



Somfit USER GUIDE

AH808-0

Part Number: 8040-0001-00

© Compumedics Ltd

Document No.	Release date	Language
AH808 Issue 0	19 August 2019	English

For other languages, please contact Compumedics.

This work is copyright. Apart from any use as permitted under the Copyright Act 1968 no part may be reproduced by any process without written permission from Compumedics Limited.

Request and inquiries concerning reproduction and rights should be addressed to:

The Documentation Manager
Compumedics Limited
30 – 40 Flockhart Street
Abbotsford, Victoria, 3067
AUSTRALIA



Table of Contents

1. Before You Begin.....	1
1.1 Limited Warranty	2
1.2 Limited Warranty - Electrode	2
1.3 Intended Use	3
1.4 Intended Population	3
1.5 Contraindications.....	3
1.6 Labelling Definitions	4
1.7 Warnings and Cautions	7
1.8 Tips	9
1.9 Prescription Device	9
1.10 Product Support	10
2. Product Overview	13
2.1 Somfit device.....	13
2.2 Somfit charger	14
2.3 Somfit electrode	15
2.4 Somfit application	15
3. Using the Somfit	17
3.1 Before use	18
3.2 Prep Forehead	19
3.3 Prep Somfit	20
3.4 Apply Somfit	21
3.5 Open App	21
3.6 Go to sleep.....	23
3.7 Wake	24
3.8 Review	26

4. Service and Maintenance	27
4.1 Cleaning instruction	27
4.2 Periodic Maintenance and Inspection	29
5. Associated Equipment	31
5.1 Associated Device	31
5.2 Related Equipment.....	32
6. Specifications	33
6.1 Regulatory compliance	33
6.2 Transport and Storage conditions	33
6.3 Operating Conditions	34
6.4 Functional Oxygen Saturation	34
6.5 Heart Rate	34
6.6 Sleeping position	34
6.7 Sound.....	34
6.8 Light	35
6.9 EEG	35
6.11 Environmental Protection	36
6.12 Electromagnetic Emissions Statement	37

1. Before You Begin

The **Somfit** User Guide contains the necessary information for the proper use of the **Somfit** device and its application.



WARNING

Read this manual. Please familiarise yourself with the contents of the manual before using the device. Failures to comply with these instructions may result in damage to device, device contents.

1.1 Limited Warranty

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.

1.2 Limited Warranty - Electrode

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

1.3 Intended Use

The **Somfit** System is intended to help maintain and encourage a general state of health and/or healthy sleep. **Somfit** is for users who are interested in understanding their sleep architecture derived from a measure of brain waves (EEG), functional oxygen saturation (SpO2), heart rate, relative sound in the environment (including snoring), light intensity and sleeping position overnight. It is indicated for adult users or children under the supervision of an adult and can be used for spot-checking, collection, and recording of data in home environments.

1.4 Intended Population

The **Somfit** is indicated for adult users or children under the supervision of an adult and can be used for spot checking, collection and recording of data in the home environment.

1.5 Contraindications

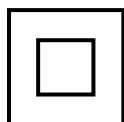
Discontinue use if the patient displays distress, discomfort, or adverse reaction.

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

1.6 Labelling Definitions



Where you see this symbol, it means “**WARNING**” or “**CAUTION**”. Failure to follow operating instructions could put the patient or operator at risk.



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”.



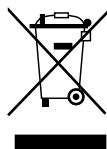
Where you see this symbol, it means “Refer to operating instructions is advisory”.



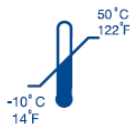
Where you see this symbol on any device label it means “Refer to instruction manual/booklet is mandatory”.



Where you see this symbol, it means that the indicated action is mandatory



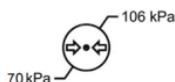
Separate collection of waste electrical and electronics equipment (WEEE) necessary (European Union directive 2002/96/EC on WEEE)



This symbol indicates the temperature limits within which the package can be kept and handled



This symbol indicates the Humidity limits within which the package can be kept and handled



This symbol indicates the Pressure limits within which the package can be kept and handled



This symbol indicates the manufacturer of this medical device.



This symbol indicates the manufacture date of the equipment



This symbol indicates the serial number of the unit



This symbol indicates the reference or part/assembly number of the unit



This symbol indicates the authorize representative in the European Community.

IP22

This symbol indicates the degree of protection provided by an enclosure. In this case the **X** means that the protection against solid objects is not specified and the **1** means the enclosure protects against vertically falling water drops.



This symbol indicates that the product has “European Conformity” and meets the required regulations


1.7 Warnings and Cautions




This symbol, when used with the word **WARNING**, highlights a situation that is potentially harmful to the patient or operator.

When used with the word **CAUTION** it highlights a condition which may lead to equipment damage, malfunction, or inaccurate operation.

	WARNING
	The Somfit is not intended to diagnose any medical condition.
	Do not use the Somfit during Magnetic Resonance Imaging (MRI) or in an MRI environment. Avoid looking directly at the LED Sensor Array.
	Use only the Power Adapter and Charging Cable provided with the Somfit to recharge the battery.
	Use of the Somfit adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Somfit and the other equipment should be observed to verify that they are operating normally.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Somfit System. Otherwise, degradation of the performance of the Somfit System could result

	WARNING Do not immerse in fluid or run fluid over the Somfit .
--	---

	CAUTION Do not use the Somfit if it appears or is suspected to be damaged. Do not repair, open or modify the Somfit . Do not use the Somfit if the internal parts have been exposed to liquids. Do not use the Somfit while charging or when inadequately charged. Do not use the Somfit if forehead skin shows irritation or damage. Keep Somfit out of reach of pets and children.
--	---

1.8 Tips

When using the **Somfit** with a smart device (smartphone, tablet computer), keep both devices within the recommended range of each other. Moving outside of this range may cause a loss of connection with the smart device.

The Power Adapter is double insulated and does not require a grounded outlet.

The **Somfit** has a Lithium-ion battery which may be restricted for certain types of travel. The **Somfit** is not provided sterile.

Somfit performance may be affected if used outside the operating ranges specified.

Avoid the following to optimize measurements:

- Improper **Somfit** placement or alignment
- Externally applied skin products such as make-up or skin lotion applied to the sensor location
- Excessive motion

Use a new Sensor for each new test. Do not re-use Sensors. Re-use of Sensors may result in degraded sensor performance and user experience. The following health conditions may reduce the accuracy of the measurements:

- Extremely low arterial perfusion

1.9 Prescription Device

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

1.10 Product Support

If you have a question regarding the correct use of the **Somfit** 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.

Compumedics will provide service and support for **Somfit** for at least seven years after its purchase date.

When you call please provide the following information:

- The version of software, hardware 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 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.

Compumedics Service Addresses



Compumedics Ltd
30 – 40 Flockhart Street
Abbotsford, VIC, 3067
Australia

Phone:
+61 3 8420 7300
Fax:
+61 3 8420 7399

Compumedics USA
5015 W W.T.
Harris Blvd. Suite E
Charlotte, NC 28269
USA

Phone:
+1 704 749 3200
Fax:
+1 704 749 3299



Compumedics Germany GmbH
Werdauer Str.1-3,
01069 Dresden,
Germany

Phone:
+49 7731 79 769 0
Fax:
+49 7731 79 769 99

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>

2. Product Overview

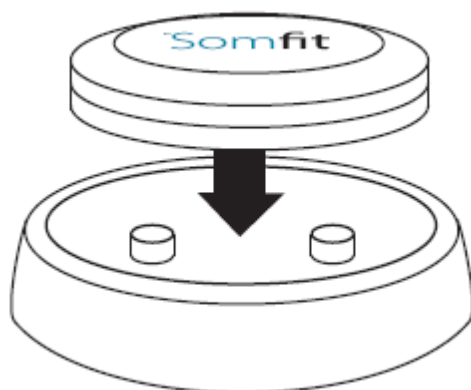
The **Somfit** system consists of four components that the user can interact with.

2.1 Somfit device

This is the actual **Somfit** device that does the recording and transmission of the data which represents your sleep signals.

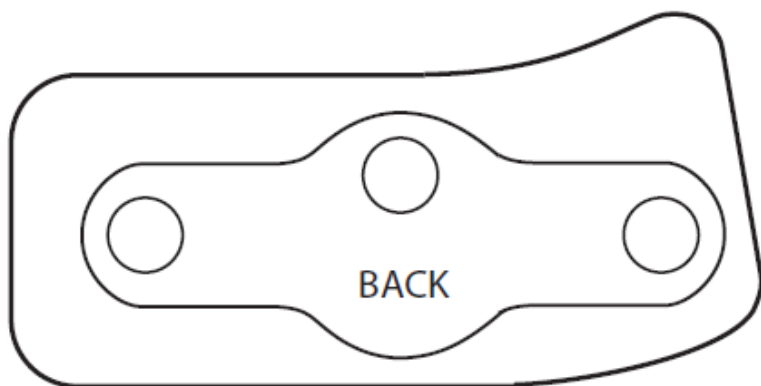
2.2 Somfit charger

The **Somfit** charger. The **Somfit** charger is used to charge the **Somfit** device. The charger has a standard USB-C connector and can be charged with any USB compliant charger.



2.3 Somfit electrode

This is a single use medical grade electrode for measuring your brain waves and also holding the **Somfit** in place.



2.4 Somfit application

This is loaded onto an android or iPhone and provides the user interface to start and manage the recording.

This page is intentionally blank

3. Using the Somfit

The Somfit is designed to be used every night of the week. You can also use it less often but it's a good idea to use it often enough to build up some history of your sleeping patterns as this will help in determining the best course of action.

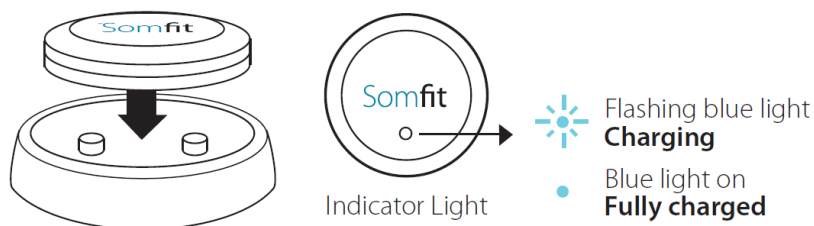
In order to record a night sleep, you will need:

- Somfit device (charged)
- Electrode (new as these are single use)
- Phone with **Somfit** application installed

3.1 Before use

Before using the Somfit you need to make sure the device is charged.

BEFORE USE



Charge the Somfit – prior to using insert Somfit into the USB charging cradle provided.

Once you have confirmed the device is charged you are ready to apply the device using the electrode.

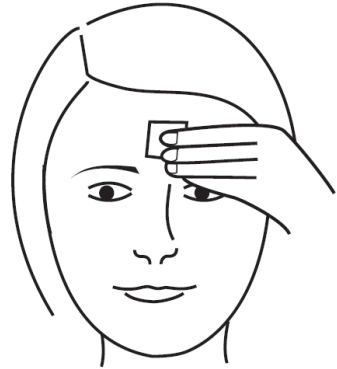
3.2 Prep Forehead

First you need to prepare the forehead.

PREP FOREHEAD

Wash and dry your face.
Clean the forehead area with
the Prep Pad to give the
best signal quality.

Dry forehead with a clean towel
before applying sensor pad.



3.3 Prep Somfit

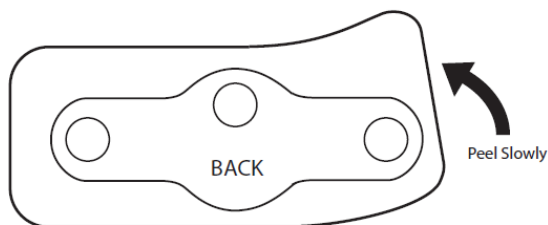
Take the Somfit off the charger and attach it to the electrode that you have for the nights study.

PREP SOMFIT



Apply the **Somfit** device to the sensor pad ensuring all 3 snap-ins are in place.

Slowly remove the clear backing from the sensor pad to reveal the adhesive area. Avoid touching the adhesive area.

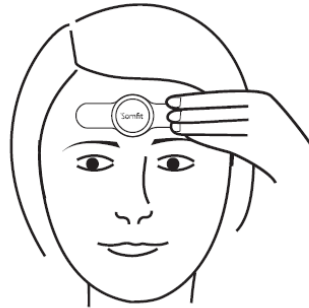


3.4 Apply Somfit

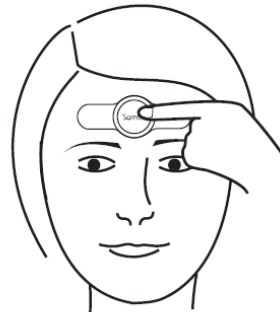
Now apply the Somfit to your forehead.

APPLY SOMFIT

While looking a mirror, apply the sensor pad to the **centre** of the forehead approximately one finger's width above the eyebrows.



Press the sensor in place with your finger including pressing the device itself so the sensor pad is securely attached to your forehead.



3.5 Open App

Open the application on the phone. Make sure you are signed into your account and then you can start recording.

OPEN APP

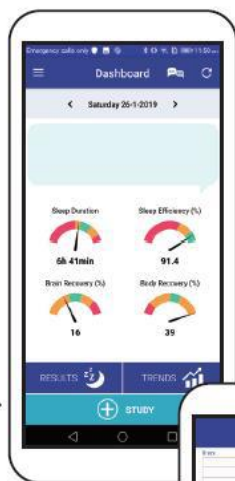
Ensure Bluetooth is enabled on the phone.



Run the **Somfit App**.

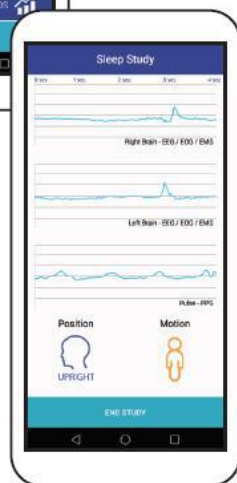


From the start-up Dashboard screen, press the **(+) STUDY** button to start a new study.



START RECORDING

The recording screen will appear with live readings.



3.6 Go to sleep

Now you can just go to sleep as normal. Note that even if you are aware of the Somfit you will soon forget and sleep normally.

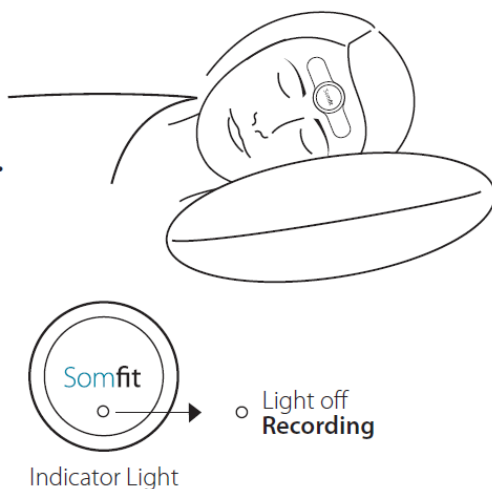
GO TO SLEEP

You are all set to go.

Go to sleep in your normal sleep position.

Sleep Well!

It is normal for the indicator light to be turned off during recording.



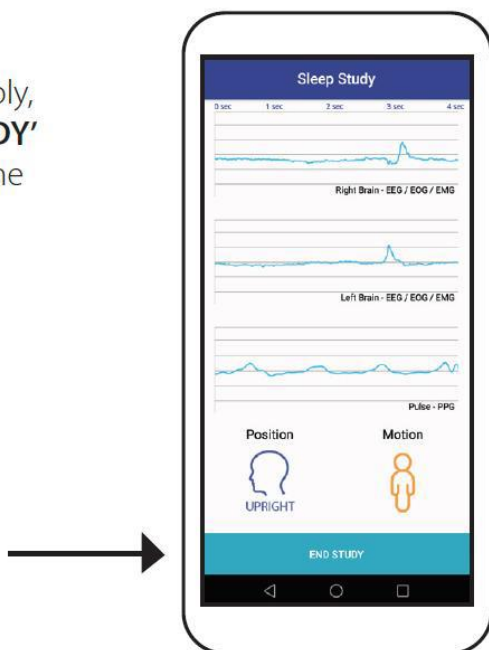
3.7 Wake

When you want up you just use the phone and press end study.

WAKE

When you wake simply, press the **“END STUDY”** button to return to the Dashboard screen.

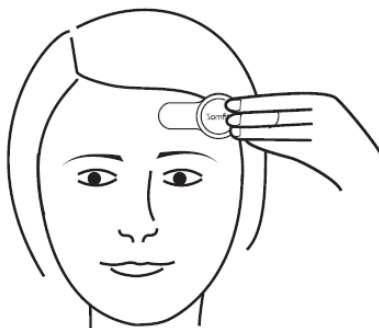
Data upload will automatically occur.



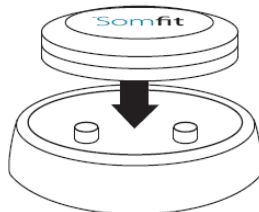
Once the study is stopped you can carefully remove the electrode and Somfit from the electrode then return it to the cradle.

Carefully remove the Somfit from your forehead.

Remove the sensor pad from the somfit and discard the sensor pad.



Return Somfit to the charging cradle.

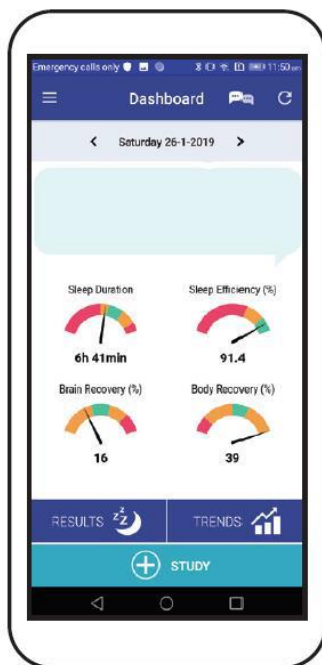


3.8 Review

Once the study is stopped the data will automatically be sent to the Somfit server for analysis. Once analysis is complete you can review the results of your sleep.

REVIEW

When analysis is complete review your night's sleep from the **APP Dashboard**.



4. Service and Maintenance

4.1 Cleaning instruction



WARNING

This is an electrical device. Confirm that the **Somfit** is not charging. Symbols or specific instruction etched on the instruments should be strictly followed.

Preparation for cleaning:

Remove any cables that are attached to the instruments.

Cleaning internal components is not necessary. Do not disassemble the instruments.

Cleaning (Manual):

Clean the surfaces with a damp cloth and mild detergent.

Note: Do not immerse in liquids. Only use a dry rag or cloth.

The following values are recommended for water quality:

- Total hardness: <3° dH
- Total salt: < 500 mg/l
- Chloride content: <100 mg/l
- pH value: 5-8

Disinfection:

Wipe the surfaces with a 7% isopropyl alcohol solution.

Note: Do not soak or wet internal components.

Drying:

Remove excess moisture from the instrument with a clean, absorbent, and non-shedding wipe.

Maintenance:

Inspect the device to ensure all visible contamination has been removed.

Visually inspect for completeness, damage, and/or excessive wear.

Sterilisation:

Do not sterilise.

Packaging:

The device does not require packaging.

Storage:

There is no specific storage requirement for this device. Compumedics recommend to store the device in area that provides protection from dust and extreme temperature/humidity.

4.2 Periodic Maintenance and Inspection

No regular maintenance or calibration is required for this device, although a regular annual inspection is recommended. Grounding continuity, leakage current and isolation should be checked periodically by a qualified technician. Where appropriate such tests should conform to any standard applicable to the country in installation.

Inspection should also consist of checking that any plugs are engaged and not damaged. Any cords should not be damaged or knotted. Damage to the enclosure or any parts of the device should be evaluated by the manufacturer.

Frequency of inspection and cleaning is dependent on the location type and use and should be determined by a qualified engineer, the equipment maintenance department or personnel. Inspect the device at a minimum of once per year.

Technical information such as diagrams and parts list are available on request from service@compumedics.com

This page is intentionally blank

5. Associated Equipment

5.1 Associated Device and Consumeables

Somfit main unit
P/N: 8040-0001-00

Somfit Charger
P/N: 8040-0101-00

USB-C Cable
P/N: 3140-0001-00

Somfit Carry Bag
P/N: 4640-0001-00

Somfit Sensor pad
P/N: 7040-0001-00

Preppad
P/N: 95000016

5.2 Related Equipment

Equipment such as computers, surveillance cameras and network switches are released with very short update cycles. As such specific model numbers may be available for less than twelve month and, as such, cannot be listed here. If you need additional equipment of this type, that was not purchased as part of your Grael system, then please contact your Compumedics representative for advice on compatible devices.

6. Specifications

6.1 Regulatory compliance

Type:	Class II equipment
Applied parts:	There are no patient applied parts
Degree of protection:	IP22
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 Transport and Storage conditions

Temperature range:	-10°C (+14°F) to 50°C (+122°F)
Humidity:	20 to 90% RH (non-condensing)
Atmospheric pressure:	70 kPa to 106 kPa
Altitude:	Less than 3,000 m (9,843 ft)

6.3 Operating Conditions

Temperature range:	0°C (+32°F) to 40°C (+104°F)
Humidity:	20 to 90% RH (non-condensing)
Atmospheric pressure:	70 kPa to 106 kPa
Altitude:	Less than 3,000 m

6.4 Functional Oxygen Saturation

Resolution:	1%
Measurement Range:	70% to 100%
Accuracy:	<= 3.5%

6.5 Heart Rate

Resolution:	1 bpm
Range:	25 bpm to 250 bpm
Accuracy:	3 bpm or 3%, whichever is greater

6.6 Sleeping position

Range	Front, back, left, right, upright
-------	-----------------------------------

6.7 Sound

Range	Envelope detected sound non calibrated
-------	--

6.8 Light

Range	Indication of relative light
-------	------------------------------

6.9 EEG

Number:	2 differentials
Type:	2 Channels with three electrodes. Shared middle electrodes
Connection:	Press stud to custom Somfit electrode
Sample rate:	159 sample per second
Input Impedance:	> 24 MΩ at DC, > 18 MΩ at 10Hz
Input bias current:	< 500 pA
CMRR:	>100dB (5KΩ imbalance)
Differential input voltage range:	± 400mV
Resolution:	24 bits
Noise:	7uV p-p

6.10 Environmental Protection




WEEE 2002/96/EC is a European Directive that requires the proper disposal of electrical and electronic equipment. These devices should be disposed of separately, not as unsorted municipal waste. To dispose of your device, you should use appropriate collection, reuse and recycling systems available in your region. The use of these collection, reuse and recycling systems is designed to reduce pressure on natural resources and prevent hazardous substances from damaging the environment. If you need information on these disposal systems, please contact your local waste administration. The crossed-bin symbol invites you to use these disposal systems. If you require information on collection and disposal of your Compumedics device please contact your Compumedics office or local distributor.

6.11 Electromagnetic Emissions Statement


This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

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

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the **Somfit**, including cables specified by manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

	CAUTION
	The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.


Guidance and manufacture's declaration – electromagnetic emission		
The device <i>is</i> intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it used in a residential environment (for which CISPR11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of COMPUMEDICS 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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for a.c. Power Ports ±2 kV for d.c. Power Ports ±1 kV for input/output lines	±2kV for a.c. Power Ports ±2 kV for d.c. Power Ports	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.

<p>Voltage dips, short interruptions and voltage variations on power supply input lines</p> <p>IEC 61000-4-11</p>	<p>>95% dip in U_T for 1 cycle 40% U_T</p> <p>(30% dip in U_T) for 0.5 sec</p> <p>>95% dip in U_T for 5 sec</p>	<p>>95% dip in U_T for 1 cycle 40% U_T</p> <p>(30% dip in U_T) for 0.5 sec</p> <p>>95% dip in U_T for 5 sec</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the COMPUMEDICS requires continued operation during power mains interruptions, it is recommended that the COMPUMEDICS be powered from an uninterruptible power supply or a battery.</p>
<p>Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8</p>	<p>30 A/m</p>	<p>30 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>NOTE U_T is the a.c. mains voltage prior to application of the test level.</p>			

Guidance and manufacture's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 V _{rms} 150 kHz to 80 MHz 6 V _{rms} in ISM band	3 V _{rms} 6 V _{rms} in ISM band	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = 1,2\sqrt{P}$</p> <p>$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2,3\sqrt{P}$ 800 MHz to 2,7 GHz</p> <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 strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <p></p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	

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.

NOTE 3 The product also complies with enclosure port immunity to RF wireless communication equipment as specified in table 9 of EN 60601-1-2:2015.

^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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

^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 Somfit.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1,16\sqrt{P}$	80 MHz to 800 MHz $d = 1,16\sqrt{P}$	800 MHz to 2,7 GHz $d = 2,33\sqrt{P}$
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.			

This page is intentionally blank



For more information please contact:

**Compumedics Limited,
Australia:**

Headquarters
30-40 Flockhart Street
Abbotsford VIC 3067,
Australia

Ph: +61 3 8420 7300
Fax: +61 3 8420 7399
Free Call: 1800 651 751

Compumedics USA, Inc.:

5015 West WT Harris Blvd,
Suite E
Charlotte, NC 28269

Ph: +1 704 749 3200
Fax: +1 704 749 329
Toll Free: +1 877 717 3975

**Compumedics Europe
GmbH:**

Werdauer Strasse 1-3,
01069 Dresden

Ph: +49 351 5019-7682
Fax: +49 351 5019-7684