ChX, Check leads	The stimulator detected an open circuit in the stated channel – check leads.
F38: High ChX Impedance	The stated channel has unusually high impedance (>5000Ω) – check leads.
F39: Short Circuit ChX, Check leads	The OneStim detected a short circuit in the stated channel – check leads.
F40: Low ChX Impedance	The stated channel has unusually Low impedance (<200Ω). – check leads.
F44: Battery Low! Connect to mains power	The battery is below 20%. Connect to mains power.
F46: Device not for life support pacing, use Temporary Pacemaker!	The OneStim has been pacing unattended for >2 minutes without diagnostic manoeuvres. The OneStim is for diagnostic use and not for life support pacing. If patient needs cardiac pacing for bradycardia, use temporary pacemaker.
F49: QRS Sync Timeout! Pacing Anyway	No ECG sync trigger came within safety timeout, (set by config "QRS Sync Timeout") so pacing started anyway. Ensure adequate ECG trigger when enabling Sync Mode.
M27: Device is not for ECG Monitoring and will shortly go to sleep.. (Device not for use as ECG Monitor)	After 2 minutes in idle safety state, OneStim enters power saving standby mode (on battery and on Mains). Device is not intended for nor safe for ECG Monitoring.

**Table 4: Flash Messages and Meaning**

**15. Maintenance**

**15.1 Batteries**

Internal main rechargeable LiFePO4 battery and 9V Emergency Stimulation Battery are located on the underside of the device. Labels indicate the replacement date. For optimal battery life, operate device on battery power until fully discharged at least once a month.



**Warning: Avoid the remote possibility of the lithium battery overheating and causing a fire by observing the following:**

1. Do not charge battery other than inside OneStim.
2. Do not puncture or incinerate; dispose per Section 15.4 below.
3. Only replace by service staff with Micropace replacement part specified on battery cover.

**15.2 Maintenance and Calibration**

1. Suggested weekly preventative servicing:
  - Inspect, clean and check the screen for correct operation when powered on.
  - Inspect all cables and connectors for damage – such as crushing or fraying.
  - Check integrity of enclosure anti-tampering seal under the handle.
2. Suggested annual additional preventative servicing:
  - Check battery replacement due date on underside of the OneStim.
  - Check that fan operates briefly at power switch on; verify outward air flow by a tissue hung in front of the vents on the left side of the device.
  - Check calibration of Emergency Stimulation output to be  $\geq 8V$  into 1 k $\Omega$  load.
  - Check calibration of Ch1-2/4 stim outputs into 1 k $\Omega$  load as per specifications.
  - OneStim self-calibrates. If found to be out-of-calibration, request factory service.
  - Perform electrical safety tests to IEC60601-1 /UL2601-1 using a suitable commercial tester, particularly leakage currents, especially if OneStim is connected to IT equipment such as a printer via USB or to a display via HDMI.

**15.3 Cleaning Instructions**







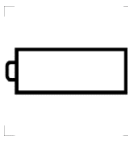






1. The stimulator parts and accessories should be inspected and if soiled, cleaned between patients using a cloth dampened with hospital equipment cleaning agents such as isopropyl alcohol (IPA), ethanol or mild soap. Do not spray or pour agents onto the equipment and do not use acetone solvents.
2. To clean the touch screen, use window or glass cleaner.
3. If using OneStim in ICU wards and also in operating rooms, take special care to avoid transfer of ICU pathogens into the operating room – clean device and accessories thoroughly and consider wrapping device in sterile plastic bag during use.















**15.4 Service, Serviceable Life and Disposal**

1. The OneStim system has no user serviceable parts apart from its two batteries and has an expected supported service life of 5 years.
2. Dispose of the LiFePO4 battery in an approved disposal or recycling facility.
3. Dispose of OneStim separately from household waste according to EU WEEE legislation – contact the distributor or Micropace for assistance.
4. Further technical and service support information is available by request at micropaceep.com.
5. Where possible, remove any study data from OneStim device prior to shipment for service or disposal.



## 16. Explanation of Symbols

Location	Symbol	Name	Meaning
On device side connector		Requirement to refer to instructions for use	Requirement to refer to instructions for use prior to use.
		General warning sign	To signify a general warning
		Type CF defibrillator proof	To identify a defibrillation-proof type CF applied part complying with IEC 60601-1
		Patient applied parts connections	To indicate the two connections to the patient from the side panel of the OneStim console
	 <b>ECG</b>	ECG cable connection point	Indicates the location of the ECG cable connection socket
		Connection for patient connection box	Indicates the location of the socket for the Patient Connection Box cable
On front panel of device		Battery power	To identify the power supplies status from the battery. On the left side, the image is backlit in 4 sections, indicating the power remaining in the battery. On the right side, image is green for nominal charge and red for depleted state.
		On / off / sleep	Indicates the push button on side of device for On/Off/Sleep functions
On rear panel		General warning sign	General warning sign
	<b>0 / I</b>	Power OFF / ON	Device is switched OFF and battery is NOT charging or device is ON and Battery Charging
	<b>HDMI</b>	HDMI video output	External Monitor Output
	<b>Aux</b> 	Input / output Auxiliary Port	Auxiliary Connector for high level ECG signal input and output
		Speaker output	High level speaker output to external speakers <b>Note:</b> The OneStim also contains an internal speaker to allow for communicating operational states
		USB	USB connector
		Equipotential Earth	Equipotential earthing socket for optional use with MP4118 Cable to connect to Hospital POAG (Potential Equalisation) socket. Intended for reduction of electrical signal interference noise; not for protective earthing; max current 0.5A.

Location	Symbol	Name	Meaning
On underside of device		Rechargeable battery location	Indicates the location of the main rechargeable battery
		9V battery	Indicates the location for the 9 volt battery for emergency stimulation
		Crossed-out wheeled bin	Do not dispose in general household waste
		General symbol for recovery/ recyclable	To indicate that the rechargeable battery and its material is part of a recovery or recycling process.
On patient connection box		Requirement to refer to instructions for use	Requirement to refer to instructions for use prior to use.
		Pace	Emergency channel stimulation
On patient connection box		Positive Output	Positive stimulus output
On patient connection box		Negative Output	Negative stimulus output
On patient connection box	Ch1 – Ch4	Ch1-Ch2 or Ch1-Ch4	Stimulation channel outputs
On medical device product/shipping label.		Manufacturer	Legal manufacturer
		Date of manufacture	Indicates the date when the medical device was manufactured
		Country of Origin	Indicates country of origin being Australia
		EC Rep	European representative
		UKRP	UK Responsible Person
		Catalogue No. Serial No. Lot No.	Catalogue Reference Number Product Serial Number Product Lot Number









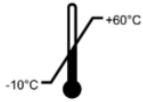




Location	Symbol	Name	Meaning
		Distributor	Distributor of product
		Importer	Importer of product
		Read Instruction for Use	Refer to Instruction for Use
		Is a Part of	Item is a part of named product
On Rear of Device and On Power Supply Unit		Alternating current	Alternating current
		Direct current	Direct current
On Power Supply Unit	<b>IP22</b>	Ingress protection	Protected from touch by fingers larger than 12 millimeters. Protected from water spray less than 15 degrees from vertical
		Indoor, dry location use only	For use indoor or dry locations only
		Consult Instructions for use	Indicates the need for the user to consult the instructions for use
On Package Shipping Label		Temperature limit	Harmonized symbol for temperature limit -10°C to +60°C
		Humidity limit	Harmonized symbol for Humidity from 10% to 85% RH
HDMI Cable		Video display	Connect cable to video display
ECG Cable		Do not Re-use	Indicates the cable is intended for single use only
eIFU		Electronic Instructions for Use	Software needed to download eIFU

Table 5: Meaning of symbols on device

## 17. Electromagnetic Interference (EMI) and Compatibility

### 17.1 EMI Warnings

This device is suitable for use in hospital environments only. It may be used in conjunction with RF ablation and surgical diathermy instruments.

This device is not rated for use in the vicinity of MRI equipment.

**WARNING:** Strong electromagnetic interference may cause corruption or loss of ECG trace and might cause erratic or un-programmed stimulation which may or may not be apparent on displayed ECG. In case of unexpected or erratic pacing by this device, inability to stop pacing via touch screen, or in case of defibrillator-resistant ventricular arrhythmias, immediately disconnect patient from this device and do not use device until serviced.

**WARNING:** The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

**WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12") to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

**WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.

## 17.2 Cable Lengths

OneStim with the cables and cable lengths listed in section 4.1 above comply with:

- Emissions CISPR 11, Class A / Group 1
- EN 60601-1-2: 2014

**WARNING:** The use of accessories or cables other than those specified may result in increased emission and/or abnormal function of the Micropace Stimulator.

## 17.3 EMI / EMC Specifications - Summary

OneStim was tested according to IEC 60601-1-2:2014 guided by TR 60601-4-2:2016. For details, refer to OneStim Technical Service Manual.

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	OneStim uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Immunity test	IEC 60601 test level	Compliance
Electrostatic discharge (ESD) IEC 61000-4-2	Level, 4 ± 8 kV contact ± 15 kV air	Complies
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Complies
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Complies
Voltage dips, variations, short interruptions on power supply input IEC 61000-4-11	Per standard	Complies
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Complies
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Complies
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	Complies

## 18. OneStim Specifications

### 18.1 General

Specifications V1.5

Parameter	Value
Power Source	Input Class I, 100-240VAC to 18V 60W medical grade Power Supply
	Rechargeable Battery, LiFePO <sub>4</sub> , 4S2P 12.8V 38.4Wh
Power Consumption	Normal operation: 15W Average Sleep Mode: < 0.5W
Operating time on battery	2 hours continuous 8 hours typical use (sleep after 3 min idle)
IPXX Rating	None. Protected according to IEC60601-1. Refer to Technical Manual for detail.
Applied Parts Classification	sECG and Stimulation Outputs: Class CF, Defibrillation proof.
Display Resolution	HD 1280 x 800 pixels
USB Port	USB A, compatible with Sandisk drives
Weight / Dimensions	3.7 kg (4.55 kg with accessories) / 33 cm x 12 cm x 29 cm
Environmental	Operating T° Range: +5°C to +35°C (30% to 80% RH) Storage T° Range: -10°C to +60°C (10% to 85% RH) Altitude (transport): 0 to 14,000ft (4,267m)

## 18.2 Stimulation Electrical Specifications

Stimulation Parameter	Value
Stimulation Channels	2 (Pace Mode) 4 (EP Mode)
	1 Emergency Pace Output (EPO) 100ppm / 8mA nominal
Stimulation Circuit Isolation	Type CF, IEC60601-1, CM 5kV, DM 500V energy attenuating,
Current range	0.1 to 25mA into 200Ω to 1000Ω
Voltage Range	0.1 to 25V, max 25mA (EP Mode) 0.1 to 8V, max 25mA (PACE Mode)
Pulse waveform	Monophasic (Mono) (EP Mode) or Asymmetrical Biphasic (Asym) (Pace Mode) with charge recovery.
Pulse duration	0.1 to 10ms (EP Mode) 0.1 to 20ms (EP Mode, Config 31. Esophageal mode) 0.1 to 2ms (Pace Mode)

## 18.3 Stimulation Timing Specifications

Pacing Parameter	Value
S1	280 - 5000 ms in Pace Protocol, 10ms step 100 - 5000 ms in Burst Protocol, 10ms step 30 - 100 ms in Optional HFS Protocol, 1ms step
Extra-stimuli	S2,S3,S4,S5 (EP Mode) S2 (PACE Mode)

Pacing Parameter	Value
S1	280 - 5000 ms in Pace Protocol, 10ms step 100 - 5000 ms in Burst Protocol, 10ms step 30 - 100 ms in Optional HFS Protocol, 1ms step
S2-S5 interval	30 - 5000 ms
Interstimulus interval accuracy	±1ms
Auto-Decrement	-50 to +50 ms, on highest enabled Sx
QRS Refractory / Blanking	50 - 990 ms, ±5ms
QRS Sync Delay	10 - 2000 ms

### 18.4 Intra-cardiac iECG Specifications

iECG Sensing Parameter	Value
Channels	Equal to Stimulation Channels
Input ranges (FSD)	± 300mV
Common Mode Range	±300 mV
Software display sweep speeds	10, 25, 50, 100, 200 mm/s (additional 2, 5, and 400 mm/s in the review screen and PDF printout)
Frequency Filter Settings	HPF: 0.05, 0.5, 1, 5, 30 (default), 80, 150 Hz LPF: 250 (default), 500 Hz Individual Trace Control: Filtered: 30Hz / Unfiltered: 0.05Hz
Input impedance	60 KΩ (pacing charge dissipating)
Input CMRR	>80 dB
iECG Sampling:	2000 Hz(sps), Sampling effective 16 -bits, 4.7 uV/bit resolution
Pacing Impedance Measure	Range: 50 Ω ('<50') to 9000 Ω ('> 9k')
Defibrillation Recovery Time	< 5 seconds

### 18.5 sECG Specifications

sECG Sensing	Value
Leads	Standard 5 or 12 Lead sECG
Input ranges	±10 mV
ECG display amplitude scales	1, 2, 5, 10, 25, 50, 100 mm/mV
ECG display sweep speeds	10, 25, 50, 100, 200 mm/s (& 2, 5, 400 mm/s in review screen)
Input impedance	>1 GΩ
Input CMRR	90 dB
sECG Sampling	1000 Hz, 19-bit, 20 uV/bit
Defibrillation Recovery Time	< 5 seconds

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### 18.6 Ext. Input ECG Specifications

Extern. ECG Sensing	Value
Inputs	One, galvanically isolated to 1.5kV
Input ranges	$\pm 1V$ Accuracy $\pm 10\%$
External ECG Amplifier Gain	1 to 250
Frequency Range(-3dB)	0.5 Hz to 250 Hz nominal

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### 18.7 ECG Notch Filter

ECG Notch Filter	Value
Channels	When enabled applies to sECG, iECG and Ext.
Notch Frequency	Selectable 50Hz / 60Hz

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### 18.8 Emergency Stimulation Channel

Emergency Stimulator	Value
Power	9V LiMn Battery, 10 year standby life, >8 hours operation
Pacing Activation	Activated by connection to intra-corporal pacing electrode pair (activating impedance <50 k $\Omega$ approximate)
Pacing Parameters	100ppm, 8mA (+1/-3 mA), up to 8V, 2ms pulse duration
Warnings	Low Battery: Red battery LED & Pacing rate falls to 50 min <sup>-1</sup> Disconnection: 3 seconds long pacing sound