

powered by
smartz  **USER MANUAL**



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Table of Contents

Copyright Information	2
Table of Contents	3
Preface	4
Purpose of this manual.....	4
Qualification of Personnel	4
Warranty.....	4
Document Conventions	4
Accessibility of this Manual	4
1.0 Safety Information	6
1.1 Definitions.....	6
1.2 Warnings.....	7
1.3 Cautions	11
1.4 Symbols and markings	12
1.5 Labels	15
1.6 Patient Privacy and Security	17
2.0 Overview	19
2.1 What is the Smartz™ system	19
2.2 Indications for Use	19
2.3 Features	20
2.4 Benefits of the Technology.....	21
2.5 The Smartz™ System Components	21
3.0 User Instructions	27
3.1 Smartz™ pod Battery Installation & Replacement.....	27
3.2 The Smartz™ sensor pads	28
3.3 Clipping Smartz™ pod onto Smartz™ sensor pad	28
3.4 Smartz™ pod Indicator Light Colours.....	31
3.5 Using the Smartz™ monitoring apps.....	31
3.6 Understanding the Smartz™ System Features & Notifications.....	53
3.7 Smartz™ dashboard	59
3.8 Smartz™ pod Cleaning Instructions	65
3.9 Disposal.....	66
4.0 Troubleshooting, Contact and Support.....	69
4.1 Troubleshooting.....	69
4.2 Contact and support	69
5.0 Appendix A Smartz™ System Specifications.....	71
Smartz™ Physical Specifications	71
Smartz™ Electrical Specifications	71
Smartz™ pod Bluetooth Specifications.....	71
Smartz™ Software Specifications.....	72
Smartz™ System Transport and Environmental Specifications	72
Smartz™ System Patient Environment	73
6.0 Appendix B: Accessories.....	80
6.1 Smartz™ node	80
7.0 Glossary.....	84

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.



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. Smartz Operations Ltd., 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 Smartz Operations Ltd.

Warranty

Information regarding product warranty will be available from a sales representative or Smartz Operations Ltd.,

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 from the Smartz™ Monitoring app. A hard copy of this IFU can be requested free of charge by contacting Smartz Operations Ltd and may be delivered within up to 14 calendar days.

SECTION 1

SAFETY INFORMATION

1.0 Safety Information

1.1 Definitions

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



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.

1.2 Warnings

General Warnings Related to the Use of Smartz™



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 should 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 with 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 Smartz Operations Ltd.

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 and 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 3.4 Smartz™ pod Indicator Light Colours 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.

Patients may safely use all the functions of the pod described in this user manual when in use.

No parts of the Smartz™ system are intended to be supplied sterile.

For Smartz™ to work effectively the pad must 1) be capable of managing (acquiring and storing) typical void output from the individual when a fresh pad is applied; if in doubt larger capacity products should initially be used; and 2) the pad must be applied correctly as per manufacturer instructions as incorrectly fitted pads may result in leakage.

General Warnings Related to System Installation



The following warnings are related to the use of the device in reasonably foreseeable environmental conditions:

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



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 your 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.

The only servicing of the Smartz™ pod required by the operator is to replace the battery – refer to Section 3.1 Smartz™ pod Battery Installation & Replacement.

Warnings Regarding Oxygen



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



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.

Warnings Regarding Home Use



If sensors show signs of degradation, functional performance may be effected and device use should be discontinued

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.

In the event that pets, pests or children tamper with or affect the device, the performance of the device may be effected and device use should be discontinued. Store the device securely away from pets, pests and children when not in use.

The following warnings are related to the use of the device in reasonably foreseeable environmental conditions:

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 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.

1.3 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, analyse, evaluate and control these risks before connecting the Smartz™ system to the network.







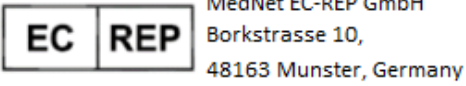

Changes to the IT network including but not limited to changes in the IT network configuration, connection of additional items to the IT network, disconnection of items from the IT network, the update of equipment connected to the IT network and upgrade of equipment connected to the IT network, could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




1.4 Symbols and markings

Table 1. Symbols

Symbol	Description
	IEC 15223 -1General Warning sign. This symbol accompanies WARNING in Smartz Operations Ltd 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 3.9 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,

	<p>including interference that may cause undesired operation.</p> <p>This FCC ID appears on the pod Label.</p>
<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 Section 1.5 Labels Error! Reference source not found.</p>
	<p>Indicates the acceptable humidity range for transport and storage.</p> <p>This symbol appears on the Smartz™ pod packaging label.</p>

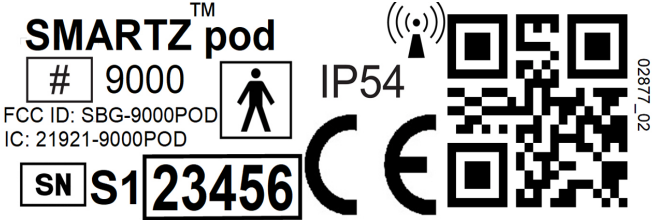
	Refer to Section 1.5 Labels Error! Reference source not found.
	Indicates that the device is a Medical Device. This symbol appears on the Smartz™ pod Packaging label.
	IEC 15223-1 Device Manufacturer The symbol appears on the Smartz™ pod Package Label.
	The date when the Smartz pod was manufactured. The symbol appears on the Smartz™ pod Package Label. The date will be adjacent to the symbol in the YYYY-MM format.
	IEC 15223-1 Manufacturers Catalogue Number This symbol appears on the Smartz™ pod Packaging Label.
	IEC 15223-1 Indicates electronic instruction for use This symbol appears on the Smartz™ pod Package label.
	IEC 60417-5333 Type BF Applied Part This symbol appears on the pod label.
	European Authorized Representative This symbol appears on the Smartz™ pod Package label , Shipper carton label and in the user manual.
	Model Number This Symbol appears on the pod label and package labels

	<p>Country of Manufacture</p> <p>This Symbol appears on the Pod package label</p>
	<p>Unique Device Identifier</p> <p>This symbol appears on the Pod package label</p>
 <p>TRANSLATED S.R.L. VAT number IT07173521001 R.E.A. 1015467 Registered Office: Via Indonesia 23 - 00144 Roma (Italy) Headquarters: Via Nepal 29 - 00144 Roma (Italy)</p>	<p>Translation</p> <p>This Symbol appears in the User manual</p>

1.5 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

Label	Description	Location
	<p>Smartz™ pod Label</p>	

<p>powered by smartz™ # 9000</p> <p>UDI</p> <p>Contents 2 x Smartz pod</p> <p>SN S000A33 SN S000A54</p> <p>2 x CR2016 Battery</p> <p>(01) 0 9342124 00071 1 (21) S000A33 (21) S000A54</p> <p>MD</p> <p>0% 90% +70°C +158°F -20° -4°F</p> <p>POL YYY-MM</p> <p>EC REP MedNet EC-REP GmbH Borkstrasse 10, 48163 Munster, Germany</p> <p>Smartz Operations Ltd Suite 2.0.2, L2,54 Miller St. North Sydney, NSW 2060, Australia. www.smartzhealth.com 02886_05</p>	<p>Smartz™ pod Packaging Label</p>	<p>Packaging box.</p>
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<p>powered by smartz™ # 9000</p> <p>Contents: 48 x Smartz pods</p> <p>UDI</p> <p>(01) 0 9342124 00072 8</p> <p>90% 0% +70°C +158°F -25°C -4°F</p> <p>EC REP MedNet EC-REP GmbH Borkstrasse 10, 48163 Munster, Germany</p> <p>Smartz Operations Ltd Suite 2.0.2, L2,54 Miller St., North Sydney, NSW 2060, Australia. www.smartzhealth.com</p> <p>02884_04</p>	<p>Smartz™ Shipper Box Label</p>	<p>Shipper Box</p>
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<p>powered by smartz™ # 9000</p> <p>Contents: 480 x Smartz pods</p> <p>UDI </p> <p>(01) 0 9342124 00074 2</p> <p>  </p> <p>EC REP MedNet EC-REP GmbH Borkstrasse 10, 48163 Munster, Germany</p> <p> Smarz Operations Ltd Suite 2.0.2, L2,54 Miller St., North Sydney, NSW 2060, Australia. www.smarzhealth.com</p> <p> 0% 90%  -25°C -4°F +70°C +158°F </p> <p> </p> <p>02924_04</p>	<p>Smarz™ Carton Box Label</p>	<p>Carton Box</p>
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1.6 Patient Privacy and Security

Users are required to accept the EULA (end user licence agreement) and read the privacy policy prior to using the product. All patient data is held on secure Smartz™ cloud servers. It is the responsibility of the User to review their Patient’s personal and consent data approximately every 6 months. It is the responsibility of the User to ensure that the physical security of all devices used for Smartz™ monitoring is maintained. The privacy policy and EULA can be accessed at: <https://smartzhealth.com/downloads/>

SECTION 2
OVERVIEW

2.0 Overview

2.1 What is the Smartz™ system

Smarztz™ is a safe, smart solution for aged care capable of monitoring 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. Data is transmitted safely and securely from the Smartz™ pod to the Smartz™ app for processing and display.

2.2 Indications for Use

Smarztz™ 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.

Intended User Population

The operator of the device may be the Carer or the Patient.

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 should be changed. Carers are notified via the app based on a 'traffic light' system which indicates; Green light – pad dry, Yellow light – some wetness in pad, and Red – pad reaching 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 current body position of the patient. The positions 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 tracked include lying down on back, lying on stomach, lying on one side, sitting and standing.

Surrounding Pod Temperature – Indicates the approximate temperature of the pod's surrounding environment (i.e. ambient temperature surrounding the pod).

Note: This temperature feature is not intended to measure the physiological temperature of the Patient.

Falls Detection – Indicates whether the Patient has fallen over.

Pad Fill Profile – Droplets indicate pad volume of the chosen date range. The Average volume for the time period is also shown in the chart.

Voiding Chart – A chosen date range provides a history of voids of different droplet sizes, new pad, pad removed, pod unclipped, wetness outside pad, no pod data and time to change status.

Position Chart – This chart shows the position and recorded time in position of the Patient as detected when the Smartz™ pod is clipped on the Smartz™ pad.

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 Smartz™ delivers 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 described in the following table:

Table 3. System Components

Component	Description	User interaction
<p>Smartz™ pod</p>	<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.</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> <div data-bbox="496 737 967 1045" data-label="Image"> </div> <p style="text-align: center;">Figure 2. Smartz™ pod</p>	<p>Carer, Patient</p>
<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>	<p>Carer</p>

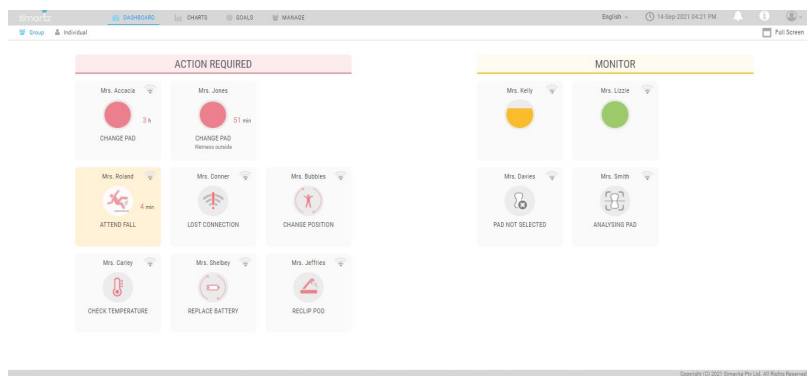


Figure 3. Smartz™ App

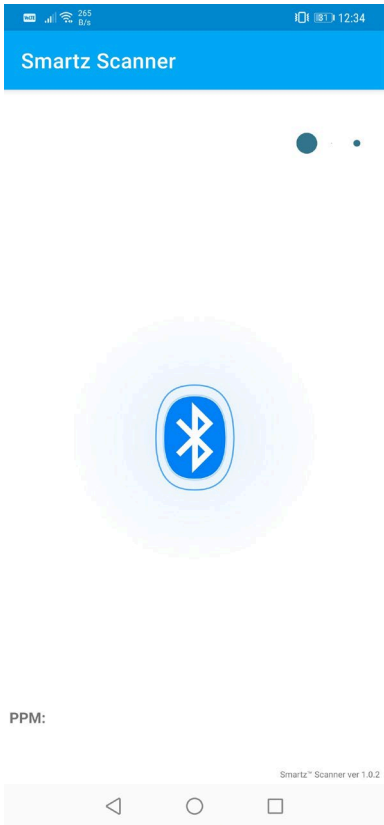
Smartz™ dashboard

A website that allows monitoring of multiple Patients at once on a smart device, such as a desktop PC, laptop or iPad, giving a holistic view for Carers.

Carer



Compatible component for the Smartz™ System		
Smarz™ pad*	<p>Disposable Single-Patient-use continence pad (diaper), with an integrated wetness Smartz™ sensor technology for daily use.</p> <p>The Smartz™ sensor pad consists of a standard continence pad (diaper) with printed sensors in the form of 3 lines. The sensor has 2 sets electrodes for improved reliability and coverage. The sensors detect the accumulation of liquid in the diaper over time.</p>	Carer, Patient
Accessories to the Smartz™ system (refer to Appendix B for instruction for use of these accessories)		
Smarz™ node*	<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> <div data-bbox="488 827 983 1146" data-label="Image"> <p>The image shows a circular, white, dome-shaped device with a green ring around the top edge. The word 'smartz' is printed in the center of the top surface, accompanied by a small antenna icon. The device has a small, dark, rectangular protrusion at the bottom, likely a port or connector.</p> </div> <p data-bbox="655 1245 804 1268">Figure 4. Node</p>	Carer, (or IT staff during setup)

<p>Smartz™ Scanner app</p>	<p>A mobile app that runs in the background of the user's phone that receives Bluetooth pod signals and forwards them via the internet to the Smartz™ Cloud. It is a software accessory to the system as it only transmits data from the pod to the cloud and does not perform a medical purpose on its own, nor does it create information on its own for one or more medical purposes.</p> 	<p>Carer or IT staff</p>
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***Note:** The Smartz™ pad and the Smartz™ node are not manufactured by Smartz Operations Ltd. The Smartz™ pads are manufactured by the pad manufacturer that the Smartz™ system was supplied with.

SECTION 3

USER INSTRUCTIONS

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.

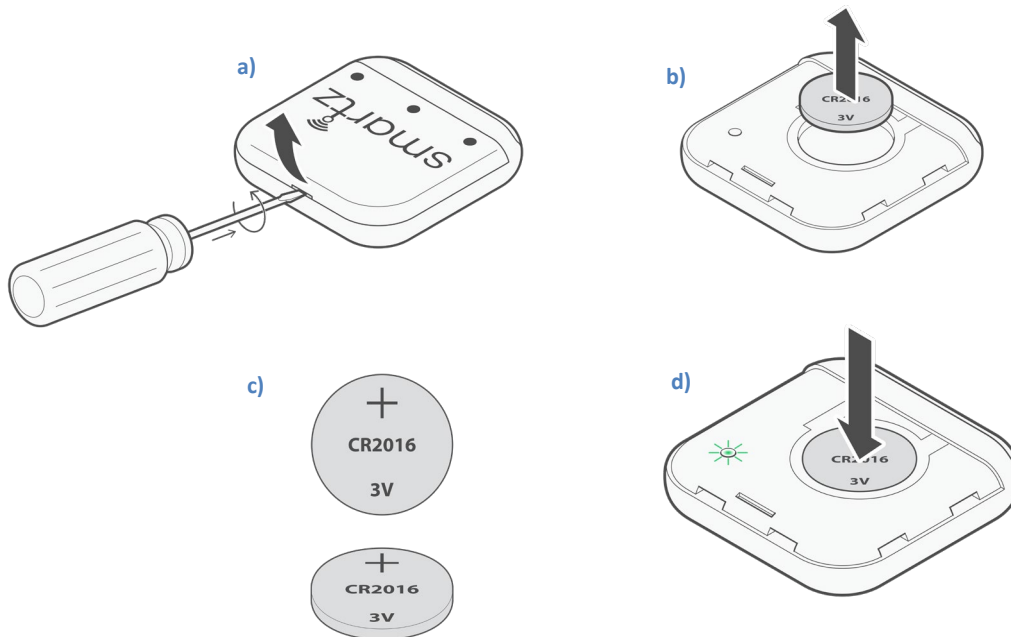


Figure 5. Battery Replacement

4. The light on the Smartz™ pod will flash green momentarily to indicate that battery has been installed correctly. For all other pod LED light instructions, refer to Section 3.4 Smartz™ pod Indicator Light
5. Gently slide the battery compartment closed until it clicks shut.

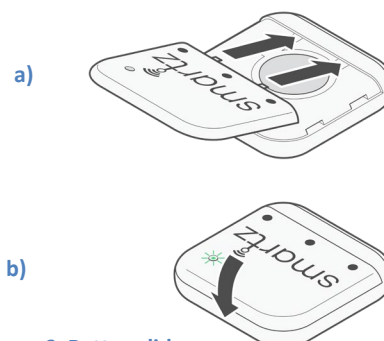


Figure 6. Battery lid

3.2 The Smartz™ sensor pads

The Smartz™ system, consisting of the Smartz™ pod and Smartz™ software, is intended to be used with Smartz™ sensor technology applied to compatible pads. Smartz™ will not function without a compatible and validated Smartz™ sensor pad. The Smartz™ sensor pads are supplied from your pad manufacturer or distributor. To identify compatible Smartz™ pads for use with this Smartz™ system, identify:

- The Smartz™ branding and logo from your pad manufacturer's package labelling as pictured below.

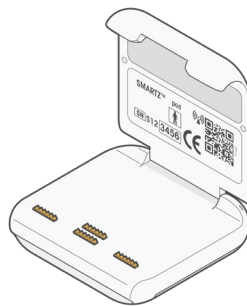


- The pad manufacturer code supplied by your pad manufacturer/distributor (a 4-digit number entered into the Smartz™ mobile monitoring app when first creating a patient). This will unlock all the compatible pads, identifiable through the pad description, within the app that can be used with your Smartz™ system. Refer to 'Manage Patients' in Section 0 3.5 Using the Smartz™ monitoring apps.

3.3 Clipping Smartz™ pod onto Smartz™ sensor pad

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

- Open the Smartz™ pod – take note of the unique pod serial number on the inside of the lid as it is needed when setting up the Patient on the app.



- Line up the three (3) stripes of the Smartz™ sensor pad with the three (3) gold pins on the Smartz™ pod and clip the Smartz™ pod onto the front of the Smartz™ sensor pad ensuring that the (3) dots line up with the (3) stripes after clipping.

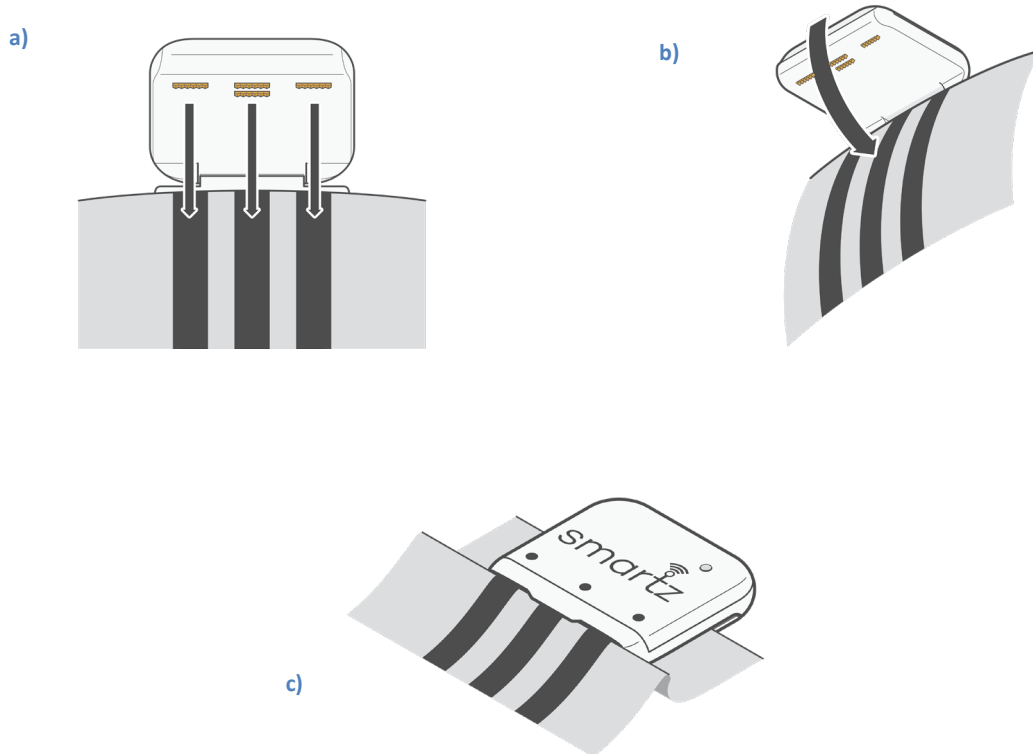


Figure 7. Clip onto pad location

- The light on the Smartz™ pod flashes green quickly for 3 seconds, then flashes solid green for 1 second to indicate that it has been clipped onto the Smartz™ sensor pad correctly. For a complete list of pod LED light instructions, refer to Section 3.4 Smartz™ pod Indicator Light

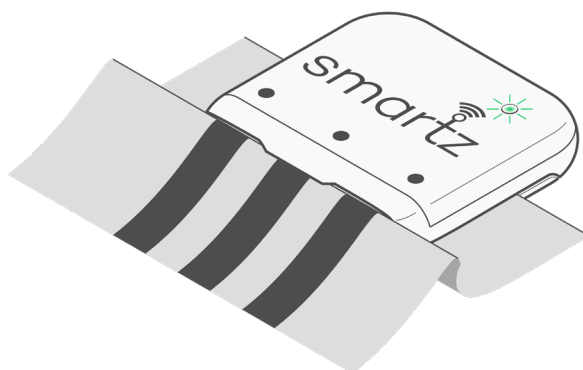


Figure 8. Pod Light will flash

- **Note:** If the light does not flash green, then unclip and re-clip the Smartz™ pod.
- For correct operation, the Smartz™ pod must be attached to the Smartz™ sensor pad and worn around the waist region. The Smartz™ pod should 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.

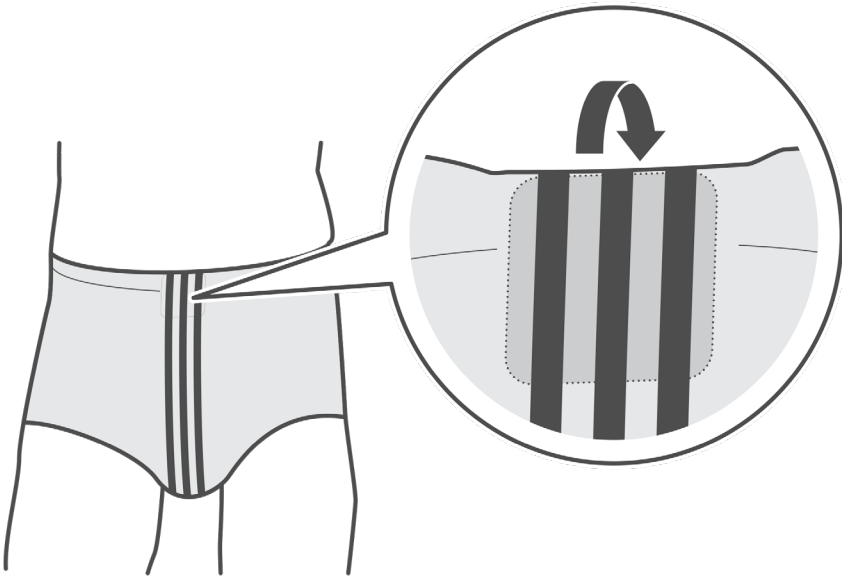


Figure 9. Flip pod inwards towards body once and tuck in securely

3.4 Smartz™ pod Indicator Light Colours

The following 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
Smartz™ pod has been correctly clipped onto pad	Flashes green quickly for 3 seconds. Then flashes solid green for 1 second.	Smartz™ sensor pad connected
Default state	Off	No action required
Low Battery	Red flashes	Replace Battery
Dead Battery	Off <i>(when connecting pod to pad)</i>	Replace Battery or replace Smartz™ pod

3.5 Using the Smartz™ monitoring apps

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.

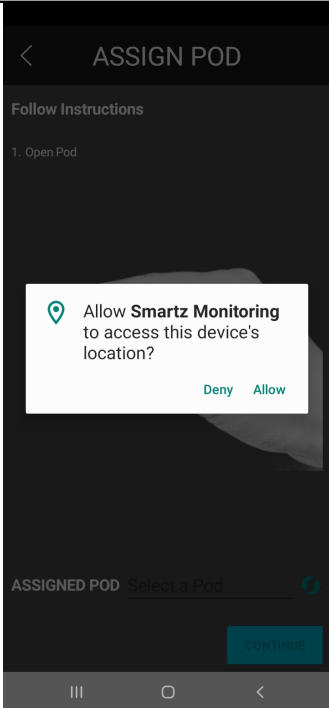
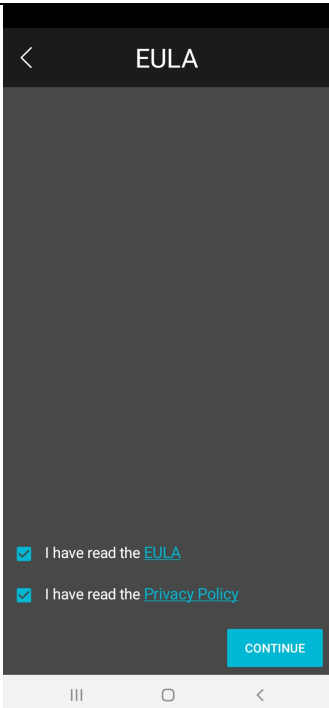
First opening the app and set up

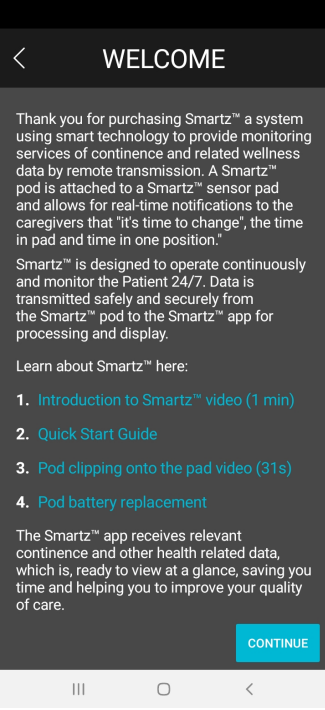
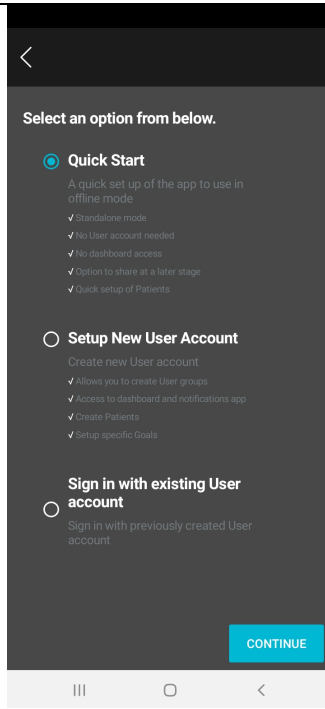
Ensure that the Wi-Fi (or 3G/4G/5G) and Bluetooth of the smart device are turned on and remain on during the lifetime of using the Smartz™ system. This is required for proper and full functioning of the Smartz™ System. If these are not available, some of the functionalities may not be available, such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

Ensure the time-zone is set to your location of use. This may be done using the automatic time-zone setting on your phone settings, depending on your network coverage.

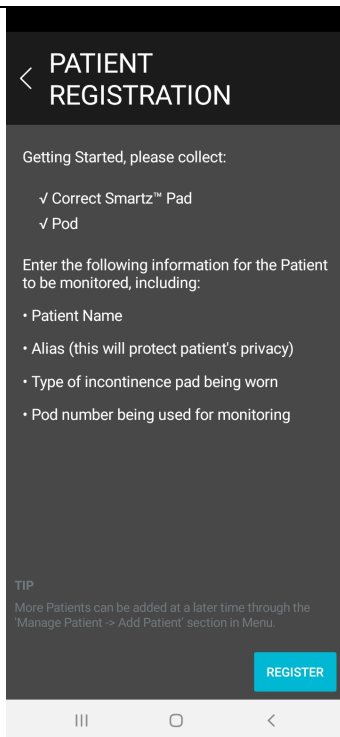
When the app is first opened, choose the language and then there are a series of welcome screens with information and videos to help with set up. Follow the instructions on screen.

Table 5. Setup of the app

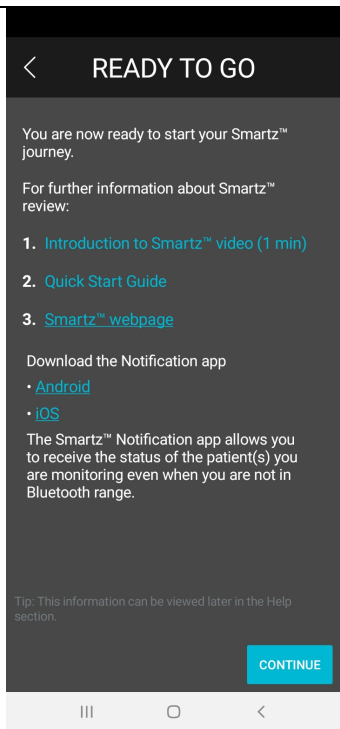
Screen	Image
Allow Access	 A screenshot of a mobile application screen titled "ASSIGN POD". At the top left is a back arrow. Below the title, it says "Follow Instructions" and "1. Open Pod". A white dialog box is centered on the screen with a location pin icon and the text: "Allow Smartz Monitoring to access this device's location?". Below the text are two buttons: "Deny" and "Allow". At the bottom of the screen, there is a section labeled "ASSIGNED POD" with a dropdown menu showing "Select a Pod" and a refresh icon. A blue "CONTINUE" button is at the bottom right. The Android navigation bar is visible at the very bottom.
Accept EULA & Privacy	 A screenshot of a mobile application screen titled "EULA". At the top left is a back arrow. Below the title, there are two checkboxes, both of which are checked. The first checkbox is followed by the text "I have read the EULA ". The second checkbox is followed by the text "I have read the Privacy Policy ". A blue "CONTINUE" button is located at the bottom right of the screen. The Android navigation bar is visible at the very bottom.

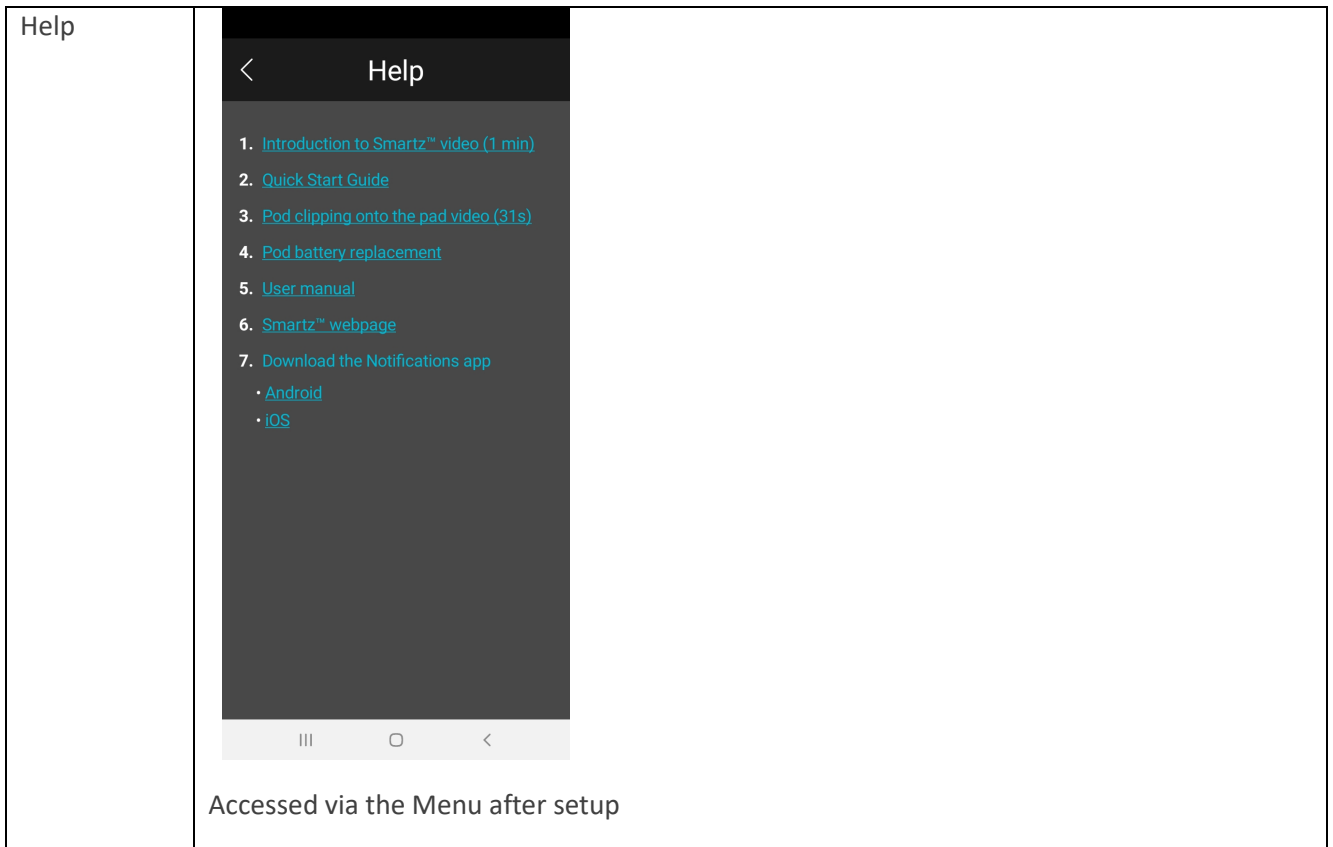
<p>Welcome</p>	 <p>The screenshot shows a mobile app interface with a dark background. At the top, there is a back arrow and the word 'WELCOME' in white. Below this, there is a paragraph of text explaining the Smartz™ system. This is followed by a section titled 'Learn about Smartz™ here:' with a numbered list of four items: 'Introduction to Smartz™ video (1 min)', 'Quick Start Guide', 'Pod clipping onto the pad video (31s)', and 'Pod battery replacement'. Another paragraph of text follows, and at the bottom right, there is a blue 'CONTINUE' button. The bottom of the screen shows a white navigation bar with three icons: a hamburger menu, a circle, and a back arrow.</p>	
<p>Set up a Standalone or Shared Device</p>	 <p>The screenshot shows a mobile app interface with a dark background. At the top, there is a back arrow. Below it, the text 'Select an option from below.' is displayed. There are three radio button options: 'Quick Start' (which is selected), 'Setup New User Account', and 'Sign in with existing User account'. Each option has a list of bullet points describing its features. At the bottom right, there is a blue 'CONTINUE' button. The bottom of the screen shows a white navigation bar with three icons: a hamburger menu, a circle, and a back arrow.</p>	

Register a Patient (see Section Manage Patients)



Ready to go





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. These options are available when setting up the app for the first time.

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

Using the device as a standalone Monitor

In this mode, the data from the monitoring device is not shared with other devices and does not require a user account, so access to cloud functionality is limited. That is, there is no access to the Smartz™ dashboard or Smartz™ Notification app. This mode is beneficial for Carers who wish to monitor one or several Patients in a small area on one device and do not wish to have additional dashboard and push notifications functionality.

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

Refer to 'Smartz™ Membership' Section.

Manage Patients

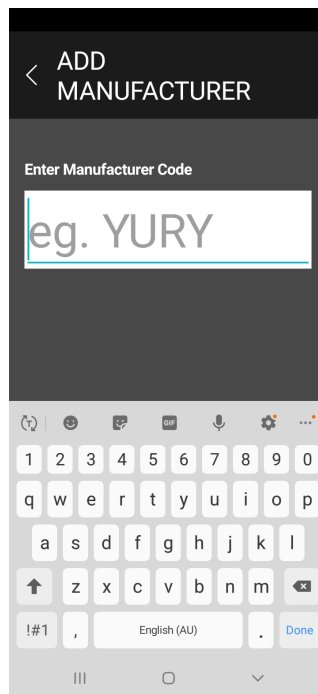
Patient details must be set up on the app. Patients to be monitored must be assigned a Smartz™ pod using the unique pod serial number found on the inside of the pod lid.

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

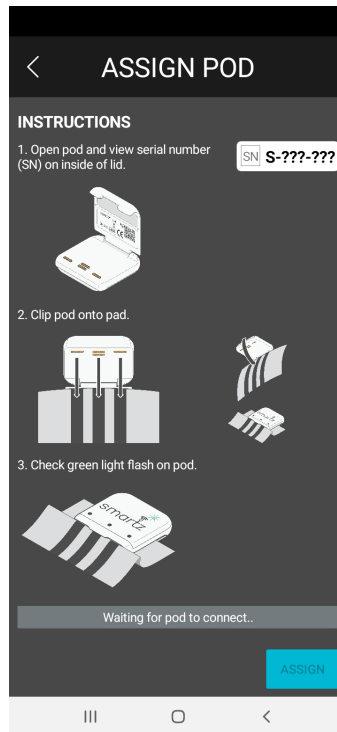
- Go to Menu Tap “Manage Patients”
- Tap “Add Patient”
- Enter the Patient Name and Display Name
- **Note:** Only the Display name is displayed on all software interfaces. It can be any unique identifier for the Patient. This allows for Patient privacy throughout the system.
- For example, when the system is being used in a group setting, the “Display Name” is required for Patient privacy – the Display used could be the Patients room number.

The screenshot shows the 'ADD PATIENT' screen in the Smartz app. The screen is dark-themed. At the top, there is a back arrow and the title 'ADD PATIENT'. Below the title are two text input fields: 'Patient Name' with a placeholder 'firstname lastname' and 'Display Name' with a placeholder 'e.g. initials, room number'. Underneath is a blue link labeled 'Add Manufacturer'. The 'Products Used' section contains two rows: 'DAY' and 'NIGHT'. Each row has a 'Time' field with two dropdown menus (e.g., '8 am' to '9 am'), a 'Manufacturer' dropdown menu (set to 'None'), and a 'Product' dropdown menu (set to '(tap to select)'). At the bottom, there is a 'Pod' field with a text input area and a blue 'ADD' button.

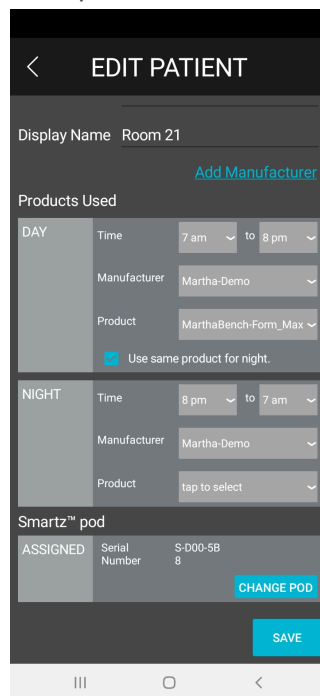
- You will need to tap on ‘add Manufacturer’ and type in the code – this will allow you to choose the Manufacturers products from the dropdown list. This code will be supplied by your pad manufacturer/distributor.
- All compatible pads from supplied by this pad manufacturer with the Smartz™ sensor technology will now be unlocked and identifiable by the pad description. Multiple codes may be entered to unlock more pad types.



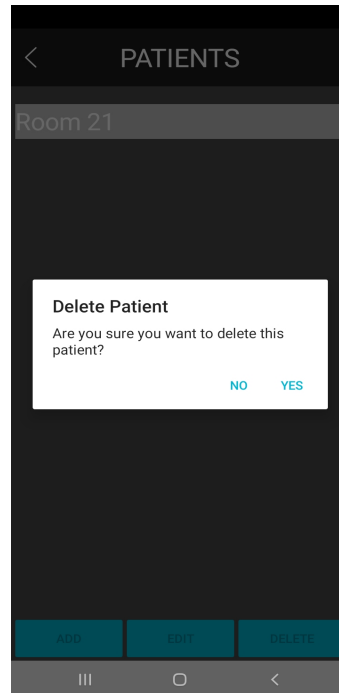
- Enter the products this Patient uses for the Day pad and Night pad variations and tap “Add” after selection
- Define the Day and Night times for an individual Patient for when they are expected roughly to change from a day pad to a night pad and from a night pad to a day pad
- The Smartz™ pod which was last connected to the Smartz™ sensor pad and was allocated to the Patient will be displayed in the Pod Assigned window
- Tap the ‘Change Pod’ button in order to assign a different Smartz™ pod
- Read the Smartz™ pod number on the inside of the pod e.g. SN S-000-050. The Smartz™ pod will need to be attached to the Smartz™ sensor pad in order for the phone to pick up the unique pod number.
- Assign the uniquely identified Smartz™ pod by tapping “Assign”. If the Smartz™ pod is not showing, check that the pod is close enough to the phone and that the Smartz™ pod has been correctly connected to the Smartz™ sensor pad.



- If the pod number does not appear, unclip and re-clip the pod to the pad
- To save Patient details, Tap “ADD” on the bottom right of the screen
- 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, highlight the Patient name, tap “Edit” and make the changes and tap “SAVE”.



- To delete (remove) a Patient from the smart device, select the Patient to delete (remove) and tap “Delete”.



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 depending on the cycle mode option which has been selected. The notifications are prioritised depending on the events occurring across the shared Patients.



In **cycle mode** the app will continue to change the monitoring screen automatically to the next Patient but displays only the highest priority Patients in the cycle. The notifications described in Section 3.6 show the priority of status display, followed by the red time-to change, yellow and then green state. i.e. Patients who are displaying 'Green' on their monitoring screen will not be shown if there are any other high priority notifications in that group of Patients.

By choosing the **lock mode**, the app will remain on the selected patient's monitoring screen.

Other Patient's monitoring screens can be viewed by selecting the back and forth arrows to manually cycle through the Patients in this group, regardless of status priorities.

When there is only one patient on a phone, there is no lock and cycle feature.

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 Notification Section)

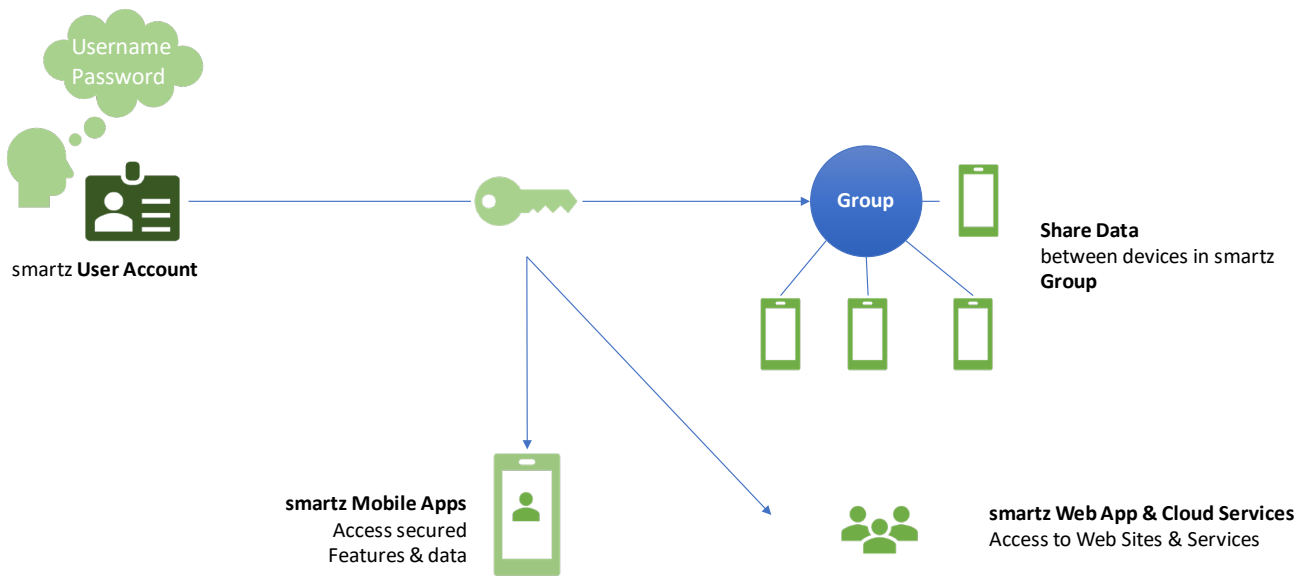
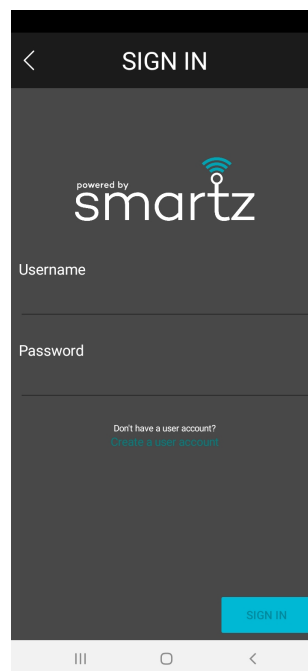


Figure 10. Data Access & Sharing with a Membership User Account

Data can be shared by forming Groups. A group is a set of Patients that may be categorised based on the user’s choice. 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.

- Go to “Menu”
- Tap “Manage User”



- Either create a new User account or log in with your existing account. Note that you may have already created a User account or signed in to an existing User account when first starting the app on a fresh monitoring device. In this case, you will see your existing user credentials on this page.

- 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.
- The User group name is shown in the highlighted box and can be renamed.
- You will be prompted to use these login credentials for the Dashboard or Notification app.

CREATE USER

Username
deb

Email
deb@gmail.com

Password
.....

Repeat Password
.....

This User group will be named:
Group-deb

TIP
Tap into the highlighted box to rename the group e.g. floor 1

Creating a User account allows you to generate Groups, manage groups of Patients and log in to internet services e.g. dashboard, notification app and User Manual.

ADD

- Tap “ADD”
- You will be prompted to either add a patient OR tap “Use Share Code” if you want to share your device

CREATE USER

Add Patient
Add new patient

Use Share Code
Use share code to share data with other devices

CONTINUE

- The User is now added. Multiple Users can be added to a smart device via the Smartz™ app.

Note: 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.

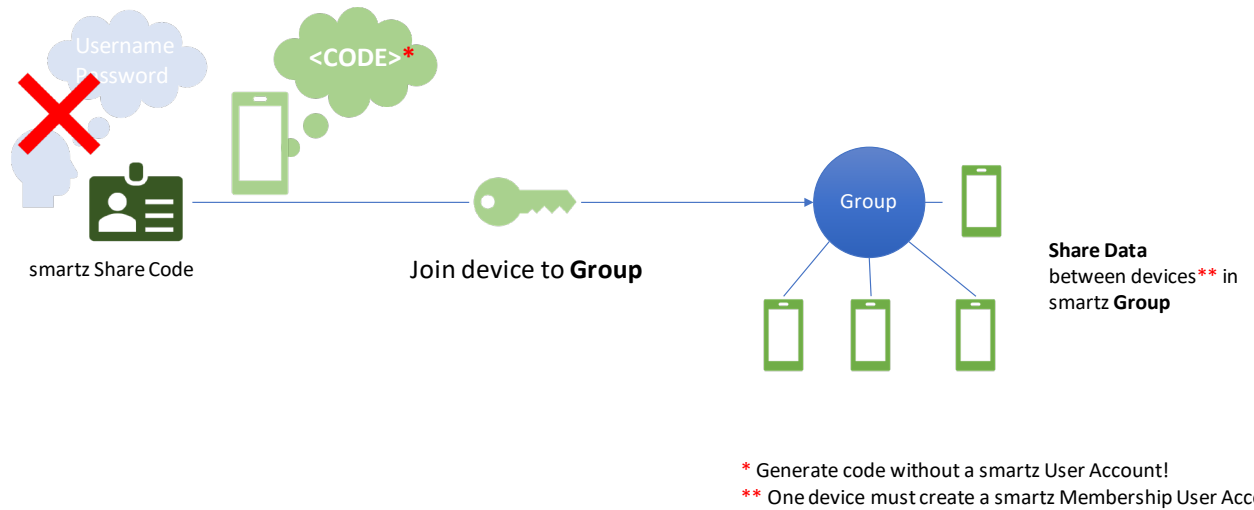
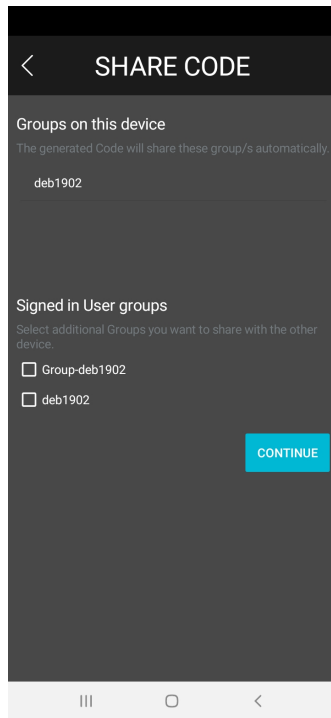


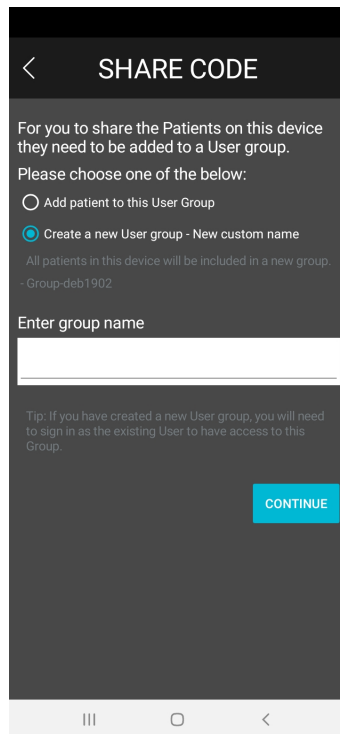
Figure 11. Data Sharing with a Membership Share Code

To enable this sharing:

- Go to “Menu” on one of the smart devices intended to be shared to the group
- If the device already has a group by default or more than one group:



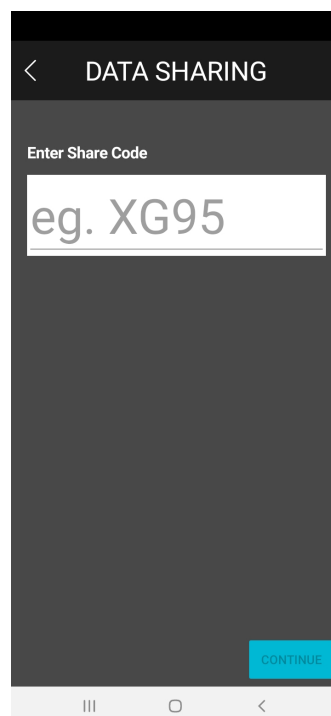
- If the device has no group yet:



- Tap “Get Share Code”



- **For security reasons the code only lasts 10 minutes!** Otherwise, a new Share code will have to be generated.
- On the other smart device, go to Menu and tap *Share Data*.

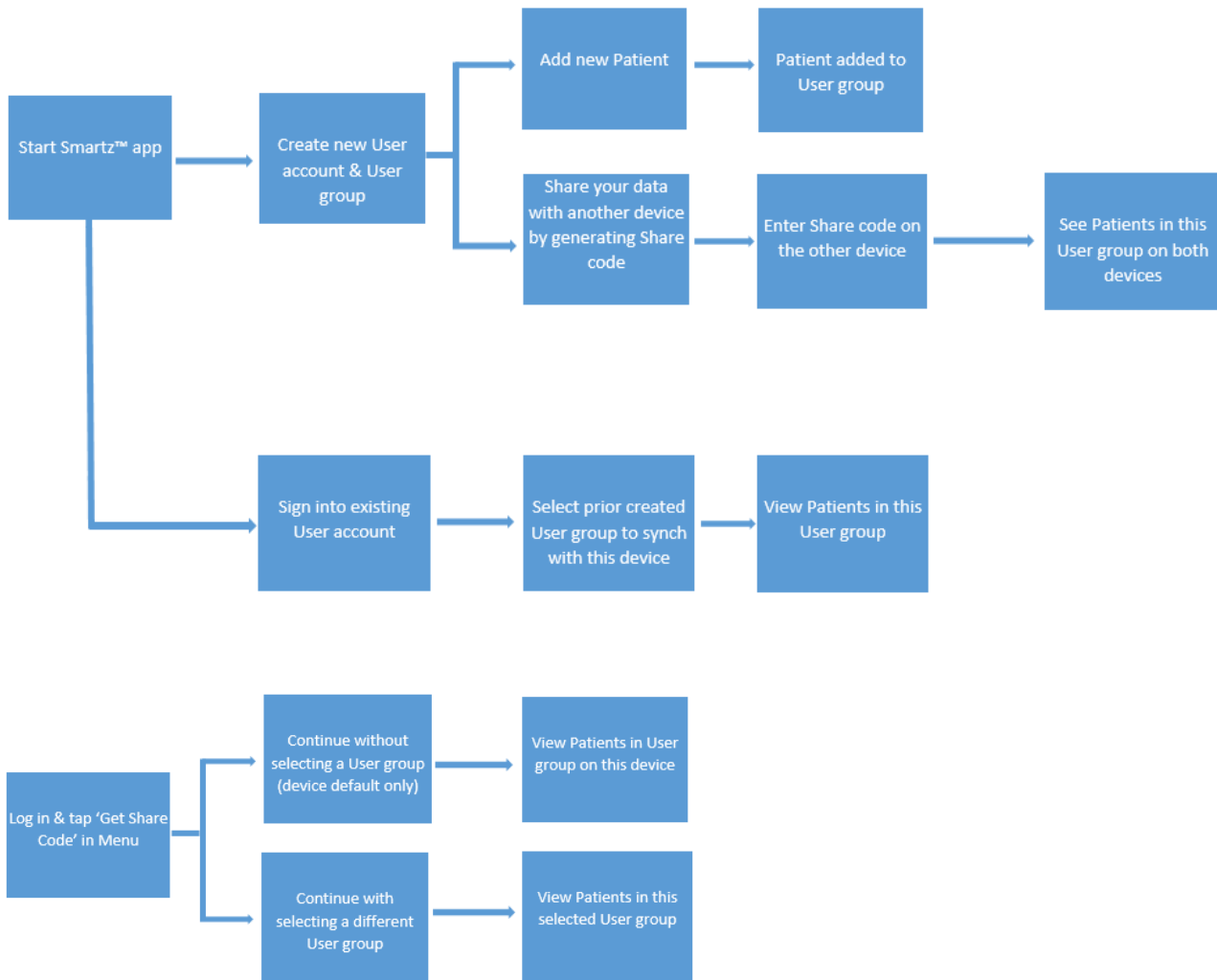


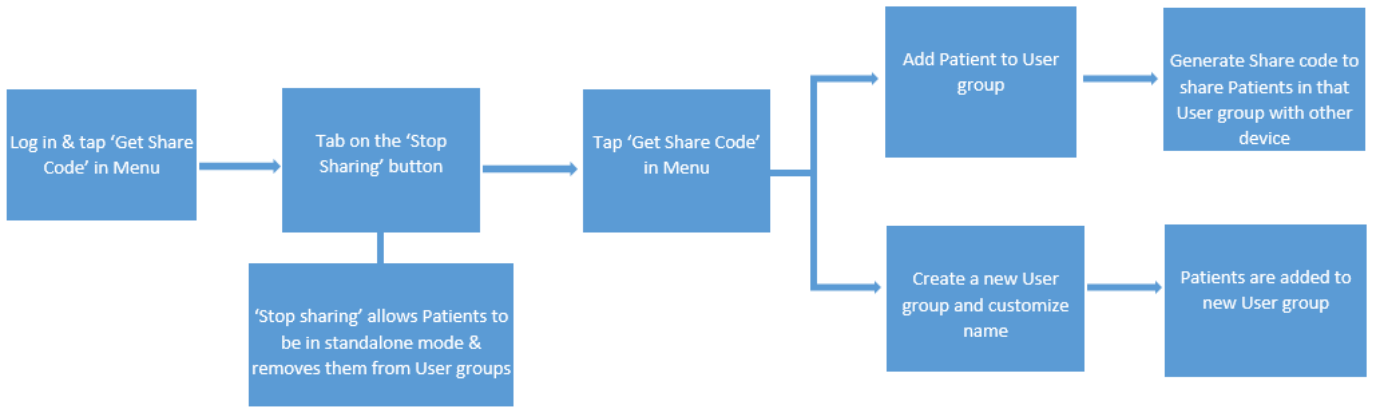
- Enter the code from the other device. The smart devices are now in the same Group and will cycle through all of the Patients in that Group.

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 “Menu”, “Share Data” and tap on “Stop Sharing”.

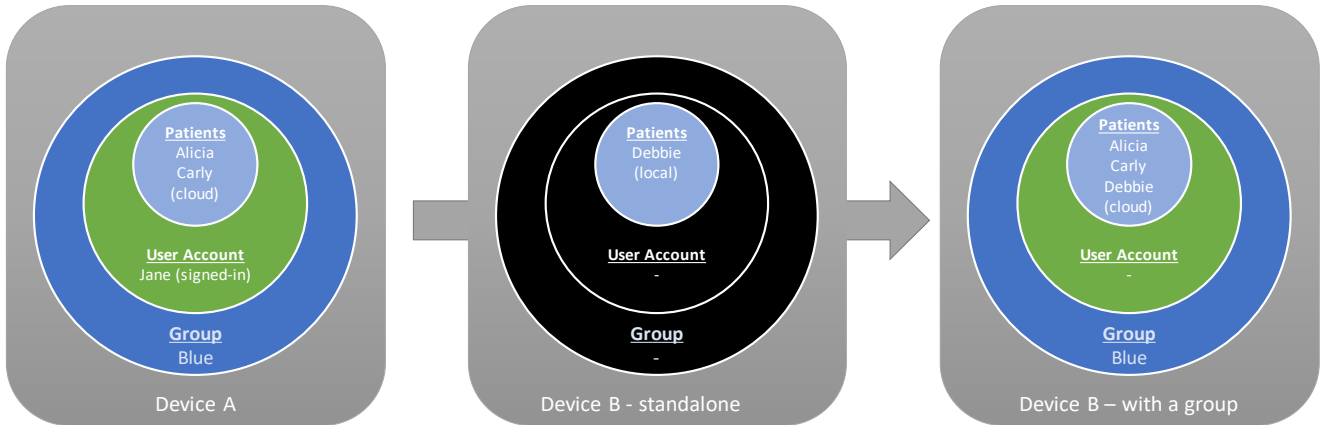
To summarise all of the workflows in the app for using the membership features of Smartz™, including stopping sharing, signing out and some examples of Group membership, please refer to the diagrams below.





Sharing and Status Display of Models Scenario

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



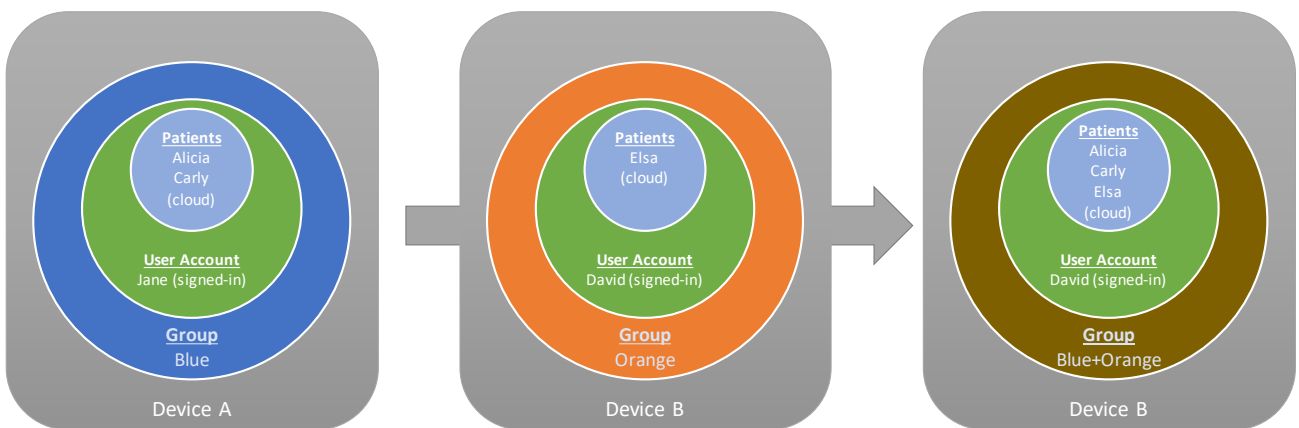
1. Generate Share Code from Device A

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

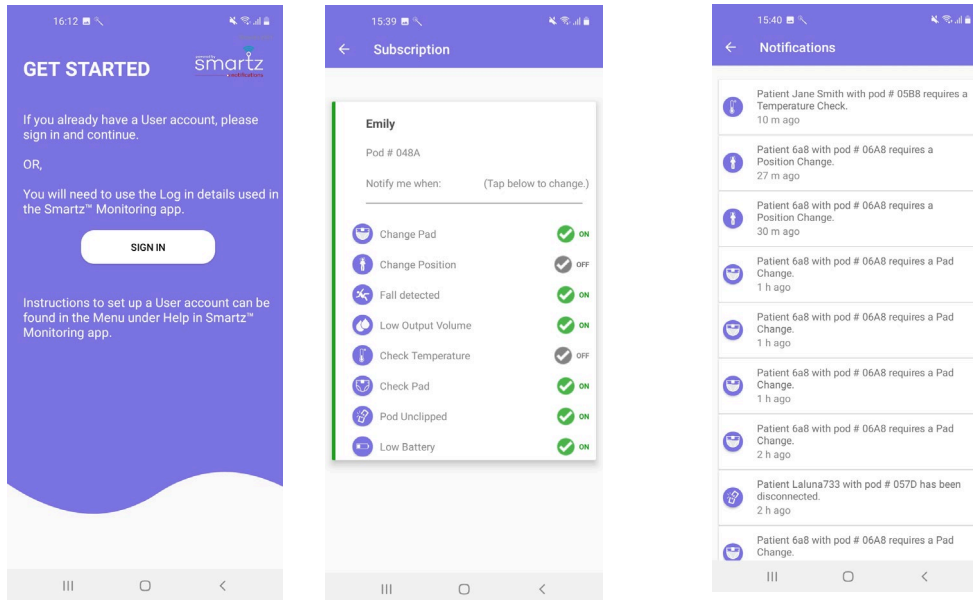
2. Use Share Code from Device A

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 allowing users with User accounts to subscribe to push notification events for each Patient. This app is available from the Apple store and Google Play store as 'Smarz™ Notification'.



Users will receive remote notifications on the event statuses of their Patients when their device is connected to the internet, irrespective of their location. 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 Shared 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

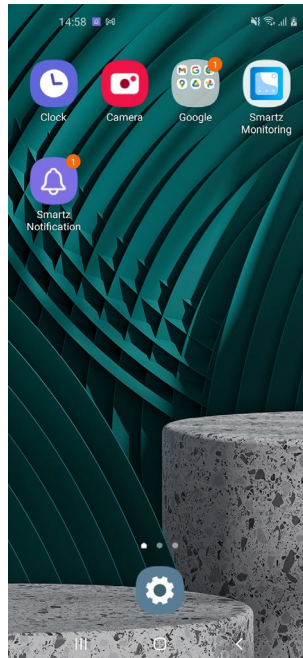
The notifications that can be subscribed to are the:

- Change Pad
- Change Position
- Fall Detected
- Low Output Volume
- Check Temperature
- Check Pad
- Pod Unclipped
- Low Battery

Note: Notification subscriptions are applied at a user level. Any changes to a notification subscription setting will affect other device notifications logged in to the same user account.

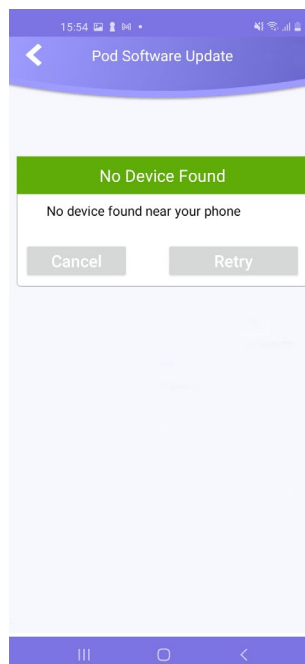
Pod Version Upgrades

Pods must be upgraded wirelessly over the air from time to time. A notification will be provided when there is a new pod upgrade version.

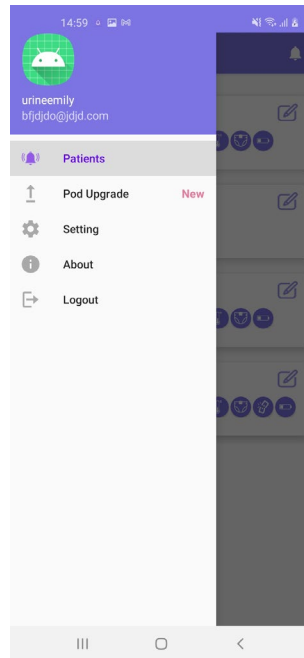


The steps to upgrade a pod are as follows:

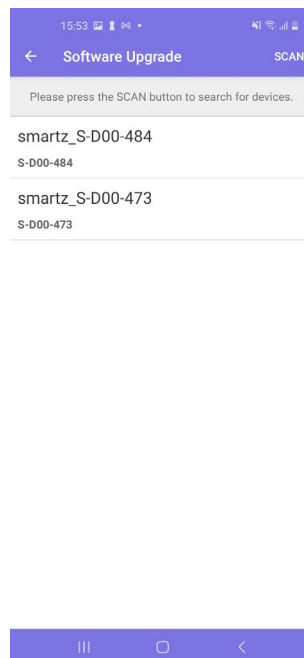
- Keep the pods to upgrade nearby the mobile device. Retry if no device has been found.



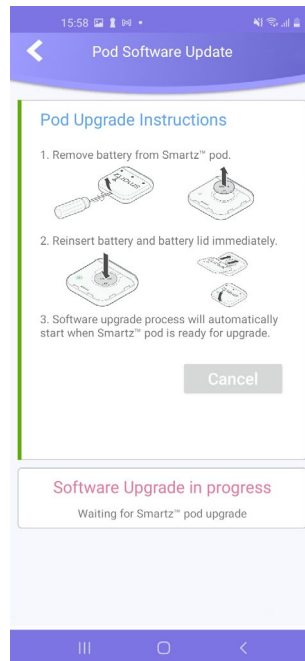
- Tap the 'Pod Upgrade' item in the Menu of the Smartz™ Notification app



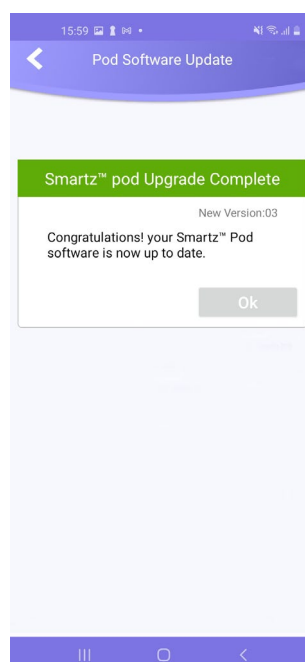
- Tap Scan' and search for the pod you wish to upgrade by finding it's unique Serial Number



- Choose the pod Serial Number and follow the on-screen instructions. If the pod is already up to date, 'No Update Required' will be displayed.



- The battery will need to be removed and replaced to start and complete the upgrade. To see how to remove the battery, please refer to Section 3.1 Smartz™ pod Battery Installation & Replacement.
- Remove and reinsert battery and close the battery lid immediately to start the upgrade.
- The progress of the upgrade is shown at the bottom of the screen.
- The pod version is now upgraded



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 shared must be updated independently.

3.6 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:

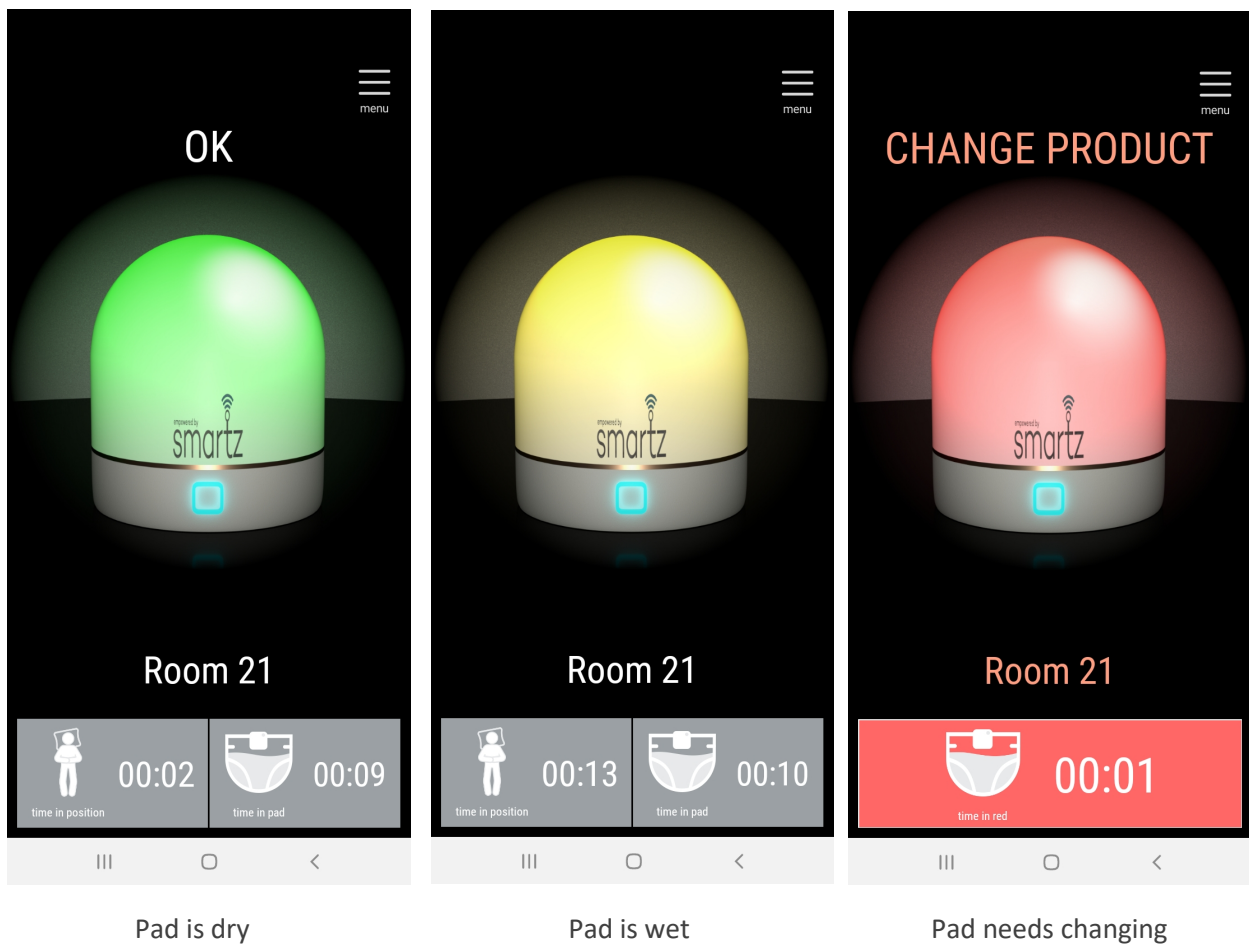





Figure 12. Traffic light display for time to change

The following are recommended actions based on the status shown.

Table 6. Traffic Light

Status Colour	Action	Description
	No action required	Smartz™ sensor pad is not yet approaching capacity
	Be prepared to change	Smartz™ sensor pad is reaching capacity
	Change product	Smartz™ sensor pad has reached risk of leakage threshold

After unclipping and re-clipping the Smartz™ pod onto a Smartz™ sensor pad, the pod signal is in a transitional state for a few seconds, trying to determine if it is a previously used or a new Smartz™ sensor pad. This is displayed as 'Checking Pad' in the Smartz™ Monitoring app and Smartz™ dashboard.

Smartz™ indicates a functional time-to-change slightly before any possible risk of leakage. This may be different to what you are used to in terms of assessing saturation during pad changes. Overall, this method greatly reduces risk of leakage, which can lead to skin irritation and the need to change bed linen.

Note: Lying on side may trigger an earlier 'Time to Change' than when in other positions due to the fluid pressure on the side cuffs of the Smartz™ pad.

Time in pad

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

Time in red

Time in red indicates how long the red status has been displayed, to the nearest minute.

Time in Position

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

Falls Detection

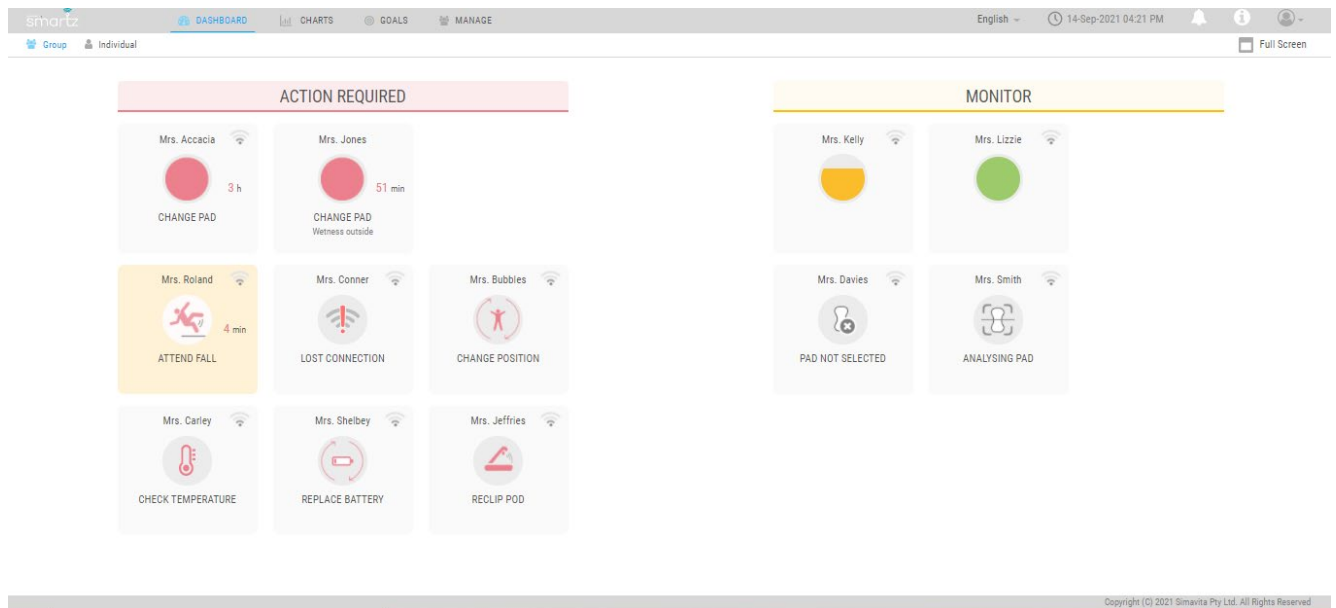
The Smartz™ falls detection feature is designed to detect a range of falls from a range of typical heights. While every effort is made to capture every type of fall, some people may fall in a manner outside of this range. Furthermore, there may be false positive falls events as a result of specific movement of the device. There may be periodic network latencies during use outside of the control of the Smartz™ product. As a result, a falls notification may not be reported immediately after the event.

If a fall has occurred the notification will be displayed flashing under the 'Action Required'. By silencing the fall in the 'Individual' page the icon will be removed from the main dashboard.

When setting up a new Patient the falls detection is OFF by default. To activate the falls detection, go to the dashboard, Goals section. To turn the falls detection ON, move the slider to the ON position and tap or press Save. By default, the 'Time in Position' is automatically turned on and set at 2 hours. Turn OFF falls by moving the slider to OFF and click Save and note, the time in Position will be automatically switched OFF.

If the "fall detected" is ON in the Smartz™ Notification app the user will be sent a notification indicating a fall has occurred. To reset the falls, the pad must be changed and the pod applied to a new dry Smartz™ sensor pad or press the Silence button in the Individual page.

Note: Falls will not be triggered within the first 5 minutes of clipping to a pad.




Ambient Temperature

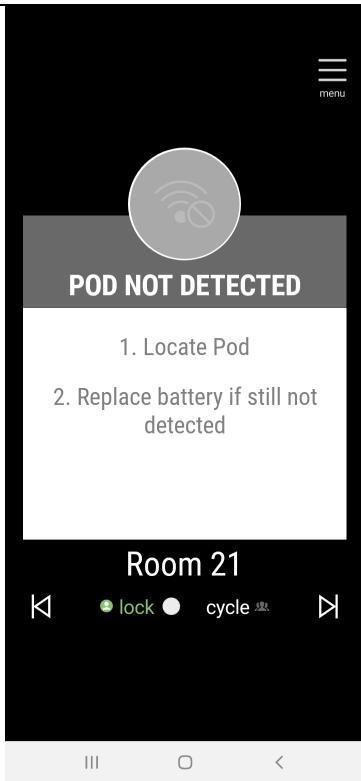
Ambient temperature indicates the approximate temperature of the pod surroundings to within +/-2°C. The units of Degrees Celsius or Degrees Fahrenheit can be changed in the settings Menu.

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.

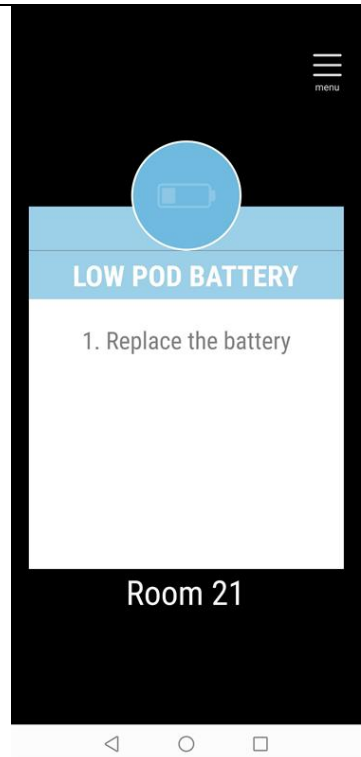
Table 7. Notifications

Notification	Description
 <p>The image shows a mobile application interface with a black background. At the top right, there is a white menu icon and the word 'menu'. In the center, there is a light blue circle containing a white icon of two people. Below this is a light blue banner with the text 'NO PATIENT(S) SETUP' in white. Underneath the banner, the text '1. Add Patient below' is displayed. At the bottom of the screen, there is a light blue button with the text 'ADD PATIENT' in white. The bottom of the screen shows a white navigation bar with three icons: a square, a circle, and a triangle.</p>	<p>This occurs when there are no Patient pods connected to the smart device app.</p>



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 Section 3.1 Smartz™ pod Battery Installation & Replacement.



This occurs when the battery is low and requires replacement as per Section 3.1 Smartz™ pod Battery Installation & Replacement.

Note: The Low Battery status only appears on Smartz™ monitoring app when the pod is clipped to the Smartz™ sensor pad. If it is not connected, the status will go back to the pod unclipped instead of the pod low battery.

The red LED flashing light on the pod will show in both scenarios.



This occurs when the Pod is no longer clipped to the Patient's pad when in range or not clipped on correctly.

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



This occurs after unclipping and re-clipping the Smartz™ pod onto a Smartz™ sensor pad, the pod signal is in a transitional state for a few seconds, trying to determine if it is a previously used or a new Smartz™ sensor pad.

3.7 Smartz™ dashboard

Using the Smartz™ dashboard

Note: To use the Smartz™ 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 3.5).

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

Note: The smart devices must be shared to the Smartz™ cloud as per *Sharing Devices* Section with an assigned user account before the dashboard can be used.



ACTION REQUIRED

The red icons shown provide visual notification to indicate 'Change Pad' and time since pad required change.

MONITOR

The fill and colour of the icons indicate that the pad is either dry showing a full green circle or approaching its capacity showing a three quarter filled yellow circle.

More information can be found here.

The screenshot displays the Smartz monitoring dashboard. At the top, there is a navigation bar with 'smartz' logo, 'DASHBOARD', 'CHARTS', 'GOALS', and 'MANAGE' tabs. The user is logged in as 'Group' and 'Individual'. The date and time are '14-Sep-2021 04:21 PM'. There are notification and user profile icons in the top right corner, and a 'Full Screen' button.

The dashboard is divided into two main sections:

- ACTION REQUIRED:** This section is highlighted with a pink header. It contains a grid of patient cards. Mrs. Accacia and Mrs. Jones have red circles with '3 h' and '51 min' respectively, labeled 'CHANGE PAD'. Mrs. Roland has a yellow circle with a red figure falling, labeled 'ATTEND FALL' with '4 min'. Mrs. Conner has a red figure with a lightning bolt, labeled 'LOST CONNECTION'. Mrs. Bubbles has a red figure with a lightning bolt, labeled 'CHANGE POSITION'. Mrs. Carley has a red thermometer, labeled 'CHECK TEMPERATURE'. Mrs. Shelbey has a red battery, labeled 'REPLACE BATTERY'. Mrs. Jeffries has a red recliner, labeled 'RECLIP POD'.
- MONITOR:** This section is highlighted with a yellow header. It contains a grid of patient cards. Mrs. Kelly has a yellow circle, labeled 'PAD NOT SELECTED'. Mrs. Lizzie has a green circle, labeled 'ANALYSING PAD'. Mrs. Davies has a grey circle with a plus sign, labeled 'PAD NOT SELECTED'. Mrs. Smith has a grey circle with a plus sign, labeled 'ANALYSING PAD'.

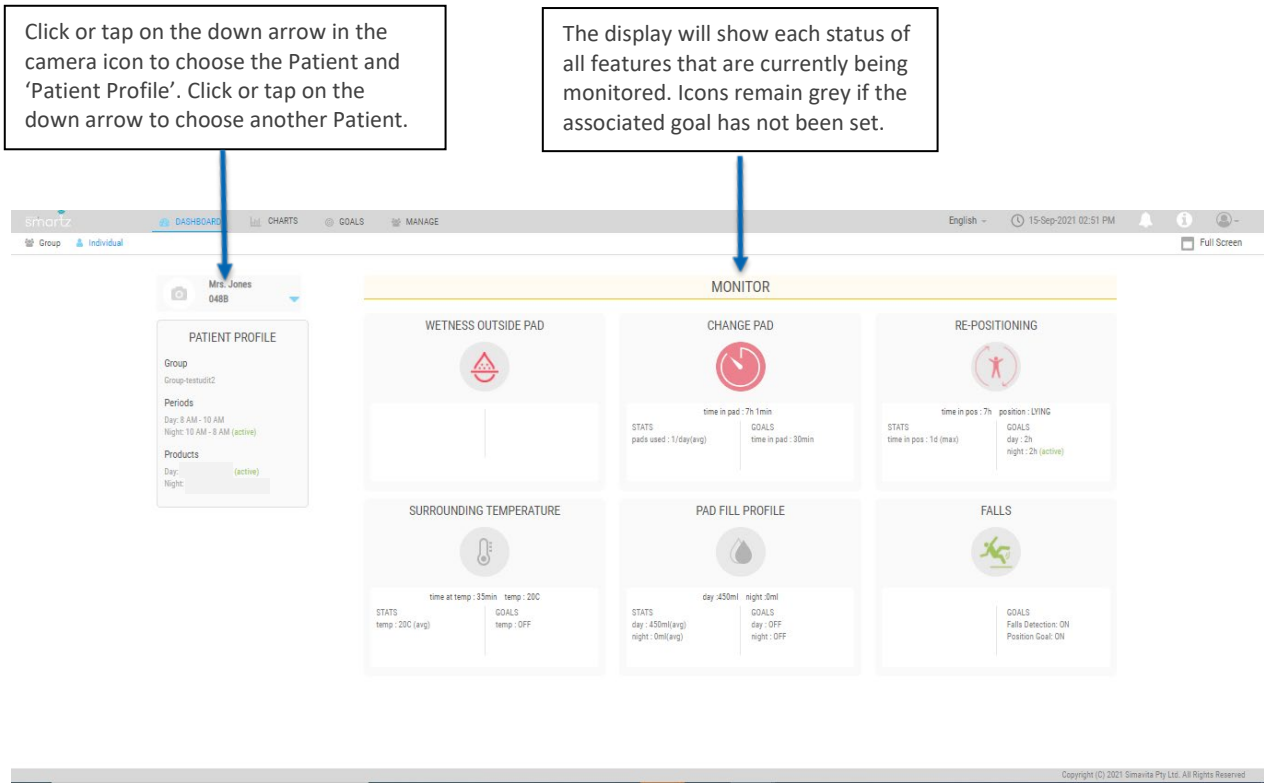
Blue arrows point from the text boxes above to the corresponding sections in the dashboard. A copyright notice 'Copyright (C) 2021 Simavita Pty Ltd. All Rights Reserved' is visible at the bottom of the dashboard.

Columns will alternate between Patients one after another with a 9 seconds interval to ensure all Patients are shown.

Goals that have been set and triggered include: 'Change Position', 'Check Temperature', 'Check Pad' and a flashing 'Attend Fall' icon indicating the time since the fall occurred. The 'Reclip Pod', 'Lost Connection' and 'Replace Battery' indicate the action to be taken.

Under the 'Monitor' section, if no pad has been selected for either the day or night on the Monitoring app the dashboard icon indicates 'Pad not selected' and when the pod is first connected to the pad the 'Analysing Pad' icon will show until the pad status is recognised.

Figure 13. Individual Page on the Dashboard



Wetness detected on the outside of the pad

If a wetness on the outside of the pad has been detected for more than approximately 60 minutes, e.g. transferred from the Caregiver, sweat, moisture from surrounding environment. The group dashboard will indicate a red 'Time to Change' stating wetness outside pad under the icon.

Pad Fill Profile

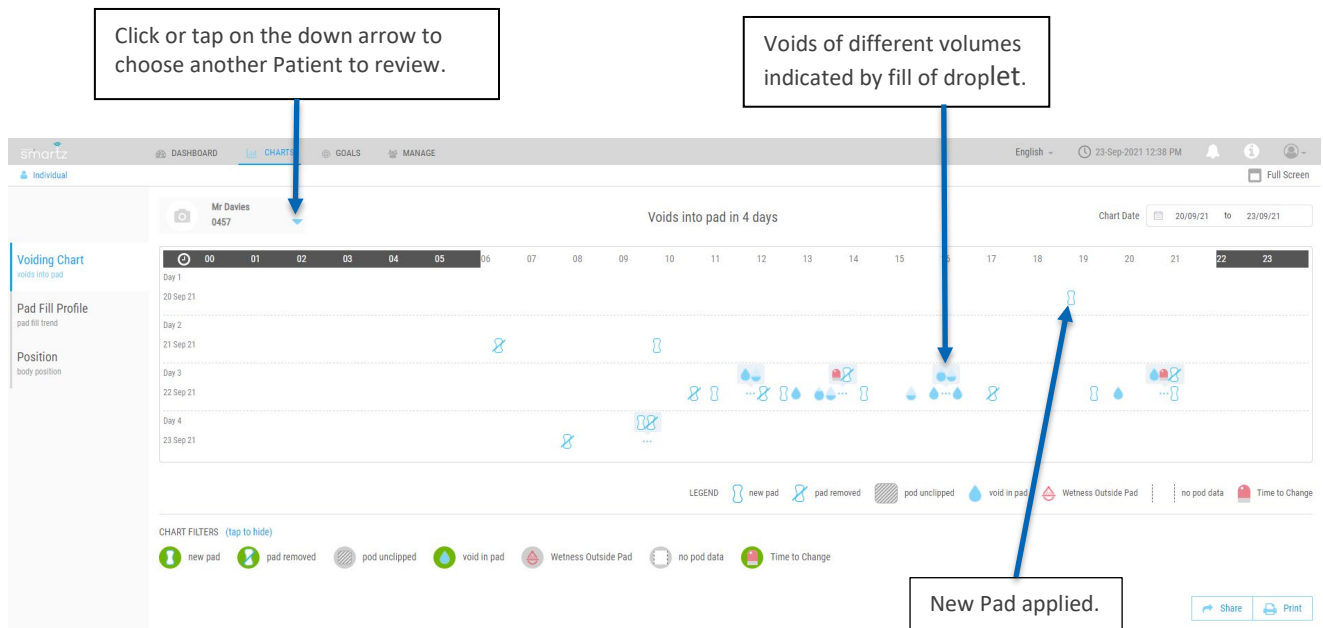
The screenshot shows the 'Pad Fill Profile' for 'Mr Kelly 03A1'. The interface displays a 'Total daily profile' for the last 7 days (16/09/21 to 22/09/21). The profile shows fluid volume in drops for each day: Wednesday (700ml), Thursday (1000ml), Friday (700ml), Saturday (700ml), Sunday (100ml), and Monday (1600ml). Tuesday shows 'Insufficient data'. An 'Average' section shows 300ml for the last 7 days. A 'PAD FILL PROFILE GOAL' is set to 'ON'. Callouts provide instructions: 'Click or tap on the down arrow to choose another Patient to review.' (pointing to the patient dropdown), 'Display up to seven days of data.' (pointing to the date range), 'Tap to setup Pad Fill Profile goals.' (pointing to the goal toggle), and 'Share or print the chart.' (pointing to the share/print buttons). A legend indicates that a red drop icon means 'check pad fill profile'.

The total daily profile shows the total amount of fluid that has gone into the pad during 24 h period. Toggle to see either the day and night profiles separately. The drops indicate the volume output into the pad. The 'Average' icon indicates volume output over the period of the time selected.

Warnings:

- Pad fill profile is only the volume captured in the pad and does not account for any lost fluid due to toileting, sweat, pad leakage and other losses
- It is not intended to give a measure of bodily function
- It is only a statistical average over 7-days and compares to average per current day and night only when there is enough data
- All volume above the estimated leakage point for each pad is not counted in the calculation for pad fill profile since the leakage volume may be lost outside of the pad

Voiding Chart



Chose the date range you wish to view. The voiding chart displays: 'New pad', 'Pad removed', 'Pod unclipped', 'Void in pad', 'Wetness Outside Pad', 'No pod data' and 'Time to Change' which can be deselected. Icons can be filtered by selection.

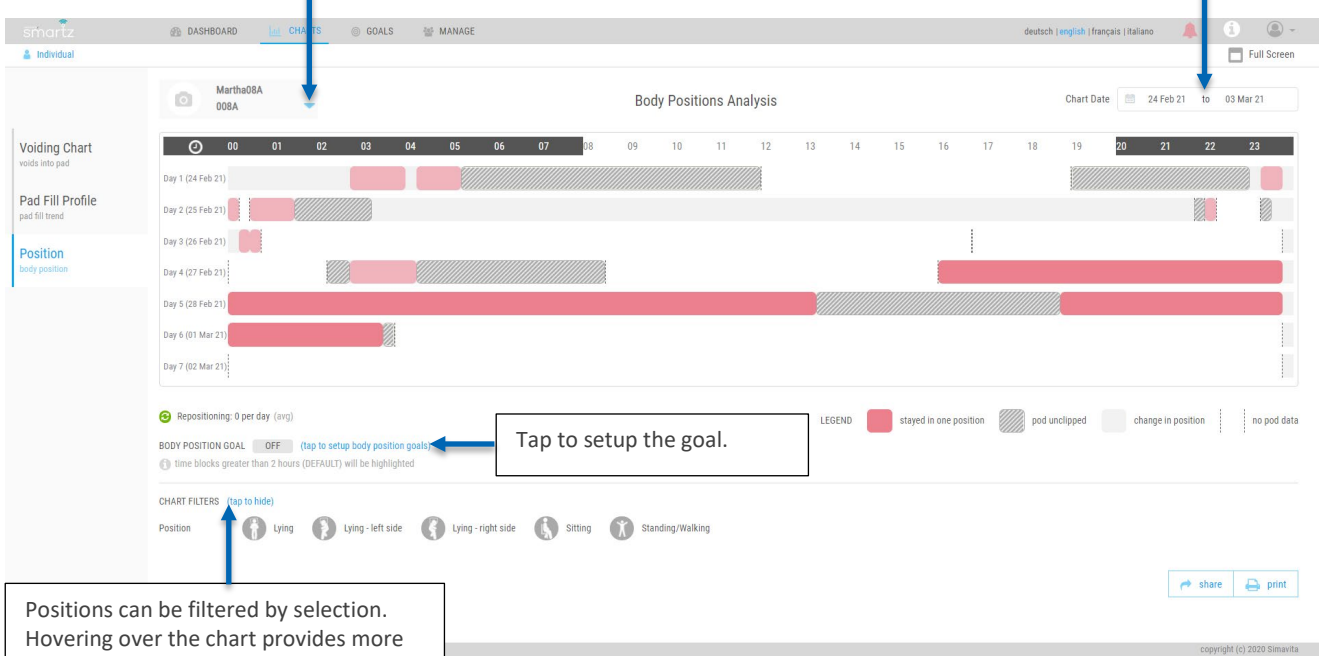
Voids will be displayed and rounded to the nearest 15 minutes with a maximum of four voids being displayed on the chart in the one hour.

Position Profile Chart

The Position Chart visually displays the length of time in each position of a patient. The changes and also length of one position are indicated by coloured time blocks. A single (RED) colour is used to signify a long exposure of time in one position. The intensity of the colour indicates the length of time spent in that one position e.g. dark red means the Patient stayed in one position more than 2 hours or as based on the set Position goal and light red highlights a position length of less than 2 hours or the specified goal.

Click or tap on the down arrow to choose another Patient to review.

This chart shows the position and recorded time in position when using Smartz™. Display up to seven days of data and share or print the chart.



Positions can be filtered by selection. Hovering over the chart provides more detail. The chart indicates if a Body Position goal has been set.

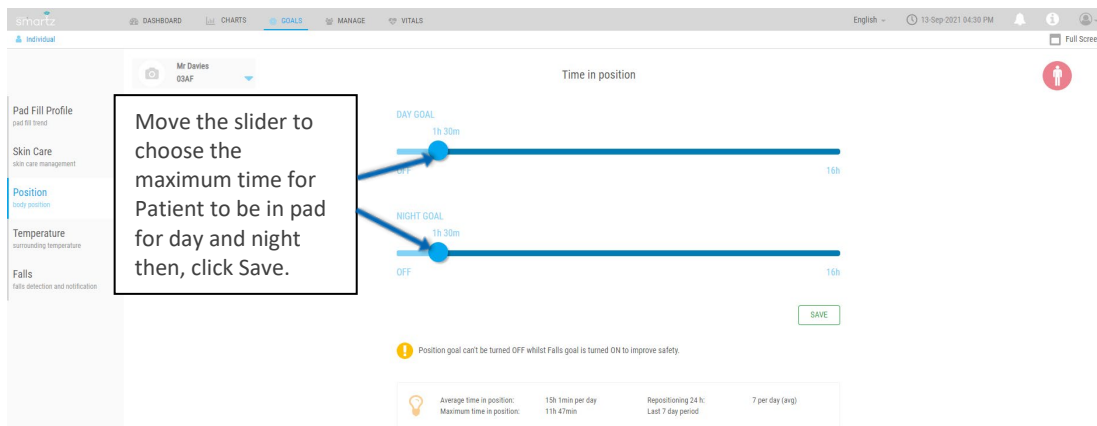
The exact time length will be shown when hovering over the individual coloured time blocks and will also be listed in a detailed chart when printed.

Any grey coloured time blocks will mark changes in position e.g. from lying on back to lying on side or rapid movements. Only positions that are stable for at least a few minutes will be displayed and rounded to the nearest 15 minutes of the hour on the chart. Time windows with no data, such as when the pod is not detected or the pod is unclipped, are indicated by a blank time block.

Goals



Note: The statistical values below the goals and on the individual page of the dashboard are generally calculated from the previous 7 days of data. Therefore, a continuous set of 7 days of data is required to show meaningful statistical results.



Troubleshooting the Smartz™ dashboard

To trouble shoot the Smartz dashboard go to: smartzhealth.com/FAQs

3.8 Smartz™ pod Cleaning Instructions

Smartz™ pod cleaning Guide

Smartz Operations Ltd recognizes that cleaning and disinfection practices vary amongst Home and Care Facilities. It is not possible for Smartz Operations Ltd 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

Smartz Operations Ltd 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 Smartz Operations Ltd products with small surface areas.

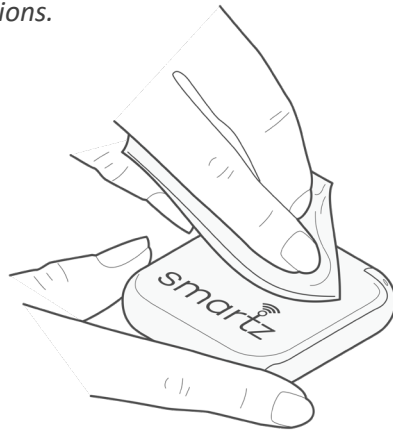
CAUTION

- 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:

- *The Smartz™ pod is IP54 rated for protection from water splashes from all direction, and dust ingress. However, it is not waterproof.*
- *Clean the Smartz™ pod by wiping with cleaning solutions according to the above recommended cleaning Solutions.*



- *Dry the Smartz™ pod thoroughly, especially around the gold pins. Be careful of the sharp edges of these pins.*
- *Store in a cool, dry place free of dust and lint, with the clip lid closed, until next use.*

3.9 Disposal

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

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.

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 Smartz Operations Ltd devices, please contact Smartz Operations Ltd .

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

View Troubleshooting: smartzhealth.com/FAQs

4.2 Contact and support

Please contact Smartz Operations Ltd 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 746 736

Outside Australia Phone: +61 (2) 8405 6300

Email: customerservice@smartzag.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™ mobile apps

Monitoring App

Description	Specification
Name	Smartz™ Monitoring
Operating System	Android 6 or greater
Version of app	Refer to app interface

Push Notifications App

Description	Specification
Name	Smartz™ Notification
Operating System	Android 6 or greater, iOS 13 or greater
Version of app	Refer to app interface

Smartz™ dashboard specifications

Description	Specification
Dashboard URL	dashboard.smartzhhealth.com
Browser	Google Chrome, Microsoft Edge and Safari
Version of dashboard	Refer to dashboard

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.

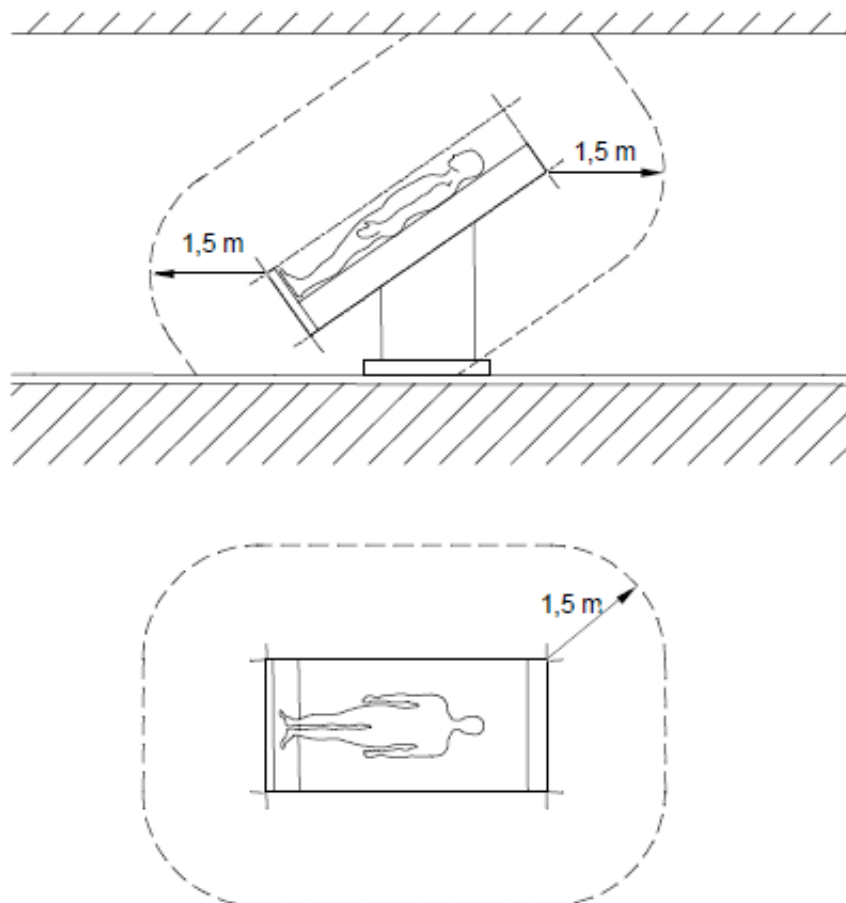
The user must take precaution to ensure they use the device within these conditions during foreseeable use. If the environmental conditions are outside these limits, the user shall not use the device.

Smartz™ System Patient Environment

The Smartz™ system is Radio Equipment Device certified for use in a medical environment. Smartz Operations Ltd. 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.



WARNING

IEC 2431/05

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.

FCC COMPLIANT STATEMENT

Changes or modifications not expressly approved by *Smartz Operations Ltd.* 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.

The Smartz™ pod Model 9000 requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these accompanying documents.

- WARNINGS


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 Smartz™ pod Model 9000, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

A risk of increased emissions or decreased immunity may result if any additional cables are attached.

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.

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


1	Guidance and Manufacturer’s Declaration – electromagnetic emissions		
2	The Smartz™ pod Model 9000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartz™ pod Model 9000 should assure that it is used in such an environment.		
3	Emission Test	Compliance	Electromagnetic environment –guidance
4	RF emission CISPR 11	Group 1	The Smartz™ pod Model 9000 uses 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.
5	RF emissions CISPR 11	Class B	The Smartz™ pod Model 9000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.

Guidance and Manufacturer's Declaration – electromagnetic immunity			
The Smartz™ pod Model 9000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartz™ pod Model 9000 should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1 Test level	Compliance Test	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+ 8kV contact + 15kV air	+ 8kV contact + 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) 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.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Smartz™ pod Model 9000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = [3.5/10] \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = [7/10] \sqrt{P} \text{ 800 MHz to 2.7 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
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 Smartz™ pod Model 9000 is used exceeds the applicable RF compliance level above, the Smartz™ pod Model 9000 should be			

observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Smartz™ pod Model 9000.

Guidance and Manufacturer’s Declaration – electromagnetic immunity

The Smartz™ pod Model 9000 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartz™ pod Model 9000 should assure that it is used in such an environment.

Immunity Test	IEC 60601-1 Test level	Compliance Test	Electromagnetic environment - guidance
IMMUNITY to proximity fields from RF wireless communications equipment	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Smartz™ pod Model 9000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $E = [6/d] \sqrt{P}$ $d = [6/E] \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended distances between portable and mobile RF communications equipment as well as RF wireless communications equipment the Smartz™ pod Model 9000

The Smartz™ pod Model 9000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Smartz™ pod Model 9000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Smartz™ pod Model 9000 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)			
	80 to 800 MHz $d = [3.5/10] \sqrt{P}$	800 MHz to 2.7 GHz $d = [7/10] \sqrt{P}$	710, 745, 780, 5240, 5500, 5785 $d = [6/9] \sqrt{P}$	385, 450, 810, 870, 930, 1720, 1845, 1970, 2450 $d = [6/28] \sqrt{P}$
0.01	0.035	0.070	0.067	0.021
0.1	0.110	0.221	0.211	0.070
1	0.350	0.700	0.667	0.214
10	1.107	2.213	2.108	0.700
100	3.500	7.000	6.670	2.143

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

Appendix B

Smartz™ Accessories

6.0 Appendix B: Accessories

6.1 Smartz™ node

Smartz™ 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 not 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.

Smartz™ node and Mesh Network Setup

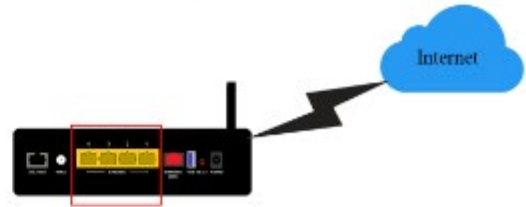
Refer to the following page.

Smartz Mesh Setup Guide

Connect Master Node to Internet



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 change from flashing green to solid green as shown below. The light should turn off after 15 minutes

NOTE

- *The light will be off but the node will continue to transmit data.
- *Light turns on again after an hour, if there is poor or no internet connectivity.
- *Light turns off after 15 minutes if signal has stabilized.

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. Nodes can also be mounted on the ceiling for improved coverage. To setup more child nodes,



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



2. Wait for the node to change from flashing green to solid green as shown below. The light should turn off after 15 minutes

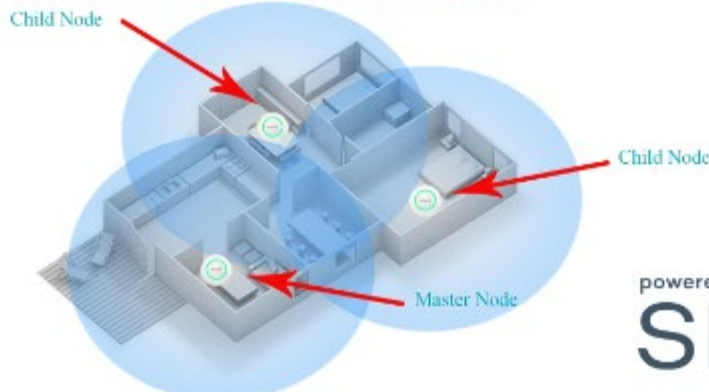
NOTE: *If not the node doesn't turn green in 15 minutes please move the node closer to the MASTER NODE.

*Please see the diagram below for placement of the child nodes.

*The maximum distance between the child and master nodes should be 2 rooms.

*If the light continues to flash or stay solid GREEN after 15 minutes, notify your IT provider

*The light should only be GREEN while the node is establishing connection. If any other colour light is observed for prolonged time, notify your IT provider



powered by
smartz

Smartz™ node specifications

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

Description	Specification
Smartz Operations Ltd. Product Name	Smartz™ node
Node Model No.	9100

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:

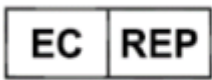
Smart Alert System

URL:

Uniform Resource Locator

WEEE:

Waste Electrical and Electronic Equipment



MedNet EC-REP GmbH
Borkstrasse 10,
48163 Munster, Germany



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See www.Smartzhealth.com for more information.