

WARDRAY PREMISE

MR200 Pure Sound II Audio Relaxation System



OPERATORS MANUAL

Introduction

Thank you for purchasing this MR Conditional product. Manufactured and tested to the highest standards it is guaranteed MR Conditional to 7.0T for the parts installed inside the MR scan room.

The unit has also been tested to the following standards:

EMC Directive 2004/108/EC, Low Voltage Directive 2006, 95/EC and RoHS Directive 2011/65/EU

The Harmonised standards that have been applied are: EN60950-1:2001+A12:2011
CE Certified

EMC Test Standards EN6100-6-3:2007 Radiated disturbance - CISPR16 inc A1:2001 - Conducted disturbance - CISPR16

EN61000-3-2:2006 - Mains harmonics - Class A

EN61000-3-3:2009 - Mains Voltage flicker (dmax=4%)

Product Complies with RoHS Directive 2011/65/EU

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 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.

New 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 nonconductive, non-metallic, and nonmagnetic.



MR CONDITIONAL:

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.

Specification

The MR200 is MR Conditional to 7.0T for the parts installed inside the MR scan room:

Audio Control Unit - **MR Unsafe**

Microphone - **MR Unsafe**

DVD/CD Player - **MR Unsafe**

Noise Reducing Headphones - **MR Conditional to 7T**

Earphones - **MR Conditional to 7T**

Stereo Acoustic Converter - **MR Conditional to 7T**

Audio Control Unit

Width mm	Depth mm	Height mm	Weight Kg
250	300	100	2.5

Microphone

Width mm	Depth mm	Height (max) mm	Weight Kg
190	190	500	1

Stereo Acoustic Converter

Width mm	Depth mm	Height mm	Weight Kg
120	170	500	0.5

Important note: Equipment should be set up in accordance with the layout diagram (page 15).

MR Unsafe items must not be taken into the MR scan room.

General Information

Contents and Cabling included

Item:
DVD/ CD Player
Noise Reducing Headphones (MR125) / Earphones (MR151) - Including:
100 pairs of disposable Headphone covers and 20 pairs of disposable Ear tips
Pure Sound II Audio Control Unit
Pure Sound II Microphone with attached cable
Pure Sound II Stereo Acoustic Converter
3.5mm male to male cable
Power Cable (3amp)
2.5mm to 3.5mm jack
2m left / right phono cable (male to male)
30m Audio Cable 4Core screened with plug to headset socket
20m Audio Cable 4Core screened with plug to Stereo Acoustic converter
2 x Velcro Strips for securing Stereo Acoustic Converter to Scanner if required
2 x Euro Plugs if required
For MR Installations only: MR120A RF Filter Kit
4 x RF Filters (50-60Hz / 10 Amp / 250 VAC)
1 x 12mm Drill Bit
8 x Ring Connectors for the RF filter

Important note: For use in the MR environment, a filter kit must be installed. See Page 15 for installation guide. A competent / qualified person should install the electrical filters. If in doubt guidance should be sought from Wardray Premise Limited.

We recommend that this equipment is PAT (Portable Appliance Test) tested every 2—3 years to verify it's continued electrical safety.

Operating Instructions

Unit Usage – Important Information

Power Requirements: 100-240V, 0.5A, 50/60Hz – suitable for use in all markets.

Mains current: 120w maximum.

Inputs: DVD / CD player, Mobile Phone, IPod, Microphone.

Outputs: Stereo Acoustic Convertor, Speakers (not supplied, source locally).

Microphone to patient: Push button to talk.

Muting: Automatically mute when microphone is not in use.

Environmental Requirements: The system is designed for use in environments with a maximum ambient operating temperature of 40°C, in an ordinary 'office' environment, with particular attention to avoiding excessive levels of humidity and dust.

The Audio Control Unit is located and operated from the MRI control room.

The Audio Control Unit **MUST** be positioned to allow operator access to the on/off power switch at the rear of the unit and requires the free flow of air around the unit.

The Audio Control Unit, Microphone and optional DVD/CD player units in the control room are designed for desk and/or shelf mounting.

Pure Sound II is designed to receive audio media via the 3.5mm jack (Fig 1, page 12) from a mobile phone or digital music device. **NB: In order to use a mobile phone for the replay of audio media, the phone must be set to a 'flight only' state** otherwise interference with the device and other units is possible.

Pure Sound II can also receive audio media via the optional DVD/CD unit.

In all cases of Audio Input via either 3.5mm Jack or DVD input, the volume of the supplying device should be set to a 'mid' volume level and the volume adjustment to be made via the Audio Control Unit volume dial **ONLY** (see page 11). This is to avoid 'clipping' or 'distortion' of the audio media.

The Headphone playback is designed only for short periods of time as defined as the time for an MRI Scan. Repeated or longer term usage of the headphone output at high volume can cause damage to the hearing of the patient. If for any reason the headphone playback is to be used for a long term treatment, the **volume needs to be set to a low level** to avoid damage to the patient.

Important note: At all times this product must be used in accordance with this operator manual and by appropriately trained staff who understand the risk to patients' hearing if incorrectly used.

MR200 parts reference

MR125

DVD/CD Player

Noise Reduction Headphones



Stereo Acoustic
Convertor

Audio Control Unit

Soft Touch Microphone



MR125
(inc. 100 pairs of
disposable covers)



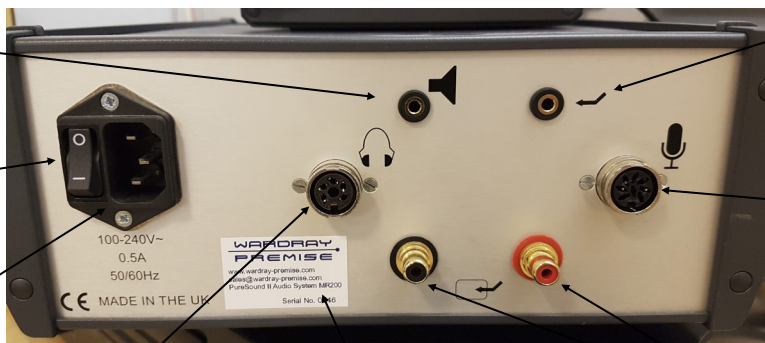
MR151
Earphones
(inc. 20 pairs of disposable
ear tips)

Rear of Audio Control Unit

Power Speaker
Output

On / Off
Power Switch

Power Socket



Patient Headphone
Output

Product Serial No.

Audio Input Socket

Operator Microphone
Input Socket

Audio Input from
(optional) DVD

Operating Instructions

General Information

Pure Sound II is designed specifically for the replay of audio material to patients whilst undergoing MRI Procedures and allows one way communication with the patient (from the operator to the patient) via the supplied microphone unit and the optional replay of the unit output via powered speakers to either a waiting room or control room.


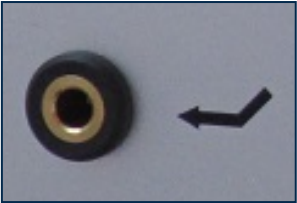


Please note that powered speakers are NOT included/supplied, they need to be sourced locally.

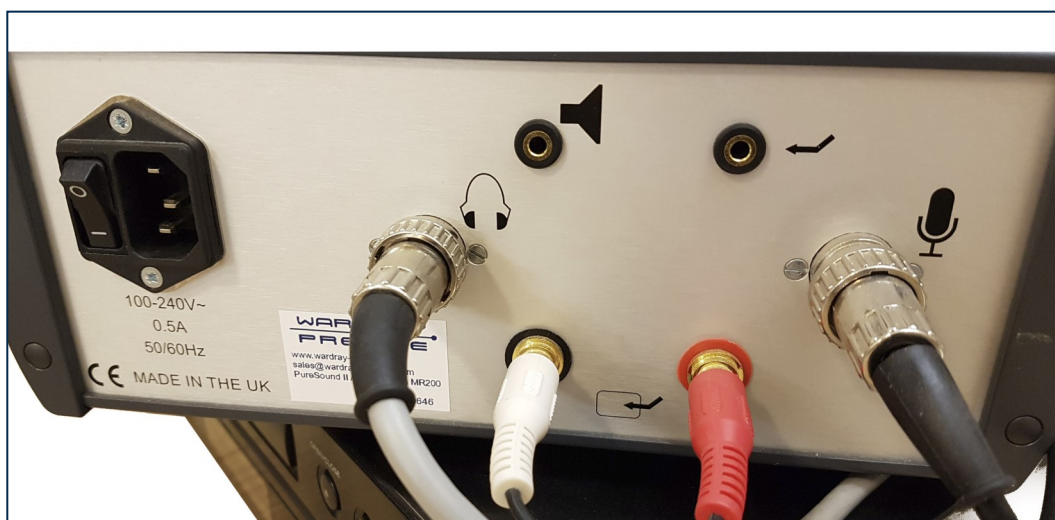
The control unit has 7 connections on the rear panel.

Connection (Icon)	Description
 <p>Power Socket and switch</p>	<p>A 3 pin power socket with unit on/off power switch (Power Lead included).</p>
 <p>Patient Headphone Output Socket</p>	<p>A Patient Headphone Output (via the Stereo Acoustic Converter) multi pin socket (Cables included). (Noise Reducing Headphones and Earphones included)</p> 
 <p>Operator Microphone Input Socket</p>	<p>Operator Microphone Input multi pin socket (microphone supplied).</p>

Operating Instructions

General Information


Connection (Icon)	Description
 <p>Power Speaker Output Socket (3.5mm)</p>	Power speaker output (speakers not included) for use in operator room or waiting room.
 <p>Audio Input Socket (3.5mm)</p>	3.5mm audio input. (eg: Mobile Phone or other audio) To be used with the 3.5mm male to male extension lead (supplied) to allow easy changing between audio inputs. 
 <p>Audio Input Sockets from (optional) DVD</p>	Pair of input sockets to be connected to (optional) DVD player (lead supplied).



Operating Instructions




General Information

Connection	Description
 <p>7 Pin Connector Plug</p>	<p>Stereo Acoustic Convertor Unit - Power</p> <p>Push to connect (It can only locate one way - Do not force). Tighten the outer ring in a clockwise direction to secure.</p> 
 <p>Airline Connector</p>	<p>Patient Headphones Airline Connectors</p> <p>Depress silver colour disc and push the airline into the opening. Releasing the clip will secure the airline in place. Repeat with the second airline.</p> 

Headphones and Earphones	Recommended
	<p>The disposable headphone covers or disposable ear tips should be replaced between patients.</p> <p>100 pairs of headphone covers included.</p> <p>Replacement covers are available in packs of 100 (MR150) pairs.</p> <p>20 pairs of ear tips are included.</p> <p>Replacement ear tips are also available in packs of 20 (MR152) 50 (MR153) and 100 (MR154) pairs.</p>

Operating Instructions

General Information

Control/Indicator	Description
 <p>Power on LED</p>	<p>A power on LED repeater. This will illuminate when the power cable is connected, power is present AND the power switch on the rear of the unit is turned on.</p>
 <p>Operator Microphone Volume Dial</p>	<p>Volume control for the microphone output. Turning the dial clockwise will increase the volume, anti-clockwise will decrease the volume.</p>
 <p>Audio Output Volume Dial</p>	<p>Volume control for the audio output. Turning the dial clockwise will increase the volume, anti-clockwise will decrease the volume.</p>

Operating Instructions

Playing music to the patient

Power on the unit by first turning on power (at the wall socket) to the power cable and then turning on the on/off switch at the rear of the unit.

Connect the patients choice of music:

- ◇ If by personal music device (MP3/iPod/Mobile Phone etc)
 - Connect the device to the 3.5mm jack (if the device requires a 2.5mm jack, please use the supplied adaptor*) (Fig 1).
 - If the device is a **mobile phone**, ensure the phone is set to '**Airplane Mode**'.
 - Set the device volume to a mid-point
 - Familiarise yourself with how to start the music playlist
 - Once the patient is in place, adjust the playback volume by using the Pure Sound II volume control ONLY.
- ◇ If by CD/DVD input (via optional DVD player)
 - Place the music media into the DVD player
 - If the optional DVD player has a volume control, ensure this is set to a mid-point
 - Once the patient is in place, adjust the playback volume by using the Pure Sound II volume control ONLY.



Fig 1

*Please note that for **Apple iPhone 5** and above, a 'Lightning Adaptor' (Fig 2) is required.

(Not supplied, source locally)

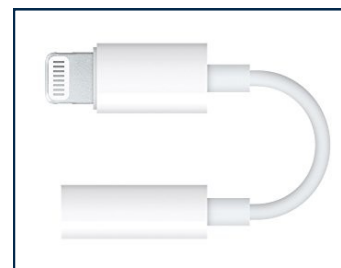


Fig 2

Important Note: The Patient playback via headphones is ONLY for the duration of the patient undertaking MRI processes. The Unit can play at high volumes (to overcome the noise of the MRI operation) and long periods of exposure to high volumes may cause discomfort or damage to the patients hearing.

Playing Music via Powered Speakers

Whether located in the MRI control room or an adjacent waiting room, music playback can be achieved by connecting the 'input' of a powered speaker system to the 3.5mm speaker output on the rear of the Pure Sound II Unit.

The volume of the playback can be adjusted by both the Pure Sound II volume control or the volume control on the powered speakers (not supplied). It is recommended that the volume control on the Pure Sound II unit is used in preference.



CAUTION

WE STRONGLY RECOMMEND VOLUME IS CHECKED
PRIOR TO EACH EXAMINATION



ATENCIÓN

ES ALTAMENTE RECOMENDABLE COMPROBAR EL VOLUMEN
ANTES DE CADA EXPLORACION



ACHTUNG

ES WIRD EMPFOHLEN DIE LAUTSTÄRKE EINSTELLUNG VOR
JEDER ANWENDUNG ZU ÜBERPRÜFEN



ATTENTION

NOUS VOUS FORTEMENT RECOMMANDONS DE VÉRIFIER
LE NIVEAU SONORE AVANT CHAQUE EXAMEN



ATTENZIONE

PRIMA DI FARE OGNI ESAME E CONSIGLIO VIVAMENTE
CONTROLLARE IL VOLUME

Operating Instructions

Communicating with the patient

- Ensure that the Pure Sound II is turned on (check the red LED on the front panel) Fig 1.
- Set the microphone volume dial to the mid-point (the dial cut out pointing vertically) Fig 2.
- To test the volume of the microphone output, press the button on the microphone unit, when the circuit is open to talk, an LED will light on the microphone base (Fig 3).
- Talk at a normal volume to the patient and confirm that the level of the transmission is acceptable. If not, adjust microphone volume up/down accordingly and retest.
- Care must be taken to check that the microphone is not 'open' (e.g. transmitting to the patient) when discussing anything that may be worrying, offensive or inappropriate. While the LED illumination is a guide, it is not recommended that this be taken as a definitive guide and that discretion is used at all times when a patient is being examined.



Fig 1

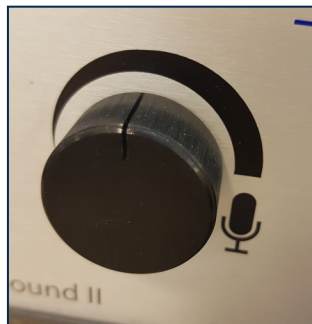


Fig 2

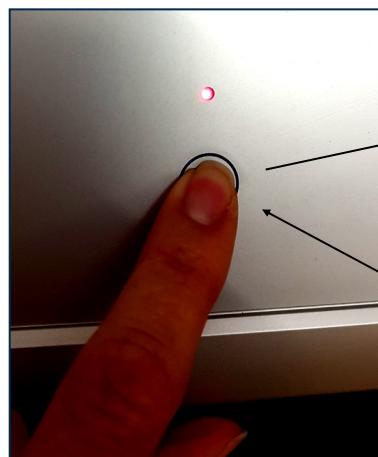
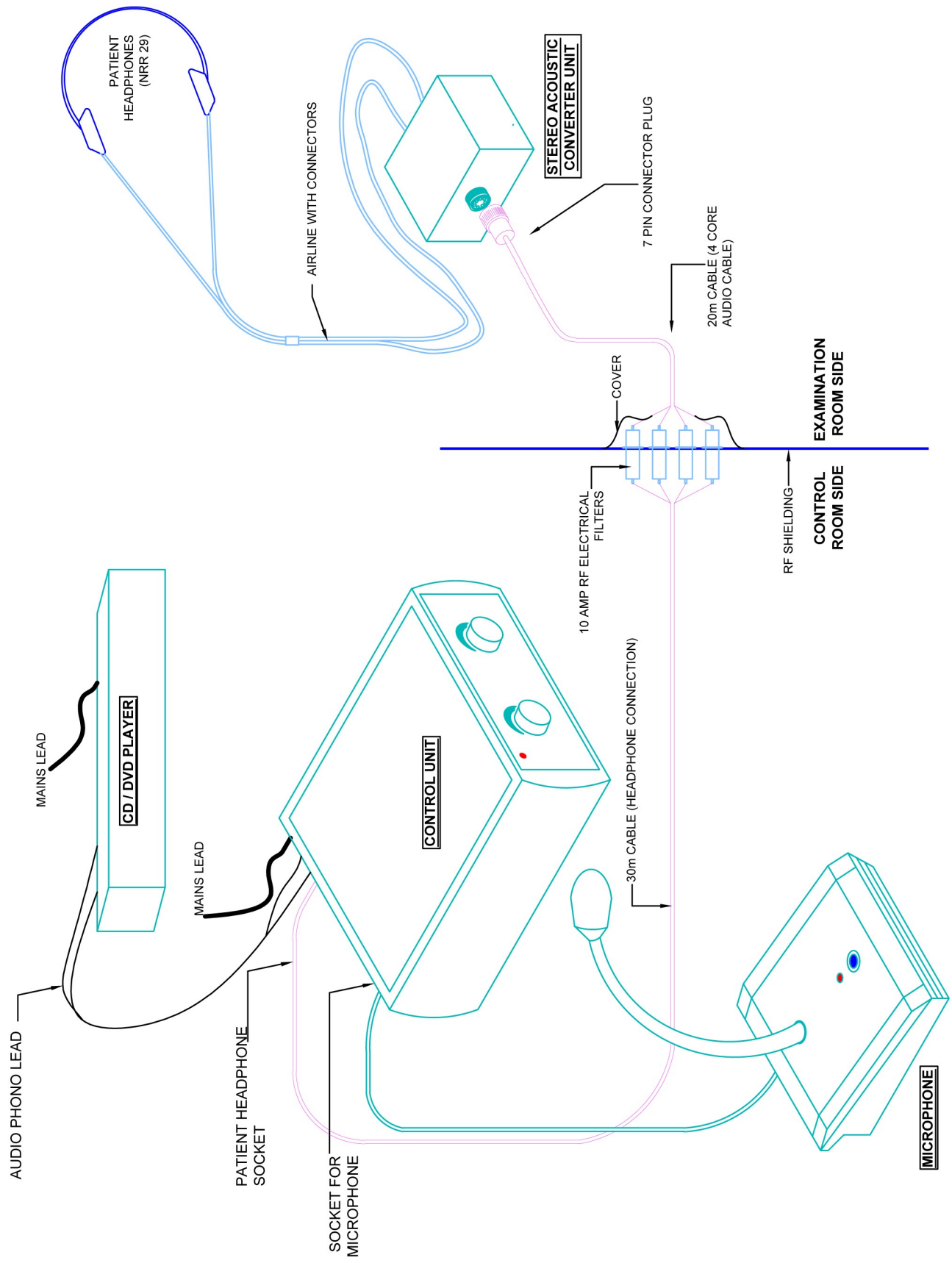


Fig 3

NOTES



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Issued for	INFORMATION
Project	FITTING DETAILS
Title MRI AUDIO RELAXATION SYSTEM MR200	
Scale NTS	Date 29.08.2019
Job Number	Drawing Number 1591
	Drawn by MC / NT
	Revision C
	Checked

General Maintenance

It is strongly recommended that the following checks are carried out on a weekly basis by trained personnel, to ensure trouble free operation of the unit.

- Check cables for obvious signs of damage or contamination. Report any damage found.
- Check headphones for any sign of damage or contamination. Report damage or clean where necessary following your local guidelines or instructions.

Please register your product with us, via the Warranty Registration Form (see page 22), for ease of contact in case of urgent upgrades or recalls.

If the unit or any of the parts are 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

Please include the product code and the product's serial number when contacting Wardray Premise.



General Information

Cleaning

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

There are NO SERVICEABLE PARTS WITHIN THE CONTROL UNIT OR STEREO / ACOUSTIC CONVERTER. Any attempt to open the unit parts will invalidate the warranty.

Any removal of covers or connections to the unit requires turning the unit OFF, AND the complete removal of the power lead.

If any of the above give cause for concern, please contact your Wardray Premise service provider.

EU Declarations of Conformity and Magnetic Testing

Documentation is available upon request.



HURSLEY
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EMC TEST REPORT

No. 13R309 ER

Issue#1: 22nd August 2013

UKAS Accredited
EU Notified Body
FCC & VCCI Registered
BSMI Lab ID: SL2-IN-E-3008
KC Lab ID: EU 0176

EMC Test Report

for the

Square Tower Enterprises Limited

**Pure Sound II
Sound System**

Project Engineer: R. P. St John James

Approval Signatory

Approved signatories: S. M. Connolly ☐ J. A. Jones ☒

The above named are authorised Hursley EMC Services engineers.

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**HURSLEY
EMC
SERVICES**

Certificate of Test

No. 13R309 EC

Issue#1: 13th August 2013

**UKAS Accredited
EU Notified Body
FCC & VCCI Registered
BSMI Lab ID: SL2-IN-E-3008
KC Lab ID: EU 0176**

**This document is hereby issued by Hursley EMC Services Limited to the named manufacturer.
It is valid only for the product identified below in respect, either in part or in full, to the relevant electromagnetic requirements necessary for compliance with the EMC Directive 2004/108/EC.**

PRODUCT:	PURE SOUND II SOUND SYSTEM
Serial number:	EMC001 (designated by Hursley EMC Services)
<i>Product manufacturer:</i>	Square Tower Enterprises Ltd & Wardray Premise Ltd
<i>Product mains rating:</i>	230V/50Hz
<i>Product build level:</i>	Production sample
<i>Product build description:</i>	Ref. Job sheets 13R309 defining product & support equipment
<i>Product modifications:</i>	None to sample submitted
<i>Customer:</i>	Square Tower Enterprises Ltd Suite 119, 5 Charter House, Lord Montgomery Way, Portsmouth PO1 2SB. UK.
<i>Test commissioned by:</i>	Mr Michael Buchan
<i>Test dates:</i>	1 st August 2013
<i>Test measurement site:</i>	Hursley EMC Services Limited Trafalgar House, Trafalgar Close, Chandlers Ford, Eastleigh, Hampshire
<i>Test deviations:</i>	None
<i>EMC product family:</i>	Generic standards for residential, commercial and light-industrial environments

Applied and met EMC test standards:

Emissions:

EN 61000-6-3:2007	Radiated disturbance	- CISPR 16
inc A1:2011	Conducted disturbance	- CISPR 16
EN 61000-3-2:2006	Mains harmonics	- Class A
EN 61000-3-3:2009	Mains voltage flicker (dmax=4%)	

UKAS uncertainty statement: The uncertainty of measurement for each test has been included to support a level of confidence of approximately 95%.

This product complies with the technical requirements concerning the applied sections of the above identified test standards.

This certificate relates to the product as tested and may not represent the entire population. Test data and product details for reporting purposes are filed (ref: 13R309) at Hursley EMC Services Ltd.



R. P. St John James

TEST ENGINEER: R. P. St John James

Approved signatories: S. M. Connolly () J. A. Jones (✓)
The above named are authorised Hursley EMC Services engineers

[Signature]
APPROVAL SIGNATORY

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Project number	13J309
Review date	15 th August 2013
Standard title	BS EN 60950-1:2006 inc A12:2011 safety report
Equipment under test:	Pure Sound II Audio Unit
Model / serial number:	Labelled "Pure Sound II" and "Wardray premise" Serial number not stated but same as EMC test sample provided to Hursley EMC
Summary	Complies with requirements subject to additional items being addressed as detailed below.
Recommendation	Whilst not mandatory within this standard, we advise that a maximum sound level measurement is made at the headphones and recommend that the maximum permitted level be set at 85dBA
Customer	Square Tower Enterprises Limited
Address	Suite 119 5 Charter House Lord Montgomery Way Portsmouth Hampshire PO1 2SB United Kingdom
Contact	Mr Michael Buchan

II



HURSLEY
EMC
SERVICES

SAFETY REPORT

No. 13J309 SR

Issue#1: 16th August 2013

EN 60950-1:2006 inc A12:2011
Safety Review Report
for the
Square Tower Enterprises Limited
Pure Sound II Audio Unit

Project Engineer: Mr Charles Blackham

Approval Signatory

Approved signatories: S. M. Connolly ☐ J. A. Jones ☐ R. P. St John James ☒

The above named are authorised Hursley EMC Services engineer

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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

Reply e-mail: sales@wardray-premise.com

Reply Fax: +44 (0)20 8398 8032

Name:	
Job Title:	
Company:	
Address:	
Telephone:	
Fax:	
Email:	
Product Code/ Description:	
Product Serial/ Reference No:	
Please enter date Product received:	

If your department currently has any other Wardray Premise Ltd. equipment, which is not already covered under a service contract, please contact Servicing-Admin@wardray-premise.com to discuss an all-inclusive package.

If you would like any further information or would like to be contacted regarding any of our products, please add your enquiry to the box below.