



USER MANUAL



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Preface

Purpose of this manual

This manual contains important information regarding the safe operation of the Smartz™ system.

Ensure that the information contained in this manual has been read and understood before operating any component of Smartz™ system.

Further help on Smartz™ system is available in the Smartz™ APP.

The word **Patient** is defined as the person being cared for.

This manual forms the Instructions for Use of the Smartz™ device.



WARNING

Before operating the Smartz™ system read, understand and strictly follow the information contained in Section [1.0 Safety Information](#).

Qualification of Personnel

Read the Smartz™ system warnings and cautions prior to usage. Simavita recommends that the registration and maintenance of the Smartz™ system be performed by personnel with authority to make decisions on behalf of the organization. Only use original parts and equipment approved by Simavita.

Warranty

Information regarding product warranty will be available from a sales representative or Simavita.

Document Conventions

This document uses the following typographic conventions:

Screen names and screen displays: **BOLD+Calibri**

Accessibility of this Manual

This IFU can be accessed at: www.SmartzHealth.com. A hard copy of this IFU can be requested free of charge by contacting Simavita and may be delivered within up to 7 calendar days.

SECTION 1

SAFETY INFORMATION

1.0 Safety Information

Definitions

This manual uses three indicators to highlight critical information: **WARNING**, **CAUTION** and **Note**. These are defined as follows:

WARNING

A **WARNING** indicates a condition that can endanger the Patient or the Smartz™ system operator.

CAUTION

A **CAUTION** indicates a condition that can damage the equipment.

Note:

A Note indicates points of particular emphasis that make the operation of the Smartz™ system more efficient or convenient.

In order to use the system correctly and efficiently, and to help prevent incidents, please pay attention to [Section 1.2 Warnings](#), [Section 1.3 Cautions](#), as well as all warnings and cautions contained throughout this manual.

Warnings

General Warnings Related to the Use of Smartz™

WARNING

The Smartz™ system must be used according to the instructions provided.

A Patient in a clinical environment is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the Smartz™ pod regularly and systematically, before and after each use. Follow all internal procedures within your organization, as well as any maintenance procedures, to reduce the risks of infection.

To reduce the risk of infection, organization's standard operating procedures for cleaning, disinfection and hygiene must be followed at all times. At a minimum thorough handwashing should be performed before and after handling any part of the Smartz™ system.

Smartz™ is not a substitute for standard care practices. Ensure that the care personnel is able and prepared to take suitable action in the event if any part of the Smartz™ system experiences a problem.

If there is a leakage, as there may be with any continence product, there may be a risk of rash, sores and/or compromise of skin integrity requiring medical intervention during a continence assessment. Care personnel should continually monitor and interact with the Patient.

The Smartz™ sensor pad should not be applied to a Patient who has a known pre-existing skin condition, such as a rash, sores and/or a compromise of skin integrity in accordance to organization clinical practices.

Some Patients may be sensitive to materials used in the Smartz™ components. It is important that the Patient's care provider continually monitors and interacts with the Patient. If the Patient is sensitive to the materials used in the Smartz™ components, discontinue use and contact Simavita.

If a Patient develops a skin irritation as a result of wearing the Smartz™ sensor pad or pod, discontinue use and care personnel should continually monitor and interact with the Patient. The Smartz™ sensor pad or pod should not be worn for prolonged periods of time in one use.

If the ambient temperature is not reported correctly to within ± 2 Degrees Celsius within the immediate vicinity of the pod, please disregard the measurement. Care personnel should continually monitor and interact with the Patient.

Falls are not guaranteed to be detected all of the time and this feature is not intended to be a substitute for standard care practices. Care personnel should continually monitor and interact with the Patient.

Smartz™ sensor pads could potentially pose a biohazard risk. The Smartz™ sensor pads should be disposed of, as per the standard operating procedures of your organization.

The LED Indicator lights on the Smartz™ pod indicate different events and functions. Refer to the Section [Smartz™ pod Indicator Light Colors](#) for information on the LED Indicator light definition before determining the relevant user action.

Ensure Smartz™ system components are stored and transported according to the specifications defined in 5.0 Appendix A Smartz™ System Specifications.

Antivirus is recommended for the smart devices using the Smartz™ app to reduce the risk of third party intervention

General Warnings Related to System Installation

WARNING

The Smartz™ system must not be installed in an environment that limits or prohibits RF transmitting devices.

The Smartz™ pod, sensor pad and app must not be used in the presence of medical imaging equipment such as MRI machines, ECG machines, Defibrillators, etc.

Do not connect items which are not specified as part of the Smartz™ system.

The Smartz™ pod and Smartz™ sensor pad must not be stored or placed close to radiant heat sources, such as a lit fireplace or radiant heater.

The Smartz™ pod and sensor pad must not be stored or placed close to the sources of steam, such as steam kettles.

The Smartz™ pod and sensor pad must not be stored or placed close to microwave ovens.

Do not make changes to the App settings as this may render the system inoperable.

Warnings Regarding Maintenance

WARNING

The Smartz™ pod should be inspected for any visible damage during everyday use and not less frequently than every 12 weeks.

Never use any component or accessory of the Smartz™ system that appears to be damaged or not functioning correctly. If any signs of damage or malfunction are evident, discontinue use and contact the supplier of the Smartz™ system. Examples may include a broken hinge pin, sensor gold teeth, clip mechanism, or battery lid and contacts.

If the cause of the problem with any component or accessory of the Smartz™ system cannot be determined, contact supplier of the Smartz™ system. Do not use the Smartz™ system until the problem has been corrected.

Do not attempt to repair, modify or service any component or accessory of the Smartz™ system. The system does not contain any user serviceable parts. Doing so might cause damage and/or void warranty.

Only clean Smartz™ components with cleaning agents specified in cleaning instructions. Read and follow the cleaning and additional instructions on the cleaning agents to clean the Smartz™ components.

The Smartz™ sensor pad is intended for single use only. Use and disposal of the pads shall be as per pad manufacturer instruction.

Only perform upgrades to any software components of the Smartz™ system by following instructions provided by the supplier of the Smartz™ system.

Never use accessories, detachable parts or materials that are not described in this User Manual. To order new accessories, please contact supplier of the smartz™ system.

The Smartz™ pod must not be serviced or maintained when in use on a Patient.

Warnings Regarding Oxygen

WARNING

The Smartz™ system is NOT suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or with OXYGEN or NITROUS OXIDE.

Warnings Regarding Instructional Safeguards for batteries

WARNING

The Smartz™ pod contains a user replaceable coin cell battery, type CR2016, contained behind a snap-fit battery compartment lid that requires a small flat tool to open.

Do not ingest battery as it may result in a Chemical Burn Hazard.

If the coin cell battery is swallowed it can cause severe internal burns in just 2 hours and lead to death.

Keep new and used batteries away from children.

If the battery compartment or the pod housing does not close securely or is damaged, stop using the product and keep it away from children.

If batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.

Cautions

General Precautions for Use

CAUTION

The Smartz™ pod may be damaged by excessive force being applied during cleaning. The cleaning procedures specified in Smartz™ components Cleaning Instructions must be followed to prevent damage.

The components of the Smartz™ system may be damaged through the use of harsh cleaning products. The cleaning procedures specified in Smartz™ components Cleaning Instructions must be followed to prevent damage.

Precautions should be taken when handling the Smartz™ pod. Avoid touching the gold pins.

Precautions regarding Electromagnetic Interference

CAUTION

The Smartz™ system requires special precautions for electromagnetic compatibility and should be operated in accordance with the recommendations in this manual.

Note: The use of nearby mobile and portable communications equipment using radio frequencies exceeding the levels set in the IEC 60601-1-2 standard may affect its operation.

The use of any accessory other than those specified may lead to an increase in electromagnetic emissions or a decrease in the equipment protection against electromagnetic emissions.

General Precautions Related to the incorporation into the IT-network








CAUTION






The connection of Smartz™ system to an IT network that includes other equipment could result in previously unidentified risks to Patient, operators or third parties. The use of other medical or non-medical devices in the Smartz™ IT network is not recommended. The IT administrator should identify, analyze, evaluate and control these risks before connecting the Smartz™ system to the network.








Changes to the IT network including but not limited to changes in the IT network configuration, connection of additional items to the IT network, disconnection of items from the IT network, the update of equipment connected to the IT network and upgrade of equipment connected to the IT network, could affect the operation of Smartz™. The IT administrator should assess the risks to the Smartz™ system before implementing any of these changes.

Symbols and markings

Table 1. Symbols

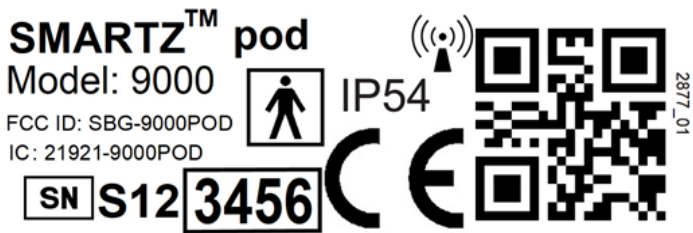

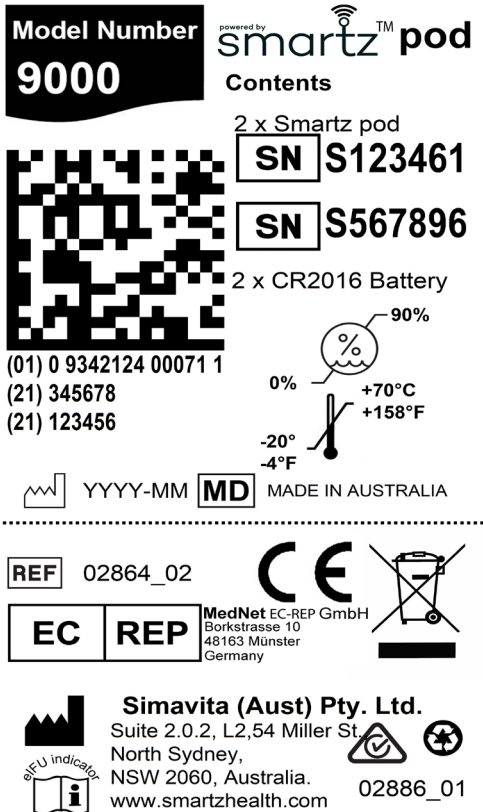
Symbol	Description
	IEC 15223 -1General Warning sign. This symbol accompanies WARNING in Simavita product literature.
	IEC 60417-5140 (2003-04) Equipment includes an RF transmitter. This symbol appears on the Smartz™ pod.
	IEC 15223-1Serial Number This symbol appears on all Smartz Pod label and package label
	WEEE (Waste Electrical and Electronic Equipment) This means the product must not be disposed of as household waste. Observe local ordinances for proper disposal. This symbol appears on all Smartz™ components. Refer to section 1.6 Disposal for information and instructions for disposal.
	RCM Compliance with Electrical Equipment Safety System (EESS) of Australian Communications and Media Authority (ACMA) Regulation. This symbol appears on the Package Label
	CE Marking. Declares that the product conforms to the essential requirements of the applicable EC directives. This symbol appears on the Smartz pod label and all accompanying documentation and packaging.
	United States FCC FCC ID : SBG-9000POD This Smartz™ pod complies with Part 15 of the Federal Communications Commission (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 FCC ID appears on the pod Label







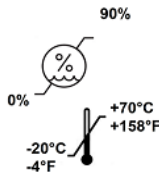

<h1>IP54</h1>	<p>IP rating code of Smartz pod, which classifies the protection against intrusion from dust and water.</p> <p>This symbol appears on the Smartz pod.</p> <p>The first digit indicates the level of protection that the enclosure provides against access to hazardous parts The number 5 indicates that the enclosure is protected from limited dust ingress.</p> <p>The second digit indicates the level of protection that the enclosure provides against harmful ingress of water. The Number 4 on Smartz pod indicates that pod is protected against water splashed from all directions.</p>
	<p>Keep Dry.</p> <p>This symbol appears on the Smartz pod packaging.</p>
	<p>Keep Away from direct Sunlight</p> <p>This symbol appears on the shipper carton package</p>
	<p>Indicates that the packaging should be recycled.</p> <p>This symbol appears on the Smartz pod packaging.</p>
	<p>Indicates the acceptable temperature range for transport and storage</p> <p>This symbol appears on the Smartz pod packaging label</p> <p>Refer to Smartz™ System Transport and Environmental Specifications</p>
	<p>Indicates the acceptable humidity range for transport and storage</p> <p>This symbol appears on the Smartz Pod packaging label</p> <p>Refer to Smartz™ System Transport and Environmental Specifications</p>

	<p>Indicates that the device is a Medical Device</p> <p>This symbol appears on the Smartz Pod Packaging label</p>
	<p>IEC 15223-1 Device Manufacturer</p> <p>The symbol appears on the Smartz Pod Package Label</p>
	<p>The date when the Smartz Pod was manufactured</p> <p>The symbol appears on the Smartz Pod Package Label</p> <p>The date will be adjacent to the symbol in the YYYY-MM format</p>
	<p>IEC 15223-1 Manufacturers Catalogue Number</p> <p>This symbol appears on the Smartz Pod Packaging Label</p>
	<p>IEC 15223-1 Indicates electronic instruction for use</p> <p>This symbol appears on the smartz pod Package label</p>
	<p>IEC 60417-5333 Type BF Applied Part</p> <p>This symbol appears on the pod label</p>
	<p>European Authorized Representative</p> <p>This symbol appears on the Smartz Package label , Shipper carton label and in the user manual</p>

Labels

Various labels and specific markings are affixed to the Smartz™ system components that describe precautions and contribute to traceability of the product. The labels are identified in the table below with illustrations of their location.

Table 2. Labels	Description	Location
 <p>SMARTZ™ pod Model: 9000 FCC ID: SBG-9000POD IC: 21921-9000POD IP54 SN S123456 2877_01</p>	Smartz Pod Label	
 <p>Model Number 9000 powered by smartz™ pod Contents 2 x Smartz pod SN S123461 SN S567896 2 x CR2016 Battery (01) 0 9342124 00071 1 (21) 345678 (21) 123456 0% 90% -20° -4°F +70°C +158°F YYYY-MM MD MADE IN AUSTRALIA REF 02864_02 EC REP MedNet EC-REP GmbH Borkstrasse 10 48163 Münster Germany Simavita (Aust) Pty. Ltd. Suite 2.0.2, L2, 54 Miller St North Sydney, NSW 2060, Australia. www.smartzhealth.com 02886_01</p>	Smartz Pod Packaging Label	Packaging box.

<div data-bbox="228 176 443 310"> Model Number 9000 </div> <div data-bbox="454 176 798 262"> Contents: 48 x Smartz pods </div> <div data-bbox="228 331 564 445"> <p>powered by</p>  </div> <div data-bbox="593 302 823 520">  </div> <div data-bbox="625 531 790 562"> (01) 0 9342124 00072 8 </div> <div data-bbox="233 510 323 594">  </div> <div data-bbox="362 510 435 594">  </div> <div data-bbox="507 516 552 600">  </div> <div data-bbox="239 655 443 739"> <div>EC</div> <div>REP</div> </div> <div data-bbox="443 655 632 739"> MedNet EC-REP GmbH Borkstrasse 10 48163 Münster Germany </div> <div data-bbox="237 770 303 831">  </div> <div data-bbox="322 783 647 819"> Simavita (Aust) Pty. Ltd. </div> <div data-bbox="322 825 617 930"> Suite 2.0.2, L2,54 Miller St., North Sydney, NSW 2060, Australia. www.smartzhealth.com </div> <div data-bbox="651 627 810 800">  </div> <div data-bbox="593 869 807 957">  </div> <div data-bbox="735 980 798 997"> 02884_01 </div>	Smartz Shipper Box Label	
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Patient Privacy and Security

Users are required to accept an EULA (end user licence agreement) to use the product. All patient data is held on secure Smartz™ cloud servers. It is the responsibility of the User to ensure that the physical security of all devices used for Smartz™ monitoring is maintained.

The background is a solid teal color. A dark grey, curved band sweeps across the middle of the page, starting from the left edge and ending on the right. The text is positioned within this band.

SECTION 2 **OVERVIEW**

2.0 Overview

2.1 What is the Smartz™ system

Smartz™ is a safe, smart solution for aged care that can monitor a variety of wellness signs in Patients. A Smartz™ pod is attached to a Smartz™ sensor pad (Figure 1). The sensor pad has embedded sensors which allow for real-time notifications to the caregivers that “it’s time to change”. Smartz™ is simple to use, intelligent, affordable, safe and provides peace of mind to caregivers.



Figure 1 Smartz™ sensor pad and pod

The Smartz™ pod is a lightweight, slim, wearable data logger that clips onto a Smartz™ sensor pad. It is sufficiently economical for everyday use and comfortable for the Patient. The pod is easy to use and simple for the carer to clip and unclip from a Smartz™ sensor pad.

The Smartz™ system is designed to operate continuously and monitor the Patient 24/7. In addition to the time to change, the device tracks the Patients time in a particular body position. Data is transmitted safely and securely from the Smartz™ pod to the Smartz™ app for processing and display.

2.2 Indications for Use

Smartz™ system is indicated for use by, or under the direction of, healthcare professionals, caregivers and personal use to collect, transmit and report medical information from multiple patients within a clinical setting (e.g., hospitals, skilled nursing facilities, rehabilitation facilities and home care environments), or within a home environment, to provide effective continence care and related conditions.

Contraindications

There are no known contraindications.

Intended Use

The Smartz™ system is intended to provide monitoring services of continence and related wellness data by remote transmission. It is intended for use by, or under the direction of, healthcare professionals, caregivers and for personal use to collect, transmit and report information related to body position, falls monitoring, continence product status and related wellness data for individuals in institutional environments, including hospitals, nursing homes, rehabilitation facilities and within home environments.

2.3 Features

Time to Change - the time to change feature is designed to provide a guide to Carers when the sensor pad has reached capacity and needs to be changed. The Carers are notified via the app with a traffic light system which indicates; Green light – pad dry, Yellow light – some wetness in pad and Red – pad at capacity and needs to be changed.

Time in Pad– Indicates the time that the Patient has been in the current pad.

Time in Red– Indicates the time that the Patient pad was at capacity and required to be changed.

Body Position – Indicates the actual current body position of the patient. The positions that are tracked include lying down on back, lying on stomach, lying on one side, sitting and standing.

Time in Position - Indicates the time the Patient was in a particular single position. The positions that are tracked include lying down on back, lying on stomach, lying on one side, sitting and standing.

Ambient Temperature – Indicates the approximate temperature of the pod's surrounding environment. Note this feature is not intended to measure any such physiological temperature of Patient.

Falls Detection – Indicates whether the Patient has fallen over.

2.4 Benefits of the Technology

It is important for Carers to take a proactive approach focused on pressure injury prevention. In certain circumstances, the clinical benefits of using a wearable technology indicating the time to change the diaper may include:

- Reduced leakage onto clothing and subsequent risk of skin breakdown,
- Reduced risk of Urinary Tract Infections (UTI's) and Incontinence Associated Dermatitis (IAD),
- The Red notification and time since the notification prompts carers to prioritize care and could prevent the risk of wearers sitting for long periods in wet diapers.
- Reduced pressure sore injury due to notification of times in a particular body position

This wearable technology may reduce the diaper absorbency required, a reduction in diaper changes by changing the diaper only when really needed thus saving time and improving toileting routines. These benefits may result in lower overall cost, fewer hospital admissions, less waste, and more significantly, better individualised care. Patients in Aged Care have a high risk of Pressure Injury, especially those who have limited mobility and are incontinent.


The information these systems deliver can be integrated into continence care plans created by Carers and will more accurately meet the true needs of each individual Patient.

2.5 The Smartz™ System Components

Smartz™ uses industry standard Bluetooth technology to connect to smart devices available on the market. Sensor data and knowledge can be shared to distribute workload and improve continuity of care.

Smartz™ consists of a number of components to enable the system to function. These components are stated and described in the following table:

Table 3. System Components

Component	Description	User Interaction
Smartz™ sensor pad	<p>Disposable Single-Patient-use continence pad (diaper), with integrated wetness sensor for daily use.</p> <p>The Smartz™ sensor pad consists of a standard continence pad (diaper) with printed capacitive sensors in the form of 3 lines. The sensor has 2 sets capacitive electrodes for improved reliability and coverage. Sensors work on the principle of capacitance similar to touch screens on mobile phones. The sensors detect the accumulation of liquid in the diaper over time.</p>	Carer, Patient
Smartz™ pod	<p>A portable, reusable data transceiver that is connected to the Smartz™ sensor pad and worn continuously or as needed by the Patient.</p> <p>The Smartz™ pod is a small and lightweight data logging device. The pod has been designed to an IP54 rating, allowing it to be cleaned by wiping with cleaning solutions. The Smartz™ pod contains a CR2016 Lithium battery and an electronic circuit board containing Bluetooth radio module, micro-controller, memory, and charging circuitry. Smartz™ pod is equipped with a safety circuit that limits the electrical energy available when a Smartz™ sensor pad is connected.</p> <p>Smartz™ pods should be linked to a Patient prior to use via the Smartz™ app. The Smartz™ pod requires connection to Smartz™ sensor pad and Smartz™ app to perform its monitoring and notification function.</p>  <p>Figure 2 Smartz™ pod</p>	Carer, Patient

<p>Smartz™ app</p>	<p>A software application operating on a smart device performing data collation, storage, processing and display functions. Analysed data is transmitted from the Pod to the smart device via Bluetooth technology and informs the user of the ambient temperature surrounding the pod, body position, time in position and the best time to change product based on the sensor pad wetness. A smart device can function as a 'Monitor' when the Smartz™ app is installed. The app extends the monitoring capability by analysing and presenting health status information through the touch screen interface.</p> <div data-bbox="496 499 935 1419" data-label="Image"> </div> <p>Figure 4 Smartz™ App</p>	<p>Carer</p>
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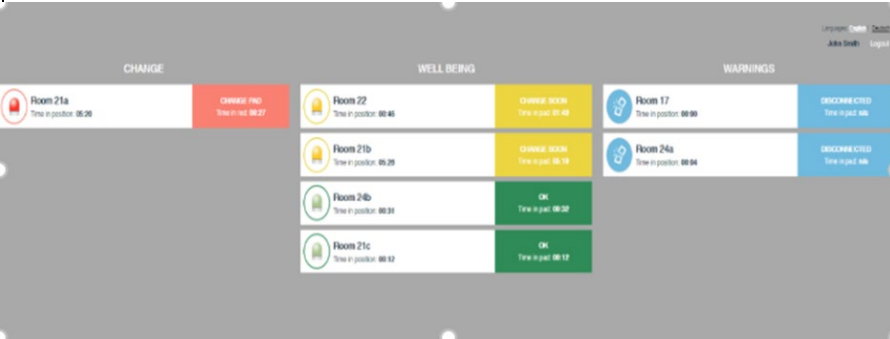

<p>Smartz™ dashboard</p>	<p>A website that allows monitoring of many Patients at once on a smart device, such as a laptop or iPad, giving a holistic view for Carers.</p> 	<p>Carer</p>
<p>Accessories to the Smartz™ system (refer to Appendix B for instruction for use of these accessories)</p>		
<p>Smartz™ nodes</p>	<p>An IT router accessory to the system which allows an extended range of Bluetooth signal and sends the data via Wi-Fi to allow remote monitoring on the Smartz™ dashboard. A mesh network consisting of connecting multiple Smartz™ nodes can be made to extend the network signals; useful in larger facilities.</p> 	<p>Carer, (or IT staff during setup)</p>

	Figure 5 Node	
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The interaction of all IoT components of the Smartz™ system is show below.

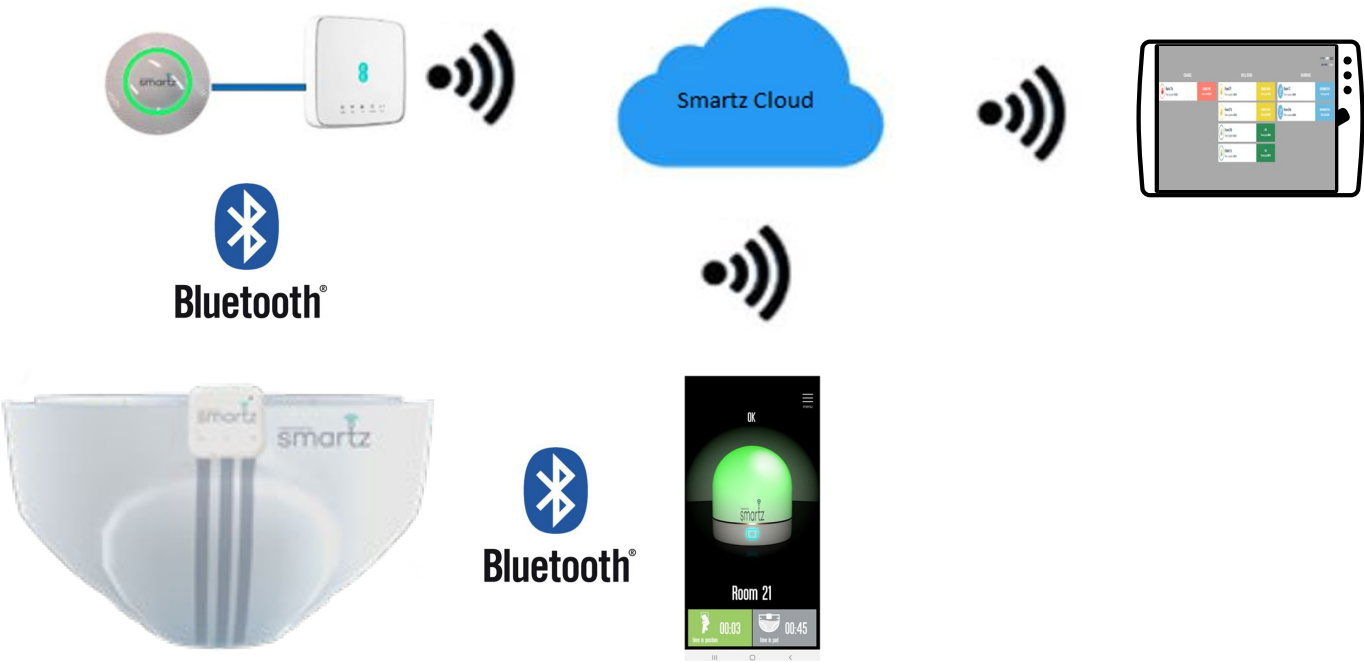


Figure 3 Smartz™ network

3.0 User Instructions

3.1 Smartz™ pod Battery Installation & Replacement

The Smartz™ pod uses a replaceable Panasonic CR2016 battery. Follow the instructions below to install the battery for first time use or to replace the battery:

1. Place the Smartz™ pod face up on a flat surface.
2. Insert a flat tool into battery compartment and carefully pry the battery compartment open.
3. Remove the old battery and install the new one (CR2016) with the plus (+) symbol facing up.



Figure 4. Battery Replacement

4. The light on the Smartz™ pod will flash green for a moment to indicate that battery has been installed correctly. For all other pod LED light instructions, refer to Section 3.3 Smartz™ pod Indicator Light Colours.
5. Gently slide the battery compartment closed until it clicks shut.



Figure 5. Battery lid

3.2 Clipping Smartz™ pod onto Smartz™ sensor pad

To enable the monitoring function, the Smartz™ pod needs to be clipped onto the Patients Smartz™ sensor pad as follows:

1. Open the Smartz™ pod clip



Figure 6. Pod label

2. Line up the three (3) stripes of the Smartz™ sensor pad with the three (3) dots on the Smartz™ pod.



Figure 7. Clip onto pad location

- Clip the Smartz™ pod onto the front of the Smartz™ sensor pad
3. The light on the Smartz™ pod will momentarily flash green to indicate that it has been clipped onto the Smartz™ sensor pad correctly. For all other pod LED light instructions, refer to Section 3.3 Smartz™ pod Indicator Light Colours.
 4. Note: If the light does not flash green, then unclip and re-clip the Smartz™ pod.
 5. For correct operation, the Smartz™ pod needs to be attached to the Smartz™ sensor and worn around the waist region. The Smartz™ pod needs to be flipped inwards towards the body and tucked in securely when worn. **That is one flip in only.** The positioning response relies on the correct and secure position relative to the body.



Figure 8. Flip pod inwards towards body once and tuck in securely

3.3 Smartz™ pod Indicator Light Colours

The following is a table is a summary of instructions for the different Smartz™ pod LED indicator lights mentioned previously in this instructions document.

Table 4. Pod Indicator Light Colours

Pod State	Indicator Light	Notification to user
Battery inserted	One green flash	Battery OK
Sensor has been correctly clipped on pad	One green flash	Sensor connected
Default state	Off	No action required
Low Battery	Red flashes	Replace Battery or replace Smartz™ pod
Dead Battery	Off <i>(when connecting pod to pad)</i>	Replace Battery or replace Smartz™ pod

3.4 Using the Smartz™ app

Keeping the phone charged

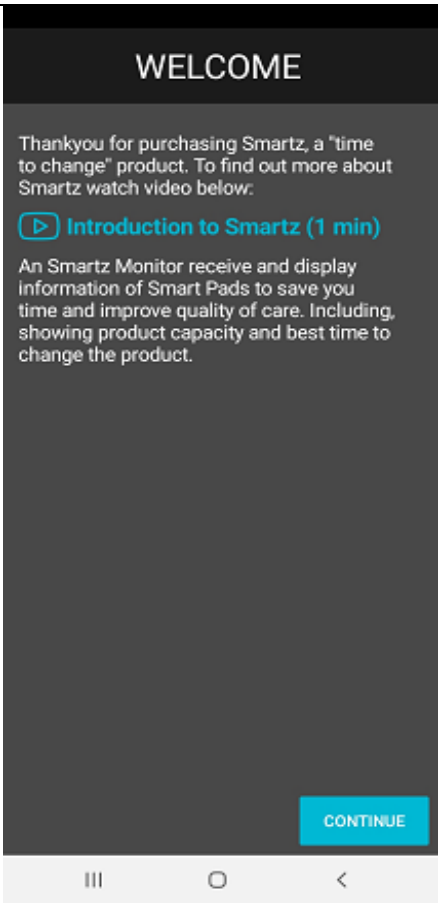
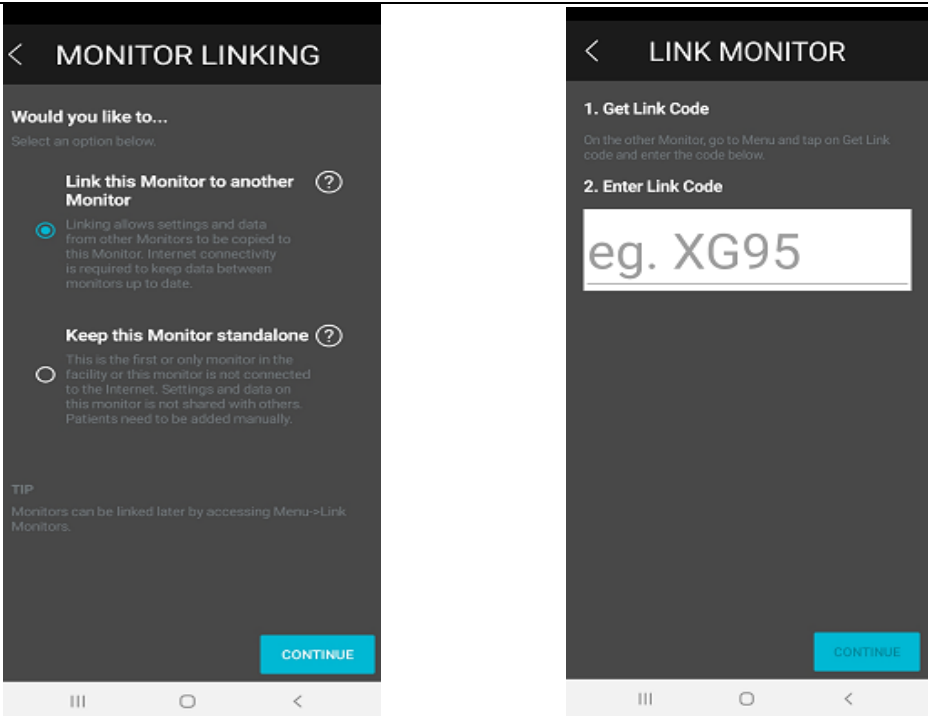
Please note that it is strongly recommended that the device used for monitoring is always charged so that it can be used for monitoring 24/7.

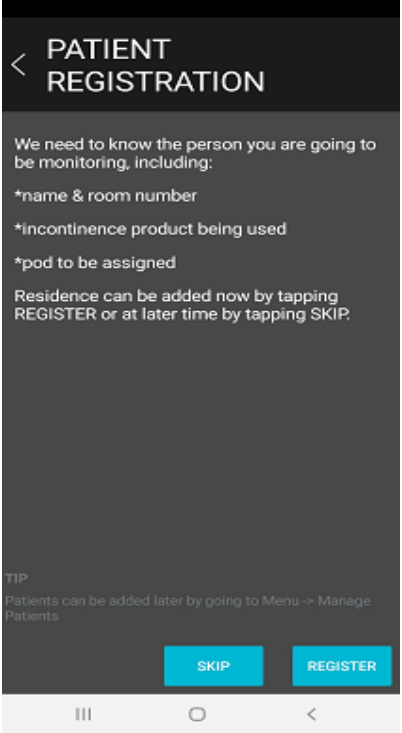
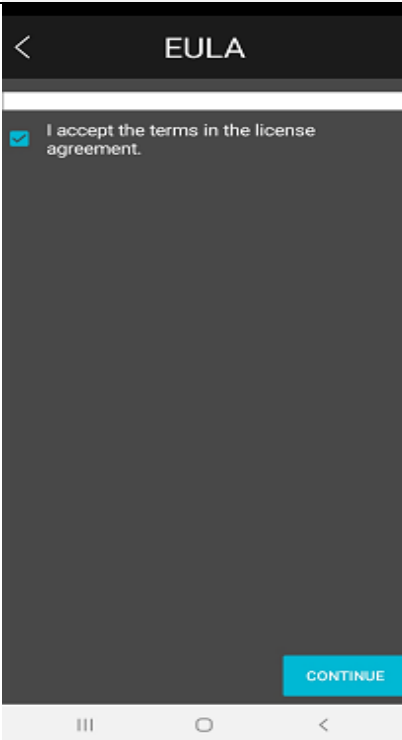
First opening the app and set up

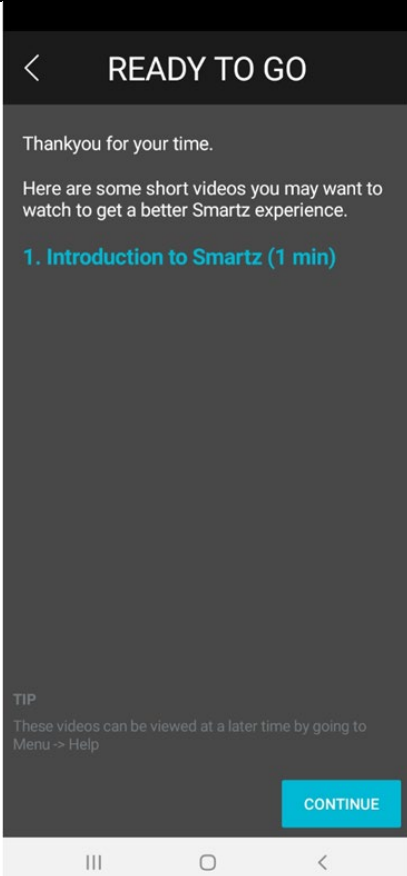
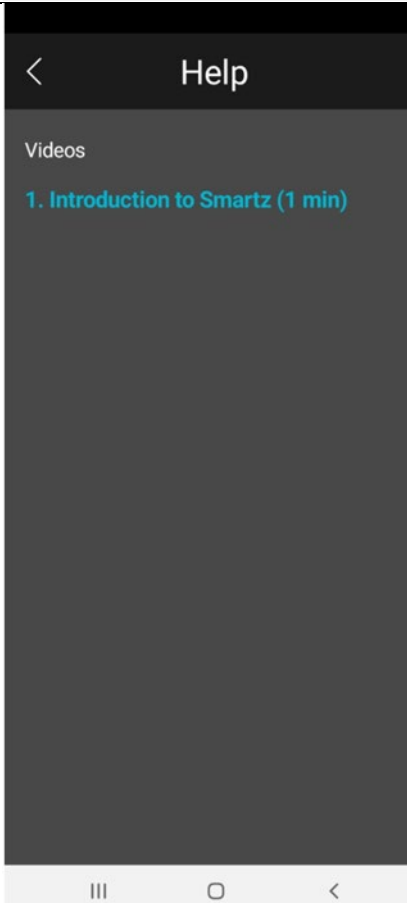
Ensure that the Wi-Fi (or 3G/4G/5G) and Bluetooth of the smart device are turned on and remain on during the lifetime of using the Smartz™ system. This is required for proper and full functioning of the Smartz™ System. If these are not available, some of the functionalities may not be available. Ensure the smart device is not in airplane mode.

When the app is first opened, there are a series of welcome screens with information and videos to help get with set up. Follow the instructions on screen.

Table 5. Setup of the app

Screen	Image
Welcome	
Standalone or Shared Device	

<p>Register a Patient (see section Manage Patients)</p>		
<p>Accept EULA</p>		

Ready to go		
Help Videos		Accessed via the Menu after setup

Standalone versus Group Membership Devices

The monitoring device can be used as either a standalone monitoring device or it can be used to create a user account to manage groups of Patients or join another user account that already exists.

/ A user account is required to manage a group of Patients /

Using the device as a standalone Monitor

In this mode, the monitoring device does not interact with any cloud functionality. All data is kept locally on the smart device running the monitoring app and no consent is required because of this. This mode is beneficial for Carers who wish to Monitor one or several Patients on one device and do not wish to have additional web functionality, such as access to the Smartz dashboard or Push Notifications.

Using the device as part of a User account within in a Group

Refer to 'Smarz™ Membership' section.

Manage Patients

Patient details must be set up on the app. Patients to be monitored must be assigned a Smartz pod using the unique pod serial number.

To add a Patient with a unique Smartz™ pod through the Smartz™ app:

1. Go to Menu
2. Press *Manage Patients*
3. Press *Add*
4. Enter the *Patient Name* and *Alias Name*.

NOTE: Only the *Alias name* is displayed on all software interfaces. It can be any unique identifier for the Patient. This allows for patient privacy throughout the system.

For example, when the system is being used in a group setting, the "Alias Name" is required for Patient privacy – the alias used could be the Patients room number.

< ADD PATIENT

Patient Name _____

Alias Name _____

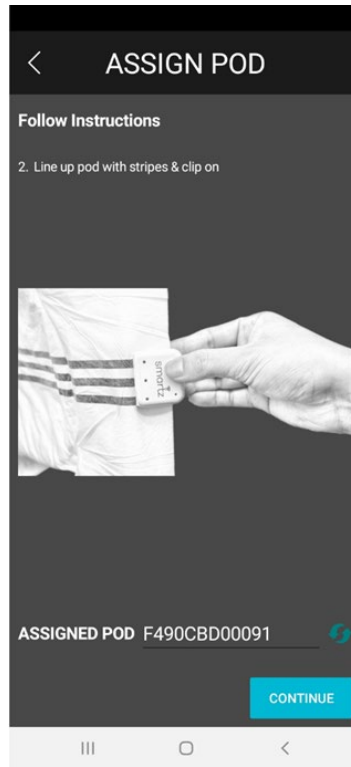
Pod Assigned ASSIGN

Products Used

	Manufacturer	Product
DAY	_____	_____
NIGHT	_____	_____

ADD

5. The Smartz™ pod will need to be attached to the Smartz™ sensor pad. Read the Smartz pod number on the inside of the pod eg. SN S-000-050.
6. Assign the uniquely identified Smartz™ pod by pressing *Assign* and a list of pods available will be shown.



7. Press *Save* when the correct pod number appears.
NOTE: If the pod number is not the one intended for the Patient, click the number to show a selection of all pods nearby.
8. Edit the products that this Patient uses for the *Day pad* and *Night pad* variations and Press *Add* after selection
9. Press *Save* on the bottom right of the screen to save Patient details

< ADD PATIENT

Patient Name Jane Smith

Alias Name Room 22

Pod Assigned F490CBD00091 CHANGE

Products Used

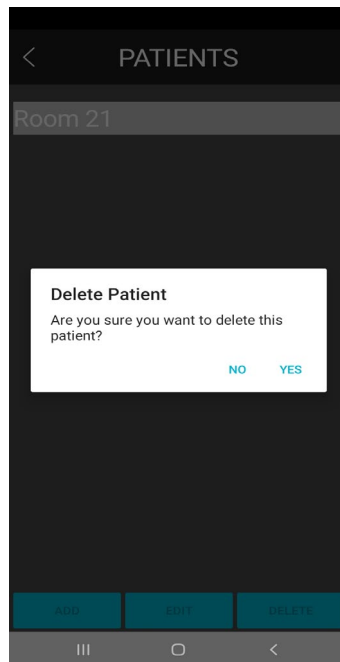
DAY	Manufacturer	Brand A
	Product	Product 1
	<input type="checkbox"/> Use this product for night	
NIGHT	Manufacturer	
	Product	

CONTINUE

The Patient is now added. Multiple Patients can be added to a smart device via the Smartz™ app and can be seen on the screen.

To edit Patient details or assign a new unique Smartz™ pod to that Patient, press *Edit* and select the Patient to edit.

To delete (remove) a Patient from the smart device, press *Delete* and select the Patient to delete (remove).



NOTE: Patients will only be monitored on the app when the device running the app is in Bluetooth range of the Patients.

Order of Status Display

If multiple Patients are being monitored on a single smart device within the Bluetooth vicinity of that device, the Smartz™ app will shuffle through these Patients monitoring status.

The notifications are prioritised depending on the events occurring across the shared Patients.

Smartz™ Membership and User Accounts

NOTE: Smartz™ Membership will only work when the device running the app is connected to the internet through Wi-Fi or 3G/4G/5G.

The Smartz™ Membership feature allows users to:

- Access protected data and features
- Share data between other devices within a Group to:
 - Monitor patients from many devices
 - Reduce administrative effort
- Access smartz sensor data anywhere by **sharing** device data with Smartz Cloud
 - Web Dashboard (see Smartz Dashboard section)
 - Push Notifications (see Push Notifications section)

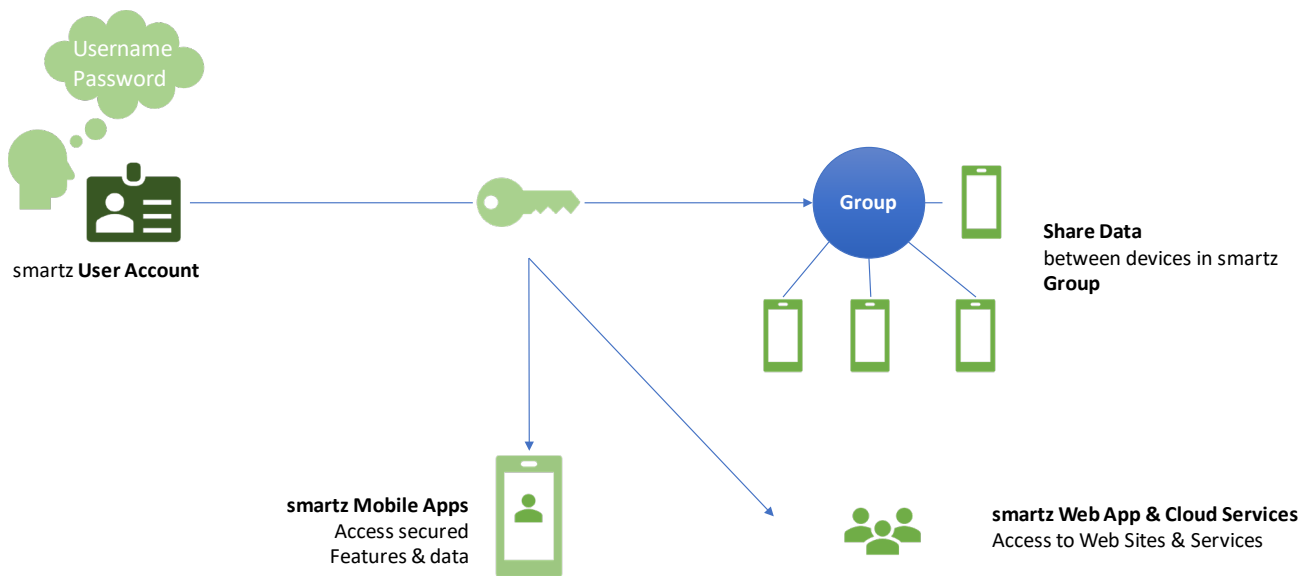
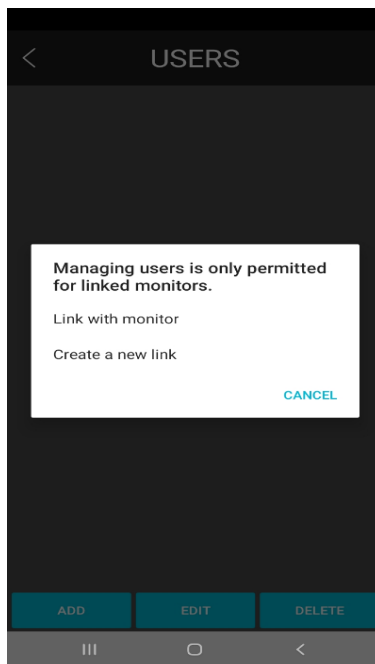


Figure 9. Data Access & Sharing with a Membership User Account

Data can be shared by forming Groups. These groups can grow by sharing codes between devices that wish to join the Groups or by adding devices under User accounts. To create a group and share patient data between the monitoring devices and gain access to these additional benefits, see the steps below.

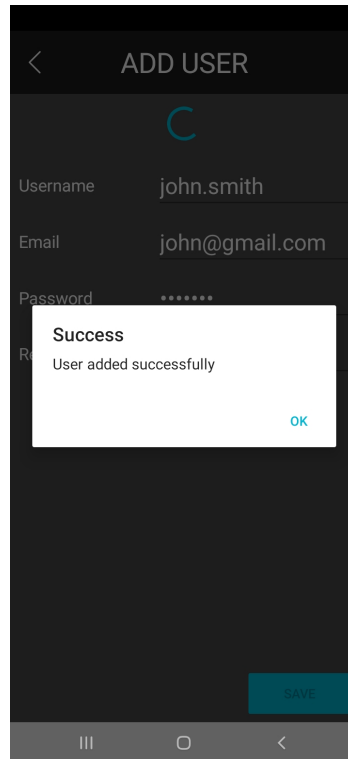
1. Go to Menu
2. Press *Manage Users*



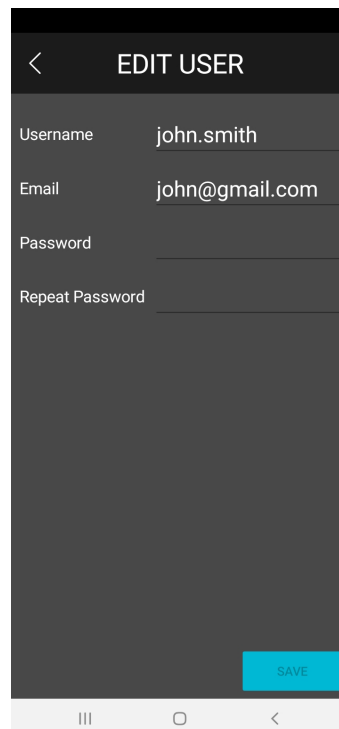
3. Press *Add*
4. Enter the *Username*, *Email Address* and *Password* for this user. Ensure the password is strong by utilising upper and lower case characters, symbols and numbers.

A screenshot of a mobile application interface titled 'ADD USER'. At the top, there is a back arrow and the title 'ADD USER'. Below this, there are four input fields: 'Username' with the value 'john.smith', 'Email' with the value 'john@gmail.com', 'Password' with a masked value '.....', and 'Repeat Password' with a masked value '.....'. A 'SAVE' button is located at the bottom right of the form. The bottom of the screen shows a standard Android navigation bar with three icons: a square, a circle, and a triangle.

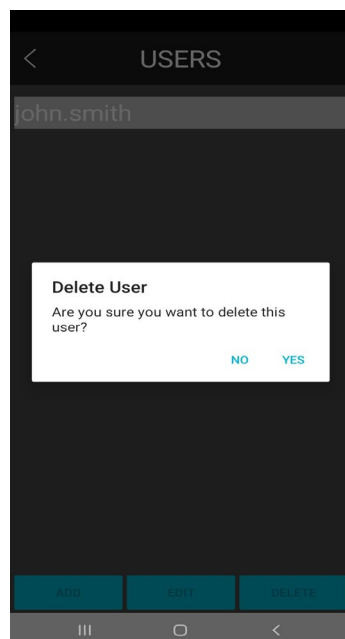
5. Press *Save*



The User is now added. Multiple Users can be added to a smart device via the Smartz™ app. To edit Users details or assign a new unique Smartz™ pod to that Patient, press *Edit* and select the User to edit.



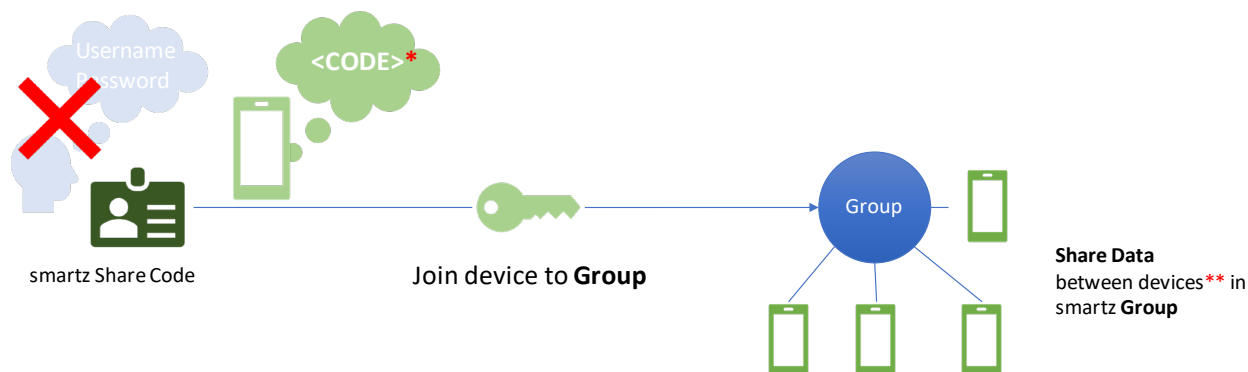
To delete (remove) a User from the smart device, press *Delete* and select the User to delete (remove).



Note that the monitoring status of each Patient's pod is not shared across the smart devices through this membership unless the monitoring app is in the same Bluetooth range of the shared Patients.

SHARE CODE

Groups can be expanded by having new monitoring devices share secure one-time codes with other monitoring devices, which already have a Group association. This enables access to the group's patient and user data for this new monitor.



* Generate code without a smartz User Account!

** One device must create a smartz Membership User Account

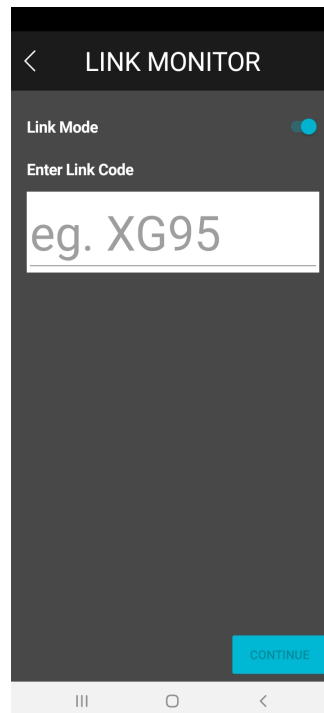
Figure 10. Data Sharing with a Membership Share Code

To enable this sharing:

1. Go to Menu on one of the smart devices intended to be shared to the group
2. Press *Get Link Codes*



3. **The code only lasts 10 minutes!** Otherwise, a new link code will have to be generated.
4. On the other smart device, go to Menu and press *Share Monitor*



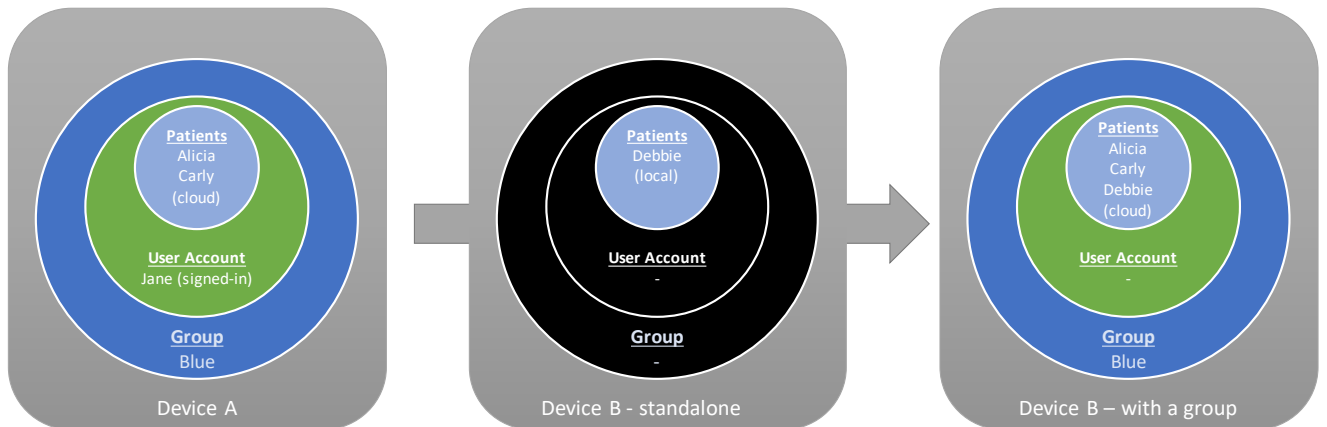
5. Enter the code from step 4. The smart devices are now in the same Group and will cycle through all of the Patients in that Group.

This process can be repeated indefinitely until the desired number of smart devices for Patients are all in the Group. One user can belong to many groups. One Group can have many users which may belong to other groups.

NOTE: A monitoring device can be removed from a group in the Settings Menu.

Linking and Status Display of Models Scenario

Share Code - Example #1 (device B not in a Group)



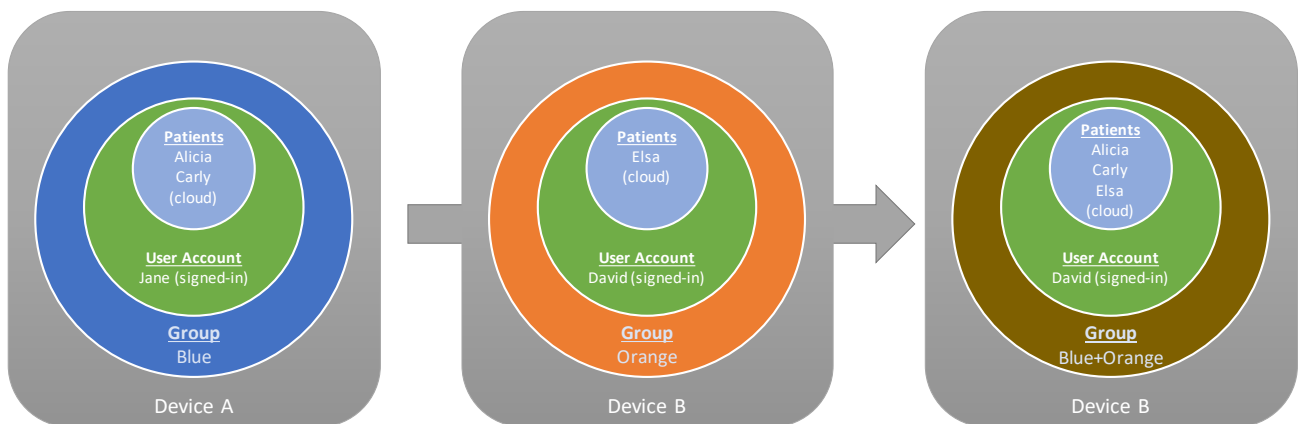
1. Generate Share Code from Device A

2. Use Share Code from Device A

3. Result of joining device B to Jane's **Group (Blue)**

4. Device A will now see Debbie

Share Code - Example #2 (device B in a Group)



1. Generate Share Code from Device A

2. Use Share Code from Device A

3. Result of joining device B to Jane's **Group (Blue)**

4. Device A can only see Group Blue

Push Notifications

The Smartz™ notification app is a mobile app extension to the monitoring app which allows users with user accounts to subscribe to push notification events for each Patient. This means users will receive remote notifications on the event statuses of their Patients when their device is connected to the internet, anywhere they are. This app can be obtained from app stores. To use this additional feature:

- 1) Ensure the device is connected to the internet
- 2) Obtain the Smartz™ Notification app from the app store of the device
- 3) Login using the same user account as that created in the Smartz™ app
- 4) A list of Patients linked to this user account will appear
- 5) Select the Patient and then the specific events to be subscribed to for these push notifications
- 6) Wait for the notification to come through the device, so long as there is a connection to the internet

The notifications that can be subscribed to are the:

- Time to change notification

Language

The language is selected by default when installing and first opening the Smartz™ app. The language of the interface can be changed within the settings menu.

Updates to the app

Occasionally, the Smartz™ app will require an update. Ensure that when the update is in progress that the device is connected to the internet at all times to prevent the risk of errors. Devices that are linked must be updated independently.

3.5 Understanding the Smartz™ System Features & Notifications

The Smartz™ app is used to monitor the wellness features of the Patient.

Wetness

The Smartz™ app will show the following status based on wetness detected:

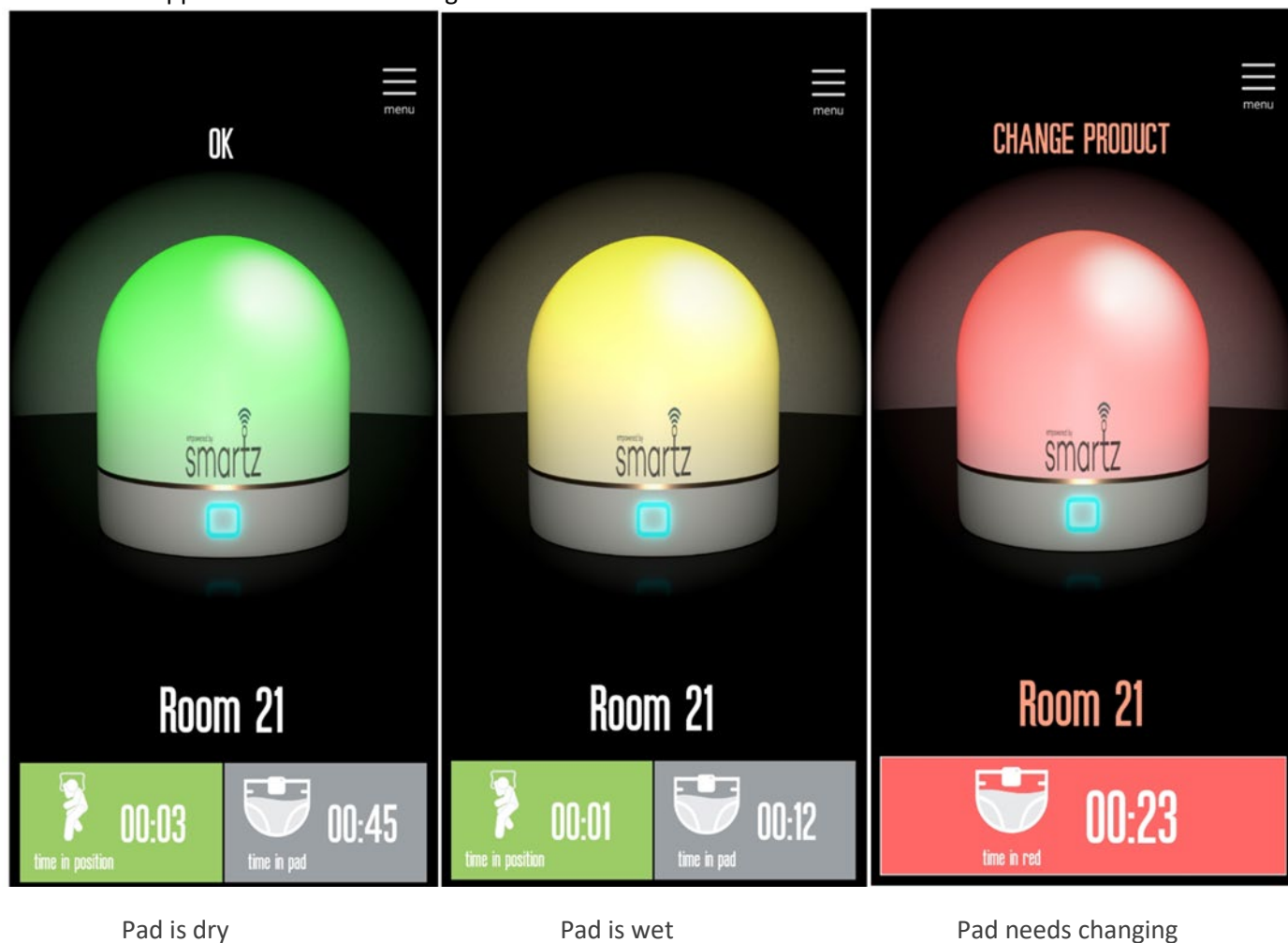


Figure 11. Traffic light display for time to change

The following are recommended actions based on the status shown

Table 6. Traffic Light

Status Colour	Action	Description
Green	No action required	Pad is mostly dry
Yellow	No action required	Pad is wet
Red	Change product	Pad has reached risk of leakage threshold

Time in pad

Time in pad is shown to indicate how long the Patient has been in the same pad.

Time in red

Time in red indicates how long the red status has been displayed.

Time in Position

Time in position indicates how long the Patient has been in one position. The positions recognised are sitting, standing, lying on back, lying on their front and lying on either side.

Falls Detection

When a patient is falling, the pod detects this motion and a notification is received by the mobile device. The fall detection is indicated to the user in the app.



Ambient Temperature

Ambient temperature indicates the approximate temperature of the pod surroundings to within +/-2°C. The units of Degrees Celsius or Degrees Fahrenheit can be changed in the settings Menu.

Notifications

There are a series of other warning notifications aside from the regular features monitoring as described in the table below which appear in priority order.

Table 7. Notifications

Notification	Description
	<p>This occurs when there are no Patient pods connected to the smart device app.</p>
	<p>This occurs when the battery is low and requires either to replace the battery as per <i>3.1 Battery Installation & Replacement</i>.</p>



This occurs when the Pod is no longer clipped to the Patient's pad when in range.

Ensure the pod is correctly attached to the Patient's pad.



This occurs when the pod is not in range, or, if it is in range, the battery is completely drained.

Bring the pod into range or replace its battery if it is in range and this message appears. See *3.1 Battery Installation & Replacement*.

3.6 Smartz™ dashboard

Using the Smartz™ dashboard

Note: to use the dashboard, there must be an internet connection via the Smartz™ node. The setup of the Smartz™ node is not included as part of the scope of this User Manual and is assumed to be setup.

The Smartz™ dashboard can be accessed on any device (such as a desktop, laptop or tablet) with a secure login via: <http://dashboard.smartzhhealth.com/>

Please note that it is strongly recommended that the device used for monitoring is always charged so that it can be used for monitoring 24/7.

The login is the same as the user credentials set up on the app (see section 3.4).

The dashboard is a website that allows multiple Patients to be monitored via a web browser. This is useful in facilities where many Patient Smartz™ pods require monitoring at once, for example, in the Carer's staff office or common room.

Note: The smart devices must be linked to the Smartz™ cloud as per *Linking Monitors* section with an assigned user account before the dashboard can be used.

An example of the dashboard is as below. It requires no user interaction apart from logging in and logging out or changing the interface language.

The layout of the dashboard includes the patients where 'time-to-change' is required on the left, all other wellbeing statuses in the centre and specific warning notifications of the pod status.

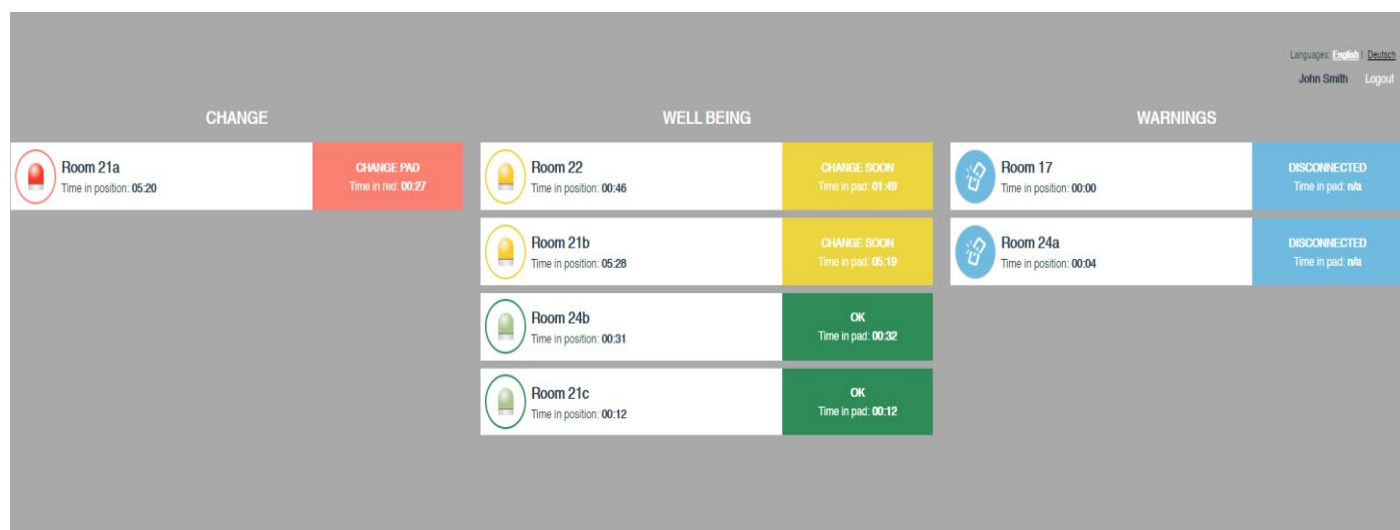


Figure 12. Dashboard

Troubleshooting the Smartz™ dashboard

Symptom	Corrective Action
Dashboard shows no Patient	<ul style="list-style-type: none">• Check Wi-Fi connection is on• Check the User is correctly logged in

	<ul style="list-style-type: none"> • The Monitor must be linked • Ensure node/mesh network is on and has connection to the internet
--	---

3.7 Smartz™ pod Cleaning Instructions

Smartz pod cleaning Guide

Simavita recognizes that cleaning and disinfection practices vary amongst Home and Care Facilities. It is not possible for Simavita to be responsible for the effectiveness of cleaning the Smartz components.

Smartz components that come into contact with Patients need to be disinfected after each use. Otherwise transmission of infectious agents to Patients may occur through direct contact with contaminated equipment.

The level of cleaning required depends on the objects involved and the risk of contamination e.g. Surfaces that are likely to be contaminated with infectious agents (e.g. shared clinical equipment) require cleaning between each use. The Smartz pod can tolerate up to 1000 cleaning cycles.

Recommended Cleaning Solution and Precautions

Simavita products are classified as non-critical items (NHMRC 2010) and can be cleaned with a pH neutral (mild) detergent designed for general purpose cleaning. In institutional environments, an existing infection control procedure may be followed providing that it does not involve soaking of the Smartz pod. Detergent impregnated wipes may be used to clean single pieces of equipment such as Simavita products with small surface areas.

CAUTION

- To prevent disease transmission, use disposable waterproof surgical gloves when handling contaminated Smartz pods.
- Do not soak the Smartz pod in water.
- The water temperature must not exceed 40°C or 104°F

Smartz pod Cleaning and Inspection

Clean and inspect the Smartz pod as follows:

1. ***The Smartz pod is IP54 rated for protection from water splashes from all direction, and dust ingress. However, it is not waterproof.***
2. *Clean the Smartz pod by wiping with cleaning solutions according to the above recommended cleaning Solutions.*
3. *Dry the Smartz pod thoroughly, especially around the gold pins.*
4. *Store in a cool, dry place free of dust and lint, with the clip lid closed, until next use.*

3.8 Disposal

This section describes the steps to safely dispose the Smartz™ components and accessories.

1. Smartz™ sensor pad

The Smartz™ sensor pad may pose a biohazard risk after usage. The Smartz™ sensor pad should be disposed of appropriately according the pad manufacturer instructions.

2. Smartz™ pod

The Smartz™ pod contains electronic parts and CR2016 Lithium batteries. These should be disposed of in accordance with WEEE 2002/96/EC European Directive. This stipulates the proper disposal of electrical and electronic equipment. These devices should be disposed of separately, not as unsorted municipal waste. To dispose of the device, 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. For more information on these disposal systems, please contact your local waste administration. The crossed-bin symbol invites you to use these disposal systems. If further information is required for the collection and disposal of Simavita devices, please contact Simavita.

The Smartz™ pod has a design life of three (3) years.

4.8 Standards and Compliance and IEC Certifications

The smartz pod was developed in accordance with pertinent North American and international standards

Description	Specification
Model Number	9000
Mode of operation	Continuous Operation
Protection against dust and water	IP 54
Applied Part	Type BF
Use in presence of flammable aesthetic mixtures	No
Suitable for sterilization	No

General & Collateral Standards- Smartz Pod

- Medical electrical equipment - Part1: General requirements for basic safety and essential performance IEC /EN 60601-1 (2005/2006 +C1+C2)
- Medical electrical equipment - Part1: General requirements for safety –collateral standard electromagnetic compatibility requirements performance IEC 60601-1-2:2015
- Medical Electrical Equipment-Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment, IEC 60601-1-11:2015

SECTION 4

TROUBLESHOOTING, CONTACT AND SUPPORT

4.0 Troubleshooting, Contact and Support

4.1 Troubleshooting Guide

Symptom	Corrective Action
No Green Light when clipped on to Smartz™ pad	<ul style="list-style-type: none">• Check alignment of the pod on the pad to ensure the three (3) data pins on the pod are lined up with the three (3) sensor stripes on pad and re-clip pod onto pad.• Change battery in pod as required
Smartz™ pod not detected by Smartz™ app	<ul style="list-style-type: none">• Ensure Smartz™ pod is within the same room as the smart device running the Smartz™ app <p>Note: Bluetooth has short transmission range and connection is affected by obstacles and other RF interference sources.</p> <ul style="list-style-type: none">• Check if Green light appears when clipping the Smartz™ pod onto Smartz™ sensor pad. If there is no green light after multiple clips, replace the battery in Smartz™ pod. If it still does not connect, contact Simavita
Monitor not showing app	<ul style="list-style-type: none">• Ensure continually on a power supply to ensure battery does not drain• Ensure all phone setting permissions to 'allow' for the app
App shows no Patient	<ul style="list-style-type: none">• Ensure pod is correctly connected to pad• Check Bluetooth connection on the device is "ON"• Ensure Smartz™ pod is within the same room as the smart device running the Smartz™ app <p>Note: Bluetooth has short transmission range and connection is affected by obstacles and other RF interference sources.</p>
App cannot be updated	<ul style="list-style-type: none">• Ensure the device has internet connection through Wi-Fi, 3G/4G/5G
App crashes suddenly	<ul style="list-style-type: none">• Close and re-open the app• Ensure the device is compatible with the latest version of the app
Time to change alert is inaccurate	<ul style="list-style-type: none">• Ensure the day/night products are correctly setup• Check whether the correct day/night product has been applied to the Patient• Check that the pod has been folded inwards toward the body once only
Body position indicator is inaccurate	<ul style="list-style-type: none">• Check that the pod has been folded inwards toward the body once only

4.2 Contact and support

Please contact Simavita or your authorized distributor via the contact information provided for assistance, if required, in setting up, using, maintaining or purchasing the Smartz™ system or to report unexpected operation or events.

If a serious incident as occurred in relation to using this device, this should be reported to the manufacturer below and to the relevant competent authority of the Member State in which the user or patient is established.

Customer Service Contact: Australia and New Zealand

Inside Australia Phone: 1300 SIM sen (1300 746 736)

Outside Australia Phone: +61 (2) 8405 6300

Email: customerservice@simavita.com

NOTE: Authorized distributors can be found at the website below:

Website: www.SmartzHealth.com

Appendix A

Smartz SPECIFICATIONS

5.0 Appendix A Smartz™ System Specifications

Smartz™ Physical Specifications

Description	Length (mm)	Width (mm)	Height (mm)	Weight (g)
Smartz™ pod (inc. battery)	40	38	9	16

Smartz™ Electrical Specifications

Smartz™ pod Replaceable Battery

Description	Specification
Brand	Panasonic CR2016
Chemistry	Lithium
Voltage	3.0 Vdc
Ampere Hour Rating	90 mAh

The battery typically has a life of 3 months

Smartz™ pod Bluetooth Specifications

The wireless specifications are as follows;

Description	Specification
BLE	Version 4/5
Frequency Band	2.400 – 2.485 GHz

WARNING

The Smartz™ pod may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

Smartz™ Software Specifications

Smartz™ app

Description	Specification
Name	SAS_LTC

Operating System	Android 9 or greater, Apple iOS
Version of app	1.0.7

Smartz™ dashboard specifications

Description	Specification
Dashboard URL	dashboard.smartzhealth.com
Browser	Google Chrome, Microsoft Edge, Internet Explorer and Safari
Version of dashboard	1.0

Smartz™ System Transport and Environmental Specifications

System components shall be capable of transportation and storage outside of its protective packaging at the following environmental limits;

- -25°C to +5°C without relative humidity control
- +5°C to + 35°C at a relative humidity up to 90%, non-condensing
- >35°C to +70°C at a water vapour pressure up to 50hPa

When connected to a sensor, the pod shall operate across the entire range of the following environmental conditions;

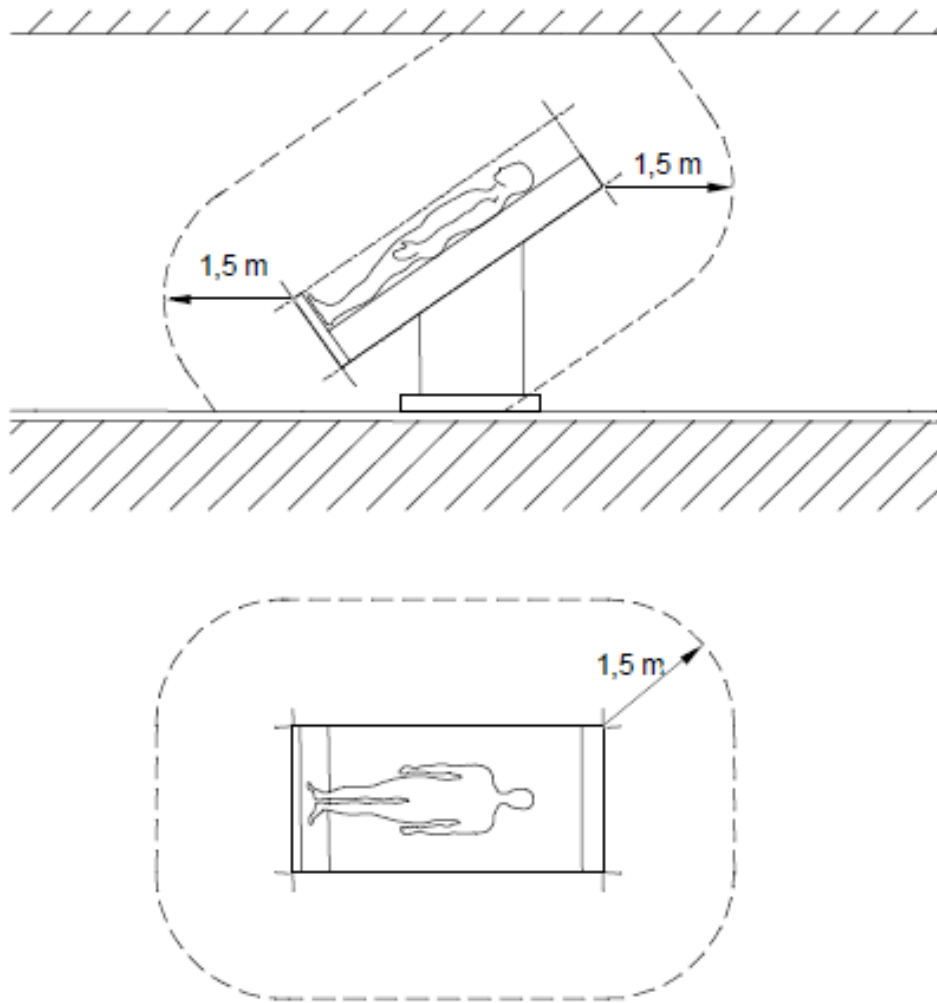
- a temperature range of + 5°C to + 40°C;
- a relative humidity range of 15 % to 90%, non-condensing but not requiring a vapour partial pressure >50hPa; and
- an atmospheric pressure range of 700 kPa to 1,060 kPa.

Smartz™ System Patient Environment

The Smartz™ system is Radio Equipment Device certified for use in a medical environment. Simavita has tested, certified and classified the Smartz™ pod as a Radio Equipment Device.

WARNING

1. In order to ensure that patient safety is maintained at all times, the Smartz pod or other electrical equipment must not be placed within the patient environment as defined and illustrated below.
2. In case of emergency, disconnect the equipment from power supply mains.
3. In order to ensure that patient safety is maintained at all times, the operator must not touch the Patient at the same time if the patient is connected to the Smartz pod and the sensor pad.



IEC 2431/05

⚠ WARNING

Portable and mobile RF communications equipment can affect the performance of the Smartz™ system. Install and use the system according to the information contained in this manual.

Appendix B

Smartz Accessories

5.0 Appendix B: Accessories

6.2 Smartz™ node

Smarztz™ node and Mesh Network Overview

A smart device with the installed Smartz™ application can pick up the short-range Bluetooth signals from the pod but does send data via Wi-Fi for data to display later on the dashboard. A Smartz™ node is used to convert the Bluetooth signal with a slightly more extended range and transmits this signal via a Wi-Fi signal or via an Ethernet cable to the internet. Multiple Smartz™ nodes can be used to form a 'mesh' network so that the range of this signal can be extended around a facility for enhanced signal coverage for Patient monitoring. The nodes should be strategically placed around the facility in order to extend the range, taking into account confined spaces around walls and open space areas. A typical maximum open range of a single node is 30 meters. The signal can extend for a maximum of 4 nodes in series. There is always one 'Master Node' that directly connects to the internet and this parent node collects data from all the other child nodes in the facility as a local network.

Smarztz™ node and Mesh Network Setup

Refer to the following page.

Smartz Mesh Setup Guide

Connect Master Node to Internet

What You Need



Ethernet Cable

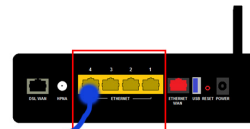


Node and Power Adapter

1. Connect the node to power



2. Using the Ethernet cable, connect the node to any spare Ethernet port at the back of your Internet Modem /Router or Switch port



3. Wait for the node to go solid or flashing Green as shown below



Connect Child Nodes to Master node

More nodes can be added as child nodes to improve signal strength after setting up the master node as above. To setup more child nodes,



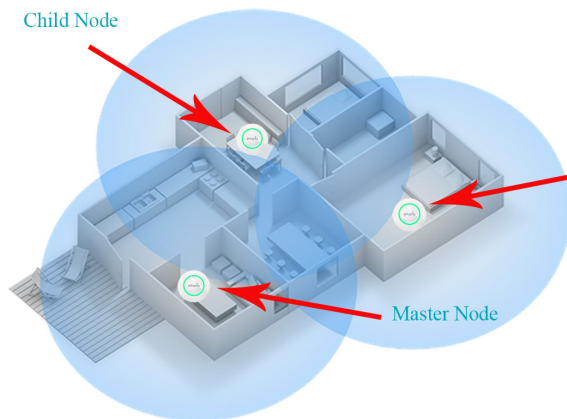
1. Connect the node to the power using the supplied power cable



2. Wait for the Node to become Solid Green or Flashing Green.

NOTE: If the node doesn't turn green in 15 Minutes please move the node closer to the MASTER NODE. Please see the diagram below for placement of the child nodes. The maximum distance between the child and master nodes should be 2 rooms. Nodes can also be mounted on the ceiling for improved coverage

Child Node



Child Node

Master Node

empowered by
smartz
Smart Diapers. Smarter Care.

Smartz™ node specifications

The Smartz™ node is an off-the-shelf hardware, customised firmware accessory.

Description	Specification
Simavita Product Name	Smartz™ Node
Simavita Product Number	02898

SMARTZ™ SYSTEM MANUFACTURER DECLARATION

FCC COMPLIANT STATEMENT

Changes or modifications not expressly approved by *Simavita could* void the user's authority to operate the equipment.

This device complies with Part 15 of 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

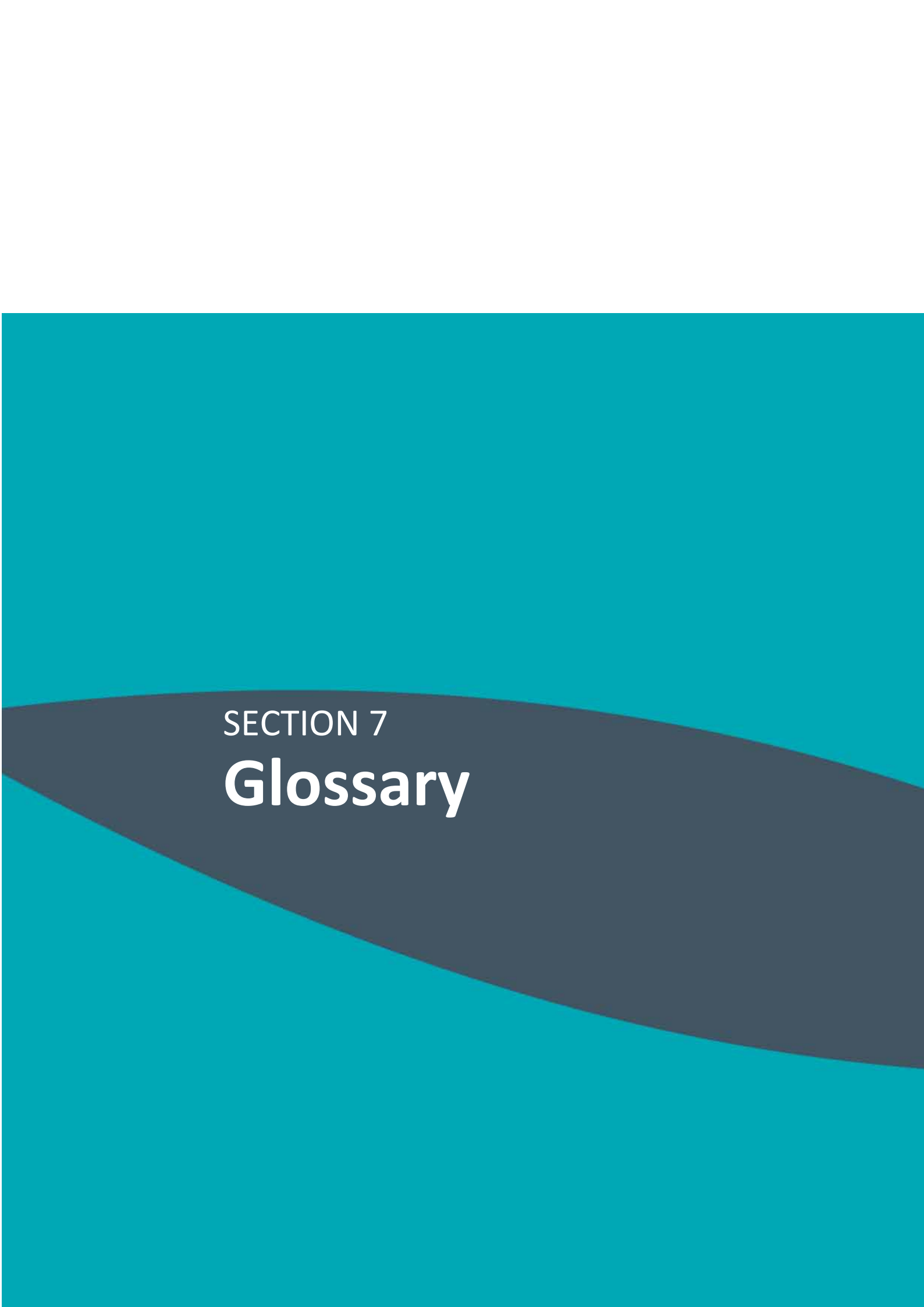
Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate 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.

DEVICES COVERED UNDER RSS

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions: 1. This device may not cause interference. 2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : 1. L'appareil ne doit pas produire de brouillage; 2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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SECTION 7

Glossary

7.0 Glossary

CE:

Conformité Européenne

FCC:

Federal Communications Commission

ID

Identification

IEC:

International Electrotechnical Commission

ISO:

International Organization for Standardization

IT:

Information Technology

MAC Address

Media Access Control Address

RCM:

Regulatory Compliance Mark

RF

Radio Frequency

SAS:

Smart Alert System

URL

Uniform Resource Locator

WEEE

Waste Electrical and Electronic Equipment



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