Vet BP





## **Spot-Check and Continuous BP Monitor for Animals**

## User Manual

### Changes

This manual is identified as part number: 80-0083-00-RevA. This manual is for use with Vet25E model M25E. 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. 507 Airport Boulevard, Suite 117 Morrisville, NC 27560 USA Tel: 800.421.8626 919.654.2300 Fax: 919.654.2301 Email: <u>CustomerService@SunTechMed.com</u> Web: <u>www.SunTechMed.com</u>

### **Copyright Information**

All content in this manual is the proprietary information of SunTech Medical and is provided solely for purposes of operation of the SunTech Vet25E. This manual and the Vet25E described in it are protected under copyright law under which they may not be copied, in whole or in part, without written consent of SunTech Medical.

The information in this manual is furnished for guidance only, is subject to change without notice, and should not be construed as a commitment by SunTech Medical. SunTech Medical assumes no liability for errors or inaccuracies that may appear in this manual.

© 2019 SunTech Medical. All rights reserved.

# CE

### •••

SunTech Medical, Inc. 507 Airport Blvd, #117 Morrisville, NC 27560-8200 Phone: 1-919-654-2300 1-800-421-8626 Fax: 1-919-654-2301



SunTech Medical, Ltd. Oakfield Industrial Estate Stanton Harcourt Road Eynsham, Oxfordshire OX29 4TS England Phone: + 44 (0) 1865-884-234 Fax: + 44 (0) 1865-884-235 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

### Welcome to the SunTech Vet25E

Thank you for choosing the Vet25E vital signs monitor! For over 30 years, SunTech Medical has been the preeminent supplier of leading edge technology and innovative products to obtain blood pressure (BP) measurements. Developed specifically for the veterinary care environment, the Vet25E can perform automatic BP measurements for veterinary professionals.

For measuring BP, a BP cuff is placed around the patient's forelimb or tail. The cuff is inflated automatically and blood pressure is determined by the oscillometric method, which senses pressure waves in the artery when occluded by pressure in the cuff. Measurement of the frequency of the pressure waves enables heart rate to also be measured.

The Vet25E is a portable device, weighing approximately 2.1 lb (952 g). Control buttons allow the user to turn on or off the device and stop/start a BP measurement. The touchscreen display shows the device status and measurement information, and allows for selection of settings. The device uses a microprocessor with software, which is not accessible to the user. The unit is powered by a single rechargeable lithium-ion battery at the bottom of the device. Bluetooth can be used to wirelessly connect and send data to a PC application, which may be downloaded from the SunTech website at: <a href="https://www.suntechmed.com/Vet25E-data-capture">https://www.suntechmed.com/Vet25E-data-capture</a>. Upper and lower alarm limits can be set for all parameters.

### **Intended Use**

The SunTech Vet25E and Vet30E monitors are clinical grade automated blood pressure measurement devices that provide oscillometric non-invasive blood pressure. The Vet30E provides additional pulse oximetry and temperature measurement capabilities. These portable devices are for use in the veterinary clinic on companion animals (cats and dogs) and horses. The devices can be used for spot-check or continuous monitoring activities. They are not intended for human use.

The devices are contraindicated for use on humans or any species other than those described above.

### Vet25E Essential Performance

The Essential Performance of the Vet25E is designed to measure, record, and display a patient's blood pressure within a blood pressure accuracy range of +/- 5 mmHg mean error & 8mm Hg standard deviation (*max inflate 280 mmHg*).

#### **User Responsibility**

The Vet25E is designed to perform in conformity with the description thereof contained in this operation manual when operated. This operation manual is for use with Vet25E model M25E. The user of this monitor shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than SunTech Medical or their authorized service personnel. The Vet25E is for use only by or on the direction of a licensed veterinarian.

#### Use of Vet25E

Use only veterinary BP cuffs supplied by SunTech Medical. Observe the patient carefully during the measurement. Accuracy of any BP reading measurement may be affected by the position of the patient, their physical condition and use outside of the operating instructions detailed in this guide. The interpretation of BP measurements should only be made by a veterinarian.

### **Table of Contents**

Changes	
Copyright Information	
Welcome to the SunTech Vet25E	
Intended Use	
1. Warnings and Precautions	
2. Icons and Symbols	6
3. Getting to Know SunTech Vet25E	8
3.1 Applied Parts	8
3.2 Device Placement	9
3.3 Front Panel	9
3.4 Connect Power, Hose, and Sensors	9
3.5 Display	10
3.6 Start/Stop Button	12
4. Selecting Your Settings	12
4.1 Animal Mode	
4.2 Volume	12
4.3 Settings	
5. Blood Pressure Measurement	16
5.1 Cuff Sizing	16
5.2 Applying the Cuff and Taking a BP	
Measurement on Small Animals	17
5.3 Applying the Cuff and Taking a BP	
Measurement on Horses	17
5.4 Interval BP Mode	
5.5 STAT Mode	18
5.6 Interrupting/Stopping a Measurement .	
6. Reviewing and Transferring Data	19

6.1 Viewing Stored Measurements	. 19
6.2 Averaging Measurements	. 19
6.3 Bluetooth Connection	. 20
6.4 Data Transfer	. 21
6.5 Reviewing Data and Creating Reports	. 21
7. Alarms	. 23
7.1 Technical Alarms	. 23
7.2 Clinical Alarms	. 23
8. Taking Care of the SunTech Vet25E	. 24
8.1 Battery	. 24
8.2 Cleaning	
8.3 Preventative Maintenance	. 24
8.4 System Components	. 25
8.5 Accessories & Replacement Parts	. 26
8.6 Status Messages	
9. Frequently Asked Questions	. 28
10. Limited Warranty	. 28
11. Technical Information	. 29
11.1 Monitor Model Numbers	. 29
11.2 Factory Default Settings	
11.3 Performance Specifications	
11.4 Radio Frequency Compliance Requirements	
11.5 Electromagnetic Compatibility (EMC)	
Appendix A: Service Screens	. 36
Service Information	. 36
Calibration Check	
Air Leak Check	. 37
Restore Factory Defaults	. 38
Software Update	

### **1. Warnings and Precautions**

General warnings and cautions are listed here and repeated where relevant throughout this guide.

A WARNING indicates a situation which, if not avoided, could result in serious injury or death.

**WARNING:** DO NOT connect patient hose or monitor to any other devices or connections, especially intravenous (IV) tubes as there is potential for air to be pumped into a blood vessel which could cause serious injury.

**WARNING:** 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.

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

WARNING: The cuff should not be applied over a wound as this can cause further injury.

**WARNING:** DO NOT use a defibrillator or ultrasonic device on the patient at the same time as it may affect the operation and/or safety of the patient due to interactions.

**WARNING:** DO NOT immerse the monitor in any fluid or attempt to clean the unit with liquid detergents, cleaning agents, or solvents. This may cause an electrical hazard. Do not use the monitor if accidental wetting occurs. Refer to the cleaning section of this guide for instructions on cleaning.

**WARNING:** Check the limb frequently to ensure that operation of the monitor does not result in prolonged impairment of the circulation of the patient.

**WARNING:** DO NOT apply the BP cuff to a limb being used for IV infusions or any other intravascular access, therapy, or an arteriovenous (A-V) shunt as the cuff inflation can temporarily block the infusion, potentially causing harm to the patient.

**WARNING:** Pressurization of the cuff can temporarily cause loss of functionality of  $SpO_2$  if simultaneously using device on the same limb.

**WARNING:** DO NOT use if device is dropped and/or is damaged. Have a qualified service representative check the unit before using again. Repairs should only be conducted by an authorized SunTech Medical service representative.

**WARNING:** Before performing a procedure when device is not plugged into main power, ensure there is sufficient battery charge. If battery loses charge, device must be plugged into power supply to function.

**WARNING:** The USB port is only a service port and cannot be used to download data or interface with the monitor. When updating the software, the monitor cannot be in use and the accessories should not be contacting the patient.

WARNING: The monitor may not be used during electrocautery.

A CAUTION indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user, patient or damage to the equipment or other property.



CAUTION: For use only by or on the direction of a licensed veterinarian. NOT for use on humans.

**CAUTION:** DO NOT use the monitor for any purpose other than specified in this manual without written consent and approval from SunTech Medical.

CAUTION: DO NOT use this monitor when oscillometric pulses may be altered by other devices or techniques.

**CAUTION:** DO NOT remove unit covers. Doing so may increase the risk of electrical shock. This monitor does not contain any user serviceable parts. Substitution of a component or accessory different from that supplied may result in measurement error. Repairs should be undertaken only by personnel trained or authorized by SunTech Medical.

CAUTION: DO NOT gas sterilize or autoclave this monitor.

CAUTION: Too frequent measurements may cause injury to the patient due to blood flow interference.

**CAUTION:** At the end of product life, the monitor, accessories, components and other consumable goods may become contaminated from normal use. Consult local codes and ordinances for proper disposal of equipment and other consumable goods.

**CAUTION:** This device contains a lithium ion battery that contains materials which may be hazardous to human health. DO NOT dispose of battery in domestic waste! Instead, please dispose of in an environmentally responsible way, or return the battery to SunTech Medical. A prepaid return label can be obtained. Please see our website for more information about our environmental policy at <u>http://www.suntechmed.com/about-suntech/environmental-policy</u>.

**CAUTION**: Accuracy of any blood pressure measurement may be affected by the position of the subject, the patient's physical condition, and use outside of the operating instructions detailed in this manual. Interpretation of BP measurement should be made only by a veterinarian or trained medical staff. Minimize limb movement during the measurement.

**CAUTION:** A compressed or kinked connection hose may cause continuous cuff pressure resulting in blood flow interference and potentially harmful injury to the patient. If the cuff fails to deflate, the operator should be instructed on how to remove the cuff.

CAUTION: Performance can be affected if used or stored outside the specified temperature and humidity ranges.

**CAUTION:** Replace user replaceable parts that are broken, worn, missing, damaged, incomplete, or contaminated. Contact SunTech Medical for service on parts that are not user replaceable and stop using device until repaired. Failure to repair a damaged product may cause injury to the user and/or patient.

### 2. Icons and Symbols

Some of the symbols, listed in the table below refer to the following FDA SDO Consensus standards:

- Recognition #5-103, ISO 7000: 2014: Graphical symbols for use on equipment Registered symbols
- Recognition #5-116, ISO 7010: 2011: Graphical symbols Safety colours and safety signs Registered safety signs
- Recognition #5-102, ISO 60417: 2002 DB: Graphical symbols for use on equipment
- Recognition #5-117, ISO 15223-1: 2016: Medical devices Symbols to be used with medical device labels, labelling, and information to be supplied Part 1: General requirements

Symbol	Description	Standard/Source
	General Warning Sign	ISO 7010-W001
LOT	Batch Code	ISO 7000-2492
$\triangle$	Caution	ISO 7000-0434A
	Classification – Class II	IEC 60417-5172
	Refer to Instruction Manual	ISO 7010-M002
EC REP	Authorized representative in the European Community	SunTech Design

•	USB-A or USB-B	Industry
	Direct Current	IEC 60417-5031
$\sim$	Alternating Current	IEC 60417-5032
♦ <del>°</del> ♦	Polarity of DC power connector	IEC 60417-5926
<b>↓</b> +/←	Rechargeable battery	IEC 60417-5639
li	Consult Instructions for Use	ISO 7000-1641
CE	This product meets the requirements of the applicable Directives	EU Directive
X	Disposal in compliance with WEEE Directive	WEEE Directive
	Manufacturer	ISO 7000-3082
[]	Date of Manufacture	ISO 7000-2497
SN	Serial Number	ISO 7000-2498
	Cuff index line must fall within range markings	SunTech Design
	Arrow should be placed over artery	SunTech Design
10)	Symbol indicating limb circumference	SunTech Design
	Index line	SunTech Design
DATEX	Not made with natural rubber latex	SunTech Design
XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	Not made with PVC	SunTech Design
REF	Reference Number	ISO 7000-2493
*	Type BF Applied Part	IEC 60417-5333
Ţ	Fragile, handle with care	ISO 7000-0621
Ŵ	Humidity Limits	ISO 7000-2620
15 -20	Temperature Limits	ISO 7000-0632
	Keep Dry	ISO 7000-0626
÷.	Accesses Settings screen	SunTech Design
	Small animal mode	SunTech Design
3	Large animal mode	SunTech Design
2	Equine mode	SunTech Design
	Opens the Icon Menu	SunTech Design
وَ اا کے لیے لیے اور	Begins Interval BP Mode	SunTech Design

<b>(</b> )	Adjusts volume	SunTech Design
<b>F</b>	View Memory	SunTech Design
×	Exits or closes a screen	SunTech Design
Ŧ	Goes back to previous screen	SunTech Design
1	Deletes all stored memory data	SunTech Design
AVG	Averages selected BP readings	SunTech Design
0	Begins STAT Mode	SunTech Design
*	Bluetooth	Bluetooth
t	Begins data transfer	SunTech Design
TIP:	Provides practical advice for using monitor	SunTech Design
θΘ	Maximize or minimize a focus screen	SunTech Design
(1)	Power on/off	IEC 60417-5009
	Start/Stop a BP measurement	IEC 60417-5107B IEC 60417-5110B
	Battery Indicator	SunTech Design

### **3. Getting to Know SunTech Vet25E**

### **3.1 Applied Parts**

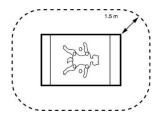
The following are the applied parts of the Vet25E:

• BP Cuffs

The Vet25E has been tested with specific parts of the system used within the Patient Environment. The parts of the system that can be used in the patient environment are:

- Vet25E monitor
- All applied parts as defined above
- All accessories as defined in Section 10.5, excluding the AC Adapter

The patient environment is defined in the following diagram:



### 3.2 Device Placement

**WARNING:** As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

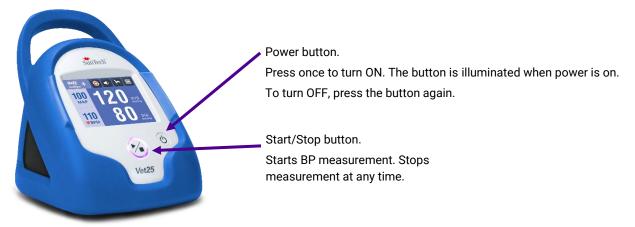
 $\triangle$ 

/ľ\

**CAUTION:** Do not position the monitor so that it is difficult to access and remove the AC adapter from the electrical supply mains. The power supply is the means of disconnection to the supply mains.

Place the Vet25E monitor in a convenient location to ensure user's ability to monitor the screen continuously. Ensure monitor is placed away from table top edges and route the patient cables so that if pulled, the monitor will not fall.

### **3.3 Front Panel**



### **3.4 Connect Power, Hose, and Sensors**

**CAUTION:** Read all warnings, cautions, and instructions provided prior to using the device.

1. Insert AC adapter plug into the Vet25E. Plug other end of the AC adapter into a power supply to begin charging the battery. Only use AC Adapter supplied by SunTech Medical.





**WARNING:** The AC adapter must be unplugged and the battery must be disconnected in order to completely disconnect device from power. See Section 8.3 for additional information on battery disconnection.

2. Connect the patient hose to the back of the monitor making sure the connector "clicks" into the locking position by rotating clockwise. For additional information on how to take a BP measurement, see Section 5.



### **3.5 Display**

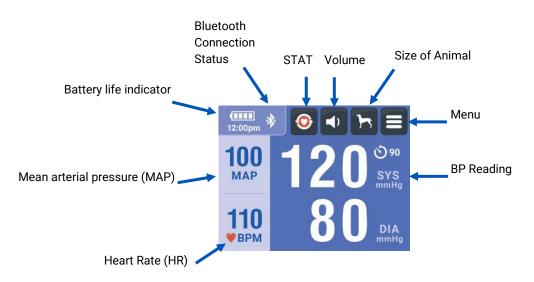
#### **Animal Selection Screen**

When you turn on your SunTech Vet25E, you will see the Animal Selection Screen. Even if you are not ready to measure BP on a patient, select an animal mode so that you can proceed to the Main Screen. This screen can be turned off (see Animal Selection in Section 4). Additionally, the animal mode can be toggled using the animal selection icon on the Main Screen.



#### **Main Screen**

After you begin using your Vet25E, your main screen will display your most recent patient measurements. Here is a quick overview of the key symbols and numeric values you will see. Prior to the first reading upon power on, the screen will display dashes instead of values.



#### Icon Menu

After you press on the Menu button on the main screen, the Icon Menu will open. Here you can access various functions and settings of the device. The Icon Menu is not accessible during a BP measurement.



- 1. Exit Icon Menu
- 2. Settings

For more information on selecting settings, see Section 4.3

- 3. Animal Selection
- 4. Speaker Volume
- 5. Memory

For more information on reviewing and transferring data, see Section 6

- 6. STAT Mode For more information STAT BP Mode, see Section 5.5
- Interval BP Mode For more information on Interval BP Mode, see Section 5.4
  Bluetooth Connect
- For more information on Bluetooth connection, see Section 6.3 9. Data Transfer
  - For more information on reviewing and transferring data, see Section 6

### 3.6 Start/Stop Button

The color of the LED on the START/STOP button indicates the status of the Vet25E.



- START/STOP button is magenta during normal operation
- START/STOP button is blue during a BP reading
- START/STOP button is white when in service mode
- START/STOP button is red during an error, when a status message is prompted or the device is unable to connect via Bluetooth

### 4. Selecting Your Settings

### 4.1 Animal Mode

Small Animal Mode should be chosen when taking BP measurements on <u>cats and dogs up to a #3 BP cuff size</u>. This size typically applies to dogs or cats weighing less than 8kg (~17.5 lbs.). Large Animal Mode has been designed for <u>animals requiring a #4 BP cuff or larger</u>. This size typically applies to dogs weighing more than 8 kg (~17.5 lbs.). Equine Mode is designed for measuring BP on horses. If a problem arises, try switching animal modes by touching the Animal Selection button on the main screen or in the menu.



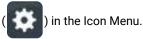
### 4.2 Volume

The Vet25E monitor's default setting is Speaker Off so that patients are not disturbed by sounds. To toggle between Speaker Off, Low Volume, and High Volume, press the Speaker button. When sound is OFF, you still will hear a very quiet clicking when you touch buttons but no beeps.



### 4.3 Settings

To access the settings screen, select the settings button (



Clinical Alarms. Provides access to turning ON and	Settings	×	Power Management. Select how long monitor stays
setting clinical alarms.	Clinical Alarms Power Management		on before Auto OFF shutdown. Auto OFF is disabled when powered by an AC adapter.
Interval BP. Select time between BP	Interval BP		powered by an Ao adapter.
measurements in Interval BP Mode.	Animal Selection		Animal Selection.
	Settings	×	
Time. Set the time.	Time		Date.
	Date		Set the date.
Language. Select desired language.	Language		

### **Clinical Alarms**

The SunTech Vet25E allows clinical alarms for all values (SYS, DIA, MAP, and HR). Factory setting is OFF.

- To change alarm values, select the Settings screen in the Icon Menu, then choose Clinical Alarms.
- Select the parameter of interest.

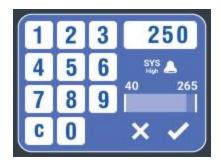


- Touch On, then Set Alarm Values.
- Touch the numeric range value that you want to adjust. The alarm range cannot be adjusted by dragging the blue bar. The value on the left side represents the value for which all values below that number will trigger the alarm. The value on the right side represents the value for which all values above that number will trigger the alarm.

265
200
222

Touch the numbers on the right or left to set the alarm limits.

• Using the keypad, type in the desired value and touch the checkmark.



- To reset to default clinical alarms, touch Use Defaults. For information on the default clinical alarm values, see Section 14.
- When alarm is triggered, values that are outside of the set ranges will turn red on the Main Screen. If speaker is ON, a beep will occur. For more information on alarms, see Section 10.

#### **Power Management**

The Vet25E includes an Auto OFF feature which turns the monitor off after a selected period. The Auto OFF timer is disabled when powered by an AC Adapter and during Interval Measurement Mode. To edit the Auto OFF timer, select the Settings screen in the Icon Menu, then choose Power Management. Factory setting is 10 minutes. Auto-off Timer may be set to 5, 10, and 20 minutes or Always ON.

TIP: Battery charge may be rapidly depleted if set to always ON.

Note: Only use the power cord provided (Part Number: 19-0020-00).



#### **Interval BP**

To set the time between BP measurements during Interval Mode, select the interval time desired. To access the Interval BP options, select the Settings screen in the Icon Menu, then choose Interval BP.

• Intervals include 1, 2, 3, 4, 5, 10, 15, 30, 60, and 90 minutes

Interval BP	-	×
3 minutes		
4 minutes		
5 minutes		
10 minutes	•	▼

#### **Animal Selection**

The animal selection start up screen can be turned OFF. This is useful for clinics catering to a specific species such as an all cat clinic. To change the animal selection screen options, select the Settings screen in the Icon Menu, then choose Animal Selection.



### Time

To set the internal clock, select the Settings screen in the Icon Menu, then choose Time.

- Two time formats are available: AM/PM and 24 Hour.
- Select the desired time format and touch Continue.



 Use the + and - buttons to select the hour and minute. In AM/PM format, touch the AM or PM button to toggle between them.

Time		+ ×	Time			+×
	$\odot$	00:00 24hr		$\odot$	00:00 A	м
<b>H</b>	+	Cancel	<b>H</b>	+	-	Cancel
00	00		00	00	AM	
	-	Set		-		Set

• To exit without changing the time, touch Cancel. To save the time, select Set.

### Date

To set the date, select the Settings screen in the Icon Menu, then choose Date.

- Two date formats are available: MM.DD.YY and DD.MM.YY
- Select between the two date formats and touch Continue.



• Use the + and – buttons to set the day, month, and year and touch Set to save the date.

Date			<b>+</b> ×
	i the	DD/MM/	YY
+	+	<b>H</b>	Cancel
00	00	00	
-	-	-	Set

• Touch Cancel to return to the Date Format screen without changing the date. Press X to exit to the main screen.

### Language

Multiple languages are available including English, French, Italian, German, Spanish and Brazilian Portuguese. To access the languages, select the Settings screen in the Icon Menu, then choose Language.

• Touch the desired language to select it. Press X to save and exit.



### 5. Blood Pressure Measurement

### 5.1 Cuff Sizing

The SunTech Vet25E comes with a variety of different BP cuff sizes. Each cuff contains important markings that help with selecting the right cuff size. These are SunTech designed symbols.



Make sure this part of cuff is placed over the patient's artery.



When the cuff is wrapped around the patient's limb or base of the tail, its Index Marker should fall within this line.



When you wrap the cuff around the patient's limb or base of the tail, the Index Marker should fall within the Range Marker on the inside of the cuff.



Indicates limb/tail circumference range of the cuff.



Not made with natural rubber latex.

80-0083-00-RevA 2019-03-08



Not made with PVC.

**TIP**: When more than one cuff size fits the limb, always choose the larger size for more accurate measurements. When a cuff is too small, it can cause BP values to be overestimated.

An alternative sizing method is to measure the circumference of the limb and choose a cuff whose width is 40% of the circumference for dogs and 30% for cats.

## 5.2 Applying the Cuff and Taking a BP Measurement on Small Animals

WARNING: The cuff should not be applied over a wound as this can cause further injury.

SunTech recommends that the cuff be placed on a front limb while the patient is lying on the right or left side. This helps ensure that the cuff is at heart level, which is best for measurement accuracy. Also, the patient is less likely to retract the front limb when the cuff gently squeezes it during the measurement. The cuff should be placed so that its artery marker aligns with the limb artery.

**Alternate Patient Positioning:** If the patient seems more comfortable seated, position the cuff as described above and hold up the limb during the BP measurement. This will help keep the cuff at heart level and relax the patient's muscles. If the patient appears agitated enough to bite or scratch, or is standing, the base of the tail is an acceptable alternate location.

1. Position patient so that they are lying down, seated, or held. Place the cuff on the limb making sure not to place it over a joint. Connect cuff hose to monitor hose.

**TIP**: The success of the BP measurement is dependent on choosing the correct cuff and attaching it to the patient correctly. The cuff is the sensor so make sure to snugly fit the cuff as this provides better signals to the monitor.

2. Press the Power Button to turn on the Vet25E. Select appropriate animal size.

**TIP**: To change animal size after initial selection, touch the Animal Selection icon on Main Screen to toggle between Large and Small. *For more information on selecting animal size, see Section 4.* 

3. If patient is awake, allow patient to acclimate for approximately 5 minutes in a quiet area. Press START/STOP button to start blood pressure measurement. START/STOP button turns blue during measurement. Reading is complete when START/STOP button returns to magenta. Main Screen will show systolic (SYS) and diastolic (DIA) values, plus mean arterial pressure (MAP) and heart rate (HR) in beats per minute.

**TIP**: During a BP reading, the Icon Menu is not available. To access the Icon Menu, either wait until the BP reading is complete or stop the reading by pressing the START/STOP button.

**TIP**: When a BP reading is in progress, pressing the START/STOP button will immediately stop the measurement and deflate the cuff.

TIP: For information on averaging BP measurements, see Section 8.2.

## 5.3 Applying the Cuff and Taking a BP Measurement on Horses

WARNING: The cuff should not be applied over a wound as this can cause further injury.

SunTech recommends that the cuff is placed at the base of the tail.

1. Position patient so that the base of the tail is at the same height as the heart. Wrap the cuff around the base of the tail. Connect cuff hose to monitor hose.

**TIP**: The success of the BP measurement is dependent on choosing the correct cuff and attaching it to the patient correctly. The cuff is the sensor so make sure to snugly fit the cuff as this provides better signals to the monitor.

2. Press the Power Button to turn on the Vet25E. Select equine mode.

3. If patient is awake, allow patient to acclimate for approximately 5 minutes in a quiet area. Press START/STOP button to start blood pressure measurement. START/STOP button turns blue during measurement. Reading is complete when START/STOP button returns to magenta. Main Screen will show systolic (SYS) and diastolic (DIA) values, plus mean arterial pressure (MAP) and heart rate (HR) in beats per minute.

**TIP**: During a BP reading, the Icon Menu is not available. To access the Icon Menu, either wait until the BP reading is complete or stop the reading by pressing the START/STOP button.

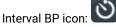
**TIP**: When a BP reading is in progress, pressing the START/STOP button will immediately stop the measurement and deflate the cuff.

TIP: For information on averaging BP measurements, see Section 8.2.

### **5.4 Interval BP Mode**

In Interval BP Mode, the SunTech Vet25E automatically takes a BP reading at set time intervals. The time interval can be changed through the Interval BP settings (see Section 4).

• To start taking BP measurements in Interval Measurement Mode, enter the Icon Menu, then touch the



- The Icon Menu will close and the first BP measurement will automatically begin. Once the BP reading has finished, the device will wait the set amount of time before automatically taking another BP reading.
- When the SunTech Vet25E is in Interval Measurement Mode, a clock icon will appear on the screen, indicating the set time interval.
- An additional BP reading can be taken by manually pressing the START/STOP button in between Interval BP readings.
- During a BP reading, the Icon Menu is not available.
- To exit Interval Measurement Mode, touch the Interval BP icon in the Icon Menu or press the START/STOP button during a BP measurement.



**TIP**: For information on setting the amount of time between interval measurements, see Section 4.3.

### 5.5 STAT Mode

**WARNING:** Check the limb frequently to ensure that operation of the monitor does not result in prolonged impairment of the circulation of the patient.

During STAT Mode, the SunTech Vet25E will automatically take continuous BP measurements for 10 minutes.

- To enter STAT Mode, select the STAT icon at the top of the Main Screen.
- Alternatively, enter the Icon Menu, then touch the STAT icon.
- When the device is in STAT Mode, the STAT icon is displayed on the main screen.
- During a BP reading, the Icon Menu is not available.
- To exit STAT Mode, touch the STAT icon again or press the START/STOP button while a BP measurement is in progress. STAT Mode will automatically stop after 10 minutes.



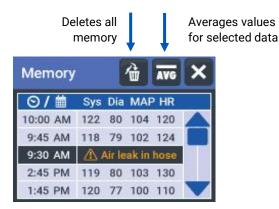
### 5.6 Interrupting/Stopping a Measurement

To stop a measurement while in progress, touch the START/STOP button. When a BP reading is in progress, pressing the START/STOP button will immediately stop the measurement and deflate the cuff. An abort message will appear on the screen and a short beep will sound if volume is on. START/STOP button returns to magenta and monitor gets ready to start a new reading.

### 6. Reviewing and Transferring Data

### 6.1 Viewing Stored Measurements

To take additional BP readings, press START/STOP again.



To view previous readings, touch Menu, then touch the Memory icon. Select the parameters to view. The time and date will alternate. Up to 960 measurements can be stored in memory.

### **6.2 Averaging Measurements**

The BP data can be averaged in the memory screen. To average measurements, touch the rows with the measurements you wish to average. Selected rows will turn green. To unselect a measurement, touch its row a second time. Limit the number of measurement rows averaged to under one hundred (100) to avoid incorrect results due to too many measurements.

Average of selected readings shows on top row with "AVG" as the identifier.



### **6.3 Bluetooth Connection**

The SunTech Vet25E can pair with a PC within a 30-foot radius to transfer data via Bluetooth. To pair with a PC, the Vet Data Capture PC application must first be installed on the PC. The application is available for download from the SunTech website at <u>https://www.suntechmed.com/Vet25E-data-capture</u>. The PC application is supported on Windows 10, Windows 8.1, and Windows 7.

#### Installation and Setup

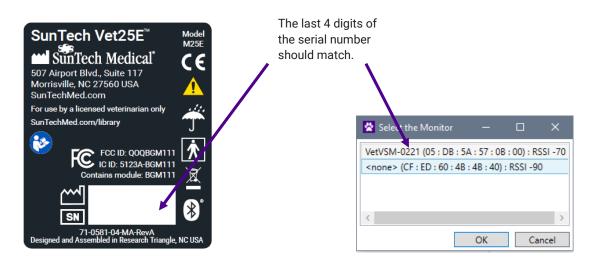
- 1. Download the Vet Data Capture application from the SunTech website. Double click on the zip file to extract the folder. The folder can be dragged onto the desktop for easy access to the application.
- 2. Insert the USB Bluetooth Transmitter into an open USB port on the PC. The computer will automatically install the Bluetooth USB.

#### Pairing with the Vet25E

- 1. To turn on Bluetooth on the Vet25E, touch the Bluetooth icon () in the Icon Menu. The monitor will automatically attempt to pair with the other device. While the device is connecting via Bluetooth, the Start/Stop button will flash blue light. Continue to step 2 while the device is flashing blue light.
- 2. Open the Vet Data Capture application by double clicking on the file with the purple paw icon:

### 😤 VetDataCapture.exe

3. When the Vet Data Capture application opens, select a Vet25E for pairing. Identify the Vet25E using the last four digits of the serial number, found on the bottom of the device. *Continue to Section 6.4 for Data Transfer instructions*.



**TIP**: If the device is unable to connect within 90 seconds, a message will be displayed. Touch Try Again to re-attempt to connect.

**TIP**: During Bluetooth pairing and data transfer, ensure that the Auto Off timer is OFF to avoid the Vet25E turning off during pairing or data transfer. For instructions on changing the Auto Off timer, see section 4.3

To turn off Bluetooth, touch the Bluetooth icon in the Icon Menu. When Bluetooth is off, the icon will be greyed out in the Icon Menu.

### 6.4 Data Transfer

Once a Bluetooth connection is established with a PC, data can be transferred to the Vet Data Capture PC application.

1. To begin a data transfer, touch the Data Transfer icon ( ) in the Icon Menu of the Vet25E. A status

message will pop up during the transfer on the Vet25E and will appear at the bottom of the Vet Data Capture application.

2. When data transfer is complete, the data will appear in the Vet Data Capture application. A "Transfer Complete" status message will appear on the Vet25E. Select OK to clear the status message.

**TIP**: The Vet Data Capture PC application does not retain data when closed. *To ensure data is saved, follow instructions in section 6.5.* 

### 6.5 Reviewing Data and Creating Reports

The SunTech PC application allows the user to create reports of patient data. Via the Bluetooth connection, all data is downloaded from the Vet25E and displayed on the software main screen in tabular format with the latest data at the top of the screen. Within the PC application, a patient name, patient ID, species, and age can be added.

### **Saving Patient Information**

Pat

- 1. Select the data points for a patient by holding Ctrl and clicking on each one. For large amounts of consecutive data points, hold Shift and click the first and last data points to be included.
- 2. Use the text bars at the top of the screen to enter Patient Name, Patient ID, Species, and Age.

	D. (*			
atient Name	Patient ID	Species	Age	
				Apply

- 3. Click the Apply button to save the Patient Name, Patient ID, Species, and Age to the selected data points.
- 4. To correct an error, entries can be overwritten. Select the data point with incorrect information and enter the correct information into the text bars. Selecting Apply will save the new information to the data point.

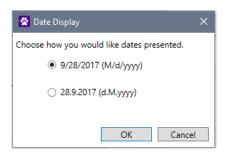
Selected portions of data can be organized into a report format that includes patient information, table of most recent vital sign data, trend graphs and notes. This report can be printed or exported as a PDF file. The tabulated raw data can also be exported as a CSV file. The Vet Data Capture PC application does not retain data when closed. To ensure data is saved, follow instructions below to export the data to a PDF or CSV file.

#### **Configuring Settings**

To change the date format, time format, or temperature units within the Vet Data Capture application, open the "Configure" menu from the top of the screen.

• "Date Format" provides the option to switch between M/d/yyyy and d.M.yyyy date formats

ply



• "Time Format" provides the option to switch between time formats.

😤 Time Display	-	-		×
Choose how you would	like tim	ies pre	sented.	
11:24AM				
○ 11:24				
	OK		Canc	el

• "Temperature Units" provides the option to switch between Celsius and Fahrenheit

😤 Temperature Scale			×
Choose which temperatur	e scale yo	ou would	like.
Celsius (°C)			
◯ Fahrenheit (°F	)		
	ОК	Car	ncel

### **Creating a Report**

1. Once data transfer is complete, select the data points to be included in the report by holding Ctrl and clicking on each one. For large amounts of consecutive data points, hold Shift and click the first and last data points to be included.

tient Name								
Date	Time	SYS	DIA	MAP	HR	SpO2%	Temp	Error
8/24/2001	12:47AM	111	74	86	108	0	-	
8/23/2001	1:54AM	112	69	80	90	0	-	
8/23/2001	1:34AM	138	80	95	103	0	-	
8/23/2001	1:12AM	88	36	48	82	0	-	
8/23/2001	12:49AM	118	91	99	91	0	-	
8/22/2001	6:40AM	74	62	65	172	0	-	
8/22/2001	4:45AM	114	87	95	76	0	-	
8/22/2001	3:17AM	153	130	136	119	0	-	

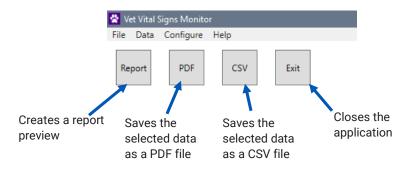
**TIP**: Only 24 hours of data can be graphed at one time. If graph contains a message saying "Maximum Limit Exceeded," review data selected to ensure that a 24-hour period is not exceeded.

2. Click "Report"

- a. Use the checkboxes on the left-hand side of the screen to choose if charts or a data table are included in the report.
- b. Select "Print" to print report. Select "PDF" to save report as a .pdf file to the computer.

Once data is selected, the following actions are also available:

- To print report, click "Data" and choose "Print Report"
- To save report as a PDF file, click "Data" and choose "Create PDF"
- To save report as a CSV file, click "Data" and choose "Create CSV"



### 7. Alarms

### 7.1 Technical Alarms

A technical alarm occurs when an error occurs during a BP measurement.

During a technical alarm, an audible tone will sound and the parameter that is malfunctioning will display dashes. Vital sign values that are outside published values will not be displayed.

When there is an error in BP measurement, values for SYS and DIA are replaced with dashes, the START/STOP button turns red, and a long audible beep sounds if volume is on. A status message will be displayed to assist with troubleshooting the problem. *For a list of status messages, see Section 10.* 

### 7.2 Clinical Alarms

Clinical alarms occur when a measured value meets or exceeds the high or low limit set for that parameter. The default mode for clinical alarms is OFF. See Section 4 for instructions on turning on clinical alarms and setting clinical alarm values. When a BP clinical alarm occurs, the measurement value will display in red and a long beep will sound. If it is appropriate for the patient, the alarms can be turned off. Alarms can be silenced by toggling the volume button to OFF. Always Ensure that appropriate resuscitation equipment and personnel are available during the procedure. Always select alarm ranges that are appropriate for the patient and procedure. All alarms indicate a potential increased risk of injury if the test is continued.

To test the clinical alarms, turn the volume of the monitor on and set the alarm at a value likely to be exceeded with the next reading. Perform the reading. When the value exceeds the limit set, the alarm should display and a beep should sound.

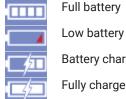
### 8. Taking Care of the SunTech Vet25E

### 8.1 Battery



WARNING: The internal user-replaceable battery must be plugged into a power source to maintain the battery to a full charge state. Check the battery charge status periodically, especially before a procedure where the monitor is not connected to a power source.

The Vet25E has an internal user-replaceable battery that is charging whenever the monitor is plugged into a power source. The last segment of the battery indicator will turn red when battery charge is low. When Interval BP measurements are set for every 5 minutes, a fully charged battery should last at least 4 hours before requiring recharging. If only taking manual BP measurements, a fully charged battery should last for at least 150 BP measurements before requiring recharging. Fully charging the battery should take under 6 hours.



Full battery

Battery charging

Fully charged

### 8.2 Cleaning

### **Cleaning the Vet25E**



WARNING: DO NOT immerse the monitor in any fluid or attempt to clean the unit with liquid detergents or solvents. This may cause an electrical hazard. Do not use the monitor if accidental wetting occurs.

As needed, clean the display using a soft, lint-free cloth sprayed with an alcohol-free glass cleaner. Dampen a soft cloth with mild medical grade disinfectant and wipe the monitor to remove surface dust and dirt.

### **Cleaning the Protective Armour**

Remove armour from device. Wash in warm, soapy water.

Due to the manufacturing process, minor molding blemishes may be present on the protective armour. These blemishes will not impact the functionality of the armour or the monitor and are not considered defects of the product.

### 8.3 Preventative Maintenance

WARNING: Do not disassemble the unit. There are no user serviceable parts except for the battery. Refer to qualified service personnel.

### System Self Checks

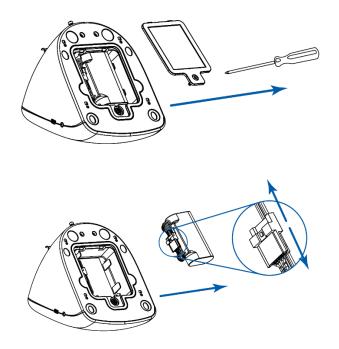
The Vet25E performs a range of system checks during normal operation. If the monitor detects a problem, it will display a status message recommending a troubleshooting action or to contact SunTech Customer Service.

### **Replaceable Parts**



CAUTION: Immediately replace parts that are broken, worn, missing, incomplete, damaged, or contaminated.

On a routine basis, inspect the monitor, cuffs, and hoses for cracks, fraying, or kinks. Immediately replace any damaged part. Device can function without a battery. However, if battery fails to maintain a charge, replace the battery. Before replacing the battery, make sure the device is turned off and disconnected from patient. Do not replace the battery without removing power supply from wall. The start/stop button does not remove power from the system. To replace the battery, use a screwdriver to unscrew the screw and open the battery bay door on the bottom of the device. Remove battery by disconnecting the electrical connector. Replace battery and reconnect the electrical connector. Replace battery bay door and secure with screw. Before use, battery must be fully charged.



### $\underline{\wedge}$

CAUTION: Use only approved accessories. Replace battery only with SunTech part number 17-0026-00.

### **Expected Service Life**

Monitor: 7 years (dependent upon internal BP pump usage)

Lithium-ion Battery: 250 cycles (before capacity falls below 80% of original capacity)

### **8.4 System Components**

Your Vet25E System should contain the following items.

Vet25E System	Standard Qty.
Vet25E System Monitor	1
Patient Hose, 6ft (1.8m)	1
Vet System Cuff Kit (6 cuffs)	1
#7 Cuff	1
#8 Cuff	1

Vet25E User Manual	1
AC Adaptor, Universal	1
Protective Armour	1

### 8.5 Accessories & Replacement Parts

Contact your sales representative to purchase the following items:

Description	Part Number	Details
#1 Cuff	98-0400-80	3 – 6 cm, white, non-locking, box of 20
#2 Cuff	98-0400-81	4 – 8 cm, white, non-locking, box of 20
#3 Cuff	98-0400-82	6 – 11 cm, white, non-locking, box of 20
#4 Cuff	98-0400-83	7 – 13 cm, white, non-locking, box of 20
#5 Cuff	98-0400-84	8 – 15 cm, white, non-locking, box of 20
#6 Cuff	98-0400-F1	12 – 19 cm, white, non-locking, box of 20
#7 Cuff	98-0400-F3	17 – 25 cm, white, non-locking, box of 20
#8 Cuff	98-0400-F4	23 – 33 cm, white, non-locking, box of 20
#9 Cuff	98-0400-F5	31 – 40 cm, white, non-locking, box of 20
Vet Cuff Pack, Slip Luer, Sizes #1-6	98-0240-00	Pack of 6 cuffs: 1 of each size 1-6
Patient Hose, 6 ft (1.8 m)	91-0028-75	6 ft (1.8 m), black, individual
Patient Hose, 10 ft (3 m)	91-0028-76	10 ft (3 m), black, individual
AC Adapter	19-0020-00	Power Supply, Universal
Armour in Flamingo Pink	39-0195-03	Protective cover, pink, individual
Armour in Peacock Blue	39-0195-04	Protective cover, blue, individual
Armour in Tree Frog Green	39-0195-02	Protective cover, green, individual
Rechargeable Lithium-Ion Battery	17-0026-00	7.2 V, 2.2 Ah, 15.8 Wh

### **8.6 Status Messages**

If the SunTech Vet25E has a problem performing a task, a short beep will occur (if speakers are ON), the START/STOP button will turn Red and a Status Message will appear on the monitor screen. Take action as directed on the screen, or as suggested in the table below.

Status Message	Reason	Solution
Air Leak	There is a leak in the cuff, hose or monitor. Also possible	Check that the hose is connected to the monitor and cuff. Check that the cuff is properly tightened.

	if cuff or hose is not attached to the monitor.	Check that the cuff is in the correct position. Check that the cuff is not leaking air. Check that the hose connections are not damaged or loose.
Value out of Range	The blood pressure value is outside of SunTech Vet25E's published ranges.	Make sure you are using the proper cuff size. Patient may have been moving too much. Check that the cuff is properly tightened and in proper position.
Poor Signal Quality	Monitor is not receiving a strong signal from patient. Also possible if a rapid deflation occurs during a measurement.	Check that cuff is in correct position. Check the patient. Check that cuff is properly tightened. Check that correct size cuff is used.
Artifact Detected	Monitor is picking up on unexpected noise or movements.	Check animal mode. It might be on wrong setting. Check patient for motion, trembling. Too much movement. Check that cuff is in correct position. Check that correct size cuff is used.
Measurement Too Long	The monitor is not detecting strong and consistent signals from the patient for an extended time period.	Check to ensure cuff is fitting snugly on patient and is positioned properly. Check that cuff is in correct position. Check patient for moving, trembling.
Check Batteries!	Battery power is low.	See the battery life indicator on the Main Screen. Replace batteries if needed.
Air Blockage	Air is not able to pass through the hose or cuff properly.	Check that hose has no sharp bends and is not pinched. Check that patient is not lying or stepping on cuff. Check that cuff is in correct position.
Cuff Overpressure	Pressure in the cuff briefly exceeded 300 mmHg due to patient movement, air blockage or using a cuff that is too small.	Check that correct size cuff is being used. Check that hose has no sharp bends and is not pinched. Check that patient is not lying or stepping on cuff. Ensure patient is not moving excessively.
Monitor Not Ready	Monitor is preparing for next measurement or may need service.	Touch START/STOP to start a new measurement. For repeated errors, calibration or service may be required.
System Failure	A monitor system has failed.	Service is required.
Error!	Connection with the Bluetooth pairing device failed.	Check to ensure that the device is within range (30 feet) of the pairing device. Check that the pairing device has Bluetooth turned on and is advertising.

Transfer Error

Bluetooth paired device became disconnected.

Check to ensure that the device is within range (30 feet) of the pairing device.

Check that the pairing device has Bluetooth turned on and is advertising.

### 9. Frequently Asked Questions

### How many measurements can I store in Memory?

You can store up to 960 measurements. The monitor has a revolving memory. When you take your 51st measurement, it will be listed as measurement #1.

#### How do I delete BP data from memory?

Select the Memory button and touch the Delete button. Before the memory is cleared, you will be asked to confirm or cancel the deletion. When you clear the Memory, you delete all measurements.

### For medium-sized dogs, which animal mode do I choose?

Use cuff size as the determination factor. If a #3 cuff or smaller is the best fit, choose small animal mode. If #4 or larger, choose large animal mode.

### How do I choose the correct cuff size?

Wrap the cuff around the patient's limb or base of tail and make sure the index line falls within the range marker. If two different cuff sizes fit the patient, choose the larger size.

### How long will the batteries last?

During continuous monitoring of  $SpO_2$  and temperature, with an Interval BP set for every 5 minutes, a fully charged battery should last at least 4 hours before requiring recharging. If only taking manual BP measurements, a fully charged battery should last for at least 150 BP measurements before requiring recharging. Fully charging the battery should take under 6 hours. Battery life is very dependent on the touch screen display ON time. To maximize life, SunTech suggests setting the Auto OFF timer to 1 minute.

#### Can I use this monitor on awake and anesthetized animals?

Yes. The Vet25E can be used on anesthetized animals as well as awake animals.

### How do I keep the cuff from slipping down the limb or coming off?

Attach the cuff as tight as possible. Extra attention will be needed on species with dense or thick fur. If the cuff will not stay attached, check the hook & loop for fur and remove if possible.

#### Are there other power options?

Yes. The device is provided with a mains power supply that recharges the internal battery when connected. When the monitor is not connected to the power supply, the battery will allow the unit to be portable for use.

#### What are the minimum and maximum cat & dog weights when taking measurements with the Vet25E?

There are none. Any cat or dog that has a limb that fits within the cuff ranges is acceptable.

### **10. Limited Warranty**

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

Monitors 24 months Cuffs/Hoses 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 instrument when returned from the customer's facility within the United States prepaid to the factory. 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. The instrument should be carefully packaged and shipped prepaid to:

### •••

SunTech Medical, Inc.

Service Department 507 Airport Boulevard, Suite 117 Morrisville, NC 27560 USA Tel: 800.421.8626 919.654.2300 Fax: 919.654.2301



SunTech Medical, Ltd. Service Department Oakfield Industrial Estate Eynsham, Oxfordshire OX29 4TS UK Tel: 44 (0) 1865.884.234 Fax: 44 (0) 1865.884.235

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. It 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.

### **11. Technical Information**

### **11.1 Monitor Model Numbers**

Part Number	Model Number	Model Description
99-0176-00	M25E	Vet25E with Flamingo Pink Armour
99-0176-01	M25E	Vet25E with Peacock Blue Armour
99-0176-02	M25E	Vet25E with Tree Frog Green Armour

### **11.2 Factory Default Settings**

Parameter Name	Default Value
Clinical Alarms Status	OFF
Clinical Alarms – Iow SYS	40 mmHg
Clinical Alarms – High SYS	265 mmHg
Clinical Alarms – Iow DIA	20 mmHg

Clinical Alarms – High DIA	200 mmHg
Clinical Alarms – Iow MAP	27 mmHg
Clinical Alarms – High MAP	222 mmHg
Clinical Alarms – low HR	15 bpm
Clinical Alarms – High HR	300 bpm
Speaker Status	OFF
Auto OFF Timer	10 minutes
Interval BP Rate	3 minutes
Language	English
Startup Animal Selection	ON
Date Format	MM/DD/YYYY
Time Format	12-hour
Bluetooth Status	OFF

### **11.3 Performance Specifications**



**CAUTION:** Performance can be affected if used or stored outside the specified temperature and humidity ranges.

<b>Operating Conditions:</b>	Vet25E Monitor: 0°C to 50°C, 15% to 90% non-condensing humidity
Storage Conditions:	-20°C to 65°C, 15% to 90% non-condensing humidity
Altitude:	Measurement accuracy not affected by altitude
Power Source:	Lithium-ion Battery and/or AC Adapter
Input Voltage Range:	Universal (100 to 240 Vac)
Input Frequency Range: Input Efficiency rating: Isolation Classification: Output Voltage: Output Current: Protection from electrical	Universal (50 to 60 Hz) DoE Level VI Class II 12 Vdc 0 to 2.5 A shock: Class 2
Duty Cycle: Battery: Dimensions: Weight:	Continuous use 7.2 V, 2.2 Ah, 15.8 Wh 6.25" x 5" x 5.25" (15.9cm x 12.7cm x 13.3cm) 2.1 lb (0.95 Kg) with battery

### **BP Specifications**

Method of Measurement:	Oscillometric	
Blood Pressure Range:	Systolic:	40 – 265mmHg

	MAP:	27 – 222mmHg
	Diastolic:	20 – 200mmHg
Pulse Rate Range:	Canine/Feline Mo	odes: 25 to 300 BPM (Beats Per Minute)
	Equine Mode: 15	to 150 BPM
Pulse Rate Units: Cuff Deflate Rate:	Beats per minute Deflation step siz	e ze varies with heart rate, cuff pressure and cuff volume
Initial Inflation Pressure:	180 mmHg (defa	ult)
Subsequent initial inflation	n: previous Systoli	c + 30 mmHg
Transducer Accuracy:	±3 mmHg betwe	en 0 mmHg and 300 mmHg
Transducer Calibration:	Recommended b	i-annually or if a calibration problem is suspected

### **11.4 Radio Frequency Compliance Requirements**

This device contains a transmitter module identified by FCC ID: QOQBGM111 and Industry Canada: IC 5123A-BGM111. It has been tested and found to comply with the limits for a Class B device. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment. This device complies with Part 15 of the FCC Rules for the United States. Operation is subject to the following 2 conditions:

1) This device may not cause interference; and

2) This device must accept any interference, including interference that may cause undesired operation of the device.

### **Radio Equipment Directive (RED)**

This is a Class I device that contains a wireless transmitter which can be used in at least one EU member state. There are no restrictions of use.

### 11.5 Electromagnetic Compatibility (EMC)

Changes or modifications to the SunTech Vet25E that are not approved by SunTech Medical may cause EMC interference problems with this or other equipment.

#### **EMC Statement**

This equipment needs special precautions regarding EMC and needs to be installed and put into service per the EMC information provided in this document. This equipment has been tested and found to comply with the limits for medical devices to IEC60601-1-2: 2014. 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.
- Connect the equipment into an outlet on a circuit different from which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.
- Portable and mobile RF communications equipment can affect Medical Electrical 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 Vet25E system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. **WARNING:** Use of accessories, transducers, and cables other than those specified may result in increased emissions or decreased immunity of the Vet25E. **WARNING:** The Vet25E should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Vet25E should be observed to verify normal operation in the configuration in which it will be used.

**WARNING:** 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 Vet25E or shielding the location.

### Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Vet25E Monitor is intended for use in a Professional Healthcare Facility within the electromagnetic environment specified below. The customer or the user of the Vet25E Monitor 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: 2014.

Emissions test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Vet25E Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class B	The Vet25E Monitor is suitable for
Harmonic emissions IEC 61000-3-2	Class A	use in all establishments other than domestic and those directly
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Vet25E Monitor 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 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 the monitor 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 IEC 60601-1-2: 2014.

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 floor is covered with synthetic material, the relative humidity should be at least 30%. Users must eliminate static in their hands before use it.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
--

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	
Electrical fast transient/burst IEC 61000- 4-4	All device input and output connections and cables	± 2kV for power supply lines 100kHz repetition frequency	Mains power quality should be that of	
	AC Mains to Line to Ground	± 0.5, 1, 2kV	a typical commercial or hospital environment (Professional Healthcare Facility)	
	AC Mains to Line to Line	± 0.5, 1kV		
Surge IEC 61000-4-5	DC Input (>3m), Line to Ground	± 0.5, 1, 2kV	DC power quality shall be provided by the supplied power adapter	
	DC Input (>3m), Line to Ground	± 0.5, 1kV		
Conducted Disturbances induced by RF fields IEC 61000-4-6	All device input and output connections and cables	3V 0.15MHz – 80MHz 6V in ISM bands between 0,15 MHz and 80MHz 80% AM at 1kHz	Mains power quality should be that of a typical commercial or hospital environment. All handheld and patient coupled parts should be consistent with intended use.	
Power Frequency (50Hz) magnetic field IEC 61000- 4-8	All device input and output connections and cables	30A/m	Power Frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Device input (AC power)	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment (Professional Healthcare Facility) If the user of the monitor requires continued operation during power mains interruption, it is recommended	
L	1			

					nonitor be powered from an otible power supply or a
NOTE: UT is the a.c. mains v	oltage prior to application	on of tl	ne test level		
Conducted RF IEC 61000- 4-6	All device input and output connections and cables	3V 10V ISM bands 150kHz to 80MHz ccordina to frequency o		Portable and mobile RF communications equipment should be used no closer to any part of the monitor including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Minimum separation distance for highe 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. $E = \frac{6}{d}\sqrt{P}$ 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	Separation distance a	ccordi	ng to frequency o	of transmitte	r meters (m)
power of transmitter. Watts (W)	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 80 d = 1			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

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.

### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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 monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.
- b) Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3V/m

Test Frequency (MHz)	Band a) (MHz)	Service b)	Modulation b)	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
358	380 - 390	TETRA 400	Pulse Modulation b) 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 b) 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 b) 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 b) 217Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation b) 217Hz	2	0.3	28
5240 5500	5100 - 5800	WLAN 802.11 a/n	Pulse Modulation b) 217Hz	2	0.3	9

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.

# Appendix A: Service Screens

**WARNING:** Do not disassemble the unit. There are no user serviceable parts except for the battery. Refer to qualified service personnel.

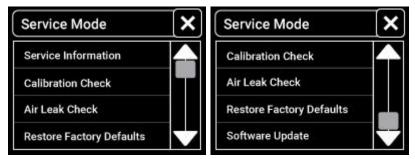
**WARNING:** The USB port is only a service port and cannot be used to download data or interface with the monitor. When updating the software, the monitor cannot be in use and the accessories should not be contacting the patient.

 $\triangle$ 

**CAUTION:** DO NOT remove unit covers. Doing so may increase the risk of electrical shock. This monitor does not contain any user serviceable parts. Substitution of a component or accessory different from that supplied may result in measurement error. Repairs should be undertaken only by personnel trained or authorized by SunTech Medical.

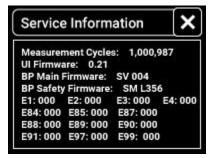
The SunTech Vet25E BP monitor includes a service mode where service information can be accessed, factory default settings can be restored and hardware verification checks can be performed. The service screens are accessed by holding down the power button for approximately 6 seconds when turning the monitor ON. When viewing service screens, the Start/Stop button LED is white.

No parts on the monitor or its accessories are serviceable.



### **Service Information**

Basic details are logged which includes the number of measurement cycles, user interface firmware version, both firmware versions for the BP algorithm as well as a count for each status message. Status codes are provided to assist in troubleshooting during a service call. The image below is provided for example only.



### **Calibration Check**

The pressure transducer in the SunTech Vet25E BP monitor is designed to hold its calibration for many years. Human NIBP devices require that the maximum static pressure accuracy shall be ± 3mmHg or 2% of the reading, whichever is greater. This is a stringent requirement and all test equipment must be in excellent working order to properly perform this test. If you do not have access to this equipment or prefer to have someone else verify the calibration,

the monitor can be sent to SunTech following the procedure described in the Limited Warranty section of this manual. There may be a charge associated with the verification if the transducer is not out of calibration.

SunTech suggests this check be performed every 2 years or if there is suspicion that the monitor may be out of calibration.



### **Equipment Needed**

Calibrated Manometer

Pneumatic "T" Adapters

Volume (500mL bottle or #6 or #7 cuff wrapped tightly around a solid object)

Hand Bulb

**Connection Tubing** 

#### Procedure

Connect a manometer, volume and the hand bulb to the end of the monitor hose using "T" adapters and connection tubing.

Touch the Start button which closes the valves and shows the pneumatic pressure.

Apply various pressures (between 0 mmHg and 250 mmHg) to the monitor with the hand bulb. INFLATE SLOWLY when adding pressure over 200 mmHg to avoid an overpressure. Verify that the module pressure is equal to the manometer pressure (±3 mmHg or 2% of the target value).

If the pressure is within limits, then touch the Stop button and the calibration check is complete.

If the pressure does not agree with the manometer, then the transducer needs to be re-calibrated. Send monitor back to SunTech Medical following the procedure in the Limited Warranty section of the manual.



### **Air Leak Check**

International standards for human NIBP devices require that air leakage within the pneumatic system must not exceed 6 mmHg/min. During manufacturing at SunTech Medical, acceptable air leakage is less than 3 mmHg/min. Both of these pass criteria will not affect the performance or accuracy of the NIBP module so the SunTech Vet25E uses the 6 mmHg/min pass criteria. If you do not have access to this equipment or prefer to have someone else perform the air leak check, the monitor can be sent to SunTech following the procedure described in the Limited Warranty section of this manual. There may be a charge associated with performing an air leak check.

SunTech suggests this check be performed if there is suspicion of an air leak.



### **Equipment Needed**

Volume (500mL bottle or #6 or #7 cuff wrapped tightly around a solid object)

Standard patient hose

**TIP**: A reduction in cuff pressure is expected during the first 60 seconds due to pneumatic expansion of the cuff, patient hose and internal tubing. Make sure cuff is wrapped tightly around a solid object. Do not perform with cuff on a patient, lying flat or wrapped loosely.

### Procedure

Connect the volume to the monitor patient hose.

Touch the Start button which begins the air leak check and shows the pneumatic pressure and a timer. This check takes approximately 2 minutes.

When the check is complete, the monitor will indicate a pass or fail result.

If pass, then touch the Pass button and the air leak check is complete.

If fail, then there is an air leak within the pneumatic system. Try repeating the check with a different cuff making sure all connections are sealed. If it still fails, you may send the monitor and cuffs back to SunTech Medical following the procedure in the Limited Warranty section of the manual.

eck	X
1 progress.	
0:45	
Stop	)
	n progress. 0:45

### **Restore Factory Defaults**

Factory defaults are restored by accessing this screen. A list of factory default settings is in the Technical Information section of this manual.

Restore to factory default	settings?
Cancel	ок

### **Software Update**

The software can be updated using a SunTech-provided USB drive.

Procedure



**WARNING**: When updating the software, the monitor cannot be in use and the accessories should not be contacting the patient.

With the USB drive inserted into the device, touch Software Update from the Service Mode screen. A status bar will indicate the progress of the update. Do not turn off the device during the update. The device will restart when OK is pressed after the update is complete.

Software Up	date 🗙
Software update Please do not tur unit.	in progress. rn power off to the