DATREND Systems Inc.

vPad-A1™

All-in-One Patient Simulator and Performance Tester

Operating Manual

MN-103d

vPad-A1™

All-in-One Patient Simulator and Performance Tester

Operating Manual

Unit 130 - 4020 Viking Way
Richmond, BC • CANADA • V6V 2L4
Tel: 800.667.6557 (North America Only) or
604.291.7747 • Fax 604.294.2355
e-mail: **customerservice@datrend.com**

DATREND Systems Inc.

To order this manual, use Part Number 6100-086

Revision	Revision History Description	Date
B	Spec Update	2017-Jan-31
C	Add AutoSetting Instructions, zeroing manual pressure	2019-Aug-22
D	Environmental Spec Update. Updated Standard Accessories.	2023-Nov-02

Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the freight carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Claims

Our routine method of shipment is via common carrier. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim.
If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact your local sales representative or DSI immediately.

Standard Terms and Conditions

Refunds & Credits

Please note only serialized products (products labelled with a distinct serial number) and accessories are eligible for partial refund and/or credit. Non-serialized parts and accessory items (cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. In order to receive a partial refund/credit, the product must not have been damaged, and must be returned complete (meaning all manuals, cables, accessories, etc.) within 90 days of original purchase and in "as new" and resalable condition. The *Return Procedure* must be followed.

Return Procedure

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from Datrend Customer Service. All items being returned must be sent *prepaid* (freight, duty, brokerage, and taxes) to our factory location.

Restocking Charges

Products returned within 30 days of original purchase are subject to a minimum restocking fee of 15%. Products returned in excess of 30 days after purchase, but prior to 90 days, are subject to a minimum restocking fee of 20%. Additional charges for damage and/or missing parts and accessories will be applied to all returns.
Products which are not in "as new" and resalable condition, are not eligible for credit return and will be returned to the customer at their expense.

Certification

This instrument was thoroughly tested and inspected and found to meet DSI's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Research Council of Canada (NRC) and/or the National Institute of Standards and Technology (NIST). Devices for which there are no NRC/NIST calibration standards are measured against in-house performance standards using accepted test procedures.

Warranty and Product Support

Datrend Systems Inc. ("DSI") warrants the Base and Simulation Modules of vPad-A1 (the "Datrend product") to be free from defects in materials and workmanship under normal use and service for one (1) year from the date of original purchase. This warranty will be automatically extended to **two (2) years** from the date of original purchase, provided that calibration is performed on an **annual** basis by a Datrend Authorized Service Center*. During the warranty period DSI will, at our option, either repair or replace defects in materials and workmanship at no charge; provided the Datrend product is returned (shipping, duty, brokerage and taxes prepaid) to DSI. Any and all transportation charges incurred are the responsibility of the purchaser and are not included within this warranty. This warranty extends only to the original purchaser and does not cover damage from abuse, neglect, accident or misuse or as the result of service or modification by other than DSI. IN NO EVENT SHALL DATREND SYSTEMS INC. BE LIABLE FOR CONSEQUENTIAL DAMAGES.

This warranty is subject to the following limitations:
- Tablet: per tablet manufacturer's original warranty
- Standard Accessories: 90 day limited warranty
- Damage due to activation of devices under test which are connected to the “applied parts” inputs is not covered under the warranty
- Re-calibration of the instrument, which has a recommended annual calibration frequency, is not covered under the warranty.

No warranty shall apply when damage is caused by any of the following:
- Power failure, surges, or spikes,
- Damage in transit or when moving the instrument,
- Improper power supply such as low voltage, incorrect voltage, defective wiring or inadequate fuses,
- Accident, alteration, abuse or misuse of the instrument,
- Fire, water damage, theft, war, riot, hostility, acts of God, such as hurricanes, floods, etc.

Only serialized products (those items bearing a distinct serial number tag) and their accessory items are covered under this warranty. PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY. Items such as cables and non-serialized modules are not covered under this warranty.

This warranty gives you specific legal rights and you may have other rights, which vary from province to province, state to state, or country to country. This warranty is limited to repairing the instrument to DSI's specifications.

When you return an instrument to DSI for service, repair or calibration, we recommend shipment using the original shipping foam and container. If the original packing materials are not available, we recommend the following guide for repackaging:
- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use non-abrasive material around all projecting parts.
- Use at least four inches of tightly packed, industrial-approved, shock-absorbent material all around the instrument.

DSI will not be responsible for lost shipments or instruments received in damaged condition due to improper packaging or handling. All warranty claim shipments must be made on a prepaid basis (freight, duty, brokerage, and taxes). No returns will be accepted without a Return Materials Authorization ("RMA”) number. Please contact Datrend (refer to Chapter 6 of this manual) to obtain an RMA number and receive help with shipping/customs documentation.

* Subject to some exclusions, based on sales territory. Contact Datrend for details.

Warranty Disclaimer

Should you elect to have your instrument serviced and/or calibrated by someone other than Datrend Systems or an Authorized Service Centre, please be advised that the original warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization. We strongly recommend, therefore, that you send your instrument to Datrend Systems or an Authorized Service Centre for service and calibration, especially during the original warranty period.

In all cases, breaking the tamper-resistant Quality Seal should be avoided at all cost, as this seal is the key to your original instrument warranty. In the event that the seal must be broken to gain internal access to the instrument (e.g., in the case of a customer-installed firmware upgrade), you must first contact Datrend Systems at 1-604-291-7747. You will be required to provide us with the serial number for your instrument as well as a valid reason for breaking the Quality Seal. You should break this seal only after you have received factory authorization. Do not break the Quality Seal before you have contacted us! Following these steps will help ensure that you will retain the original warranty on your instrument without interruption.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Datrend Systems will not be responsible for any injuries sustained due to unauthorized equipment modifications.

DSI DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

THIS PRODUCT CONTAINS NO USER-SERVICEABLE COMPONENTS. UNAUTHORIZED REMOVAL OF THE INSTRUMENT COVER SHALL VOID THIS AND ALL OTHER EXPRESSED OR IMPLIED WARRANTIES.

Note: Calibration of Datrend products typically involves adjustment of parameters stored in firmware by proprietary software. Parties other than Datrend and its Authorized Service Centers are limited to verification of the status of the accuracy of the instrument. Do not confuse verification with calibration.

Table of Contents

Abbreviations and Definitions

The following abbreviations, terms and acronyms may be used throughout this manual:

µA	Micro-ampere
A	Ampere
AAMI	American Association of Medical Instrumentation
App	Software application for a mobile device
EUT	Equipment Under Test. The electrical device being tested.
Hz	Hertz
IEC	International Electrotechnical Commission
kHz	kilohertz
LA	left arm ECG lead
LL	left leg ECG lead
RA	right arm ECG lead
RL	right leg ECG lead
V	Volt
V1-V6	Precordial (chest) ECG leads
Vrms	Volts rms

Symbol Definitions

The following symbols may be found on vPad-A1:

CONSULT MANUAL FOR PROPER OPERATION

The operating manual provides valuable information on the proper use of vPad-A1. It is highly recommended the operator read the instructions thoroughly before operating the device. It may be possible to damage the Equipment Under Test (EUT) and/or cause harm to the operator if vPad-A1 is used incorrectly.

WARNING: OPENING THE vPad-A1 MAY COMPROMISE USER SAFETY.
REFER SERVICING TO DATREND AUTHORIZED AGENT.

vPad-A1 is a complex instrument which contains Lithium Ion batteries and associated charging circuitry. Failure to observe appropriate measures when the instrument has been opened, or failure to reassemble correctly may compromise the safety of the user.

1 Specifications

The vPad-A1 All-In-One patient simulator and performance tester is a modular, stackable system comprised of a user interface or "base" module providing a tablet computer, system power and communications, and one or more of the following modules: a patient simulator (ECG, IBP, RESP, etc.); a pulse oximeter (SpO2) tester; and an NIBP simulator. Each simulation/test module can be used individually with the base, or in combination with either or both of the other modules. The base module includes hardware for charging an internal battery which provides power to the base, the pulse oximeter tester, and the ECG/IBP simulation module. The vPad-A1 software or "app" runs on the tablet computer and is used to operate the simulation/test modules.

The following specifications pertain to the vPad-A1 hardware when used with the vPad-A1 software or "app" on the tablet. As a modular system, product capabilities will depend on the modules present; specifications apply only to those modules that you have active in the system.

Equipment Performance Specifications

1.1 General Specifications

User Interface:

The simulation hardware of vPad-A1 is controlled by a tablet computer through a hardwired connection to the microUSB port on the tablet, or alternatively through wireless communication with the tablet over Bluetooth. The tablet computer is comparable in size to a conventional smartphone and fits into a cradle on the vPad-A1 base module for storage and transport.

A software application or "app" running on the tablet controls the system. As individual simulation functions are activated by the app, they remain active until explicitly turned off. The app enables numerous simulations to run concurrently, with all patient signals remaining in synchronization.

The tablet computer of vPad-A1 has these specifications:

Display.....	5" colour LCD
User Controls.....	Capacitive touchscreen

Wired Connectivity.....	Micro USB 2.0 Type B XBUS Interface (RJ12-6)
Wireless Connectivity.....	802.11 b/g/n Bluetooth 2.1+ EDR
Memory, Internal.....	8GB Storage (~6GB available)
Modes of Operation.....	USB wired connection Bluetooth wireless

Environment:

- 10°C to 40°C (50°F to 104°F)
- 10% to 90% Relative Humidity
- Indoor Use Only

Power Supply:

- Internal Lithium Ion batteries (rechargeable, 3.8V 2600 mAh each), or
- AC adapter, Input: 90-240VAC 50/60Hz
  Output: 15 VDC, 2.67A, 40W

Dimensions and Weight (maximum, all modules included):

- 9.8 cm W x 27.5 cm L x 9.7 cm D (3.86" W x 10.83" L x 3.82" D)
- 1.76 kg (3.88 lb)

Electrical Interfaces:

- 10 standard ECG snap leads
- Optional, externally-connected ECG jacks x 10 (accepts 3 mm or 4 mm plugs)
- BP 1 and BP 2: USB Type A connector, proprietary wiring
- TEMP: 6-pin mini-DIN
- AUX: 8-pin mini-DIN, to optional Cardiac Output and/or Mechanical Fetal Heart
- High-level ECG Out: 2.5mm stereo phono jack
- DACOM: 2 x RJ-12 jack, proprietary serial data interface for Datrend vPad products
- Base USB: microUSB connector (5VDC/2A)
- Tablet USB: mini/microUSB combined connector (5VDC/1A)
- DC IN: 2.1 mm coaxial power jack, to AC Adaptor (15VDC, 2.67A, 40W)

1.2 Multi-Parameter Patient Simulation

Multi-parameter patient simulation is provided by the **vPad-PS** module of vPad-A1.

ECG General:

• Simulation Type:	Full 12-Lead ECG with independent outputs for each signal lead, referenced to RL
• Output Impedance:	500, 1000, 1500, and 2000 ohms to RL
• High Level Output:	Lead II amplitude x 500 (0.5V per Lead II millivolt)
• Amplitude Accuracy:	± 2% (Lead II, 2 Hz Square Wave)
• QRS width:	80 msec (Adult) or 40 msec (Neonatal)
• Artifact:	50 Hz, 60 Hz, Muscle, Baseline (wander), Respiration
• Rate Accuracy	Better than 0.1%

Normal Sinus Rhythm:

• Rates:	10 to 360 BPM presets: 20, 40, 60, 80, 100, 120, 140, 160, 180, 200, 220, 240, 260, 280, and 300 BPM (default/user re-defineable)
• Rate Accuracy:	Better than 0.1%
• Amplitudes (Lead II):	0.05 to 0.50 mV in 0.05 mV steps, 0.5 to 5.5 mV in 0.25 mV steps. Other leads are proportional to Lead II (reference lead) in percentage:

	Amplitude		
Lead 1	70	V1	65
Lead 2	100	V2	100
Lead 3	30	V3	110
		V4	130
		V5	120
		V6	90

• Axis Deviation:	Normal (intermediate), horizontal, and vertical Modifies ECG baseline during arrhythmias

Arrhythmia:

GENERAL 1

- Asystole 1
- Asystole 2
- Asystole 3
- PVC1 Bigeminy
- PVC1 Trigeminy
- PVC2 Bigeminy
- PVC2 Trigeminy
- PAC Premature Atrial Contraction
- PNC Premature Nodal Contraction
- Multifocal PVCs (once)
- Frequent Multifocal PVCs

PREMATURE VENTRICULAR CONTRACTION (PVC) 1

- Left Ventricle (once)
- Left Ventricle (every 10th beat)
- Left Ventricle, Early (once)
- Left Ventricle, R on T (once)
- PVC1, 6/Minute
- PVC1, 12/Minute
- PVC1, 24/Minute
- PVC1, Run of 2
- PVC1, Run of 5
- PVC1, Run of 11

PREMATURE VENTRICULAR CONTRACTION (PVC) 2

- Right Ventricle (once)
- Right Ventricle (every 10th beat)
- Right Ventricle, Early (once)
- Right Ventricle, R on T (once)
- PVC2, 6/Minute
- PVC2, 12/Minute
- PVC2, 24/Minute
- PVC2, Run of 2
- PVC2, Run of 5
- PVC2, Run of 11

HEART BLOCKS AND CONDUCTION DEFECTS

- 1st Degree Heart Block
- Mobitz I, 2nd Degree AV Block
- Mobitz II, 2nd Degree AV Block
- 3rd Degree AV Block
- Right Bundle Branch Block
- Left Bundle Branch Block

FIBRILLATIONS

- Coarse Atrial Fibrillation
- Fine Atrial Fibrillation
- Coarse Ventricular Fibrillation
- Fine Ventricular Fibrillation

TACHYCARDIA

- Atrial Tachycardia
- Paroxysmal Atrial Tachycardia
- 90 BPM Supraventricular Rhythm
- 120 BPM Supraventricular Rhythm
- 140 BPM Supraventricular Tachycardia
- 150 BPM Supraventricular Tachycardia
- 160 BPM Supraventricular Tachycardia
- 170 BPM Supraventricular Tachycardia
- 180 BPM Supraventricular Tachycardia
- 190 BPM Supraventricular Tachycardia
- 200 BPM Supraventricular Tachycardia
- 210 BPM Supraventricular Tachycardia
- 220 BPM Supraventricular Tachycardia
- 160 BPM Normal Sinus Rhythm

GENERAL 2

- Atrial Flutter
- Sinus Arrhythmia
- Miss 1 Beat, 80 BPM
- Miss Every 10^{th} Beat, 80 BPM
- Miss Every 10^{th} Beat, 120 BPM
- Nodal Rhythm
- Sinus Bradycardia, <60 BPM

ECG Performance Tests:

- Square Waves: 0.125 Hz, 2 Hz, 2.5 Hz
- Triangle Wave: 0.125 Hz, 2 Hz, 2.5 Hz
- Pulse: 60 BPM or 30 BPM (60 msec)
- Sine Waves: 0.05, 0.5, 1, 2, 5, 10, 25, 30, 40, 50, 60, 100 Hz, and 150 Hz
- R-Wave Detector Test: 30, 60, 80, 120, 200, or 250 BPM haver-triangle wave with selectable width 8, 12, 20, 40, 60, 80, 100, 120, 140, 160, 180 and 200 msec
- QRS Detection Test 30, 60, 80, 120, 200, or 250 BPM QRS wave with selectable width 8, 12, 20, 40, 60, 80, 100, 120, 140, 160, 180 and 200 msec
- Tall T-Wave Test 0 to ± 150% in steps of 10% of Amplitude Setting (0, 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4 and 1.5 mV at 1 mV)

• ST Segments:	± 0, 5, 10, 20, 30, 40, 50, 60, 70, 80 % of Amplitude Setting (0, -0.05, -0.1, -0.2, -0.3, -0.4, -0.5, -0.6, -0.7, -0.8, 0.05, 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7 and 0.8 mV at 1 mV)
• Performance Amplitude:	0.05 to 0.5 mV in 0.05 mV steps, 0.5 to 5.0mV in 0.25 mV steps (applies to all performance waveforms)

Respiration:

• Rates:	15 to 150 BrPM incremental with 15 customizable presets
• Baseline Impedance:	500, 1000, 1500, 2000 ohms on Leads I, II, III
• Apnea Selections:	12, 22, 32 seconds, and continuous (0 BPM)
• Impedance Variation:	0 to 1.0 ohms in 0.05 ohm steps, 1.0 to 5.0 in 0.25 ohm steps
• Simulation Types:	Inspiration:Expiration ratios of 1:5, 1:4, 1:3, 1:2, and 1:1, and Ventilated 1:1
• Lead Reference:	LA or LL

Temperature:

• Channels:	2
• Body Temperatures:	20 to 42°C in 0.5°C steps
• Probe Compatibility:	YSI series 400 or 700
• Accuracy:	± 0.03°C , ± 0.01°C at 30, 32, 35, 37, 40, 42°C

Pacemaker:

• Simulated Rhythms:	- Asynchronous @ 75 BPM - Demand with frequent sinus beat - Demand with occasional sinus beat - A-V sequential - Non-capture - Non-function

• Pacer Pulse Amplitude:	2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 50, 100, 200, 500 and 700 mV
• Pacer Pulse Width:	0.1, 0.2, 0.5, 1.0, and 2.0 msec
• Pacer Pulse Polarity:	Positive or negative

Invasive Blood Pressure:

• Channels:	2 independent channels
• Accuracy:	± (1% setting + 1 mmHg)
• Static Pressures:	-10 to 400 mmHg; 1 mmHg increments 15 customizable presets
• Transducer Sensitivity:	5 μV/V/mmHg or 40 μV/V/mmHg
• I/O Impedance:	300 ohms ± 10%
• Excitation Voltage:	2 to 16 Vp; 0 to 5 kHz
• Dynamic Simulations:	- Arterial 120/80, 90/40, and 160/110 - Radial Artery 120/80 - Left Ventricle 120/0 - Right Ventricle 25/0 - Pulmonary Artery 25/10 - Pulmonary Wedge 10/2 - Right Atrium (CVP) 120/0 - Left Atrium 14/4
• Swan-Ganz Simulations: (Channel 1 only)	Auto or Manual
• Blood Pressure Artifact:	OFF 5% for Arterial, Radial and L. Ventricle, or 5 mmHg for others 10% for Arterial, Radial and L. Ventricle, or 10 mmHg for others

Cardiac Output:

• Baseline Temperatures:	36, 37 and 38°C.
• Injectate Thermistor Types:	- H-P/Philips - American Edwards/Spacelabs - Adjustable (default Edwards/Spacelabs at 20°C)
• Injectate Temperatures:	0, 2, 20 or 24°C. Note: 24°C Spacelabs is adjustable
• Cardiac Outputs:	3, 4, 5, 6, and 7 liters/minute
• Simulation Types:	- Slow Injection - Faulty Injection - L/R Shunt - Cal Pulse: 1°C for 1 second

Fetal ECG/Intrauterine Pressure:

• Fetal ECG Rates:	60 to 240 BPM; 1 BPM increments
• Fetal ECG Amplitudes:	See NSR specification 12 preset rates, user definable
• Fetal ECG Rate Variation:	Uniform, Early, and Late Deceleration; Uniform Acceleration
• Pressure Waveform:	Bell shaped, 0-50 or 0-90 mmHg
• Contraction Frequency:	Every 2, 3, 5 minutes, or manually triggered
• Transducer Sensitivity:	5 μV/V/mmHg or 40 μV/V/mmHg

Auto Presets:

Unlimited number of user-defined simulation setups can be programmed into the vPad-A1.

1.3 Pulse Oximetry (SpO2) Testing

Pulse oximetry or SpO2 testing is provided by the **vPad-O2** module of vPad-A1.

Saturation (SpO2):

- Range: 30 to 100% SpO2*
- Increments: 1%
- Accuracy: ±1 count + specified accuracy of the DUT when within DUT specified range
- Presets: 6, user-definable

* Range of adjustment and presets may vary according to pulse oximeter specifications

Heart Rate:

- Range: 20 to 300 BPM
- Increments: 1BPM
- Accuracy: ±0.25 BPM in sync mode
  ±1 BPM otherwise
- Presets: 6, user-definable

Pulse Amplitude:

- Range: 0 to 100%
- Increments: 1% steps
- Accuracy: ±1 %
- Presets: 6, user-definable

Signal Artifact:

- Simulations: Movement
  Tapping (Spike Artifact)
  Shivering (Tremor artifact)
  Shake Table (2.5Hz Sinewave)

AutoSettings:

- Defaults: Normal Adult
  Hypoxia
  Tachycardia
  Bradycardia
  Low Perfusion
  No Perfusion
  Movement Artifact
  Neonate
  Tremor (Shivering Artifact)
- User-defined Presets: Unlimited

Alarm Tests:

- Defaults: 5 tests:
  - Low SpO_2
  - Low Heart Rate
  - High Heart Rate
  - Low Perfusion
  - Motion Artifact
- User-defined Alarm Tests: Unlimited

1.4 Non-Invasive Blood Pressure (NIBP) Simulation

Non-invasive blood pressure or NIBP simulation is provided by the **vPad-BP** module of vPad-A1.

Power Supply:

- Three (3) Lithium Ion batteries, rechargeable, 3.8V 2600 mAh each

Simulation Specifications

NIBP General:

• Simulation Type:	Oscillometric method
• Pulse Rate:	20 to 240 BPM
• Rate Accuracy:	± 0.25 BPM in sync mode, otherwise ± 1 BPM
• Amplitude:	Hi = 2.0 ml nominal (~1.25 mmHg into 500 ml cuff)
• Amplitude Range:	0 to 150%
• Amplitude Accuracy:	better than 0.5%
• BP Envelope Shift:	± 50 mmHg max min Diastolic: 15 mmHg max Systolic: 275 mmHg
• Simulation AutoSettings:	Unlimited, and user-definable

Manometer:

• Range:	0.0 to 400.0 mmHg
• Accuracy:	± 0.5 mmHg
• Resolution :	0.1 mmHg
• Units:	mmHg, mbar, kPa, inH2O, cmH2O
• Test Modes:	Manual
• User-defined Settings:	Unlimited

Pressure Source:

• Range:	10.0 to 400.0 mmHg
• Accuracy:	± 0.5 mmHg
• Resolution :	0.1 mmHg
• Units:	mmHg
• Test Modes:	Automatic Manual Step (definable)
• User-defined Settings:	Unlimited

Leak Test:

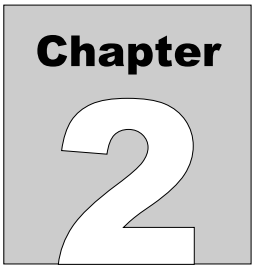
• Range:	0 to 200mmHg/min
• Inflation:	Automatic or Manual
• Pressure:	20 to 400mmHg
• Elapsed Time:	30 to 600 sec
• Presets:	Pressure, Elapsed Time 6 each, user-definable values
• User-defined AutoSettings:	Unlimited

Over PressureTest:

• Inflation:	Automatic or Manual
• Range:	20 to 400mmHg
• Release Time:	1-999 sec
• Presets:	Pressure, Release Time 6 each, user-definable values
• User-defined AutoSettings:	Unlimited

Standard Accessories:

7500-146 NIBP Hose Tubing Adapter Kit



2 Overview

vPad-A1™ is a test instrument intended to provide a means of functional testing for Pulse Oximeters, Multi-Parameter Monitors (including some Fetal Monitor parameters), and Non-Invasive Blood Pressure Monitors. When fully equipped with the available modules, the instrument is capable of simultaneously simulating all vital signs, including electrocardiogram, respiration, temperature, cardiac output, blood oxygen saturation, and blood pressure as measured invasively or non-invasively.

2.1 Modular Design

The vPad-A1's modular design combines full features with light weight and flexibility. While all vital signs can be simulated simultaneously by a complete All-In-One system, the unique design of vPad-A1 allows the three individual modules to be separated into independent testers, or to be combined (stacked) into a 2-module or 3-module system. Users can choose to include only those modules which are necessary for the tasks at hand.

Simulation modules are controlled by a user interface module (the **Base**), which may be connected through a cable to an individual module or to the top module in a stacked system. The **Base** holds a 5" tablet computer (referred to in this document as the **Tablet**) which provides the simulator's Graphical User Interface (GUI). In addition to the **Tablet**, the **Base** module provides battery power, a charger port, and a data communication hub which interfaces with the other three modules of the system. These modules are: the **vPad-PS** patient simulator, providing output of ECG, invasive blood pressure, respiration and other physiological signals; the **vPad-O2** pulse oximeter tester; and the **vPad-BP** NIBP simulator.

In its role as the communications hub of vPad-A1, the **Base** module enables connection of the simulator to additional vPad products, such as vPad-ES™, from Datrend Systems. This enables electrical safety testing to be combined with performance tests provided by the simulator to obtain an integrated, automated system for preventive maintenance inspection of patient monitoring devices.

The **vPad-BP** module, due to its higher power requirements, contains its own supplementary battery pack and charger input. As long as both the **Base** and the **vPad-BP** module are connected together, a single battery charger can supply power for both modules from either charger input.

2.2 Tablet User Interface

The user interface of vPad-A1 is a tablet computer which runs the Google Android™ platform. The use of an Android-based tablet provides several notable benefits:

- High resolution, full color display
- WiFi / Internet communication
- Bluetooth connection to many other products and accessories
- Access to a wide variety of useful Android apps
- On-tablet report review, transfer, and printout

2.3 AutoSettings

Simulation and testing functions of vPad-A1 have the ability to receive **AutoSettings**, a combination of simulation settings representing a scenario or test condition. For instance, the Multi-Parameter Patient Simulator can have a 'Hypertensive' **AutoSetting**, invoked by a single selection, that generates **ECG** at a specific **Rate** and a particular **Amplitude** with motion **Artifact**. Rather than setting each **ECG** parameter individually, selection of the Hypertensive **AutoSetting** would set all of the parameters at once.

Users can configure and save a virtually unlimited number of **AutoSettings**. Once an **AutoSetting** has been created, it can then be used in one or more **AutoSequences**.

2.4 AutoSequences

An **AutoSequence** is a user-configurable test template which causes vPad-A1 to execute an ordered sequence of **AutoSettings** (see *5.2.1 - AutoSettings*) from any of the test modules. Advantages of an **AutoSequence** are:

- Reduced setup and testing time
- Reduced human error (e.g. neglect to perform a required test)
- Objective assessment of equipment performance (with quantitative pass/fail limits)
- Increased labour efficiency (technician can perform other tasks while a test is running)
- Automated data recording (Test Record files provide traceable documentation that equipment was tested and allows notes for observations)

There can be a virtually unlimited number of **AutoSequence** files stored on the tablet.

2.5 Target Device Customization

vPad-A1 comes equipped with an extensive list of test definitions for **SpO2** and **NIBP** devices, organized by make and model, that generate precise signals which are matched to the chosen device. In the event that a particular device is not found in the list of models, tools are available in the **vPad-A1 App** for knowledgeable users to create new, custom definitions.

There can be a virtually unlimited number of make and model definitions stored on the tablet.

Chapter 3

3 Setup

vPad-A1 is a modular system having a **Base** and one, two or three additional modules which provide patient simulation or monitor testing. This chapter describes the modules and their connector interfaces, and provides instructions for assembly and setup of the system.

3.1 Modules and Interfaces

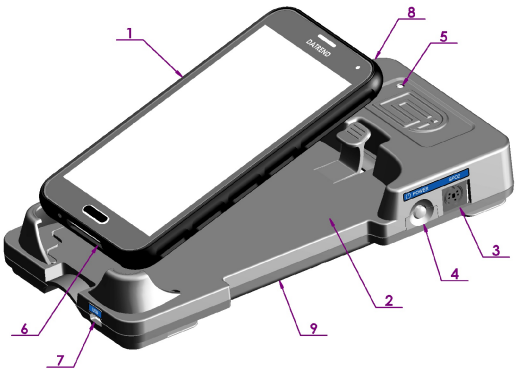
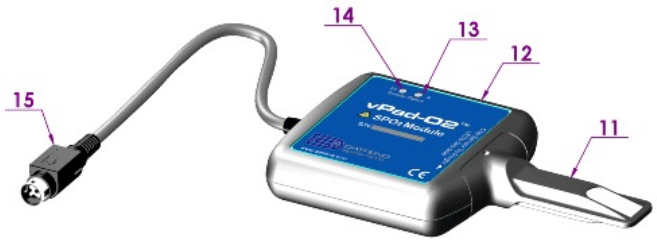


Figure 1

The vPad-A1 **Base** module (*Figure 1*) is comprised of a 5" Android **Tablet** and its cradle. The cradle incorporates a rechargeable battery which provides power to itself and to other modules of the system, as well as a communication hub to facilitate control of the test/simulation modules. The **Tablet** also has a battery, which can be recharged through the USB connection to the cradle.

Item	Name	Description
1	Tablet	Android 5" color LCD tablet with touch screen
2	Cradle	Snap-in cradle/holder for Android Controller
3	SPO2 Port	miniDIN8 connector to vPad-O2 (SpO2) accessory module
4	Power Switch	Power On/Off for all modules
5	LED Power Indicator	Power and Battery status
6	Tablet USB Port	Battery charging and data input to Android tablet (microUSB)
7	Cradle USB Port	Battery charging and data output from cradle (microUSB)
8	DACOM Port x 2	Proprietary serial data connection to other Datrend vPad products
9	Battery Cover	Locks the battery into the GUI (base bottom)



The vPad-O2 (**SpO2**) module is a pulse oximeter tester which connects to the **Base** module via a minDIN8 connector. This module provides an artificial 'finger' containing light guides which convey light to or from pulse oximeter probes and sensors.

Figure 2

Item	Name	Description
11	Optical Finger	Interface to pulse oximeter sensor
12	Enclosure	Houses the simulation electronics
13	Red Indicator	Indicates red light as detected from pulse oximeter sensor
14	Infrared Indicator	Indicates infrared light as detected from pulse oximeter sensor
15	Power and Data Cable	miniDIN8 cable to Base module

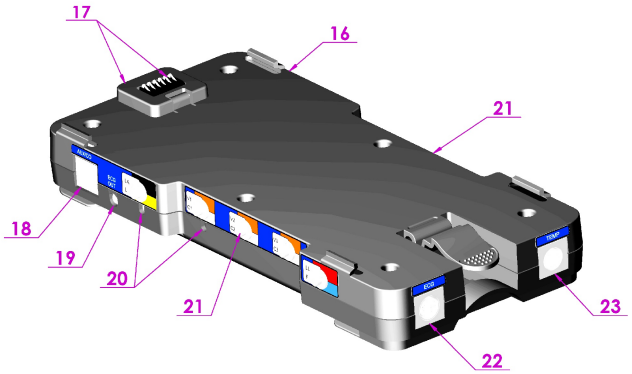


Figure 3

The vPad-PS (Patient Simulator) module snaps in below the **Base** module, connecting to power and data communication lines through contacts on the bottom of the **Base**.

Item	Name	Description
16	IBP Connection	2 channel IBP connectors, USB Type A, proprietary wiring (right side)
17	Power/Data Connector	6 pin inter-module connector for power and serial communications
18	Fetal Heart/Cardiac Output	Output to drive Mechanical Fetal Heart and Cardiac Output, miniDIN8 (fetal heart and CO interface boxes are optional)
19	High Level ECG	Amplified ECG signal, phone jack
20	Injectate Adjust	Access to coarse and fine adjustments for special cardiac output injectate temperature value
21	ECG Snap	Snap connections (10 total) for ECG monitor leads (left and right side)
22	ECG Output extension	miniDIN10 extension connection for 3 and 4 mm banana jacks
23	Temperature Connector	YSI400 and YSI700 output resistance connector, miniDIN6

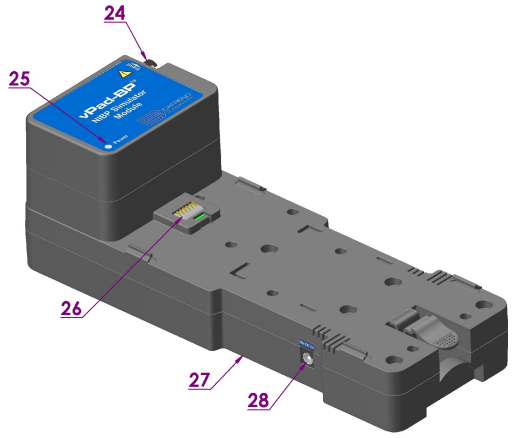


Figure 4

The vPad-BP (**NIBP**) module draws power from an internal set of three rechargeable batteries. The module's operation can be controlled through a direct connection with the **Base**, or by means of a pass-through connection in the vPad-PS module when used in the stacked configuration.

With all modules stacked, a single DC power supply can simultaneously charge all batteries in the system, including those in the **Tablet**, the **Base**, and the **NIBP** module.

Item	Name	Description
24	NIBP Cuff Connector	Pneumatic connection for cuff hose adapter
25	LED Power Indicator	Power and charge/battery status
26	Power/Data Connector	6 pin inter-module connector for power and serial communications
27	NIBP Reset	Access to NIBP module reset button (bottom)
28	DC Power Supply	Connection for NIBP + Base + Tablet charger

3.2 Assembly and Setup

To prepare vPad-A1 for use, first remove the **Tablet** from its cradle.

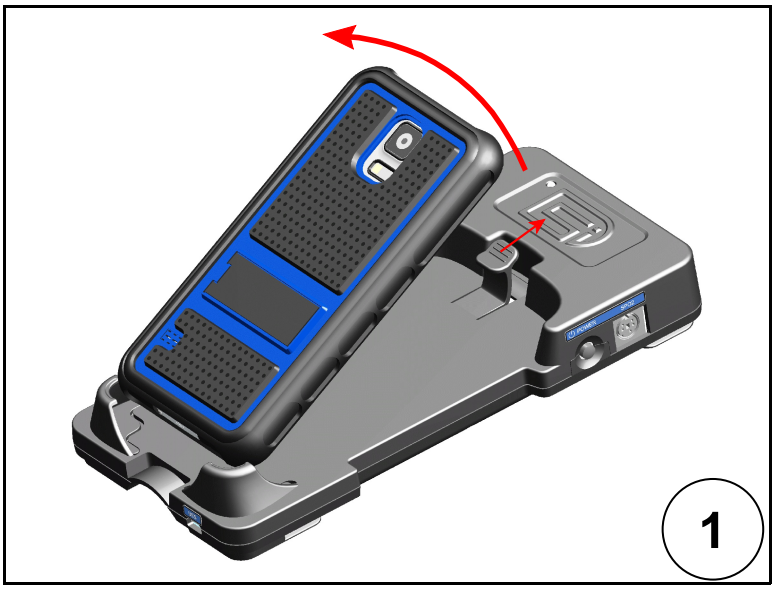


Figure 5

Next, connect as many simulation modules to the **Base** as necessary. The **vPad-PS** and **vPad-BP** modules slide and snap underneath the **Base** unit as shown in the figure below. The **vPad-O2** module connects to the **Base** unit via the "SPO2" port.

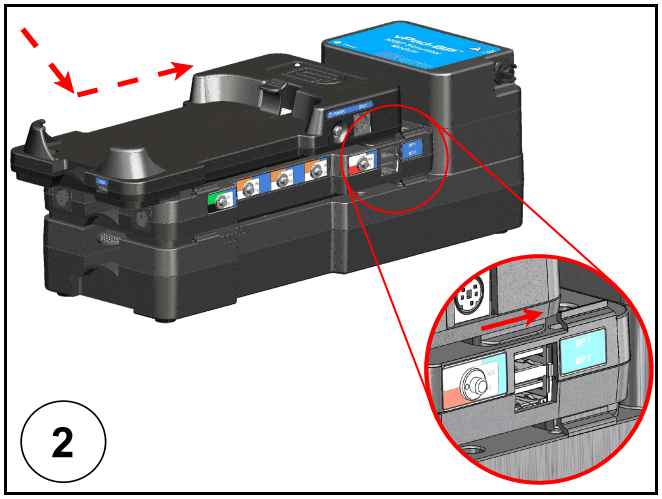


Figure 6

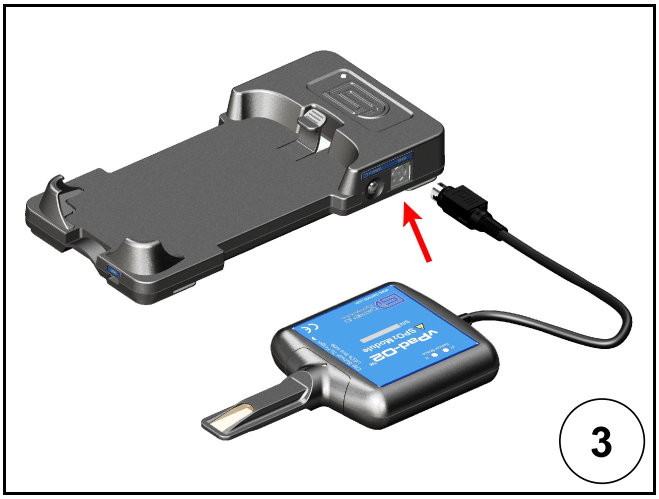


Figure 7

When ready to begin testing a patient monitor, power ON the system by depressing the pushbutton switch located at upper right on the **Base**. The power LED at top left on the **Base** should light up and display **green**.

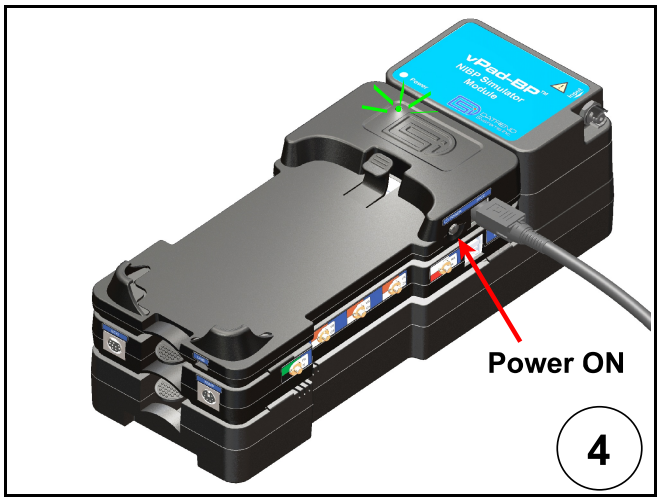


Figure 8

Switch ON the **Tablet** by pressing and holding the Power / Screen Lock button for about 5 seconds. The **Tablet** should boot up and eventually show the Home screen within 20 seconds. Launch the **vPad-A1 App** to set up and operate vPad-A1; the patient simulator is controlled wirelessly, via Bluetooth.

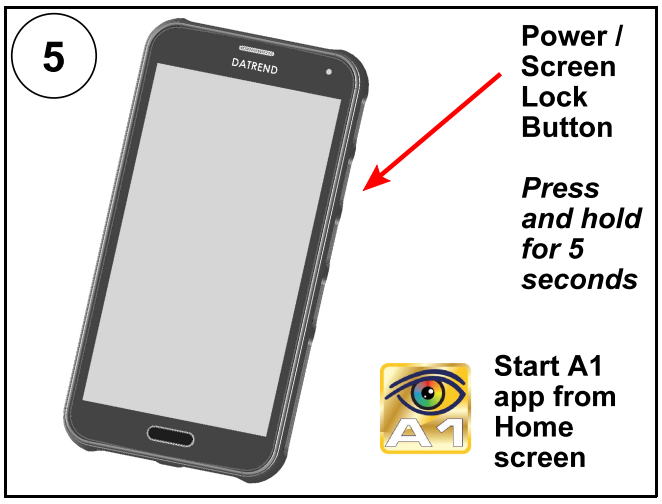


Figure 9

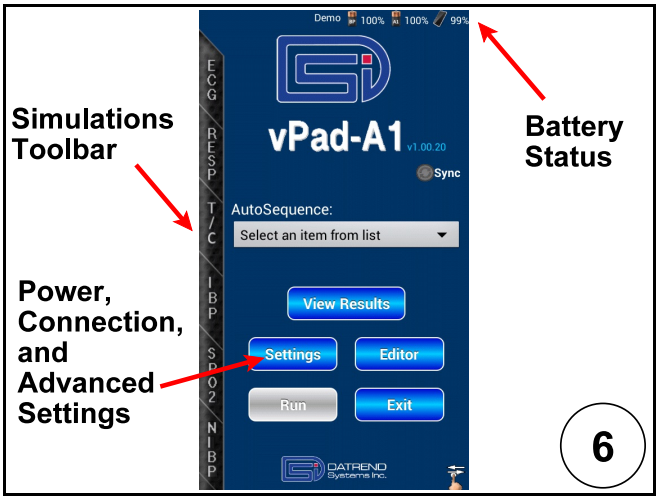


Figure 10

Note: Once the patient simulation has been set up with the **App**, it is good practice to turn the **Tablet** display OFF temporarily. Quickly pressing and releasing the Power / Screen Lock button on the **Tablet** will put its screen into a 'sleep' mode. The 'sleep' state is not the same as OFF, but it will reduce power consumption and extend battery life of the **Tablet**. Momentarily press the same button again to 'wake' the user interface.

Make connections between the patient monitor under test and the simulation/test modules of vPad-A1.

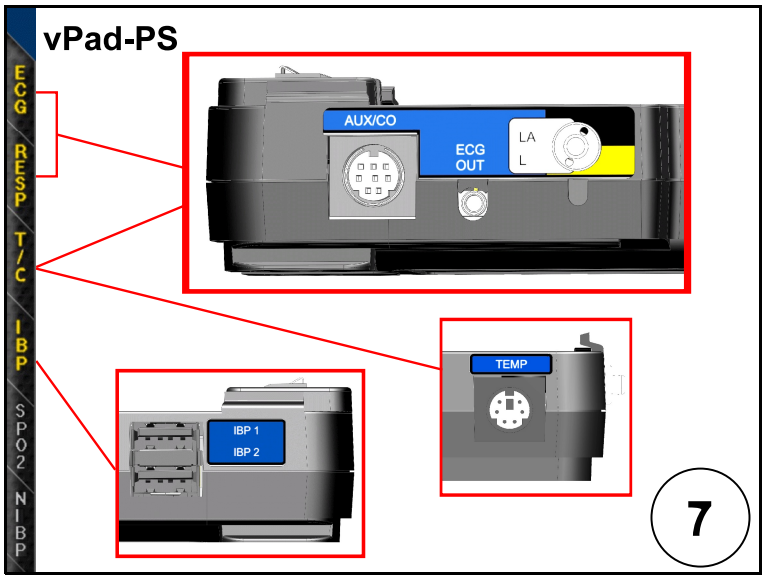


Figure 11

vPad-PS module:

- ECG – snap connectors/adapter
- Respiration – *same as above*
- Temperature – TEMP connector
- Cardiac Output – AUX/CO connector
- IBP – IBP1/IBP2 connectors

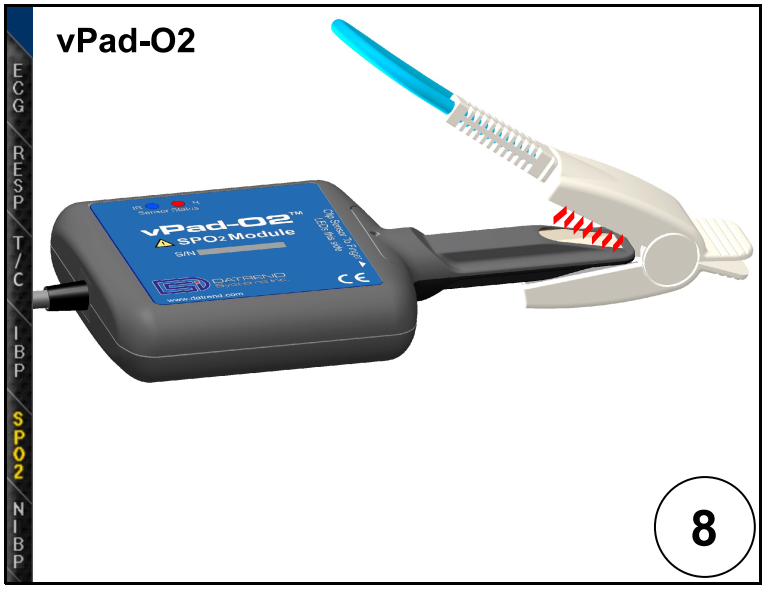


Figure 12

vPad-O2 module:

- SpO2 – probe on finger sensor
  (with red and infrared LEDs on the same side as the module's **"vPad-O2"** label)

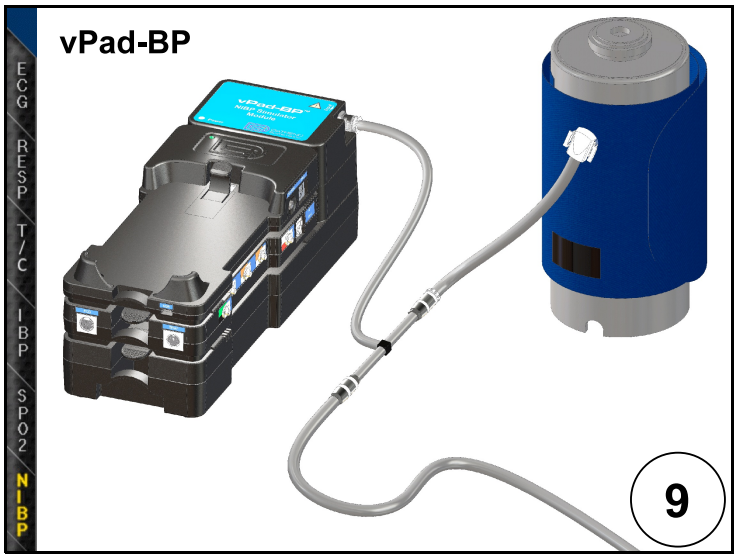


Figure 13

vPad-BP module:

- NIBP – simulator adapter between blood pressure cuff and monitor hose

vPad-A1 is normally used while running on its internal batteries. When the **vPad-A1 App** indicates that batteries are low, users should recharge the batteries by connecting the DC power supply and AC power cord between the **Base** unit and a mains outlet. The **Tablet** can be recharged by connecting it to the USB Port on the the **Base** using the microUSB cable provided with vPad-A1.

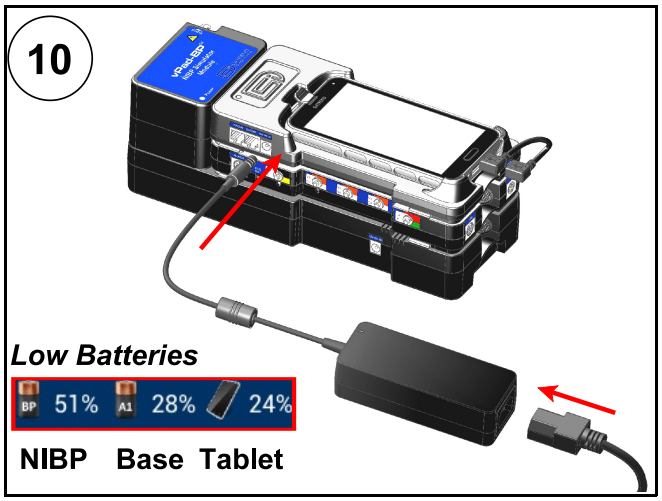


Figure 14

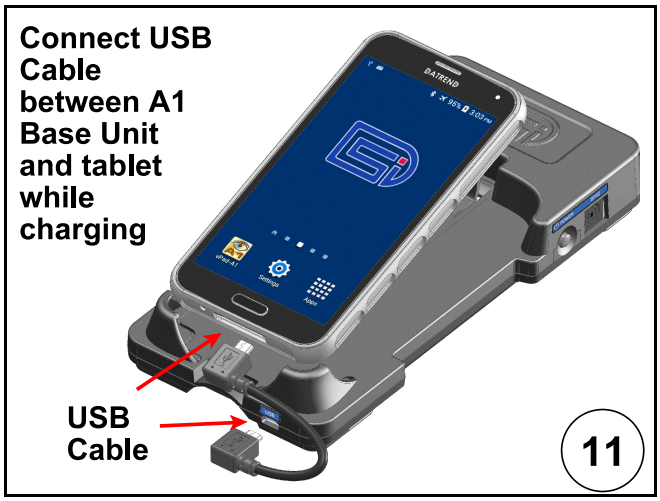


Figure 15

If the vPad-A1 will not be in use for an extended period of time, exit the **A1 App** and switch the **Base** unit and the **Tablet** OFF. To power OFF the **Tablet**, press and hold the Power / Screen Lock button until a confirmation message appears on the screen, then select the appropriate response to complete the Power Off sequence. For long-term storage or transport, simply proceed through the setup procedure in reverse from *Figure 15* to *Figure 5* above.

Chapter 4

4 Manual Operation

vPad-A1™ is a test instrument designed to provide a means of functional testing for Multi-Parameter Monitors, including ECG, Respiration, Temperature, Cardiac Output, and Invasive Blood Pressure (IBP), and some Fetal Monitor parameters; Pulse Oximeters (SpO2); and Non-Invasive Blood Pressure (NIBP) Monitors. This chapter details use of simulation features for manual or ad hoc testing of patient monitoring equipment. Automated testing of patient monitors is covered in section *5.2 - Test Automation*.

4.1 Overview of Manual Operation

4.1.1 Patient Simulator App

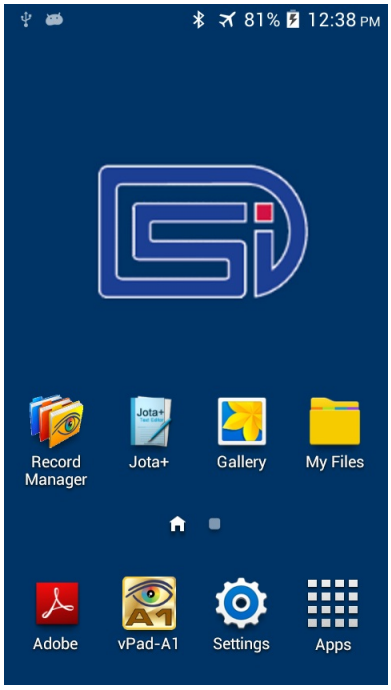


Figure 16

The **vPad-A1 Simulator App** (the **App**) runs on a 5" Android tablet (the **Tablet**). On initial power-up, the **Tablet** enters the operating system **Home** screen as shown in *Figure 16*. The **Home** screen contains shortcuts to several applications installed on the **Tablet**. An information bar at the top displays the **Tablet**'s current status, including the time of day and battery level.

Below the blue LCD screen of *Figure 16*, there is a row of three hardware buttons which are built into the face of the **Tablet**. The elongated **Home** button protrudes from the center of the **Tablet**; pressing the **Home** button returns the **Tablet**'s display to the **Home** screen of *Figure 16*.

To the right of the **Home** button is the **Back** button. It is normally not visible until pressed. The **Back** button returns users to the previous screen and cancels the current action, if possible.

To the left of the **Home** button is the **Menu** button. It is also not visible until pressed. The **Menu** button shows a context-specific menu, if one is available for the app currently in use.

To begin operating the simulator, follow instructions in *3.2 - Assembly and Setup*. The **App** should start automatically when hardware setup is complete. If the **App** does not start automatically on connection of the hardware, or to restart the **App** after exiting it, press the  icon on the **Home** screen.

The **App** adopts typical Android conventions for receiving user input, as outlined in the following sections.

4.1.2 Parameter Selection

vPad-A1 comprises three test modules: the Multi-Parameter Patient Simulator (**vPad-PS**), the pulse oximeter or SpO2 tester (**vPad-O2**), and the NIBP simulator (**vPad-BP**). "Multi-Parameter" in **vPad-PS** refers to **ECG** waveforms, **Respiration**, **Temperature**, **Cardiac Output**, and **Invasive Blood Pressure**.

Simulations and performance tests can be configured manually or recalled through an **AutoSetting**. This section covers methods of manually operating the simulator by choosing and entering new test parameters. For details on quick, automated testing with **AutoSettings** and **AutoSequences**, see section *5.2 - Test Automation*.

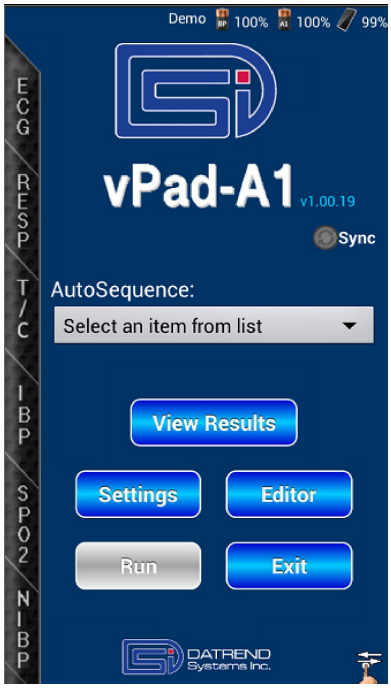


Figure 17

On startup, the **App** will display its **Main** screen as shown in *Figure 17*. A tabbed vertical toolbar on the left edge of the **Main** screen lists all the simulation categories provided, though some may be initially hidden. To reveal more tab options, touch and drag the vertical bar up towards the top of the screen. *Figure 18* shows the **Main** screen with the bottom-most tab visible.

The tabbed toolbar provides access to each type of simulation or performance test. Touching a tab will launch the main setup screen for the chosen physiological simulation (e.g. **ECG**). On these setup screens, users can select test options, enter parameter values, and record **Test Results**.

The **Tool** tab in *Figure 18* is the only tab that does not control a simulation. It provides a timer/stopwatch utility intended for timed observation and inspection procedures.

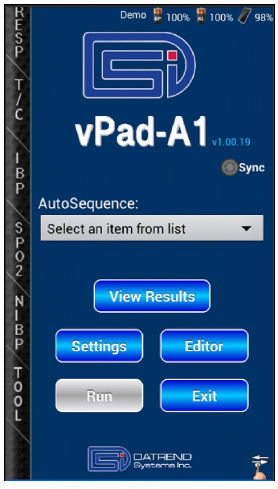


Figure 18

4.1.3 Parameter Values and Options

Simulation settings may have anywhere from two choices (e.g. Adult vs. Neonatal ECG **Mode**) to hundreds of possible values (e.g. ECG **Heart Rate**, adjustable from 20 to 360 BPM in 1 BPM steps). The manner of user input depends on the number of choices available.

4.1.3.1 Button Controls

Typically, a parameter that has a limited number of possible settings will be represented by a simple button accompanied by its title or description. An example of a button control is **ECG Mode**. Touching the **Mode** button toggles the displayed text between "Adult" and "Neonatal". For parameters with more than two settings, touching the button will cycle repeatedly through the available choices.

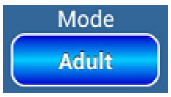


Figure 19

4.1.3.2 Numerical Input

A parameter which can be adjusted over a range of values may be represented by a group of icons as shown in *Figure 20* , or alternatively as shown in *Figure 21* for certain parameters.

Figure 20

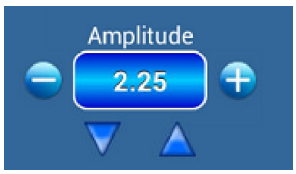


Figure 21

In either configuration, a button will display the current or active value of the parameter. Touching the button displays a data entry menu, providing a set of *preset values* from which to choose.

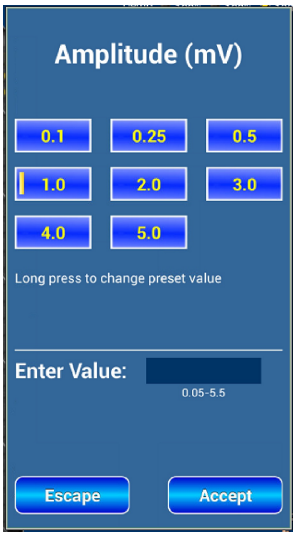


Figure 22

An example is the **ECG Amplitude** menu of *Figure 22* , which provides eight preset selections. A vertical orange bar on the left of a preset button indicates that it is the current, active value. Touching one of the preset buttons will select the value shown on the button, and return the display to the previous screen.

Some parameters have more choices than can be practically shown in a group of buttons. An example is the **ECG Amplitude** parameter, for which there are 32 choices but only 8 preset buttons on the menu. The message "*Long press to change the preset value*" is a reminder that presets associated with this parameter can be edited by the user to suit their needs or preferences.

If a value is desired that is not in the preset list, users have two options: you can type the value into the "Enter Value" box and press "Accept", or change a preset button to the desired value so it can be used again later.

To set a parameter one time only, touch the "Enter Value" box on the menu to display the soft keyboard at the bottom of the screen. Type the number and press "Done" on the keyboard. Provided the entered value is valid for the given parameter, it will be set when the "Accept" button at the bottom of the menu is pressed. If you press "Enter Value" by mistake, you can dismiss the keyboard without inputting a value by pressing the **Back** button.

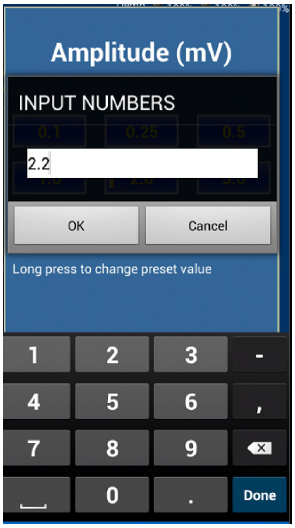


Figure 23

To edit a preset, press and *hold* the button for about one second, then release the button. When the "INPUT NUMBERS" dialog and keyboard appears (*Figure 23*), type in the new value and press "OK". If the entered preset is not a valid option, the **App** will suggest the nearest valid value, which users may then accept or reject (*Figure 24*). If accepted, the new value becomes part of the presets list and the menu buttons are then re-sorted. If the suggested value is rejected, the preset list is not changed.

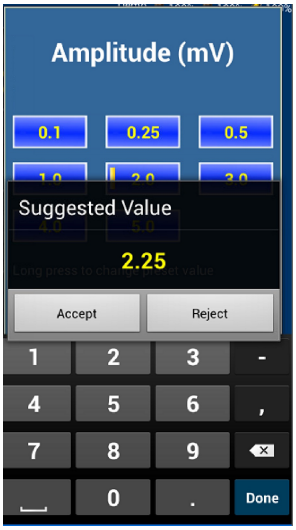


Figure 24

It is possible to scroll through preset values without displaying the data entry menu of *Figure 22*. Referring to *Figure 20* and *Figure 21*, instead of pressing the current value button use the and buttons to scroll through the presets.

Some parameters such as rate or amplitude can be adjusted incrementally, in steps of ±1 for example. When these incremental adjustments are possible, the menu will provide and buttons as shown in *Figure 21*.

4.1.3.3 Pop-up and Dropdown Lists

Some parameters offer selections in the form of a list that drops down or pops up from the parameter's indicator. For instance, **Arrhythmias** are grouped into categories, each with its own list of waveform options. The gray boxes in *Figure 25* show the **ECG** simulation type (for **Arrhythmia** waveforms), the current category or group ('General Waveforms 1'), and the specific waveform which is currently active ('PAC Premature Atrial Contraction').

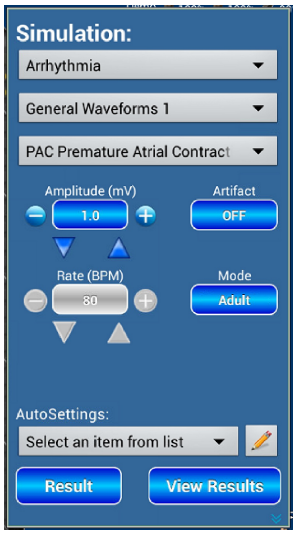


Figure 25

Figure 26

A downward arrow within a grey box indicates that touching the box will display a list of options. *Figure 26* shows the pop-up list that appears for choosing an **Arrhythmia** waveform.

A gray scrollbar on the right of a list such as *Figure 26* indicates that more options can be revealed by dragging the list up or down.

The currently active option is displayed with a green radio indicator, per *Figure 26*. Touch any option in the list to select it and dismiss the pop-up. To dismiss the pop-up without selecting an item, press the **Back** button at bottom right on the **Tablet**.

4.2 ECG

4.2.1 General

The vPad-A1's **ECG** menu provides a means to output **ECG Waveforms**, generally in the 0 - 5.5 mV range, that are representative of a physiological state or condition of the human heart. This menu also accesses **Performance Waveforms** that can be used to test transient response, frequency response, and linearity of an ECG monitoring system.

To enter the **ECG** menu shown in *Figure 27*, touch the ECG tab on the left side of the vPad-A1 **Main** screen (*Figure 17*). Entering the **ECG** setup screen activates the parameter values displayed on the screen.

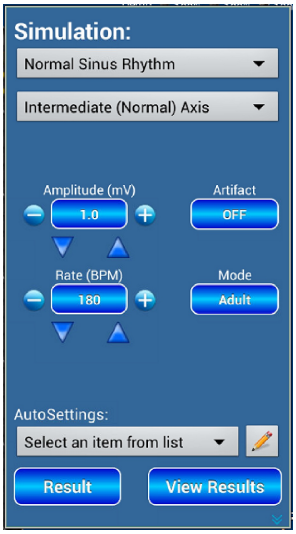


Figure 27

4.2.2 Waveforms and Parameters

ECG Waveforms can be selected from the dropdown lists at the top of the screen. There may be two or three list menus depending on the type of simulation in use.

The first dropdown menu presents the general category of **ECG Waveforms**. Touching the first list box will display a complete list of the selections available, as shown in *Figure 28*. Each category of **ECG Waveform** will be explained in the following sections.

The second dropdown list provides selections that will alter the general shape of the waveform. Options listed will differ depending on the type of **ECG Waveform** selected from *Figure 28* .

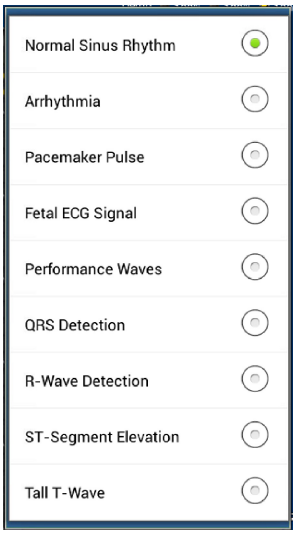


Figure 28

Referring to *Figure 27*, the middle of the screen provides a group of common **ECG** parameters that can be modified. Some waveforms may not allow a certain parameter to be changed, in which case the parameter's button is shown in grey and is disabled.

Figure 29 shows the common parameters display when all buttons are enabled. When parameter buttons are enabled, users can change the setting as detailed in section *4.1.3 - Parameter Values and Options*.

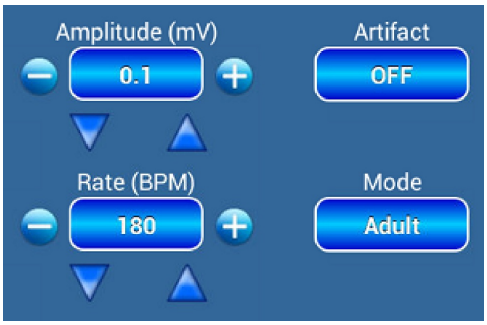


Figure 29 - Common ECG Parameters

- The **Amplitude** parameter sets the size (in millivolts [mV]) of the **ECG Waveform**.
- The **Rate** parameter sets the repetition frequency (in Beats per Minute [BPM]) of individual pulses. It may be adjustable or fixed, depending on the **ECG Waveform** in use.
- The **Artifact** parameter selects a simulated noise that is superimposed on the **ECG Waveform**, if applicable.
- The **Mode** parameter selects an **ECG Waveform** sub-type, if applicable.

Note: When simulation of **Intra-Uterine Pressure** (IUP, section *4.5.2.3*) is active, the IUP simulation overrides the **ECG** settings of *Figure 29* to output a special **Fetal ECG** waveform. Attempts to change any **ECG** settings via the menu of *Figure 29* will have no effect until a different **Invasive Blood Pressure** simulation (**Static** or **Dynamic Blood Pressure**) is selected.

4.2.3 Normal Sinus Rhythm (NSR)

Normal Sinus Rhythm (**NSR**) is a basic **ECG** simulation that tests a patient monitor's ability to correctly display and/or measure signals as produced by a normally-functioning heart. This simulation has a range of heart **Rates** and signal **Amplitudes**, two simulation **Modes** (Adult or Neonatal), as well as several different **Artifacts**.

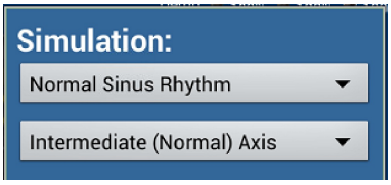


Figure 30

Besides the common **ECG** parameters, **NSR** also has an **Axis** setting that simulates different physical orientations of the heart relative to the positions of ECG chest leads. Touching the second dropdown list will display the available selections. Select a list item to set the **NSR Axis**.

Figure 31

4.2.4 Arrhythmias

Arrhythmia is a group of **ECG** simulations that test a monitoring system's ability to correctly display and/or classify signals which are the result of an abnormal cardiac condition. There are over 60 waveforms available in the **Arrhythmia** section. To make it easier to locate a waveform of interest, they have been organized into seven categories as shown below:

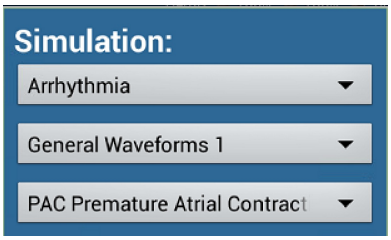


Figure 32

GENERAL 1

- Asystole 1
- Asystole 2
- Asystole 3
- PVC1 Bigeminy
- PVC1 Trigeminy
- PVC2 Bigeminy
- PVC2 Trigeminy
- PAC Premature Atrial Contraction
- PNC Premature Nodal Contraction
- Multifocal PVCs (once)
- Frequent Multifocal PVCs

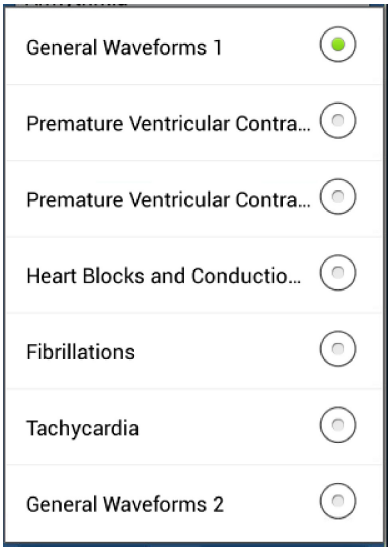


Figure 33

PREMATURE VENTRICULAR CONTRACTION (PVC) 1

- Left Ventricle (once)
- Left Ventricle (every 10th beat)
- Left Ventricle, Early (once)
- Left Ventricle, R on T (once)
- PVC1, 6/Minute
- PVC1, 12/Minute
- PVC1, 24/Minute
- PVC1, Run of 2
- PVC1, Run of 5
- PVC1, Run of 11

PREMATURE VENTRICULAR CONTRACTION (PVC) 2

- Right Ventricle (once)
- Right Ventricle (every 10th beat)
- Right Ventricle, Early (once)
- Right Ventricle, R on T (once)
- PVC2, 6/Minute
- PVC2, 12/Minute
- PVC2, 24/Minute
- PVC2, Run of 2
- PVC2, Run of 5
- PVC2, Run of 11

HEART BLOCKS AND CONDUCTION DEFECTS

- 1st Degree Heart Block
- Mobitz I, 2nd Degree AV Block
- Mobitz II, 2nd Degree AV Block
- 3rd Degree AV Block
- Right Bundle Branch Block
- Left Bundle Branch Block

FIBRILLATIONS

- Coarse Atrial Fibrillation
- Fine Atrial Fibrillation
- Coarse Ventricular Fibrillation
- Fine Ventricular Fibrillation

TACHYCARDIA

- Atrial Tachycardia
- Paroxysmal Atrial Tachycardia
- 90 BPM Supraventricular Rhythm
- 120 BPM Supraventricular Rhythm
- 140 BPM Supraventricular Tachycardia
- 150 BPM Supraventricular Tachycardia
- 160 BPM Supraventricular Tachycardia
- 170 BPM Supraventricular Tachycardia
- 180 BPM Supraventricular Tachycardia
- 190 BPM Supraventricular Tachycardia
- 200 BPM Supraventricular Tachycardia
- 210 BPM Supraventricular Tachycardia
- 220 BPM Supraventricular Tachycardia
- 160 BPM Normal Sinus Rhythm

GENERAL 2

- Atrial Flutter
- Sinus Arrhythmia
- Miss 1 Beat, 80 BPM
- Miss Every 10th Beat, 80 BPM
- Miss Every 10th Beat, 120 BPM
- Nodal Rhythm
- Sinus Bradycardia, <60 BPM

The **Rate** of **Arrhythmia** simulations is fixed, as **Rate** may be an important indicator of the cardiac disease or condition being simulated. Accordingly, the **Rate** button is greyed out when an **Arrhythmia** waveform is selected, however, adjustment of both **Amplitude** and **Artifact** remains possible. The simulation **Mode** is also selectable between Adult and Neonatal, although this setting will affect only those **Arrhythmias** which contain complete or partial simulations of **NSR** beats.

Arrhythmia waveforms that are manually activated will display a **Trigger** button that starts a simulation each time it is pressed.

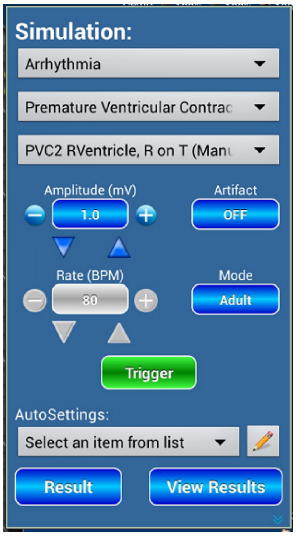


Figure 34

4.2.5 Pacemaker Pulses

The **Pacemaker Pulse** simulation tests a patient monitor's ability to correctly display and/or classify rhythms which include cardiac beats accompanied by artificial pacing pulses having significantly greater amplitude than a normal QRS complex. The **Rate** of **Pacemaker Rhythm** simulations is fixed, as the frequency is an important characteristic of the chosen waveform. The simulations permit adjustment of both the QRS **Amplitude** and baseline **Artifact**.

Figure 35

Pacer simulation **Mode** is adjustable between Atrial and Ventricular, which affects the timing of the pacing pulse that is inserted into the paced waveform.

Besides the common ECG parameters, **Pacemaker Pulse** has several additional settings that are accessible through the second dropdown list (*Figure 36*).

Figure 36

Pacer Rhythm controls the timing of the paced waveform. See the tables which follow for waveform descriptions. Additional options which are available in **Atrial Mode** are shown in *Figure 37*. **Ventricular Mode** options are shown in *Figure 38*.

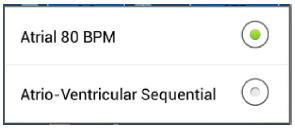


Figure 37

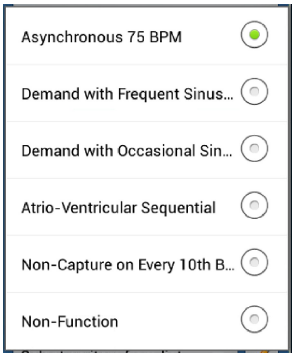


Figure 38

Pacemaker Waveform / Rhythm	Description
Atrial 80 BPM	Atrial pacemaker wave at 80 BPM, with a pacer pulse at the start of each P wave.

Pacemaker Waveform / Rhythm	Description
Atrio-Ventricular Sequential	AV-sequential-pacemaker wave with continuous paced beats, each with an atrial pulse and a P wave followed by a ventricular-paced pulse and QRS response (75 BPM)
Asynchronous 75 BPM	Asynchronous pacemaker wave with continuous ventricular-paced beats (75 BPM) and no P waves
Demand with Frequent Sinus Beats	A "demand" pacemaker wave with frequent sinus beats (forty normal beats followed by twenty ventricular-paced beats, repeated) (80 BPM)
Demand with Occasional Sinus Beats	A "demand" pacemaker wave with occasional sinus beats (twenty normal beats followed by forty ventricular-paced beats, repeated) (80 BPM)
Non-Capture	Ventricular-paced beats, where one out of ten beats has no heart response (75 BPM)
Non-Function	Continuous pacer pulses at 80 BPM with no heart response.

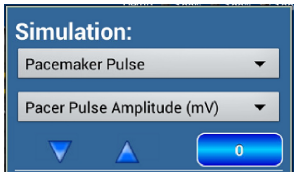


Figure 39 - Pacer Pulse Amplitude Setting

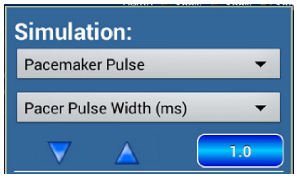


Figure 41 - Pacer Pulse Width Setting

Pacer Pulse Amplitude controls the size of the simulated pacer pulse; it can be adjusted from -700 mV to +700 mV. All possible settings are listed in the preset selection menu, as shown in *Figure 40*. This setting is not the same as the ECG **Amplitude** setting, which controls the size of the heart beats in the simulation.

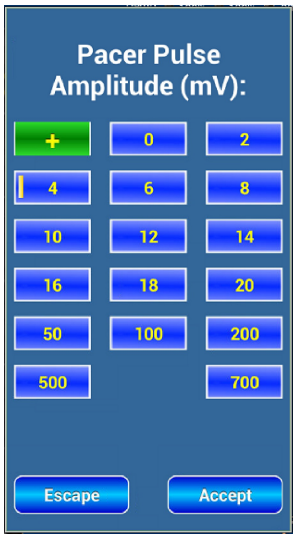


Figure 40

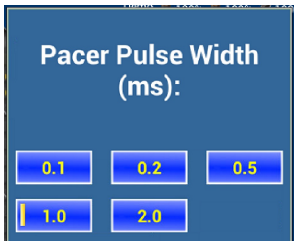


Figure 42

Pacer Pulse Width controls the duration of the simulated pacer pulse. All possible settings are listed in the preset selection window, as shown in *Figure 42*.

Note: Since it is not possible to display a selector or button for every simulation parameter at the same time, the **Pacemaker Pulse** menu displays, in yellow, a summary list of all the parameter settings which are currently in use. See *Figure 35* for an example of a parameters summary.

4.2.6 Fetal ECG Signal

The **Fetal ECG** function simulates heart beat signals obtained from the ECG leads on a direct fetal probe. **Fetal ECG** parameters are similar to **NSR** simulations as described in section *4.2.3*, except that the **Rate** setting has a more limited range, and the **Mode** setting is fixed.

4.2.7 Performance Waves

Performance Waves are a set of standard, periodic signals for testing the performance of an ECG monitoring system, including transient response, frequency response, linearity and sensitivity.

Only the **Amplitude** parameter is available for **Performance Waves** simulations. **Rate** and **Mode** settings are meaningless for these types of waveforms, and **Artifact** is not applied during performance tests.

Once **Performance Waves** is selected from the first dropdown list, the second dropdown menu provides a list of specific waveforms, as shown below:

Pulse 30 BPM 60 ms	Sine Wave 0.05 Hz	Sine Wave 40 Hz
Pulse 60 BPM 60 ms	Sine Wave 0.5 Hz	Sine Wave 50 Hz
Square Wave 0.125 Hz	Sine Wave 1 Hz	Sine Wave 60 Hz
Square Wave 2 Hz	Sine Wave 2 Hz	Sine Wave 100 Hz
Square Wave 2.5 Hz	Sine Wave 5 Hz	Sine Wave 150 Hz
Triangle Wave 0.125 Hz	Sine Wave 10 Hz	Sine Wave 200 Hz
Triangle Wave 2 Hz	Sine Wave 25 Hz	
Triangle Wave 2.5 Hz	Sine Wave 30 Hz	

4.2.8 QRS Detection

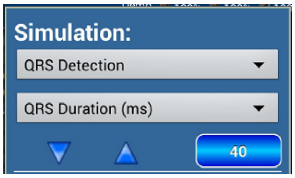


Figure 43

The **QRS Detection** feature generates standalone QRS complexes that act as triggers for pulse detection and rate measurement.

Amplitude and **Rate** settings are provided, similar to **NSR**, though the **Rate** selections are more limited. **Artifact** and **Mode** settings are not available.

Although the **QRS duration** (width of the QRS complex) is adjustable, R and S waves have relative amplitudes according to specification defined in ANSI/AAMI standard EC-13.

R wave amplitude	0.875 of the **Amplitude** setting
S wave amplitude	negative 0.125 of the **Amplitude**
R wave up slope	0.4375 of the **QRS duration** setting
R wave down slope	0.5 of the **QRS duration**
S wave up slope	0.0625 of the **QRS duration**

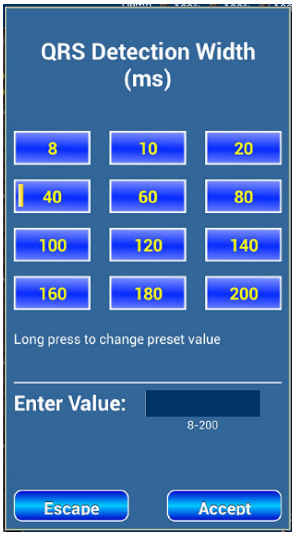


Figure 44

Touching the **QRS Duration** button will display a table of preset values. This table is a subset of the complete list:

From: 8 to 20 ms in steps of 2 ms; or
20 to 200 ms in steps of 10 ms

4.2.9 R-Wave Detection

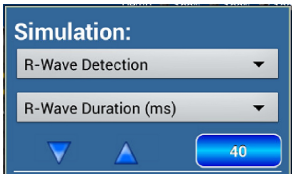


Figure 45

Simpler than the QRS complex, the **R-wave Detection** signal may also be used to rate accuracy of a patient monitor. This is a simple triangular waveform with adjustable **Rate**, **Amplitude**, and **Duration**. When selected, the top of the screen will appear as shown in *Figure 45*.

R-Wave Detection parameters behave in exactly the same manner as the **QRS Detection** parameters; the same **Duration** options are provided.

4.2.10 ST-Segment Elevation

ST-Segment Elevation simulates regular NSR waves with ST-segments that are offset from the baseline. Of the common ECG parameters, only **Amplitude** and **Artifact** are available for this test. The **Rate** is fixed at 60 BPM.

The percentage of ST-segment offset, relative to the ECG **Amplitude**, is adjustable by changing the **ST Level** setting to a value between -150% (below baseline) and +150% (above baseline).

4.2.11 Tall T-Wave

The **Tall T-Wave** simulation generates large T-waves accompanying standard QRS waves.

Per ANSI/AAMI EC-13, the QRS wave has a width of 100 ms and a QT interval of 350 ms. The T-wave has a sinusoidal shape, 180 ms wide, and **T Height** can be adjusted in amplitude from 0 to 150 % of the QRS waveform amplitude.

The QRS waveform amplitude is adjustable by changing the ECG **Amplitude** parameter. The **Rate** for **Tall T-Wave**s is fixed at 80 BPM.

4.3 Respiration

4.3.1 General

Respiration is simulated by small, rhythmic variations in impedance across the ECG signal leads, typically from the RA lead to the LA lead, or alternatively from RA to the LL lead. The simulation imitates the expansion and collapse of a patient's chest while breathing. To access the **Respiration** simulation, touch the **RESP** tab on the left side of the vPad-A1 **Main** screen (*Figure 17*).

4.3.2 Parameters

All **Respiration** parameters can be accessed from a dropdown menu. Touching it will show a list of all active settings, as shown in *Figure 47*. Current, active values can be adjusted by first selecting the desired parameter, then entering a new setting as described in section *4.1.3 - Parameter Values and Options*.

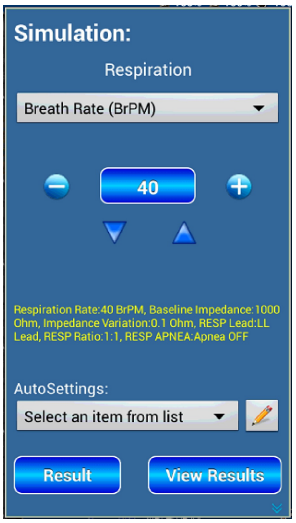


Figure 46

Note: Since it is not possible to display a selector or button for every simulation parameter at the same time, the **Respiration** menu displays, in yellow, a summary list of all the parameter settings which are currently in use. See *Figure 46* for an example of a parameters summary.

4.3.2.1 Breath Rate

Breath Rate controls the frequency of the **Respiration** simulation, shown on most patient monitors as a reading in breaths-per-minute (BrPM). It can be set from 10 to 150 BrPM in increments of 1 BrPM.

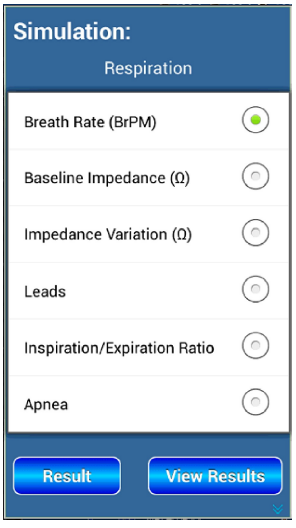


Figure 47

4.3.2.2 Baseline Impedance

Baseline Impedance controls the measured impedance when respiration is not active. It can be set to 500, 1000, 1500, or 2000 ohms.

4.3.2.3 Impedance Variation

Impedance Variation (also known as respiration strength) controls the maximum change in impedance from **Baseline Impedance** during **Respiration** simulation. If a monitor is capable of displaying the patient breathing traces, this setting will affect the size of the waveform.

It can be set from 0.05 to 1.0 ohms in 0.05 ohm increments, and from 1.0 to 5.0 ohms in 0.25 ohm increments.

4.3.2.4 Lead Selection

The **Leads** parameter selects the ECG leads across which the simulated **Impedance Variation** is applied. Choices are between the RA and LL leads, or alternatively between the RA and LA leads.

4.3.2.5 Inspiration/Expiration Ratio

The **Inspiration/Expiration Ratio** (**I:E**) defines a relationship between inspiration (inhalation) time and expiration (exhalation) time, which is an indicator of patient respiratory effort. It can be set to one of the following options:

1:1, 1:2, 1:3, 1:4, 1:5, or Ventilated 1:1

4.3.2.6 Apnea

Apnea is the temporary cessation of breathing, which may occur while sleeping or under anaesthesia. This setting imitates the condition by suspending **Respiration** simulations for the selected duration. Available settings are:

Off, Continuous, 12 seconds, 22 seconds, or 32 seconds

Note: 'Continuous' means breathing is stopped until another **Apnea** setting is chosen.

4.4 Temperature/Cardiac Output

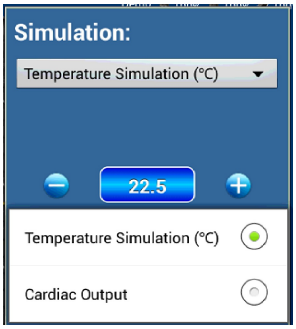


Figure 48

4.4.1 General

Temperature and **Cardiac Output** simulations are combined on the same menu since both make use of thermistor-based temperature measurements. Their common setup interface can be accessed by touching the **T/CO** tab on the **Main** screen (*Figure 17*). The topmost dropdown list allows users to select between the two different simulations.

4.4.2 Parameters

4.4.2.1 Temperature

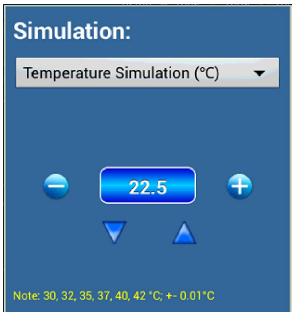


Figure 49

The A1 Patient Simulator generates **Temperature** sensor (thermistor) signals by presenting precise resistance values to two independent channels, one for YSI series 400 temperature probes, and the other for YSI series 700. The interface cable used to connect the vPad-PS module to the patient monitor will determine which of the two channels is used.

Simulated **Temperatures** range from 20 °C and 42 °C in steps of 0.5 °C. Accuracy is generally ± 0.03 °C, but the module achieves a greater accuracy of ± 0.01 °C for the following specific temperatures: 30, 32, 35, 37, 40 and 42 °C.

High-accuracy **Temperatures** are listed beneath the **Temperature** selection buttons.

4.4.2.2 Cardiac Output Testing

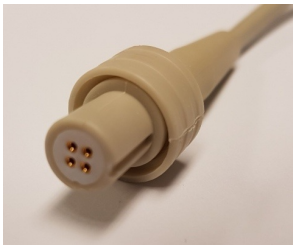


Figure 50

Cardiac Output simulations of vPad-A1 are based on the thermodilution technique for hemodynamics monitoring. Thermodilution is an invasive procedure that injects a known volume of chilled saline at a set temperature into the heart. As the saline mixes with blood at body temperature, a temperature profile is created from which the **Cardiac Output** can be calculated in Liters per minute (L/min).

An optional **Cardiac Output Adapter** box (#8000-454) is required to interface vPad-A1 with the cardiac catheter and injectate temperature probe of the monitor under test. This **CO Adapter** is compatible with Baxter (Edwards) catheters and equivalent models from other manufacturers such as Abbott and Viggo-SpectraMed. These catheters have a blood temperature connection as shown in *Figure 50*.

Also on the **CO Adapter** box is a larger, four-pin connector for the typical **Injectate** temperature probe. To determine if your device connection requires an additional adapter, contact your Datrend dealer for assistance.

Note: Since it is not possible to display a selector or button for every simulation parameter at the same time, the **Cardiac Output** menu displays, in yellow, a summary list of all the parameter settings which are currently in use. See *Figure 51* for an example of a parameters summary.

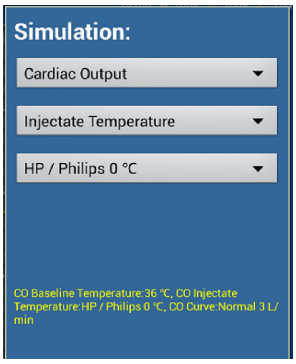


Figure 51

4.4.2.3 Cardiac Output – Baseline Temperature

Baseline Temperature sets the temperature of the patient's blood prior to injection of the saline. It can be set to 36, 37, or 38 °C.

4.4.2.4 Cardiac Output – Injectate Temperature

Injectate Temperature sets the temperature of the saline to be injected. The third dropdown menu presents the list of options as shown in *Figure 52*.

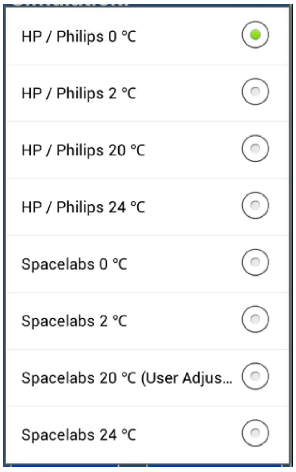


Figure 52

The second-to-last option ('Spacelabs 20 °C') is adjustable by means of user-accessible potentiometers inside the vPad-PS module. Default resistance for the Spacelabs **Injectate Temperature** is set at the factory to 68.0K ohm, but users can change this via the 100K ohm and 5.0K ohm potentiometers as indicated in *Figure 53*.

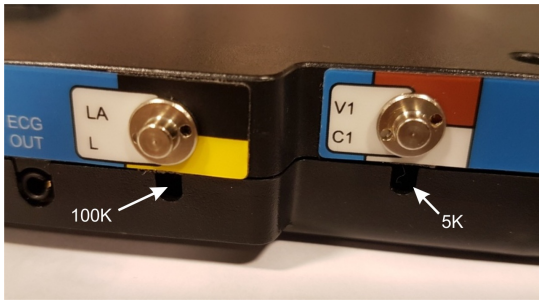


Figure 53

Note: The **Cardiac Output Coefficient** is 0.542 for 0 and 2°C, and 0.595 for 20 and 24°C.

4.4.2.5 Cardiac Output – Simulation Curve

The **Simulation Curve** sets the shape of the temperature variation as blood temperature downstream is cooled due to **Injectate Temperature** and then returned to **Baseline Temperature**. Users can choose from a set of regular curves representing a normal thermodilution routine or from a set of test curves, as shown in *Figure 54*.

A **Start** button will appear after choosing a **Simulation Curve**. Pressing the button will initiate or restart the simulation.

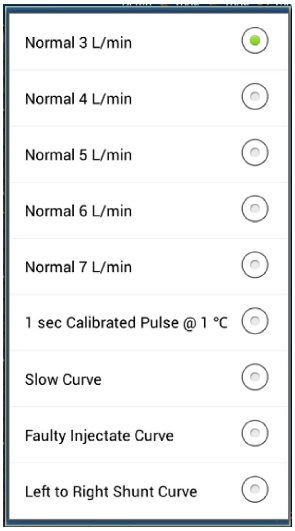


Figure 54

4.5 Invasive Blood Pressure

4.5.1 General

The **Invasive Blood Pressure** (**IBP**) simulation provides static pressure settings or dynamic output waveforms suitable for testing up to two invasive blood pressure channels of a multi-parameter monitor.

To access the IBP simulation, touch the **IBP** tab on the left side of the vPad-A1 **Main** screen (*Figure 17*). On selection, the simulation setup menu will be displayed, activating the individual parameter values shown on the screen.

4.5.2 Parameters

Parameters related to **IBP** can be selected from the dropdown lists at the top of the screen. There are three modes of operation: **Static Blood Pressure**, **Dynamic Blood Pressure**, and **Intra-Uterine Pressure**. Touching the top-most menu box will present a list of the options available, as shown in *Figure 55*.

Selecting any of these options will then display a list of relevant parameters for the second list. Users may set parameters as described in section *4.1.3 - Parameter Values and Options*.

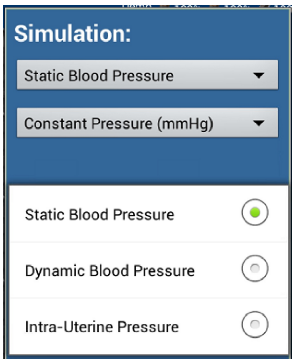


Figure 55

Note: Since it is not possible to display a selector or button for every simulation parameter at the same time, the **IBP** menu displays, in yellow, a summary list of all the parameter settings which are currently in use. See *Figure 56* for an example of a parameters summary.

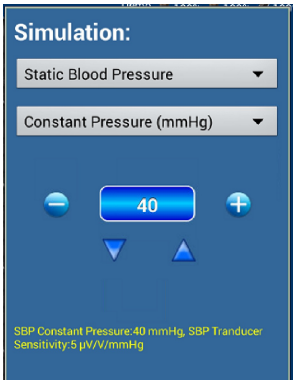


Figure 56

4.5.2.1 Static Blood Pressure

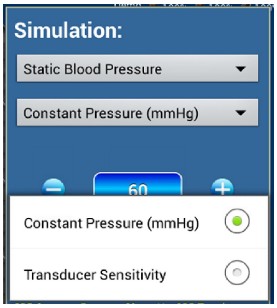


Figure 57

When **Static Blood Pressure** (**SBP**) is selected from the upper list, the module will output a single pressure from both of its **IBP** channels. Touching the second list displays parameters relevant to static pressure, as shown in *Figure 57*.

Selecting the **Constant Pressure** parameter will display controls for the static pressure output. For example, to zero the **IBP** channels at the start of a monitor test, use the button controls in *Figure 56* to change **Constant Pressure** to 0 mmHg.

Selecting **Transducer Sensitivity** displays a third dropdown list menu. Available options are 5 µV/V/mmHg and 40 µV/V/mmHg, each of which affects the baseline and scaling of the output signal. Users should select the sensitivity suitable for the type of tranducer expected by the monitor.

4.5.2.2 Dynamic Blood Pressure

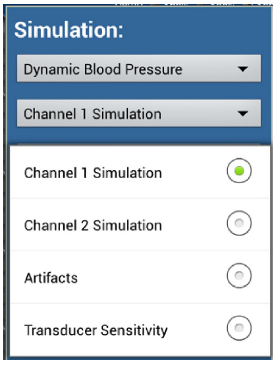


Figure 58

When **Dynamic Blood Pressure** (**DBP**) is selected from the upper list, the module can simulate various types of IBP waveforms in synchronism with the **ECG** signal. The second dropdown list allows selection of **Channel 1** or **Channel 2 Simulation**, **Artifacts**, and **Transducer Sensitivity**.

Channel 1 Simulation controls the **IBP1** port of vPad-A1, and **Channel 2 Simulation** controls the **IBP2** port. The channels are independent in this mode, and some waveforms are available only for **IBP1**.

With **Channel 1** or **Channel 2 Simulation** selected, a third dropdown menu displays the list of dynamic waveforms available:

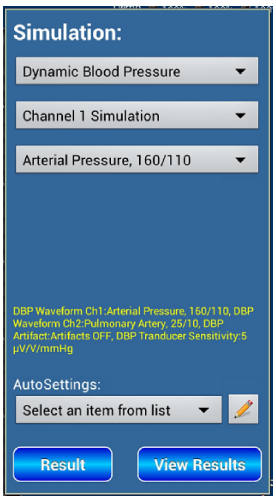


Figure 59

BOTH CHANNEL 1 AND CHANNEL 2

- Atrial Pressure, 120/80
- Atrial Pressure, 90/40
- Atrial Pressure, 160/110
- Radial Artery, 120/80
- Left Ventricle, 120/0
- Right Ventricle, 25/0
- Pulmonary Artery, 25/10
- Pulmonary Artery Wedge, 10/2
- Right Atrium (Central Venous Pressure), 15/10
- Left Atrium, 14/4

CHANNEL 1 ONLY

- Swan-Ganz AUTO 15 sec (Manual Pause)
- Swan-Ganz AUTO 25 sec (Manual Pause)
- Swan-Ganz Cycle (Manual Advance)

Swan-Ganz cycles are only available for **Channel 1 Simulation**. These options simulate the insertion and extraction of a Swan-Ganz catheter. When an "AUTO" cycle is active, the module will automatically step through the following waveforms and repeat until another **IBP** simulation is selected:

Insertion ...	Central Venous Pressure ➜ Right Ventricle ➜ Pulmonary Artery
	➜ Pulmonary Artery Wedge
Extraction ...	➜ Pulmonary Artery ➜ Right Ventricle ➜ Central Venous Pressure

A 

button allows users to stop the cycle from advancing. When pressed, the button is replaced by a 

button that resumes the cycle.

If the newly chosen Swan-Ganz option is not "AUTO", the module will begin simulating the first waveform in the cycle above but remain in a paused state. It will only advance to the next waveform in the cycle when the 

button is pressed.

To simulate noise in **DBP** waveforms for both channels, select the **Artifacts** option in the second dropdown menu. The following selections are available:

Artifact Off
5% for Arterial, Radial, and Left Ventricle waveforms, or 5mmHg for others
10% for Arterial, Radial, and Left Ventricle waveforms, or 10mmHg for others

To change the **Transducer Sensitivity**, select the parameter from the second dropdown menu and select a setting from the list that appears. Options available are 5 µV/V/mmHg and 40 µV/V/mmHg.

4.5.2.3 Intra-Uterine Pressure

Fetal monitoring devices measure **Intra-Uterine Pressure** (**IUP**) with invasive pressure probes similar in principle to IBP sensors. When the **IUP** option is selected from the upper list of the simulation menu, the module generates dynamic pressure signals which are synchronized to a **Fetal ECG** waveform. Together, the **IUP** and **ECG** signals represent the physiological state of a neonate during labour contractions.

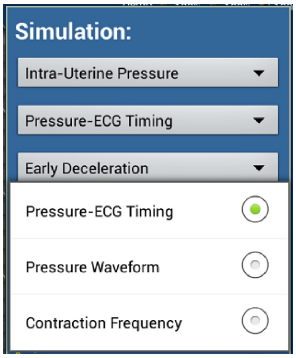


Figure 60

Touching the second dropdown list shows all applicable parameters: **Pressure-ECG Timing**, **Pressure Waveform**, and **Contraction Frequency**.

Note: When **IUP** is active, the module overrides the normal **ECG** settings to output a special **Fetal ECG** waveform. Attempts to change **ECG** settings will have no effect until a different **IBP** simulation (**Static** or **Dynamic**) is selected.

Pressure-ECG Timing selects a pre-defined synchronization pattern which is then used for the current simulation. When vPad-A1 generates an **IUP** waveform, it also changes the pulse **Rate** of **Fetal ECG** so that the fetal monitor can plot a "rate waveform/trend" that has the same period as the pressure wave. Depending on the active **Pressure-ECG Timing** pattern, the "rate waveform" drop may lead or lag peak of the **IUP** pressure wave, or the **Rate** may increase or decrease from the starting **Rate**.

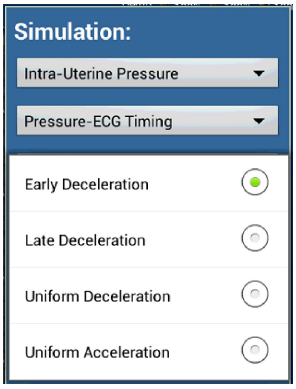


Figure 61

The **Pressure Waveform** setting controls the peak height of the pressure waveform. Available options are 50 mmHg and 90 mmHg.

The **Contraction Frequency** setting controls the length of time between the start of each contraction pressure wave: 2 minutes, 3 minutes, or 5 minutes. If the "Single Contraction" option is chosen instead, users must manually start each contraction by pressing the 

button.

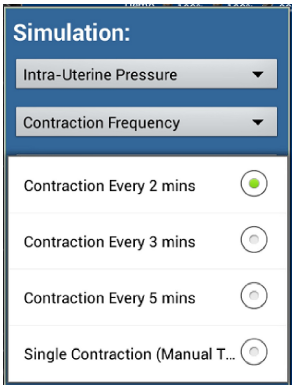


Figure 62

4.6 Pulse Oximetry (SpO2)

4.6.1 General

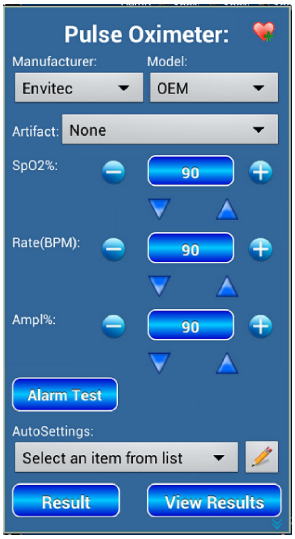


Figure 63

The A1 Patient Simulator provides the ability to simulate the light levels that specific makes and models of pulse oximeter would expect to receive (based on its approved clinical trials) for a given range of blood oxygen saturations. Clinical trials conducted by device manufacturers provide the basis for what is termed the **R-Curve**, representing the relationship between the monitor's detected optoelectronic signals and 'gold standard' hemoximetery measurements, generally performed in a lab using blood samples taken simultaneously from test subjects. A1 includes **R-Curves** for a number of common/popular makes and models of pulse oximetry technology, either built into their own branded devices or into other systems on an OEM basis.

Pulse Oximetry (**SpO2**) functional testing is used to confirm the operation of a pulse oximeter under a range of standard or error conditions, with parameters such as **Blood Oxygen Saturation**, **Heart Rate**, and **Signal Amplitude**. In addition to the basic parameters, it is possible to add an **Artifact** and to perform an **Alarm Test**. To access the **SpO2** simulation, touch the **SpO2** tab on the left side of the vPad-A1 **Main** screen (*Figure 17*).

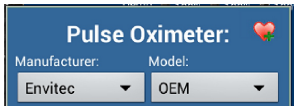


Figure 64

4.6.2 Manufacturer and Model

vPad-A1 incorporates targeted functional tests for a number of existing pulse oximetry systems, organized by the name of their **Manufacturer** and **Model**. To locate a particular device, simply select the **Manufacturer** and then the **Model** from the dropdown lists.

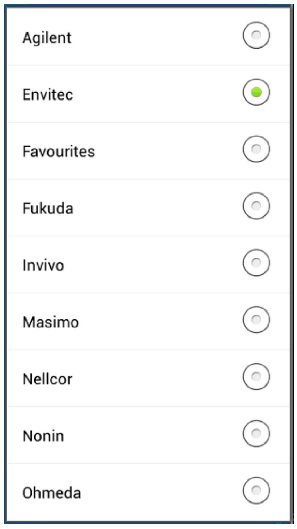


Figure 65

It is generally important to select the correct **Model** designation for the pulse oximeter as there may be significant differences between the R-Curves for different **Models** from the same **Manufacturer**, often due to subsequent clinical trials and regulatory approval. Sometimes such changes may even occur between different firmware versions of the same pulse oximeter.

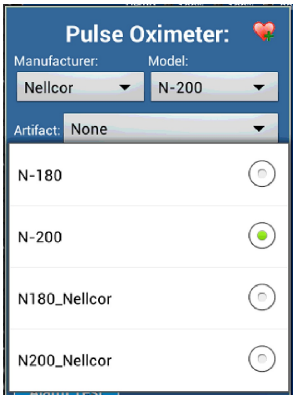


Figure 66

To capture the effect of different **Sensor** configurations (e.g. OEM or third party finger probes) on calibration of the pulse oximeter, items in the **Model** lists may include a **Sensor** designation. For example, in *Figure 66*, the item "N200_Nellcor" shows that the R-Curve was created for an N200 oximeter, using a standard Nellcor probe.

Note: To add a new **Manufacturer**, **Model**, or **Sensor** not found in the existing options, refer to section *4.8.2.3 - Calibration: SpO2 R-Curves*.

Figure 67

Contained within the **Manufacturer** menu is an item called **Favourites**, which is a custom list of frequently-tested **Models**. By default, the **Favourites** category is empty. To add a new item to the list, first select the desired **Model** as shown in *Figure 66*.

Next, touch the  icon near the top right corner of the screen. The icon launches a **Favourites Editor**, displaying items currently in **Favourites**. The "Add" button will enter the selected **Manufacturer** and **Model** (plus **Sensor** if applicable) into the list as a new item.

To delete an existing item from the list, highlight an item as shown in *Figure 67*, then touch the "Remove" button. When finished, press "Exit" to dismiss the **Favourites Editor**. All added items will be listed in the **Favourites** category under **Manufacturer**.

4.6.3 Parameters

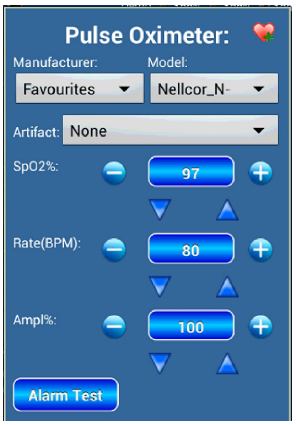


Figure 68

4.6.3.1 Blood Oxygen Saturation

The target **Blood Oxygen Saturation** (**SpO2%**) setting changes the saturation reading expected on the **DUT**. It can be modified over the range of 30 % to 100 %, in 1 % increments.

Note: Not all pulse oximeters are able to produce reliable measurements at low to very low **SpO2%** (i.e. less than 70%). See section *4.8.2.3 - Calibration: SpO2 R-Curves* for more information regarding oximeter specifications and restrictions to saturation range.

4.6.3.2 Heart Rate

The **Heart Rate** parameter sets the frequency of pulse waveforms for **SpO2**. It can be set from 20 to 300 beats per minute (BPM), in increments of 1 BPM.

4.6.3.3 Pulse Amplitude

The **Pulse Amplitude** parameter controls the relative size of the simulated plethysmogram. It can be set from 0 % (no pulse) to 100 % (normal adult pulse), in steps of 1%.

4.6.3.4 Artifact

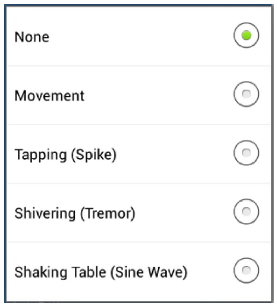


Figure 69

The **Artifact** dropdown menu displays a selection of noise signals that can be superimposed over the normal **SpO2** signal. An **Artifact** can be used, for instance, to test the ability of an oximeter to function correctly in a noisy environment.

4.6.4 Alarm Tests

The **SpO2 Alarm Test** checks a pulse oximeter for its ability to respond to an **Alarm Condition**, such as a sudden drop in **Blood Oxygen Saturation** or a deteriorated patient signal. There are four stages in an **Alarm Test**: 1) Test Setup; 2) Alarm State; 3) Alarm Stablization; and 4) Recovery.

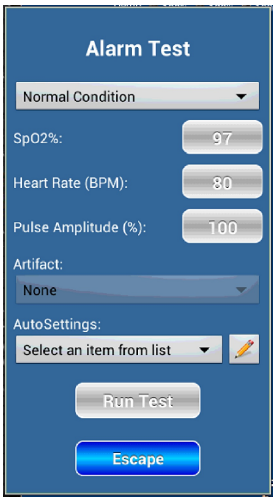


Figure 70

4.6.4.1 Test Setup

The setup stage begins as soon as the **SpO2** module is launched from the tabbed toolbar on the A1 **Main** screen. At this time, users should make sure that the pulse oximeter is displaying stable measurements in agreement with the active settings of *Figure 68*, and that an alarm is not currently active. This initial state is called the **Normal Condition**.

The 

button launches the **Alarm Test** setup interface. By default, the screen will display the **Normal Condition** as copied from the **SpO2** parameter setup which is currently in use, per *Figure 68*.

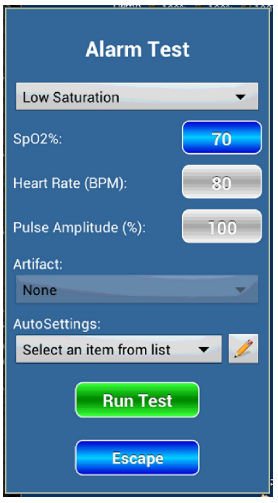


Figure 71

The upper dropdown menu includes a list of **Alarm Test** types (*Figure 72*). When a test type is selected, the setup interface enables only the controls that are relevant for that specific **Alarm Condition**.

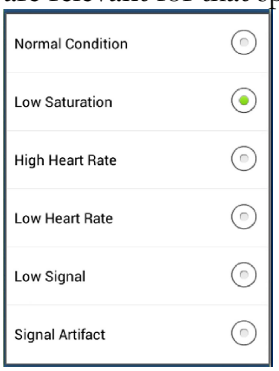


Figure 72

For example, in *Figure 71*, only **SpO2%** is enabled for the "Low Saturation" test type since it is the critical parameter responsible for this **Alarm Condition**. Users may adjust the parameter to a level that will trigger an alarm from the pulse oximeter. All other parameters are fixed and must remain the same as for **Normal Condition**.

Unlike the regular **SpO2** setup interface, changes in **Alarm Test** setup are not reflected immediately in the generated oximetry signals. The **Alarm Condition** will be applied after the **Alarm Test** begins.

When test setup is complete, the Run Test button launches a new test interface that guides use through the chosen **Alarm Test**. The screen displays a summary of both the **Normal Condition** and the **Alarm Condition**. A single action button appears near the centre of the interface:

Start Alarm

When pressed in this initial state, the action button will apply the **Alarm Condition**. The test enters the Alarm State.

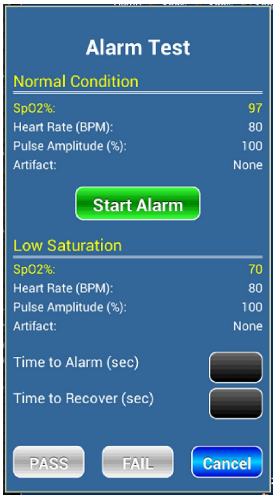


Figure 73

4.6.4.2 Alarm State

Stop

The "Time to Alarm" box will begin counting up in number of seconds. This keeps track of the amount of time required for the pulse oximeter to respond to the **Alarm Condition**. Pressing the button in this state indicates that the expected alarm has been triggered. The "Time to Alarm" timer stops, and the **Alarm Test** enters Alarm Stablization.

4.6.4.3 Alarm Stablization

5

Once the alarm has been triggered, the **Alarm Test** pauses to allow the **Alarm Condition** to stablize. During the Alarm Stablization stage, the action button is disabled. Instead of an action, it displays a countdown of five seconds. When countdown is complete, the **Alarm Test** enters Recovery.

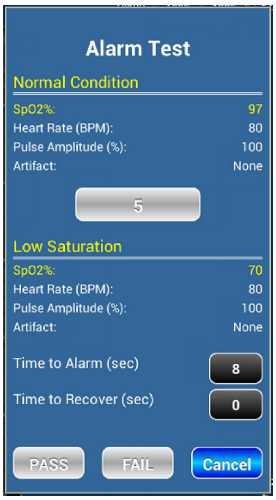


Figure 74

4.6.4.4 Recovery

The "Time to Recover" box will begin counting up in number of seconds. This keeps track of the amount of time required to recover from the **Alarm Condition** to **Normal Condition**. Pressing the button in this state indicates that the pulse oximeter has ceased to alarm. The "Time to Recover" timer stops.

At the conclusion of the Recovery stage, the test screen will appear as in *Figure 75*. The "Time to Alarm" and "Time to Recover" boxes now contain test data, and the "PASS" and "FAIL" buttons are enabled.

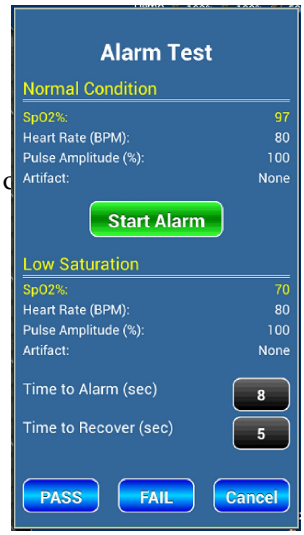


Figure 75

The action button returns to the 

state so that users c
the **Alarm Test** if desired. Restarting erases existing data and returns to the Alarm State described in section *4.6.4.2*.

4.7 Non-Invasive Blood Pressure (NIBP)

4.7.1 General

In oscillometric **Non-Invasive Blood Pressure** (**NIBP**) monitoring systems, a patient's blood pressure is assessed by inflating a cuff around the patient's arm. The cuff contains an air bladder that serves two purposes: one, to compress the arm such that blood flow can be restricted by various degrees; and, secondly, to convert changes in the arm's volume into small variations in air pressure within the cuff. Once a blood pressure measurement is complete, the cuff is deflated.

The pressure variations detected by the monitor are known as oscillometric signals. As shown in human experiments and repeatedly in clinical trials, the sizes of these oscillometric pulses can be mapped to certain clinically significant physiological parameters such as **Systolic Blood Pressure** (**SYS**), **Mean Arterial Pressure** (**MAP**), and **Diastolic Blood Pressure** (**DIA**). In general, the sizes of oscillometric pulses increase as the cuff is inflated from zero pressure, continue increasing past the **DIA**, and peaks when the cuff's internal pressure is close to the patient's **MAP**. When pressure exceeds **MAP**, pulse sizes will gradually decrease as cuff pressure rises past **SYS**, then further until the cuff fully restricts patient blood flow to the distal portions of the arm.

This relationship between cuff pressure, blood pressure, and the size of oscillometric pulses is known as an **Envelope**. As more **NIBP** monitors meet regulatory approval through clinical trials, they show that there is not one universal, ideal **Envelope** as was proposed early in the history of the oscillometric NIBP technique, but rather a "best fit" relationship that is dependant on the selected trial population.

To fully test a monitor that measures **NIBP**, the A1 provides multiple test features that can be accessed by touching the **NIBP** tab on the left side of the vPad-A1 **Main** screen (*Figure 17*).

4.7.2 NIBP Simulation

NIBP Simulation on the A1 injects small pulsatile pressure waves into a test pneumatic system that includes the NIBP monitor, its air hose(es), a blood pressure cuff, and the simulator. The cuff should be wrapped around a test cylinder or mandrel that is large enough to make a snug (not tight) fit. Hose adapters allow the simulator to be connected between the distal end of the hose(es) and the cuff, such that the injected pulses would appear to the monitor as oscillometric signals.

On the **NIBP Simulation** page in *Figure 76*, shown by default when first entering the **NIBP** tab, users can adjust the simulation parameters that will become active when the feature is launched with the Start button.

Figure 76

4.7.2.1 Heart Rate

The **Heart Rate** parameter sets the frequency of pulses during an **NIBP Simulation**. It can be set from 20 to 240 beats per minute (BPM), in increments of 1 BPM.

4.7.2.2 Pulse Volume

Pulse Volume refers to the parameter that sets the overall size of the simulated pulses. A simulation with "High" **Pulse Volume** provides the most reliable readings from the monitor's perspective, since large oscillometric signals are easier to detect. "Medium" and "Low" Pulse Volume can be used to test the monitor's ability to handle less strong or generally weak pulse signals from the blood pressure cuff.

4.7.2.3 Mode

The simulation **Mode** should be selected to suit the **NIBP** monitor type. Available options are "Adult" and "Neonatal". For a device intended for monitoring both adults and neonates, the **Mode** setting should match the currently selected options on the monitor, along with a cuff of appropriate size.

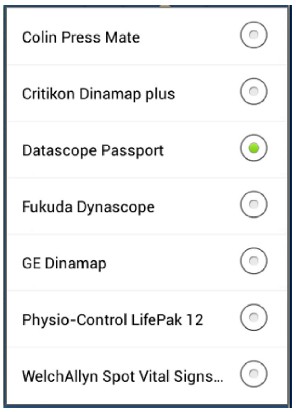


Figure 77 - NIBP Device Selection

4.7.2.4 Device

The **Device** dropdown menu contains a list of **NIBP** monitor makes and models. Users must select an appropriate target device to ensure that the calibrated **Envelopes** to be used for **NIBP Simulation** are suitable for the monitor's specific oscillometric blood pressure measurement algorithms.

Note: To add a new **Device** not found amongst existing options, refer to section *4.8.2.4 - Calibration: NIBP Envelopes*.

4.7.2.5 Simulation Envelope Selection

The A1 Patient Simulator generates **NIBP Simulations** that target a specific set of **SYS**-**DIA**-**MAP** readings. Users can select the targeted readings from the **Simulation** dropdown menu. The **Simulation** options available will depend on both the **Device** and the current **Mode** setting (see *Figure 78* and *Figure 79Figure 79*). Once a target is chosen, the module will load the calibration data from an Envelope file that was customized for the active **Device**.

Note: To add a new **Simulation** not found amongst existing options, refer to section *4.8.2.4 - Calibration: NIBP Envelopes*.

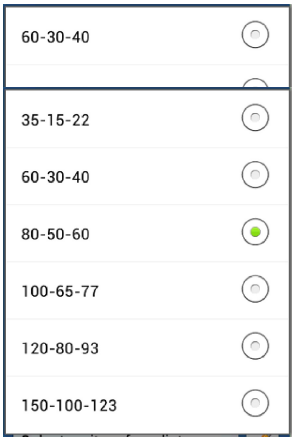


Figure 79 - Neonatal Mode Simulations

4.7.2.6 Running NIBP Simulations

When **NIBP Simulation** *setup* is complete, the Start button prepares the simulator hardware for an impending test. Blood pressure cuff inflation and deflation are entirely driven by the device under test, as is the case during a normal diagnostic **NIBP** measurement. The module will begin monitoring cuff pressure and display a **Result** screen as shown in *Figure 80*.

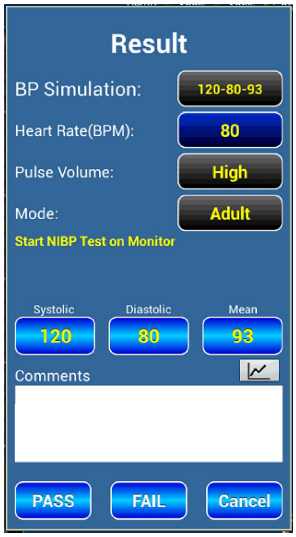


Figure 80

The **Result** screen displays a summary of the active **Simulation** parameters along with fields for entering observed readings. For details on how to enter data for **Test Records**, see section *5.1.2 - Test Results*. The interface also instructs users to initiate an **NIBP** measurement on the patient monitor.

Pressing the button will show a graphical representation of system pressure during the course of a single **NIBP** measurement. The graph is a pop-up that overlays the bottom section of the **Result** screen until it is dismissed.

The button clears Pressure from that time forward continues to be displayed.

The button hides Pressure is updated in the background.

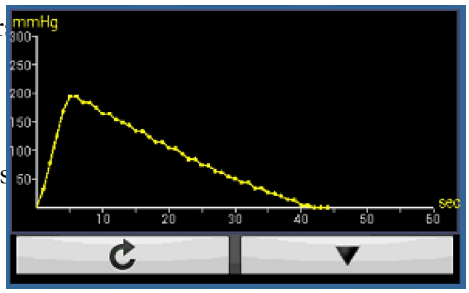


Figure 81

If the initial **DUT** measurement is unsatisfactory, users may elect to make multiple **NIBP** measurements. The unit is ready to generate multiple **Simulations** until user assigns a PASS / FAIL or Cancel.

Note: It is recommended that users exit the **NIBP Simulation Result** screen when finished to conserve battery power.

4.7.3 Pressure Source and Manometer

Figure 82 - Pressure Auto Mode

The **Pressure Source and Manometer** (**Pressure**) feature can be used to verify the pressure transducers in a **NIBP** monitor, or other pressure-measuring devices.

Pressure parameters are not active during setup. Access the feature setup page by swiping right from the **NIBP Simulation** page (*Figure 76*) or swiping left from the **Over Pressure** page (*Figure 88*), then press Start when ready.

4.7.3.1 Mode

The **Pressure** module has three **Modes** of operation.

- **Auto** - Inflates and regulates system pressure
- **Manual** - Passively measures system pressure
- **Step** - Inflates pressure in regular steps until it reaches the target pressure

4.7.3.2 Maximum Pressure

The **Maximum Pressure** parameter refers to the highest target pressure for **Auto** and **Step** regulation. It can be set from 10 to 400 mmHg, in 1 mmHg increments. Parameter controls are disabled in **Manual Mode**, since users and/or the **DUT** are in control of system pressure.

4.7.3.3 Delay Time

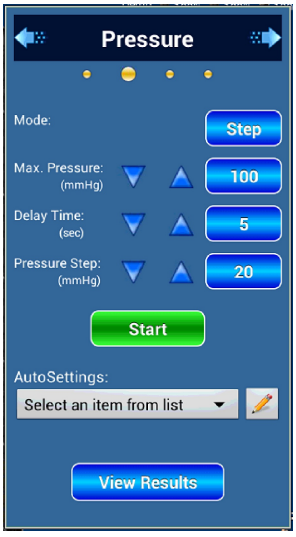


Figure 83 - Pressure Step Mode

The **Delay Time** controls the pause duration between intermediate pressure levels in **Step Mode**. It can be set from 1 to 600 seconds, in 1 second intervals. Parameter controls are disabled in **Auto** and **Manual Mode**.

4.7.3.4 Pressure Step

The **Pressure Step** parameter sets the size of each intermediate pressure interval in **Step Mode**. It can be set from 10 to 400 mmHg, in 1 mmHg increments. Parameter controls are disabled in **Auto** and **Manual Mode**.

For example, in *Figure 83*, the setup page is in **Step Mode**. Once the test is started, A1 will inflate system pressure from zero to the **Maximum Pressure** of 100 mmHg. In the process it will pause for 5 seconds **Delay Time** at every 20 mmHg **Pressure Step**.

4.7.3.5 Running Pressure Tests

Before starting a **Pressure** test, first place the NIBP monitor in its service mode or transducer test mode, as appropriate. When setup is complete, initiate the test in the selected **Mode** and show the **Result** screen by pressing the Start button.

At any point during a **Pressure** test, press Record to set of data to the **Comments** input box. Users can edit the "Actual" pressure reading or erase an entire entry, if necessary, by touching the **Comments** box to launch the on-screen keyboard.

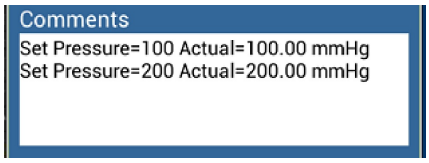


Figure 84

Figure 85 - Auto Mode Test

A Deflate button allows users to relieve system pressure during a test. This button will pause the **Pressure** test until the Continue button is pressed.

The **Result** screen will have slightly different appearance and behaviour depending on the **Pressure** test **Mode**:

- **Auto** The test begins pumping air into the test pneumatic system. Result assignment (PASS/FAIL) buttons are disabled until pressure reaches the **Maximum Pressure**.

  In this **Mode**, the Record button also activates the **Maximum Pressure** controls in the **Result** screen. Users can now set a new **Maximum Pressure** target and apply the setting by pressing the Continue button.

  Users may press the Record Continue b new **Maximum Pressure** as many times as necessary. The A1 will actively maintain the pneumatic system pressure until user assigns a PASS FAIL Cancel or .

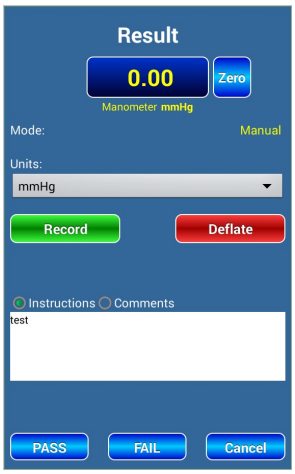


Figure 86 - Manual Mode Test

- **Manual** The test begins passively monitoring pressure in the test pneumatic system. It is possible to zero a small pressure offset.

  In this **Mode**, the display unit can be changed to any of the following: mmHg, inHg, kg/cm^2, cmH$_2$O, mBar, PSI, inH$_2$O, or kPa.

  vPad-A1 will hold the pneumatic system pressure until user assigns a PASS FAIL Cancel or .

Figure 87

- **Step** The test begins automatically, raising the system pressure to the first **Pressure Step** target. Once the target has been reached, the **Result** screen shows a countdown above the **Comments** box for the duration of the **Delay Time**.

  In this **Mode**, data sets are added without the Record butto They are automatically appended at the expiration of the **Delay Time** countdown. The test then proceeds to the next **Pressure Step**, waits for another **Delay Time** duration, and so on through every pressure interval until pressure reaches the **Maximum Pressure**. Result assignment (PASS/FAIL) buttons are subsequently enabled.

  At **Maximum Pressure**, vPad-A1 will actively maintain the pressure level until user assigns a PASS FAIL Cancel or

Note: It is recommended that users exit the **Pressure Result** screen when finished to conserve 

battery power.

4.7.4 Over Pressure and Pop-Off

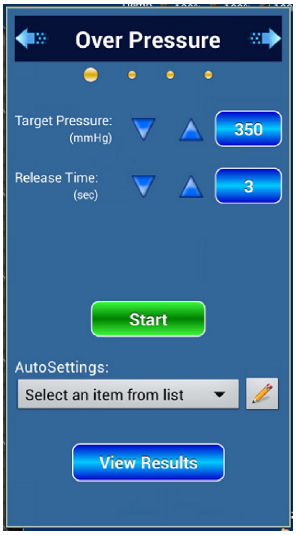


Figure 88

The **Over Pressure** feature is intended to test the pressure relief valve limits in an **NIBP** monitor. A typical test routine involves pumping air into the pneumatic system until the high pressure triggers the relief valve, which will then vent the system to a safe pressure level.

Over Pressure parameters are not active during setup. Access the feature setup page by swiping right from the **Pressure** page (*Figure 82*) or swiping left from the **Leakage Rate** page (*Figure 91*), then press Start when ready.

4.7.4.1 Target Pressure

The **Target Pressure** parameter controls the highest pressure reached during an **Over Pressure** test. This is generally the maximum acceptable relief pressure for the safety valves. It can be set from 0 to 400 mmHg, in 1 mmHg increments.

4.7.4.2 Release Time

The **Release Time** designates the amount of time allowed for the pressure relief valves to vent system pressure to a safe level. This value is generally specified by the manufacturer of the monitor. It can be set from 1 to 999 seconds, in 1 second increments.

4.7.4.3 Running Over Pressure Tests

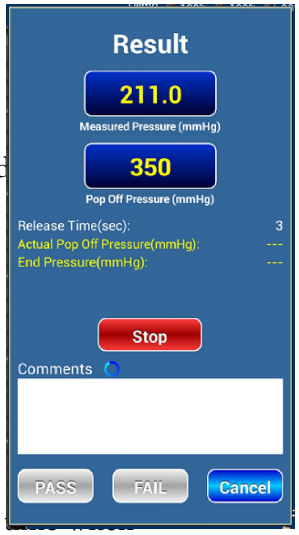


Figure 89

Before starting an **Over Pressure** test, first place the NIBP monitor in service mode or pop-off/relief pressure test mode, as appropriate. When setup is complete, the Start button will intiate the test and **Result** screen.

In the **Result** screen, the **Target Pressure** parameter is displayed as "Pop Off Pressure". The result assignment (PASS/FAIL) buttons are disabled while inflation and pressure relief is in progress, as indicated above the **Comments** box by a spinning wheel .

The Stop button can abort the **Over Pressure** test at any time it is busy. The test can then be restarted with the Start button.

When an **Over Pressure** test is started, it attempts to pump air into the pneumatic system until the relief valves are triggered. If the A1 senses a valve trigger, it will immediately stop pumping and allow the **DUT** to vent system pressure for the duration of the **Release Time**.

At the conclusion of the **Release Time** countdown, the **End Pressure** will be recorded and the tester will vent all remaining pressure and report two measurements:

- **Actual Pop Off Pressure** - exact pressure that caused valve trigger
- **End Pressure** - system pressure at the expiration of **Release Time**

See *Figure 90* for a sample **Over Pressure** test report.

If the test does not sense a valve trigger before reaching **Target Pressure**, then it will instead report the **Actual Pop Off Pressure** as "Not tripped", and the **End Pressure** will remain blank.

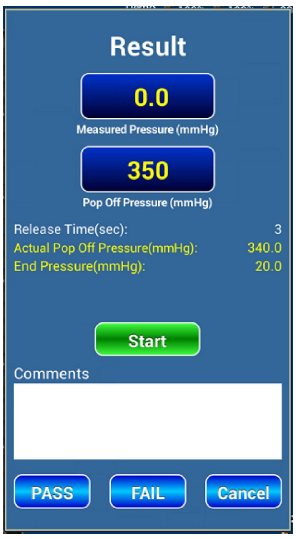


Figure 90

4.7.5 Leakage Rate

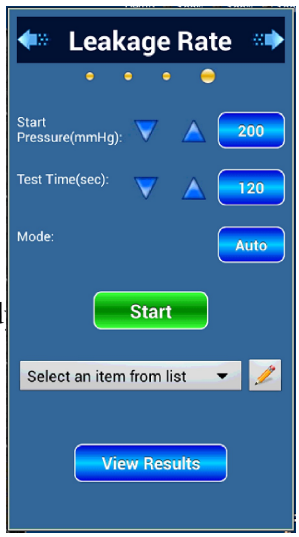


Figure 91

A **Leakage Rate** test assesses the rate at which air leaks from a pneumatic system, typically by inflating up to and then holding a certain pressure for a predetermined amount of time.

Leakage Rate parameters are not active during setup. Access the feature setup page by swiping left from the **NIBP Simulation** page (*Figure 76*) or swiping right from the **Over Pressure** page (*Figure 88*), then press Start when ready.

4.7.5.1 Mode

The **Leakage Rate** feature may operate in one of two Modes:

- **Auto** - Inflates to **Start Pressure** automatically
- **Manual** - Passively measures system pressure

4.7.5.2 Start Pressure

The **Start Pressure** parameter sets the initial pressure for the **Leakage Rate** test in **Auto Mode**. It can be set from 20 to 400 mmHg, in 1 mmHg increments. This setting has no effect in **Manual Mode**.

4.7.5.3 Test Time

Test Time determines how long the **Leakage Rate** test will try to hold the **Start Pressure** in the pneumatic system without active regulation. It can be set from 30 to 600 seconds, in 1 second increments.

4.7.5.4 Running Leakage Rate Tests

Before starting an **Over Pressure** test, first place the NIBP monitor in service mode or manual valve control/leak test mode, as appropriate. When setup is complete, users can initiate a test in the selected **Mode** and show the **Result** screen with the Start button.

In the **Result** screen, a progress bar above the **Comments** box will indicate if the test is currently active.

Figure 92

The Cancel button can abort the **Leakage Rate** test at any time. The test can then be restarted with the Start button on the setup page.

At the beginning of an **Auto Mode** test, the A1 will begin pumping air into the pneumatic system until pressure reaches **Start Pressure**. The **Test Time** countdown will automatically start after the target pressure is reached.

In **Manual Mode**, any incoming pressure must be from an external source (i.e., from the NIBP monitor itself, or alternatively from a hand pump). When pressure reaches the desired level, then users can start the **Test Time** countdown by pressing the Start button on the **Result** scree

For both **Modes**, the PASS button is initially disabled; however, users ca FAIL example, it becomes clear that a system leak is too large to reach **Start Pressure**. Otherwise, the PASS result will be available at the conclusion of the test.

When **Test Time** expires, the A1 measures the pressure one last time, then vents the pneumatic system. The test will then calculate and display the **Leakage Rate** in mmHg per minute.

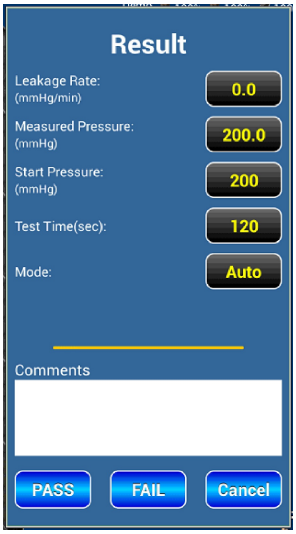


Figure 93

4.8 Tools and Utilities

4.8.1 Timer and Stopwatch

The **Timer/Stopwatch** can be accessed by touching the **TOOL** tab on the left side of the vPad-A1 **Main** screen (*Figure 17*).

A **Timer/Stopwatch** can be added to an **AutoSequence** by creating an **AutoSetting** with a specific **Time** and **Mode**.

4.8.2 App Settings

The **Settings** menu includes features which enable users to optimize performance of vPad-A1. It is accessible by touching the Settings button on the A1 **Main** screen (*Figure 17*).

4.8.2.1 Power Management

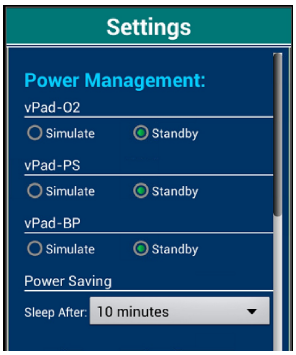


Figure 94

Each of the three simulation modules are capable of entering **Standby Mode** in order to conserve power and extend battery life. While in **Standby Mode**, module hardware will not generate any simulation or performance test signals.

If the **A1 App** detects that a module has been idle for some time, it will automatically set that module to **Standby Mode**. Each module will re-enter **Simulate Mode** if the user launches its setup interface from the tabbed toolbar on the **Main** screen:

- vPad-O2 module >> **SpO2** tab
- vPad-PS module >> **ECG**, **RESP**, **T/C**, and **IBP** tabs
- vPad-BP module >> **NIBP** tab

To manually toggle a simulation module's power mode, simply use the radio buttons inside the "Power Management" section of the **Settings** panel. Changing the power mode also sets the default state of each module on **App** startup. New configurations will be applied immediately, but they will not persist upon quitting the **App** unless the Save button is pressed.

The **Sleep After** setting controls the length of time after a setup menu is dismissed before the corresponding simulation module is considered "idle" and is then placed on standby.

4.8.2.2 Communication Management

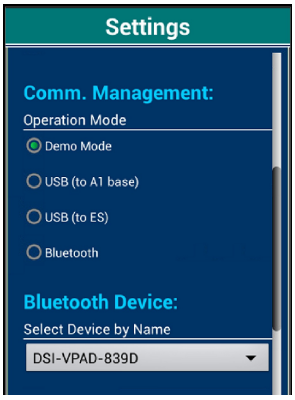


Figure 95

Communication refers to messaging from the A1 **App**, running on the **Tablet**, to the vPad-A1 **Base** module. Settings related to "Comm. Management" appear below the "Power Management" section of the **Settings** panel.

Communication of control messages is integral to the operation of the vPad-A1 Patient Simulator. Although unit is configured at the factory to suit typical operating conditions, users may wish to optimize **Communication** settings for their own environment or application.

Active **Communication** can be set to one of four modes:

- **Demo Mode** - for testing/troubleshooting with emulated A1 hardware
  - cannot be used for actual simulation or performance testing
- **USB (to A1 base)** - for wired USB connection with the vPad-A1 **Base** module
  - follow instructions in ?
- **USB (to ES)** - for wired connection with the vPad-ES Safety Analyzer
  - for remote operation via the vPad-Check™ app
- **Bluetooth** - for wireless connection with vPad-A1 **Base**, or vPad-ES tablet
  - can use **Tablet** as separate handheld control interface

Note: Two **USB** options exist for compatibility with both the A1 **Tablet** and remote control through the vPad-ES Safety Analyser (using vPad-Check). Contact *Datrend Customer Support* for more information.

To manually change the A1 **Communication** interface, simply use the radio buttons under "Operation Mode". Changing the operation mode also sets the default connection method on **App** startup. New configurations will be applied immediately, but they will not persist upon quitting the **App** unless the Save button is pressed.

When the **App** is first launched, it attempts to make a connection according to the last saved **Communication** settings. Changing the "Operation Mode" will break the current connection and cause the **App** to make another connection with the new settings.

The **Bluetooth Device** setting specifies the Bluetooth name of the target to connect with, which can be either an A1 **Base** or a vPad-ES Safety Analyser. A dropdown menu lists all Bluetooth devices currently paired with the **Tablet**; only names that begin with "DSI-VPAD" are valid targets.

4.8.2.3 Calibration: SpO2 R-Curves

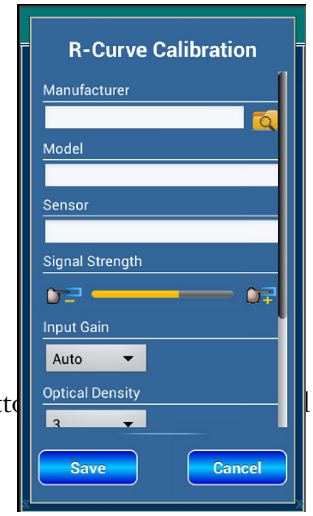


Figure 96

In a typical pulse oximeter, the **SpO2 R-Curve** is the means by which that particular device translates its measurement of light transmission through oxygenated blood to an oxygen saturation in percent. Individual **R-Curves** are derived through clinical studies and, while similar, may be different for each make and model encountered. vPad-A1 has **R-Curves** pre-programmed for a number of common monitor makes and models; however, users may need to add a new device to the make/model menus.

The 

butt launches a calibration tool for **SpO2 R-Curves**. The **Manufacturer**, **Model**, and the (optional) **Sensor** field in the calibration tool uniquely identify each individual **R-Curve**.

Note: The **Sensor** identifier accounts for small variations in output that can exist between an OEM sensor (e.g. Nellcor's DS100) and a third-party replacement sensor (e.g. EnviteC).

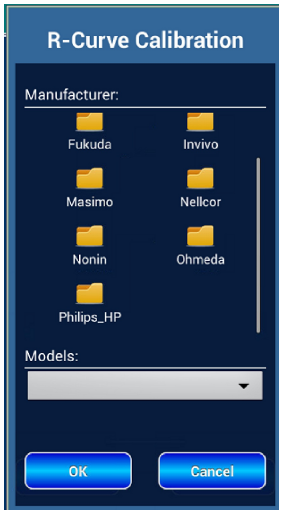


Figure 97

Users can enter new information into the three text input boxes as appropriate for the new device. Alternatively, press the  **Folder Search** icon to choose an existing **R-Curve** as template. A new window will show a folder list of known **Manufacturers**, as in *Figure 97*.

Touching any **Manufacturer** folder will populate the **Models** dropdown menu with existing devices in the same category. Once the desired **Model** is chosen from the list, users can confirm the selection by pressing 

If a template **R-Curve** was successfully selected, the **Manufacturer**, **Model**, and (optional) **Sensor** fields will now be populated with text from the template, along with all additional data fields discussed below. Users should edit the auto-filled text to create a new device **R-Curve**; otherwise, the template may be over-written with the newly-entered data.

Having identified the oximeter device, the following steps will create for it a suitable **R-Curve**.

Optimize Signal Strength

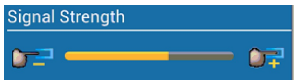


Figure 98

- When the pulse oximeter sensor is placed on the vPad-O2 finger, the **Signal Strength** indicator will display the output of the oximeter's sensor in real time.

- If **Signal Strength** is *not* showing an adequate signal level of 50% to 70%, then:

  - Change sensor position on the simulated finger; or
  - Change **Input Gain** (see below)

Adjust Input Gain (Optional)

Figure 99

- **Input Gain** should generally be set to "Auto" (automatic gain adjustment). In the rare situation where **Signal Strength** does not settle to a stable level of 50-70% in "Auto" mode, try one of the fixed gain settings provided. A larger number represents a higher sensitivity to light from the oximeter.

Adjust Optical Density (Optional)

Figure 100

- With **Signal Strength** at the ideal level, the oximeter device should begin making SpO2 readings. If the readings do not settle onto a constant SpO2 percentage, adjusting the **Optical Density** may improve performance. Density 2 is the default which is suitable for many devices.

Calibrate Red/Infrared Ratio

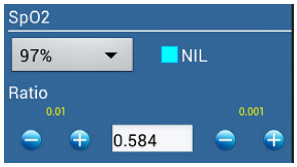


Figure 101

- The dropdown menu contains a list of **SpO2%** readings that each correspond to a calibration point. For example, in *Figure 101*, the active calibration point is 97% and its associated **Red/Infrared** (**R/IR**) **Ratio** is 0.584.

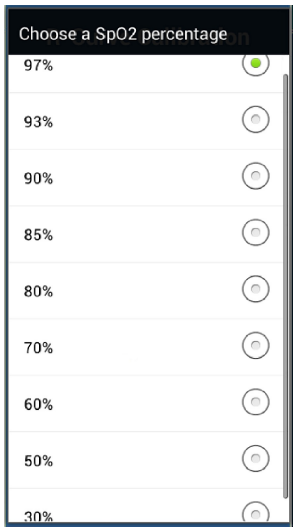


Figure 102

- Adjust the **R/IR Ratio** until oximeter reading agrees with the calibration point **SpO2%**.

- Perform ratio adjustment for each calibration point on the **SpO2%** list.

- Some pulse oximeters are not specified for measurement of low values of **SpO2%** (i.e. less than 70%). If the oximeter is unable make a good, stable reading of the saturation level, tick the NIL checkbox to mark the corresponding calibration point as invalid.

  Note: Users must individually mark each invalid calibration point as **NIL**.

- Once the calibration procedure has been completed, each calibration point in the **SpO2%** list will produce an accurate, stable reading from the oximeter, *or* alternatively will be marked as **NIL**.

Save R-Curve Data

- The Save button will save the entered R-Curve data to a new or existing device entr as identified by the **Manufacturer**, **Model**, and (optional) **Sensor** fields on the menu.
- The Cancel button will discard all entered data without saving.

4.8.2.4 Calibration: NIBP Envelopes

NIBP simulations can be customized by touching the NIBP Envelope Customization the **Settings** screen. The button will launch a special **NIBP Simulation** setup interface similar to the example of *Figure 76*, where it will be possible to select a **Device** and a **Simulation** (SYS-DIA-MAP) from the dropdown menu. Pressing the **Back** button will return to the **Settings** screen.

Note: The special **NIBP Simulation** setup interface does not allow navigation to other **NIBP** features such as **Pressure** and **Leakage Rate** via the swipe gesture.

Each **NIBP Simulation** corresponds to an **Envelope** that is specifically customized for the chosen **Device**. The **Envelope** contains parameters that allow the vPad-BP simulator unit to generate precise pressure pulses during the course of a simulation test.

When creating an **Envelope** for a new or existing **Device**, it is generally preferable to select as a starting point a set of simulation settings (including **Mode** and **Device**) that already closely resembles the desired simulation. Once an appropriate selection has been made for the template, touch the **EDIT** icon to go to the **Customize Screen** as shown in *Figure 103*.

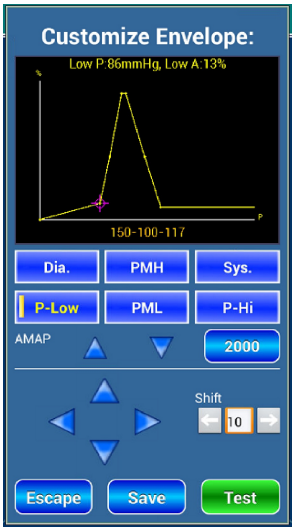


Figure 103

The "Customize Envelope" screen displays the selected **Envelope** and targeted SYS-DIA-MAP readings in a graph. Various parameters in the **Envelope** describe a relationship between the test system pressure (horizontal x-axis) controlled by the **NIBP** monitor, and the height of simulated pulses(vertical y-axis) as generated by vPad-BP.

The calibrated data points in an **NIBP Envelope** are also inflection points where a "corner" changes the normally linear relationship between pressure and amplitude, as shown in *Figure 103*. From left to right, the names of the calibrated inflection points are:

PML *PMH*
Dia. *Sys.*
P-Low *P-Hi*

Each time a change is made to an **Envelope** inflection point, users must press Test button for the new parameters to take effect.

A typical **Envelope** customization makes the following adjustments through experimentation, in no particular order.

- *PMH + PML*: Adjust these pressures (x positions) to achieve a target MAP reading.

  Some devices require both points to coincide at the desired MAP in a sharp peak.

  Other devices perform better when the points form a plateau near MAP, with one or both points offset from the target reading.

- *Sys. + Dia.*: Adjust these pressures (x positions) so that they correspond to the target SYS and DIA readings, respectively.

  Adjust amplitudes (y positions) until successive SYS and DIA readings on the **NIBP** monitor are within acceptable tolerance of the targets.

- *P-Hi + P-Low*: Different devices can have vastly different "ideal" **Envelope** shapes that conform best to their algorithms.

  If monitor **NIBP** readings are unstable (e.g. successive measurements differ by more than 5 mmHg), moving the pressures (x positions) away from the MAP peak may improve the results.

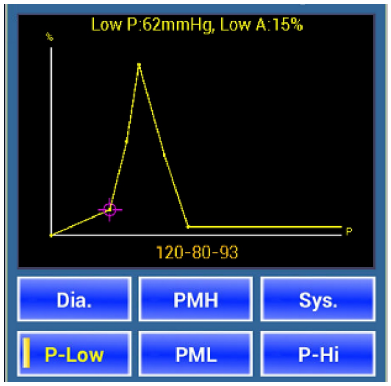


Figure 104

To select an inflection point for editing, simply press a button in *Figure 104* to highlight it on the graph. For all selected points (except for *PMH* and *PML*), a brief description above the graph shows the current pressure (x position) measured in mmHg, and amplitude (y position) as a percentage of the maximum pulse height.

PMH and *PML* are always at 100% peak, so their amplitudes are not shown and their amplitude adjustment buttons will be disabled. Instead, the description shows the pressure of both *PMH* and *PML* at once, as well as the mid-point (mean) and pressure difference (delta) between them.

The buttons in *Figure 105* change the selected point's pressure, and buttons change its amplitude.

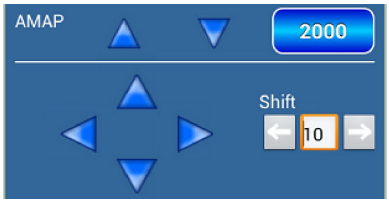


Figure 105

The **AMAP** button displays the current maximum pulse height, which defines the largest simulated pulse that vPad-BP will produce during an **NIBP Simulation**. If the device requires smaller pulses (e.g. the test cuff is smaller than the typical adult cuff), then the **AMAP** controls can be used to adjust the maximum pulse height as needed.

The **Shift** controls move the entire **Envelope** horizontally along the pressure axis. Pressing a or button moves all inflection points by the same pressure shift. The default increment is 10 mmHg of pressure, though users can enter any custom number from 0 to 50 in the input box. Changes to the **Shift** increment will only be applied after pressing the "Done" button on the keyboard.

Pressing the Escape button in *Figure 103* dismisses the tool and returns to NIBP simulation settings after warning users of unsaved changes.

After users have verified via the Test button that the dis **Envelope** produces the expected readings on the target device, the Save button will launch a "Save Envelope" form.

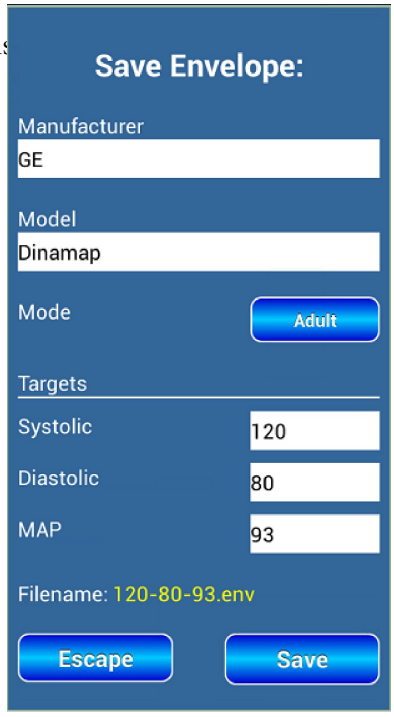


Figure 106

The form is pre-populated with information extracted from the **Envelope** template originally selected for editing. The **Manufacturer** and **Model** fields should contain the device make and model, respectively, both of which can be edited if necessary.

Pressing the **Mode** button toggles between "Adult" and "Neonatal" mode. This should be determined by the targeted monitor type and settings used during **Envelope** customization.

The **Targets** fields contain three NIBP measurements (SYS-DIA-MAP) that will later inform users on what blood pressure readings they should expect from a properly-functioning device of the same make and model. The automatically generated **Envelope** name, which will be listed in the **Simulation** dropdown menu, is derived from the entered **Targets**.

Pressing Save in *Figure 106* saves all displayed pressure parameters to an **Envelope** file. If none of the fields in the form were edited, then the originally chosen template will be overwritten.

After saving or when the 

button in *Figure 106* is pressed, the interface returns to the "Customize Envelope" screen in *Figure 103* and users can continue working on the same **Envelope**. Pressing the "Escape" button on that screen will dismiss the tool and return to NIBP simulation settings.

4.8.2.5 Self Test: NIBP Pulse Generator

The **NIBP Self Test Tool** shown in *Figure 107* checks the height of standardized test pulses. All vPad-BP simulators are calibrated before leaving factory to ensure that each pressure pulse generator can accurately produce the same range of pulse amplitudes during an **NIBP Simulation**. However, with its mechanical components under heavy use or simply over a period of time, the generator's performance may in some cases drift away from factory conditions.

Since conditions of self-test may be different from conditions at factory calibration, failing the self test is not indicative of poor performance. However, in the event that failing results as seen, it is recommended that users should schedule a re-calibration for the vPad-BP simulator unit at their earliest convenience.

Pressing the 

Settings screen launches the **Self Test Tool**.

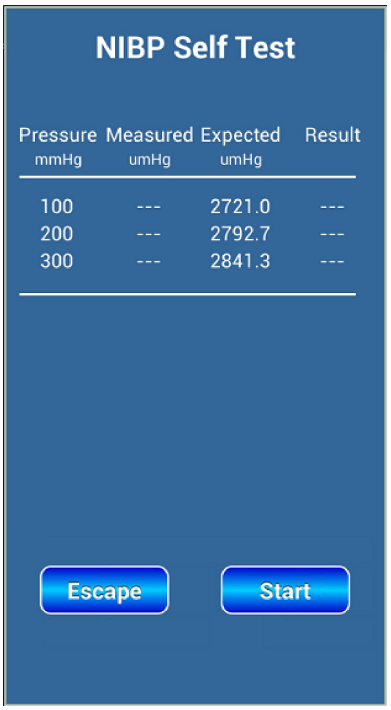
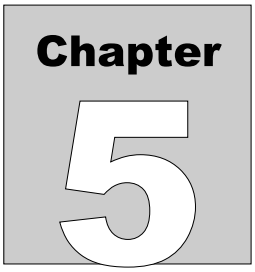


Figure 107



5 Automation and Test Records

This chapter explains how to use vPad-A1 to perform testing of multi-parameter patient monitors, pulse oximeters, and/or NIBP monitors, following a predefined sequence of steps referred to as an **AutoSequence**. The generation and management of **Test Results** and **Test Records** are also covered in this chapter.

5.1 Automated Performance Testing

An important element in the maintenance of patient-monitoring equipment is the periodic verification of the ability of a **Device Under Test** (**DUT**) to detect, measure, display, and/or interpret patient vital signs. The simulator or performance tester's role is to generate precise, calibrated signals that produce predictable results in a functional monitoring device.

A simulation or performance test would typically follow these four steps:

- Setting up the desired simulations (**ECG**, **Respiration**, **SpO2**, etc.) in the **A1 App**
- Connecting the **DUT** to A1 module(s) using signal leads, cables, hoses and adapters
- Observing the **DUT** for vital signs readings, measurements or displays
- Assigning a "PASS" or "FAIL" **Test Result** based on standards and tolerances

After generating a series of **Test Results** for the same **DUT**, the A1 can consolidate them into an equipment **Test Record** that documents in detail the conditions and outcomes of the tests performed. Furthermore, these **Test Records** can be integrated with another **Equipment Management System**, depending on institutional or regulatory requirements.

5.1.1 Sync Mode

Whenever the A1 is used as a completely assembled system, it is possible to synchronize the signals from all three simulator modules by activating the Sync control on the A1 **Main** screen. The **Sync Mode** feature ensures that all heart signals are triggered simultaneously and share a common **Heart Rate**. Outside of **Sync Mode**, patient parameters may appear incorrectly timed on monitor displays with multiple traces.

Heart beat triggers are generated whenever a patient **ECG Waveform** is active. Therefore, the vPad-PS module must be present in the system to make use of **Sync Mode**, and it must be set to simulate one of the following:

- **Normal Sinus Rhythm**
- **Arrhythmia**
- **Pacemaker Pulse**
- **Fetal ECG Signal**

When **Sync Mode** is active, the shared **Heart Rate** setting can be managed from the **ECG** setup screen. Controls for **Heart Rate** on all other modules will be disabled.

When running an **AutoSequence** in **Sync Mode**, the **ECG Heart Rate** will override all other modules in the same **AutoSequence Group**. The A1 will display a warning if no **ECG AutoSetting** was added in the **AutoSequence** to drive the synchronized heart beat.

5.1.2 Test Results and Records

When the simulation test setup is complete, whether through manual input (as described in chapter *4 - Operation: Simulation Modules*) or an **AutoSetting** or **AutoSequence** (section *5.2 - Test Automation*), users can record the values observed on the **Device Under Test** (**DUT**). A custom **Test Result** interface can be accessed with either the Result b Start he button.

5.1.2.1 Creating Test Results

When displayed, the **Result** screen will be specific to the type of simulation currently in use. It will display all the settings and options that are active in the simulation. If there is a physiological parameter that may be represented as a number on the **DUT**, an editable blue button allows a user to enter that value as shown by the **DUT**. By default, on entering the **Result** screen such buttons are initialized with corresponding settings from the A1 simulation in use.

In the example shown in *Figure 108*, the **ECG Amplitude** setting is 2.0 mV, which is shown as the default value in the editable blue button. If the **DUT** indicates the ECG is only 1.75 instead of 2 mV, the user can touch the button and then enter the **DUT**'s reading.

Figure 108

Some parameters that are recorded can not be changed, as they represent fixed values of the simulation. An example of a fixed parameter is **ECG Artifact**. If it is necessary to record an observation, for example the **DUT**'s response to an **Artifact**, it can be entered into the **Comments** field of the **Result** screen.

Figure 109

Once data and observation input is complete, users can create a temporary **Test Result** entry by pressing the PASS FAIL button. The choice depends on limits from user test proce

Press the Cancel button to dismiss the **Result** screen withou creating a new **Test Result** entry.

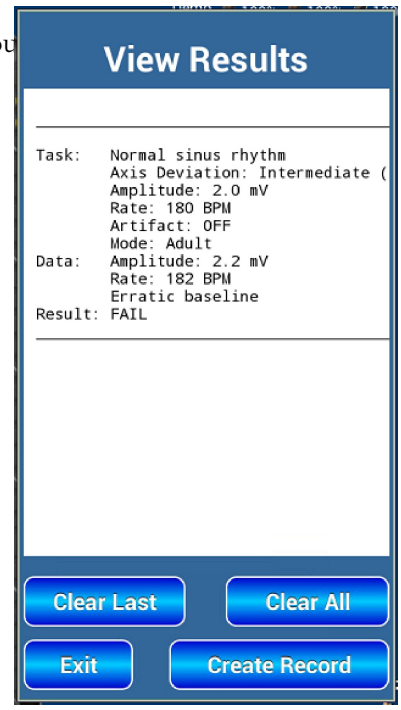


Figure 110

5.1.2.2 Reviewing Test Results

Saved **Test Result** entries can be viewed with the View Results button, which is found on the **A1 App Main Screen** and any simulation or parameter setup screen. The "View Results" screen will also show at the conclusion of an **AutoSequence**.

A typical result for an **ECG** simulation test is shown in *Figure 110*. In the **Task** section the parameter settings are recorded. In the **Data** section the **DUT** values are recorded, with the default being the setting value if it has not been changed by the user. If **Comments** have been made, they will be recorded in the **Data** section. The **Results** section will contain either "PASS" or "FAIL".

If the **Test Result** was generated by an **AutoSequence**, it may alternatively reported as "SKIPPED" or "TERMINATED" instead of "PASS" or "FAIL". Additional **Test Results** can also be appended manually after an **AutoSequence** is complete. See section *5.2.2.1 - Running AutoSequences* for details.

Drag the displayed results up and down to scroll through additional pages as more **Test Result** entries are appended to the bottom of the record. Pressing the "Clear Last" button erases the most recent entry, whereas pressing "Clear All" removes all entries from the report to enable the start of a new test session.

Note: The "Clear Last" and "Clear All" actions **cannot** be reversed. If the "View Results" screen is from completing or terminating an **AutoSequence**, the options to clear the last entry or all entries will not be available unless the **View Results** screen is closed and then re-entered.

Pressing the Create Record button will launch the **Equi Information** form. From this form, the current **Test Results** can be saved to a new **Test Record**.

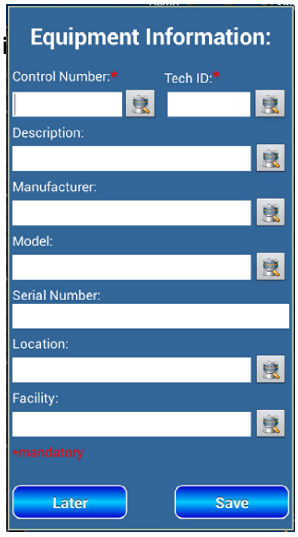


Figure 111

5.1.2.3 Entering Equipment Information

In order to create a **Test Record**, it is necessary to enter a **Control Number** (for example, a device ID number, an asset number, or another unique identifier). A **Technician ID** is also required to save a record. Additionally, for a report to stand on its own, it is frequently helpful to include some detailed information about the device, such as: **Description**, **Manufacturer**, **Model**, **Serial Number**, **Location**, and **Facility**. With vPad-A1, it is possible to enter and save this information on the **Equipment Information** screen of *Figure 111*.

As Equipment Information is saved, A1 develops an internal equipment database for later reference so as to avoid re-entering the same data in the future for the same device. There is also the possibility of pre-loading an equipment list as exported from, for instance, a CMMS system; contact Datrend for further details.

Note: **Equipment Information** data lookup is not case sensitive.

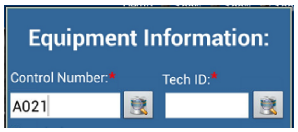


Figure 112

Any information saved in the equipment database can be recalled through the **Control Number** lookup, or as a single list entry in its specific data field.

For instance, users can perform a **Control Number** lookup by first entering the number in the input box, then touching the search icon.

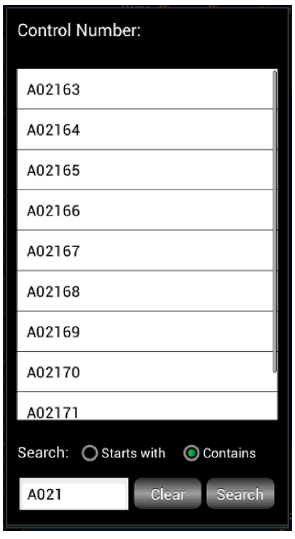


Figure 113

Entered text can be a complete or partial match for the equipment under test. If the search is successful, then the lookup window will show a list of matches as in *Figure 113*.

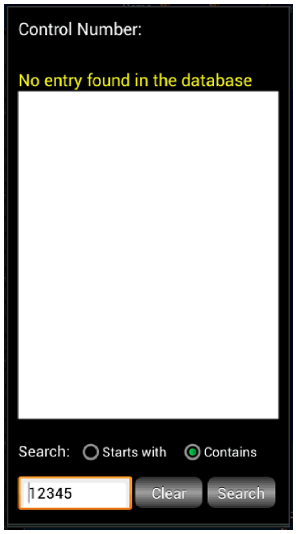


Figure 114

If the database contains no matching entry, then the lookup window will display a search failure message and the match list will be blank. To start a new search, simply enter new text into the **Search** box in the lookup window (or leave it blank) and then press the Search button.

Touching any Control Number in the match list will automatically populate the entire **Equipment Information** form.

Figure 115

Note: To clear the **Equipment Information** form, perform a new **Control Number** lookup with a blank field, then select the empty item at the top of the match list.

For new equipment not yet in the database, users have the option of creating an equipment entry either by entering new text in each information field, or by searching for similar text entries.

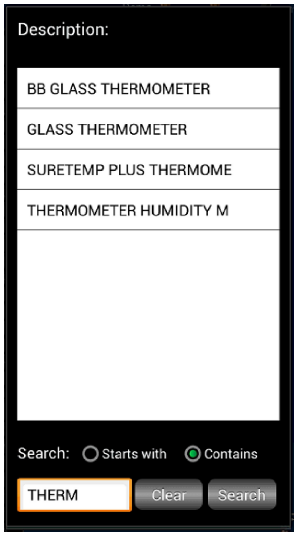


Figure 116 - Equipment Description Lookup

Touching the search icon beside any field will display a list of text entries previously saved. Besides potentially avoiding many keystrokes, information field lookups have the added advantage of improving data quality and streamlining future searches in the database.

When ready, press the Save button to create a new **Test Record**. Only the **Control Number** and **Technician ID** fields are mandatory. If one or more of these fields is empty, the save operation will not proceed.

The **Equipment Information** form will prompt the user before updating or adding any database entries. Choosing "No" will proceed to the next step without changing the database, and the new equipment entry will not appear in future searches.

Figure 117

The Later button exits the form without creating a **Test Record** or changing the equipment database.

Note: The **Equipment Information** form does not retain any text entered upon exit.

5.1.2.4 Creating Test Records

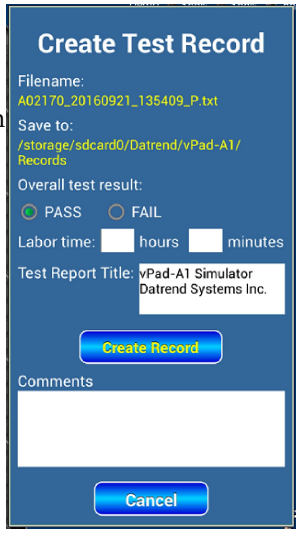


Figure 118

The Save button on the Equipment Information form displays a menu for creating new **Test Records**. It displays the new **Test Record** filename that will be saved, as well as the location of the *Records* directory on the **Tablet**.

At this point, users can override the **Overall Test Result** from "PASS" to "FAIL" and, optionally, enter reasons in the **Comments** box. Only a "PASS" result can be overridden; a record with one or more failed tests will always report the **Overall Test Result** as "FAIL", which cannot be changed.

Users may also enter the **Labor Time** and edit the default **Test Report Title**, if necessary. In the final **Test Report**, the combined total **Labor Time** (hours + minutes) will be entered as decimal hours (e.g. 1 hr 30 mins ➜ 1.5 hrs) to support CMMS system requirements.

The Cancel button will discard the entered **Equipment Information** and exit the **Test Rec** creation interface. This will not undo changes made to the equipment database. To temporarily dismiss the **Test Record** creation interface while retaining the saved **Equipment Information**, use the **Back** button instead.

Finally, pressing the Create Record button will save the **Test Record** file to **Tablet** mem which can later be recalled and viewed in the vPad-Record Manager App. The operation will also clear all current **Test Results** from the **View Results** screen.

5.1.2.5 Managing Test Records

vPad Record Manager is an app which is installed on the **Tablet** and which may be run independently of the vPad-A1 app.

Record Manager may be used to copy, print, and/or delete Test Record files saved by vPad-A1. **Record Manager** can also be used to convert Test Records to Adobe PDF documents.

Press the icon on the **Home** screen to launch the **Record Manger** app.

Refer to **MN-087 6100-081** *vPad-RM Operators Manual* for further information on use of the **Record Manager**.

5.2 Test Automation

5.2.1 AutoSettings

vPad-A1 is designed to work in both manual and automated mode. For any given type of simulation (e.g. **ECG Normal Sinus Rhythm**) there are a number of parameter values that define the simulated state (e.g. **Heart Rate**, **Amplitude**, **Artifact**, **Mode**, and **Axis**). In manual operation, every parameter can be modified individually to create a particular test condition as detailed in chapter *4 - Operation: Simulation Modules*, and the resulting response from the **DUT** can be recorded in a single **Test Result**.

Alternatively, it may be desirable to make modifications to all parameters at once before recording a new **DUT** response. This can be accomplished efficiently using module-based **AutoSettings**, in which all changes to settings are made and then saved as a named simulation state.

5.2.1.1 AutoSetting Selection

To recall an **AutoSetting**, touch the "AutoSettings" dropdown menu that can be found in every simulation or test setup interface. Selecting an **AutoSetting** will set all parameters on the screen to the previously-saved values. There is no limit on the number of **AutoSettings** that may be created and stored.

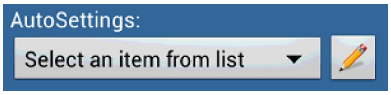


Figure 119

5.2.1.2 Creating and Editing AutoSettings

It is possible to save the current, active parameter setting(s) on a setup screen by touching the  icon next to the **AutoSettings** selector. The "AutoSetting" menu will display a summary of the parameters that will be saved.

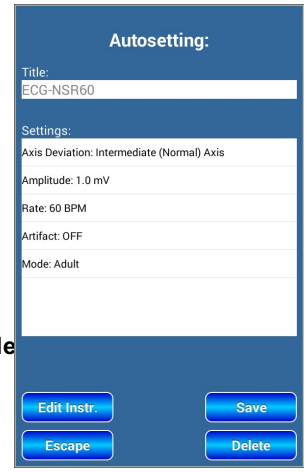


Figure 120

If an existing **AutoSetting** is active when the  icon is pressed, the **Title** box will be pre-filled with the name of an existing file where the parameters are currently stored. This **Title** (filename) can be left unchanged to update the existing **AutoSetting** file, or modified to save the parameters in a new file. A filename that is descriptive should be used so the **AutoSetting** can be easily found and recalled from the pop-up list. Touch 

to commit the changes.

When creating an **AutoSetting**, you have an opportunity to create an **Instruction** that will be visible to the user when on the **Results** screen. Press the **Edit Instr.** button to make the Instructions dialog visible. Touch inside the white text box to activate the keyboard and enter the instruction text. Press **Save** to retain the instruction. Pressing **Close** is equivalent to Cancel and no changes will be retained.

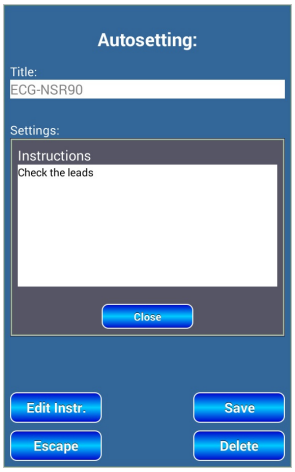


Figure 121

When the Results button is pressed, the Instructions (if any) will be shown on the screen. If you wish to enter any comments for the measurement being recorded, select **Comments** and touch inside the white text window.

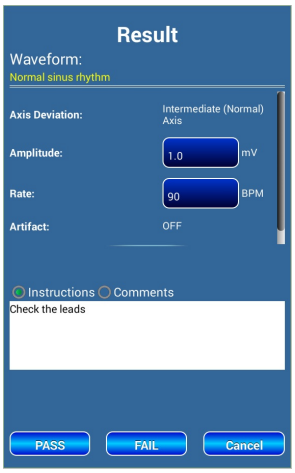


Figure 122

To delete an **AutoSetting**, press the  icon after it is selected, then use 

but

5.2.2 AutoSequences

An **AutoSequence** is a pre-defined series of simulation or performance tests. These tests may involve only one parameter or multiple A1 simulation modules acting in unison.

Each step of an **AutoSequence** is called a **Group**, which consists of one or more **AutoSettings** pulled from various simulation modules (see *5.2.1 - Auto Settings*). For instance, a particular **AutoSequence Group** may define an **ECG** state (**Waveform**, **Heart Rate**, **Amplitude**, etc.) as well as a **Dynamic IBP** waveform and a saved **NIBP Simulation**, all at the same time. The **Group** applies these definitions concurrently, as if they have been simultaneously recalled through their respective **AutoSettings** menus.

Each **AutoSetting** will correspond to a single **Test Result** entry. Users can assign a "PASS" or "FAIL", depending on the response of the **DUT**, or else bypass that prompt to record a "SKIP". After generating a **Test Result** for every **AutoSetting**, the A1 will proceed to the next step and repeat as necessary.

5.2.2.1 Running AutoSequences

Following application start-up, vPad-A1 will display the **AutoSequence** dropdown menu on its **Main** screen.

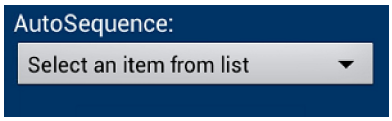


Figure 123

Touching the selection box will display the list of available AutoSequences.

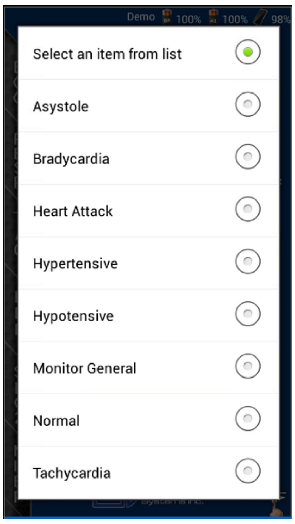


Figure 124

By default, the vPad-A1 will have a number of sample **AutoSequences** pre-installed. Note that these are examples for illustrative purposes only and they can be freely revised, copied or deleted by the user. New **AutoSequences** can be added as required for new equipment or revised procedures. There is no limit to the number of AutoSequences that can be created.

When a valid **AutoSequence** has been selected, the Run button will launch the **Equipment Information** form. It allows users to enter details on the equipment being tested, as described in section *5.1.2.3 - Entering Equipment Information*. To delay this step until the end of the **AutoSequence**, press Later instead.

Figure 125

After the **Equipment Information** form is dismissed, the A1 begins iterating through the **Groups** that comprise the **AutoSequence**. The test will sequentially activate each of the **AutoSettings** in the first **Group**, then go back and display the **Test Result** screen for each simulation or performance test setup in the same chronological order.

For instance, the sample **AutoSequence** "Hypertensive" has one **Group** of **AutoSettings**, which contains setup information for **ECG**, **Respiration**, **Temperature**, **IBP**, **SpO2** and **NIBP**. The **ECG AutoSetting** is first in the Group, so the A1 starts by displaying the **ECG Test Result** interface in *Figure 126*.

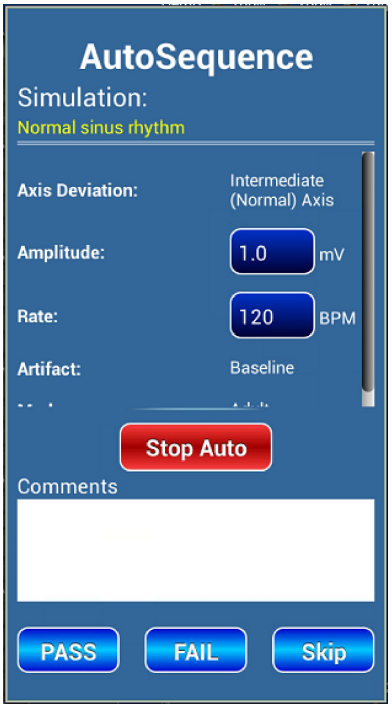


Figure 126

The **Test Result** interface displays all active parameter settings for **ECG** so that users can view them as reference to check the **DUT**'s performance. Refer to section *5.1.2.1 - Creating Test Results* for further details on working with the **Result** interface.

Assigning a "PASS" or "FAIL" will dismiss the current **Result** interface and summon the next **Result** in the Group. Users can also record a "SKIP" for this instance by pressing Skip .

Touch the Stop Auto button if at any time it bec necessary to abort the **AutoSequence**. This will stop any testing in progress and display the "View Results" screen. The most recently displayed **Test Result** entry will be marked as "TERMINATED" and the review window will show only the **Results** assigned up to the point of stoppage.

If the "View Results" screen is from concluding an **AutoSequence**, the options to erase **Result** entries will not be available until users exit and re-enter the "View Results" window. Additional tests or simulations may be added manually to the **Results** buffer unless the user elects to **Clear All** or to create a Test Record.

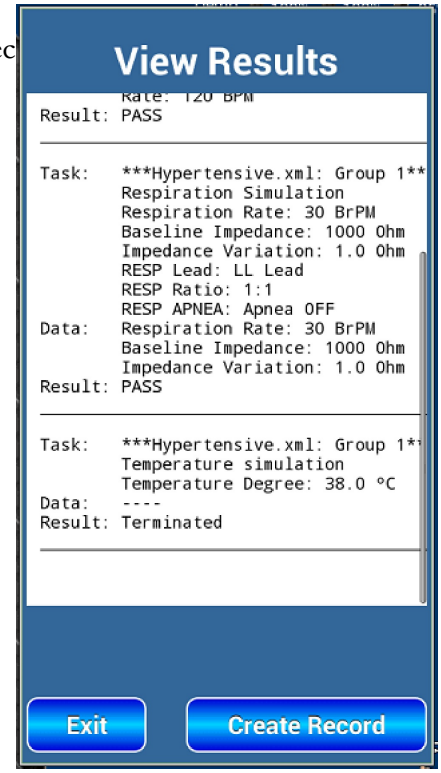


Figure 127

5.2.2.2 Creating and Editing AutoSequences

After an **AutoSequence** has been selected from the list, its name will be displayed in the menu box and the **Run** button will be enabled (turned from gray to green). At this point this **AutoSequence** is available for editing.

There are two main methods to create a new **AutoSequence**: start from scratch, or use an existing sequence as template. In the example following, an sample **AutoSequence** "Hypertensive" will be edited to create a new sequence, and to illustrate the normal process used to create and/or change the sequence groups.

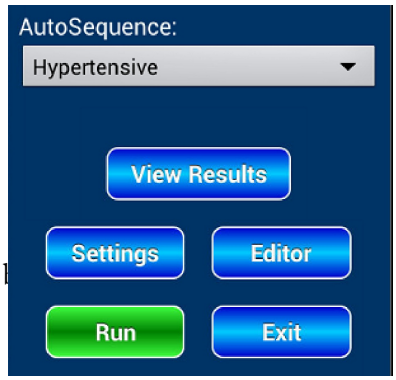


Figure 128

With the item "Hypertensive" visible in the **AutoSequence** list box, touch the 

button and the **Editor** menu will be displayed.

The **Editor** menu is divided into three sections:

- the **AutoSettings** selector;
- the **AutoSequence** tree viewer (for working with **Groups**); and
- the **Action Controls** toolbar

Note that the **Action Controls** toolbar can be enlarged:

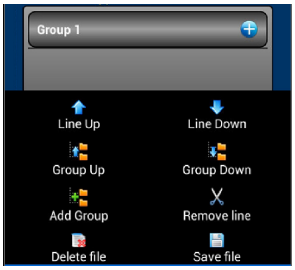


Figure 130

The larger toolbar may be displayed by pressing either of the  buttons at bottom left and right on the screen.

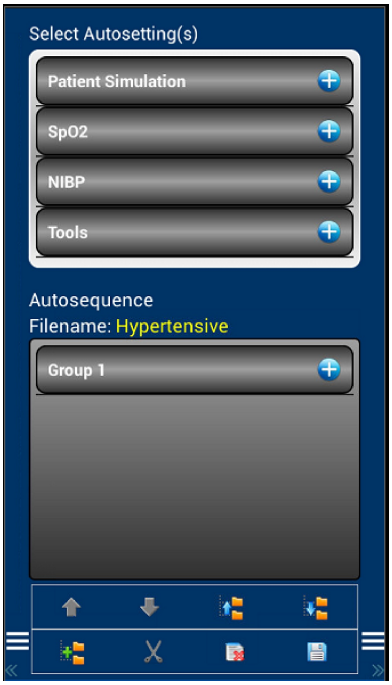


Figure 129

Starting at the top of the screen, the **AutoSettings** are organized by their corresponding A1 simulator modules.

- Patient Simulation (vPad-PS)
- SpO2 (vPad-O2)
- NIBP (vPad-BP)
- Tools (*none*)

Each of these categories will contain the **AutoSettings** that have previously been created for the parameter(s) in the group. For instance, the "Patient Simulation" group can be expanded by touching the icon on the right.

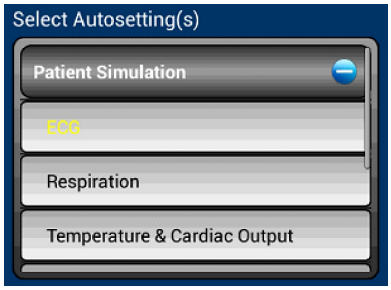


Figure 131

The **AutoSettings** selector will now display the list of parameters generated by the "Patient Simulation" module. This list can be scrolled in the selector box by dragging the items up and down, and it can be collapsed by touching the icon.

Users may recognize the list of sub-categories as the parameter names on the **Main** screen tabbed toolbar (e.g., see *Figure 17* and *Figure 18*). Touching the "ECG" sub-category, for instance, will reveal a full list of **ECG AutoSettings** previously created.

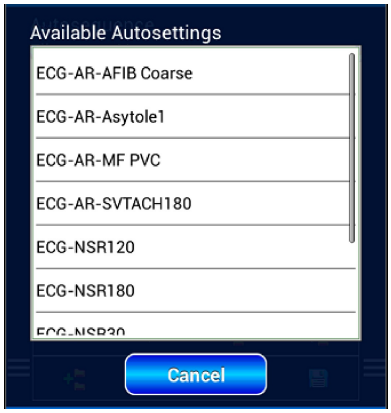


Figure 132

Selecting an **AutoSetting** from the popup list will place it in the active **AutoSequence Group**, if one exists.

Note: Only one **AutoSetting** from any given list can be included in a single **AutoSequence Group**.

The centre section of the **Editor** menu is for displaying and editing **AutoSequence Groups**. The name of the current **AutoSequence** filename will be shown here, along with a list of the **Groups** of concurrent **AutoSettings** contained within the **AutoSequence**.

In the example in *Figure 133*, there is only one **Group** called "Group 1". As with the **AutoSettings** selector, the **Group**(s) can be expanded or collapsed using the icons on a list it

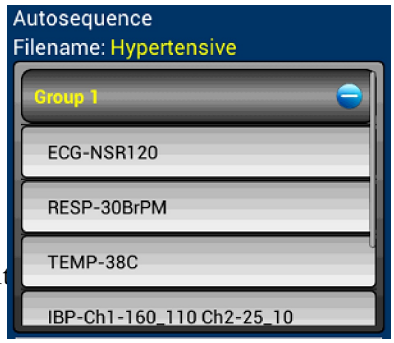


Figure 133

A **Group** or **AutoSetting** entry is considered active when its name is highlighted in yellow. Activate any entry by touching its name bar.

The **Action Controls** section of the **Editor** presents tools for working with the active **AutoSequence Group** or **AutoSetting** entry. Touching and holding a **Group** name bar will allow users to edit the name of the **Group**. The **Action Controls** can be enlarged by pressing one of the buttons at the bottom of the screen.

Figure 134 - Action Controls

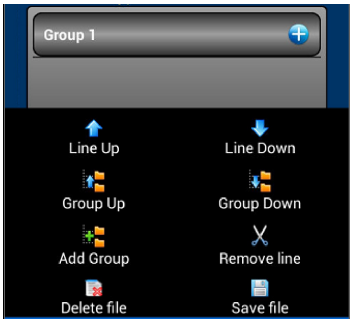


Figure 135 - Large Action Controls Toolbar

Icon	Action
Line Up	Move the active **AutoSetting** entry up one in the list.
Line Down	Move the active **AutoSetting** entry down one in the list.
Add Group	Create a new **Group** in the **AutoSequence**.
Group Up	Move the active **Group** up one in the list.
Group Down	Move the active **Group** down one in the list.
Remove line	Remove the active (empty) **Group** or **AutoSetting** entry.
Delete file	Permanently delete the selected **AutoSequence** file.
Save file	Save or rename the selected **AutoSequence** file.

When working with the **Groups** viewer and **Action Controls**, note the following:

- If users enter the **Editor** without an active **AutoSequence** selected, the **Groups** list will be empty. A user must then add at least a single **Group** before adding **AutoSettings**.
- A **Group** can contain only one **AutoSetting** from each parameters category. To replace an **AutoSetting** with another of the same type, first remove the original **AutoSetting** before adding the new selection.
- The order of **Groups** in an **AutoSequence** will affect the sequence of execution.

- The order of **AutoSettings** in a **Group** will only affect the sequence of appearance for each corresponding **Test Result** interface. **AutoSettings** in a **Group** are always applied in close succession before prompting for their **Results**.

- A **Group** can only be deleted if it contains no **AutoSettings**.

- Default **Group** names can be changed by pressing and holding the **Group** name bar until an input box appears.

Changes made in the **Editor** will not persist if users do not save the file. Saving an **AutoSequence** without changing the pre-populated file name will overwrite the selected template.

When **AutoSequence** editing is complete, return to the A1 **Main** screen by touching the  **Back** button by swiping left on the **Editor** screen.

Note that vPad-A1 can be further automated when used in conjunction with vPad-Check and the VPL procedure system. Refer to the vPad-Check manual (MN-084 vPad-Check Operators Manual, Chapter 4.2 for further details), in particular regarding the use of the ***run*** statement.

Chapter 6

6 Calibration and Maintenance

Calibration of vPad-A1* by a Datrend Authorized Service facility is recommended on an *annual* basis, and is *required* to extend the product warranty. The basic one (1) year warranty on all Simulator and Tester Units can be extended to a maximum of two (2) years provided that annual calibration is performed by a Datrend Authorized Service Center on an *annual* basis. Refer to the Calibration Decal applied to the bottom of each Simulator or Tester Unit to determine calibration status of your vPad-A1.

vPad-A1 contains no user serviceable parts. *Opening the case of vPad-A1 for any reason will void the warranty and may compromise user safety.*

Service must be performed by a factory trained, authorized service agent. This unit may contain hazardous voltages which may cause injury if correct service procedures are not followed.

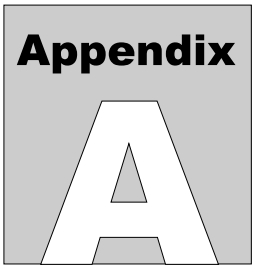
For calibration or service assistance, contact Datrend for a Return Materials Authorization (RMA) number and the location of the nearest Service Facility.

Datrend Systems Inc.
Unit 130 - 4020 Viking Way
Richmond, BC • CANADA • V6V 2L4
Tel 604.291.7747 or 800.667.6557 • Fax 604.294.2355
e-mail **customerservice@datrend.com**
www.datrend.com

vPad-A1 may be cleaned with a soft, lint free, damp cloth using a mild detergent. Use of other cleaning agents on the touchscreen may result in scratching, discolouration, streaking or even failure.

Electrical safety protection of the operator may be compromised if the instructions in this manual are not followed, or if vPad-A1 is used for a purpose not specified in this manual.

* reference to vPad-A1 includes the Base, tablet, vPad-PS, vPad-O2 and/or vPad-BP module(s)



APPENDIX A. Sample Test Record

This appendix provides an example of a vPad-A1 Test Record, illustrating the Result representation for test setup and user entered numerical data, as well as additional comments.

Note: The sample Test Record was generated in **Demo Mode**. Hence, all unit identifiers under **vPad ID** contain the word "DEMO". A normal record will contain real **vPad IDs** matching the serial number decals on each Simulator/Tester Unit, along with the date of the latest calibration.

```
                    vPad-A1 Simulator
                   Datrend Systems Inc.

File: P24601_20160926_125522_P.txt
Date: 2016 Sep 26
Time: 12:55:22
vPad ID:
vPad-A1: VBU-DEMO-BU,2016-09-26
         VSM-DEMO-PS,2016-09-26
         VSP-DEMO-O2,2016-09-26
         VBP-DEMO-BP,2016-09-26

Equipment Information...
Control Number:  P24601
Description:     PATIENT MONITOR
Manufacturer:    MED CORP
Model:           S9001
Serial Number:   30624700
Location:        CARDIAC CARE UNIT
Facility:        CITY GENERAL
Technician ID:   RW
Tech Time (hrs): 0.6
          (min): 35

Overall Result:  PASS


Signature:_____________________________  Date:__________


Detailed Test Data...

_____________________________________________________________

Task:   Normal sinus rhythm
        Axis Deviation: Intermediate (Normal) Axis
        Amplitude: 2.0 mV
        Rate: 80 BPM
        Artifact: OFF
        Mode: Adult
Data:   Amplitude: 2.2 mV
        Rate: 79 BPM
        Amplitude estimated from monitor display.
Result: PASS
_____________________________________________________________

See test comment.

END OF RECORD
```


DATREND
Systems Inc.