April 2020 GEN.S.20/296



MR105D MRI Room Oxygen Monitor - SafeAir®



OPERATORS MANUAL



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Safety Definitions for MRI as Defined by International Standard F2503-20

MR SAFE:



An item that poses no known hazards resulting from exposure to any MR environment. MR SAFE items are composed of materials that are electrically non-conductive, non-metallic, and non-magnetic.

MR CONDITIONAL:



An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.

Supplementary marking – additional information that, in association with marking as "MR CONDITIONAL," states via additional language the conditions in which an item can be used safely within the MR environment.

MR UNSAFE:



An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.



<u>Introduction</u>

Thank you for purchasing the MR105D SafeAir® Room Oxygen Monitor. This product is manufactured and tested to the highest standards.

The unit also complies with the following standards:

EMC Directive 2014/30/EU; Low Voltage Directive 2014/35/EU; and RoHS Directive 2011/65/EU

Important note: The Oxygen Monitor unit is MR Unsafe and must not be taken into the MR room.

To ensure that you obtain maximum benefit from your product, please take a few minutes to read the enclosed information regarding operation, service and maintenance.

If you have any problems in the meantime or would like any advice about this or any other MR products from the Wardray Premise range, please contact us at our **Head Office**:

Wardray Premise Limited, Hampton Court Estate, Summer Road
Thames Ditton, Surrey, KT7 0SP, UK

Tel: +44 (0) 20 8398 9911 Fax: +44 (0) 20 8398 8032

E-mail: sales@wardray-premise.com

Kindly note:

If you modify a Wardray Premise product you will invalidate your warranty.

Unless you have our express written permission to modify a product, we transfer all liabilities for modified products to you.

EU Authorised Representative:

Advena Ltd Tower Business Centre 2nd Floor, Tower Street Swatar BKR 4013 Malta



General Information

The SafeAir® Oxygen Monitor has been designed to give a warning of depleted oxygen levels in the scan room.

The unit is simple to fit either during the installation of the scanner, or retro fitted into existing MRI rooms afterwards, and does not require the scanner to be ramped down. It can be linked into an extraction system to allow automatic switch on if oxygen levels drop.

The normal oxygen concentration should be 21%. Any variation will be rapidly detected.

The system may only be installed by operators with sufficient knowledge of equipment and this operators manual.

Unit height	Unit width	Unit depth	Unit weight
mm	mm	mm	Kg
360	120 (max)	230 (inc. cable)	4.5

Room Ventilation Interface - Emergency Extract Connector

The Oxygen Monitor is fitted with a pair of contacts to enable the MRI room ventilation system to be activated due to a low oxygen level - (The alarm will sound on the monitor). The contacts are accessed via the four pin socket mounted on the rear of the unit, pin numbers are as follows:-

PIN 1 = Normally open contact

PIN 2 = Not Used.

PIN 3 = Normally open contact

PIN 4 = EARTH CONNECTION TO CASE

The switching contacts are rated at 230V AC 3A MAX / 115V AC 6A MAX.

Unit Usage

Powered by: Power Pax A/C adapter Model No: ATS065T-P180

Power Requirements:

Input: 100-240V A/C 50/60Hz 1.4A Max

Output: 18V DC 3.62A

Suitable for use in all markets.



Contents included

1	SafeAir® Oxygen Monitor unit
2	230V AC - 18 V DC Transformer - Part No: MR40-LR
3	2 pin European / continental socket plug
4	3 pin UK socket plug
5	30m Flexible PVC hose
6	Vent Relay / Emergency Extract Connector
7	Envitec - Instructions for use and PC software CD
8	Envitec - Short manual leaflet















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System Description

The SafeAir® unit comprises an Envitec O2 oxygen monitor system supported by an air sampling pump, HEPA air filter, pressure switch, alarm buzzer and associated airlines.

The unit has an internal 'dryfit' battery which powers the external alarm and vent relay circuits in the event of mains power loss. In normal operation the system is powered by an external 18v DC desktop power supply.

In operation, air is drawn through a 6mm PVC flexible hose via a user replaceable HEPA filter, past the sensor in the Blue T piece housing and via the sampling pump (See page 13), it exits via a pressure switch and exhaust valve combination.

If the pressure switch detects a drop in pressure the system will activate an alarm buzzer, located on the rear of the unit, and illuminate the 'Airflow Fault' light on the front.

This can happen if the air sampling pipe becomes blocked or kinked or, after an extended operational time, the HEPA filter reduces airflow and needs replacing. (See page 12)

In this condition the O2 sensor will not sense enough oxygen and the Envitec unit will also alarm until the airflow is restored and the O2 is back to its normal levels.

The Envitec alarm will cause the '% oxygen' display to turn red, the 'Vent Active' light on the front will illuminate and the vent relay will operate.

If the unit has been connected to an external magnet room venting system (Emergency Extract) then this will be active whilst the alarm condition exists.

The alarms and LED indicators are intended to get the attention of operations staff and for them to remedy the problem.

Important Note: Should the operator decide to unplug the unit at the mains, in an attempt to silence the alarm, the alarm (now powered by the internal 'dryfit' battery) will continue to sound until the battery finally runs down (several hours). For correct procedure to preserve batteries See page 11 for Power Down guide.



MR105D SafeAir® Room Oxygen Monitor parts reference





System Installation

Please note: This unit is specifically designed to monitor oxygen levels within the MRI Scanner room safely from within the control room.

Unpack the items and check against the packing list.

- 1. Position the Oxygen monitor in a suitable location in the MRI Control Room to allow the end user to be able to see the LCD screen and, under fault conditions, hear the audible alarm.
- 2. If not already fitted remove the back of the unit by undoing the six Philips screws and fit the Sensor Cell and HEPA Vent Filter (See Page 12). Replace the back.
- 3. The power supply unit is plugged into the DC input socket (on the back of the unit Fig 1) and the mains plug inserted in a suitably positioned wall socket.
- 4. Connect the PVC flexible hose to the chromed 'Air Inlet' nozzle on the back of the unit (Fig 2).
- 5. The other end of the flexible hose should be routed through a suitable open wave guide into the MR Scan room, allowing the hose to be routed to the close proximity of the cold head of the MRI scanner. This is usually within the suspended ceiling cavity and secured in place along the run with cable ties. Any excess tubing should be cut off.

(see Drawing 1420C on page 9)

The unit can now be switched on at the mains.

Please see page 10 of the Manual for final power up guidance.

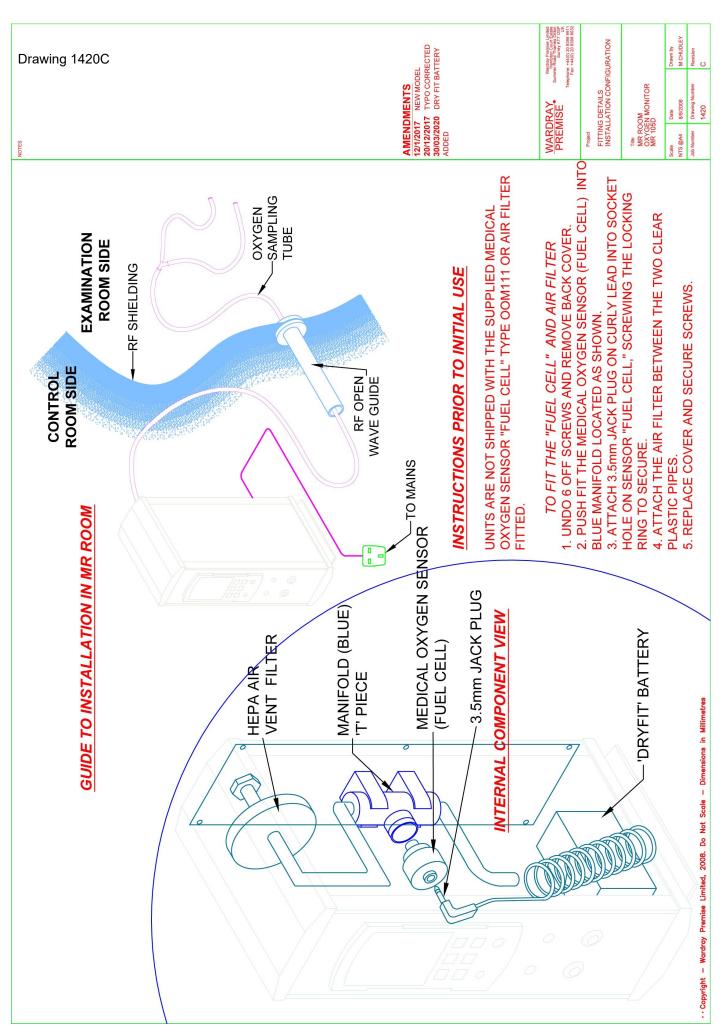




Fig1 Fig 2

The unit is also supplied with a vent relay/emergency extract connector plug to allow an emergency extractor fan to be connected.

The emergency extractor fan, if required, is supplied by others and final connection made by others.





Power Up Guide

For the first time, or after an extended period of being disconnected from the main supply, the unit should be left powered on whilst the internal 'dryfit' battery and Envitec batteries are charged up - ideally overnight. However, we recommend that the unit is left on permanently.

The Envited screen will display an animated battery charging symbol (See Fig 1).

Once charged the animated battery symbol will become static and the Envitec unit can be switched on (Press On button - See Page 11 opposite: Fig 3).

The Envited unit will go through a self-test procedure which includes activating the alarm. This self-test will activate the vent relay and also the 'Vent Active' light on the front.

As the self-test procedure finishes the Envitec alarm condition will clear but the 'Vent Active' LED will remain lit. The user must clear the condition by pressing the 'Vent Reset' switch on the front of the unit below the Vent Active LED (see Page 11 opposite: Fig 4).

On newly installed systems or systems where the O2 sensor has been replaced (see Page 12 for instructions), the Envitec unit will generally need to be recalibrated.

This can be done with a 100% O2 source or more commonly with the current ambient levels of O2 assumed to be acceptable.

The default screen of the Envited unit includes 'Alarm Limits' and 'Calibration' legends. Press the relevant function key, below the screen, depending on the application (see Fig 2).

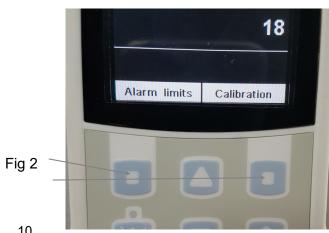
Use the Calibration function to calibrate the unit: Ambient Air - 21%; Pure Oxygen - 100%.

Use the alarm limits button to set the %O2 upper and lower limits outside of which the system should alarm.

Caution! Danger! The oxygen concentration of the breathing air supply must not be lower than 18%

These procedures are described in the Envitec user manual supplied with the system on a CD. We recommend printing the manual for future reference.







Power Down Guide

The system can be left running 24/7.

If the user requires the system to be powered down, either due to an alarm condition or power saving over a long weekend when O2 monitoring is not required, then a shutdown procedure must be followed to avoid flattening the internal batteries.

The correct procedure is:

- 1. Turn off the Envitec unit first using the on/off button* (See Fig 3).
- *Turning off the Envitec unit involves holding the on/off button whilst the display shows a countdown of 3, 2, 1 then release button promptly.
- 2. Then unplug from the mains and press the battery on/off button again* (this will silence the alarm).

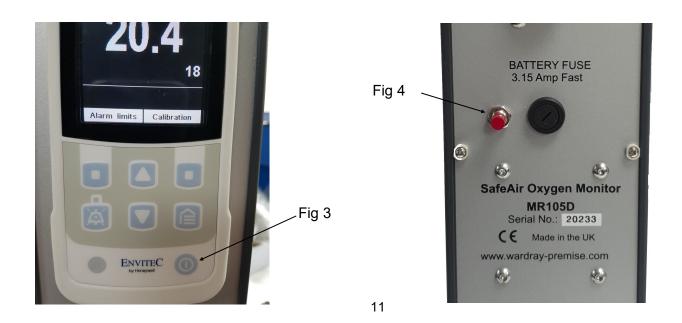
Important note:

Failure to turn off the Envitec unit whilst the SafeAir unit is unplugged will cause the Envitec internal battery to go flat. This may cause the display to lock up with an invalid O2 level displayed.

If the unit has been powered down incorrectly (not following the steps above), and the batteries have been allowed to go flat, then to recover the situation there is a reset switch (red button) on the rear of the unit (See Fig 4).

With the unit still unplugged press the reset switch for 5 seconds, release and then follow the 'Power up guide'.

The reset switch disconnects the Envited battery momentarily.





Maintenance

Installation and Replacement Procedure For The Oxygen Fuel Cell and HEPA Vent Filter

Before attempting any maintenance to the oxygen monitor system, <u>disconnect the mains</u> <u>supply and switch off oxygen monitor</u>. (See Power down guide on Page 11)

It is recommended that both the oxygen fuel cell and air line filter are replaced together. This is available as a kit from Wardray Premise Ltd. (Ref: MR106).

Undo the six screws securing the back

Oxygen Fuel Cell—see image on page 13

- Remove the fuel cell cable from the bottom of the fuel cell by pulling upwards.
- Gently ease the fuel cell out of the retaining body (blue section). Unscrew the bottom part of the fuel cell (see Fig 1)
- Screw the replacement oxygen sensor into the fuel cell connector, being careful not to over tighten and reinstall into the blue section, attach the fuel cell cable connector.

HEPA Vent Filter—see image on page 13

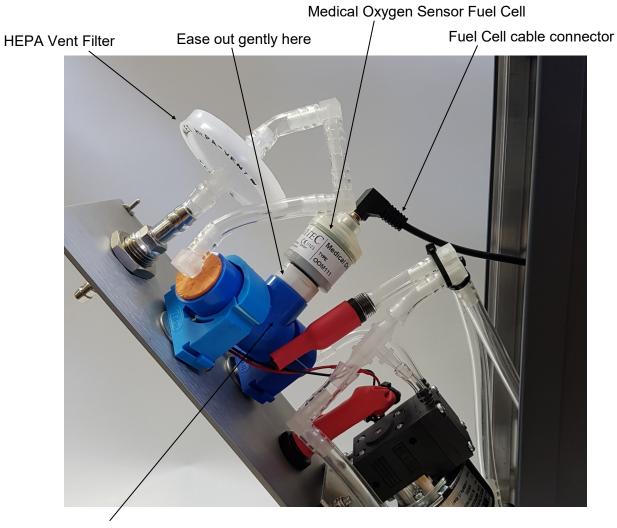
- Gently pull the air lines to disconnect from both ends of the air filter. Replace the filter and
 reconnect both inlet and outlet air lines, making sure that the inlet side of the filter faces the
 inlet nozzle (Side with the writing on—see Fig 2). Ensure that the air lines are securely
 connected.
- Re-fit the back case with the six screws.
- Check the operation and calibration of the oxygen monitor by switching on the pump, battery and monitor (See Power up guide on Page 10). In normal air the display will read 21% oxygen content.

Important

It is recommended that the filter and fuel cell sensor are replaced every 6 months. The replacement kit (Ref: MR106) may be obtained directly from Wardray Premise Ltd or in overseas countries from our local agents.

When switched on the fuel cell cable plug has a voltage on its terminals (to power the fuel cell), which must not be allowed to touch the chassis if left disconnected. If the unit is shipped without the fuel cell fitted, the plug will have a cover fitted to prevent contact with the chassis if the unit is inadvertently switched on. Please ensure that the contacts of this connector are not allowed to touch any part of the chassis during the fitting of a fuel cell.





O2 Sensor 'T' Piece Housing



Fig 1



Fig 2



Servicing

The system may only be serviced by authorised personnel. The system automatically tests all of its functions every time it is switched on and will show any faults it detects. The system also continuously monitors all of its functions while operating.

Always check the unit and cables for external damage before use.

<u>Cleaning</u>

Cleaning is limited to wiping down the control unit with a clean dry cloth for the removal of dust / debris.

The unit may only be disinfected by wiping it gently with a soft, disposable cloth soaked in isopropyl alcohol.

Do not allow any moisture to enter the device.

Warranty

The SafeAir Oxygen Monitor comes with a 12 months warranty against defective components or faulty workmanship.

Please register your product with us, via the Warranty Registration Form (see page 15), for ease of contact in case of urgent upgrades or recalls.

If the unit is damaged please do not attempt to repair as this could invalidate your warranty and could compromise its safety, please call or email Wardray Premise Limited:

T: +44 (0) 20 8398 9911 F: +44 (0) 20 8398 8032

E-MAIL: sales@wardray-premise.com

<u>Please include the product code and the product's serial number when contacting</u>
<u>Wardray Premise.</u>



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WARRANTY REGISTRATION FORM

To receive full warranty cover on your equipment, please complete and return this form at your earliest convenience

Name:	
Job Title:	
Company:	
Address:	
Telephone:	
Fax:	
Email:	
Product Code/ Description:	
Product Serial/ Reference No:	
Please enter date Product received:	
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	y further information or would like to be contacted regarding any of our products, quiry to the box below.

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