OneStim

USER INSTRUCTION MANUAL

OneStim-CRM

Cardiac Stimulator / Recorder

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Micropace Cardiac Stimulator OneStim
User Instruction Manual
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1. INTRODUCTION

1.1 Device Description

OneStim is a portable diagnostic programmable cardiac stimulator with an integrated ECG display for performing simple cardiac electrophysiological investigations.

The portable stimulator has four channels for cardiac stimulation and electrogram recording together with 5 or 12 Lead surface ECG. Stimulation is current controlled or voltage controlled suitable for cardiac stimulation via diagnostic catheters, pacing leads or trans-oesophageal electrodes.

The device displays up to 8 channels of intra-cardiac and surface ECG signals on a 12” touch display. Analysis may be performed on a triggered display with sweep speed up to 400mm/s, with interval measurements and a review page with print to PDF files onto 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
ECG	Generic Electrocardiogram – iECG or sECG or endo-oesophageal electrogram
EP	Electrophysiology
iECG	Intra-cardiac ECG
sECG	Surface ECG
QRS	P wave or QRS; also signifies any iECG complex
RA	Right Atrium
RV	Right Ventricle
RF	Radiofrequency, e.g. RF Ablation
RR	R-R interval on ECG or peak-to-peak interval on iECG.
Drive Train	Also called S1; the 6-8 regular pacing stimuli before any extra-stimuli is applied
S1	Basic stimulation interval
Sx	The name for and the coupling interval of extra-stimuli added after S1 Drive Train called S2, S3, S4
SNRT	Sinus Node Recovery Times
HFS	High Frequency Stimulation, for cardiac Ganglionic Plexus stimulation
Sync	Synchronization / trigger stimulus to ECG event
CM / DM	Common Mode / Differential Mode
EP / CP Mode	Electrophysiological / Conduction System Stimulator mode
EPO	Emergency Pacing Output
PSA	Pacemaker System Analyser

2. ESSENTIAL PRESCRIBING INFORMATION

2.1 Intended use

The OneStim Cardiac Stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachy-arrhythmias, refractory measurements and measurements of electrical conduction.

2.2 Indications for Use

The OneStim Cardiac Stimulator is an electrical stimulus generator for diagnostic cardiac stimulation during electrophysiological testing of the human heart.

2.3 Intended Operating Environment and Users

The OneStim Cardiac Stimulator is intended for use in hospital cardiac electrophysiology laboratories and high-dependency hospital wards equipped and staffed for advanced cardiac resuscitation.

Examples of suitable environments include:

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

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.

Device is not intended for use with flammable gasses or liquids, including oxygen rich environments; the required electromagnetic environment is described in the Technical Manual.

Device is intended to be used by licensed specialist cardiologist physicians or surgeons expert in arrhythmia management and trained on OneStim, with device operated by them or by trained cardiac technicians under the physician's direct supervision.

2.4 Intended Patient Population

The OneStim Cardiac Stimulator is intended for use on all patients for whom the treating licensed physician prescribed electrophysiological testing of the heart, without limitations on age including neonates, gender, race, body size or degree of illness.

2.5 Contraindications

Do not use the Stimulator system for life support in patients with life-threatening bradycardia; use instead temporary external pacemaker

2.6 Clinical Benefits

The OneStim portable variant of the Micropace family of Diagnostic Cardiac Stimulators, when combined with stated compatible catheters and equipment enable specialist physicians to perform cardiac electrophysiological studies (EP studies) for the diagnosis of a variety of symptomatic and life-threatening cardiac arrhythmias and guiding life-preserving therapies including cardiac ablation, permanent pacemakers, automatic implantable defibrillators and cardiac arrhythmia surgery.

Over 5,500 Micropace cardiac stimulators distributed since 2001 into over 59 vcountries are estimated to have been used in 3.7 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 Guidelines.

2.7 Compatible Equipment

Micropace OneStim Cardiac Stimulator is intended for use with the following equipment:

Diagnostic and Ablation 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 transesophageal 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 7000, XT).

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 NOT tested for compatibility with Pulsed Field Ablation devices.

2.8 Important Patient Safety Warnings

The OneStim produces standard cardiac stimulation outputs similar to other existing programmable cardiac stimulators in use for the past 30 years; there are no known adverse effects from short term diagnostic use of such stimulation when applied correctly. Following is a list of potential adverse events from Stimulator device malfunction or human error (in alphabetical order):

- ❑ Arrhythmia
- ❑ Death
- ❑ Explosion or fire
- ❑ Myocardial injury
- ❑ Operator electrocution

Refer to below Warnings and Precautions.

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 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.

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: Permanent Pacing Lead measurements

- When performing electrophysiological measurements using permanent pacing leads, in order to avoid exposing electrodes to excessive currents, always use OneStim in PACE Mode, limiting stimulation pulses to 10V and pulse widths to 2 ms and no more than values available on the lead manufacturer's Pacing System Analyser.
- 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

- W6.1 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.

2.9 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 stimulator 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.

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.
- 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 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 PACE OUTPUT socket on the right side of Console.
- Use of excessive stimulation currents may induce fibrillation and produce misleading results in ventricular stimulation studies.
- OneStim is protected against lightly splashed liquids from above only; the Operator should protect it from liquids and contamination on the touch screen and into 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 6 hours of typical intermittent use with power saving sleep states enabled.

- 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 of soft surfaces such as a bed.
- OneStim can resist the maximum high energy (up to 5kV) from defibrillation 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 other than MRN and delete or transfer all patient data from OneStim to a secure location, such as the Hospital Information System (HIS) promptly after procedures.

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**
    - Medical Device Regulations (2007/745), Rule 10 classification: **Class IIb** medical device
    - FDA Medical Device Classification: **Level 2 (performance standards)**

3.2 Medical Electrical Equipment

- IEC60601-1 Class II ME Equipment
- Power supply mains Input Class I (3rd conductor is only functional earth, 2 x MOPP)
- Type CF applied parts: ECG leads, Stimulation channels
- Console: Protected from vertical rain (Cl201.11.6.5 of IEC60601-2-27)
- Patient Box: Protected from 500ml 5%NaCl spill (Cl201. 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 60601-1-2:2015 (EMC)
    - EN/IEC 60601-1-6:2010 (Usability)
    - EN/IEC 60601-2-27:2011 (ECG Monitors), applicable clauses
- EN/IEC 62304:2006 (Medical device software - Software life-cycle processes)
- EN 62133:2013 (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: +5ºC to +35ºC
- Operating Relative Humidity Range: 30% to 80% RH

4. OneStim Description and Connections

4.1 Unpacking components, installation and training

Ordering No. (REF)	Description
MP5001-2PA	OneStim-CRM Cardiac Stimulator

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

Part Number	Part Name	Part Description	Length
MP4011-2BC	OneStim-CRM Cardiac Stimulator	OneStim-CRM Console 2 Channel	N/A
MP4075-2B	Patient Connection Box 2CH	Patient Connection Box 2 Channel	2.5 m
MP4105	ECG Cable, 10 lead	ECG Cable, 10 lead Integrated IEC	4.6 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-EU	Mains Cable, EU	Mains Cable, European style	2.0 m
MP3059-UK	Mains Cable, UK	Mains Cable, UK style	2.0 m
MP3059-IT	Mains Cable, IT	Mains Cable, Italy style	2.0 m
MP4006-CRM	User Instruction Manual	User Instruction Manual	N/A

Part Number	Part Name	Part Description	Length
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-EU	Mains Cable, EU	Mains Cable, European style	2.0 m
MP3059-UK	Mains Cable, UK	Mains Cable, UK style	2.0 m
MP3059-IT	Mains Cable, IT	Mains Cable, Italy style	2.0 m

Optional components:

Part Number	Part Name
MP4085	4 Channel Unipolar Reference Adaptor Cable
MP4136	Equipotential Grounding Cable 5M
MP4009	Carrying Case
MP4003	SIP/SOP Cable Adaptor
MP3058	Circuit Continuity Test Led
MP4138	HDMI Male to DVI Male Cable 5M
MP4140	HDMI Male to HDMI Male Cable 5M

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

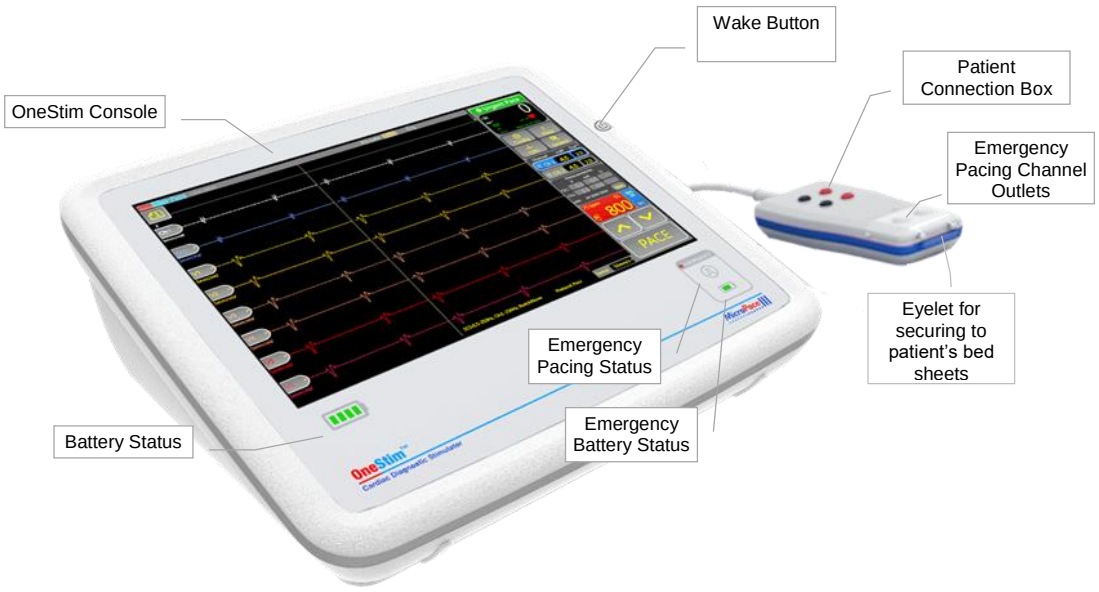


Figure 1: OneStim Product Appearance

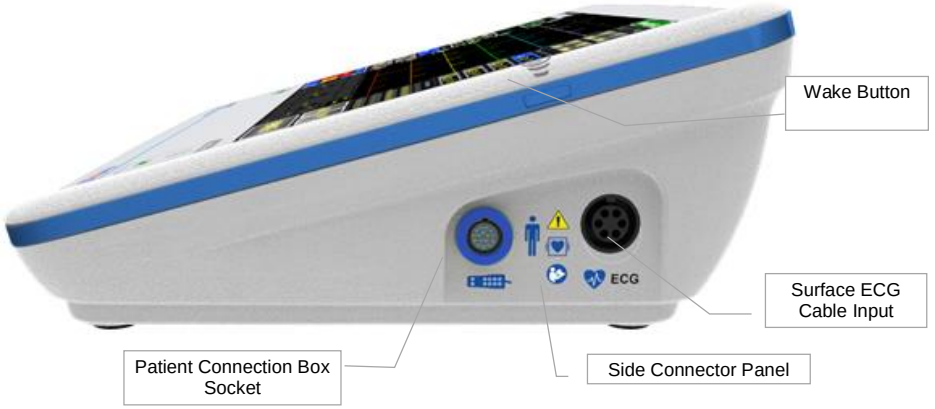


Figure 2: OneStim Product Connection Ports

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 3rd 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.

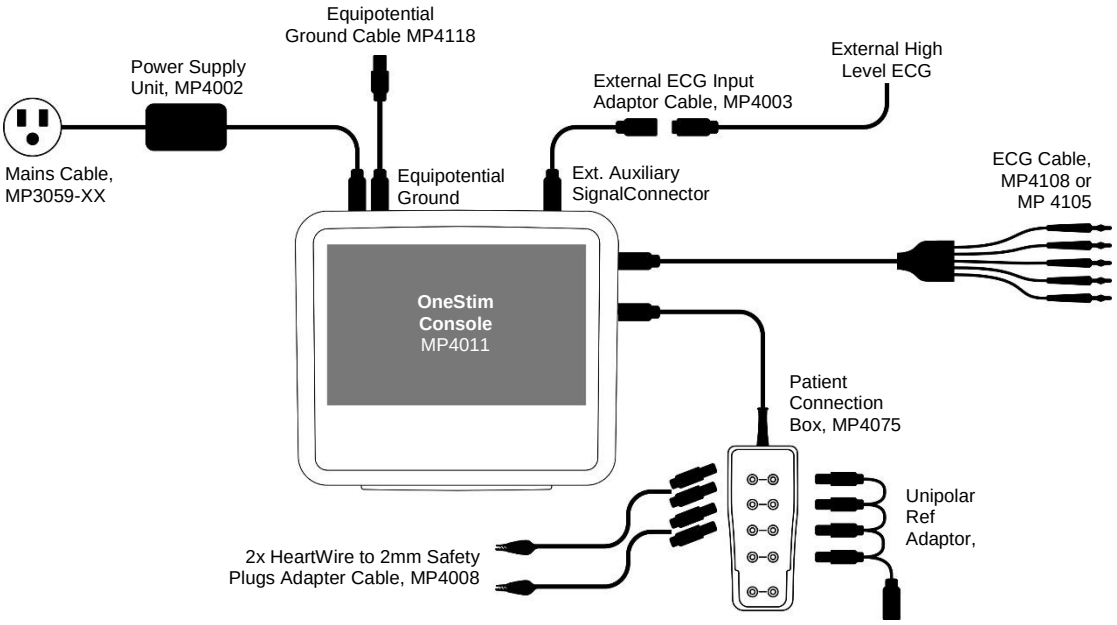


Figure 3: OneStim Components Connection Diagram

4.4 Turning on, verifying and operating device

Switch On 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.

OneStim will display POST self-test results on power up. 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 6 hours has elapsed since last use, a Safety Message and a dialog box to create New Study number appear.

OneStim enters Sleep Mode and 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 wake button on right side of screen.

4.5 Connecting OneStim to the Patient – PACE Mode

Connect Patient pacemaker lead to Patient Connection Box and to pacemaker PSA as required as shown.

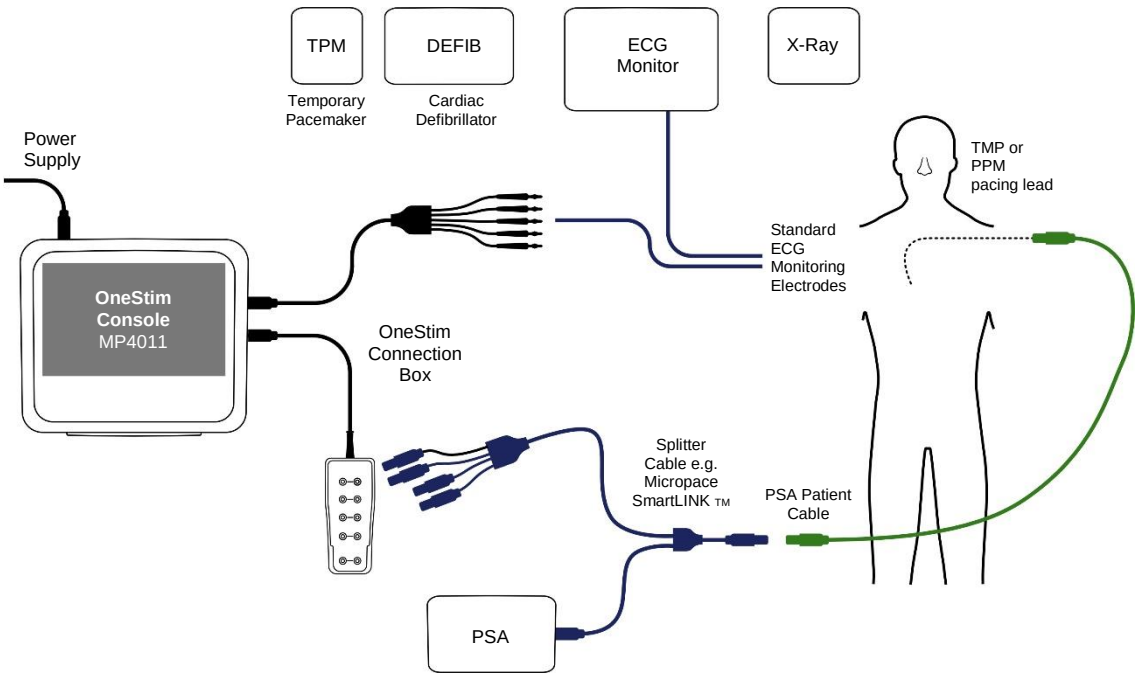


Figure 4: Example of Patient connections to pacing lead

5. OneStim Basic Operation

5.1 PACE Mode Main Screen

The PACE Mode is a simplified interface with limited voltage controlled stimulation intended for measurement of cardiac conduction using permanent pacing leads at different locations and intra-cardiac and surface electrocardiograms, prior to pacing lead implantation.

PACE Mode facilities include:

- Stimulation Voltage Control, with limited voltage and current output for compatibility with permanent pacing leads.
- Surface ECG trace display
- Two intra-cardiac channels with a single Pace pacing protocol.

PACE Mode Main Screen has the following controls.

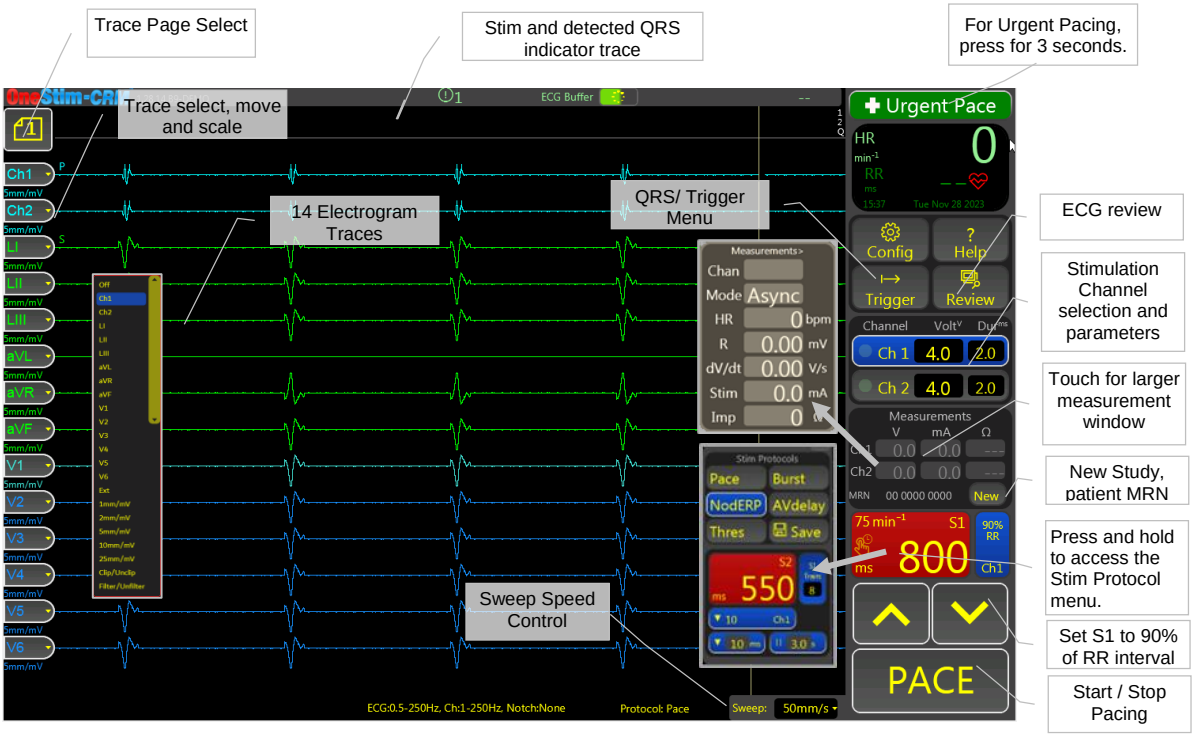
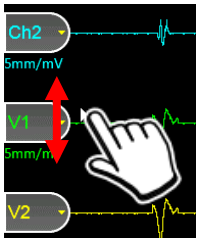
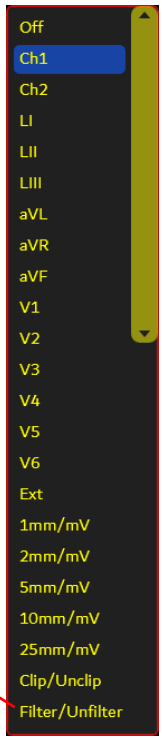


Figure 5: Main OneStim Touch Screen in Pace Mode

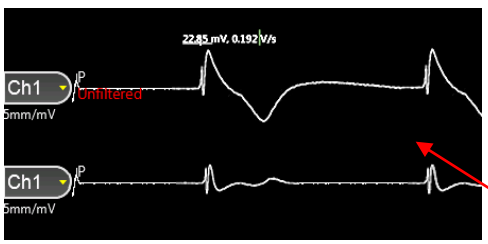
6. ECG Signals

6.1 Setting up ECG Sources for display



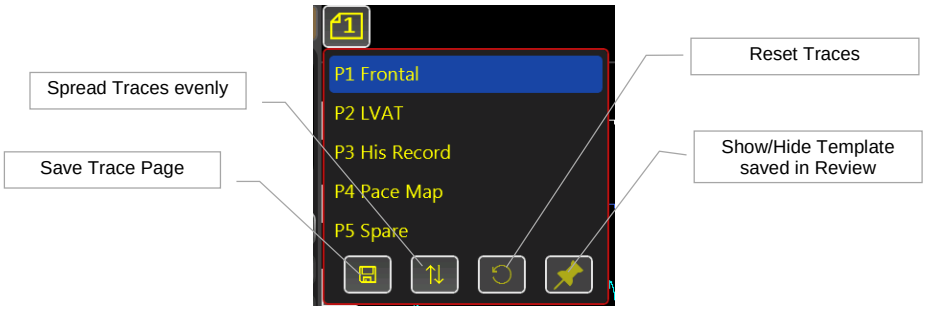


1. Single-tap the Trace Control Tab to show its menu to select source of ECG and the vertical scale (only one item may be selected from menu at a time).
2. ECG signal may be from:
   - Surface leads (sECG): I, II, III, aVR, aVL, aVF, V1, (and V2, V3, V4, V5, V6 for 12 Lead ECG)
   - Stimulation channels iECG: Ch1 to Ch4 or
   - External High Level ECG input: Ext
3. For External High Level ECG input (e.g. from a bedside ECG Monitor), set Configuration parameter B23 ‘Amplifier gain External ECG’ to the ECG monitor’s gain. (For example, an ECG monitor outputting ±1V signal representing ±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



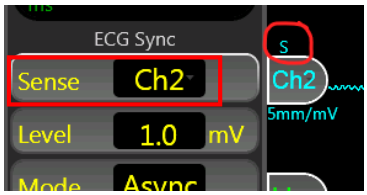
6.2 ECG Trace Page Menu

The ECG Trace Page menu allows you to select and save different trace pages. Trace 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.

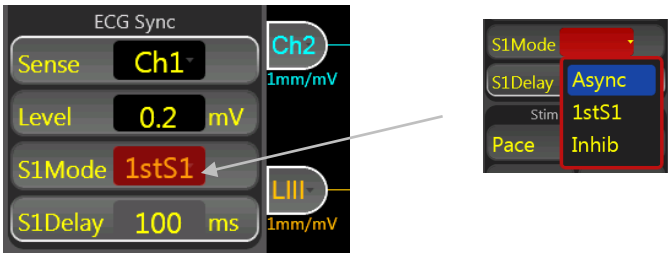
6.3 Selecting Sensed ECG source



1. Select ECG for sensing by Sync or trigger for stimulation by double-tapping the Sense Parameter and selecting channel from menu.
2. The Sensed Display Channel is indicated by an ‘S’ symbol above the channel handle.
3. Note: augmented leads aVL, aVF and aVR can be displayed on screen but cannot be used for sensing.

6.3.1 Setting Stimulation Sync to ECG

Stimulation S1 train by OneStim is asynchronous (VOO or AOO) except for the first S1 stimulus which may be synchronized to the intrinsic electrogram with a set delay, after which pacing is always asynchronous overdrive. Synchronization source 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 Handle.

S1Mode: Mode of Stimulation**:**
Select from:

1. **Async**: asynchronous pacing, pacing starts immediately and regardless of patient’s intrinsic ECG activity.

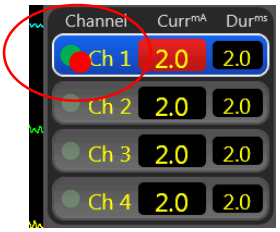
2. **1stS1**: synchronizes onset of pacing (1st S1) to be a set delay after first sensed QRS, following which stimulation is asynchronous (VOO/AOO).
3. **Inhibited**: each S1 is inhibited if earlier QRS is sensed in ECG indicated by Flash "Inhibited". When inhibited pacing, checks for noise i.e. moving average of HR in last 2 seconds is more than set reversion rate, displays a flash message & reverts to Async.

   Note1: 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 10-990ms; Special value 0 sets delay to '=S1'.

6.3.2 Selecting Stimulation Channel

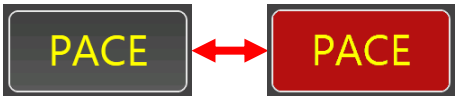


Touch Stimulation channel to select it.

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.

6.3.3 Pace On / Off

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

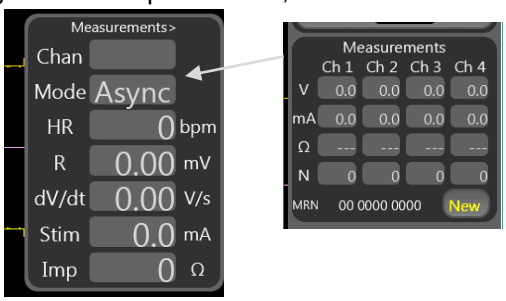


6.4 Stimulus pulse measurements

The measurement Panel displays measured resulting stimulation parameters, for each stimulus or averaged for stable readable display.

- V: Voltage, in Volts
- mA: Current, in mA
- Ω: Impedance, (= Volts / mA)

Touching the measurements displays a larger format summary panel, including also A / V wave amplitude and dV/dT.



7. Performing Diagnostic Stimulation

7.1 Pace Mode Pacing Protocols

Pacing Protocol menu may be displayed by prolonged press of S1 button, containing 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: 'Nodal ERP' single S2 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.

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 adjust speed of reducing current.

Icons:  = Pause,  = S2 Decrement.

8. QRS /Trigger Submenu:

This menu provides navigation to Configuration and Help pages and QRS display in a triggered sweep page. QRS Detection menu allows synchronization of start of pacing to sensed ECG as in EP Mode.

8.1 QRS Trigger Page

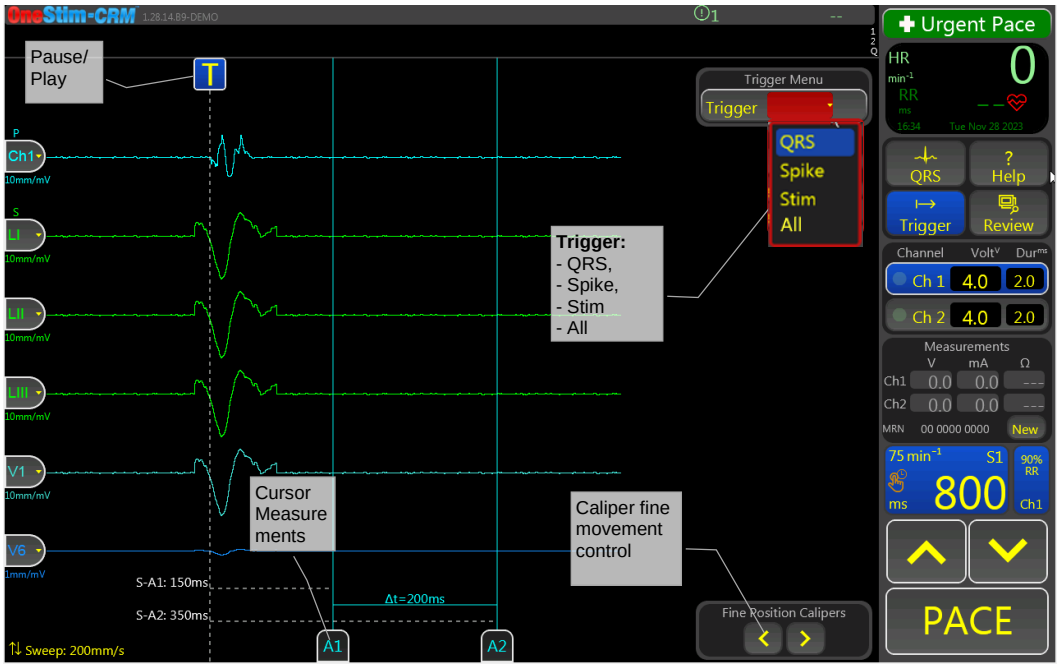


Figure 6: QRS Triggered Sweep page

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

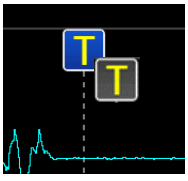
1. **QRS**: Detected QRS (first peak)
2. **Spike**: Pacemaker Spike (External PPM or PSA)
3. **Stim**: OneStim pacing stimulus
4. **All**: Any above events will trigger

The Page provides three measurements in milliseconds:

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

8.1.1 Pause / Go button

This control “T” pauses and restart the triggering of display.



8.1.2 QRS Detection

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.

8.2 Urgent Pace

For urgent physiological pacing, no matter which protocol and what parameters are set at the time, press and hold 'Urgent Pace' **for 3 seconds** – OneStim will enter Urgent Pace Protocol, stimulating at 600ms into all channels at a higher current.

Select any Protocol to exit this mode.

Note: this is distinct from independent separate battery powered Emergency Pace Output (EPO) described below.

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

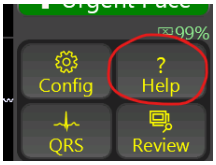
9. Auxiliary Menus

9.1 Config Menu

Allows configuration of Background Parameters related to Basic Operation, including idle and sleep timeouts, ECG Settings, Stimulation Settings and Advanced Settings.

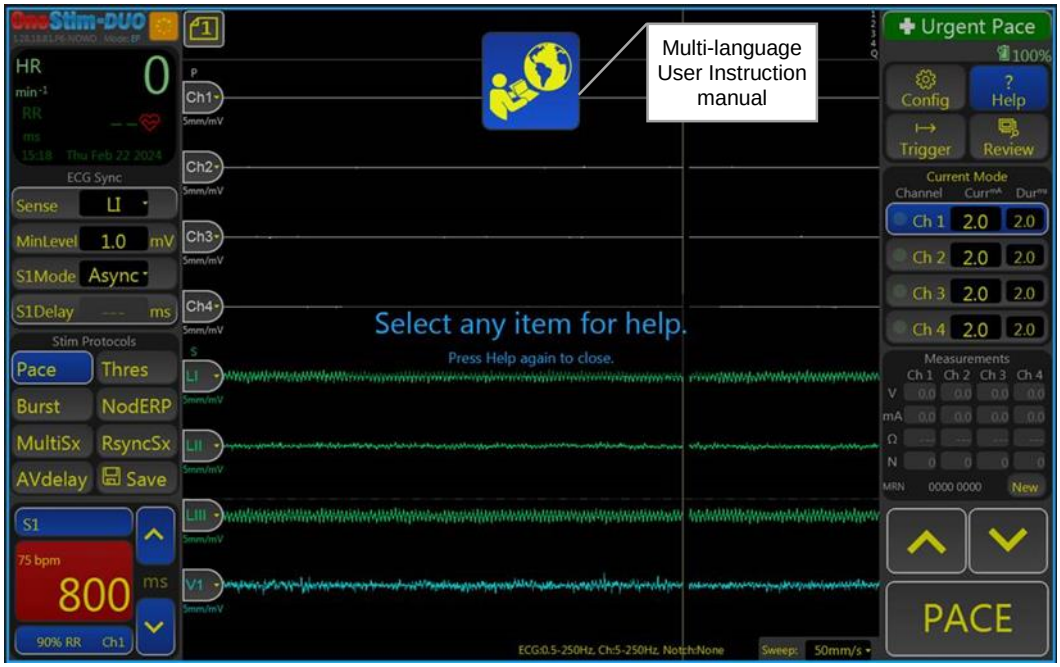
9.2 Help Menu

To obtain help information on parameters, press the 'Help' icon and then click the element for which help is required.

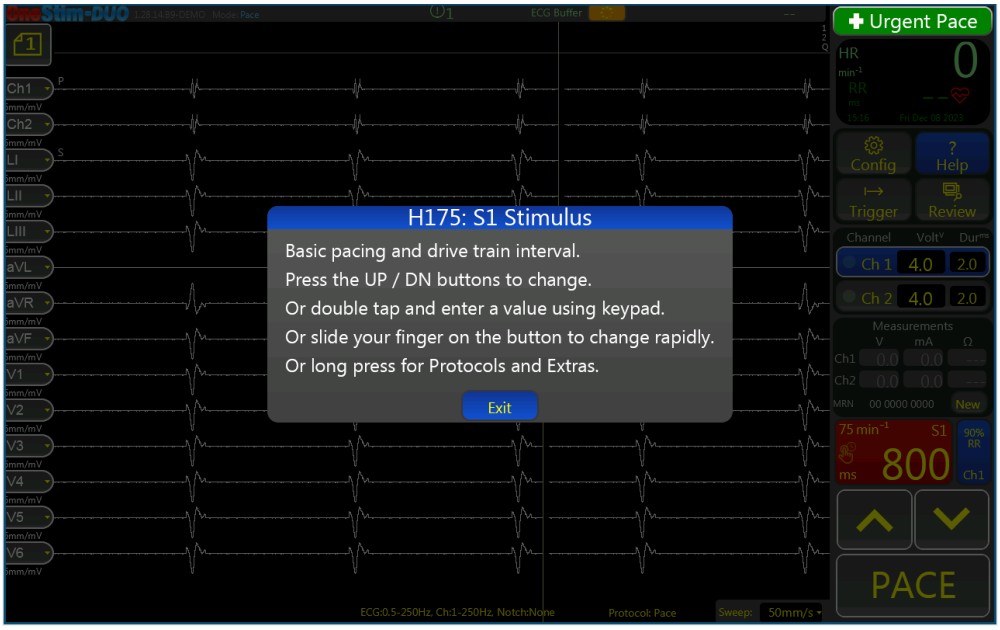


For example, to get help on S1 Stimulus, press 'Help'.

Press the Book Icon at the top for multi-lingual User Instruction manual.



Then touch the S1 field:



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:

Swiping left or right on the trace to pan sideways.

Swiping up or down to change sweep speed.

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.

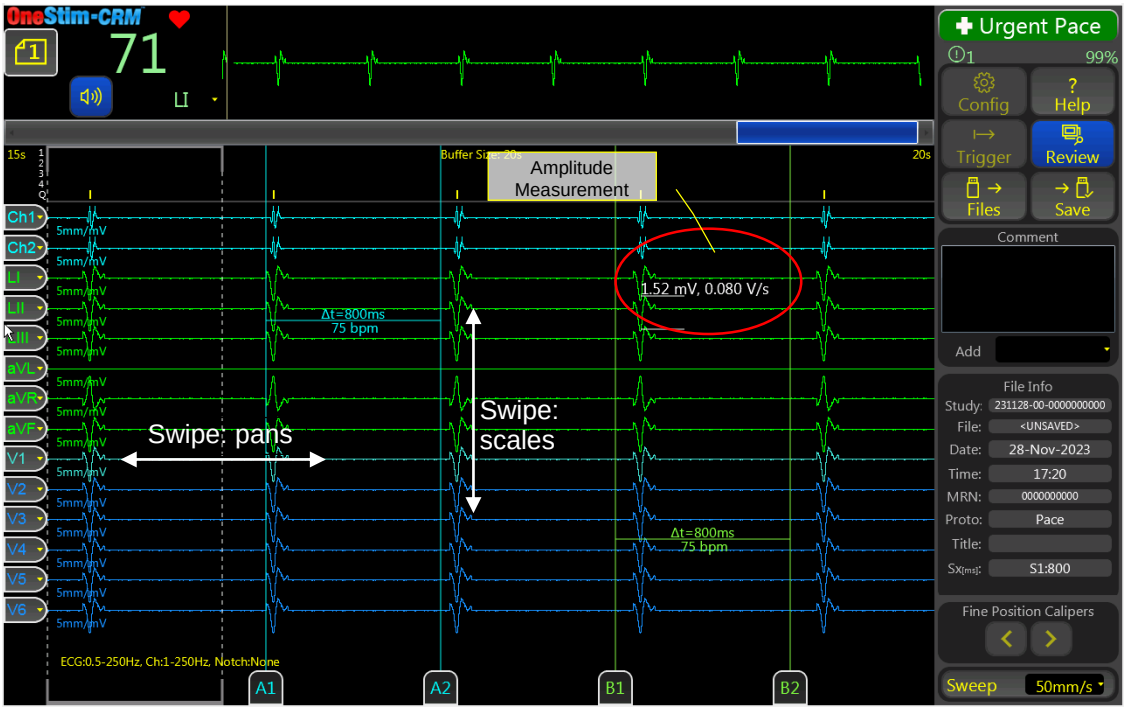


Figure 7 Review Screen with Time callipers and amplitude calliper (circled).

Electrogram size and timing may be measured as follows:

Touching the electrogram feature for 1 second will show the amplitude (red circled - Figure 7).

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 allow users to save the leftmost of traces as a template.

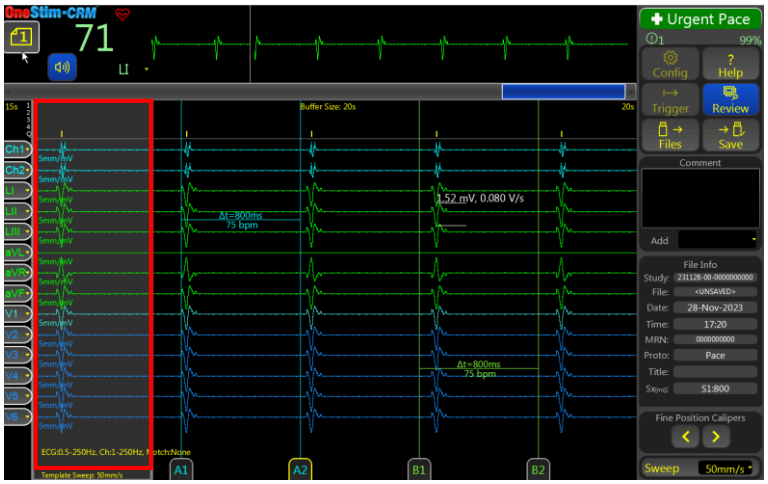
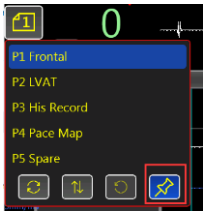


Figure 8 Review Template/Freeze column



- 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 but not sweep speed may be changed in the Template.
- 'Freezed' column follows changes of trace selection, trace position, scale and page on review page.

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

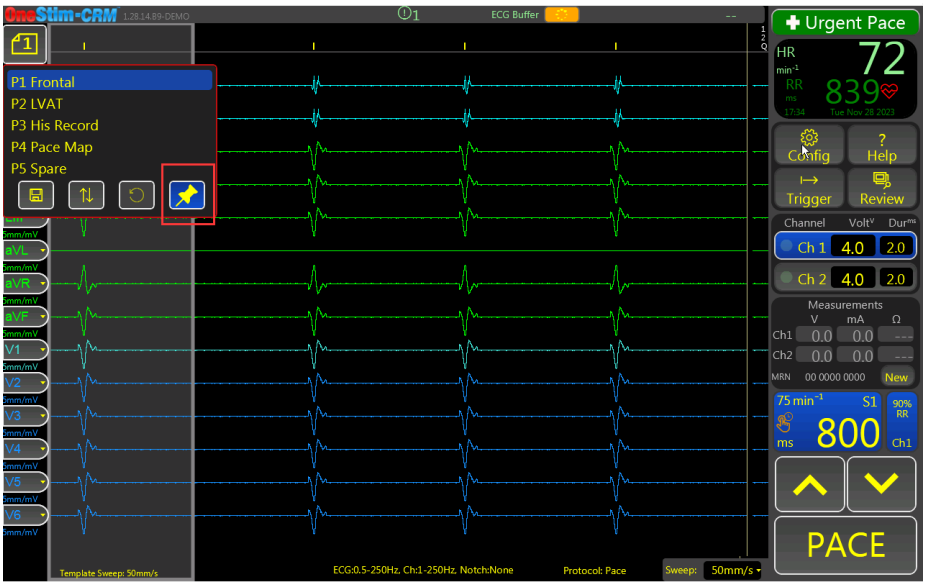
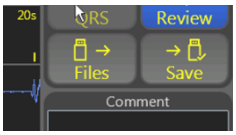


Figure 9 Load Freezed Column on the main page

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. Cruzer Blade. Some other brands may fail to be detected. Format must be FAT32.

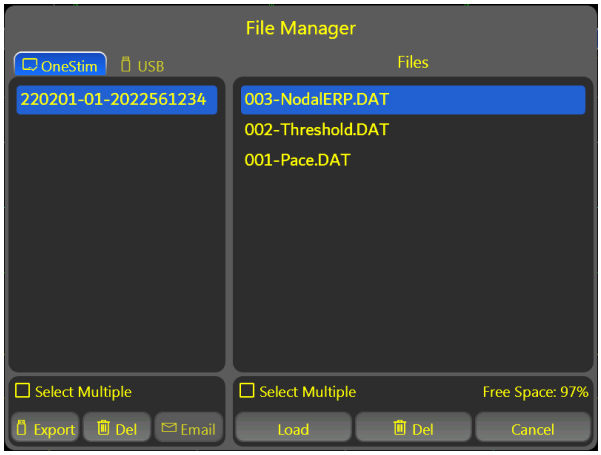


Figure 10: Study and File recall and management

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.

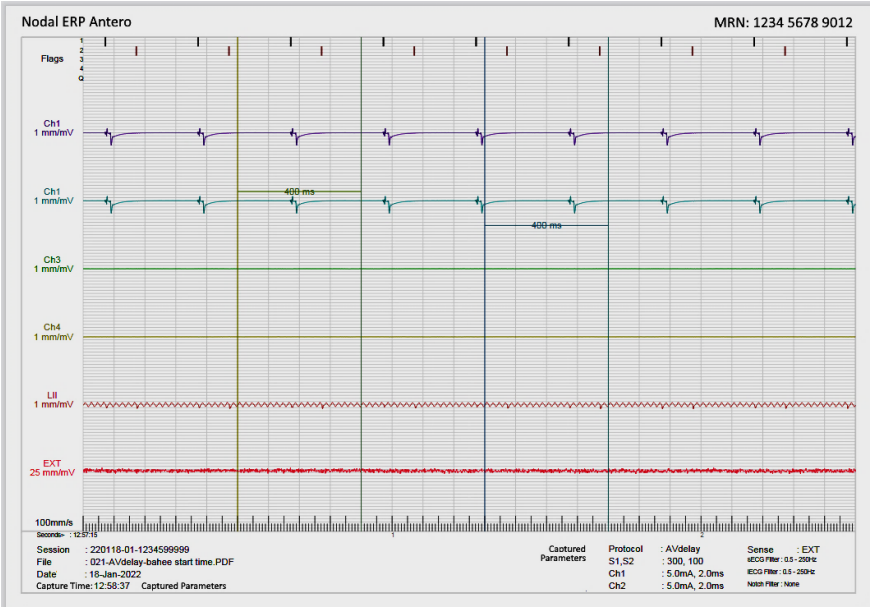


Figure 11: Example of ECG PDF Printout

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 and 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).

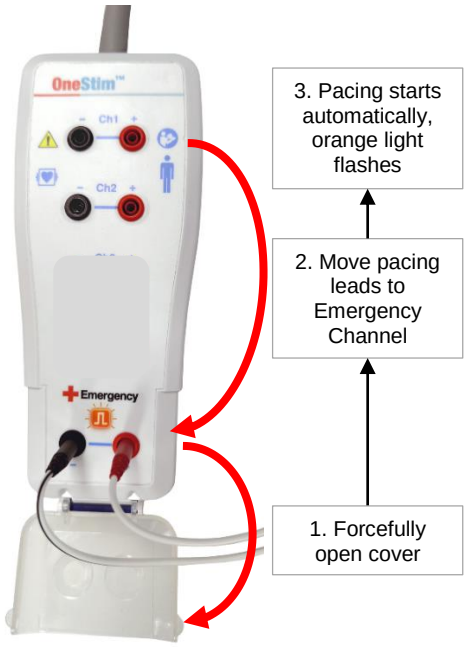


Figure 12: Emergency Stimulation Channel connection.

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^{-1}.

12. Device Configuration

The device may be configured in the Configuration Menu. Refer to the Help Menu.

13. Troubleshooting

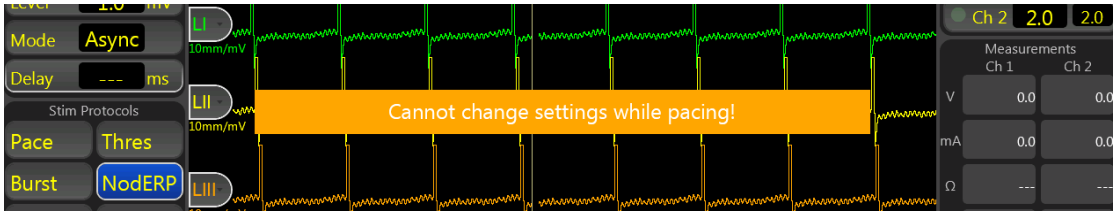
Problem	Solution
OneStim is unresponsive when I press the ON (Sleep/Wake) button on the right hand side.	1. Ensure that device is switched ON at the Power Switch on the rear–underside of device.
	2. Battery may be depleted - connect to external power supply and try again.
OneStim is stimulating, but 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 (Ω) symbol for the paced channel. It should be between 300 and 1200 Ω for the intra-cardiac and between 500 and 2500 Ω for the oesophageal 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 kΩ)
	2. Test Emergency Stimulation by inserting the Micropace Test LED, MP4086, 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 ±1ms.

Figure 13: 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 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.
F49: QRS Sync Timeout! Pacing...	No ECG sync trigger came within safety timeout, (set by config (51) "QRS Sync Timeout") so pacing started anyway. Ensure adequate ECG trigger when enabling Sync Mode.
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 (>2000Ω) – 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.
F27: 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.

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: In order to avoid the remote possibility of the lithium battery overheating and causing a fire,

(i) only replace by service staff with Micropace replacement part specified on battery cover.
(ii) do not charge the battery other than inside OneStim.
(iii) do not puncture or incinerate; dispose of as below.

15.2 Maintenance and Calibration

(i) 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.

(ii) 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 ≥ 8V into 1 kΩ load.
- Check calibration of Ch1-4 stim outputs into 1 kΩ 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

(iv) The stimulator parts may be cleaned 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.

(v) To clean the touch screen, use window or glass cleaner.

(vi) 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 thoroughly and consider wrapping in sterile plastic bag. Ideally, also consider having a dedicated OneStim device for operating rooms.

15.4 Service, Serviceable Life and Disposal

(i) The OneStim system has no user serviceable parts apart from its two batteries and has an expected supported service life of 5 years.

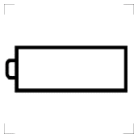
(ii) Dispose of the LiFePO4 battery in an approved disposal or recycling facility.

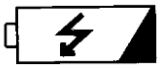
(iii) Dispose of OneStim separately from household waste according to EU WEEE legislation – contact the distributor or Micropace for assistance.

(iv) Further technical and service support information is available by request at micropaceep.com.

(v) Where possible, remove any patient 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
	 ECG	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
	0 / I	Power OFF / ON	Device is switched OFF and battery is NOT charging or device is ON and Battery Charging
	HDMI	HDMI video output	External Monitor Output
	Aux 	Input / output Auxiliary Port	Auxiliary Connector for high level ECG signal input and output
		Speaker output	High level speaker output to external speakers **Note:** 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		Rechargable battery location	Indicates the location of the main rechargable 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	Channel 1 to 4	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	EC Rep	European representative
	UKRP	UKRP	UK Responsible Person
	REF SN LOT	Catalogue No. Serial No. Lot No.	Catalogue Reference Number Product Serial Number Product Lot Number

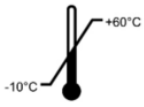
Location	Symbol	Name	Meaning
		Distributor	Distributor of product
		Importer	Importer of product
		Read Instruction for Use	Refer to Instruction for Use
		Is a Part of	Item is a part of named product
On Rear of Device and On Power Supply Unit	 	Alternating current Direct current	Alternating current Direct current
On Power Supply Unit	**IP22**	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

Table 1: 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 equipmen 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 listd in section 4.1 above comply with:

- ❑ RF emissions, EN 55011, Class B/Group 1
- ❑ EN 60601-1-2: 2007

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	OneStim is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
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, $LiFePO_4$, 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 2.0, 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: +5ºC to +35ºC (30% to 80% RH) Storage T° Range: -10ºC to +60ºC (10% to 85% RH) Altitude (transport): 0 to 14,000ft (4267m)

18.2 Stimulation Electrical Specifications

Stimulation Parameter	Value
Stimulation Channels	2
	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 2000Ω
Voltage Range	0.1 to 8V, max 25mA (PACE Mode)
Pulse waveform	Monophasic (Mono) with charge recovery.
Pulse duration	0.1 to 2ms (Pace Mode)

18.3 Stimulation Timing Specifications

Pacing Parameter	Value
S1	100-5000 ms in Pace Protocol, 10ms step (Pace Mode)
Extra-stimuli	S2 (PACE Mode)
S2 interval	30 – 990 ms

18.4 Intra-cardiac iECG Specifications

iECG Sensing Parameter	Value
Channels	Equal to Stimulation Channels
Input ranges (FSD)	±1 mV to ±16.5 mV
Common Mode Range	±0.3V
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, 0.2, 1, 5, 30 (default) 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:	1000Hz, 16-bit, 50 uV/bit based on 3.3V full-scale
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 mm/mV
ECG display sweep speeds	10, 25, 50, 100, 200 mm/s (& 400 mm/s in review screen)
Input impedance	>1 GΩ
Input CMRR	90 dB
SECG Sampling	1000 Hz, 16-bit, 50 uV/bit based on 3.3V full-scale
Defibrillation Recovery Time	< 5 seconds

18.6 Ext. Input ECG Specifications

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

18.7 ECG Notch Filter

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

18.8 Emergency Stimulation Channel

Emergency Stimulator	Value
Power	9V LiMn Battery, 10 year standby life, >12 hours operation
Pacing Activation	Activated by connection to intra-corporal pacing electrode pair (activating impedance <50 kΩ 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^{-1} Disconnection: 3 seconds long pacing sound