

DATREND Systems Inc.

BIOMEDICAL TEST INSTRUMENTATION

AcuCare (Pty) Ltd

Innovation by Design

ACCURACY MATTERS

DATREND Systems Inc.

BIOMEDICAL TEST INSTRUMENTATION

innovation bydesign

Quality, Dependability, and Value...

Datrend Systems Inc. is a Canadian based biomedical engineering company focused on developing and manufacturing leading edge biomedical instruments and devices for hospitals, clinics, and medical equipment manufacturers. Since our launch in 1991, Datrend has expanded steadily to serve the global markets. Today, we have more than 40 authorized distributors and 10 service centers to serve our customers worldwide.

Datrend subscribes to the regulatory standards and directives of CSA, UL, FDA, and the European CE mark. Products are designed and manufactured following the quality system principles of ISO9001:1994 and FDA QSR/cGMP. Additionally, Datrend's Quality System is registered to ISO13485:2003.



Vision-Pad Technology™

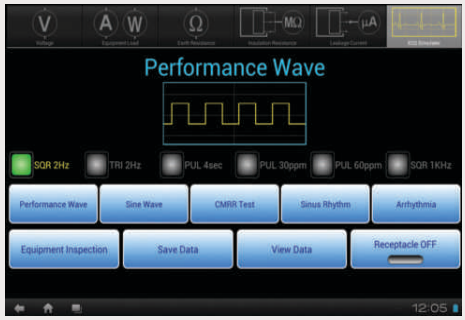
Electrical Safety/Performance Assurance and Preventive Maintenance

The vPad series of electrical safety testing devices combines an Android tablet (wired or wireless) with a measurement platform to create a revolutionary test system. The measurement platform provides the normal assortment of electrical measurements (voltage, current, and resistance) of the commonly used medical Electrical Safety Standards. The Android tablet provides unprecedented usability and scalability. The screenshots here show typical displays with large, easy-to-read measurement results and function selection buttons.









The basic manual safety analyzer is provided in three versions: vPad-ES, vPad-353, and vPad-ES Rugged. The manual versions allow all required parameters to be measured individually. As results are saved, a test record is created. While testing, comments can be added to results as they are saved, and a 25 point Equipment Inspection (ECRI) can be performed. When testing is complete on a device, the test results can be saved as a report.

CMMS Integration

- Complete integration with Computerized Maintenance Management Software (CMMS) Systems to the vPad Safety Analyzers for better management of Preventive Maintenance and Repairs
- Datrend Safety Analyzers communicate with many commercially-available CMMS Systems (AIMS, HEMS, Medimizer, TMS, TMA, Connectiv, and more.)
- Bi-directional communication – download equipment list and/or work orders automatically, complete work orders and upload completed test records back to CMMS Systems
- Local and remote access capabilities
- Supports both web-based and legacy medTester™ type CMMS Systems

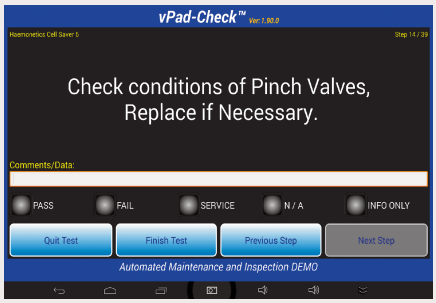
Vision-Pad Technology ™

vPad Apps

vPad-AS, vPad-NFPA, and vPad-A3

Expand your inspection capabilities, standardize your test methods, and reduce testing times

The vPad-AS, vPad-NFPA, and vPad-A3 are fully automated applications for the vPad Series of Electrical Safety Analyzers. These Apps provide the ability to include customizable inspection checkpoints, and user defined electrical safety test sequences to the Standards you require.



User customizable PM Procedure

vPad Check - The ultimate level of automation

Using an user customizable checklist, the auto-sequence can now be any number of tasks, including inspect, measure, electrical safety, user defined images, manufacturer PM instructions, in any order, with pass/fail limits applied.

vPad-EQM - Track equipment and work orders

vPad-EQM is an easy-to-use equipment and work order management App for those without the need for a full CMMS system.

vPad-CAL - Track test equipment inventory and calibration status

vPad-Cal tracks your test equipment inventory, its calibration status, and includes this information in the completed test results.

vPad-STM - Create automated electrical safety tests

vPad-STM™ is a software to create automated electrical safety tests of arbitrary complexity including instances where each medical function may have a differing number of applied parts (patient leads) and protection class (Type B, BF or CF).

vPad-IDE - Customization of PM procedures

vPad-IDE is a PC software free to all users. This simple-to-use application allows users to modify procedures to their business needs by creating and/or customizing PM procedures for the vPad technology.

Other vPad APPS

There are a wide range of vPad-Apps available, each with a different purpose to help our customers to achieve their business goals.

Vision-Pad Technology™

vPad-ES Rugged™

Designed for the Toughest Environments.

Housed in an Extreme Duty case, the vPad-ES Rugged™ offers the functionality and scalability that you have come to expect from Vision-Pad Technology products plus the added assurance of knowing your system will be protected in the harshest of environments. vPad-ES Rugged™ is built into a Crush Proof case and has a lockable latching system with a soft grip foldable handle.

vPad-ES™

A New Era in Biomedical Instrumentation Testing.

Performs tests to ANSI/AAMI ES1, IEC 60601, and NFPA 99-2012 standards.

vPad-353™

Benefit from Tablet Technology!

Performs tests to ANSI/AAMI ES-1, IEC 60601, NFPA 99-2012, as well as IEC 62353, AS3551 standards.



Main Features:

- Hi-resolution Graphical User Interface (1920 x 1200)
- Built in Wireless communication allows for full CMMS integration (local/cloud based)
- Bluetooth connectivity for data transfer
- Configurable to control and retrieve test data from Datrend and 3rd party devices
- Available Automated Electrical Safety Testing with inspection procedure check points





Vision-Pad Technology™

vPad-A1™

The vPad-A1 is an all-in-one patient simulation system that is modular and is comprised of a Multi-Parameter Patient Simulator, a SpO2 test module, and a Non-Invasive Blood Pressure simulation module which may be used together or independently in various combinations, with an Android hand-held device or vPad tablet providing the user interface.

Key Features:

- 12 lead ECG simulation with 9 independent outputs for each signal lead
- 16 total ST Segments: 8 elevated and 8 depressed
- Axis Deviation: Normal (intermediate), horizontal, and vertical
  (Modifies baseline ECG during arrhythmias)
- Neonatal Mode
- ECG Performance Testing
- 60 Arrhythmia selections
- 2 Channel Invasive BP simulation
- Temperature and Respiration simulations
- Pacer simulations
- Cardiac output
- Intra-Uterine Pressure simulation
- Control via Bluetooth or USB
- SpO2 Pulse Oximeter simulator and Non-Invasive BP modules are compatible with all major industry manufacturers
- Auto Settings
- Auto Sequences
- Test reports



Vision-Pad Technology™

vPad-RF™

vPad-RF is the smallest full-featured performance analyzer for the testing of Electrosurgical Units (ESUs) with integrated HF digital storage oscilloscope and spectrum analyzer.

Key Features:

- Digital Signal Processor (DSP) enables accurate testing of all ESU makes and models with continuous and pulsed-waveforms
- High powered HF load provides settings required for all IEC 60601-2-2 tests, including Covidien ForceTriad maintenance procedures
- Wide measurement range - up to 8.5A
- Pre-Configured automated PM routines for most major manufacturers
- vPad-RF can be controlled through vPad Electrical Safety Analyzers for CMMS integration with complete physical, electrical, and ESU testing



Vision-Pad Technology™

vPad-IN™

The vPad-IN is an Infant Incubator and Radiant Warmer Testing System.
Using wireless control, test parameters and test protocols can be measured and modified without disturbing the equilibrium of the testing environment.

Key Features:

- Compatible with closed, forced air convection incubators, and open, radiant infant warmers
- Simultaneous measurement of humidity, airflow, sound, and 6 different temperatures
- All sensors are independently adjustable, to be placed in positions required by the Standard
- Sound level measurements may be taken outside the incubator for external alarm test
- Results can be merged with vPad Electrical Safety Test results and imported into commonly-used CMMS systems
- Digitally controlled heater permits testing of body temperature sensor accuracy



Ventilator Test System

venTest™

venTest™ is designed to accurately test the performance of Ventilators and Anesthetic systems. With a small footprint, data analysis and waveforms are generated on-board and displayed on its 7” touch screen display.

Key Features:

- 7” capacitive widescreen display with LED backlight
- Intuitive graphical operating interface for measuring devices
- FlowSense bidirectional airflow sensor (±300 L/min or ±12 L/min)
- Automatic flow sensor detection
- 2 measured curves displayed simultaneously
- 11 numeric parameters displayed, freely configurable
- Option: oxygen measurement
- Option: anesthetic gas measurement, IRMA AX+
- User configurable test setups
- SD card or USB external memory
- Wireless, Ethernet, and PC network connectivity
- Report formatting and printing
- High Frequency Ventilation testing
- Data logging



Electrical Safety Analyzer - ES601

- Manual & Automated Solutions available
- Integrated ECG & Arrhythmia Simulation
- Internal test record storage
- Automated Testing Sequences for defibrillators, infusion devices, patient monitors, and more...
- Automatic “flagging” of test results that are outside of pre-established test limits
- All Autosequences and Checklists are 100% editable for total procedural customization
- Increases quality and accuracy
- Utilizing automation increases throughput – saves more than 50% over manual testing & hand-written records
- Automated & Manual Electrical Safety Testing per AAMI/ANSI ES-1, IEC 60601 and IEC 62353, and VDE 751 standards
- US and International versions available
- USB, Ethernet, and RS-232 communications
- Optional USB Flash drive storage for expansion of checklists, checkitems
- Test reports and equipment database files

ES601





Pulse Oximeter Tester

Oxitest

The **Oxitest Plus 7** Pulse Oximeter Tester is a portable, battery operated device designed to quickly test the operation of pulse oximeters and their optical sensors and cables.

Defibrillator / Pacer Analyzer

Phase 3

Phase 3 is a portable, automated system for verifying performance of defibrillators with monophasic, biphasic, or Multipulse Biowave® (pulsed biphasic) pulse discharges, including the integrated transcutaneous pacemaker function. Phase 3 provides capability to test delivered energy, charge time, pulse characteristics, AED performance and much more.



Oxitest



Phase 3



Variable Load Module

Infusion Device Analyzers

Infutest 2000 Series E and Infutest Solo

Conduct the full range of flow, pressure, volume, and interval tests on practically any fluid delivery system including single rate, dual rate, and patient-controlled analgesia (PCA) devices.

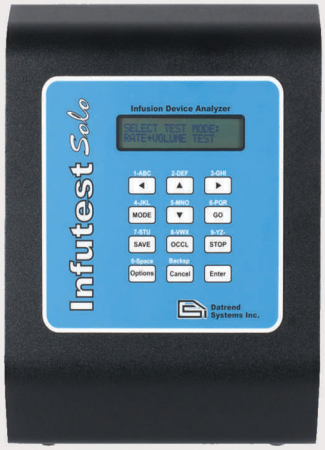
These tests are performed following easy-to-use manual or autosequence formats using the front panel keypad and graphical display.



Remote Sensor Module



Infutest 2000



Infutest Solo

Patient Simulators

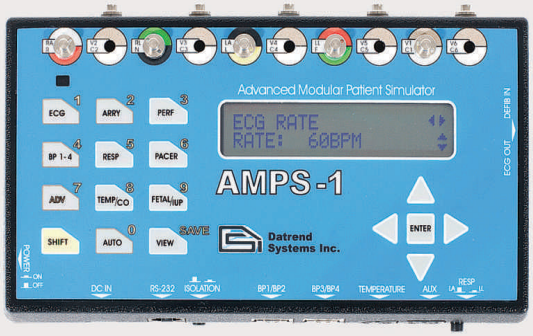
Datrend offers a variety of Patient Simulators, from the quick and easy-to-use 20A to the feature–packed AMPS-1 and FMS-3.

AMPS-1

Advanced Modular Patient Simulator

Add-on Modules include:

- 2 or 4 Electrically Isolated BP Channels, including Swan-Ganz simulation
- Cardiac output
- Mechanical Fetal Heart
- Fetal, Maternal and IUP simulations



AMPS-1

FMS-3

Fetal Maternal Simulator

- Fetal simulation – two direct Fetal ECGs
- Five Maternal ECG leads
- Three Fetal ultrasound channels with “triplets” capability
- Portable, battery-operated



FMS-3

CERTIFICATE OF REGISTRATION

This is to certify that

Datrend Systems Inc.

Unit 130 – 4020 Viking Way, Richmond, British Columbia V6V 2L4 Canada

operates a

Quality Management System

which complies with the requirements of

ISO 13485:2016

for the following scope of certification

Design, manufacture and servicing of electronic equipment for medical applications and for the testing of medical equipment. Originally certified by Intertek on the 22nd of October 2003.

Certificate No.:	CERT-0137631	Original Certification Date:	April 28, 2020
File No.:	1718358	Certification Effective Date:	December 20, 2020
Issue Date:	February 25, 2021	Certificate Expiry Date:	December 19, 2023

Frank Camasta
Global Head of Technical Services
SAI Global Assurance

ISO 13485

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INFORM. INSPIRE. IMPROVE.

DATREND Systems Inc.

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Richmond, BC V6V 2L4 CANADA

EC Declaration of Conformity
EG Konformitäts-Erklärung
Déclaration CE de Conformité
Declaración de Conformidad tipo EC

We, Datrend Systems Inc, declare in exclusive responsibility that the product:
Wir, Datrend Systems Inc, erklären in alleiniger Verantwortung, daß das Produkt:
Nous, Datrend Systems Inc, déclarons sous notre seule responsabilité que le produit:
Datrend Systems Inc declaramos en la responsabilidad exclusiva que el producto:

Model / Modell / Modèle / Modelo: **vPad-Rugged 2 Electrical Safety Analyzer**

to which this declaration relates is in conformity with the following Directives:
auf die sich diese Erklärung bezieht, steht im Einklang mit den folgenden Richtlinien:
auquel se réfère cette déclaration est conforme aux Directives suivantes:
a cuál se relaciona este declaración es conforme a las siguientes Directivas:

2014/30/EU - Electromagnetic Compatibility (EMC)
2014/35/EU - Low Voltage Directive (LVD)

Standards used:
Verwendete Standards:
Normes utilisées:
Normas utilizadas:

EN 55011
EN 61000-3-2
EN 61000-3-3
EN 61000-4-2
EN 61000-4-3
EN 61000-4-4
EN 61000-4-5
EN 61000-4-11
EN 61010-1

Lloyd Van't Haaff
Quality Manager


DUT
vPad-RF
Load Current
0.549 A

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Datrend subscribes to the regulatory standards and directives of CSA, UL, FDA, and the European CE mark. Products are designed and manufactured following the quality system principles of ISO and FDA QSR/cGMP. Datrend's Quality System is registered to ISO 13485:2003.

ISO13485:2003 Registered

DATREND Systems Inc.

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