

USER INSTRUCTION MANUAL

OML Remote

Model: OML Remote V1.0

Software: V1.0



Keep these instructions for future reference.



Read the instructions and precautions before using this device.

...a confident choice

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The OML Remote kit contains the following items:

1x OML Remote

Part number: 01-001-0022

1

1x OML Remote mains charger (power supply unit)

Part number: 05-001-0011

1x Instruction manual - English

Part number: 11-003-0086

1x Warranty card

Part number: 11-003-0067

Intended Purpose

The OML Remote is a hand-held wireless remote control for compatible OML Stimulators, such as the ODFS® Pace XL. It is intended to be used to remotely pause and activate stimulation, trigger a test stimulation burst, adjust pulse width (intensity of stimulation) and switch between stimulation modes (e.g. Exercise and Walking modes).

Intended User

The OML Remote is intended to be used by Functional Electrical Stimulation (FES) users of compatible Odstock Medical Limited (OML) stimulators, such as the ODFS® Pace XL.

Introduction

The OML Remote can be used to control a maximum of 2 stimulators. It is powered using an internal rechargeable battery and can be carried using a lanyard (not supplied). The product is also capable of wireless charging which eliminates the need to plug in a charger by placing it on an appropriate charging mat (not supplied). The OML Remote does not need to be present in the system in order for the ODFS® Pace XL to be used. The ODFS® Pace XL can still be operated directly.

This User Manual explains the key features of the OML Remote, describes how it is paired with the ODFS® Pace XL and how it can be used to control it. This manual should be kept for future reference.

Intended Environment

The OML Remote is intended to be used in the home, public and clinical environment. It is expected that users would store the OML Remote in their pocket, on a lanyard or in a handbag when out and about.

1 Following charging of the battery, the OML Remote may be warm and may need to be left to cool prior to use. (See page 9)

When the OML Remote is stored in a hot or cold environment it may be necessary to wait until the OML Remote has reached operating temperature before use.



The user must familiarise themselves with these warnings and precautions prior to using the device.

Strangulation

There is a risk of strangulation with the charger leads and lanyard. Do not place charging leads around the neck. Keep out of reach of children. If using a lanyard, it is advised to use a lanyard with a safety break release clip.

Children

The OML Remote is not a toy! Keep out of reach of children.

Batteries

All battery technologies carry a very small risk of fire or explosion if used incorrectly. Do not expose the OML Remote to fire. Do not charge, operate or store the device outside the specified temperature ranges (see page 51). Do not expose the product to temperatures above 60 °C (140 °F).

Wireless Communications

The OML Remote relies on radio-frequency (RF) communication to control the stimulator(s). This may be subject to interference from electromagnetic fields or other wireless communication equipment which may cause it to stop communicating correctly. Move away from or turn off sources of interference.

Air Travel/Wireless Restricted Areas

The OML Remote could cause radio-frequency (RF) interference to other critical equipment. Do not use the OML Remote in areas where radio frequency devices are prohibited (e.g. on aircraft).

Flammable Cleaning Products

Do not use flammable cleaning products to clean the device.

Flammability

Do not use the device near flammable fuels, fumes or chemicals.

Allergies

The OML Remote is covered with a rubber effect coating which may cause skin irritation or allergic reaction. If a reaction appears discontinue use and inform the manufacturer.

Oxygen Rich Environments

Do not use the OML Remote within an oxygen rich environment such as a hyperbaric oxygen chamber or in close proximity to an oxygen mask.

Important Information (Precautions)

Charging

Only use wired chargers and power supplies recommended or supplied by Odstock Medical Limited.

Only use Qi compliant wireless chargers with a single coil or those recommended by Odstock Medical Limited. Use of a non-Qi compliant wireless charger poses a risk of burns or battery explosion.

Whilst the OML Remote is being charged (wired or wirelessly) it may get hot along with the power supply or wireless charging mat, which may in extreme circumstances cause skin burns. When charged in a warm environment above 36 °C the surface of the OML Remote and wireless charging mat may exceed 41 °C Do not handle the device until it has cooled.

Charge the OML Remote if the battery warning is displayed.

The OML Remote cannot be operated (to control a connected stimulator) whilst it is being charged.

Do not cover the OML Remote when charging, ensuring air is free to flow round the device.

Damage

If the device has been impacted or has signs of damage, return to the manufacturer for assessment prior to use of the device.

Degradation

Do not use the OML Remote or accessories if the devices are damaged or degraded in any way.

Machinery Operation and Driving

The OML Remote should not be used when driving, operating machinery, or during any activity when use of the device could distract or put the user or others at risk of injury.

Water Ingress

Do not get the OML Remote wet. Do not use (operate or charge) if the OML Remote is wet. Water ingress may stop the OML Remote from working. If submerged, turn off the device, dry out thoroughly and return to the manufacturer for assessment prior to re-use.

Equipment Modification

Do not tamper with or modify the equipment. Risk of electrocution from the charger and damage to the OML Remote. Doing so will invalidate the warranty.

Storage Temperature

Do not store the device or accessories (e.g. charger) outside of the temperature limits as detailed in the specification on pages 50-53. If the OML Remote or accessories have been stored at the minimum or maximum storage temperatures, allow at least 10 minutes in ambient temperature before use to reach operational temperature.

Use

Only use the OML Remote with other Odstock Medical Limited products. The OML Remote can only be joined to other compatible wireless Odstock Medical Limited stimulators.

Important Information (Precautions)

Do not connect non-Odstock Medical Limited products to the OML Remote either through a wired or wireless connection. No device should be connected to the charging socket other than those accessories provided or supplied by Odstock Medical Limited.

Environment

Do not leave the OML Remote or accessories in direct sunlight for an extended period.

Electromagnetic Compliance

Use of accessories, transducers and cables other than those specified or provided by Odstock Medical Limited could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the OML Remote including the stimulators joined to it and their accessories. Otherwise, degradation of the performance of this equipment could result.

Adverse Reactions

The user should report any undesirable outcomes, malfunctioning of the device, mistakes in using the device, or injury from the use of this device to their clinician.

The clinician is responsible for reporting all adverse events to Odstock Medical Limited, or their local representative.

Residual Risk

2 The internal battery may explode if impacted, crushed, incorrectly charged or immersed in water.

Do not touch the terminals of the charging socket.

The ODFS® Pace XL may not immediately unpause or pause upon pressing the pause button on the OML Remote. Wait for confirmation from the ODFS® Pace XL or OML Remote prior to walking.

Safe Disposal of Equipment

Care should be taken to dispose of device parts and accessories in the correct manner. In order to protect the environment, the product and its accessories should not be disposed of in household waste. Please dispose of as per local regulations. Alternatively, equipment can be returned to Odstock Medical Limited for disposal.

Symbol Definitions



Caution (used throughout the instruction manual to identify caution items).



Read the instructions before use.



Consult the instructions for use.



Do not charge if the OML Remote is wet, the charger is wet, or your hands are wet.



Warning, surfaces may be hot!



This product should not be disposed of with other household waste. Your OML Remote and accessories can be returned to Odstock Medical Limited for appropriate disposal.



Date of manufacture.



The CE mark indicates that the OML Remote complies with the European Union Medical Device Regulations.

IP22

Protected against the ingress of solid foreign objects of diameter 12.5 mm or greater. Vertically falling water drops have no harmful effects.



Direct Current (DC)



Not to be used by persons under the age of 3 years.



The OML Remote contains a radio transmitting device.



Do not get any part of the system wet.



Expiry date (Year, Month, Day) of product (may relate to specific components).



Do not use the OML Remote or accessories if the packaging is substantially damaged. Proceed with caution and check components for damage prior to use.



Do not store outside of the specified temperature limits. If accompanied by <mo; for storage less than 1 month. If >mo; for storage greater than 1 month.

Symbol Definitions



Do not store outside the specified relative humidity limits.



Do not store outside the specified atmospheric pressure limits.



Batch number.



Unique serial number of the OML Remote.



Odstock Medical Limited device reference number.



European authorised representative.



Manufactured by Odstock Medical Limited: Odstock Medical Limited, National Clinical FES Centre, Salisbury District Hospital, Salisbury, Wiltshire, UK, SP2 8BJ

Lock/Unlock

The buttons of the OML Remote will be locked (disabled) after 15 seconds of no use, to prevent accidental activation. Press the 'standby' button to unlock the buttons. If already unlocked press the 'standby' button if you want to lock the buttons before 15 seconds has elapsed.

Stimulation Intensity

This is a stimulation parameter that affects the strength of the stimulation delivered. It is given in percentage of strength from 0% to 100%.

Pause Mode

In this mode, the ODFS® Pace XL does not deliver stimulation except when using the test button. This mode should be used when stimulation is not needed or when resting for example.

Active Mode

In this mode the ODFS® Pace XL delivers stimulation when in walking or exercise mode.

Test Stimulation

The ODFS® Pace XL can deliver a burst of stimulation when the test button is pressed. The ODFS® Pace XL must be in pause mode. This is used to check the stimulation response before using for walking or exercise.

Number of Stimulators

Up to two ODFS® Pace XLs can be joined and controlled using the OML Remote.

Stimulation Channel

Each pair of electrodes attached to one lead from the stimulator makes a stimulation channel. The stimulation intensity of each channel can be adjusted separately.

Joining a Stimulator to the OML Remote

This is the method by which the stimulator and OML Remote connect wirelessly; allowing the OML Remote to control the stimulator(s). See page 27.

Wireless Charging

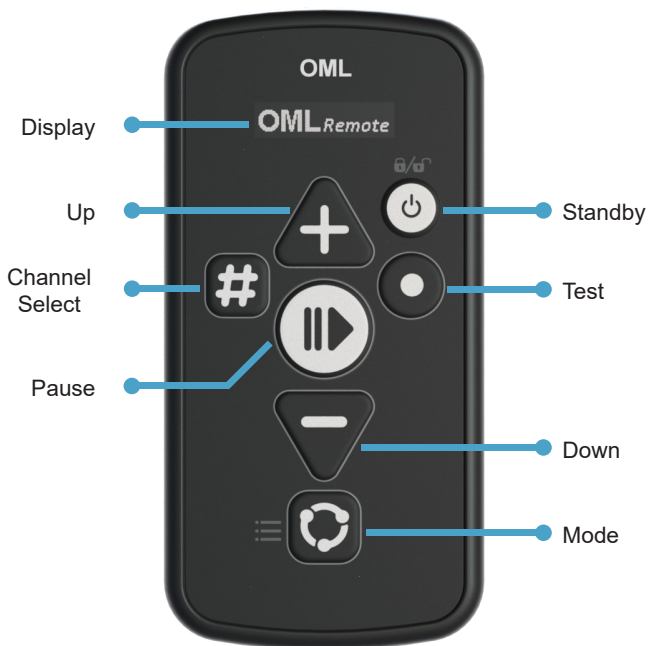
This is a technique used to charge the internal battery of the OML Remote without connecting it directly to the mains charger. The transfer of energy is done without wires attached. A wireless charger is not included. See page 39 (Wireless Charging).

Warranty

The OML Remote is warranted for a period of one year from the date of sale or fitting. Should any failure of the device occur during the warranty period, the device should be returned to Odstock Medical Limited for inspection. Should the failure be due to manufacturing or material defect the device will be repaired or a replacement supplied free of charge.

The warranty is valid providing that the failure cannot be attributed to misuse and the warranty registration card has been completed and returned to Odstock Medical Limited as soon as possible. Alternatively, this information can be completed online at:

www.odstockmedical.com



Front View of the OML Remote

Key Features

	Display Displays information about the OML Remote and the stimulator(s) it controls.
	Standby Button Press and hold to power the OML Remote ON and OFF. Press to lock and unlock the use of the OML Remote.
	Pause Button Press to pause and activate stimulators remotely. If navigating a menu, press to select menu options.
	Channel Select Button For more than one channel of stimulation, press to switch channels. Also to display stimulator battery level.
	Up Button Press to increase intensity of stimulation.
	Down Button Press to decrease intensity of stimulation.
	Test Button Press to start and stop test stimulation on the stimulator(s).
	Mode Button Press to change stimulation mode on the stimulators(s) e.g. to change between walking and exercise mode. Press and hold to enter the user menu.



Rear View of the OML Remote

Key Features

OML Logo

This marks the centre of the back of the OML Remote. Use it to align the OML Remote on a wireless charger.

Lanyard Attachment

Use to attach a lanyard.

Charging Socket

Plug in the charger to charge the battery.

Charger Alignment Guide

Align this arrow with the matching arrow on the connector of the charger.

Turning the OML Remote ON & OFF

Turning ON



To turn the OML Remote ON, press and hold the standby button for 1 second. The OML Remote turns on and vibrates twice. “OML Remote” is displayed on the screen. Release the button once this is shown.



If the OML Remote does not turn on it may need charging. Please refer to page 38.

Turning OFF

3 To turn the OML Remote OFF, ensure the OML Remote is unlocked (press and release standby button, see page 24). Press and hold the standby button for 1 second until one long vibration is felt. “OML Remote” is displayed on the screen and fades away.

Hardware Reset

If the OML Remote is not responding, it may need to be reset. To do a hardware reset of the OML Remote, press and hold the standby button for 6 second until the screen turns off.



The OML Remote may need to be left for a few seconds before it will turn on again.

Battery Level

The battery level of the OML Remote is displayed at turn on and when the OML Remote is unlocked (see page 24).

Battery full (100%)



Battery half-full (50%)

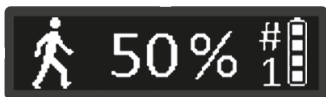


Battery empty (<5%)



When the battery level reaches battery empty the OML Remote must be charged.

The battery level of the connected ODFS® Pace XL can also be seen on the right hand side of the display when the stimulation intensity level is displayed. This can be accessed by pressing the channel select button until the desired channel is shown (see page 32).



Unlocking and Locking

To prevent accidental adjustment of the ODFS® Pace XL, the OML Remote automatically locks its buttons if not used for more than 15 seconds. The OML Remote needs to be unlocked before it can be used to control the ODFS® Pace XL.

Unlocking



Press the standby button to unlock the OML Remote. The OML Remote can now be used to control the stimulator(s).



Locking

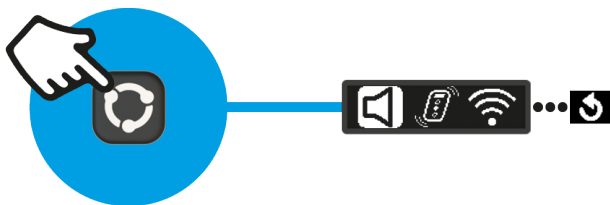


Lock the buttons of the OML Remote by pressing the standby button.



Options Menu

≡ The OML Remote includes a menu that allows the configuration of beeps, vibration and the wireless network. This can be accessed by pressing and holding the Mode button for approximately 2 seconds:



Press the Mode button to cycle between menu options. There are 4 options in this menu:



Beep Options



Vibration Options



Wireless Connectivity



Back/Exit



Press the Pause button to select the option

Beeps



The OML Remote generates beeps when buttons are pressed to inform you that a button press has been registered. Enter the Options Menu and select the beeps option to turn beeps on or off; use the pause button to select this option.



Beeps ON



Beeps OFF

Vibration



The OML Remote vibrates when buttons are pressed to inform you that a button press has been registered. Enter the Options Menu and select the vibrate option to turn vibration on or off:



Vibration ON



Vibration OFF

Wireless Connectivity



The OML Remote allows up to two ODFS® Pace XLs to be paired with it. Enter the Options Menu and select the wireless option to start the joining process:

Joining an ODFS® Pace XL

To join an ODFS® Pace XL stimulator to the OML Remote you need to initiate joining on both the ODFS® Pace XL and the OML Remote.

Turn on OML Remote and enter Options Menu.



Select the wireless option. If no stimulators have previously been joined it will start the joining process for stimulator 1. The OML Remote will wait for up to 2 minutes for the ODFS® Pace XL to join.



On the ODFS® Pace XL, enter the wireless options in the User Accessible Menu and select 'JOIN REMOTE'.

If successful, the ODFS® Pace XL will beep and the OML Remote will show a tick to indicate that the stimulator has been successfully joined.



The OML Remote will then automatically try to join a second stimulator. Press the Pause button on the OML Remote to exit joining or repeat the process if you wish to join a second ODFS® Pace XL.



Any OML LINQ™s previously joined to the ODFS® Pace XL will need to be re-joined.

Replacing or Rejoining a Stimulator



Replacing one of the joined ODFS® Pace XLs with a new one.

Enter the Options Menu and select the wireless option.



Select which stimulator you would like to replace.



By pressing the pause button, the stimulator previously joined and selected above will be lost from the network.

Now you can join an ODFS® Pace XL as the selected stimulator (1 or 2), see page 27. Refer to your ODFS® Pace XL manual for joining instructions.

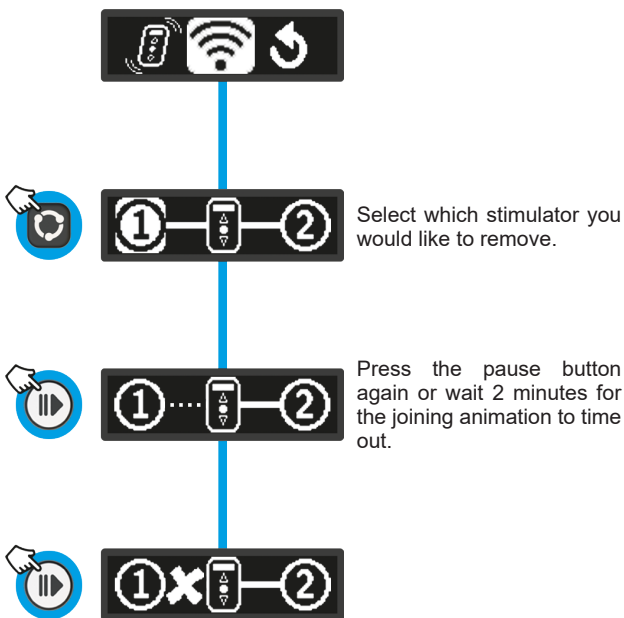
Removing a Stimulator



If an ODFS® Pace XL is not required anymore (e.g. going from 2 ODFS® Pace XLs to just one), it can be removed from the network. To do this, follow the process below.



Once an ODFS® Pace XL is removed, it can no longer be controlled using the OML Remote.



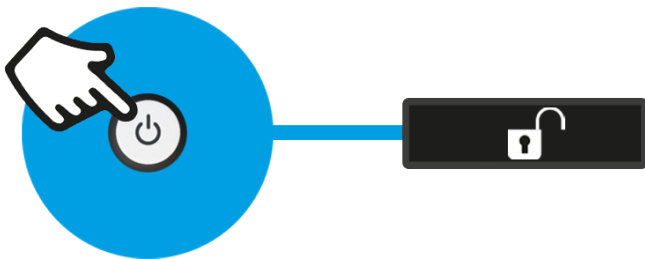


When an OML Remote is joined to an ODFS® Pace XL, any connection to previously joined wireless footswitches will be lost. These will need to be rejoined to the ODFS® Pace XL.

To join a wireless footswitch, follow the instructions from the stimulator manual or the stimulator joining process sheet.



The OML Remote will need to be unlocked to allow the stimulator to join to a wireless footswitch.



Single Wireless Footswitch with Two ODFS® Pace XLs

If two ODFS® Pace XLs have been joined to the same OML Remote, both can be used with a single wireless footswitch. (This may need some input from your clinician to ensure that triggering is set up correctly.)

Join a wireless footswitch to one of the ODFS® Pace XL.

The ODFS® Pace XL with the wireless footswitch joined to it becomes the 'primary' stimulator, the trigger from the wireless footswitch is forwarded to the 'secondary' stimulator.

If unpausing directly on the ODFS® Pace XL (i.e. without using the OML Remote), the 'primary' stimulator will need to be unpaused first.



The 'secondary' stimulator will not trigger wirelessly without the 'primary'.

When in Airplane Mode on the ODFS® Pace XL, wired footswitches will be needed to replace the joined wireless footswitch. As the trigger signal cannot be transmitted wirelessly from the 'primary' stimulator, both stimulators will need to have a wired footswitch attached. Both wired footswitches will need to be placed in the same position as the single wireless footswitch.

Stimulator Battery and Changing Channel



The channel selection button can be used to cycle between available channels of all joined stimulators.

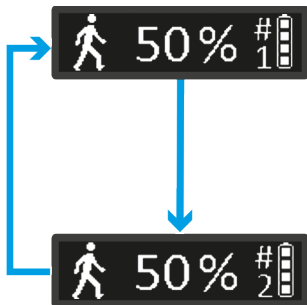
It is also used to show the stimulation strength percentage and battery level of the stimulator.



Ensure that the OML Remote is unlocked.



Only changes channel if set up with multiple channels of stimulation.



Press the channel select button until the desired stimulation channel is selected.

Adjusting Intensity



The Up button is used to increase the intensity (pulse width) of stimulation.

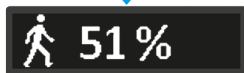


The Down button is used to decrease the intensity (pulse width) of stimulation.

The intensity of stimulation is displayed on the OML Remote as a percentage and ranges from 0% to 100%.



Ensure that the OML Remote is unlocked.



Note: Press and hold the Up or Down button to quickly increase or decrease the stimulation intensity.

Testing Stimulation



The Test button on the OML Remote is used to produce a short burst of stimulation to test the effect. This can be useful to check the response to stimulation before unpausing.



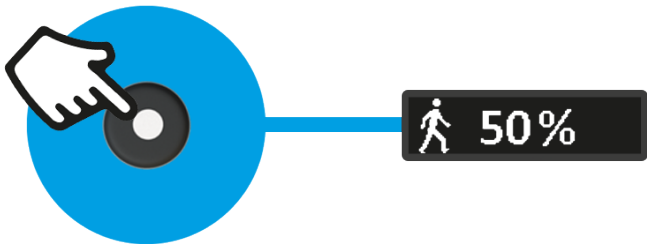
Ensure that the OML Remote is unlocked.



Select the stimulator to test by pressing the channel selection button.



The Test button or the Pause button can be used to stop test stimulation.

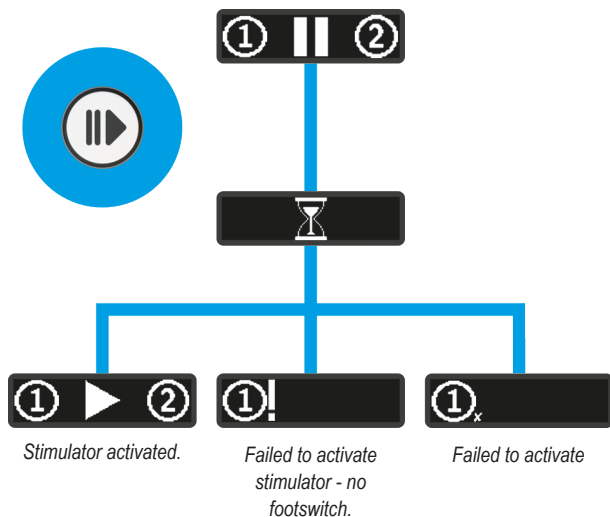




Press the Pause button of the OML Remote to start stimulation and observe the display to confirm that all joined stimulators have entered an active state.



Ensure that the OML Remote is unlocked.





The Pause button of the OML Remote is used to stop stimulation.



Ensure that the OML Remote is unlocked.



Stimulator activated.



Stimulator paused.

Stimulation Mode Selection



If your clinician has set-up more than one stimulation mode on your stimulator (for example a walking mode and an exercise mode), press the Mode button to switch between these.



Ensure that the OML Remote is unlocked.

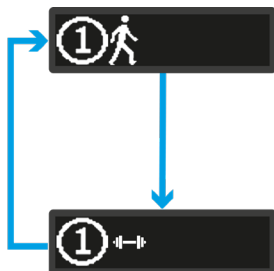


When multiple stimulators are joined, these screens indicate that only one stimulator has changed to exercise as the other stimulator does not have exercise mode enabled.

Press the Mode button until the desired stimulation mode is selected.



Stimulator changed to Walk mode.



Stimulator changed to Exercise mode.



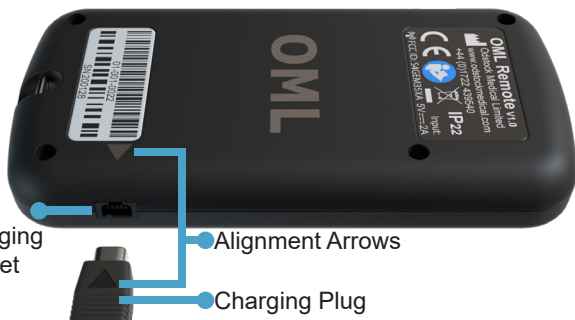
Note: A description of the stimulation modes can be found in the User Instruction Manual of the stimulator.

Charging the OML Remote



Only use the supplied charger when charging the OML Remote with a wall charger.

Charge the battery before use if the OML Remote has not been operated for an extended period of time.



Battery charging animation



Battery fully charged



Do not charge if device is wet.



Surface of the OML Remote may get hot.

Wireless Charging the OML Remote



If using the wireless charging capabilities of the OML Remote, only use a Qi compatible wireless charger.

Ensure the OML Remote is located in the centre of the wireless charger.



Battery charging animation



Battery fully charged



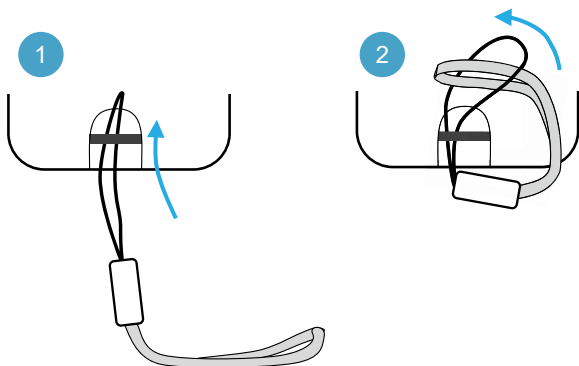
Do not charge if device is wet.



Surface of the OML Remote may get hot.

Attaching a Lanyard

You can attach a lanyard or wrist strap to the OML Remote by fixing it to the dedicated attachment on the back of the OML Remote as shown below:



Only use a lanyard around the neck that has a safety break release clip.

OML Remote Symbols



Stimulator 1 and Stimulator 2



Walking mode and Exercise mode



Channel number and stimulator battery level



Not allowed



Please wait, connecting to stimulator



Failed to activate. No response. (Try again)



No connection to stimulator. (Try again)



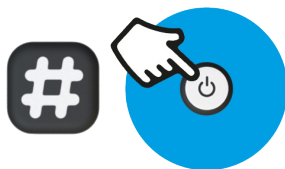
Failed to activate. No footswitch!



Waiting to join

OML Remote Software Version

To check the software version of the OML Remote, turn the OML Remote off.



Hold the Channel Select button while turning the OML Remote on. The software version is displayed

Press the Power button again to fully turn on the OML Remote.

Servicing

The OML Remote does not require regular servicing. If it becomes faulty please refer to the troubleshooting section or return to Odstock Medical Limited.

The operation of the system should be checked regularly. If there is any damage to the OML Remote or accessories they should be replaced.

Turn off the OML Remote if it is not to be used for an extended period of time. This is achieved by pressing and holding the standby button as shown on the key features page.



If you suspect that the OML Remote has been impacted strongly or you notice cracks or deformation to its plastic casing, send it to Odstock Medical Limited for inspection.



The internal battery of the OML Remote is not user replaceable. Please return to Odstock Medical Limited or a local representative for replacement.

Maintenance

The OML Remote does not need maintenance beyond that described in the cleaning and care instructions.

To prolong the life of the internal battery it should be fully charged every 3 months if the OML Remote is not used regularly.

Calibration

The OML Remote or accessories do not need calibrating.

Cleaning and Care Guidance

The system does not require regular cleaning, only as necessary. Please follow the instructions below.



Do not scrub with any abrasive material.

Make sure all parts are dry before re-use.

If the OML Remote or accessories are very dirty or not easily cleaned, replace with new ones.

OML Remote

The OML Remote can be cleaned by wiping with a damp cloth or anti-bacterial wipes.



Make sure that the OML Remote is turned off prior to cleaning.

Do not immerse in water.

Do not clean with solvents.

Make sure the OML Remote is dry before re-use.

Power Supply Unit

The power supply unit can be cleaned by wiping with a damp cloth or anti-bacterial wipes.



Do not immerse in water.

Do not clean with solvents.

The power supply unit must not be plugged into a socket or the OML Remote during cleaning.

Make sure the power supply unit is dry before re-use.

To help you understand some of the problems that might occur, here is a list of potential faults with some solutions. For assistance in setting up, using or maintaining the equipment please contact Odstock Medical Limited or their local representative.

Fault/Problem	Solution/Action
OML Remote does not switch on	1. Follow the instructions on how to turn on the OML Remote on page 22. 2. Ensure the battery is charged (refer to page 38). 3. If none of the above works, contact the manufacturer (contact details are on the back of this manual).
Nothing happens when I press the buttons	1. Ensure the OML Remote is ON, refer to page 22. 2. Ensure the OML Remote is unlocked, refer to page 24. 3. If the OML Remote is being charged, it will not respond to button presses, remove from the charger to be able to control stimulators

Fault/Problem	Solution/Action
'Not allowed' symbol is displayed on the OML Remote 	1. This could mean that no stimulators are joined to your OML Remote. Join your stimulator(s) (see page 27). 2. When at least one stimulator is in active stimulation mode, testing stimulation and changing stimulation mode are not allowed. Ensure stimulator(s) are paused and then press Test or try to change stimulation mode.
Stimulator(s) not responsive to the OML Remote 	1. Ensure that the stimulator(s) are switched on and within range. Try pressing buttons to control stimulation again. 2. Ensure that stimulator(s) is/ are not in airplane mode (wireless disabled). 3. Turn off stimulator and OML Remote and try again. 4. Re-join the stimulators to the OML Remote if the network has been lost on them. Refer to the sections on joining (page 27) and the stimulator manual.

Fault/Problem	Solution/Action
The OML Remote does not charge when put on a wireless charger	1. Ensure that you are using a Qi compliant wireless charger recommended by OML and that it is powered as per the instructions for use of the charger. 2. Follow the instructions on how to place the OML Remote on the charger on page 39. 3. Ensure that no metal objects (e.g. keys) are on the wireless charger next to the OML Remote. 4. If none of the above works, contact OML (details on the back of product).
OML Remote not responsive and error symbol shown on the display. “!! ER” and followed by a two digit number. !! ER01	1. Switch the OML Remote OFF, leave it for one minute and then switch it ON again. 2. If the above does not fix the issue, contact the OML (contact details are on the back of the product).

Fault/Problem	Solution/Action
Stimulation mode symbol is missing or incomplete.  	1. Switch the OML Remote OFF and ensure all stimulators are on and within range. Turn The OML Remote back on after a few seconds. 2. If the above does not fix the issue, switch OFF the stimulator(s) and the OML Remote, switch stimulators back ON and then the OML Remote. 3. Press the Channel Select button to check if the symbol for stimulation mode is visible.
Only one stimulator changes stimulation mode.  	1. The stimulator that is not changing mode might not be configured to have a compatible stimulation mode (e.g. Exercise mode is not enabled). Confirm with your clinician if necessary. 2. Try repeating mode change by pressing the Mode button a few times. 3. Ensure that both stimulators are turned ON. 4. Ensure that Airplane Mode is disabled on the stimulator (refer to the stimulator instruction manual).

Fault/Problem	Solution/Action
Stimulation intensity cannot be adjusted and I get a screen similar to one of these ones below:	The mode on the OML Remote does not match the selected/available mode on the stimulator. This is the case if one of your stimulators does not have a stimulation mode that is available on your other stimulator, the stimulation mode on the stimulator has been changed directly on the stimulator or the OML Remote has been switched off and back on. Try the following: 1. Press the Mode button to change stimulation mode until you find the stimulation mode you would like to use. 2. If one of the stimulators does not have a stimulation mode that is available on your other stimulator, speak to your clinician for further information.

Fault/Problem	Solution/Action
Intermittent or no wireless connection to stimulators	1. Move away from potential source of interference 2. Turn the system and wireless accessories off and on. 3. Removing both stimulators from the OML Remote network and re-join them (see page 28-29). Remember re-join any wireless footswitches in the system.
Joined OML Remote to stimulator but now wireless trigger does not work.	When a stimulator is joined to an OML Remote a new network is created on the stimulator losing all previous wireless connections. Therefore, any previously connected OML LINQ™s will need to be re-joined to the stimulators (see page 27).
Stimulator or OML LINQ™ is not working after changing a battery.	1. Turn off all devices. 2. Turn on the ODFS® Pace XL that the OML LINQ™ is joined to. 3. Replace OML LINQ™ battery. 4. Unpause ODFS® Pace XL and test OML LINQ™. 5. Turn on OML Remote. Note: Repeat steps 1-3 if using a second OML LINQ™.

OML Remote

Classification	Class I medical electrical equipment, internally powered, portable and hand-held, continuous operation. No applied part(s).
Expected service life of device	2 years
Ingress protection rating	Rating of IP22. Vertically falling drops have no harmful effects when the stimulator is tilted at any angle up to 15° on either side of the vertical. Do not get the device wet. Protected against objects entering the stimulator of 12.5 mm and above.
Power source	Internal lithium-ion battery. Nominal voltage 3.7 V DC. Rated for up to 1200 mAh (note capacity may reduce with age and number of charge/discharge cycles). Expected battery life cycle: > 500 cycles for > 70% of initial capacity
Battery certification	Cell is approved according to UL1642 and UN38.3 certified. The battery meets the requirements of Battery Directive and the battery packs are RoHS compliant. The battery is UL2054 listed and certified according to IEC62133 edition 2.

OML Remote

Temperature	Operational
	5 °C to 40 °C (41 °F to 104 °F)
	Charging
	Wired: 5 °C to 40 °C (41 °F to 104 °F)
	Wireless: 5 °C to 30 °C (41 °F to 86 °F)
	Storage and Transport
	1 months: -20 °C to 60 °C (-4 °F to 140 °F)
	3 months: -20 °C to 45 °C (-4 °F to 113 °F)
	1 year: -20 °C to 30 °C (-4 °F to 86 °F)
Relative humidity	45% to 85% maximum, non-condensing
Atmospheric pressure	700 hPa to 1060 hPa
Device size	Length 105 mm x Width 52.5 mm x Height 15 mm
Device weight	85 g

Power Supply Unit

Classification	TR15RAM Series 15 W Medical Switching Adaptor. Meets 2 means of patient protection with continuous short circuit protection.
Expected service life of device	2 years
Ingress protection rating	Do not get the device wet.
Input	90~264 VAC
Output	5 V DC, 2 A
Switching Frequency	95 kHz typical
EMC	EN55011 Class "B", FCC Part 15 Class "B", EN60601-1-2, EN61000-3-2, EN61000-3-3
Safety	IEC60601-1:2005, EN60601-1:2006, ANSI/AAMEI ES60601-1:2005
Certification	The power supply unit is listed under UL E252331

Power Supply Unit

Temperature	Operational
	5 °C to 40 °C (41 °F to 104 °F)
	Storage and Transport
	-20 °C to 85 °C (-4 °F to 185 °F)
Input	90~264 VAC
Relative humidity	93% maximum, non-condensing
Atmospheric pressure	700 hPa to 1060 hPa
Device size	80.6 mm x 47.9 mm x 43.3 mm
Lead Length	1800 mm
Device weight	130 g

OML Remote

Contains RF Transmitter (FCC ID)	S4GEM35XA
Industry Canada (IC-ID)	8735A-EM35XA
Frequency band	2.4 to 2.483 GHz (2.4 GHz ISM band)
Radiated power	+8 dBm
Wireless compliance	The wireless module used has been designed to meet all national regulations for worldwide use. The wireless module is EC-R&TTE certified (CE0681) and complies with FCC CFR Part 15 (USA) meeting the requirements for modular transmitter approval as detailed in the FCC public notice DA00.1407.transmitter.
Quality of service	The OML Remote is designed and tested to have a wireless message latency of less than 100ms depending on system configuration.
Co-existence and interference	The system has been tested in a range of scenarios showing that it is resistant to interference. However, there is no guarantee that other wireless communication devices will not interfere with wireless communications.
Co-existence and interference continued	The module is also certified to European Certification (ETSI) EN 300 328:V1.8.1 (radio), EN 301 489-17:V2.2.1 (EMC) and EN 60950-1:2006+A12:2011

OML Remote

Wireless Communication indications	Any button pressed on the OML Remote that leads to a command being successfully sent to the stimulator will result in the screen being updated. If the communication fails, the OML Remote shows the symbol of the stimulator not communicating with a cross. This is accompanied with short beeps and vibration. Refer to the troubleshooting section.
Security requirements	No user security measures required. AES-128 hardware supported encryption implemented. No patient identifiable data is transmitted or retained by the device.
Cautions	 If the performance of the system is compromised by other equipment (such as home routers), the user should turn off the system and move away from the interfering equipment. Please refer to troubleshooting section.  Like all radio telemetry devices, the OML Remote and other OML wireless devices and accessories should not be used while flying. Turn off the OML Remote.

OML Remote

Manufacturer's declaration of electromagnetic emissions		
The OML Remote is intended for use in the electromagnetic environment specified below. The customer or user of the OML Remote should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The OML Remote 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.
Radiated Spurious Emissions ETSI EN 300 328 V2.1.1	Clause 5.4.9 (30 MHz to 12.75 GHz)	
Radiated emissions FCC/CFR 47:Part 15.209:2017	Class B (30 MHz to 25 GHz)	
RF emissions CISPR 11	Class B	The OML Remote is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Yes	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Yes	

OML Remote

Manufacturer's declaration of electromagnetic immunity		
The OML Remote is intended for use in the electromagnetic environment specified below. The customer or user of the OML Remote should ensure that it is used in such an environment.		
Immunity test	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 6100-4-2	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2 kV	
Voltage dips, short interruptions and variations IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital or domestic environment.

OML Remote

Manufacturer's declaration of electromagnetic immunity continued

Portable and mobile RF communications equipment should be used no closer to any part of the OML Remote, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz to 80 MHz) 6 Vrms in ISM bands	Recommended separation distance: $d = 1.2 * \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	Recommended separation distance: $d = 1.2 * \sqrt{P}$ (80 MHz to 800 MHz) $d = 2.3 * \sqrt{P}$ (800 MHz to 2.5 GHz)

Note 1: Where (P) is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in metres (m).

Note 2: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol.



Note 3: At 80 MHz and 800 MHz, higher frequency range applies.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in which the OML Remote is used, exceeds the applicable RF compliance level above, the OML Remote should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the OML Remote.

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

OML Remote

Manufacturer's declaration of electromagnetic immunity continued

The OML Remote is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OML Remote can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OML Remote as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 * \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 * \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.79	3.79	7.27
100	12.0	12.0	23.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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



Odstock Medical Limited

The National Clinical FES Centre
Salisbury District Hospital,
Salisbury, Wiltshire SP2 8BJ
United Kingdom

Registered Company No. 5532620

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+44 (0) 1722 439540



www.odstockmedical.com



enquiries@odstockmedical.com