



grael™

User Guide



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Before You Begin

The **Grael User Guide** contains procedures and information for you to work with the Compumedics **Grael** or **Grael EEG** patient physiological recorders.

Limited Warranty – Hardware

Compumedics Limited warrants each new device to be free from defects in workmanship and materials under normal use and service for a period of twelve (12) months from the date of shipment. Compumedics' sole obligation under this warranty will be to repair or replace, at its option, products that prove to be defective during the warranty period. The foregoing shall be the sole warranty remedy. Except as set forth herein, seller makes no warranties, either expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. The warranty is not assignable.

The warranty is invalidated if anyone other than Compumedics Limited or an authorised service agent attempts to repair or disassemble the unit.

Limited Warranty – Electrodes, Sensors And Leads

Compumedics Limited warrants each of the Products as free from material defect for a period of three (3) months from the date of delivery to the Distributor. During such period of three (3) months as aforesaid, Compumedics will replace without charge any component

Before You Begin

found to be materially defective and shall be responsible for all labour or other charges involved in repairing the Product(s) provided that Compumedics shall not be liable to replace components which are defective due to accident or misuse.

Safety And Effectiveness Considerations

Sleep or neurological studies should only be carried out under the recommendation of a physician.

This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information contained in this User Guide before using the equipment.

Do not use in conditions where vibrational stresses are excessive.

Do not use in excessively unhygienic locations.

Do not operate the equipment at ambient temperatures above +40°C or below 0°C (+104°F and +32°F respectively).

Do not use in conditions where the device may be exposed to liquids (e.g. in shower).

Transport And Storage Conditions

-10°C (+14°F) to 50°C (+122°F) 20 to 90% relative humidity, non-condensing.

Indications For Use

The **Grael** is intended for use in the recording, displaying, analysis, printing and storage of human biological parameters such as heart and muscle activity, eye movement, breathing and body movements to assist in the diagnosis of various sleep disorders or neurological disorders. The **Grael** is designed for use in a hospital or other clinical environment. The **Grael** is only to be used under the direction of a physician.

Contraindications

Discontinue use if the patient displays distress, discomfort or adverse reaction to electrode and/or sensor attachment.

Discontinue use if the patient perspires excessively. This may cause signal distortion.

The **Grael** is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

Labelling Definitions

Where the following symbols appear on equipment according to IEC60601-1 / EN60601-1 they have the following definitions:



Where you see this symbol on any device label it means “Attention, consult ACCOMPANYING DOCUMENTS”.



Where you see this symbol on any device label it means “Type CF Applied Part”.



Where you see this symbol on any device label it means “Type BF Applied Part”.



Where you see this symbol on any device label it means “Type B Applied Part”.



Where you see this symbol on any device label it means “Class II Equipment”.



Where you see this symbol on any device label it means “RF electromagnetic energy emitted for diagnosis or treatment”.

Before You Begin

Warnings And Cautions



This symbol is used to indicate a **WARNING**. These highlight potentially harmful (to the patient or operator) situations.



This symbol is used to indicate a **CAUTION**. These are conditions which may lead to equipment damage, malfunction or inaccurate operation.



WARNING The *Grael* should not be used in the presence of flammable liquids or gasses. This may present an explosion hazard.

The *Grael* device must be either wall mounted or positioned on a bedside table. It must not be placed on or in the patient bed.

The operator must not touch either the network cable or connector while simultaneously touching the patient.

Any power over Ethernet switch or power injector used with the *Grael* must conform with IEC60950 / EN60950 and must be located outside of the patient environment.

Do not use respiratory impedance plethysmography or the related ECG channel (channel 33) if the patient has any implanted devices, e.g.: a pacemaker. Doing so may interfere with the operation of the implanted device. For further information please contact the manufacturer of the implanted device.

Use only the sensors and electrodes supplied with or specifically intended for use with the *Grael*. Failure to do so may result in invalid study data.

Do not connect sensor lead wires into electrical outlets. Lead wire contact with electrical outlets presents a serious shock hazard.

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Pacemaker Patients – Heart rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meters.

Burns may occur at the electrode sites when the **Grael** is used in conjunction with high frequency surgical or diathermy equipment due to high frequency currents flowing in the electrode lead wires. To minimise this risk:

- the electrodes should be positioned as far as practical from the patient electro-surgical equipment connections or the electro-surgical site on the patient
- use bipolar electro-surgery if possible
- use as low power as possible for the electro-surgical procedure in order to minimise the current.

The equipment is not serviceable by the User's service personnel.

The **Grael** should undergo regular electrical safety testing in accordance with your hospital's medical equipment routine testing procedures. This should be done at least annually.

The **Grael** does NOT have defibrillator protected patient circuits. If the patient needs to be de-fibrillated, remove all patient connected leads from the **Grael** before activating the defibrillator.



CAUTION

Operation may be affected in the presence of strong electromagnetic sources such as electro surgery equipment.

Compumedics recommends the patient be supervised at all times during a study to prevent possible injury due to excessive patient movement.

Before You Begin

Prescription Device



CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician.

Placement of Equipment

Do not operate the **Grael** near flammable or explosive gases or materials.

Interference

The **Grael** records physiological electrical signals which can be influenced by external electrical interference. Filtering techniques can be used to reduce the impact of external sources of interference. However, by being alert to signal interference, the potential effect of interference can be minimised.

Keep the **Grael** at least one metre (three feet) away from all electrical appliances. Examples of these include TV sets, electric blankets, air conditioners, microwave ovens, cordless and cellular telephones and walkie-talkies.

Interference to physiological signals could be caused by strong transmitter signals such as TV, radio, airport, police, fire and ambulance stations. If recording will occur within two kilometres (1.3 miles) of one or more of these sources, then ask Compumedics Product Support to help you to determine if your system will operate properly.

Synthetic fabric from draperies or carpets can cause interference due to static electricity. Touching an electrically conductive and earthed object before handling the patient or the **Grael** can prevent interference from static charges.

Manufacturer's Recommendations

Use only Compumedics supplied accessories with the **Grael**. Be sure to read, understand and follow the instructions in this User Guide and others that come with the system and its components.

Cleaning

Unless specified otherwise within these instructions follow the manufacturer's recommendations and instructions for reusing, cleaning, disinfecting or sterilising sensors, sensor cables and monitoring equipment used with the **Grael**.

Do not autoclave, gas or pressure sterilise any of the **Grael** components.

If any liquid is spilled on any **Grael** component discontinue using it until it is determined that the component can be safely operated. Contact Compumedics Product Support or your authorised representative for assistance.

Wiring



WARNING Do not connect sensor lead wires into electrical outlets. Lead wire contact with electrical outlets presents a serious shock hazard.

Keep children and pets away from the **Grael**. Children or pets could accidentally disconnect the equipment or cause other incidents.

Do not allow the sensor wires or connecting cables to become tangled, coiled, crossed or wrapped around the patient's neck, arms or legs. This condition may cause strangulation. Compumedics recommends bundling electrode and sensor lead wires and using tape to hold them in place.

Handle sensor wires carefully to prevent them breaking inside the insulation. Always grasp and pull wires at the strain relief area when disconnecting them from the **Grael**.

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Care

Do not drop the components of the **Grael**. If a component is dropped discontinue using it until it is determined that the component can be safely operated. Contact Compumedics Product Support or your authorised representative for assistance.

Product Support

If you have a question regarding the correct use of the **Grael** and/or any of its components first refer to the relevant sections in this User Guide for the solution. If you are unable to find the answer in this User Guide contact Compumedics Product Support on:

Australia	1800 244 773
New Zealand	0800 888 015
USA	877 294 1346
International	+61 3 8420 7396

or your authorised representative.

If you call you should be close to the product so that questions by trained Compumedics technicians can be answered efficiently. You should also have this manual at hand. When you call please provide the following information:

- The version of software and operating system being used
- A description of what happened and what you were doing when the problem occurred
- The exact wording of any messages that appeared on your screen
- A description of any attempts made to fix the problem

Repairs of Compumedics Limited equipment under warranty or service contracts must be made at authorised repair centres. If the equipment needs repair contact Compumedics Limited service department to request an RA Number (Return Authorisation). When calling have the device model and serial number ready.



Service items received without an RA number may be returned to the sender or remain un-repaired until such time as a number is raised.

If you need to ship the equipment pack it and its accessories carefully to prevent shipping damage. All relevant accessories should accompany the equipment.

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Compumedics E Mail Address

Compumedics can also be contacted by sending e mail via the Internet. This will be most beneficial to international users.

The Compumedics e mail address is:

support@compumedics.com

Compumedics Home page

Visit Compumedics home page on the World Wide Web at:

<http://www.compumedics.com>

Before You Begin

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1 Introducing Grael

The **Grael** is a device used to collect a number of physiological parameters, including EEG, EOG, ECG and respiratory signals, which are then used as an aid in the diagnosis of respiratory and/or neurological related sleep disorders or other neurological conditions by qualified physicians. Data is transmitted to a PC for viewing and analysis during acquisition, and subsequent review and reporting.

The system is comprised of hardware and software which, depending on the model type, provides up to 60 separate parameters for recording, review and analysis.

The data is acquired from a combination of electrodes, sensors and transducers. Depending on which model **Grael** is used signal types can include EEG, EOG, EMG, ECG, pressure, airflow, snore, respiratory effort, body position, limb movement, oxygen saturation, pulse rate and pulse waveform.

The electrodes and sensors used to acquire patient data are connected between the patient and the **Grael** unit.

Two different **Grael** models are available. The **Grael**, Compumedics part number 8028-0001-01, is a full channel device suitable for conducting either sleep or EEG studies while the **Grael EEG**, Compumedics part number 8028-0002-01, is a reduced channel device suitable for EEG studies only. Unless otherwise noted the information in this manual applies to both devices and the name **Grael** is used to refer to either device type. Where necessary the name **Grael EEG** will be used to explicitly indicate functionality that is either not present in or unique to the **Grael EEG**.

1.1 Primary System Components

The **Grael** or **Grael EEG** is a standalone unit, which together with sensors and a PC running either Compumedics **PSG Online** and **Profusion PSG** software for sleep studies or **Profusion EEG** for EEG studies can record, review and analyse study data.

1.1.1 Grael Device

The **Grael** device can be table or wall mounted. It records signals from the electrodes and sensors applied to the patient. All electrodes and sensors in turn connect directly to the device. Power to the **Grael** is provided by the network cable.



Figure 1-1: **Grael** unit



WARNING For sleep use the **Grael** device must be positioned on a bed side table or be wall mounted. It must not be placed on or in the patient bed. Similarly for EEG use the **Grael** device must be placed or mounted on a suitable table or trolley beside the patient.

The power over Ethernet switch or power injector must be placed outside of the patient environment.

The operator must not touch either the network cable or network connector at the same time as the patient.

1.1.2 Review PC

The review personal computer (PC) is used to operate the **Profusion PSG** or **Profusion EEG** software packages. Data is transferred between the **Grael** unit and a review PC using a standard network interface.



CAUTION Power is supplied to the **Grael** via the network cable using either a power over Ethernet switch or power injector. A variety of solutions are available, contact your Compumedics representative for advice.



WARNING Do not connect external devices such as respiratory monitors, oximeters or CO₂ monitors directly to the **Grael** recorder. Such devices may compromise patient safety.

Both the review PC and the power over Ethernet device must comply with the requirements of standard IEC60950 / EN60950 (Safety of Information Technology Equipment).

1.2 Software

Several Compumedics application software programs exist to facilitate the recording and subsequent analysis of studies.



CAUTION All Compumedics software programs require the use of a special hardware device (called a software protection key or dongle) to protect against unauthorised use or copying. In addition the dongle must be configured with specific activation codes for each program to be used.

1.2.1 PSG Online

PSG Online (v3.1 or later) is required for conducting sleep studies. It allows the user to:

- Configure the **Grael** device prior to recording.

- Configure the patient name and other details.
- Record study data to the review PC hard disc.
- Record digital video (as well as the physiological data) to a study on the review PC hard disc.
- Monitor and analyse study data during recording.
- Add technician comments to the study.

Note that while the **Grael EEG** will work with **PSG Online** it is not possible to use a **Grael EEG** device for conducting sleep studies as it does not provide the necessary respiratory effort, pressure or airflow channels.

1.2.2 Profusion PSG

Profusion PSG (v3.1 or later) is used to review or analyse sleep study data after acquisition. It allows the user to:

- Automatically analyse sleep staging and arousals.
- Automatically analyse respiratory, PLM and heart rate data.
- Fully edit data to mark and reclassify sleep staging, arousal events, respiratory events, limb movement events, ECG events, study start/stop time and other physiological features.
- Generate new reports.
- Edit report templates – including header and footer.
- Add technician and physician comments to a study.



WARNING Study data must be reviewed by a trained physician and all relevant results manually verified prior to making any diagnosis.

1.2.3 Profusion EEG

Profusion EEG (v4 or later) is required for conducting EEG studies. It can be used with either the **Grael** or **Grael EEG** device. It allows the user to:

- Configure the **Grael** device prior to recording.
- Configure the patient name and other details.
- Record study data to the review PC hard disc.

- Record digital video (as well as the physiological data) to a study on the review PC hard disc.
- Monitor and analyse study data during recording.
- Add technician comments to the study.
- Analyse recorded studies.
- Create report templates.
- Generate study reports.



WARNING Study data must be reviewed by a trained physician and all relevant results manually verified prior to making any diagnosis.

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2 Setting Up Grael

This chapter details the set up requirements for the **Grael System** and basic operation of the **Grael** device. Included are the basic computer system requirements necessary to be able to install and run the Compumedics application software.

2.1 Computer System Requirements

Following are the recommended minimum hardware and software requirements to run **PSG Online**, **Profusion PSG** or **Profusion EEG** on a single computer. Additional applications that run in conjunction with **PSG Online**, **Profusion PSG** or **Profusion EEG**, for example Compumedics **Digital Video**, may require extra processing resources. These applications are referred to as the **Profusion Software Suite**.

2.1.1 PC Configuration

Component	Minimum	Recommended
Processor	1.8 G Hz – Analysis only 2.4 G Hz – Analysis and Digital Video	3.0 G Hz P4 class or greater
RAM	512MB	1GB or greater
Hard Disc	20GB – Analysis only 60GB – Analysis and Digital Video	250GB or greater
Display Adapter	32 MB display memory	128MB display memory
Monitor	1024 X 768 pixels	1600 X 1200 pixels

Component	Minimum	Recommended
Archive Recorder	CD-R	DVD±R or DVD±RW

2.1.2 Operating System And Additional Software

- Microsoft Windows XP (with service pack 3 or later) or Windows Vista (with service pack 1 or later) or Windows 7. Earlier versions of Microsoft Windows are not supported.
- Microsoft Word (for Report Wizard in **Profusion PSG** or viewing **Profusion EEG** reports)



The **Profusion Software Suite** is not compatible with the Windows NT, Windows ME, 98 or 95 operating systems.

2.1.3 Software Protection Key

The **Profusion Software Suite** requires a “Software Protection Key” (also known as a dongle) attached to the PC to run. If you try to start any of the applications and the dongle is not installed the software will either:

- Display a message that the dongle is missing and not start.
- Start in “read only” mode.



Figure 2-1: Parallel port and USB port dongles

Before starting any of the application programs the dongle must be installed on the parallel (printer) port or USB port of the computer (depending on the type of dongle). If using a parallel port dongle you

may piggyback another parallel device such as a printer to the dongle with no side effects.

**CAUTION**

It is not possible to use more than one Compumedics dongle on a PC. If it is necessary to run more than one Compumedics software program on a single PC then the dongle must be programmed to allow operation of all of those programs.



The dongle is in effect your software license. Compumedics does not issue replacement dongles. Should you lose it for any reason you will be required to purchase another software license.

2.2 Installing Grael Hardware

The **Grael** cradle can be wall-mounted or placed on a suitable flat surface such as a bed side table. The only non-patient connection required to the **Grael** is an Ethernet cable. The **Grael** uses power over Ethernet (POE) to obtain its power. As such the network cable must be sourced from either a POE power injector or POE capable network switch. At the **Grael** end the network cable must be plugged into the connector labelled LAN on the underside of the **Grael** cradle. Ensure that the network cable is correctly plugged in at each end. There should be an audible click as it engages.

The recording computer can either use a dedicated network card for the **Grael** (as shown in figure 2.2 below) or else must be on the same network as the **Grael**. If using a POE injector it should be located close to the computer or network switch, it must not be placed in the patient environment. The **Grael** network connector is an “auto MDIX” type and can be used with either a straight through or cross over network cable whether it is connected to a switch or directly to a PC, it will automatically make the necessary adjustment.

For more complex networking environments please contact your Compumedics representative for advice or recommendations.

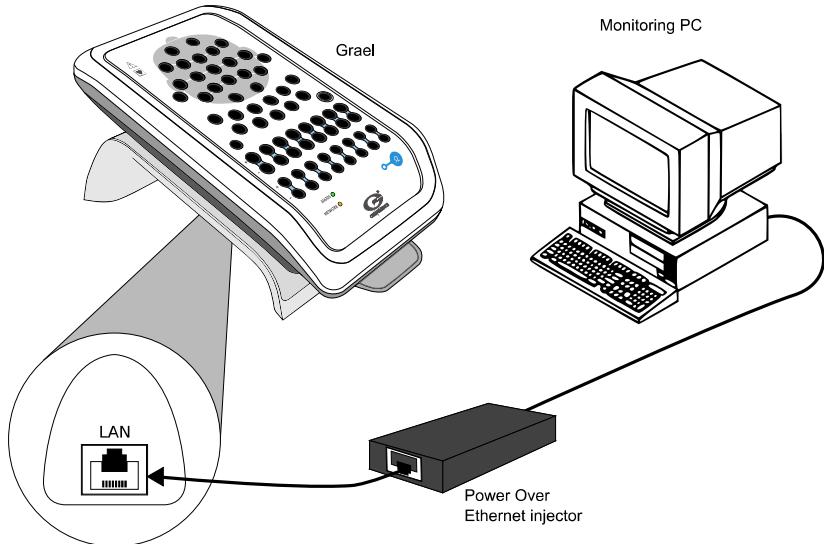


Figure 2-2: Grael connection to PC

2.3 Installing Software

Before installing any of the **Profusion** software suite ensure your computer is running Microsoft Windows XP (service pack 3 or later) or Windows Vista (service pack 1 or later) or Windows 7 and, if using the **Profusion PSG Report Wizard**, Microsoft Word. Microsoft Word can also be used to view the RTF format reports created by **Profusion EEG**. Please consult your Microsoft documentation for information on installing or using these products.

To install the Compumedics software:

1. Insert the CD into the CD-ROM (or DVD) drive.
2. Wait for the software installation to start or, if auto start is disabled, from the Windows desktop select Start | Run, then enter D:\SETUP.EXE (where D: is the drive letter that has been assigned to the CD-ROM drive) and press <Enter>.

3. Select the programs that you wish to install (and that your Dongle has been programmed for).
4. The install wizard will guide you through the installation process.

2.3.1 Updating Compumedics Software

When you update your Compumedics software to a newer version it may be necessary to also re-program the dongle for that version of the software. Generally this is only required when the major version number of the application changes (for example from v2 to v3).

If it is necessary to re-program the dongle then, when you purchase the software upgrade, you will also be supplied with a software unlock code. The first time you try to run the upgraded software an “unlock code dialogue box”, similar to the following figure, will be displayed.

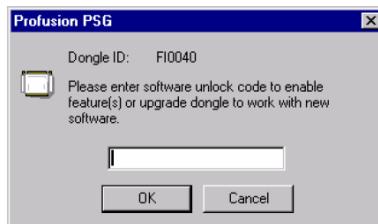


Figure 2-3: Unlock code dialogue box

At this point do the following:

1. Enter the software unlock code (supplied with the new software release) into the edit window.
2. Click the **OK** button.

Provided that you have entered the correct code the new version of the software will be opened.

2.4 Operating The Grael Device

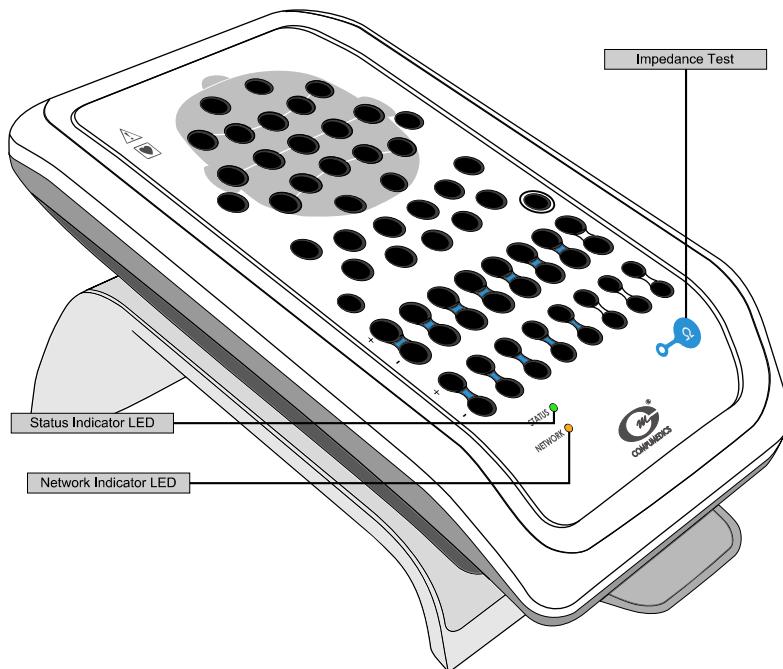


Figure 2-4: **Grael** recorder main features

2.4.1 Powering the Grael

Seat the **Grael** into the cradle to turn the unit on. You should hear an audible click as the retention latches engage, if not make sure that the rear end of the case is correctly hooked over the cradle and gently push down at the front edge near the Compumedics logo.

The **Grael** takes approximately 10 seconds to load the firmware required to operate. During this time the status indicator will be illuminated white. If the **Grael** has not started after this time it may not be correctly seated in the cradle, lift it from the cradle and reseat it.

2.4.2 Status Indicator

The status indicator uses colour and blinking patterns to indicate the current status of the **Grael**. The possible status and corresponding indicator colours are:

- Off:** The unit is turned off.
- Solid white:** Program loading.
- Solid yellow:** Initialisation and self test.
- Pulsing blue:** Idle.
- Pulsing green:** Sending data.
- Pulsing purple:** Test mode.
- Red:** Error. The unit must be turned off and then back on to continue. If this condition persists contact Compumedics customer support or your service representative.

2.4.3 Network Indicator

The network indicator gives the current state of the Ethernet network connection as follows:

- Off:** The unit is turned off or the network is either not connected or faulty.
- Solid orange:** Network link is OK but inactive.
- Blinking orange:** Network activity (send/receive).

2.4.4 Impedance Indicators

Channels 1 through to 40 and the REF electrode have impedance measurement capability and a corresponding impedance indicator built into the touch proof connector. Whenever the impedance measurement function is enabled and the electrode impedance is

higher than the threshold set in either **PSG Online** or **Profusion EEG** the corresponding input connector illuminates.

2.4.5 Buttons



Impedance Test

Press to start Impedance testing. The indicator next to the Impedance Test button lights up to show the test is active. Touch-proof connectors which have attached electrodes will light up (orange) when their impedance is above the threshold set in the **PSG Online** or **Profusion EEG** software. You can check the impedance value in **PSG Online** or **Profusion EEG**.

Press the button again to stop impedance testing.

Impedance testing is available for channels 1 through to 40. The REF input impedance can also be tested.



CAUTION Impedance measurement will not function as expected unless both the REF and GND electrodes are connected to the patient.

2.5 Configuring the Grael

The **Grael** provides the user with almost unlimited configuration options that are set prior to recording a study. When conducting sleep studies configuration is performed using the **PSG Config** software application prior to running **PSG Online**. Consult the **PSG Config** User Guide or online help for details on customising the recording configuration to meet your requirements. When conducting EEG studies configuration is performed within **Profusion EEG** prior to starting a recording. Consult the **Profusion EEG** User Guide or online help for details on device configuration.

Depending on the model certain electrode channels are, by default, allocated to specific functions such as chin EMG, eye movements and leg movements for the **Grael** or the standard 10-20 electrode placement for both the **Grael** and **Grael EEG**. Labels adjacent to the touch proof connectors identify all such channels. There is,

however, nothing “special” about these channels. You may reassign these functions to other electrode channels as desired or use these channels for other functions.

The ECG channel, however, is a special case and, in addition to connecting to the ECG amplifier, it also connects to the respiratory impedance plethysmography circuitry for either the **Grael** or **Grael EEG**. This provides a single channel of respiratory effort via the ECG electrodes. It should be used only for ECG. If additional ECG channels are required then any of the other electrode channels may also be used for ECG. Also you should not connect channel 33 to patients with any implanted electronic devices (e.g.: a pacemaker) as it may interfere with operation of the implanted device. In this case use one of channels 34 to 40 for ECG.

Channels 41 through to 48 (these channels *are not* present on the **Grael EEG**) are for use with Compumedics specified sensors only, they must not be connected to the outputs of any other equipment. If necessary they may also be used for patient electrodes although in this case impedance measurement will not be possible.

The connectors on the end panel of the **Grael** or **Grael EEG** are for use with the indicated sensors only, they cannot be used for any other function.

2.5.1 Sensor Calibration

This section is not applicable to **Grael EEG** since it does not include pressure or position channels and cannot be used for sleep studies.

The recording configurations shipped with the **Profusion PSG** software suite (version 3.1 and higher) include calibrations for the following inputs:

- Pressure
- Position
- SpO₂ (including HR)

The Pressure and Position inputs can be re-calibrated if required. See the **PSG Online** User Guide or online help for details. Re-calibration of the SpO₂ input is not required.

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3 Using Grael For Sleep Studies

This chapter provides an overview of what is required to use **Grael** to record a sleep study once the system has been set up for general use according to Chapter 2 of this user guide. It is applicable only to **Grael** and not **Grael EEG** which cannot be used for sleep studies.

Monitored recording is performed using **PSG Online**. For information on using **PSG Online** please refer to its documentation and help files. The steps required to record a study are listed below and considered in more detail in the following sections.

1. Turn on the **Grael**.
2. Open **PSG Online**.
3. Select the appropriate recording configuration.
4. Verify that there is adequate recording time available on the storage device (hard drive or network storage).
5. Connect the electrodes and sensors to the patient and verify the signal quality.
6. Record study.
7. Analyse and review study.
8. Report study.

3.1 Turn On Grael

Turn on the **Grael** by connecting it to the cradle. You will hear a click when it has connected correctly.

When the **Grael** powers up its operating programs must be loaded into internal memory. This takes approximately 10 seconds, during this time the status indicator will glow white.

Once the programs have been loaded the status indicator will turn yellow while the **Grael** performs a number of self-tests.

If any of the internal self tests fail then the status indicator will turn solid red indicating an error. If this happens then you should turn the unit off and back on again to clear the error.



WARNING Contact Compumedics or your authorised representative should errors persist.

3.2 Configure PSG Online

PSG Online (v3.1 or higher) is required to view data and record studies from the **Grael** device. To open **PSG Online**, select the appropriate **Grael** device in the **NetBeacon** application, available on the recording computer's desktop. Users of Compumedics Nexus Lab Management software should use the "Acquire Study" function of the Nexus Control Centre.

Once **PSG Online** has opened, select the New Study icon. Enter the relevant patient details, and select the desired Recording Configuration. Only configurations compatible with **Grael** will be displayed.

The New Study dialogue also shows the available storage space. **Grael** sleep studies typically require 50 to 200 Mbytes per hour. This requirement will vary depending on the number of channels and data rates selected (more channels or higher data rates require more storage space). Ensure there is enough space to record the desired study duration. Click OK to initialise the study.

Press the Record icon in **PSG Online** to start the recording.

During recording the **Grael** may be un-docked from the cradle if it is necessary for the patient to move about, for example to go to the toilet. No data will be recorded while the **Grael** is un-docked. When the **Grael** is replaced in the cradle it will go through the normal start up sequence and automatically resume recording.

The recording can be paused or closed at any time. **PSG Online** displays the current recording status of the unit. Please refer to the **PSG Online** User Guide or online help for more details on recording studies and the functionality available during study acquisition.

3.3 Available Inputs

With the exception of the oximeter channels all channels on the **Grael** are DC coupled with the low pass filter set by the sample rate as described in section 6.8 . The twenty-four bit analogue to digital converters provide a wide dynamic range and gain switching is not required, for example all electrode channels can measure $\pm 300\text{mV}$ peak to peak with a resolution of approximately $0.02\mu\text{V}$. If desired high pass display filters, available in both **PSG Online** and **Profusion PSG**, can be used to removed any DC offset caused by electrode drift.

All channels are sampled at the same rate and can be set to one of 256, 512, 1024 or 2048 samples per second. **PSG Online** allows different samples rates to be chosen for each channel and will automatically set the **Grael** sample rate to match the maximum sample rate selected for the study. **PSG Online** then filters and reduces the rate for the slower channels. When configuring a study you should choose the lowest reasonable sample rate for all channels, this both reduces the data space requirements for the study and, in the case of the **Grael** device, improves the overall noise performance of the channels.

The following tables provide a complete list of the inputs available on the **Grael** device. See section 3.4 for details on electrode and sensor positioning.

3.3.1 Front Panel

Channel	Connector Label	Comments
Reference	REF	Reference electrode required for all recordings. Electrode impedance test is available for this channel.
Ground	GND	Ground electrode required for all recordings.
1 to 32	Channel number and default function.	Thirty two referential (single ended) channels for electrode connections. Electrode impedance test and a calibration waveform are available for these channels.
33	Channel number, ECG, positive and negative indicators.	Differential channel for ECG. Also used by the respiratory impedance plethysmography channel. Should not be used on patients with implanted electronic devices (e.g.: a pacemaker) as impedance plethysmography may interfere with the operation of the implanted device. Refer to the implanted device manufacturer for further information. Electrode impedance test is available for this channel.
34 to 40	Channel number, default function, positive and negative indicators.	Seven differential channels for electrode connections. Electrode impedance test is available for these channels.
41 to 48	Channel number, positive and negative indicators.	Eight differential channels for sensor connections. If necessary may also be used for electrodes but impedance measurement is not possible. Must only be used with Compumedics specified sensors.

3.3.2 End Panel

Channel	Connector Label	Comments
Pressure	P	Used for measuring the DC pressure in a CPAP mask.
Airflow	F+ and F-	This is a DC coupled differential pressure channel. It is used for measuring respiratory "airflow" via a nasal cannula connected to F- (leave F+open). This results in an upward trace movement for inspiration.
Snore	MIC	Only the Compumedics Tracheal Microphone for Grael should be connected to this input. Other snore sensor types may be connected using one of channels 41 to 48.
Thoracic Effort	THOR	Measures thoracic respiratory effort via an inductive band. Use only Compumedics Grael RIP bands. An inward breath results in a positive waveform deflection.
Abdominal Effort	ABDO	Measures abdominal respiratory effort via an inductive band. Use only Compumedics Grael RIP bands. An inward breath results in a positive waveform deflection.
Body Position	POS'N	Only the Compumedics Position Sensor for Grael should be connected to this input. The position sensor calibration should be checked before use, and re-calibrated if necessary. Provides left, right, supine, prone and upright body position indication.
Pulse waveform	S _P O ₂	Low pass filtered by the oximeter at 30 Hz.
S _P O ₂	S _P O ₂	If the oximeter status is bad this signal is forced to 127.
Pulse rate	S _P O ₂	If the oximeter status is bad this signal is forced to 511.
Oximeter status	S _P O ₂	Bit encoded signal indicating "Good", "Marginal", "Out of Track", or "Lead Off".

3.3.3 Default Electrode Channel Assignments

Although all electrode channels on the **Grael** can be used for any type of electrode signal (EEG, ECG, EOG, EMG, etc.) certain channels are, by default, assigned to specific functions within a sleep

study. Where this is the case the default function is indicated by labels adjacent to the connector on the front panel. Each of these channels is described in the following table. This labelling is only a recommendation for how the channel is used; all electrode channels (with the exception of channel 33, ECG) may be used for any electrode signal.

Channel	Connector Label	Default Function
1 through to 21	10-20 system naming	EEG with the electrodes placed as per the 10-20 system.
22	E1	Left eye EOG.
27	E2	Right eye EOG.
29	EMG1	Chin EMG, electrode 1.
30	EMG2	Chin EMG, electrode 2.
31	EMG3	Chin EMG, electrode 3.
33	ECG	Differential channel for ECG. Also provides the connections for the respiratory impedance plethysmography channel. Do not use this channel on patients with implanted electronic devices (e.g.: a pacemaker). Doing so may interfere with the operation of the implanted device. Refer to the implanted device manufacturer for further information. Use one of channels 34 to 40 instead.
34	LEG/L	Left leg EMG.
35	LEG/R	Right leg EMG.

3.4 Connect Electrodes And Sensors

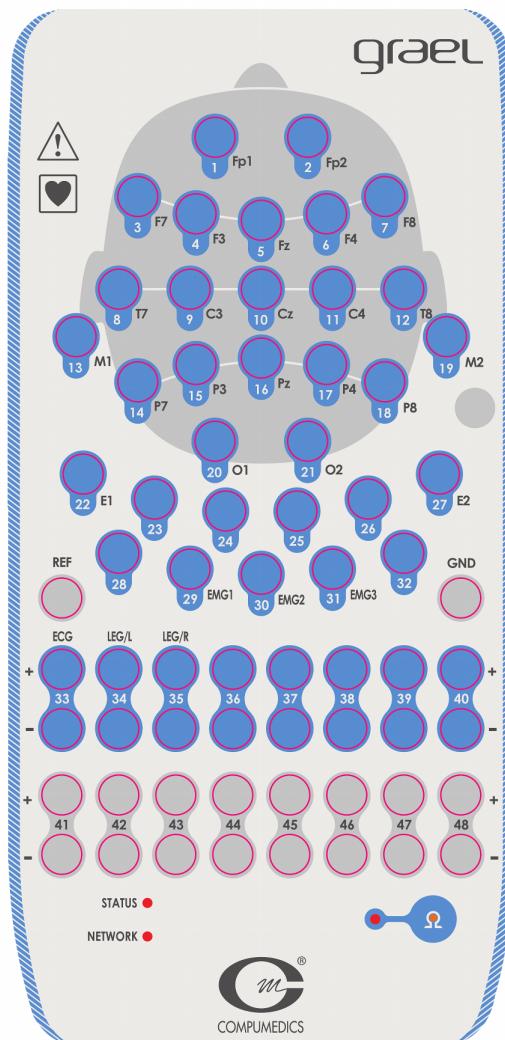


Figure 3-1: Grael Front Panel

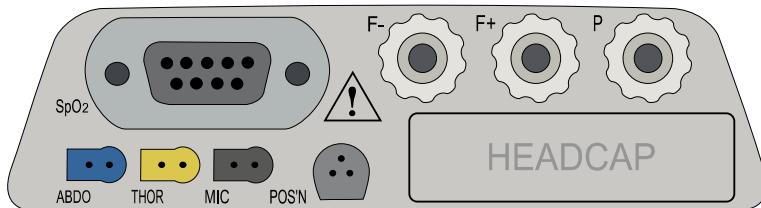


Figure 3-2: Grael End Panel

Electrodes and sensors are connected to the **Grael** front connectors or the end panel connectors. Placement of the various types of sensors or electrodes is described in more detail in the following subsections.



WARNING Use low allergenic tapes and gels to apply electrodes and sensors to the patient's skin. If in doubt test on a small area of skin before use.

Do not apply any sensor or electrode to broken skin.

All sensors and leads should be cleaned and disinfected as appropriate before use.



CAUTION The electrode impedance measurement capability of the **Grael** and **PSG Online** should be used to verify satisfactory electrode connection prior to commencing a study or if signal quality deteriorates during a study.

The calibration waveform capability of channels 1 through to 32 can be used to verify correct operation of the **Grael** prior to connecting electrodes or commencing a study. This tests the operation of the channel amplifiers, analogue to digital converters and data transmission to the review PC.

3.4.1 Respiratory Bands

Grael supports two inductive respiratory bands. The end panel connectors are colour coded as shown below.

Colour	Designation	Panel Label
Yellow	Thoracic band	THOR
Blue	Abdominal band	ABDO

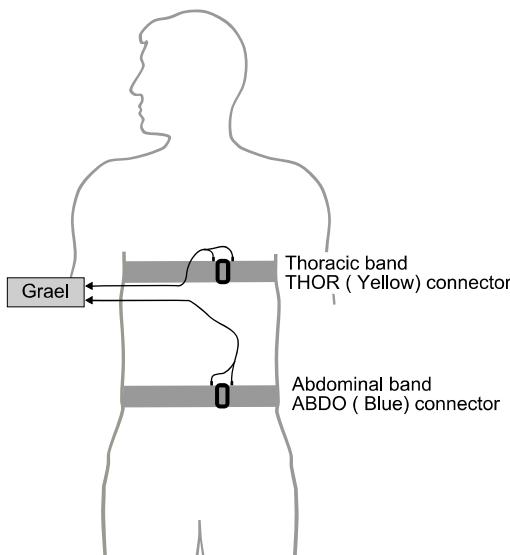


Figure 3-3: Respiratory band placement

1. Attach the thoracic respiratory band around the patient's chest. Make sure that the band is attached firmly but is not too restrictive or uncomfortable for the patient.
2. Attach the abdominal respiratory band as low as possible around the patient's abdomen. Make sure that the band is attached firmly but is not too restrictive or uncomfortable for the patient.

3.4.2 Electrodes

3.4.2.1 ECG Electrodes

Two electrodes must be connected for the ECG signal (channel 33). The **ECG+** electrode should be placed on the left side of the patient's body, between the fifth and sixth rib while the **ECG-** electrode should be placed on the right side over the clavicle.

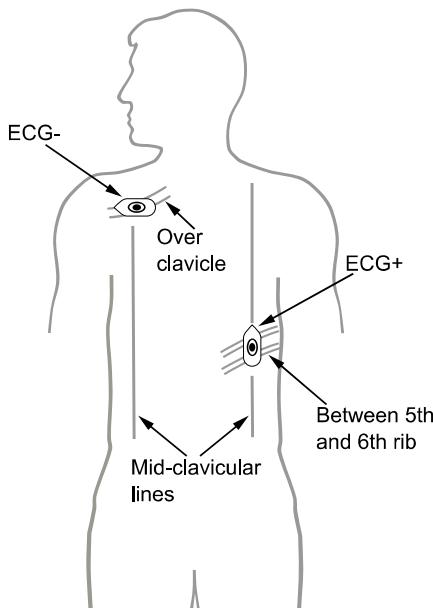


Figure 3-4: ECG electrode placement

The ECG electrodes can also be used to record a single channel of respiratory impedance plethysmography.



WARNING Channel 33 should not be used for ECG monitoring if the patient has an implanted device (e.g.: a pacemaker) since impedance plethysmography may interfere with the operation of the implanted device. Refer to the implanted device manufacturer for further

information. One of channels 34 to 40 can be used as an alternative.

3.4.2.2 EEG Electrodes

EEG electrodes should be placed according to the International 10-20 system. The **Grael** allows acquisition of the full range of 10-20 placements. The recommended placements are F4, C4, O2 and M1. Compumedics recommends placing backup electrodes at F3, C3, O1 and M2.

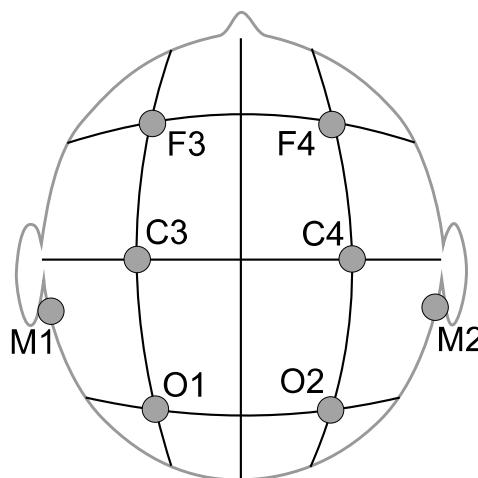


Figure 3-5: EEG electrode placement

3.4.2.3 EOG Electrodes

1. Position the E1 electrode 1 cm lateral and below the left eye outer canthus.
2. Position the E2 electrode 1 cm lateral and below the right eye outer canthus.

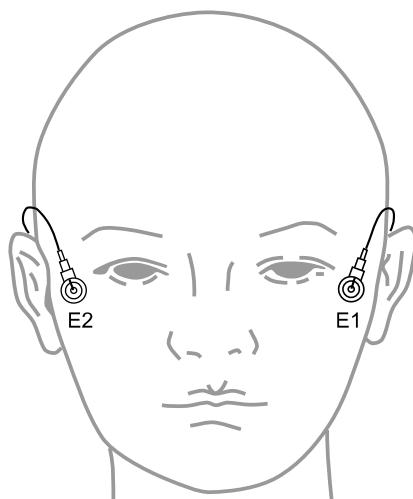


Figure 3-6: EOG electrode placement

3.4.2.4 EMG Electrodes

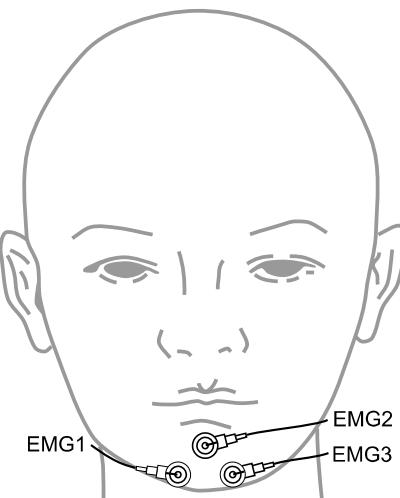


Figure 3-7: EMG electrode placement

Three electrodes should be placed to record chin EMG:

- EMG1: 2cm below the inferior edge of the mandible and 2cm to the right of the mid line.
- EMG2: In the mid line 1cm above the inferior edge of the mandible.
- EMG3: 2cm below the inferior edge of the mandible and 2cm to the left of the mid line.

If desired, two electrodes can be used, and should be placed in the positions described above for EMG1 and EMG3

3.4.2.5 Ground and Reference Electrodes

The **Grael** system uses a driven patient ground to reduce common mode voltages. This is based on two electrodes:

1. **Ground**, the driven electrode

The ground electrode may be attached to any convenient location on the patient, for example near M1 or M2 or over the left clavicle. The exact location is not important but it should be at least 5 cm (2 inches) from any other electrode.

2. **REF**, the sensing electrode

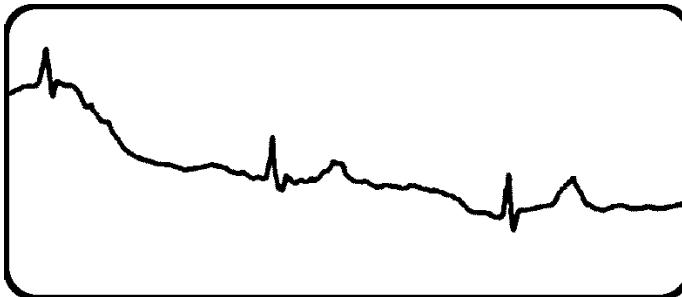
The Reference electrode is best placed in a central position, such as Cz.

It is vital that the Reference electrode site has been prepared well to provide a good impedance. The Reference electrode impedance can be checked against a set threshold by pressing the Impedance Test button on the **Grael**, and the true impedance value can be seen in the **PSG Online** software application.

3.4.2.6 Troubleshooting Electrode Signals

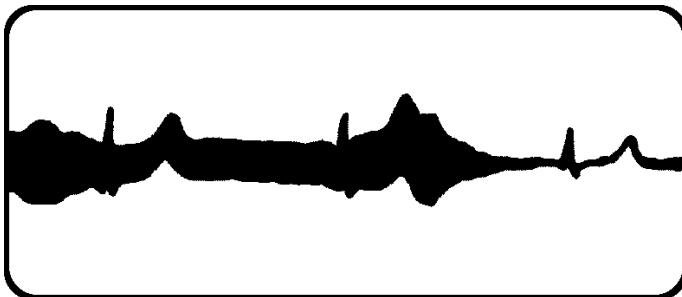
The following examples show various problems that may occur with electrode waveforms together with the most common cause and possible solutions. Although all of the examples shown use ECG waveforms the discussion is equally relevant to all electrode signals.

Baseline Wander



- Patient moving? Secure the lead wires and cable to the patient.
- Caused by the patient respiration? Reposition the electrodes.
- High electrode impedance? Re-prep the patient's skin.
- Static build up around the patient? Get the patient to touch an electrically conductive and earthed object.

Noise



- High electrode impedance? Re-prep the patient's skin.
- Excessive mains interference? Check the environment.

Intermittent Signal



- Connection not tight and secure? Check the electrode connection to the patient input box.
- High electrode impedance. Re-prep the patient's skin.
- Faulty electrode cable? Replace the electrode cable.

Low Amplitude



- Improper electrode position? Reposition the electrodes.
- High electrode impedance? Re-prep the patient's skin.

3.4.3 Nasal Cannula – Airflow

The **Grael** provides for measurement of airflow through the Flow input (F-) on the end panel. A standard nasal cannula is used as the sensor.

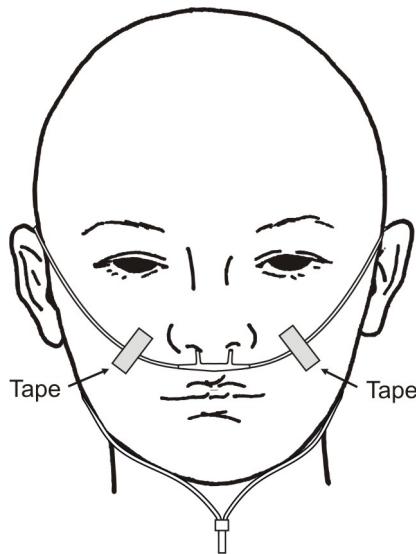


Figure 3-8: Nasal cannula placement

Place the nasal or nasal/oral cannula so that the prongs sit comfortably in the patient's nostrils. Place the tubing behind the ears and adjust the toggle under the chin to hold the cannula in place. Tape can be placed to secure the tubing on the cheeks if necessary (see Figure 3-8).

3.4.4 CPAP Monitoring

The Pressure input (P) on the rear panel of **Grael** can be used for monitoring the mask pressure during CPAP studies. The full scale pressure range of $\pm 100\text{cmH}_2\text{O}$ means it is compatible with all CPAP devices.

Use a length of 4mm ID tubing to connect the pressure port on the **Grael** to the outlet port on the CPAP mask or its connector.

3.4.5 Differential Pressure

If not using a nasal cannula the **Grael** allows monitoring of differential pressure via the F+ and F- inputs. The maximum allowable pressure range is $\pm 10\text{cmH}_2\text{O}$.

3.4.6 Microphone

A tracheal microphone is used to record snoring sounds. The microphone connects to the MIC input on the **Grael** end panel.

Place the microphone on the patient's neck in an unobtrusive area. Do not place directly over the larynx. Attach firmly to the skin with tape intended for use on the face.

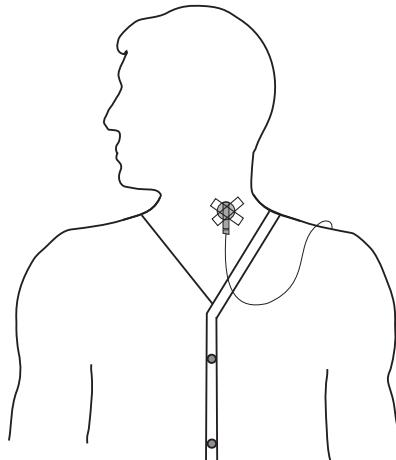


Figure 3-9: Tracheal Microphone placement

3.4.7 Oximeter Probe

The **Grael** contains a built in oximeter with the probe connector located on the rear panel (refer to Figure 3-2). If using a soft tip oximeter probe:

1. Place the probe on the patients finger so that the tip of the finger just touches the end of the probe. The removal of any nail varnish is recommended.
2. Apply a small piece of tape to hold the cable in place on the back of the hand.
3. Wait 10 seconds and then verify that the oxygen saturation is in the normal region (in the order of greater than 95% saturation, or as expected for the patient).
4. Adjust the probe position as necessary.

Alternately, for a flex-wrap oximeter probe:

1. Apply to finger with the sensors aligned and the cable on the palm side of the finger. The removal of any nail varnish is recommended.
2. Apply tape or similar to hold the probe in place.
3. Run the cable out to the back of the patient's hand, make a small loop in the cable and tape this to the back of the patient's hand or on the wrist.
4. Wait 10 seconds and then verify that the oxygen saturation is in the normal region (in the order of greater than 95% saturation, or as expected for the patient).
5. Adjust the probe position as necessary.

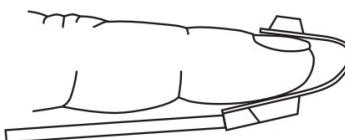


Figure 3-10: Flex wrap oximeter probe placement

- Do not tape the oximeter probe on too tightly as this will affect the reading.
- The oximeter provides four channels: pulse waveform, heart rate, oxygen saturation ($S_P O_2$) and probe status.
- In most cases the oxygen saturation reading from the oximeter should be greater than 95% when awake.

3.4.8 Limb EMG

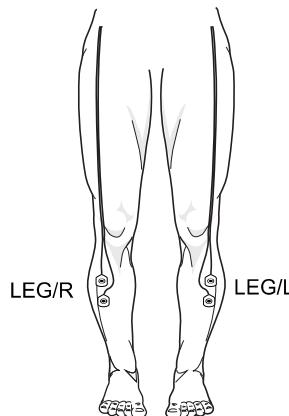


Figure 3-11: Limb electrode placement

Each leg should have two electrodes placed longitudinally and symmetrically over the bulk of the tibialis anterior muscle where greatest movement occurs, so that they are 2 to 3cm apart. Include a small loop in the wires to relieve stress and ensure that the electrodes and wire are taped in place. The limb EMG electrodes connect to channels 34 and 35 on the **Grael** front panel.

3.4.9 Position Sensor

The **Grael** records body position via an external position sensor, which connects to the POS'N input on the rear panel. This position sensor monitors five positions: supine, prone, left, right and upright. The external position sensor should be attached to the thoracic band using the Velcro™ tab on the flat surface at the back of the sensor. Observe the correct orientation of the patient's left and right using the label on the top of the sensor body.

Prior to attachment of an external position sensor to the patient it is recommended to test position detection by moving the position sensor through the various positions: While moving the position sensor observe that the correct position is displayed in **PSG Online**. If the display is incorrect the sensor will need to be re-calibrated (see **PSG Online** User Guide or online help file for details on calibration).

3.5 Start The Recording

When ready to start recording press the record icon in **PSG Online**.



During recording the **Grael** status indicator light pulses green.

3.6 Quick Disconnect

Once a recording has been started from **PSG Online**, **Grael** can be disconnected at any time. Data transmission will stop, but the **PSG Online** recording will continue (with no data). Data acquisition will recommence when **Grael** is reconnected (note that **Grael** will take approximately 10 to 15 seconds to establish the connection to **PSG Online**).

To disconnect **Grael**, press down on the release lever at the base of the cradle. Lift the **Grael** device away from the cradle. As all electrodes and sensors are attached to the **Grael**, there is no need to disconnect any of these. The carrying lanyard (if attached) can be used to carry the **Grael**.



WARNING While disconnecting (or reconnecting) the **Grael** from (to) the cradle the operator must not touch either the network cable or connector on the cradle while simultaneously touching the patient.

3.7 Stop The Recording

To stop the recording click the Close icon in **PSG Online**.

3.8 Review The Study

After stopping the recording open the recording in **Profusion PSG** to review and report the study.

Refer to the relevant software documentation and on line help for more information on using **Profusion PSG**.

3.9 Cleaning

3.9.1 Contamination With HIV, Hepatitis Or CJD

If an electrode, sensor or lead is used on a patient suspected of having HIV or being infected with Hepatitis or Creutzfeldt-Jakob disease it is currently recommended that it is not reused. Dispose of any such electrode, sensor or lead as per hospital procedures or local guidelines.

3.9.2 Damage Or Deterioration

Unless noted on the relevant packaging sensors and electrodes manufactured by Compumedics are designed to be reused (exceptions include self-adhesive pads for snap-on electrodes and oral-nasal cannula). If damage, deterioration or loss of performance is observed then it is recommended that the sensor be replaced or returned to Compumedics or your authorised representative for repair evaluation.

3.9.3 Primary Components (Grael Main Unit And Cradle)

- Clean the surfaces with a damp cloth and mild detergent.
- Do not immerse in liquids.
- If disinfection is required wipe the surfaces with a 7% isopropyl alcohol solution. Do not soak or wet internal components.
- Do not sterilise.

3.9.4 Snap Leads For Disposable Electrodes

Cleaning:

- After each use wipe leads with a damp cloth.

Disinfecting:

- If disinfection is required use one of the two methods recommended for gold cup electrodes from section 3.9.5.

3.9.5 Gold Cup Electrodes, Position Sensor

The following cleaning and disinfecting procedures are recommended for gold cup electrodes and the position sensor.

Cleaning:

- After each use allow the electrode or sensor body to soak in a solution of warm water and mild liquid soap for ten minutes.
- If required use a toothbrush to scrub clean.
- Rinse the sensors thoroughly with warm water to remove all debris and soap.

Disinfecting: (recommended method #1)

- After cleaning soak the electrode or position sensor body in an aqueous solution of 0.5% Cidex OPA for 20 minutes.
- After immersion in the Cidex OPA flush the sensor with water to remove all Cidex OPA residue or soak in water for ten minutes. Any remaining residue may cause irritation or burns if it comes in contact with the mucosa.
- Allow the sensor to air dry.

Disinfecting: (recommended method #2)

- After cleaning soak the sensor body in a solution of diluted bleach (a 1:10 or 1:5 dilution of 5.25% NaOCL) for a minimum of ten minutes.
- A 1:5 dilution (one part bleach to four parts water) will provide a solution of >5000 ppm chlorine concentration good for 30 days when stored in a covered, opaque container.
- A 1:10 dilution (one part bleach to nine parts water) will provide a solution >2000 ppm chlorine concentration which must be used within twenty-four hours.
- After processing flush with clear water and air dry.



- The position sensor is a re-usable device. This sensor has been tested for 100 cleaning and disinfection cycles without deterioration or compromise of function.
- The position sensor does not need disinfecting unless it comes into contact with mucous, blood or other bodily fluids.

**WARNING Do Not Use:**

- **100% Glutaraldehyde solution:** This will damage sensors and leads.
- **Acetone:** This will damage sensors and leads.

3.9.6 Oximeter Probe

The following cleaning procedure is recommended for re-usable oximeter probes:

Cleaning:

- Remove adhesive residue with 7% isopropyl alcohol following each use.
- Do not immerse or soak the sensors or connectors in liquids.
- Do not use caustic or abrasive cleaning agents on the sensor.



- Oximeter probes as supplied by Compumedics are intended to be reused by multiple patients.
- Inspect the sensor before each use and, if there is visible separation between the circuit film and backing silicon base, replace the sensor.



WARNING Do not use solvents (e.g.: acetone, MEK, toluene) to clean the oximeter probe. Use of any agent other than a 7% solution of isopropyl alcohol may cause delamination of the sensor assembly.

The oximeter probe should be replaced if there is visible evidence of sensor delamination or insulation damage.

3.9.7 Abdominal And Thoracic Respiratory Bands**Cleaning:**

- If necessary gently hand wash bands with fabric cleaner.

Drying:

- Lay out on a flat surface to dry. Ensure there are no kinks in the wires and that there are no tears or other damage.

3.9.8 Nasal Cannula

The nasal cannula is designed for single use only. Replace after each use and dispose of as per hospital procedures or local guidelines.

4 Using Grael For EEG Studies

This chapter provides an overview of what is required to use **Grael** to record an EEG study once the system has been set up for general use according to Chapter 2 of this user guide. It is applicable to both **Grael** and **Grael EEG**.



CAUTION: If using the **Grael** device, rather than the **Grael EEG**, for recording an EEG study and you wish to record PSG specific channels or sensors (this includes the pressure and airflow channels, the RIP bands, the position sensor and the oximeter) you must use **Profusion EEG** v4.2 or later.

The steps required to record a study are listed below and considered in more detail in the following sections. For complete information on using **Profusion EEG** please refer to the relevant user manual or online help.

1. Turn on the **Grael** or **Grael EEG** device.
2. Open **Profusion EEG** (v4 or later).
3. Select the appropriate configuration and device.
4. Connect the electrodes to the patient and verify the signal quality.
5. Record the study.
6. Analyse, review and report the study.

4.1 Turn On Grael

Turn on the **Grael** (or **Grael EEG**) by connecting it to the cradle. You will hear a click when it has connected correctly.

When the **Grael** powers up its operating programs must be loaded into internal memory. This takes approximately 10 seconds, during this time the status indicator will glow white.

Once the programs have been loaded the status indicator will turn yellow while the **Grael** performs a number of self tests.

If any of the internal self tests fail then the status indicator will turn solid red to indicate the error. If this happens then you should turn the unit off and back on again to clear the error.



WARNING Contact Compumedics or your authorised representative should errors persist.

4.2 Configure The Device

Profusion EEG (v4 or higher) is required to record EEG studies using **Grael** or **Grael EEG**. Start **Profusion EEG** running by selecting the appropriate choice from the Windows start menu.

If this is the first time you have used **Grael** for EEG recording you should check that the device configuration, which specifies the electrodes to record, is as required. Once **Profusion EEG** has opened click on the *Device Configuration* icon to open the configuration window. Use the device type drop down arrow, under device settings, to display the list of known devices and select **Grael** to use either **Grael** or **Grael EEG**. Now select the drop down arrow for device configuration to select from the list of available **Grael** configurations. If none of the available configurations match your requirements you should follow the instructions in the **Profusion EEG** online help to create a new one.

Once the configuration is correct click on the *New Study* icon to open the study configuration window. As well as entering the necessary patient details you should click on the *Configure equipment...* link to

open the *Recording Devices* window. This window has drop down arrows allowing selection of the appropriate device and configuration. Note that the device you wish to use *must* be turned on or it will not appear in this list, also **Grael** devices will not appear for between 5 and 10 seconds *after* their start up self test is complete. After entering the patient details and selecting the device click the *Create Study* button. The main trace window will open and traces will start to scroll across the screen.

4.3 Connect Electrodes

Electrodes are connected to the **Grael** or **Grael EEG** front panel or end panel connectors. Figure 4-1, on the next page, shows the **Grael EEG** front panel while 4-2 show the **Grael EEG** end panel. Figures 3-1 and 3-2, from the previous chapter, provide similar views for the **Grael**.

All electrode channels on the **Grael** are DC coupled with the low pass filter set by the sample rate as described in section 6.8 . The twenty-four bit analogue to digital converters provide a wide dynamic range and gain switching is not required, for example all electrode channels can measure $\pm 300\text{mV}$ peak to peak with a resolution of approximately $0.02\mu\text{V}$. If desired high pass display filters, available in **Profusion EEG**, can be used to removed any DC offset caused by electrode drift.

All channels are sampled at the same rate and can be set to one of 256, 512, 1024 or 2048 samples per second. When configuring a study you should choose the lowest reasonable sample rate based on the study type being conducted. This both reduces the data space requirements for the study and, in the case of the **Grael** or **Grael EEG**, improves the overall noise performance of the channels.

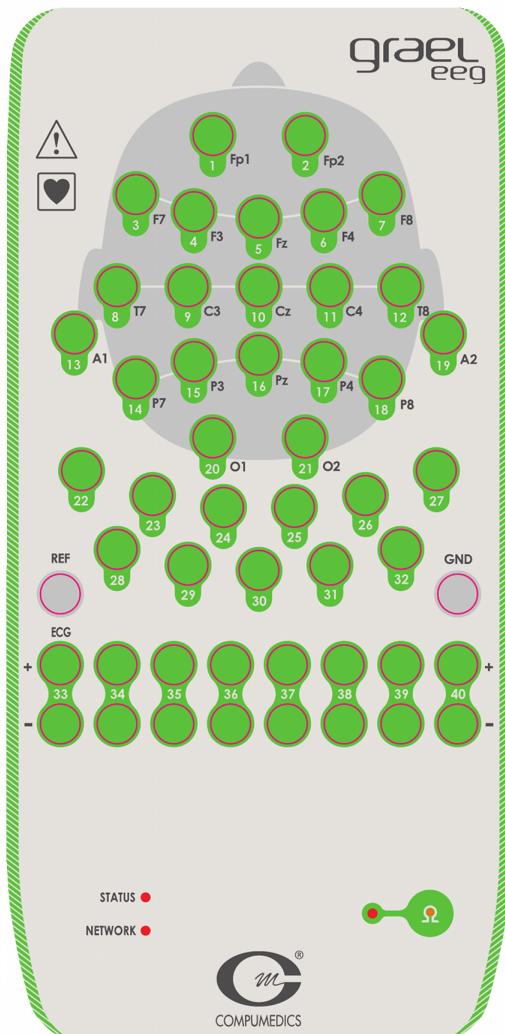


Figure 4-1: Grael EEG Front Panel

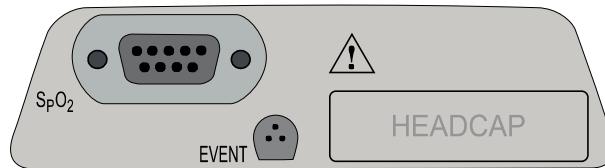


Figure 4-2: Grael EEG End Panel

The following tables provide a list of the EEG specific inputs available on the **Grael** and **Grael EEG**. Any PSG specific inputs available on the **Grael** are not listed here but may still be used in EEG studies recorded using **Profusion EEG** v4.2 or later.



WARNING To use the head cap connector insert a small flat blade screw driver in the slot on the inside edge of the cover and gently lift it off. Make sure you do not loose the cover. For patient safety the cover should always be in place when a head cap is not used.

4.3.1 Front Panel

Channel	Connector Label	Comments
Reference	REF	Reference electrode required for all recordings. Electrode impedance test is available for this channel.
Ground	GND	Ground electrode required for all recordings.
1 to 32	Channel number and default location.	Thirty-two referential (single ended) channels for electrode connections. Electrode impedance test and calibration waveforms are available for these channels.

Channel	Connector Label	Comments
33	Channel number, ECG, positive and negative indicators.	Differential channel for ECG, also used by the respiratory impedance channel. Should not be used on patients with implanted electronic devices (e.g.: a pacemaker) as it may interfere with operation of the implanted device. Electrode impedance test is available for this channel.
34 to 40	Channel number, positive and negative indicators.	Seven differential channels for electrode connections. Electrode impedance test is available for these channels.
41 to 48	Channel number, positive and negative indicators.	Eight differential channels, <i>not</i> available on Grael EEG . Normally used for PSG sensors but may be used for electrodes if impedance check is not required.

4.3.2 End Panel

Channel	Connector Label	Comments
1 to 32	HEADCAP	Removable cover over the head cap connector. This provides a parallel connection to the 32 referential channels, REF and GND for use with a Compumedics head cap (not provided as part of the Grael EEG system). The front panel connectors are normally not used if the head cap connector is used.
Event button	EVENT	Connector for a Compumedics event button, part number 7028-0006-01. If using a Grael , rather than Grael EEG , then the event button is connected to the POS'N input.

Channel	Connector Label	Comments
Pulse Waveform	S _P O ₂	Low pass filtered by the oximeter at 30 Hz.
S _P O ₂	S _P O ₂	If the oximeter status is bad this signal is forced to 127.
Pulse rate	S _P O ₂	If the oximeter status is bad this signal is forced to 511.
Oximeter status	S _P O ₂	Bit encoded signal indicating "Good", "Marginal", "Out of Track" or "Lead Off".

4.4 Start The Recording

When ready to start recording press the *Record* icon in **Profusion EEG**.



During recording the **Grael** status indicator light pulses green.

Once a recording has been started from **Profusion EEG** the **Grael** can be disconnected from the cradle at any time. Data transmission will stop but the **Profusion EEG** recording will continue (with no data). Data acquisition will re-commence when **Grael** is reconnected to the cradle. Note that the **Grael** will take approximately 10 to 15 seconds to establish the connection to **Profusion EEG**.

To disconnect **Grael** press down on the release lever at the base of the cradle. Lift the **Grael** device away from the cradle. As all electrodes are attached to the **Grael** there is no need to disconnect any of these from the patient. The carrying lanyard, if attached, can be used to carry the **Grael**.



WARNING While disconnecting (or reconnecting) the **Grael** from (to) the cradle the operator must not touch either the network cable or connector on the cradle while simultaneously touching the patient.

4.5 Review The Study

When ready stop the recording by clicking the **Profusion EEG Record** icon again (it has a toggle action).

After stopping the recording use the *Study Tools* from within **Profusion EEG** to review or report the study.

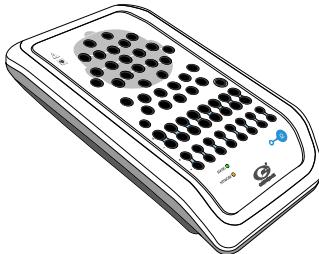
Refer to the relevant software documentation and online help files for more information on using **Profusion EEG**.

4.6 Cleaning

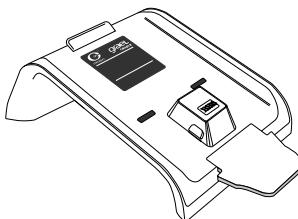
Follow the instructions given in section 3.9 for cleaning the **Grael** or any of its components or leads.

5 Grael Parts

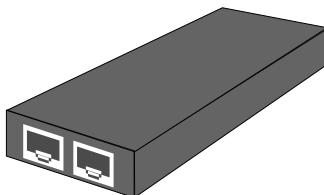
5.1 Recorder and Accessories



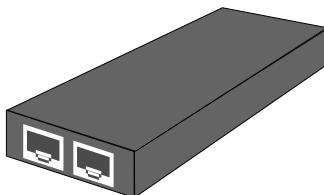
Grael main unit
P/N: 8028-0001-01



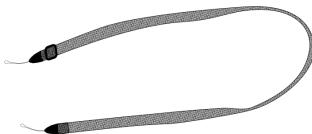
Grael EEG main unit
P/N: 8028-0002-01



Grael Cradle
P/N: 8028-0003-01

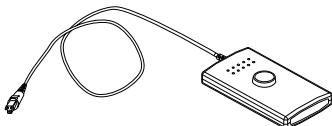


Power Over Ethernet
mid-span power injector
P/N: 0400-0041-00



Grael lanyard

P/N: 4628-0001-04

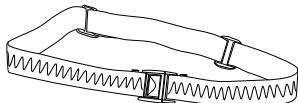


Grael event button

Only for use with **Profusion EEG**

P/N: 7028-0006-01

5.2 Electrodes and Sensors



Grael RIP band

Thoracic or Abdominal

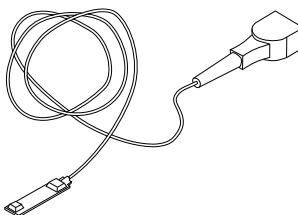
Not for use with **Grael EEG**



P/N: 7028-0005-01 (band and cable)

P/N: 7028-0003-01 (band only)

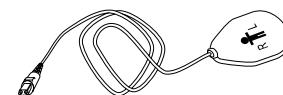
P/N: 7028-0004-01 (cable only, 205cm)



Oximeter Probe

Patients greater than 20kg, 3m cable

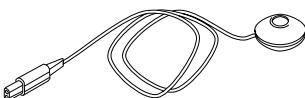
P/N: 7001-0008-00



Grael position sensor

Not for use with **Grael EEG**

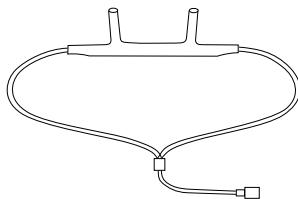
P/N: 7028-0001-01



Grael tracheal microphone

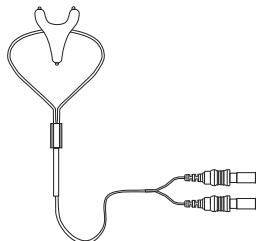
Not for use with **Grael EEG**

P/N: 7028-0002-01



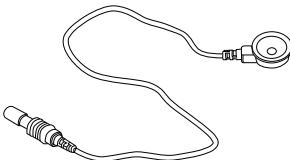
Nasal Cannula, 7ft with female luer
Not for use with **Grael EEG**

P/N: 5400-0011-00 (1 off)
P/N: 5400-0011-01 (25 pack)



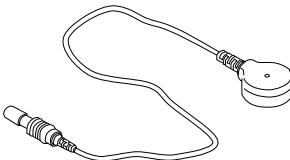
Triple Thermocouple Airflow Sensor, Adult

P/N: 00103750



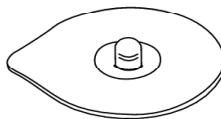
Gold cup electrodes, 180cm, 10 pack

P/N: 7000-0044-00



Snap leads, 180cm, 10 pack
For self adhesive electrodes

P/N: 00103469



Meditrace mini, adhesive electrodes

5400-0012-00 (30 pack)

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6 Grael Specifications

6.1 System Classification

Type:	Class II equipment (double insulated).
Degree of protection:	Type CF applied parts.
Degree of safety:	Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or with OXYGEN or NITROUS OXIDE.
Mode of operation:	Continuous.

6.2 System Environmental Requirements

6.2.1 Transport And Storage Conditions

Temperature:	-10°C (+14°F) to 50°C (+122°F).
Humidity:	20 to 90% RH, non-condensing.
Altitude:	Less than 3,000m (9850ft).

6.2.2 Operating Conditions

Temperature:	0°C (+32°F) to 40°C (+104°F).
Humidity:	20 to 90% RH, non-condensing.
Altitude:	Less than 3,000m (9850ft).

6.2.3 Electromagnetic Compatibility



CAUTION The *Grael* has no “essential performance” when the term is used as per its meaning in standard IEC 60601-1-2 . As such, device operation may not be error free in the electromagnetic environment specified by the following tables.

Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Grael is intended for use in the electromagnetic environment specified below. The customer or user of the Grael should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Grael uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Grael is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 6100-3-2	Class A	The Grael is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Grael is intended for use in the electromagnetic environment specified below. The customer or user of the Grael should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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 for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode. ±2 kV common mode.	±1 kV differential mode. ±2 kV common mode.	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 0,5 cycle <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 0,5 cycle <5% U_T (>95% dip in U_T) for 5 sec	Main power quality should be that of a typical commercial or hospital environment. If the user of the Grael requires continued operation during power mains interruptions, it is recommended that the Grael be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Grael is intended for use in the electromagnetic environment specified below. The customer or user of the Grael should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms	<p>Portable and mobile RF communication equipment should be used no closer to any part of the Grael, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, 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.

^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 the location in which the Grael is used exceeds the applicable RF compliance level above, the Grael should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Grael.

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

Recommended separation distances between portable and mobile RF communications equipment and the Grael			
Rated maximum output power of transmitter W	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d 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.

6.3 Physical

6.3.1 Main Unit

Width:	144 mm
Height:	50 mm
Length:	240 mm
Weight:	800 gm
Case material:	Plastic, ABS / Polycarbonate blend, UL94V0 rated.

6.3.2 When seated on cradle

Width:	144 mm
Height:	115 mm
Length:	235 mm
Weight:	1050 gm

6.4 Power Supply

Power source:	Any power over Ethernet network switch or mid-span power injector that complies with both 802.3af and IEC60950 / EN60950.	
Operating voltage:	48 volts.	
Consumption:	< 10 watts.	

6.5 Status Indicator

Type:	Multi-colour light emitting diode.	
Function:	Solid white:	Program loading.
	Solid yellow:	Initialisation and self test.
	Pulsing blue:	Idle.
	Pulsing green:	Sending data.
	Pulsing purple:	Test mode.
	Red:	Error.

6.6 Infra Red Interface

Type:	Compatible at the physical layer with IrDA v1.3 low power.
Range:	Up to 20 cm.
Supported protocol:	Compumedics specific (not compatible with IrLAP or IrLMP, operating system drivers must not be loaded at the PC end of a link).
Baud rate:	1200 through to 115200 baud supported by the device hardware, Compumedics

system software supports only 115200 baud.

Function: Factory test only.

6.7 Network Interface

Type:	802.3/802.3u Ethernet with auto MDIX. Requires 802.3af compliant switch or mid-span power injector.
Data Rate:	10 or 100 Mbit/second
Connector:	RJ45 (8 pin)
Cable:	Unshielded twisted pair, up to 100m.
Indicator:	Illuminated for link OK, blinks if data (send or receive) active.

6.8 Patient Inputs

6.8.1 Referential channels

Number:	32 (channels 1 through to 32).
Type:	Single ended referenced to REF input for patient electrode connection.
Connector:	Single pin touch-proof, conforms to DIN 42-802 type BU. Transparent to allow for illumination.
Sample rate:	User selectable, one of 256, 512, 1024 or 2048 samples/second (all channels must be at the same rate).
Input impedance.	> 100 MΩ (at 3 Hz).
Input bias current:	< 5 nA.
CMRR:	> 100 db (10 kΩ electrode imbalance between REF and channel input, common mode signal between earth and channel input).

Allowed electrode	
DC offset:	±300mV (between REF and input).
Full scale range:	600 mVpp (< 0.7% distortion with 3 Hz sine signal).
Gain accuracy:	±2% (at full scale).
DC offset:	±0.2 mV.
Noise:	< 20 µVpp (over 10s full bandwidth) < 2 µVpp typical (4 µVpp max) at 256 samples/second.
Low pass filter (3db):	71 Hz at 256 s/s 143 Hz at 512 s/s 284 Hz at 1024 s/s 580 Hz at 2048 s/s
High pass filter:	DC coupled.
Crosstalk:	< -60dB to adjacent channels FSR.
Electrode impedance measuring range:	1 kΩ to 1 MΩ, (± 1 kΩ or 10% whichever is greater).
Electrode impedance indicator:	Connector glows orange if impedance exceeds user set threshold.

6.8.2 Differential Channels

Note: Channels 41 through to 48 are not present on **Grael EEG**.

Number:	16 (Grael , channels 33 through to 48) 8 (Grael EEG , channels 33 through to 40).
Type:	Differential with positive and negative inputs. All channels may be connected to electrodes or sensors but channels 33 to 40 are optimised for electrodes and channels 41 to 48 are optimised for sensors. Channels 33 to 40 include impedance indicator lights.

	REF and GND electrodes are required for optimum performance if any channel is used for electrodes.
Connectors:	Two by single pin touch-proof, conforms to DIN 42-802 type BU. Transparent on channels 33 to 40 to allow for illumination.
Sample rate:	User selectable, one of 256, 512, 1024 or 2048 samples/second (all channels must be at the same rate).
Input impedance.	$24 \text{ M}\Omega \pm 10\%$ (each electrode at 3 Hz). Channel 33 only: $22 \text{ M}\Omega \pm 10\%$
Input bias current:	< 5 nA.
CMRR:	> 100dB (5 KΩ imbalance, common mode signal between earth and both inputs).
Allowed electrode DC offset:	$\pm 300\text{mV}$ (between inputs).
Full scale range:	600 mVpp (< 0.7% distortion with 3 Hz sine signal).
Gain accuracy:	$\pm 2\%$ (at full scale).
DC offset:	$\pm 0.2 \text{ mV}$.
Noise:	< 20 μVpp (over 10s full bandwidth) < 3 μVpp typical (6 μVpp max) at 256 samples/second.
Low pass filter: (3db)	71 Hz at 256 s/s 143 Hz at 512 s/s 284 Hz at 1024 s/s 580 Hz at 2048 s/s.
High pass filter:	DC coupled.
Crosstalk:	< -60dB to adjacent channels FSR.
Electrode impedance measuring range:	1 kΩ to 1 MΩ (channel 33 to 40 only).
Electrode impedance measuring accuracy:	$\pm 1 \text{ k}\Omega$ or 10% whichever is greater.

Electrode impedance indicator: Connector glows orange if impedance exceeds user set threshold (channels 33 to 40 only).

6.8.3 Pressure Channel

Note: The pressure channel is not present on **Grael EEG**.

Number: 1.

Type: Single ended pressure transducer.

Connector: Male luer (plastic) with screw lock.

Sample rate: User selectable, one of 256, 512, 1024 or 2048 samples/second (all channels must be at the same rate).

Full scale range: $\pm 100 \text{ cm H}_2\text{O}$.

Gain accuracy: $\pm 1 \text{ cm H}_2\text{O}$ at 25°C
 $\pm 5 \text{ cm H}_2\text{O}$ 0°C to 40°C .

Offset: $\pm 1 \text{ cm H}_2\text{O}$ at 25°C
 $\pm 2 \text{ cm H}_2\text{O}$ 0°C to 40°C .

Noise: $< 0.06 \text{ cm H}_2\text{O pp}$ (over 10 seconds, full bandwidth)
 $< 0.02 \text{ cm H}_2\text{O pp}$ (over 10 seconds, 256 samples/second).

Low pass filter (3db): 71 Hz at 256 s/s
143 Hz at 512 s/s
284 Hz at 1024 s/s
580 Hz at 2048 s/s.

High pass filter: DC coupled.

Crosstalk: $< -60\text{dB}$ to adjacent channels FSR.

6.8.4 Airflow Channel

Note: The airflow channel is not present on **Grael EEG**.

Number: 1.

Type: Differential pressure transducer.

Connectors:	Two by male luer (plastic) with screw lock.
Sample rate:	User selectable, one of 256, 512, 1024 or 2048 samples/second (all channels must be at the same rate).
Full scale range:	$\pm 10 \text{ cm H}_2\text{O}$.
Gain accuracy:	$\pm 0.6 \text{ cm H}_2\text{O}$.
Offset:	$\pm 0.3 \text{ cm H}_2\text{O}$ at 25°C $\pm 0.5 \text{ cm H}_2\text{O}$ 0°C to 40°C .
Noise:	< 0.02 cm H ₂ O pp (over 10 seconds, full bandwidth) < 0.01 cm H ₂ O pp (over 10 seconds, 256 samples/second).
Low pass filter (3db):	71 Hz at 256 s/s 143 Hz at 512 s/s 284 Hz at 1024 s/s 580 Hz at 2048 s/s.
High pass filter:	DC coupled.
Crosstalk:	< -60dB to adjacent channels FSR.

6.8.5 Inductive Plethysmography Channels

Note: The inductive plethysmography channels are *not* present on **Grael EEG**.

Number:	2 (1 by thoracic, 1 by abdominal).
Type:	Single ended, dedicated sensor.
Sensor:	Compumedics RIP band part number 7028-0003-01.
Connector:	1mm 2 pin touch proof right angle jack, thoracic yellow, abdominal blue.
Sample rate:	User selectable, one of 256, 512, 1024 or 2048 samples/second (all channels must be at the same rate).
Excitation frequency:	Thor: 1.6 MHz $\pm 20\%$ Abdo: 820 kHz $\pm 20\%$.

Low pass filter (3db): 6 Hz (all sample rates).

High pass filter: DC coupled.

6.8.6 Respiratory Impedance Plethysmography Channel

Number: 1.

Type: Differential, dedicated function.

Connector: Shared with channel 33 (ECG).

Sample rate: User selectable, one of 256, 512, 1024 or 2048 samples/second (all channels must be at the same rate).

Excitation frequency: 85.019 kHz \pm 0.1%.

Excitation current: < 300 μ Arms.

Baseline impedance range: 100 Ω to 2000 Ω .

Respiratory impedance change: 5 Ω maximum.

Low pass filter (3db): 6 Hz (all sample rates).

High pass filter: DC coupled.

6.8.7 Oximeter

Type: Compumedics 2024-0001-xx

Probe: Compumedics flex probe 7001-0008-01.

Probe connector: Right angle female DB9.

SPO₂ range: 25 to 100%.

Heart rate range: 18 to 300 pulses per minute.

SPO₂ accuracy: 70 – 100% \pm 2.5 digits within 1 standard deviation.

Heart rate accuracy: \pm 1% \pm 1 digit.

Sample Rate

SPO₂, HR, status: 1 s/s, up sampled to match other channels.

Plethysmograph: 256 s/s, up sampled to match other channels.

6.8.8 Room light channel

Note: The room light channel is not present on **Grael EEG**.

Type: Inbuilt sensor

Sample rate: User selectable, one of 256, 512, 1024 or 2048 samples/second (all channels must be at the same rate).

High pass filter: DC coupled.

6.8.9 Position channel

Note: The position channel is not present on **Grael EEG**.

Sensor: Compumedics p/n 7028-0001-01, measures prone, supine, left, right and upright.

Type: Three axis accelerometer, powered from **Grael** (at 3.3 V).

Connector: 1mm 3 pin touch proof right angle jack.

Sample rate: User selectable, one of 256, 512, 1024 or 2048 samples/second (all channels must be at the same rate).

6.8.10 Event Button channel

Note: When using **Grael** connect the event button to the channel labelled POS'N. It is not possible to use an event button and position sensor at the same time.

Sensor: Compumedics p/n 7028-0006-01.

Type: Momentary contact push button.

Connector: 1mm 3 pin touch proof right angle jack.

Sample rate: User selectable, one of 256, 512, 1024 or 2048 samples/second (all channels must be at the same rate).

6.8.11 Microphone channel

Note: The microphone channel is *not* present on **Grael EEG**.

Sensor: Compumedics p/n 7028-0002-01.

Type: Electret microphone, biased from **Grael** (at 2.5 V).

Connector: 1mm 2 pin touch proof right angle jack.

Sample rate: User selectable, one of 256, 512, 1024 or 2048 samples/second (all channels must be at the same rate).

Low pass filter (3db):
71 Hz at 256 s/s
143 Hz at 512 s/s
284 Hz at 1024 s/s
573 Hz at 2048 s/s.

High pass filter: 5.3 Hz (all sample rates).