Somfit
USER GUIDE

Document Title: **Somfit User Guide**

Document Number: **AH808**

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

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

CE 2797

AH808 Version 0
Part Number: 8040-0001-00

Document No.	Release date	Language
AH808 Version 0	04 November 2020	English
AH808 Issue 1	*Draft*	English
AH808 Issue 0	*Draft*	English

For other languages, please contact the manufacturer Compumedics Ltd.

Table of Contents

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

Note: This intended use specifically excludes use of the Somfit as life support equipment, for example vital signs monitoring in intensive care unit.

1.4 Intended Population

The ***Somfit*** is indicated for adult users and can be used for spot checking, collection and recording of data in the home environment. There is no prerequisite training other than reading this document and basic operation of smartphones.

1.5 Contraindications

Discontinue use if the patient displays distress, discomfort, or adverse reaction. The Somfit should only be applied to intact skin and should not be used if the forehead area has scabs, lesions or other skin damage.

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

The ***Somfit*** and its reported data is intended to assist physicians and is not intended to provide a diagnosis on its own.

1.6 Labelling Definitions

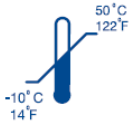
Where you see this symbol, it means **"WARNING"** or **"CAUTION"**. Failure to follow operating instructions could put the patient or operator at risk.

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

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

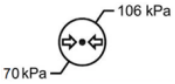
Where you see this symbol on any device label it means "Type BF".

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 serial number of the unit

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

This symbol indicates the lot or batch within which the device was manufactured

This symbol indicates the item should not be used after the date accompanying the symbol

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 first '2' means that the protection against solid objects of dimension more than 12.5mm and the second '2' means the enclosure protects against vertically falling water drops.

This symbol indicates the pulse oximeter monitor is not provided with a low SPO2 alarm condition.

This symbol indicates the item is for single use only and must not be used more than once

Caution: Federal Law restricts this device to sale by or on the order of a physician

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 without input from the physician. Do not use the ***Somfit*** during Magnetic Resonance Imaging (MRI) in an MRI environment or with high frequency electrosurgery. Failure to comply may result into skin burns. 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**. Do not use Somfit if the tamper-proof label is off. Do not use Somfit if the plastic enclosure is broken. Do not apply Somfit/Electrode onto wet skin. Do not use Somfit electrode if the packaging is damaged. Do not re-use Somfit electrode. Do not replace or remove the battery from ***Somfit***. If the device malfunction, discontinue using it until it is determined that the ***Somfit*** can be safely operated. Contact Compumedics Product Support or your authorised representative for assistance. When used according to its intended use there remains residual risk of misdiagnosis, electric shock, skin irritation and system malfunction.' Use of the Somfit may cause undesirable side-effects such as skin irritation and may not be comfortable for some users. The equipment is not serviceable by the user and should be returned to Compumedics if any repair is required or there are changes to the performance of the device.

	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*** when inadequately charged. Do not use the ***Somfit*** if forehead skin shows irritation, redness, rashes, lesions, or damage. It is recommended for the first-time users and people with sensitive skin to test the electrode on a small area of skin before conducting an overnight study. Do not use Somfit electrode if the packaging is damaged. Do not re-use Somfit electrode. Keep ***Somfit*** out of reach of pets and children. Use only Compumedics supplied accessories with the ***Somfit***. Be sure to read, understand and follow the instructions in this User Guide and others that come with the system and its components.

1.8 Tips

Somfit electrode is snapped into the device. As there is no lead wire involved, the risk of accidental contact between the conductive parts is not applicable.

There is no time required for the device to warm from the minimum storage temperature between uses until it is ready for intended use.

There is no time required for the device to cool from the maximum storage temperature between uses until it is ready for intended use.

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
- loosen electrode
- degraded or expired electrode
- Externally applied skin products such as make-up or skin lotion applied to the sensor location
- Unprepared or greasy skin
- Sweaty forehead
- Excessive motion

- Excessive sunlight

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

- Extremely low arterial perfusion

1.9 Cybersecurity Tips

Prior to using Somfit it is important to be aware of cybersecurity risks and best practices.

- Never reveal your password to others
- Using special characters, numbers, and a combination of upper and lower case letters increases password complexity
- Longer passwords are generally more secure
- Do not reuse passwords
- Do not use passwords that can be easily guessed
- Do not input your password while others may be physically watching
- Do not view your study results or other personal information while others may be physically watching
- Be aware that in a dense public area the Somfit may be visible to Bluetooth smartphones and others may attempt to connect to the Somfit, temporarily removing your ability to do so. Any such event can be easily resolved by following suggestions in section 7 Troubleshooting
- Set a screen lock mechanism on any smartphone running the Somfit app for additional security
- Contact Compumedics if the device label shows evidence of tampering

1.10 Installing the Application

The Somfit mobile application can be installed through the Google Play store. This can be accessed on an Android device by navigating to the apps section, and opening Google Play Store app. Searching Somfit will locate the Somfit app which can be downloaded. Once opened for the first time it will prompt the user for Bluetooth and Storage permissions, which are required to use the app.

1.11 Prescription Device

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

1.12 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.

The service life for the device will be 7 years. Compumedics will provide service and support for ***Somfit*** for at least seven

years after its purchase date. As a best practice, Compumedics suggests the electrode to be used before the indicated expiry 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.

Document Title: **Somfit User Guide**

Document Number: **AH808**

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 Europe 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

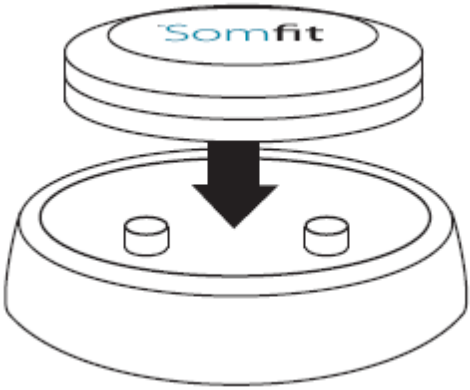
The ***Somfit*** system consists of four components that the user can interact with.

2.1 Somfit device

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

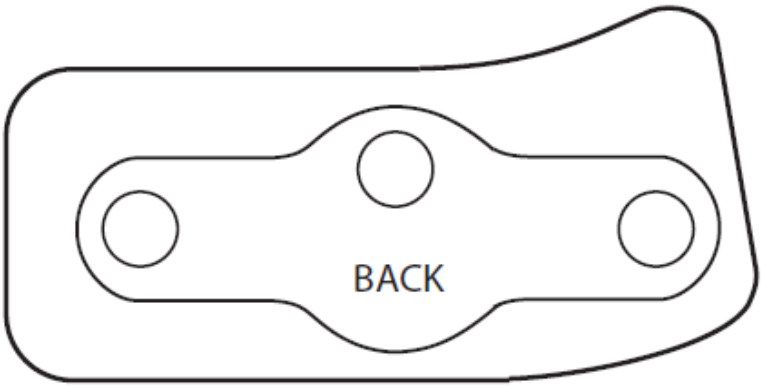
2.2 Somfit charger

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 recommended by Compumedics.



2.3 Somfit Electrode

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



2.4 Somfit Application

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

3. Using the Somfit

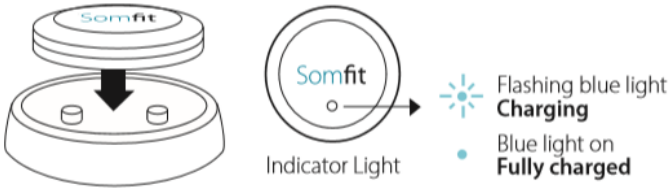
The Somfit is designed to be worn overnight during sleep. It can be used for a single night, or multiple nights to provide your physician with additional data.

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

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

3.1 Before use

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



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 Prepare Forehead

First you need to prepare the forehead.

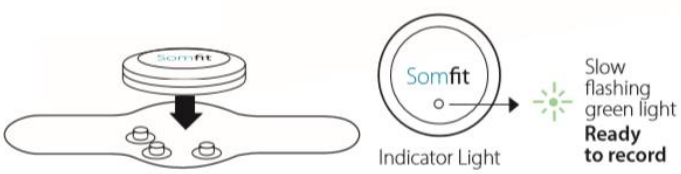
Wash and dry your face.

Clean the forehead area with the Prep Pad to give the best signal quality.

Dry forehead with a clean towel before applying sensor pad.

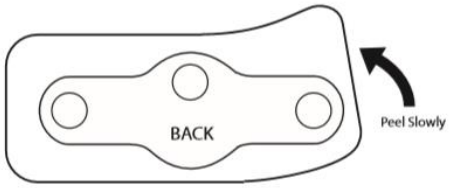
3.3 Prepare Somfit

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



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

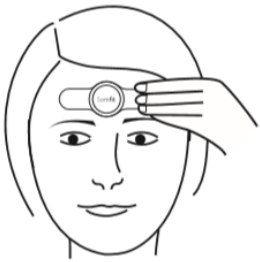
Slowly remove the clear backing from the sensor pad to reveal the adhesive area. Avoid touching the adhesive area.



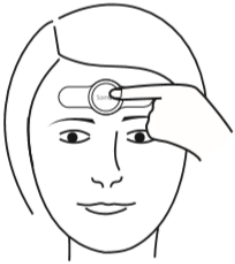
3.4 Apply Somfit

Now apply the Somfit to your forehead.

While looking at 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.



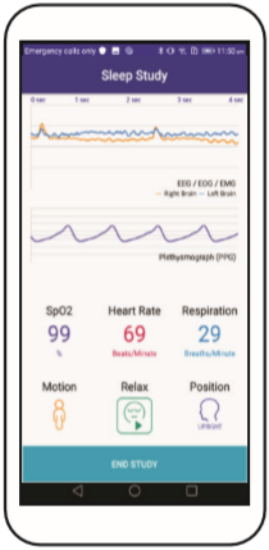
3.5 Open App - Start Recording

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

Ensure Bluetooth is enabled on the phone.

Run the **Somfit App.**

Press the '+' button to start a new study.

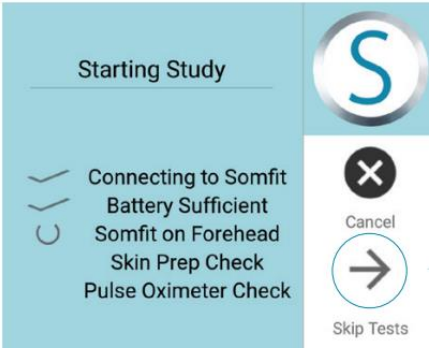


After Somfit completes pre-checks the recording screen will appear with live readings.

Lock the phone screen to black and place beside bed.

Somfit will perform some prestart checks to ensure the best signal quality and user experience. The pre-start test checks for whether

1) The Somfit is nearby and the phone can connect to it
2) Somfit battery is sufficient for at least 9-hour recording
3) Somfit is on the forehead
4) Sufficient skin preparation has been done
5) Pulse oximeter status and quality of the pleth signal

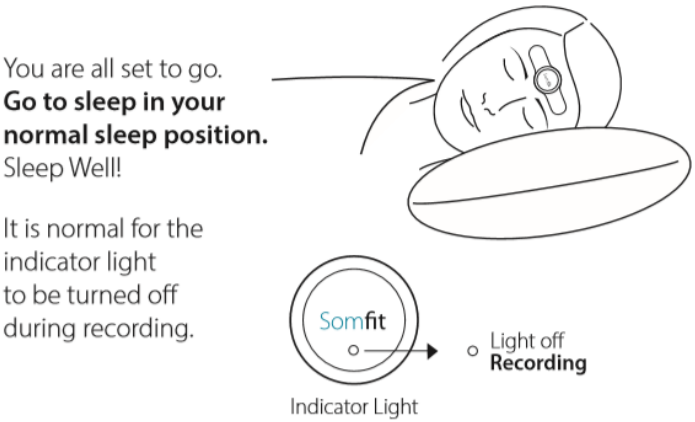


Note: In presence of excessive motion, the displayed values can potentially be unreliable. If excessive motion is detected by the device, the App will hold the values until the motion is below a certain limit.

No Motion Excessive motion

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.



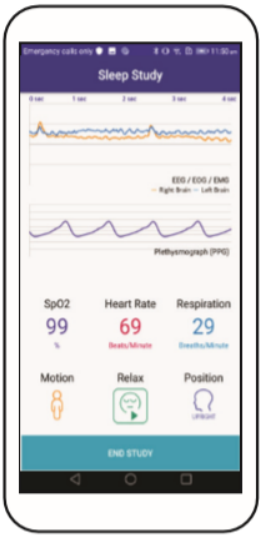
3.7 Wake

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

When you wake simply, press the **'END STUDY'** button. Confirm you wish to end study by clicking **'Yes'**.

Complete post-sleep survey.

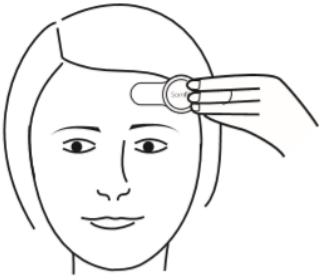
Data upload will automatically occur.



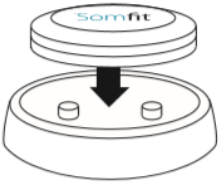
Once the study is stopped you can carefully remove the electrode and Somfit from the electrode then return it to the cradle. Data will automatically be uploaded to the Somfit server for analysis and review by your physician.

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.



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 the charging cable that is attached to the device.

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

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. Temperature and humidity limits are found in section 6 – Specifications.

4.2 Periodic Maintenance and Inspection

The oximeter has been calibrated to display functional oxygen saturation. No regular maintenance or calibration is required for this device.

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.

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

4.3 Disposal

As the Somfit device does not store any patient data or information, there are no cybersecurity concerns with regards to its disposal. Since it constitutes electronic waste; however, it should be disposed of in a socially responsible manner that is also conforming to local laws and regulations. See section 6.12 Environmental Protection.

5. Associated Equipment

5.1 Associated Device and Consumables

The following may be identified by their labelling with below part number.

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 / electrode
P/N: 7040-0001-00
Prep-pad
P/N: 95000016

6. Specifications

6.1 Regulatory compliance

Compliance Verified:	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-26 IEC 80601-2-61
Type:	Class II equipment
Applied parts:	Type BF
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)
Relative Humidity:	Less than 95 % RH (non-condensing)
Atmospheric pressure:	54 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:	54 kPa to 106 kPa
Altitude:	Less than 3,000 m

6.4 Power Supply

Power Source:	3.7 VDC Lithium Battery
Battery Charger input:	5 VDC (USB Type C)
Charger:	Any USB Type C charger that complies with IEC 60950 as recommended by Compumedics.

6.5 Wireless Interface

Type:	Bluetooth Low Energy (BLE) 4.2
Transmit Power:	< -6.0 dBm
Frequency band:	2402.0 to 2483.5 MHz
FCC ID:	2AT9S8040-0001

6.6 Functional Oxygen Saturation

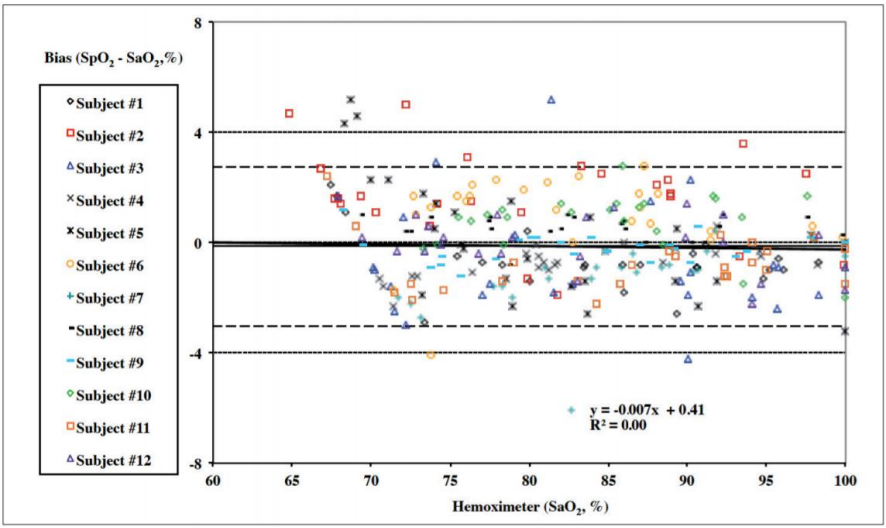
Resolution:	1%	
Measurement Range:	70% to 100%	
Accuracy:	< 2.5%	
Peak Wavelengths:	Red: 660 nm ,	IR: 950 nm
Radiant intensity:	Red: 2.6 mW/sr	IR: 2 mW/sr

Note: functional tester cannot be used to assess the accuracy of the pulse oximeter.

See graph 1 and table 1 for test results obtained from an ISO 80601-2-61 desaturation study.

Somfit/SpO2 Bias								
Hemoximeter Range	**60-80**	**80-100**	**60-100**	**60-70**	**70-80**	**80-90**	**90-100**	**70-100**
Mean	0.24	-0.16	0.00	1.99	-0.12	0.02	-0.37	-0.14
Count	118	176	294	20	98	96	80	274
Missing Data	0	0	0	0	0	0	0	0
Standard Deviation	1.74	1.40	1.56	1.58	1.55	1.51	1.24	1.45
Standard Error	0.16	0.11	0.09	0.35	0.16	0.15	0.14	0.09
95% Confidence Interval	0.32	0.21	0.18	0.74	0.31	0.31	0.28	0.17
Limits of Agreement	-3.21 to 3.69	-2.95 to 2.63	-3.08 to 3.08	-1.24 to 5.21	-3.20 to 2.96	-3.00 to 3.03	-2.82 to 2.07	-3.03 to 2.74
Maximum	5.20	5.20	5.20	5.20	5.00	5.20	3.60	5.20
Minimum	-4.10	-6.10	-6.10	-0.10	-4.10	-6.10	-4.20	-6.10
Root Mean Square	1.75	1.41	1.55	2.51	1.55	1.50	1.28	1.46

Table 1: Somfit Bias



Graph 1: Desaturation Study Test Results

6.7 Heart Rate

Resolution:	1 bpm
Range:	25 bpm to 250 bpm
Accuracy:	3 bpm or 3%, whichever is greater (compared to Masimo Radical-7® Pulse CO-Oximeter®)

6.8 Sleeping position

Range	Front, back, left, right, upright

6.9 Sound

Range	Envelope detected sound non calibrated

6.10 Light

Range	Indication of relative light

6.11 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
Frequency Range:	0.5 – 30 Hz

6.12 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.

6.13 Electromagnetic Emissions Statement

This product needs special precautions regarding EMC and needs to be 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 any other devices than a mobile phone 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 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 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 situation.

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 *is* 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.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% dip in U_T for 1 cycle 40% U_T (30% dip in U_T) for 0.5 sec >95% dip in U_T for 5 sec	>95% dip in U_T for 1 cycle 40% U_T (30% dip in U_T) for 0.5 sec >95% dip in U_T for 5 sec	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.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 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 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	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. **Recommended separation distance** $\boldsymbol{d = 1,2\sqrt{P}}$ $\boldsymbol{d = 1,2\sqrt{P}}$ **80 *MHz to* 800 *MHz*** $\boldsymbol{d = 2,3\sqrt{P}}$ **800 *MHz to* 2,7 *GHz*** 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
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.

7. Troubleshooting

If you experience a problem with your device, you should first try the following troubleshooting suggestions. If the problem cannot be solved, please contact your supplier or Compumedics.

Problem	Possible Cause	Solution
Somfit is not charging	Faulty USB cable	Check the USB cable for sign of damage. Replace the cable.
Somfit cannot be found by the phone	Somfit is out of battery	Connect Somfit to the charger until fully recharged.
	Phone Bluetooth is off	Turn the Bluetooth on and try again
	Bluetooth is out of range	Bring Somfit closer to the phone
	Invalid MAC address is set in the APP	Go to the App setting and delete the existing MAC address. Enter the MAC address available on device label or leave the field empty and let the app search for available devices.

	Someone else has already connected to the Somfit device.	Take the Somfit device out of Bluetooth range of a potential attacker and repeat connection steps.
No PPG waveform or SPO2 is displayed	Device may be operating in direct sunlight or in a room with high intensity ambient light	Move the device away from direct sunlight and high intensity light source.
EEG signal is noisy	Electrode to skin impedance is high	Remove the electrode, wash your forehead, dry it completely with a dry and clean towel. Use the provided alcohol swab to clean the skin. Dry the skin with a clean and dry towel. Apply a new electrode. Avoid touching the gels and adhesive while removing the backing paper to obtain optimum performance.
Invalid time is shown on the report	The phone time is not set properly.	Set the phone time to correct time zone.

Document Title: **Somfit User Guide**

Document Number: **AH808**

COMPUMEDICS™
'Defining *Life's* Signals'

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