SUNTECH

Foxtrot

Automated Blood Pressure Device

For Clinical Settings

User Manual

WK100

Welcome to Foxtrot!

Thank you for choosing the SunTech Medical Foxtrot blood pressure device.

For over thirty years, SunTech Medical has been the preeminent supplier of leading-edge technology and innovative products to obtain blood pressure measurements when manual readings are unreliable or simply not possible. Today, we remain focused on the continual advancement of clinical grade blood pressure technology.

This manual is identified as part number: 80-0097-01. An updated version may be available for download from the SunTech Medical website. Should you notice errors or omissions in this manual, please notify us at:

SunTech Medical, Inc.
5827 S. Miami Blvd, Suite 100
Morrisville, NC 27560 USA
Tel: +1.800.421.8626
+1.919.654.2300
Fax: +1.919.654.2301
Email: CustomerSupport@SunTechMed.com
Web: www.SunTechMed.com

Copyright Information

SunTech Medical
5827 S. Miami Boulevard, Suite 100
Morrisville, North Carolina 27560-8394
Phone: 1-919-654-2300
1-800-421-8626
Fax: 1-919-654-2301

Other Office Location:

SunTech Medical (Shenzhen) Co., Ltd.
105 HuanGuan South Road, Suite 15 2~3/F
DaHe Community Guanlan,
LongHua District, Shenzhen
GuangDong PRC 518110
Tel: + 86-755-29588810
+ 86-755-29588986 (Sales)
+ 86-755-29588665 (Service)
Fax: + 86-755-29588829

Table of Contents

1. Safety Considerations

Intended Use

Foxtrot is a portable, body-worn non-invasive blood pressure device (NIBP), with the optional capability to measure oxygen saturation (SpO2), for use in clinical settings. It measures, displays, and can transmit results to a central station via a paired ECG telemetry unit, including a patient's heart rate, systolic and diastolic blood pressure (BP), and, with SpO2 option, percent oxygen saturation of arterial blood. Use Foxtrot only with adult patients, under the supervision of a physician. The Foxtrot can also be used as a stand-alone device.

Indications for Use

The SunTech Medical Foxtrot NIBP device, with optional pulse oximeter, is indicated for use during both motion and non-motion conditions while measuring and displaying blood pressure, pulse rate, and functional oxygen saturation of arterial hemoglobin (SpO2) of adult patients in hospitals, medical facilities, and subacute environments. Presence of arterial or ventricular fibrillation, arrhythmias, pacemakers, etc. may interfere with the normal functionality of the Foxtrot device.

User Responsibility

Your Foxtrot is designed to perform in conformity with the description thereof contained in this operation manual and accompanying labels and inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided. It is your responsibility to:

- Check calibration of this device annually.
- Never knowingly use a defective device.
- Immediately replace parts that are broken, worn, missing, incomplete, or contaminated.
- Contact the nearest SunTech approved service center should repair or replacement become necessary.
  A list of approved service centers appears in the guide or on our website at www.SunTechMed.com.
- The reliability of the device depends upon conformance with the operation and service instructions, as detailed in this manual.

Further, the user of the device bears sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than SunTech Medical or authorized service personnel.

Precautions & Possible Adverse Reactions

Use of Foxtrot

Use only blood pressure (BP) cuffs supplied by SunTech Medical.

Observe the patient carefully during use. Ensure pressure compatibility to all patients. If any abnormality occurs, either in the unit or the patient, suspend immediately and disconnect the BP cuff and SpO_2 sensor from the patient.

Accuracy of any blood pressure or oxygen saturation readings may be affected by the position of the subject, their physical condition, or use outside of the operating instructions detailed in this guide. The interpretation of blood pressure and oxygen saturation measurements should only be made by a physician.

Safety and effectiveness have not been established when used with pregnant women, children under 13 years of age, and neonates.

Pulse Oximetry

Use only pulse oximeter (SpO_2) systems and sensors supplied by SunTech Medical. Using other pulse oximeters may cause improper sensor performance.

 CAUTIONS:

Check the application site of the SpO2 sensor frequently to confirm proper positioning of the sensor and to check the circulation and skin sensitivity of the patient.

Monitor patient to ensure that all cables to the patient are secured to prevent entanglement with the patient during the use of the Foxtrot system. If necessary, use the wrist straps to secure the cables to the patient's wrist.

Do not use a SpO2 extension cable with the Foxtrot system. An inaccurate SpO2 measurement may result.

Factors that may affect the accuracy of pulse oximetry:

- electrosurgical interference
- arterial catheters, blood pressure cuffs, infusion lines, etc.
- moisture in the sensor
- improperly attached sensor
- incorrect sensor type
- poor pulse quality
- venous pulsations
- anemia or low hemoglobin concentrations
- cardiovascular dyes
- sensor not at heart level
- artificial fingernails and dark-colored nail polish

Possible Adverse Reactions

In the area of the BP cuff or SpO_2 sensor an allergic exanthema (symptomatic eruption) may result, including the formation of urticaria (allergic reaction including raised edematous patches of skin or mucous membrane and intense itching) caused by the fabric material of the cuff, sensor, or electrodes.

Following the application of the BP cuff, petechia formation (a minute reddish or purplish spot containing blood that appears in the skin) or Rumpel-Leede phenomenon (multiple petechia) on the arm, which may lead to idiopathic-thrombocytopenia (spontaneous persistent decrease in the number of platelets, associated with hemorrhagic conditions) or phlebitis (inflammation of a vein) may be observed.

Warnings, Cautions, and Contraindications

Warning: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed health care practitioner.

 The Foxtrot NIBP device is defibrillator protected. The pulse oximeter is not defibrillator protected. After defibrillation, the Foxtrot may require up to 3 seconds to recover.

Contraindications:

This system is contraindicated for use in the presence of a Magnetic Resonance Imaging (MRI) device.

DO NOT USE on neonates, children, and patients known to be readily susceptible to bruising.

This system is contraindicated for patients with presence of arterial or ventricular fibrillation, arrhythmias, pacemakers, etc.

WARNINGS:

No modification of this equipment is allowed. Serious injury could occur.

Ensure that appropriate resuscitation equipment and personnel are available at all times during the procedure. All Event Codes indicate a potential increased risk of injury if the test is continued.

DO NOT USE the device if it has failed its diagnostic self-test, or if it displays a greater than zero pressure with no BP cuff attached, or a value of oxygen saturation with no SpO_2 sensor attached. The values displayed by such a unit may be inaccurate.

DO NOT attach the cuff to a limb being used for IV infusions or any other intravascular access, therapy or an arteriovenous (A-V) shunt. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.

Check periodically that operation of the AUTOMATED SPHYGMOMANOMETER does not result in prolonged impairment of the circulation of the blood of the patient.

DO NOT apply the BP cuff over a wound as this can cause further injury.

DO NOT apply the BP cuff to the arm on the side of a single mastectomy. In the case of double mastectomy use the side of the least dominate arm.

Too frequent BP measurements can cause injury to the patient due to blood flow interference.

Pressurization of the BP cuff can temporarily cause loss of function of simultaneously used equipment on the same limb.

DO NOT attach the SpO_2 sensor to the same limb as the BP cuff or any other blood flow restrictors. Loss of performance can occur due to the hindering of pulse measurements.

DO NOT USE in the presence of flammable anesthetics; this could cause an explosion. This device is not suitable for use in an oxygen enriched environment.

Avoid compression or restriction of the patient cable tubing as it will affect the BP reading.

DO NOT immerse the device in any fluid, place fluids on top of, or attempt to clean the unit with any liquid detergents or cleaning agents. This may cause an electrical hazard. Refer to the cleaning section of this guide for instructions on cleaning. If any of these situations occur, please contact SunTech Medical. The device is ordinary equipment and is rated for no ingress protection (IPX0).

DO NOT allow the SpO_2 sensor to become wet.

DO NOT use a damaged BP cuff or SpO_2 sensor. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.

DO NOT REMOVE UNIT COVERS. Doing so may expose hazardous voltage and cause electrical shock. The device does not contain any user serviceable components.

DO NOT MAKE REPAIRS YOURSELF: No repair should be undertaken or attempted by anyone not having been service trained by SunTech Medical or having a thorough understanding of the repair and operation of automatic blood pressure equipment. (Substitution of a component different from that supplied might result in measurement error).

DO NOT connect the device to equipment that does not meet EN60601-1.

DO NOT use if device is dropped and/or is damaged in use or shipping. Have a qualified service representative check the monitor before using again.

Performance can be affected by extremes of temperature, humidity and altitude.

CAUTION:

A compressed or kinked connection hose may cause continuous cuff pressure resulting in blood flow interference and potentially harmful injury to the patient.

Should the cuff maintain pressurization for more than three (3) minutes, disconnect the cuff from the patient hose and remove the cuff from the arm. Contact SunTech Medical. DO NOT MAKE REPAIRS YOURSELF.

Icons, Symbols and Abbreviations

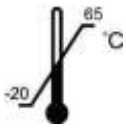
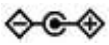
Icons

The following icons used in this guide and on Foxtrot equipment and packaging are unique to SunTech Medical.

Icon	Definition	Standard/Source
	Patient Cable connection for BP cuff (pneumatic).	SunTech Design
	Patient Cable connection for K-sound microphone.	SunTech Design
	Interval Program	SunTech Design
	View Menu Options	SunTech Design
	Select Menu Option	SunTech Design
	Power On/Off	SunTech Design
	ECG Signal	SunTech Design
	Heart Rate	SunTech Design
	Wireless Signal	SunTech Design
	Battery Level Indicator	SunTech Design
	Warranty Seal	SunTech Design
	No serviceable parts inside	SunTech Design

Symbols

Symbol	Definition	Standard/Source
	Warning message	ISO 7010-W001
	Caution message	ISO 7000-0434A
	Medical Device	ISO 15223-1-2021
	Serial Number	ISO 7000-2498
	Model number	IEC 60417-6050
	Warning: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed health care practitioner.	FDA
	USB-C	Industry
	Defibrillation-proof type BF applied part	IEC 60417-5334
	SpO_2 Sensor. Type BF Applied Part	IEC 60417 - 5333
	DC input.	IEC 60417-5031
	Do not discard as unsorted or household waste.	IEC 60417-6414
	Refer to Instruction Manual	ISO 7010-M002
	No SpO_2 Alarms	IEC 60417-5319
	Consult operating instructions	ISO 7000-1641
	Manufacturer	ISO 7000-3082
	Manufacture Date	ISO 7000-2497

	For indoor use only	IEC 60417-5957
	Meets ELSA 2007, CEC efficiency level V EU (EC) No 278/2009 Phase II	
	Fragile; handle with care	ISO 7000-0621
	Temperature limitation	ISO 7000-0632
	Humidity limitation	ISO 7000-2620
	Keep dry	ISO 7000-0626
	Class II isolation equipment	IEC 60417-5172
	Polarity of DC Power Connector	IEC 60417-5926.

Commonly Used Abbreviations

BP	Blood Pressure	NIBP	Non-Invasive Blood Pressure
BPM	Beats Per Minute	OSC	Oscillometric
DKA™	DimensionalK-sound Analysis	SpO_2	Percent Oxygen Saturation of Arterial Blood (hemoglobin)
K-sounds	Korotkoff sounds	SPU	Single Patient Use
DIA	Diastolic BP	SYS	Systolic BP

2. Setting up Foxtrot

Foxtrot is designed to work directly with a central station/telemetry system. When the Foxtrot and Central Station/Telemetry systems are properly connected, the Central Station will automatically prompt the device to take blood pressure readings. Foxtrot will send blood pressure, SpO_2 (if connected), and heart rate readings back to the central station at the completion of each reading. This section describes how to set up the device.

Register the Foxtrot

Ensure the highest level of support and protection for your product by registering today. Submit registration online at www.SunTechMed.com/register.

Unpacking the Device

As you unpack your Foxtrot, check to make sure you have all the proper components. Refer to the separate packing label on the inner tray stating which components you should receive based on the options you ordered with your Foxtrot.

Foxtrot Connections

All Foxtrot connections are on the top of the device. See Figure 2.

Installing the Battery Pack

The separate rechargeable Li-Ion battery pack supplied with the Foxtrot should be fully charged before first use. Once charged, the battery pack can be attached to the end of the Foxtrot by carefully sliding it into place starting at the top.

Please read the battery instructions and the label on its surface before use. Allow 8 to 12 hours for charging before installation and first use. The battery charge indicator LED will glow yellow when the battery is charging and green when fully charged.

Battery Charging Indicator (on battery pack)

- Charge status provided by a single two-color LED
- No power supply connected: LED off
- Charging in Progress: Yellow LED on solid
- Charging complete: Green LED on solid
- Fault condition: Green and Yellow alternate at 1 second intervals.

Battery Level Indicator (on Foxtrot)

If the battery icon on the display is flashing, it is recommended that the battery pack be removed and recharged or replaced with a charged battery pack.

When the battery icon on the display is flashing, the Foxtrot device will continue to operate properly to full depletion of the battery. At that time, the device will turn off. However, repeated use of the battery to full depletion will reduce the life of the battery.

The battery should be fully recharged every 2 months when monitor is in storage.

⚠ CAUTION:

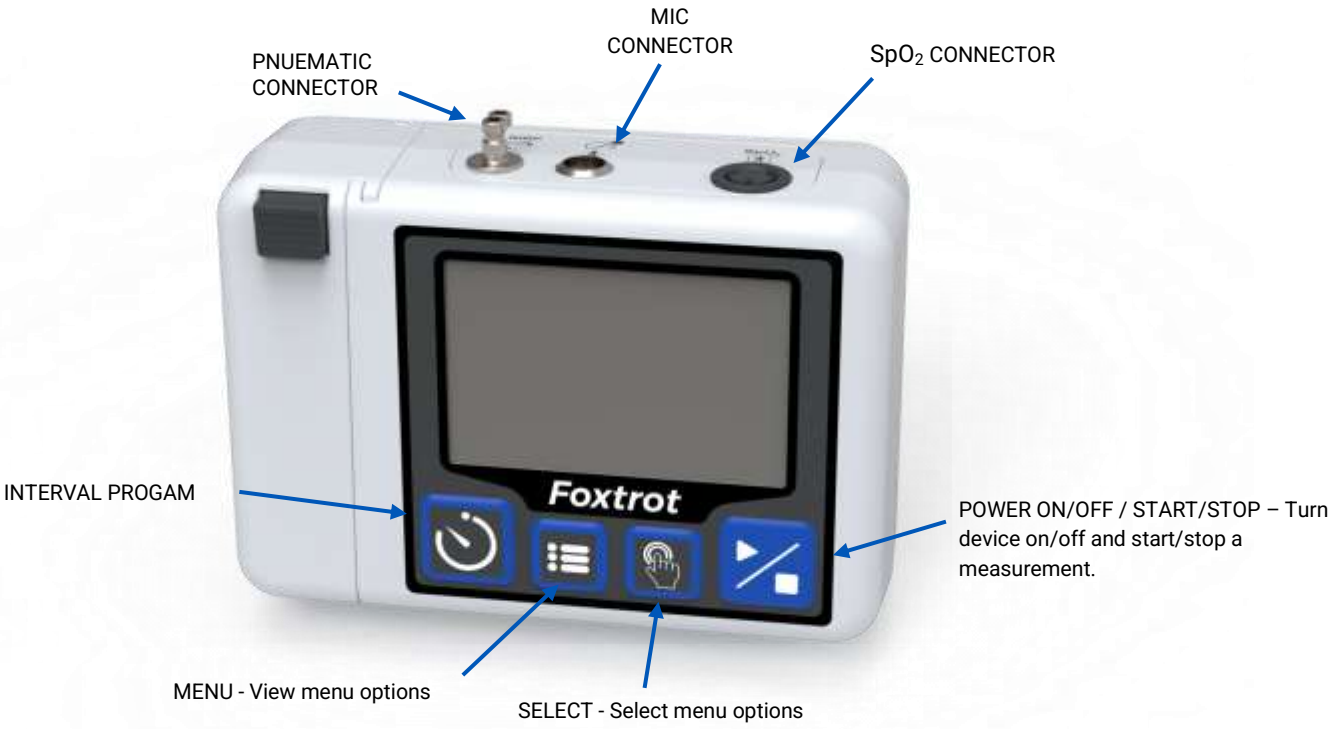
Fire, explosion and severe burn hazard. Replace battery pack only with SunTech part number: 97-0242-00. The battery shall be kept away from heat, fire or other high temperature environments. Keep the battery in a dry place stored at room temperature. Do not disassemble, attempt to repair or use the battery for any other device or for any other purpose. Do not short across the contacts of the battery or attempt to discharge the battery by shorting as a risk of fire or explosion may result. Do not dispose of battery in fire as it may explode. Do not expose or immerse the battery in water or attempt to clean with any cleaning agents. Only wipe battery with a damp cloth if necessary.

Battery Disposal

The SunTech Foxtrot device and battery pack contain a lithium-ion battery that contains materials which may be hazardous to human health. Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2012/19/EU of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). Please dispose of in an environmentally responsible way or contact SunTech Medical to return the battery. See our website for more information about our environmental policy at: https://www.suntechmed.com/about-suntech.

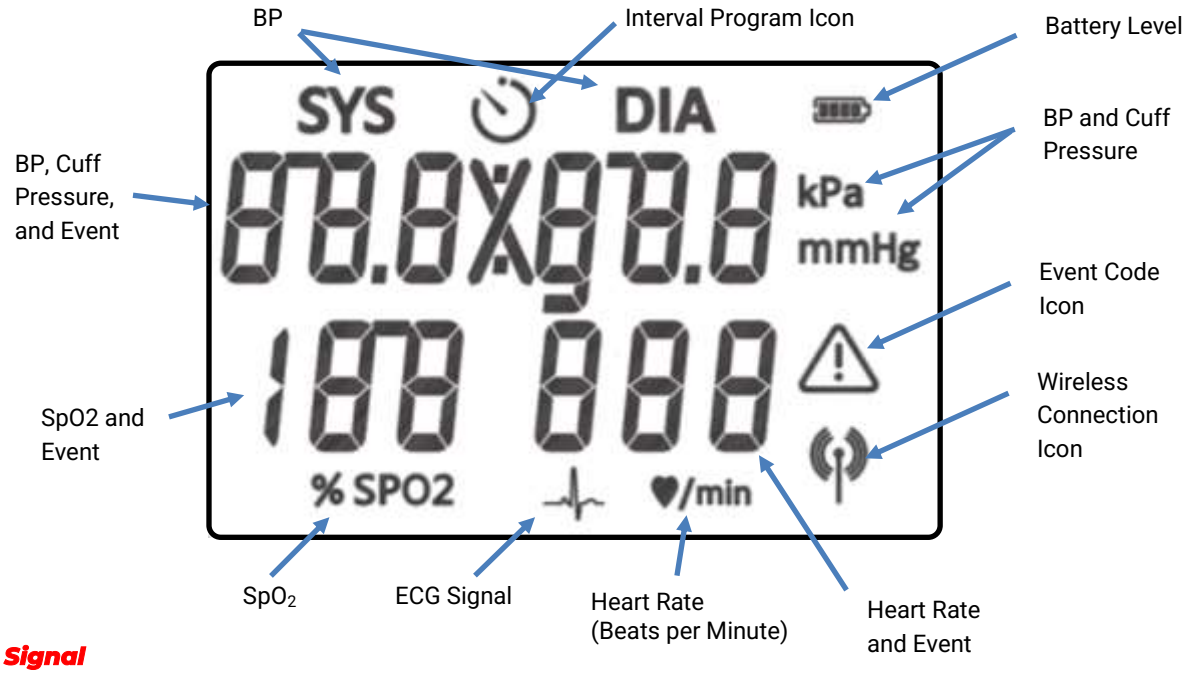
3. Getting to know Foxtrot

Front Panel (Figure 1)



Top Panel with Connections (Figure 2)

LCD Screen Layout (Figure 3)



ECG Signal

The ECG signal will be displayed continuously if the Foxtrot is receiving ECG triggers from a paired telemetry system.

During the BP cycle in AUS mode the ECG signal will flash each time it receives an ECG trigger.

Heart Rate

♥/min In OSC mode, heart rate value is not displayed until the end of each BP measurement.

In AUS mode, heart rate value will be displayed continuously.

During an AUS mode BP cycle the ♥ will flash each time a K-sound is detected.

Also when starting an AUS mode BP, if no heart rate is available an Event Code will be displayed instead of taking a BP

SpO_2

SpO₂

The SpO_2 field will be blank if no SpO_2 sensor is attached to the device.

The SpO_2 field will display dashes if the SpO_2 sensor is attached to the device but is not connected to a patient.

The SpO_2 results are displayed in black if SpO_2 is connected to a patient.

If no SpO_2 is available, an Event Code will be displayed.

BP Reading / Cuff Pressure

- The most recent BP reading will appear on the screen.
- While a measurement is being taken, the cuff pressure will be displayed on the screen. The cuff pressure units indicator will show if this reading is in mmHg or kPa.
- If no BP is obtained, an Event Code will be displayed.

Attach Connections to the Monitor

Connect the Patient Cable to the microphone and pneumatic connectors on the top of the monitor. Attach the optional SpO_2 system, if supplied, with the device to the SpO_2 connector.

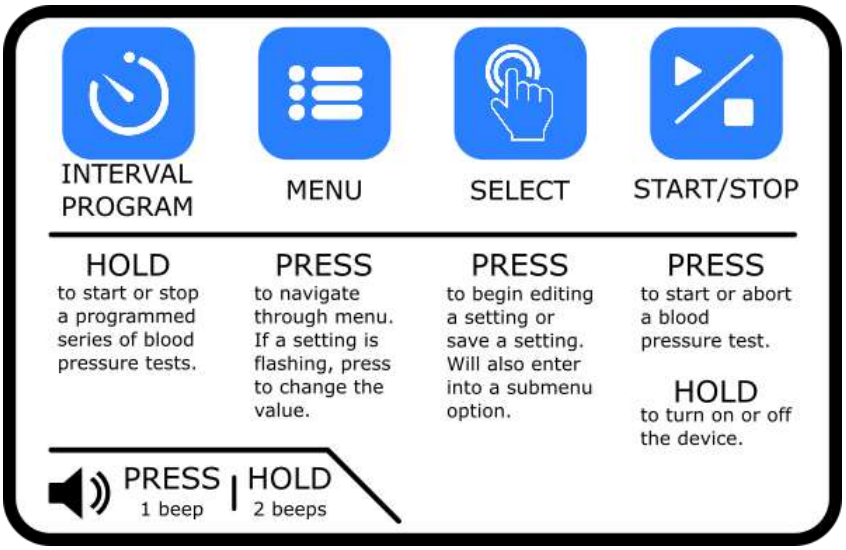
Turning the Foxtrot On and Off

Press and hold the ON/OFF button on the front of the Foxtrot for one second to turn it on. The Foxtrot will go through a self-diagnostics menu that takes about 10 seconds. The device is now ready to be programmed or used. To turn the device off, press and hold the ON/OFF button for 2 seconds; the device will beep 2 times. Release the button after two beeps and the unit will power off.

USB-C Port

The USB-C port on the end of the Foxtrot monitor where the battery pack is attached, is for service use only and is not intended for use by the end user.

Quick Reference for Button Operations



Main Menu

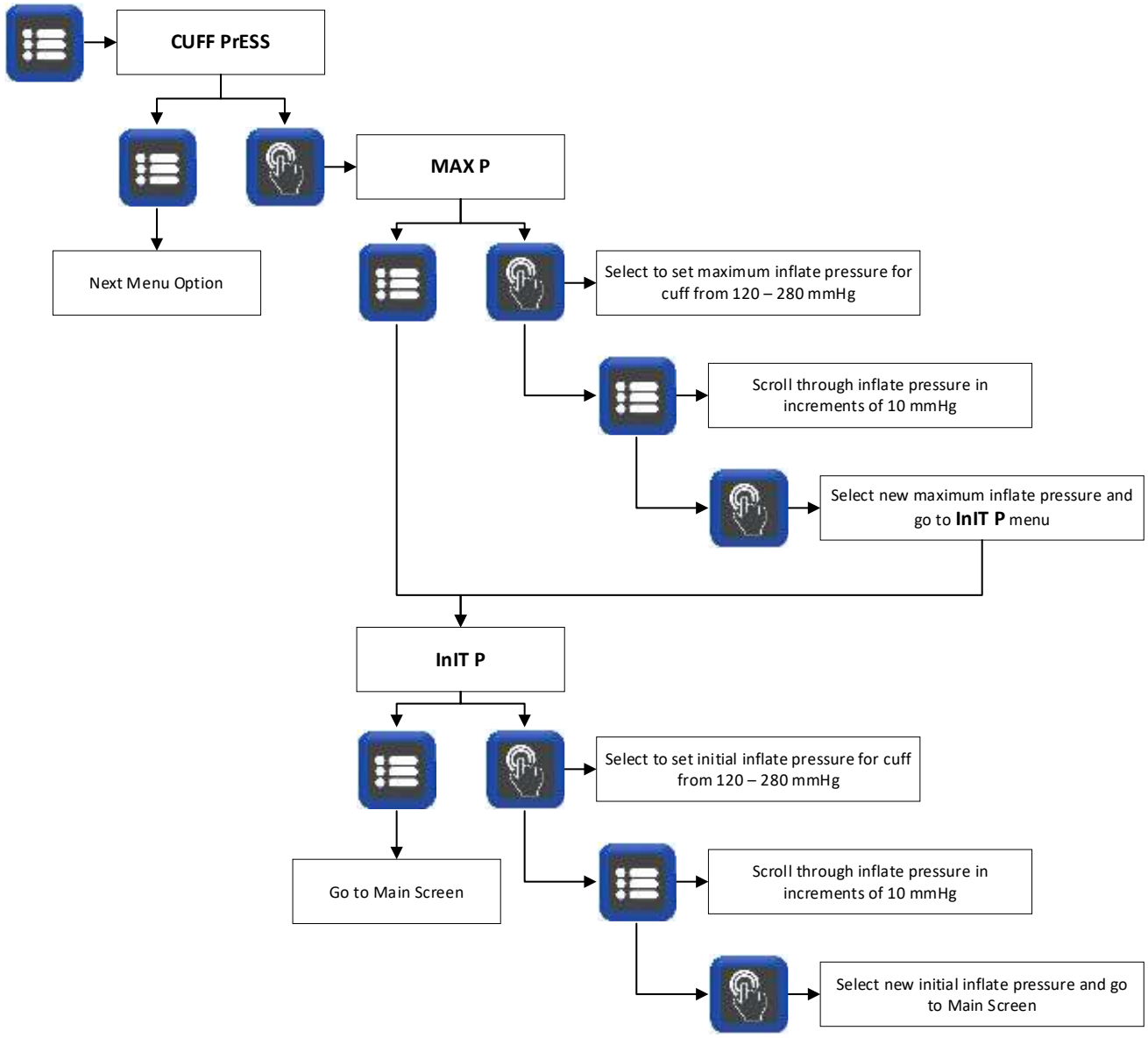
Below is a listing of the options available in the Main Menu.

Menu Options	Description	Default	Options
CUFF PrESS	Max P (Max Pressure) - Set maximum inflate pressure for cuff from 120—280mmHg in increments of 10 mmHg.	280	120-280
	InIT P (Initial Pressure) - Set maximum inflate pressure for cuff from 120—280mmHg in increments of 10 mmHg.	180	120-280
Prog	rATE - Set reading intervals in minutes	10 minutes	1-99 minutes
	LEngTH - Set program duration in minutes	000 minutes	0-399 minutes
bP MOdE	Choose BP mode.	AUTO	AUTO/AUS/OSC
bp bEEP	Set Beeper On or Off after a BP Cycle is complete	ON	ON/OFF
CLOC	Set time of day.	24-hour format	N/A
dATE	Set the date.	Year/Month/Day Format	N/A
ConnEc	This displays the device ID and allows the Foxtrot to be paired with an ECG telemetry unit.	Device ID	N/A
UnITS	Select unit of measure for BP readings.	mmHg	mmHg / kPa

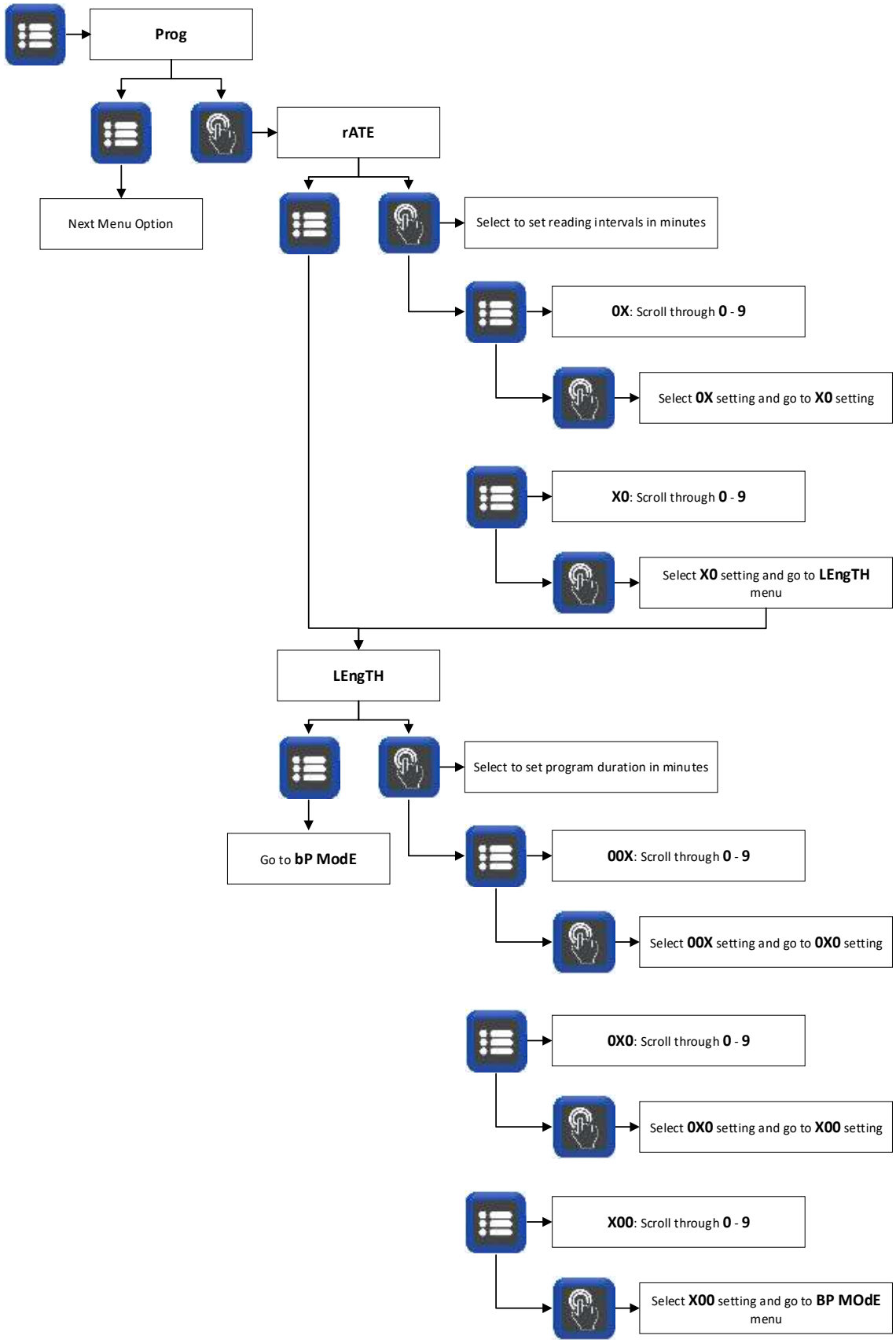
Programming the Foxtrot

NOTE: At any time in the menu, except for setting the CLOC and dATE, you can save your settings, exit the menu, and go to the Main Screen by pressing the  START/STOP button. For CLOC and dATE, the settings are not saved until all values are selected.

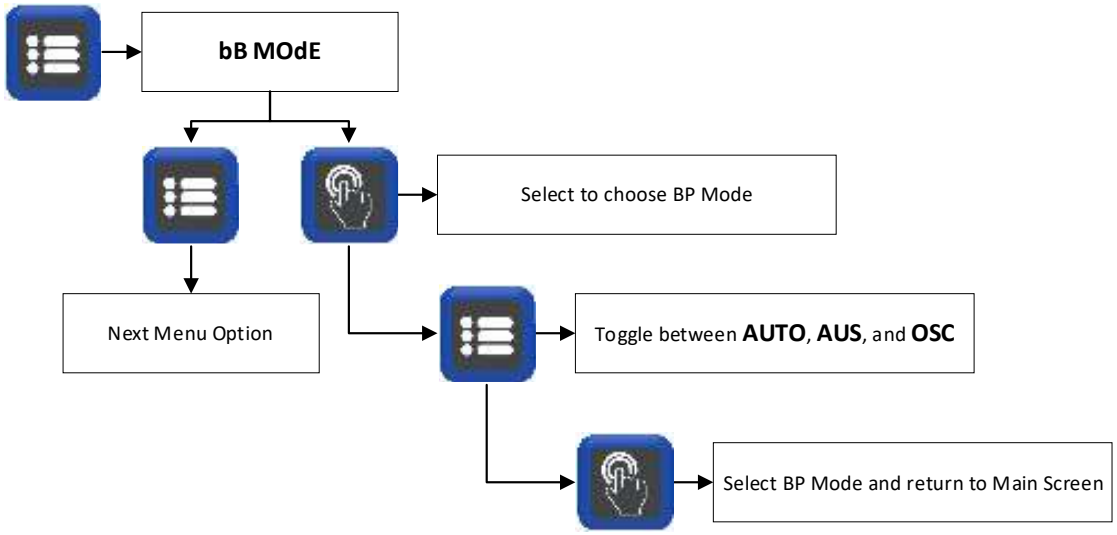
CUFF PrESS


CUFF PrESS
MAX P
Next Menu Option
Select to set maximum inflate pressure for cuff from 120 – 280 mmHg
Scroll through inflate pressure in increments of 10 mmHg
Select new maximum inflate pressure and go to InIT P menu
InIT P
Select to set initial inflate pressure for cuff from 120 – 280 mmHg
Go to Main Screen
Scroll through inflate pressure in increments of 10 mmHg
Select new initial inflate pressure and go to Main Screen

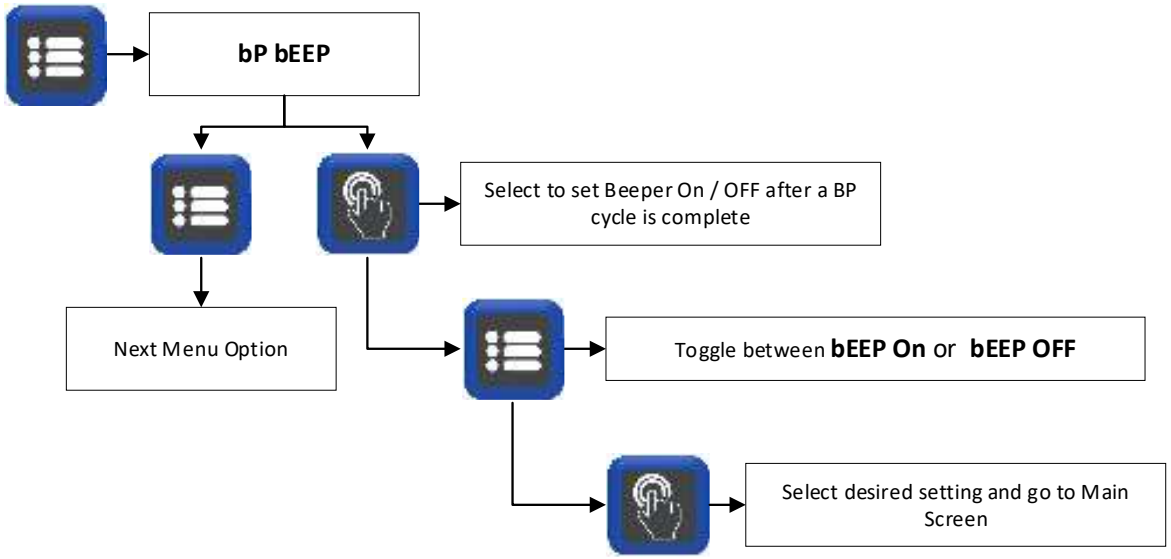
Prog


Prog
rATE
Next Menu Option
Select to set reading intervals in minutes
0X: Scroll through 0 - 9
Select 0X setting and go to X0 setting
X0: Scroll through 0 - 9
Select X0 setting and go to LEngTH menu
LEngTH
Select to set program duration in minutes
Go to bP ModE
00X: Scroll through 0 - 9
Select 00X setting and go to 0X0 setting
0X0: Scroll through 0 - 9
Select 0X0 setting and go to X00 setting
X00: Scroll through 0 - 9
Select X00 setting and go to BP MOdE menu

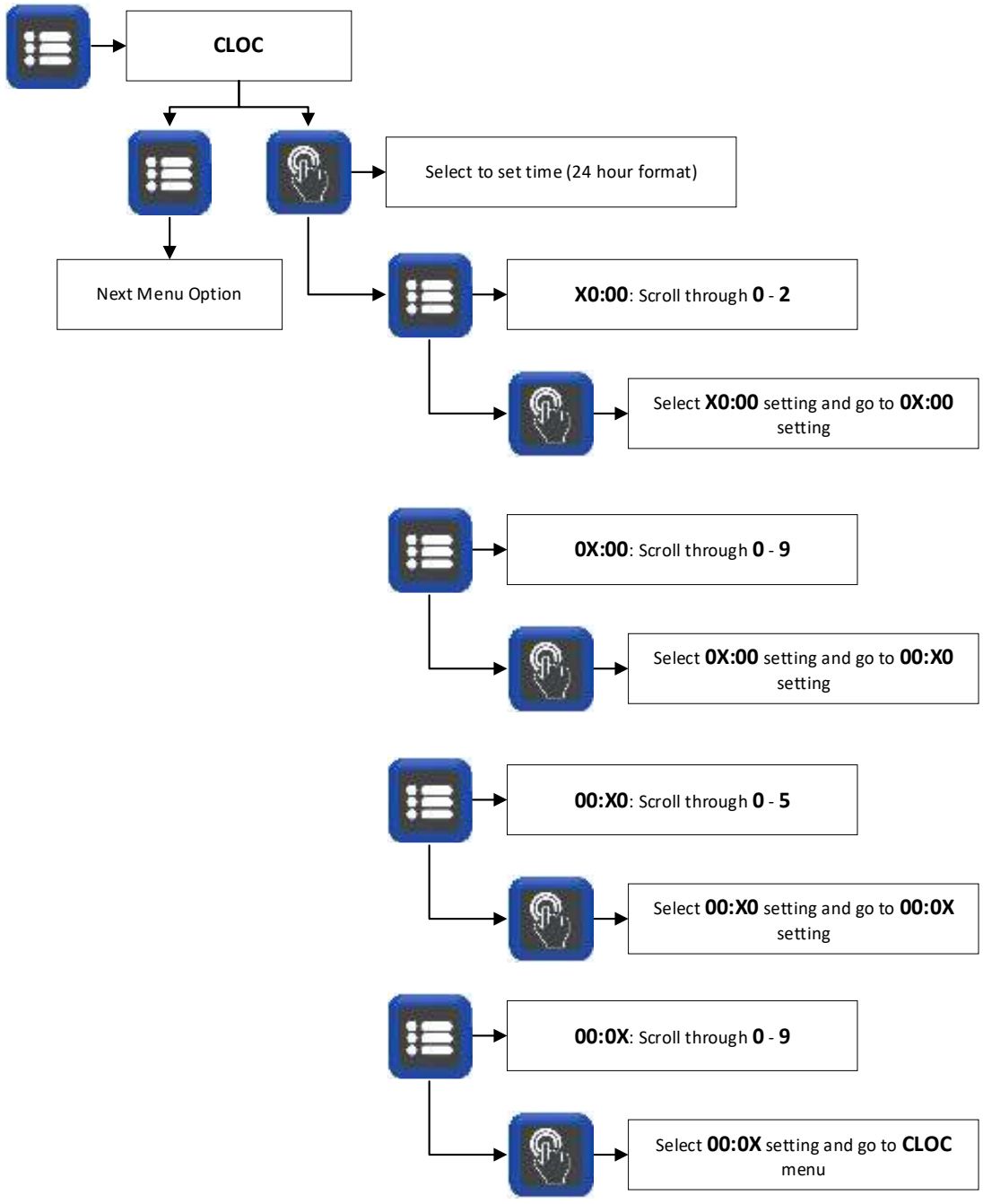
bP MOdE



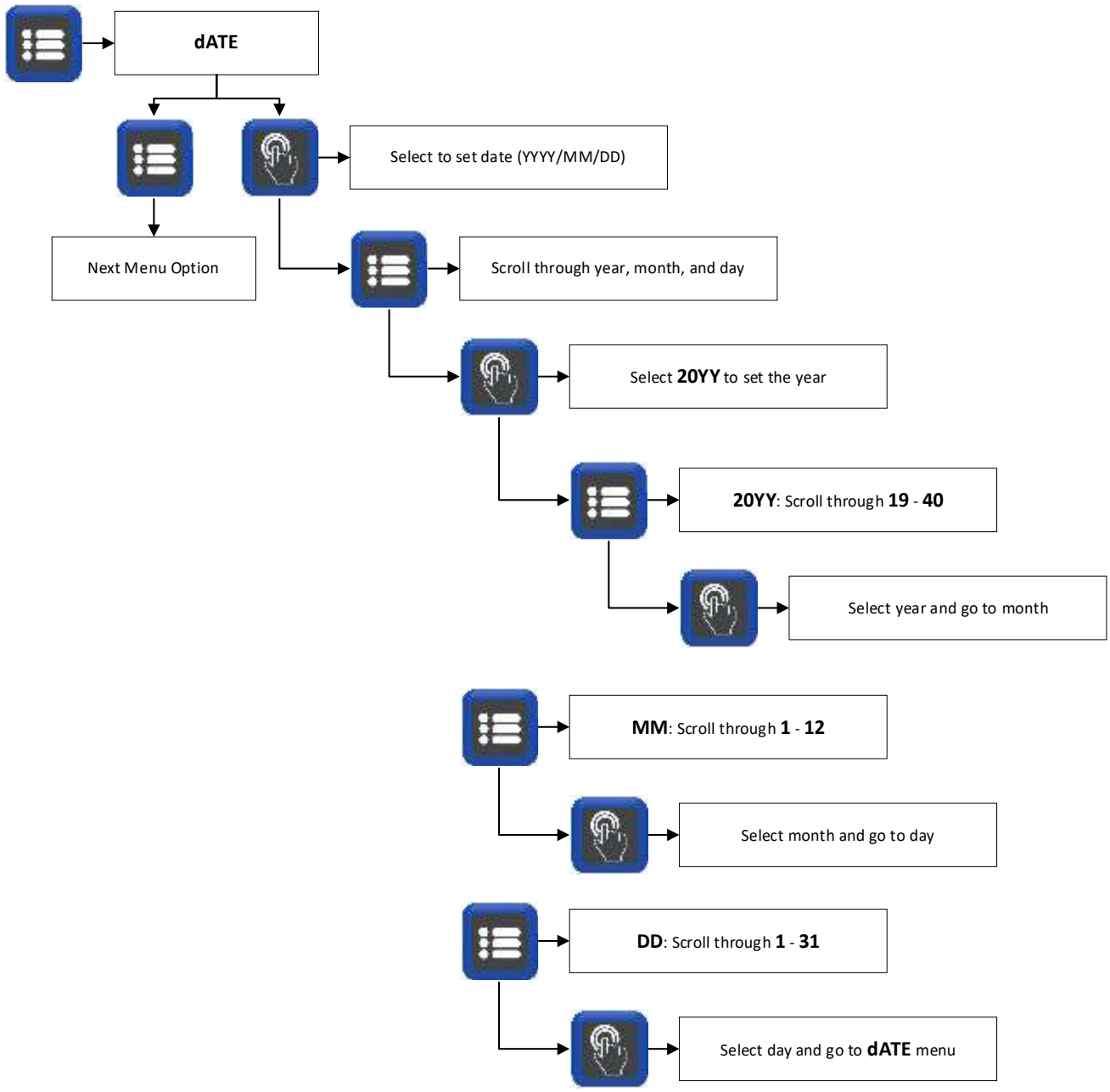
bP bEEP



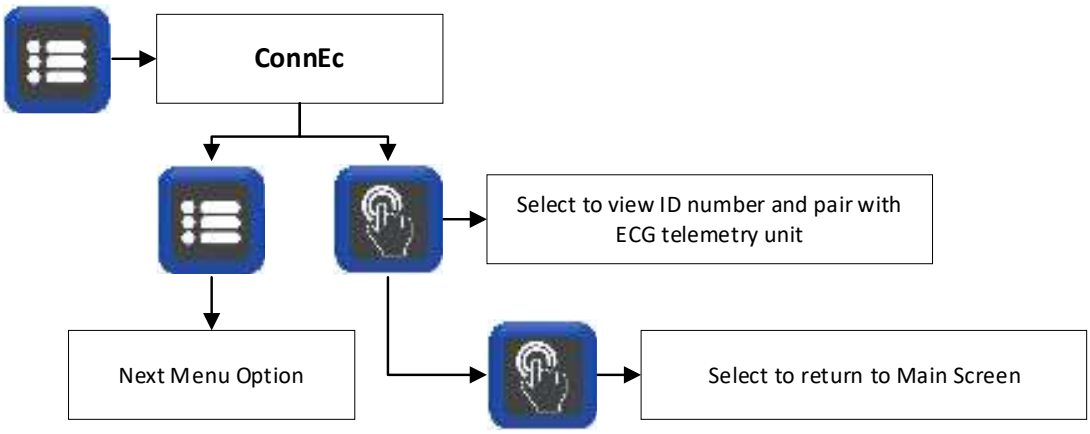
CLOC


CLOC
Select to set time (24 hour format)
Next Menu Option
X0:00: Scroll through 0 - 2
Select X0:00 setting and go to 0X:00 setting
0X:00: Scroll through 0 - 9
Select 0X:00 setting and go to 00:X0 setting
00:X0: Scroll through 0 - 5
Select 00:X0 setting and go to 00:0X setting
00:0X: Scroll through 0 - 9
Select 00:0X setting and go to CLOC menu

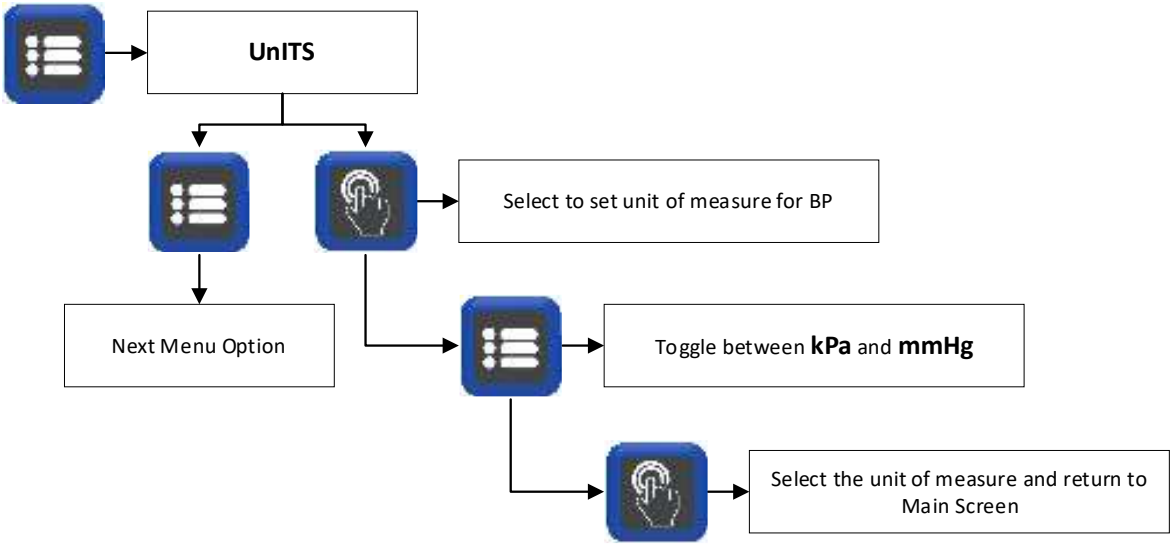
dATE


dATE
Select to set date (YYYY/MM/DD)
Next Menu Option
Scroll through year, month, and day
Select 20YY to set the year
20YY: Scroll through 19 - 40
Select year and go to month
MM: Scroll through 1 - 12
Select month and go to day
DD: Scroll through 1 - 31
Select day and go to dATE menu

ConnEc



UnITS



Pairing Foxtrot with a telemetry system

Foxtrot is designed to interface (pair) with a central station/telemetry system. For specific information on how to pair the Foxtrot with your system, utilize the Pairing Guide provided by your department or contact the manufacturer of the telemetry system.

4.Using Foxtrot

Follow these steps to use Foxtrot when performing a six-minute walk test:

1. Measure the patient's arm to ensure proper cuff sizing.
2. Place the blood pressure cuff on the patient's arm and ensure the microphone is properly placed over the brachial artery.
3. If indicated, place SpO_2 sensor on the index finger on the arm opposite the cuff.
4. Make sure the device is receiving an ECG signal via the telemetry module.
5. Take a blood pressure reading.
6. Begin test and allow the central station to initiate programmed readings.

You should be familiar with taking blood pressure measurements and managing the central station system before using Foxtrot.

Step 1. Blood Pressure Cuff Placement

Use either a SunTech Orbit-K™ blood pressure cuff or a SunTech Single Patient Use kit (containing a disposable blood pressure cuff and microphone pad). This section gives directions for proper size selection and placement of either style of cuff.

⚠ CAUTION:

It is important that the cuff is properly fitted to the patient's arm, and that the microphone is placed over the brachial artery (between the bicep and triceps). Improper cuff sizing and a misplaced microphone can lead to missed or poor readings and accuracy.

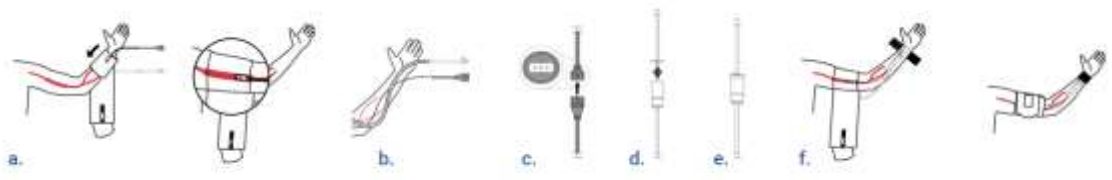
Orbit-K™ Cuff

The Orbit-K cuff is available in four sizes. For sizes please see Section 7. To check that the cuff is the correct size:

1. Fold the grey sleeve inside the blue cuff (away from the hook and loop strip).
2. Wrap the cuff around the patient's upper arm.
3. Make sure the INDEX (the end of the cuff) falls within the RANGE (printed inside the cuff).
4. If the INDEX falls outside the RANGE, select a new cuff size.

For proper cuff placement:

a. Locate the brachial artery, between the bicep and the triceps of the upper arm. The left arm is preferred. Slide the cuff sleeve up the patient's arm, with the "ARTERY" marker pointing down the arm. There is a microphone located under the "ARTERY" marker. Make sure the microphone is placed on the inner portion of the arm, directly over the brachial artery between the bicep & triceps. There should be about 3 to 5 cm (two finger widths) between the edge of the cuff and the elbow.
b. The patient hose and microphone connectors should be oriented to the wrist.
c. Insert the 3-pin microphone connector from the cuff into the corresponding connector on the Patient Cable. The connector can be inserted in any orientation.
d. Connect the connector from the cuff into the corresponding connector on the Patient Cable.
e. Push until a click is heard and felt to ensure a tight connection.
f. Wrap the cuff around the arm and secure. Use the wrist straps to secure the cables to the patient's wrist.



NOTE: You may find it easier to connect the Patient Cable to the cuff before applying the cuff to the patient.

Disposable Cuff

The SunTech Single Patient Use (SPU) kit is available in five sizes. Each SPU kit contains one disposable cuff and one disposable microphone pad. Use the microphone from the Orbit-K cuff included with the device, or you can order the 12" K-Sound microphone, part number 98-0235-01, designed for use with the SPU Kits from SunTech Medical.

To remove the microphone from the Orbit-K cuff, open the Velcro strip and gently pull the microphone out of the sleeve. Clean the microphone before using with a mild medical grade disinfectant (see section 6 for cleaning).

Check that the cuff is the correct size:

1. Wrap the cuff around the patient's upper arm.
2. Make sure the INDEX (the end of the cuff) falls within the RANGE (printed inside the cuff).
3. If the INDEX falls outside the RANGE, select a new cuff size.

WARNING:

Using an incorrect cuff size could result in erroneous and misleading BP measurements!

NOTE: Adhesive pads should be used or discarded by the "use by date" given by the manufacturer.

a. Locate the brachial artery, between the bicep and the triceps. Place the microphone onto the microphone pad.
b. Peel the protective film from the microphone pad.
c. Place the microphone on the patient's arm making sure that the microphone is placed on the medial part of the arm, directly over the brachial artery between the bicep and triceps. There should be about 3 to 5 cm (two finger widths) between the microphone pad and the elbow.
d. Wrap the cuff around the arm and secure. The patient hose and microphone connectors should be oriented to the wrist.
e. Insert the 3-pin microphone connector from the cuff into the corresponding connector on the Patient Cable. The connectors can be inserted in any orientation. Connect the connector from the cuff into the corresponding connector on the Patient Cable.
f. Use the wrist straps to secure the cables to the patient's wrist.

Step 2. Confirm ECG Signal

Foxtrot requires an ECG signal to take BP measurements during motion, such as during a Six Minute Walk test (6MWT). The device receives this ECG signal wirelessly from the ECG telemetry system once the patient ECG connections are in place and the units are paired. ECG acquisition can be confirmed when the ECG icon is solid.

CAUTION:

Foxtrot can be used in OSC mode to take blood pressure readings without an ECG signal before exercise begins. The patient must remain still while these readings are being taken! Refer to the DKA mode vs. OSC mode section below for more information.

If patient ECG connections are not already in place, follow the instructions provided with your telemetry system for placement of ECG electrodes and connection of lead wires. Make sure that a stable heart rate is displayed on the Foxtrot device before proceeding with use.

Step 3. Take BP Readings

Once the session begins, the central station will prompt the device to take blood pressure readings. The cuff will automatically inflate for each measurement. You can also press the START/STOP button to manually prompt the device to take blood pressure readings. This same button can be used to abort a reading if necessary.

Display of Readings

Blood pressure readings are displayed as soon as each measurement is complete.

Readings at Timed Intervals:

If Controlled by the Central Station:

When the Foxtrot is connected to a telemetry system the Central Station will control the BP readings. The Foxtrot will follow a predetermined BP interval protocol driven by the Central Station. In this instance, the timed intervals do not need to be programmed into the Foxtrot.

When Not Controlled by the Central Station:

The Foxtrot can be set to initiate blood pressure readings at intervals from one to 99 minutes, for periods up to 399 minutes. The interval is set by selecting the Main Menu > Prog > Rate option. The duration of the timed intervals is set by selecting the Main Menu > Prog > Rate > Length option.

Press and hold the Interval Program button until 2 beeps are heard to initiate timed interval BP readings. The interval readings will stop after the duration period has passed or by pressing and holding the Interval Program button until 2 beeps are heard.

Stopping a Reading

Press the START/STOP button to stop a blood pressure measurement in process. The device will display an EC86 code first, indicating a user abort of the BP reading. Then the unit will go back to flashing the time.

DKA™ Mode vs. OSC Mode

SunTech Medical's proprietary Dimensional K-sound Analysis (DKA™) algorithm uses the supplied ECG signal (from the telemetry system) and K-sound pattern recognition (K-sounds are from the microphone) to filter out noise, making DKA™ mode highly tolerant to patient movement. DKA™ mode requires that the device receives an ECG signal from the patient via the telemetry module. The Foxtrot displays this as AUS mode.

An alternate oscillometric method (OSC mode) is available to take blood pressure when an ECG signal is not present.

NOTE: The patient must remain still while oscillometric measurements are being taken.

Step 4. Tips for Obtaining Accurate Readings

Practice measurements

Take a few measurements before starting exercise. Take one or two blood pressure measurements with the patient seated or standing still in DKA mode. This creates a baseline BP and allows the patient to become familiar with the BP process.

Make sure your patient's arm is relaxed

Have your patient limit the movement of the cuff arm while their blood pressure is being measured. A gentle swinging is acceptable; bending at the elbow is not. Avoid flexing the muscles of the cuff arm.

Watch for Information Signals and Event Codes

The ECG signal icon will be displayed continuously if the Foxtrot is receiving ECG triggers from a paired telemetry system. During the BP cycle in AUS mode the ECG signal icon will flash each time it receives an ECG trigger. If the ECG icon is not flashing or is flashing erratically check the ECG connections and the telemetry system.

Also during the BP cycle in AUS mode the ♥ icon will flash each time a K-sound is detected by the microphone in the cuff sleeve.

There is a full description of Foxtrot Information Signals and Event Codes in the Information Signals & Event Codes section of this guide which will help ensure correct hook up and placement of the BP cuff.

When the clinical session is finished, remove the cuff from the patient's arm. Disconnect the cuff from the Patient Cable.

Notes on Blood Pressure Data

Any blood pressure reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition. Environmental or operational factors which can affect the performance of the device and/or its blood pressure reading are pacemakers and common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, patient motion, trembling, and shivering.

NOTE: If using the Orbit-K cuff, clean the cuff sleeve and the inside of the cuff with a mild medical grade disinfectant. If using a SPU kit, discard the used disposable cuff and microphone pad. Clean the microphone with a hospital-grade mild disinfectant (see section 6).

5. Using Foxtrot Options

Pulse Oximetry (SpO_2)

The optional SpO_2 sensor allows you to measure the oxygen saturation of arterial blood and displays this reading on the Foxtrot. If your Foxtrot did not come with an SpO_2 sensor you can order this option from your local SunTech Medical representative. Plug the SpO_2 sensor cable into the SpO_2 connector on the top of the device.

***WARNING*:**

DO NOT use the SpO_2 sensor on the same arm as the blood pressure cuff. The SpO_2 reading may be compromised, unattainable, or inaccurate.

***CAUTIONS*:**

If the sensor is not positioned properly, light may bypass the tissue and result in pulse oximetry inaccuracies. Proper sensor placement is critical for good performance.

Insert a finger (preferably the index, middle or ring finger) into the SpO_2 sensor until the end of the finger reaches the finger stop. Do not use the thumb. Keep the fingernail facing the sensor top. Make sure that long fingernails are not interfering with proper finger position.

Some nail polish colors (particularly dark shades), or artificial fingernails may reduce light transmission and affect pulse oximetry accuracy. Remove any nail polish or artificial fingernails before using the SpO_2 sensor.

Inspect the sensor application site to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensor may vary due to medical status or skin condition. Check frequently. If allergic reaction develops, stop use immediately and contact SunTech Medical.

Use medical tape around the base of the fingers to secure the sensor cable during a session. Make sure that the tape securing the cable does not restrict the blood flow.

NOTE: Patient sensitivity to tape may vary due to skin conditions. Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive materials.

An SpO_2 reading will be displayed after a few seconds. The SpO_2 measurement data is updated every second, and the displayed value is updated every 1 second. A 4-beat SpO_2 average is used to display a reading. Any temporary loss of signal will affect the accuracy of this reading due to this averaging.

There are Event Codes associated with SpO_2. An SpO_2 reading will not be displayed due to any of the following issues: weak or loss of signal, or an open circuit due to a damaged cable. The Foxtrot may shut down if the cable's voltage is shorted to ground until the fault is removed. In the case of a damaged cable, remove the SpO_2 cable from the Foxtrot and resume normal use of the Foxtrot. Call SunTech Customer Service for assistance with the damaged SpO_2 cable.

6. Taking Care of Foxtrot

Cleaning

Foxtrot Monitor

***CAUTION*:**

Foxtrot is not sterilizable. Do not immerse the device in any fluid or attempt to clean with any liquid detergents, cleaning agents, solvents, or harsh disinfectants (such as Quaternary Ammonium) which may damage the product.

Cleaning Process:

1. Dampen a soft cloth with mild medical grade disinfectant (such as Clorox Wipes, Dispatch Wipes, Sani-Cloth (PDI) Wipes)
2. Wipe the device thoroughly until surface dust and dirt has been removed.

Orbit-K Cuff

Cleaning Process:

1. Remove bladder & microphone from cuff sleeve.
2. Soak cuff sleeve in warm water for 5 minutes to loosen soil.
3. Rinse under running warm water (50-140°F or 10-60°C) for 1 minute. A soft bristle brush may be used to remove visible soil.
4. Fold up cuff so that hook is attached to loop with approximately ½" overlap and place in washing machine.
5. Use a fresh solution of STERIS® Prolystica® 2X Concentrate Neutral Detergent.
6. Machine wash the shell in warm water (50-140°F or 10-60°C).
7. Remove shell from washing machine and rinse and massage under warm water for 5 minutes to remove any residual detergent. Run rinse water over both sides of the cuff as well as directly into the inner portion where the bladder is placed.
8. Lay flat or line dry the shell.
9. The bladder & microphone needs to be inserted back into the cuff sleeve so the pneumatic hose portion of the bladder is outside the sleeve.

NOTE: Do not place the cuff (sleeve) in a dryer.

Disinfection Process

NOTE: Before disinfecting, ensure that no liquid enters tubing by using a plug or taping off.

1. Spray cuff with Quaternary Ammonium until soaked.
2. Leave to soak for at least 10 minutes.
3. Rinse with distilled water, ensuring liquid does not enter tube connector, and line dry.

CAUTION:
DO NOT machine wash bladder or microphone.

Patient Cable

 Cleaning Process:

1. Dampen a soft cloth with mild medical grade disinfectant (such as Sani-Cloth, Sani-Cloth PDI, Clorox Wipes, Clinell Universal Wipes, or ≥70% Isopropyl Alcohol-Based Wipes).
2. Wipe the cable thoroughly until surface dust and dirt has been removed.

NOTE: To control infection, follow your facility's established protocol. For cleaning, use your facility's established protocol.

Backpack Carry System

 CAUTION:

Failure to sufficiently remove residual detergent or Quaternary Ammonium may result in skin irritation.

Cleaning Process

1. Dampen a soft cloth with mild medical grade disinfectant (such as Clorox Wipes, Dispatch Wipes, Sani-Cloth (PDI) Wipes)
2. Wipe the backpack thoroughly until surface dust and dirt has been removed.

Disinfection Process

1. Close straps on pouches so that the hook is attached to the loop.
2. Use mild cleaning detergent.
3. Machine wash the shell in warm water (50-140°F or 10-60°C).
4. Remove backpack from washing machine and rinse and massage under warm water for 5 minutes to remove any residual detergent. Rinse water over both sides of the backpack.
5. Lay flat or line dry the backpack.

NOTE: Do not place the backpack in a dryer.

SpO_2 Sensors

 CAUTION:

Never immerse sensors and clips in fluids. Do not pour or spray any liquids onto the sensor. Caustic or abrasive cleaners will cause permanent damage. Do not open the case of the finger clip sensor more than 45° or the case will be damaged.

For SpO2 sensor cleaning instructions, see the User Manual/Instructions for Use that accompany the SpO2 finger clip sensor.

Preventative Maintenance

System Self Checks

Foxtrot performs a range of system and software checks during normal operation. If Foxtrot detects a problem, it will display an event code. If the problem persists, contact SunTech Technical Support. See Section 8, Service Centers.

 ***WARNING:***

DO NOT USE the device if it displays a greater than zero pressure with no cuff attached.

Replaceable Parts

On a routine basis, inspect the Foxtrot monitor, cuffs, SpO_2 sensor, cables, and hoses for cracks, fraying, kinks, or any other sign of damage. If the Foxtrot monitor or any part appears damaged do not use it. Immediately replace any damaged part or call SunTech Technical Support. Refer to the list of Accessories & Replacement Parts in this guide listed in Section 7. Use only approved accessories with the Foxtrot. Inaccurate readings may result if non-approved accessories are used.

***CAUTION*:**

The device does not contain any user serviceable parts and should only be opened by an authorized service representative. DO NOT remove covers or break the warranty seal as this will void the manufacturer's warranty.

Orbit-K Cuff

It is recommended that you replace the Orbit-K cuffs, microphones, and patient cable annually to maintain measurement accuracy. If the cuff does not need replacement, you can replace just the microphone. To remove the microphone from cuff, open the hook and loop flap and gently pull the microphone out of the sleeve.

SpO_2 Sensor

You can replace the SpO_2 sensor by unplugging it from the Foxtrot device and replacing it with a new SpO_2 sensor. The finger sensor expected service life is 1 year.

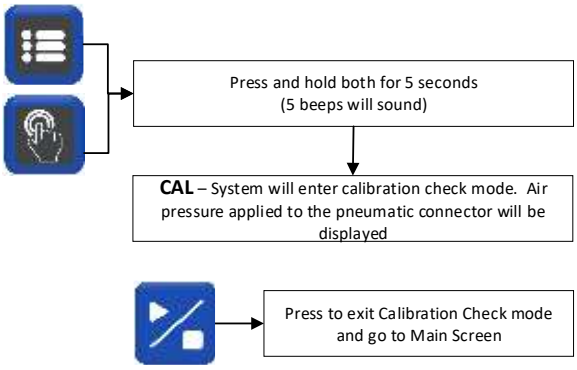
Routine Calibration Check

Check the calibration of your Foxtrot annually to verify the accuracy of the pressure transducers and indicators.

Equipment Required:

1. Calibrated electronic manometer or equivalent.
2. 500mL volume or the Orbit-K Adult Plus cuff wrapped around something that will not break or crush (no glass).
3. Hand Inflation Bulb with bleed valve.
4. Tubing, T pieces, and miscellaneous connectors or you can order the T-Tube Kit (SunTech part # 98-0030-00).

The calibration check mode can be accessed by:



***CAUTION*:**

Calibration should only be done by a biomedical technician or other person familiar with the Foxtrot device. Please contact SunTech Medical for instructions to access "Verify Calibration".

SunTech Medical, Inc.
Service Department
5827 S. Miami Boulevard, Suite 100
Morrisville, North Carolina 27560-8394
Tel: +1.800.421.8626
+1.919.654.2300
Fax: +1.919.654.2301

Product Disposal

Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2012/19/EU of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). Do not dispose of battery in fire as it may explode.

The SunTech Foxtrot device contains a lithium battery pack and printed circuit (PC) boards. These items may be hazardous to human health. Do not dispose of device in domestic waste! Instead, please recycle the device in an environmentally responsible way or return the device to SunTech Medical.

Cuff Disposal

Do not return used cuffs. Used blood pressure cuffs may be contaminated medical waste and should be dealt with in accordance with your local regulations. The Orbit-K cuff contains a microphone/cable assembly which should be removed and disposed of separately as an electrical/electronic component.

7. Accessories & Replacement Parts

Contact your SunTech Medical sales representative to purchase the following items. Visit www.suntechmed.com. for additional information for the following items:

Orbit-K™ Cuffs With K-Sound Microphone:		
Description	Part Number	Details
Small Adult	98-0062-38	18 – 27 cm
Adult	98-0062-39	25 – 35 cm
Adult Plus	98-0062-40	27 – 40 cm
Large Adult	98-0062-41	32 – 44 cm
18-inch K-Sound microphone	98-0235-00	Replacement

Single Patient Use Kits: SPU Kits are packaged 20 kits to a box (microphone is not included).		
Description	Part Number	Details
SPU Kit Small Adult	98-0700-13	17 - 25 cm
SPU Kit Adult	98-0700-14	23 - 33 cm
SPU Kit Adult Long	98-0700-15	23 - 33 cm
SPU Kit Large Adult	98-0700-16	31 - 40 cm
SPU Kit Large Adult Long	98-0700-17	31 - 40 cm
12-inch K-Sound Microphone	98-0235-01	

Foxtrot: Cables & Accessories	
Description	Part Number
Patient Cable 1 Meter	91-0127-05
Patient Cable 1.5 Meter	91-0127-06
Battery Pack Li-ion	97-0242-00
Battery Charger (Wall Plug)	19-0020-00
Nonin LPXpod Kit	98-0233-03
Nonin LPXpod Pulse Oximeter Cable	91-0125-10
Nonin Adult Finger Clip Sensor	52-0003-00
SunTech SpO_2 Kit	98-0260-00
SunTech Pulse Oximeter Cable	91-0145-00
Unimed Adult Finger Clip Sensor	52-0032-00

8. Information Signals and Event Codes

Device BP Status Information

If Foxtrot has a problem taking a blood pressure measurement, an Event Code will appear on the device screen. When an Event Code is displayed both the Event Code icon and the Event Code itself will flash. Take action as suggested in the table below. The Event Code will clear after a short period of time. Event Codes will also clear when a BP measurement is initiated.

Event Codes Displayed in AUS MODE (600 series codes)		
Information Signal	Reason	Solution
CODE 086: User Abort	User aborted BP reading.	Take another BP reading.
CODE 601: Check Mic: Check mic position and cable connection.	Weak, missing, or no K-Sounds detected. No BP reported.	Make sure microphone is positioned over the brachial artery. Make sure cuff connections to patient cable are secure. Make sure that patient cable connections are secure. Check microphone. If it is bent, or its wire is not securely connected, replace microphone. Replace microphone and cuff annually.
CODE 602: Excessive Arm Movement or Excessive Microphone Noise	Excessive K-sound noise or arm movement.	Instruct patient to drop arm to side, reduce the bending of the arm and relax arm muscles.
CODE 603: Measurement Out of Range	BP not reported.	Check initial and max inflate settings. Take another BP reading.
CODE 605: No ECG detected: Not receiving ECG signal. Check leads and cables for good connections.	Device is not receiving ECG signal.	Make sure that ECG leads are correctly positioned on the patient. Check telemetry system for proper pairing to Foxtrot.
CODE 606: Check ECG	ECG signal is weak, erratic or missing for more than 3 seconds. No BP reported.	Press START/STOP to take another reading. If error repeats, patient may have ECG problems which prevent Foxtrot from reading their blood pressure in DKA mode. If ECG signal is not present: Check telemetry system for correct pairing. Make sure patient's skin is properly prepared and that ECG electrodes are correctly placed.
CODE 607: Inflation Too Low: Check Max Inflate setting	K-Sounds were detected within 10 mmHg of target cuff inflation pressure. BP not reported.	BP reading may be inaccurate. Check Initial and Max Inflate settings. Have patient drop arm by their side during BP reading and avoid excessive movement or bending of the arm. Take another BP reading.
CODE 608: Check ECG/Mic: Check that the ECG and microphone connections are secure.	Weak or missing K-sounds or the ECG signal is erratic.	Make sure microphone is positioned over the brachial artery. Make sure cuff connections to patient cable are secure.

		Make sure that the patient cable connections are secure. Make sure that ECG leads are correctly positioned on patient. Check microphone. If it is bent, or its wire not securely connected, replace microphone. Replace microphone and cuff annually. Check telemetry system for proper pairing to Foxtrot.
CODE 609: Repeat BP: Drop arm to side and repeat BP.	The device/device could not get a BP reading.	Start new BP reading via the Central Station or using the Foxtrot START/STOP button. Have patient drop arm by their side during BP reading (avoid excessive bending of the arm).
CODE 683: Measurement Delayed: This measurement has been delayed. Next reading will occur as scheduled.	Measurement was delayed.	Next BP reading will occur as scheduled.
CODE 684: Duration Violation: Exceeded short term mode limit.	Leakage or excessive movement.	Make sure cuff and connections are secure. Instruct patient to drop arm to side, reduce the bending of the arm and relax arm muscles. Make sure patient cable is not pinched or blocked.
CODE 685: Blocked Hose: Make sure there are no sharp bends or pinches in the patient hose.	Pneumatic hose blockage.	Make sure there are no sharp bends or pinches in the patient hose.
CODE 687: Air Leak: Check cable connections at cuff and Foxtrot.	Device will terminate a BP reading if target inflation is not reached in 60 seconds.	Make sure cuff and patient cable are not leaking. Make sure patient cable is properly connected to device.
CODE 688: Error Taking BP: Unknown BP error	BP not reported	Take another BP reading. If error persists, contact SunTech Technical Support.
CODE 689: Cuff Overpressure: Check patient cables for kinks. Drop arm to side and relax.	Device will terminate a BP reading if air hose or BP cuff has reached an unreasonably high pressure. No BP reported.	Have patient drop arm by their side during BP reading (avoid excessive bending of the arm). Make sure patient cable is not pinched or blocked.

Event Codes Displayed in OSC MODE (700 series codes)		
Information Signal	Reason	Solution
CODE 086: User Abort	User aborted BP reading.	Take another BP reading.

CODE 701: Check cuff: Check the cuff for correct size and placement.	Weak or no Oscillometric signal.	Make sure cuff is properly connected. Make sure cuff is the right size.
CODE 702: Excessive Arm Movement:	Excessive arm movement. May result in no BP reading.	Set device to DKA MODE.
CODE 703: Measurement Out of Range	BP not reported.	Check initial and max inflate settings. Take another BP reading.
CODE 709: Repeat BP: Drop arm to side and repeat BP.	The device/device could not get a BP reading.	Start new BP reading via the Central Station or using the Foxtrot START/STOP button. Have patient drop arm by their side during BP reading (avoid excessive bending of the arm).
CODE 783: Measurement Delayed: This measurement has been delayed. Next reading will occur as scheduled.	Measurement was delayed.	Next BP reading will occur as scheduled.
CODE 784: Duration Violation: Exceeded short term mode limit.	Leakage or excessive movement.	Make sure cuff and connections are secure. Instruct patient to drop arm to side, reduce the bending of the arm and relax arm muscles. Make sure patient cable is not pinched or blocked.
CODE 785: Blocked Hose: Make sure there are no sharp bends or pinches in the patient hose.	Pneumatic hose blockage.	Make sure there are no sharp bends or pinches in the patient hose.
CODE 787: Air Leak: Check cable connections at cuff and Foxtrot.	Device will terminate a BP reading if target inflation is not reached in 60 seconds.	Make sure cuff and patient cable are not leaking. Make sure patient cable is properly connected to device.
CODE 788: Error Taking BP: Unknown BP error	BP not reported	Take another BP reading. If error persists, contact SunTech Technical Support.
CODE 789: Cuff Overpressure: Check patient cables for kinks. Drop arm to side and relax.	Device will terminate a BP reading if air hose or BP cuff has reached an unreasonably high pressure. No BP reported.	Have patient drop arm by their side during BP reading (avoid excessive bending of the arm). Make sure patient cable is not pinched or blocked.

Device SpO2 Status Information

If Foxtrot has a problem taking an SpO2 measurement, an Event Code will appear on the device screen. When an Event Code is displayed both the Event Code icon and the Event Code itself will flash. Take action as suggested in the table below. The Event Code will clear after a short period of time. Event Codes will also clear when a BP measurement is initiated.

Event Codes Displayed in SpO2 section of display (100 series codes)		
Information Signal	Reason	Solution

CODE 181: SpO2 Error Detected	Unknown error	Check sensor connections. If event code persists, replace sensor.
CODE 182: SpO2 Error Connection	Sensor connection error	Check sensor connections. Check for proper placement of finger in sensor.
CODE 183: SpO2 Error Perfusion	Brief perfusion error	Check for proper finger placement in sensor. Confirm no foreign material, such as nail polish, is on finger.
CODE 184: SpO2 Error Missing	Missing sensor value. No code displayed, only - - displayed.	Check for proper placement of finger in sensor.
CODE 185: SpO2 Error Sensor	Brief sensor wiring error	Check sensor connections. If event code persists, replace sensor.

Other Device Status Information

Should your device display an Event Code that is not listed or if the device is indicating an anomalous condition, try restarting the device and if the issue persists, call SunTech for further assistance.

Service Center

For customers in the Americas:

SunTech Medical, Inc.
Service Department
5827 S. Miami Boulevard, Suite 100
Morrisville, North Carolina 27560-8394

Tel: +1.800.421.8626
Tel: +1. 919.654.2300
Fax: +1.919.654.2301

9. Frequently Asked Questions

The Foxtrot displays an Information Signal. What does it mean and what do I do?

Look in the Foxtrot User Manual under the Information Signals & Event Codes section for details on each Information Signal and solution.

The Foxtrot device returns a result of 0/0 after blood pressure (BP) measurements. What do I need to do to get a BP reading?

There are certain noisy conditions where the Foxtrot cannot accurately measure BP. When the Foxtrot encounters these situations, it returns a reading of 0/0. Microphone placement is critical for reliable operation of the Foxtrot; there are many places to find cuff placement help.

1. Look in the Foxtrot User Manual under the Using Foxtrot during a session for details on each type of cuff; the Orbit-K and the Single Patient Use (SPU) kit.
2. Follow the instructions in the Cuff Tutorial (located on the SunTech Medical website under (Support > Product Training and Tutorials > Stress) scroll down to the video Orbit-K Proper Cuff Placement for correct microphone placement.

Can I use a heart rate or blood pressure simulator to test whether the Foxtrot is working correctly?

You cannot use a heart rate or blood pressure simulator to test whether the Foxtrot is working with your telemetry module. The Foxtrot device requires that the ECG signal and the Korotkoff sounds, collected by the microphone in the cuff, originate from the same source, meaning the patient.

10. Technical Information

Changes or modifications to the SunTech Foxtrot that are not approved by SunTech Medical may cause EMC interference problems with this or other equipment.

EMC Statement

This equipment has been tested and found to comply with the limits for medical devices to IEC60601-1-2: 2020. These limits are designed to provide reasonable protection against harmful interference in a typical medical 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 other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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 device.
- Increase the separation between the equipment.
- Consult the manufacturer or field service technician for help.

Follow all instructions and warnings included within this manual to maintain safety and functionality of the Foxtrot with regard to electromagnetic disturbances for the service life of the device.

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 [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Use of accessories, transducers, and cables other than those specified may result in increased emissions or decreased immunity of the Foxtrot.

The Foxtrot should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Foxtrot should be observed to verify normal operation in the configuration in which it will be used.

This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Foxtrot or shielding the location.

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 Foxtrot including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Foxtrot is intended for use in a Professional Healthcare Facility within the electromagnetic environment specified below. The customer or the user of the Foxtrot should assure that it is used in such an environment. This equipment has been tested and found to comply with the limits for medical devices to IEC60601-1-2: 2020.		
Emissions test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Foxtrot uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any data innce in nearby electronic equipment.
	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
The Foxtrot is intended for use in a Professional Healthcare Facility within the electromagnetic environment specified below. It is not intended for helicopter transport, hospital ambulance or home use. It is not intended for use near active HF SURGICAL EQUIPMENT and the RF-shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCE is high. The customer or the user of

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

the device should assure that it is not used in such an environment. This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2: 2020.

Signs of possible EMC interference may include unexpected results, display not functioning, loss of power to the device, or other unexpected behaviors in the Foxtrot. Should any of these conditions occur and the device does not recover, the device should be power cycled. If the device still does not recover, contact SunTech Medical Technical Support.

Immunity Test	Applies to	Compliance Level	Electromagnetic Environment-Guidance for Professional Healthcare Facility Environment
Electrostatic discharge (ESD) IEC 61000-4-2	All device input and output connections and cables	± 2, 4, 6, 8kV contact ± 2, 4, 8, 15kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Users must eliminate static in their hands before use it.
Radiated RF EM fields IEC 61000-4-3	All device input and output connections and cables	3V/m 80 MHz to 2700MHz 80% AM at 1kHz	Radiated electromagnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Radiated RF Wireless communication equipment IEC 61000-4-3	All device input and output connections and cables	See Table A below	This device has been subjected to RF wireless communication bands from cell phones, and other communication devices
Power Frequency (50Hz) magnetic field IEC 61000-4-8	All device input and output connections and cables	30A/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	DC Input, NIBP Port, and all Cables	3V 10V ISM bands 150kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Minimum separation distance for higher IMMUNITY TEST LEVELS shall be calculated using the following equation. 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) and E is the Immunity Test Level in V/m.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
			$E = \frac{6}{d}\sqrt{P}$
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range

Rated maximum output power of transmitter. Watts (W)	Separation distance according to frequency of transmitter meters (m)		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b) Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3V/m

Table A – Test specifications for the device's Signal Input Parts/Signal Output parts to RF wireless communication equipment.

Test Frequency (MHz)	Band (MHz) [a]	Service [b]	Modulation [b]	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse Modulation 18Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse Modulation 217Hz	0.2	0.3	9

810 870 930	800 - 960	GSM 800/900, TETRA 800, Iden 820, CDMA 850, LTE Band 5	Pulse Modulation 18Hz	2	0.3	28
1720 1845 1970	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse Modulation 217Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217Hz	2	0.3	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse Modulation 217Hz	0.2	0.3	9

NOTE:

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Specifications, Blood Pressure Measurement

Measurement:	Auscultatory, using R-wave gating and k-sound analysis, during all static and active phases of blood pressure readings. Systolic pressures correlate to a K-1 Korotkoff sound. Diastolic pressures correlate to K-5 Korotkoff sound. The device is designed to function in the presence of a normal ECG sinus rhythm. There are some physical conditions (i.e., Bundle Branch Block, Arrhythmias, Arial Fibrillation, Ventricular Fibrillation, Pacemakers, etc.) that may limit the ability of Foxtrot to obtain an accurate reading.	
Range:	Pressure (DKA Mode): Diastolic: 20-160 mmHg / Systolic: 40-270 mmHg Pressure (OSC Mode): Diastolic: 20-160 mmHg / Systolic: 40-260 mmHg	Heart Rate: 40-200 BPM (beats per minute)
Accuracy:	Meets or exceeds ANSI/AAMI/ISO 81060-2:2013 standard for non-invasive accuracy (±5mmHg mean error with 8mmHg standard deviation).	
Conditions for Use:	Operating: 10°C (50°F) to 40°C (104°F) 15 – 90% RH non-condensing - 70 kPa - 106 kPa. Operating the device in an environment at maximum temperature can produce temperatures exceeding 41°C (41.6°C highest recorded) on a patient applied part. It is up to the operator to determine if this temperature is too high based upon the condition of a patient and, if so, to ensure the ambient temperature of the environment is 38°C or below. Storage: -20°C (-4°F) to 65°C (149°F) 15 – 90% RH non-condensing - 50 kPa - 106 kPa. Performance can be affected if, used or stored outside the specified temperature, humidity, or altitude listed in the ranges above.	
Power:	Supplied SunTech Li-Ion battery pack PN: 97-0242-00 Output: 2.6Ah/18.72Wh 7.2V ⎓	
Calibration:	The accuracy of cuff -pressure transducers/indicators should be verified annually.	

Safety Systems:	Independent hardware over-pressure circuit and redundant software overpressure algorithm to limit cuff pressure to less than 300 mmHg (+20/-10mmHg). Independent hardware timing circuit and redundant software timer algorithm to limit the duration of a blood pressure cycle to less than 180 seconds.
Dimensions:	Weight: 1.3 lbs / 0.6 kg Size: 140 mm long x 98 mm High x 47 mm Wide 5.5 inches long x 3.9 inches High x 1.8 inches Wide
Classifications:	Equipment Classification: Battery operated. Mode of Operation: Continuous.
Wireless Communication	Frequency Band: 2401 MHz – 2481 MHz Frequency spacing: 1 MHz GFSK modulation data rate: 250 kbs

Standards

Standard Designation	Description/Title
ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1 General Requirements
IEC TR 60878:2022/COR1:2023	Corrigendum 1 - Graphical symbols for electrical equipment in medical practice
IEC 60601-1 Ed. 3.2 en:2020	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
AAMI/ANSI/ISO 10993-1:2018	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process
ANSI/AAMI/ISO 81060-1:2012	Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement
ANSI/AAMI/ISO 81060-2:2013	Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
IEC 60601-1: 2022, A1:2012, C1:2022	Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2: 2020	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 80601-2-30:2018	Medical electrical equipment - Part 2-30: Particular Requirements for the Basic Safety and Essential Performance of Automated Non-Invasive Sphygmomanometers
ISO 80601-2-61: 2017	Medical Electrical Equipment - Part 2-61: Particular Requirements for Basic Safety and Essential Performance of Pulse Oximeter Equipment
IEC 62366-1: 2020	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
IEC 60601-1-6:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability – Consolodated Reprint.
IEC 60601-1-8:2020	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for Event Codes systems in medical electrical equipment and medical electrical systems
IEC 62304: Ed. 1.1 (2015)	Medical device software – Software life cycle processes
ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO 13485:2016	Medical devices – Quality Management Systems – requirements for regulatory purposes
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer

Wireless Communication

Quality of Service

The Foxtrot device is designed to wirelessly pair with specific telemetry systems via a proprietary radio frequency (RF) communication protocol. This protocol utilizes encrypted device-to-device, single-priority, communication between the Foxtrot device and telemetry system. Each packet of data contains an integrity

check to ensure data transmission is complete and accurate. This prevents radio frequency interface (RFI) caused by the presence of other devices from being mistaken as valid data.

Data Security

The communication between Foxtrot and the telemetry system occurs through wireless radio frequency (RF) communication via a proprietary protocol. The Foxtrot device receives an ECG trigger from the telemetry system, and sends physiological results through the proprietary wireless RF communications channel. The proprietary protocol keeps unauthorized devices from connecting to the Foxtrot device and intercepting the transmission. Additionally, encryption is utilized for securing data in transit over the wireless channel to protect patient data confidentiality and integrity. The communication protocol contains an integrity check within each packet to ensure that the data transmissions are correctly received. For any detected vulnerabilities with the paired telemetry system, contact the system's manufacturer. For any detected vulnerabilities with the Foxtrot device, contact SunTech Medical, Inc.

FCC/USA Statements

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

Changes or modifications to the wireless system not expressly approved by SunTech Medical could void the user's authority to operate the equipment.

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.

ISED/Canada Statements

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.

Appendix A. SpO_2 Specifications and Accuracy

Nonin Pulse Oximetry Specifications (Nonin 8000AA with XPOD OEMIII)

Weight .....75g (.2.7 oz.) (including 6' cable and connector)
Oxygen Saturation Range (SpO2) .....0 to 100%
Pulse Rate Range .....18 to 321 beats per minute (BPM)
Measurement Wavelength.....Red: 660 nanometers @ 0.8 mW Max. avg.

SpO2 Accuracy over the range.....70-100%

No Motion	± 2 digits
Motion	± 2 digits
Low Perfusion	± 3 digits

Pulse Rate Accuracy

No Motion (18-300 BPM)	± 3 digits
Motion (40-240 BPM)	± 5 digits

Temperature (Operating) .....-5°C to +50°C for XPOD, 0 to +40C for sensor
Temperature (Storage/Transportation) .....-40°C to +70°C
Humidity (Operating) .....10 to 95% non-condensing
Humidity (Storage/Transportation) .....10 to 95% non-condensing
Power Draw .....Typical 35mW or less
Voltage Input .....1.0 to 5.5 VDC, w/100 mV max. ripple

Classifications per IEC 60601-1 / CSA 601.1/ UL 60601-1:

Degree of Protection:	Type BF-Applied Part Enclosure
Degree of Ingress Protection:	IPX3
Mode of Operation:	Continuous

SpO_2 Accuracy Testing - Nonin

SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark skinned subjects during motion and no-motion conditions in an independent research laboratory. Study subjects were comprised of male and female participants between the ages of 19 and 35. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SpO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61.

Pulse Oximeter Equipment measurements are statistically distributed, therefore, only about two-thirds of Pulse Oximeter Equipment measurements can be expected to fall within +/- Arms of the value measured by a Co-Oximeter.

CAUTION: Use only 52-0003-00 Nonin SpO2 sensor with 91-0125-01 Nonin LPXpod Pulse Oximeter Cable.

SunTech Pulse Oximetry Specifications

SpO_2 Range:	**0-99%**
SpO_2 Accuracy:	±2% at 70%-99% <70% unspecified
SpO_2 Resolution:	1% increments
SpO_2 Averaging:	8 pulse beat average

Calibration:	Factory calibrated over the range of 70% to 99% SpO_2 using human blood samples to functional saturation. Test methods available upon request. No in-service calibration is required.
Sensor Wavelength:	Red 660nm, 2mW (typical) Infrared 905nm, 2-2.4mW (typical)
Display Update Rate:	1 Hz (maximum age of SpO_2 and pulse rate data is 20 seconds)
Pulse Oximetry Units:	% SpO_2
Pulse Rate Range:	18-400 BPM
Pulse Rate Resolution:	1 BPM
Pulse Rate Units:	Beats per minute
Pulse Rate Accuracy:	±2% or 2 BPM, whichever is greater
Pulse Rate Averaging:	8 second average
Ingress Protection:	IPX2

SunTech Reflectance Sensor Specifications

SpO_2 Range:	**50-100%**
SpO_2 Accuracy:	±1% at 70%-100% ±2% at 50%-69%
SpO_2 Resolution:	1% increments
Ingress Protection:	IPX2

SpO_2 Accuracy Testing - SunTech

SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, light-to-dark skinned subjects during motion and no-motion conditions in an independent research laboratory. Study subjects were comprised of male and female participants between the ages of 19 and 40. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial oxygen saturation (SaO_2) value determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61.

Pulse Oximeter Equipment measurements are statistically distributed, therefore, only about two-thirds of Pulse Oximeter Equipment measurements can be expected to fall within +/- Arms of the value measured by a Co-Oximeter.

CAUTION: Use only 52-0032-00 Unimed SpO2 sensor with 91-0145-00 SunTech Pulse Oximeter Cable.

Appendix B. Limited Warranty

Limited Warranty

SunTech Medical, Inc. provides to the original purchaser the following limited warranty from date of invoice.

All serialized devices	24 Months
Orbit-K Cuffs	6 Months
Accessories, i.e. patient cable, microphone, disposables	90 Days

SunTech Medical, Inc. warrants each instrument to be free from defects in material and workmanship. Liability under this warranty covers servicing of the device. SunTech Medical, Inc. will repair any component(s) or part(s) that it finds to be defective during the period of this limited warranty. Should a defect become apparent, the original purchaser should first notify SunTech Medical, Inc. of the suspected defect.

See separate enclosed Warranty Return Card for specific information about returning your device for warranty service.

The instrument will be repaired in the shortest possible time and returned prepaid by the same shipping method as received by the factory.

This limited warranty is void if the instrument has been damaged by accident, misuse, negligence, act of God or serviced by any person not authorized by SunTech Medical, Inc.

This limited warranty contains the entire obligation of SunTech Medical, Inc. and no other warranties expressed, implied or statutory are given. No representative or employee of SunTech Medical, Inc. is authorized to assume any further liability or grant any further warranties except as herein.