7
SYSTEM LASTS UP TO 7 DAYS

ACRYLIC ADHESIVE

SHOWER PROOF DRESSING

smith&nephew

SANDY◇ 2012980

Healthcare Professional User Manual

Thank you for participating in our SANDY◇ Clinical Study

EN

1 Description

What is SANDY°?

SANDY° is a motion tracking and feedback system for the daily management of a chronic disease or condition.

What does SANDY° do?

SANDY° collects motion data over a 7 day period and provides contextual feedback on activity in a mobile application.

How does it work?

SANDY° uses a family of STRIDE° sensor devices applied to the skin and off-loading device. Motion data is collected, analyzed and output to a mobile application to determine activity and compliance to prescribed therapy.

Where can I use it?

SANDY° can be used in both a hospital and home environment.

2 Indications for Use

SANDY° is indicated for the following:

- Diabetic Foot Ulcers (DFUs)

3 Contraindications

The use of SANDY° is contraindicated in the presence of:

- Broken skin or a wound in the sensor device application area
- Fragile Skin or dermatological conditions

4 Kit Components

Two STRIDE° Sensor Devices

1. Do not place in a load bearing location.
2. Do not cut.

Adhesive Film — A

Ensures the devices will stay in place.

Wake button — B

Wakes the device to pair with the application. Press to wake the device and turn on bluetooth.

LED Indicators — C

LED indicators that display pairing status (see software tutorials for more information).

QR Code — D

Unique Identifier for each sensor Device. Scan this with the Smart Device to pair the Sensors

SANDY° Smart Device

Power Button — E

Turns the Device on/off, and toggles standby.

Sign-in Button — F

Signs in to the device. Press this button when first using the smart device.

User Information Sheet — G

Reference information for the user. Space to write phone number and address of practice.

5 Warnings

Application

- **Do not apply the STRIDE° sensors to a load bearing location** (i.e. areas vulnerable to pressure damage)or in a position where it may easily **be leaned, lay, or sat on**.
- When applying the STRIDE° sensor devices, **Do not cut the device or film**

Magnetic Resonance

- **MRI Unsafe. The STRIDE° sensors are not MRI compatible. Remove the device before entering the MRI suite.**

Defibrillation

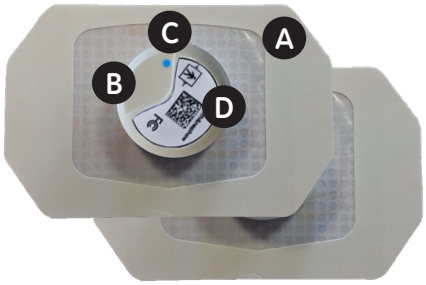
- If defibrillation is required, immediately replace the STRIDE° sensor device(s) following the defibrillation event

General

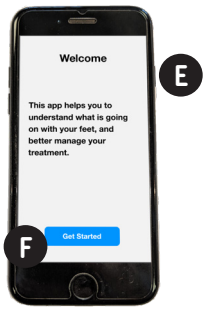
- **Do not cover The STRIDE° Sensor** in a manner that prevents **regular inspection.**
- The STRIDE° sensors are **unsuitable** for areas where there is **danger of explosion** (e.g. hyperbaric oxygen unit).
- **Do not submerge** the STRIDE° sensors.

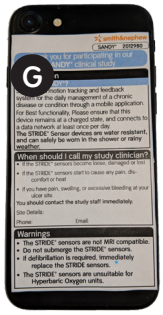
6 Precautions

- The STRIDE° Sensor **should not be covered** by rigid immobilization device or casts that could apply pressure to the sensor devices.
- **Do not use** The STRIDE° sensors with **oil-based products** such as petrolatum as it may compromise the adhesive.
- The potential for electromagnetic interference in all environments cannot be eliminated. **Use caution** if The STRIDE° sensors are **near electronic equipment** such as RFID (Radio Frequency Identification) readers, anti-theft equipment, or metal detectors.
- **The STRIDE° sensors are single use only.** Do not re-use the STRIDE° sensor devices on more than one user.
- **CT scans** and **x-rays** have the potential to **interfere** with some electronic devices. **Keep the STRIDE° sensors out** of the **x-ray or scanner range**.



Note: Both STRIDE° sensors are identical. One sensor must be placed on the shin below the knee, and one must be placed on the user's off-loading device.



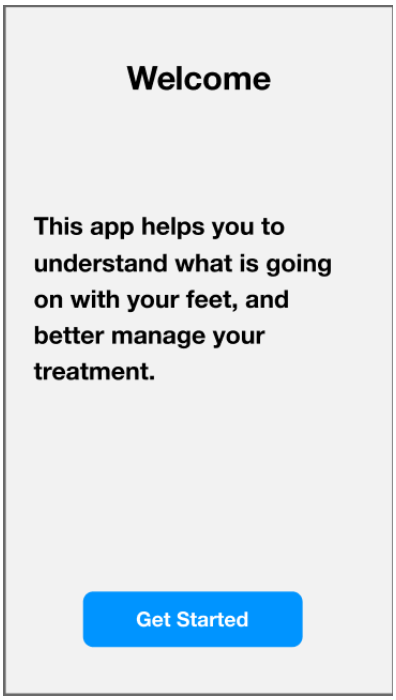


7 Instructions for Use

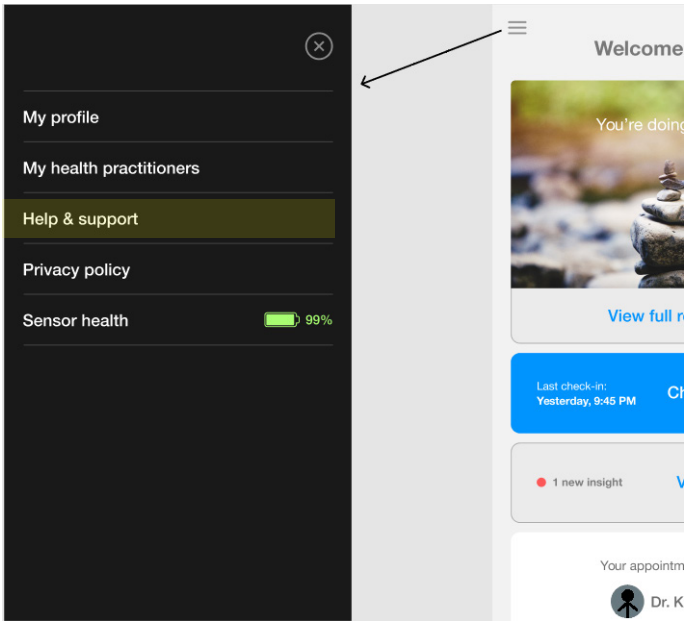
7.1 First Time Setup

1 Turn on the SANDY° Smart Device, ensuring that it has sufficient charge (>50%) and can connect to a data network before the appointment.

2 You will see the following screen. Enter your information, and follow the steps on screen.



3 View the tutorials from the side bar to view functions of the application.



4 Familiarise yourself with the SANDY° software and functions

7.2 Introduce the wearer to System

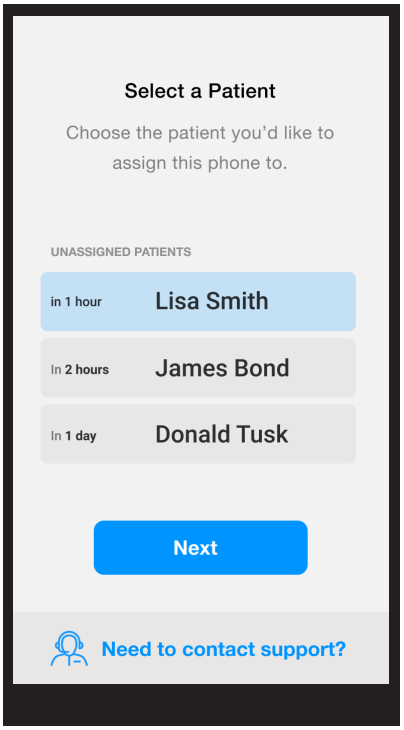
6 Welcome the user, and hand them the SANDY° smart device.

7 Introduce the user to the system, and explain the purpose of the SANDY° System and STRIDE° devices.

IMAGE

7.3 Add the user to the system

8 Press the “Get Started” button



9 Follow the instructions on-screen and assist the user in entering their details.

10 Unpack the sensors and proceed to Applying the sensors (Step 8.1)

Diagnostic Procedure Compatibility

The STRIDE° sensors are not compatible with defibrillation. If in the event that defibrillation is required, replace the STRIDE° sensor device(s) immediately after a defibrillation event as damage may have occurred.

The STRIDE° sensors are not MRI compatible.

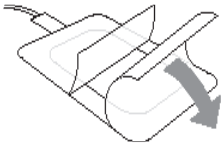
The STRIDE° sensors are not compatible with hyperbaric oxygen (HBO).

⑧ Sensor Application

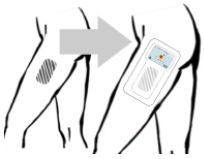
8.1 Primary Sensor

1 Take either of the sensor devices. Wipe clean the application site, and pat dry any excess moisture.

2 Remove the first backing film.

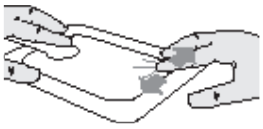


3 Apply the exposed part of the film to the side of the shin just below the knee.



NOTE: DO NOT place the sensor on a load bearing location

4 Remove the other backing film.



5 Remove the paper frame by pulling from the tab.

IMAGE

6 Press the button on the sensor.

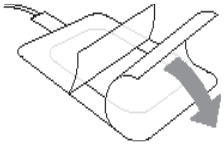
IMAGE

7 Follow the application prompt to scan the QR code on the sensor.

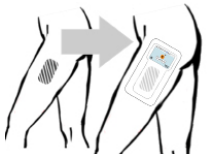
8.2 Secondary Sensor

1 Take the remaining sensor device

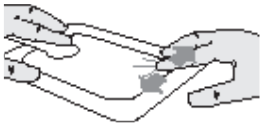
2 Remove the first backing film.



3 Apply the exposed part of the film on to the off-loading device, in a non load-bearing location



4 Remove the other backing film.



5 Remove the paper frame by pulling from the tab.

IMAGE

6 Press the button on the sensor.

IMAGE

7 Follow the application prompt to scan the QR code on the sensor.

⑨ Discuss Goals

Discuss long-term goals of the system, and initial activity levels for the first few weeks.

⑩ Send The User Home

Set an appointment within 7-14 days, and set he appointment within the application.

⑪ Troubleshooting

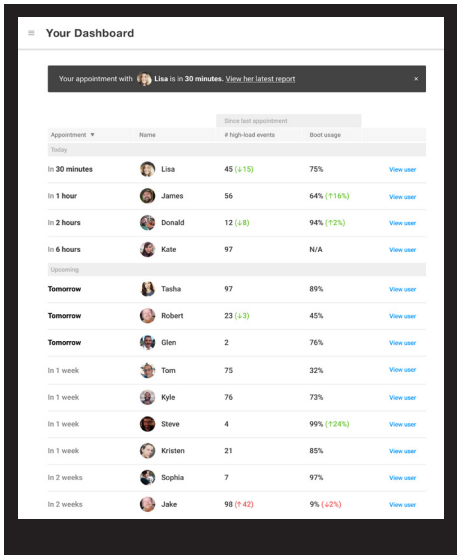
Status	Recommended action
Difficulty with software	View the tutorials in the options menu (See step 6.1 - 4). If difficulty continues, contact our Smith & Nephew representative.
Sensors not pairing	Cycle the power on the sensor devices. If difficulty continues, remove and replace the sensor device(s) with difficulties with new sensors. If difficulties continue, contact your Smith & Nephew Representative.
Sensors not responding	Remove and replace the sensor device(s) with difficulties with new sensors. If difficulties continue, contact your Smith & Nephew Representative.
Smart device not responding	Cycle the power on the smart device. If difficulties continue, contact your Smith & Nephew Representative.

⑫ Prepare for next Appointment (Opt)

1 If permission is given by the user, their activity progress, as well as added contextual tags can be observed.

This can be done via a web portal or a tablet.

Data can be viewed in multiple different views.



2 Prepare the data for the appointment.

Set the data to be displayed in “User Mode” [TBC].

⑬ Next Appointment

13.1 Remove Sensors

1 (Optional) Manually sync data if data is not up to date as of the appointment.

2 Examine the Foot ulcer and observe the progression of the wound. Determine if the DFU is in better or worse condition.

3 Remove sensor devices by slowly peeling the film back from one corner.

Removed devices should be returned to Smith & Nephew.

IMAGE

4 Discuss the activity data together.

5 Determine if the user would benefit from continued use of the SANDY° system.

If they can, proceed to step 13.3

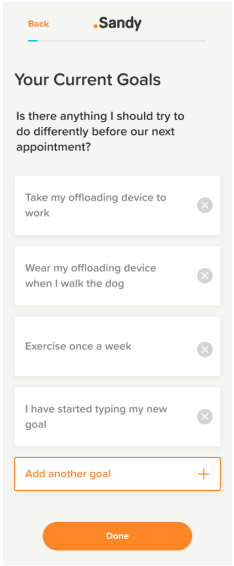
If they Cannot, Proceed to Step 14

13.2 Disposal of STRIDE° Sensors

Following removal, the STRIDE° sensors are to be disposed of by returning them to a Smith & Nephew representative.

13.2 Apply New Sensors

1 Discuss new goals for the user, and set activity goals into the application

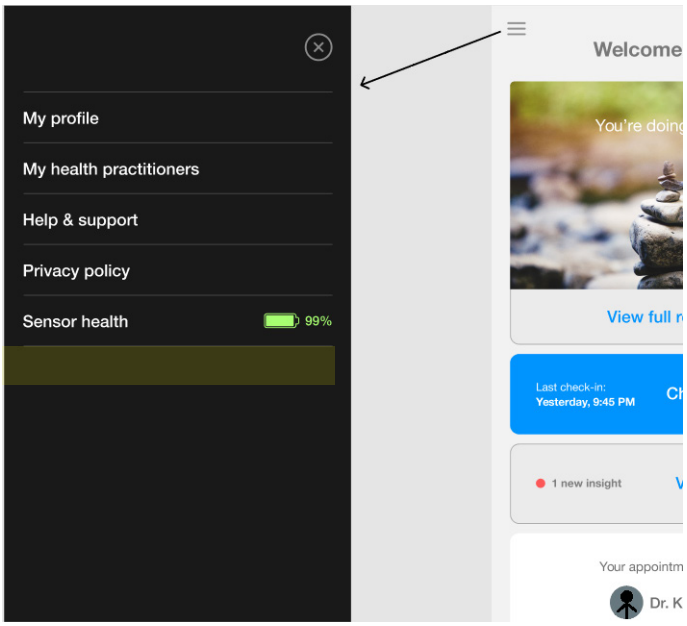


2 Apply new Sensor devices as per step 8.

3 Repeat steps 10-13 as is appropriate for the user over the trial period.

⑭ Terminate SANDY° System

If it is determined that the user can no longer benefit from SANDY°, then they can be removed from the system in the settings menu. This can be confirmed by a Smith & Nephew Representative.



⑮ Notes

Please use this space to write down any notes you have regarding your experience with the SANDY° system.
Any feedback can be used to help improve the system in the future.

⑮ Notes (Cont)

⑯ Symbols Glossary

	International Classification		Single use. Do no reuse.		Manufacturer
	Keep product out of sunlight		Caution: Federal (USA) law restricts this device to sale by or on order of a physician		Date of manufacturer
	Atmospheric pressure		Relative Humidity		Storage temperature
	MR Unsafe - Keep away from magnetic resonance imaging (MRI)		Do not use if package is damaged		Follow Instructions for Use
	Healthcare Professional		System lasts up to 7 days	LOT	Lot number

⑰ Specifications

Device Dimensions	
Weight	12g
Operating Time	7 Days
Battery Type	***CR2032 3V (Non Replaceable)***
Ingress Protection	IP 67
Mode of Operation	Continuous
Patient Protection	Type BF
Storage/Transport	5-25°C, (-25°C to +5°C allowable for up to 7 days), 10 - 75% relative humidity 700 to 1060 mbar atmospheric pressure
Operating Environment	5 - 40°C, 10 - 95% relative humidity 700 to 1060 mbar atmospheric pressure
Compliance	Conforms to: AAMI STD ES60601-1, IEC STDS 60601-1-6 and 60601-1-11
	Certified to: CSA STD C22.2 # 60601-

⑱ Safety of The STRIDE° sensors

When used in accordance with the manufacturer's instructions, SANDY-STRIDE° complies with the General Requirements for Safety of Electrical Medical Equipment (IEC 60601-1). The STRIDE° sensors are intended for uncontrolled environments e.g. home use (IEC60601-1-11).
SANDY-STRIDE° has no Essential Performance, and no extra specific precautions are needed regarding basic safety.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV For power supply lines	SANDY-STRIDE° is a battery powered device.	Not applicable
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line	SANDY-STRIDE° is a battery powered device.	Not applicable
Voltage dips, short Interruptions and voltage variations on power supply input lines IEC 61000-4-11	At 0°, 45°, 90°, 135°, 180°, 225°0, 270° and 315° phases 0% UT (100% dip in UT) for 0.5 cycle At 0° single phase 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 250 cycles 0% UT (100% dip in UT) for 300 cycles	SANDY-STRIDE° is a battery powered device.	Not applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz 100 A/m 50 or 60 Hz 150 A/m 50 or 60 Hz 200 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz In ISM and amateur radio bands	SANDY-STRIDE° is a battery powered device.	Portable and mobile communications equipment should be separated from the device by no less than distances calculated/ listed below: Recommended separation distance: d = 0.58 √P
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz IEC 60601-1-2:2014 Table 9	10 V/m 80 MHz to 2.7 GHz IEC 60601-1-2:2014 Table 9	d = 0.175 √P (80 MHz to 800 MHz) d = 0.35 √P (800 MHz to 2.7 GHz)

NOTE 1: At 80 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the STRIDE° Sensor is used exceeds the applicable RF compliance level above, the STRIDE° Sensor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m. 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, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

⑲ Electromagnetic Compatibility

The STRIDE° Sensors have been tested and found to comply with the limits for medical devices to IEC 60601-1-2. These limits are intended to provide reasonable safety with regard to electromagnetic disturbances when The STRIDE° Sensors° are used in a typical medical installation and uncontrolled environment like home use.
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 other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.
For additional information on electromagnetic immunity and electromagnetic emissions ask your Smith & Nephew representative for a hardcopy.

Guidance and Manufacturer's Declaration - Electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidelines
RF emissions CISPR 11	Group 1	SANDY° uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	SANDY° is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

WARNING: The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Do not use cables and accessories other than those specified or sold by Smith & Nephew as it may result in increased electromagnetic emissions or decreased electromagnetic immunity of the STRIDE° devices. Portable and mobile RF communication devices (mobile telephones) can affect The STRIDE° Sensors

Guidance and Manufacturer's Declaration - Electromagnetic emissions

The STRIDE° Sensors are intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

WARNING: 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 SANDY-STRIDE SYSTEM, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Rated maximum output power of Transmitter (W)	Separation distance according to frequency of transmitter (m):		
	150 kHz to 80 MHz d = 0.58√P	**80 MHz to 800 MHz d = 0.175√P**	**800 MHz to 2.7 GHz d = 0.35√P**
0.01	Not applicable	0.02	0.03
0.1	Not applicable	0.05	0.1
1.0	Not applicable	0.2	0.3
10	Not applicable	0.5	1.1
100	Not applicable	1.7	3.5

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.

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 power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Smith & Nephew Medical Ltd.
101 Hessle Road
Hull, HU3 2BN
England

United States
Smith & Nephew, Inc.
5600 Clearfork Main Street, Suite 600
Forth Worth, TX 76109
Customer Care Center: +1 817 900 4000

07/2018 XXXXX A