vPad-A1™
All-in-One Patient Simulator and Performance Tester

Operating Manual
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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.

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Please note only serialized products (products labelled with a distinct serial number) and accessories are eligible for partial refund and/or credit. Nonserialized 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.

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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

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 nonserialized 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.

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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.
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# Abbreviations and Definitions

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

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<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>µA</td>
<td>Micro-ampere</td>
</tr>
<tr>
<td>A</td>
<td>Ampere</td>
</tr>
<tr>
<td>AAMI</td>
<td>American Association of Medical Instrumentation</td>
</tr>
<tr>
<td>App</td>
<td>Software application for a mobile device</td>
</tr>
<tr>
<td>EUT</td>
<td>Equipment Under Test. The electrical device being tested.</td>
</tr>
<tr>
<td>Hz</td>
<td>Hertz</td>
</tr>
<tr>
<td>IEC</td>
<td>International Electrotechnical Commission</td>
</tr>
<tr>
<td>kHz</td>
<td>kilohertz</td>
</tr>
<tr>
<td>LA</td>
<td>left arm ECG lead</td>
</tr>
<tr>
<td>LL</td>
<td>left leg ECG lead</td>
</tr>
<tr>
<td>RA</td>
<td>right arm ECG lead</td>
</tr>
<tr>
<td>RL</td>
<td>right leg ECG lead</td>
</tr>
<tr>
<td>V</td>
<td>Volt</td>
</tr>
<tr>
<td>V1-V6</td>
<td>Precordial (chest) ECG leads</td>
</tr>
<tr>
<td>Vrms</td>
<td>Volts rms</td>
</tr>
</tbody>
</table>
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:
  • 15°C to 40°C (59°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.
- 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 10th Beat, 80 BPM
- Miss Every 10th 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)
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• 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 5.0 mV 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: Auto or Manual
  (Channel 1 only)
• 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:** 1 BPM
- **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 SpO₂
  - 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 200 mmHg/min
- Inflation: Automatic or Manual
- Pressure: 20 to 400 mmHg
- Elapsed Time: 30 to 600 sec
- Presets: Pressure, Elapsed Time (6 each, user-definable values)
- User-defined AutoSettings: Unlimited

Over Pressure Test:

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

• Adapter/Hoses: Male/Female Luer
  Male/Female Clippard (GE Medical, Draeger/Siemens)
  Colder/CPC (GE Medical, Protocol Systems)
Self Test Accessories:
  Pressure Bulb Assembly (tees into any Cuff Adapter)
  Self system leak test hose (plugged at distal end)
  OBAC Quick Release (Philips Medical)
  Universal 5/32" I.D. Hose
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.
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

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.

**Figure 1**

<table>
<thead>
<tr>
<th>Item</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tablet</td>
<td>Android 5&quot; color LCD tablet with touch screen</td>
</tr>
<tr>
<td>2</td>
<td>Cradle</td>
<td>Snap-in cradle/holder for Android Controller</td>
</tr>
<tr>
<td>3</td>
<td>SPO2 Port</td>
<td>miniDIN8 connector to vPad-O2 (SpO2) accessory module</td>
</tr>
<tr>
<td>4</td>
<td>Power Switch</td>
<td>Power On/Off for all modules</td>
</tr>
<tr>
<td>5</td>
<td>LED Power Indicator</td>
<td>Power and Battery status</td>
</tr>
<tr>
<td>6</td>
<td>Tablet USB Port</td>
<td>Battery charging and data input to Android tablet (microUSB)</td>
</tr>
<tr>
<td>7</td>
<td>Cradle USB Port</td>
<td>Battery charging and data output from cradle (microUSB)</td>
</tr>
<tr>
<td>8</td>
<td>DACOM Port x 2</td>
<td>Proprietary serial data connection to other Datrend vPad products</td>
</tr>
<tr>
<td>9</td>
<td>Battery Cover</td>
<td>Locks the battery into the GUI (base bottom)</td>
</tr>
</tbody>
</table>
The vPad-O2 (SpO2) module is a pulse oximeter tester which connects to the Base module via a miniDIN8 connector. This module provides an artificial ‘finger’ containing light guides which convey light to or from pulse oximeter probes and sensors.

**Figure 2**

<table>
<thead>
<tr>
<th>Item</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Optical Finger</td>
<td>Interface to pulse oximeter sensor</td>
</tr>
<tr>
<td>12</td>
<td>Enclosure</td>
<td>Houses the simulation electronics</td>
</tr>
<tr>
<td>13</td>
<td>Red Indicator</td>
<td>Indicates red light as detected from pulse oximeter sensor</td>
</tr>
<tr>
<td>14</td>
<td>Infrared Indicator</td>
<td>Indicates infrared light as detected from pulse oximeter sensor</td>
</tr>
<tr>
<td>15</td>
<td>Power and Data Cable</td>
<td>miniDIN8 cable to Base module</td>
</tr>
</tbody>
</table>
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**.

**Figure 3**

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

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

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

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.
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](image)

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](image)

**Figure 9**

![Figure 10](image)

**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.

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

**vPad-O2 module:**
- SpO2 – probe on finger sensor
  (with red and infrared LEDs on the same side as the module's "vPad-O2" label)
vPad-A1 OPERATORS MANUAL

vPad-BP module:

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

Figure 13

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.

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.
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

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*.

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.
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.

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.

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.

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.

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.

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').
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.

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.
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*.

- 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**.

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**.
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:

**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 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.
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.

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).

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.

<table>
<thead>
<tr>
<th>Pacemaker Waveform / Rhythm</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial 80 BPM</td>
<td>Atrial pacemaker wave at 80 BPM, with a pacer pulse at the start of each P wave.</td>
</tr>
</tbody>
</table>
### Pacemaker Waveform / Rhythm Description

<table>
<thead>
<tr>
<th>Pacemaker Waveform / Rhythm</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrio-Ventricular Sequential</td>
<td>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)</td>
</tr>
<tr>
<td>Asynchronous 75 BPM</td>
<td>Asynchronous pacemaker wave with continuous ventricular-paced beats (75 BPM) and no P waves</td>
</tr>
<tr>
<td>Demand with Frequent Sinus Beats</td>
<td>A “demand” pacemaker wave with frequent sinus beats (forty normal beats followed by twenty ventricular-paced beats, repeated) (80 BPM)</td>
</tr>
<tr>
<td>Demand with Occasional Sinus Beats</td>
<td>A “demand” pacemaker wave with occasional sinus beats (twenty normal beats followed by forty ventricular-paced beats, repeated) (80 BPM)</td>
</tr>
<tr>
<td>Non-Capture</td>
<td>Ventricular-paced beats, where one out of ten beats has no heart response (75 BPM)</td>
</tr>
<tr>
<td>Non-Function</td>
<td>Continuous pacer pulses at 80 BPM with no heart response.</td>
</tr>
</tbody>
</table>

**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.

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

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**

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

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-Waves 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.

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.

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

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

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

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.

### 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*.

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*.

**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.
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.

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.
4.5.2.1 Static Blood Pressure

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 transducer expected by the monitor.

4.5.2.2 Dynamic Blood Pressure

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 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:

- **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:

<table>
<thead>
<tr>
<th>Insertion ...</th>
<th>Central Venous Pressure</th>
<th>→ Right Ventricle</th>
<th>→ Pulmonary Artery</th>
<th>→ Pulmonary Artery Wedge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extraction ...</td>
<td>→ Pulmonary Artery</td>
<td>→ Right Ventricle</td>
<td>→ Central Venous Pressure</td>
<td></td>
</tr>
</tbody>
</table>

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.

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.

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 Trigger button.
4.6 Pulse Oximetry (SpO2)

4.6.1 General

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).

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.

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.

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.

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

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

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 Stabilization; and 4) Recovery.

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.

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.
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 button launches a new test interface that guides users 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:

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

4.6.4.2 Alarm State

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

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.
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.

The action button returns to the **Start Alarm** state so that users can restart the **Alarm Test** if desired. Restarting erases existing data and returns to the Alarm State described in section 4.6.4.2.

![Figure 75](image-url)
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.
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.

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 79). Once a target is chosen, the module will load the calibration data from an Envelope file that was customized for the active Device.
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.

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 graph 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 the graph. Pressure from that time forward continues to be displayed.

The [ ] button hides the graph. Pressure is updated in the background.

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 / or presses 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

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

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 the Record button to add a 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.

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 PASS and FAIL buttons to set a new Maximum Pressure as many times as necessary. The A1 will actively maintain the pneumatic system pressure until user assigns a PASS / FAIL or Cancel.

• Manual The test begins passively monitoring pressure in the test pneumatic system.

In this Mode, the display unit can be changed to any of the following: mmHg, inHg, kg/cm², cmH₂O, mBar, PSI, inH₂O, or kPa.

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

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**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

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 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

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 initiate the test and show the 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 when it is busy. The test can then be restarted with the Start button.

Figure 88

Figure 89
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.
4.7.5 Leakage Rate

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.
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** screen.

For both **Modes**, the **PASS** button is initially disabled; however, users can assign it if, for 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.
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 button on the A1 Main screen (Figure 17).

4.8.2.1 Power Management

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 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

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

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 SPO2 R-Curve Calibration button in the Settings panel 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).

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 OK.

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**

- 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)

• **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)

• 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**

• 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.

• 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 entry 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 **Edit** button on 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**.

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:
Each time a change is made to an Envelope inflection point, users must press \( \text{button} \) 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.

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.

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 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 button that the displayed Envelope produces the expected readings on the target device, the button will launch a “Save Envelope” form.

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 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 button on the Settings screen launches the Self Test Tool.
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 button or the Start 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 cannot 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.

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

Press the button to dismiss the Result screen without creating a new Test Result entry.

### 5.1.2.2 Reviewing Test Results

Saved Test Result entries can be viewed with the 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 **Equipment Information** form. From this form, the current **Test Results** can be saved to a new **Test Record**.

### 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.

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.

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**.
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 **button**.

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

**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.

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.

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.

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**Figure 114**

**Figure 115**

**Figure 116 - Equipment Description Lookup**

**Figure 117**
5.1.2.4 Creating Test Records

The **Save** button on the Equipment Information form ([Figure 111](#)) 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 Record** 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** memory, 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 **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.

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.

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.

To delete an AutoSetting, press the icon after it is selected, then use the button.
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 - AutoSettings). 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 121](image)

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

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.

![Figure 122](image)
When a valid AutoSequence has been selected, the 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 instead.

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 124.
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 Button](image).

Touch the ![Stop Auto Button](image) button if at any time it becomes 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.

![View Results](image)

*Figure 125*
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.

With the item “Hypertensive” visible in the AutoSequence list box, touch the Editor 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:

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

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.

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 131**, there is only one **Group** called “Group 1”. As with the **AutoSettings** selector, the **Group(s)** can be expanded or collapsed using the and icons on a list item.

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 132 - Action Controls](image)

<table>
<thead>
<tr>
<th>Icon</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Line Up" /></td>
<td>Move the active <strong>AutoSetting</strong> entry up one in the list.</td>
</tr>
<tr>
<td><img src="image" alt="Line Down" /></td>
<td>Move the active <strong>AutoSetting</strong> entry down one in the list.</td>
</tr>
<tr>
<td><img src="image" alt="Add Group" /></td>
<td>Create a new <strong>Group</strong> in the <strong>AutoSequence</strong>.</td>
</tr>
<tr>
<td><img src="image" alt="Group Up" /></td>
<td>Move the active <strong>Group</strong> up one in the list.</td>
</tr>
<tr>
<td><img src="image" alt="Group Down" /></td>
<td>Move the active <strong>Group</strong> down one in the list.</td>
</tr>
<tr>
<td><img src="image" alt="Remove line" /></td>
<td>Remove the active (empty) <strong>Group</strong> or <strong>AutoSetting</strong> entry.</td>
</tr>
<tr>
<td><img src="image" alt="Delete file" /></td>
<td>Permanently delete the selected <strong>AutoSequence</strong> file.</td>
</tr>
<tr>
<td><img src="image" alt="Save file" /></td>
<td>Save or rename the selected <strong>AutoSequence</strong> file.</td>
</tr>
</tbody>
</table>

![Figure 133 - Large Action Controls Toolbar](image)

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.
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.

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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 OPERATORS MANUAL

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