DATREND
Systems Inc.

vPad-IV™

Modular Infusion Device Analyzer

App Version 5.01.x

Operating Manual

MN-138b

vPad-IV™
Modular Infusion Device Analyzer
Operating Manual

DATREND
Systems Inc.

	Revision History	
Revision	Description	Date
A	Initial release	2021-May-31
B	Added precaution on the usage of tap water.	2024-May-09

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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.

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

Return Procedure

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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 and Product Support

Datrend Systems Inc. ("DSI") warrants each Module of vPad-IV (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 PC: per tablet manufacturer's original warranty
- Standard Accessories: 90 day limited warranty
- Damage to Module caused by use of incompatible test fluids or cleaning agents is not covered under the warranty
- Water/fluid damage to tablet PC is not covered under warranty
- Re-calibration of the instrument, which has a recommended annual calibration frequency, is not covered under the warranty.

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

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

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

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

DSI will not be responsible for lost shipments or instruments received in damaged condition due to improper packaging or handling. All warranty claim shipments must be made on a prepaid basis (freight, duty, brokerage, and taxes). No returns will be accepted without a Return Materials Authorization ("RMA") number. Please contact Datrend (refer to Chapter 5 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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Table of Contents

Abbreviations and Definitions

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

App
Application software that causes a computer or tablet to perform tasks for vPad product users.

Basal delivery
A continuous ongoing infusion of an IV fluid delivered at a relatively low rate. A basal infusion may be periodically interrupted for more rapid delivery of a bolus dose of the same IV fluid or medication. See also "bolus", "PCA" and "IV".

Bolus
A single dose/delivery of medication given to a patient in a short period of time.

Channel
An identification or reference number shown by the vPad-IV app which represents the vPad-IV Controller unit or a Module. The channel number corresponds to a numeric readout which is on the front of the Controller or Module.

Controller
A type of vPad-IV Module which interfaces with the tablet and which provides means for the tablet to work with up to five additional Modules in the system. A vPad-IV system will always include at least the Controller. See also "Module".

Data Log
A text file in comma-separated variables or "CSV" format which contains the individual measurements of time, volume, flow and/or pressure acquired over the course of a test.

Dose
A preset volume of medication or other solution to be dispensed from an infusion device. After the dose is delivered, the infusion device will automatically stop pumping or alternatively change to "KVO" delivery mode. See also "KVO" and "VTBI".

DUT
Device Under Test. The infusion device being tested.

IEC
International Electrotechnical Commission

in.H_2O
inches of water

IV
intravenous

kPa
kilopascals

KVO
Keep-Vein-Open; an infusion delivered at a relatively low rate for purposes of preventing a clot or other occlusion from developing at the needle tip inside the vein.

Luer
A fluid connector having male and female parts which are sometimes threaded to provide a "lock", and which are typically found on IV sets, syringes, and hypodermic needles; see also "Set".

mbar	millibar
ml	milliliter
ml/h	milliliter per hour
mmHg	millimeters of mercury
Module	A unit which measures flow, volume, pressure and time. There may be up to six Modules in a vPad-IV system. One of the Modules will always be the Controller Module. See also "Channel" and "Controller".
PCA	Patient-Controlled Analgesia, a method of enabling a patient to administer their own pain relief by means of a programmable infusion device which responds to the patient's control. An overriding delivery schedule is programmed into the PCA pump by the prescribing clinician, so that overdose is prevented.
Piggyback infusion	A delivery schedule which may be programmed into some infusion devices, comprising infusion of primary and secondary doses. The piggyback delivery begins with infusion of the preset dose of *secondary* medication, which is then followed by infusion of the *primary* medication. See also "primary" and "secondary" dose.
Primary dose	A preset amount of primary medication to be delivered as part of a piggyback infusion. The primary medication is dispensed *after* the preset dose of secondary medication has been delivered. See also "piggyback infusion" and "secondary dose".
Priming	The act of preparing a vPad-IV module for use, purging air within the module by filling it completely with water.
psi	Pounds per square inch
Occlusion pressure	The maximum pressure which can be developed by an infusion device when delivering into an IV line that has been completely blocked or occluded. Most infusion devices will stop pumping and produce an audio-visual alarm if the occlusion pressure limit is reached or exceeded during a delivery.
Secondary dose	The secondary medication to be delivered as part of a piggyback infusion. The infusion device delivers the preset secondary dose first, after which the infusion device automatically changes the rate and begins delivery of the primary medication. See also "piggyback infusion" and "primary dose".
Set	A single-use assembly of plastic tubing through which an infusion device will deliver medication or other solution to a patient. Sets may be specific to the make and model of infusion device with which they are used, and may include various components such as clamps, valves, chambers or "cassettes" and so on.
Stopcock	A tee-shaped fluid connector providing a rotatable control to connect two of the available ports while blocking flow from the third port.

VTBI	Volume-To-Be-Infused; a preset dose of medication or other solution to be dispensed from an infusion device. After the VTBI is delivered, the infusion device will automatically stop pumping or alternatively change to "KVO" delivery mode. See also "Dose" and "KVO".
µl	microliter

Symbol Definitions

The following symbols may be found on vPad-IV:

⚠ CONSULT ACCOMPANYING DOCUMENTS

The Operating Manual provides valuable information on the proper use of vPad-IV. It is highly recommended the operator read the instructions thoroughly before operating the device. It is possible to damage vPad-IV and/or cause harm to the operator if vPad-IV is used incorrectly. Note that the operating manual is incorporated into the vPad-IV app and may be accessed through the app's "Help" function.

⚠ IMPORTANT: Recommended test fluid is distilled water or clean drinking water

This label appears on the left panel of each vPad-IV Module. The test fluid recommended for use with vPad-IV is distilled water or clean drinking water, for example, bottled water which is demineralized and not carbonated. DO NOT use saline, dextrose, coloured fluids or opaque fluids with vPad-IV, or connect IV sets to vPad-IV which may have been contaminated by such fluids. Failure to observe these instructions may result in damage to the internal flow sensor which is not covered under warranty. Further instructions with respect to the test fluid may be found in Section 3.5 of this manual. In some cases, cleaning the flow sensor may overcome the detrimental effects of contamination by an incompatible fluid; refer to Chapter 5, Calibration and Maintenance, for further instructions.

⚠ INPUT

This labelling appears at the fluid input on the front panel of each vPad-IV Module. Refer to the instructions above with respect to test fluids. Additionally, do not apply a pressure exceeding +2600 mmHg (50 psi or 344 kPa), or a vacuum less than -260 mmHg (-5 psi or -34.4 kPa), to the INPUT as doing so may create a safety hazard for the operator and/or cause damage to internal components of the Module.

⚠ CAUTION: Refer servicing to qualified personnel.

This warning appears on the serial number label of each vPad-IV Module. Users should read the Operators Manual to determine what actions to take in the event of failure of the vPad-IV analyzer or app software. Further instructions may be found in Section 3.6, Troubleshooting, and Chapter 5, Calibration and Maintenance.

Chapter

1
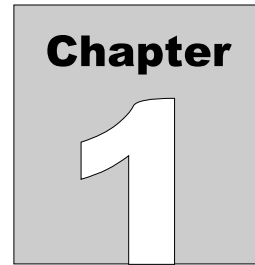
1   Specifications

Equipment Performance Specifications

1.1 Instrument Specifications

1.1.1 Flow Rate Measurement

Method .... Flow is calculated by measuring volume over time
Range .... Measured: 0.1 ml/h to 3000 ml/h
                                                                   Displayed: 0.01 ml/h to 3200 ml/h
Maximum display resolution ...... 0.001 ml/h
Accuracy .... $\pm$(1% + 0.005 ml/h) at 0.1-9.9 ml/h for volume > 100 μl;
                                                                   $\pm$1% at 10-1200 ml/h for volume > 1 ml;
                                                                   $\pm$2% at 1201-3000 ml/h for volume > 10 ml

1.1.2 Volume Measurement

Method .... Volume is measured directly in sample sizes of 20 μl
Range .... 0 to 9999 ml
Maximum display resolution ...... 0.01 ml
Accuracy .... $\pm$(1% + 1 LSD) at 0.1-9.9 ml/h for volume > 100 μL;
                                                                   $\pm$(1% + 1 LSD) at 10-1200 ml/h for volume > 1 ml;
                                                                   $\pm$(2% + 1 LSD) at 1201-3000 ml/h for volume > 10 ml

1.1.3 PCA Bolus or Piggyback Dose Measurement

Method .... See volume measurement above
Min. detectable bolus or dose .... 0.5 ml
Bolus or dose uncertainty .... $\pm$10 μL for volume > 0.5 ml
PCA pump trigger output
    Physical .... 3.5 mm monaural phono jack
    Electrical .... SPST normally-open contact, rating 30V/300 mA

1.1.4 Pressure Measurement

Range
   General .... -260 to +2600 mmHg
   Back Pressure .... -100 to +300 mmHg operational range
Accuracy .... $\pm$(1% + 5 mmHg)
Selectable units .... mmHg, psi, bar, mbar, kPa, in.H_2O, torr
Barometric compensation .... 715 to 1095 mbar

1.1.5 Time Measurement

Elapsed Time Range .... 0 to 240 hours
Elapsed Time Accuracy .... $\pm$0.5 seconds
Elapsed Time Format .... HHH:MM:SS
PCA Lockout Time Range .... 1 to 240 minutes
PCA Lockout Time Accuracy ..... $\pm$0.05 minutes

1.1.6 Fluid Ports

Input .... Luer lock female
Output .... Hose barb, for 1/8" I.D. tubing
Material ....Stainless or nickle-plated steel

1.1.7 Communication Interface Ports

Controller Module
   To Tablet .... USB-A receptacle
   PC Remote .... USB-B receptacle
   vPad XBUS RJ12-6p6c
Controller and Accessory Modules
   vPad-IV bus RJ45-8p8c

1.2 User Interface

Display .... 10.1" colour LCD (minimum 1280 x 800 resolution)

User Controls .... Capacitive touchscreen

Wired Connectivity .... microUSB OTG or USB Type C (tablet model dependent, shared with analyzer interface)

Wireless Connectivity .... WiFi (802.11)
Bluetooth

Memory, Internal .... Minimum 1 GB available for user data storage

Memory, Expansion .... By micro SD Card (8 GB or more, tablet model dependent); FAT32 LFN format

Equipment Technical Specifications

1.3 Electrical Ratings

90 to 264 V ac rms, 47 to 63 Hz, 60VA max.

1.4 Fuses

Internal, not replaceable by user

1.5 Environment for Use

15 to 40 °C
10% to 90% RH
Indoor use only
Pollution Degree 2
Maximum altitude 3000 meters

1.6 Dimensions

Tablet PC (detached) .... 27 x 17 x 1.3 cm (10.5 x 6.7 x 0.5 in.)
Single-channel configuration .... 11.2 x 20.0 x 23.6 cm (4.4 x 7.9 x 9.3 in.)
Dual-channel configuration .... 16.3 x 20.0 x 23.6 cm (6.4 x 7.9 x 9.3 in.)
Three-channel configuration .... 21.3 x 20.0 x 23.6 cm (8.4 x 7.9 x 9.3 in.)
Four-channel configuration .... 26.4 x 20.0 x 23.6 cm (10.4 x 7.9 x 9.3 in.)
Five-channel configuration .... 31.5 x 20.0 x 23.6 cm (12.4 x 7.9 x 9.3 in.)
Six-channel configuration .... 36.6 x 20.0 x 23.6 cm (14.4 x 7.9 x 9.3 in.)

1.7 Weight

Single-channel configuration .... 1.34 kg (2.95 lbs.)
Dual-channel configuration .... 2.32 kg (5.10 lbs.)
Three-channel configuration .... 3.30 kg (7.25 lbs.)
Four-channel configuration .... 4.28 kg (9.40 lbs.)
Five-channel configuration .... 5.26 kg (11.55 lbs.)
Six-channel configuration .... 6.24 kg (13.70 lbs.)

1.8 Standard Accessories

Vision-Pad Tablet ....P/N 7050-128
Tablet Stand .... P/N 5550-106
Tablet Charger .... P/N 3000-087
Charger Blade Set .... P/N 7500-491

Power Supply, 12VDC 60VA .... P/N 3000-103

Power Cord (country specific):

North America (Nema 5-15P) 3000-471	Denmark (Type K) 3000-013
United Kingdom (Type G) 3000-004	Israel (SI-32) 3000-014
Australia/China (Type I) 3000-005	Switzerland (SW1-10P) 3000-473
Europe (Schuko) 3000-006	Brazil (BR2-10P) 3000-474
India/South Africa (Type M) 3000-007	Chile (Type L) 3000-475

vPad-IV input/output tubing set (one per module) .... P/N 7300-004

USB-A OTG adaptor .... According to tablet model:
P/N 3140-390 (microUSB); or
P/N 3140-391 (USB-C)

USB-A to tablet cable .... According to tablet model:
P/N 3140-396 (microUSB); or
P/N 3140-500 (USB-C)

Interconnection cable
(provided with secondary/optional module only) .... P/N 3140-071

Accessory Bag
(provided with primary/controller module only)............................ P/N 7006-066

1.9 Optional Accessories

For a complete list of available accessories, visit www.datrend.com or contact Datrend Customer Service (see Chapter 5 for contact details)

1.10 Compliance With Standards

vPad-IV is in compliance with these safety standards:

CAN/CSA-C22.2 No. 61010-1-(2nd Edition) - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements

UL Std. No. 61010-1 (2nd Edition) - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements

Following manufacture, all units are subjected to, and have passed the requirements of the 'Routine Tests' defined in Annex F of the above Standard(s).

Chapter

2

2   Overview

The Vision-Pad Automated Infusion Device Analyzer, or **vPad-IV™**, enables inspection and testing of all types of infusion devices, including syringe pumps, cassette pumps, linear and rotary peristaltic pumps, enteral feeding pumps, ambulatory infusion pumps, and patient-controlled analgesia (PCA) pumps. A vPad-IV system will provide a Vision-Pad tablet and a vPad-IV Controller, and it may optionally include one, two, three, four or five "secondary" vPad-IV Modules. The tablet runs the vPad-IV software application or "app" which provides a user interface for the system. The Controller and optional Modules measure fluid flow and pressure and are referred to as *channels*. *Figure 1* shows an example vPad-IV system providing the maximum number of channels.
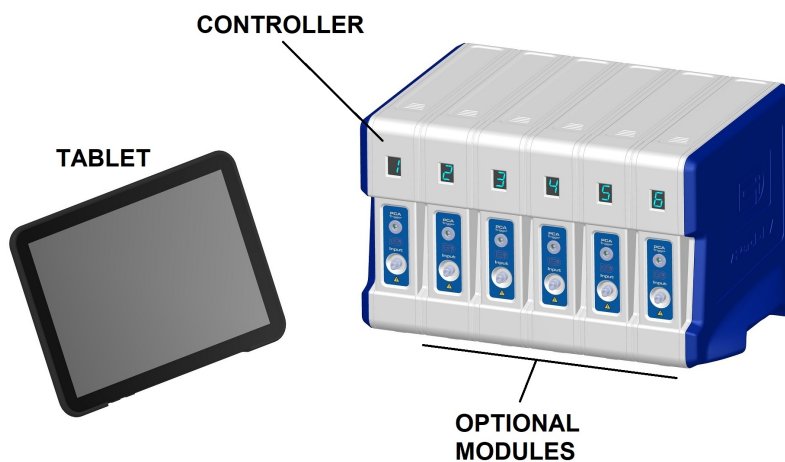
CONTROLLER

TABLET

OPTIONAL MODULES

Figure 1

vPad-IV enables users to conduct tests on up to six different infusion devices simultaneously. Channels may be optionally linked to streamline testing of infusion devices which incorporate multiple pumps within a single unit. AutoSequence mode provides user-customizable protocols which integrate inspection and maintenance steps with automated tests of flow, volume and pressure. Results of a test or AutoSequence may be saved as a Test Record for later review or transfer to a maintenance management system. Equipment information and test setup can be recalled automatically from Equipment Records which are stored locally on the tablet. Such records are created or updated as tests of infusion devices are completed with the analyzer.

2.1 Modules and Channels

The vPad-IV Controller and optional "secondary" Modules measure flow, pressure and time and are represented by the app software as *channels*. Any configuration of vPad-IV will include at least a Controller, which is a "primary" Module providing extra features that enable the tablet to interface with up to five "secondary" Modules in the system. Each Module is set to a unique channel number which is indicated by a LED display on the front panel. Per *Figure 1*, in most setups the Controller is typically assigned to channel number *one*.

At startup, the vPad-IV app searches for attached Modules and accordingly enables or disables corresponding channels as shown on the left of the tablet screen (*Figure 2*). Enabled channels are selectable via the highlighted number icons at left; disconnected or absent Modules are represented by greyed-out icons and the corresponding channels are not selectable.
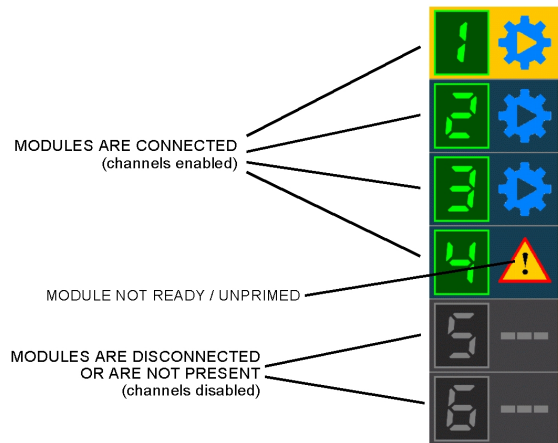

MODULES ARE CONNECTED
(channels enabled)

MODULE NOT READY / UNPRIMED

MODULES ARE DISCONNECTED
OR ARE NOT PRESENT
(channels disabled)

Figure 2

Once the app has started up, each enabled channel is then monitored by the app and its status is represented as an icon beside the channel number. A ⚙ icon ("setup and run") means the corresponding Module is idle and is ready to perform a test. A ⚠ icon ("alert") typically indicates the corresponding Module requires *priming*; for further information on vPad-IV setup and priming, see Chapter 3 on page 13.

2.2 Test Setup

If a Module is ready to run a test, selecting its channel in the app displays the Test Setup menu. Test setup begins with input of a device control number or ID, which will identify the **Test Record** and **Equipment Record** that will be created when testing of the device is completed. In addition to the ID, users may optionally enter other equipment information such as make, model, serial number and so on.

To simplify testing of an infusion device which incorporates multiple pumps within a single unit, vPad-IV channels may be optionally *linked* so that a test configuration which has been set on one of the channels will be copied to all linked channels when the test is started.

After input of a device ID and optional entry of equipment information, test setup continues with selection of a test type: **Flow Rate**, **Piggyback / KVO**, **PCA Pump**, or **Occlusion Pressure**.

2.3 Test Types

vPad-IV provides four test types.

The **Flow Rate Test** measures flow and volume of a dose delivered at a single rate.

The **Piggyback / KVO Test** measures an infusion having two distinct rates of delivery, where the first delivery is infused at a substantially greater rate than the second delivery.

The **PCA Pump Test** measures the bolus output and lockout timing of a patient-controlled analgesia (PCA) pump, with optional measurement of a basal flow which may occur between bolus infusions.

Finally, the **Occlusion Pressure Test** determines the maximum pressure developed by an infusion device when it pumps into a blocked IV line.

While any test is in progress, vPad-IV periodically displays measurements of flow, volume and pressure, which are then summarized on completion of the test to create a **Test Record**.

2.4 Automatic Testing

After selecting a test type, a channel may be configured to perform the test automatically. An automatic test requires input of infusion device settings such as flow rate and volume-to-be-infused (VTBI) or dose, along with a choice of how the test will be ended. Depending on the infusion device settings and tolerance entered at the start of the test, the app will automatically assess the measurement results and assign a PASS or FAIL to the Test Record when the test is completed.

2.5 Manual Testing

A vPad-IV channel can be configured to run a test manually. Simply select the test type, switch to manual mode, and start the test. The manual test will continue until it is stopped by the user, at which time the user will be asked to enter the infusion device settings and to choose a PASS or FAIL result for the Test Record.

2.6 Test Monitoring

The vPad-IV app provides various display modes for monitoring a test in progress. Users can switch between numerical readouts and a real-time graphical representation of acquired measurements. For analyzers with multiple Modules, the "View All" display shows an overview for all enabled channels which includes the current status and measured values for each channel.

2.7 AutoSequences

AutoSequences combine one or more automated tests of flow, volume or occlusion pressure with user-customizable prompts and inspection checkpoints. An AutoSequence can be selected from the Test Setup menu in the same manner as an automatic test or a manual test.

2.8 Test Records

Infusion device tests and AutoSequences create **Test Records** which are saved on the tablet. Test Records are files which can be later reviewed, printed, or exported to a computerized maintenance management system (CMMS). Test Records are identified by the ID or "control number" of the infusion device, which is entered at the start of each test or AutoSequence. When channels are *linked* for testing of a multi-pump infusion device, the results from the linked channels are combined into a single Test Record identified by the device ID. Users may view and manage Test Records with the **vPad Record Manager**, a standard app included with each vPad product.

2.9 Equipment Records

Each time vPad-IV completes a test and saves a Test Record, an **Equipment Record** is also saved. Equipment Records are identified by the ID or "control number" of the infusion device, which is entered at the start of each test or AutoSequence. Equipment Records may include the device manufacturer; model; serial number; location; facility or owner; and so on as optionally entered by the technician at the start of a test. In addition to the equipment information, each Equipment Record contains a reference to a *test setup* that was used to evaluate the device.

When a new test is started, input of a device ID or control number causes the vPad-IV app to search for a corresponding Equipment Record. If an Equipment Record is found, the user is given the option of recalling the equipment information and test setup from the Record. This saves time when starting a new test for an infusion device which has been previously tested by vPad-IV.

2.10 Settings and Options

The vPad-IV app offers many customizable settings for analyzer operation, user convenience, and organizational needs. Under the Settings menu of the app, you will find AutoSequence customization, Test Record preferences, and editors for pick-lists used by the equipment information menu.

Chapter

3

3   Setup

This chapter explains how vPad-IV Modules are assembled and primed in preparation for infusion device testing.

3.1 Assemble the Analyzer

Identify the **vPad-IV Controller** or Module #1, as indicated by the removable adhesive label applied to the front of the unit. You can also identify the Controller by the USB communication ports on its rear panel. If you will be assembling a multi-channel analyzer, remove the Controller's left side panel as viewed from the rear, by depressing the left thumb lock and sliding the panel toward you (see *Figure 3*). Slide and lock additional "secondary" Modules into place next to the Controller, in order starting with Module #2 and proceeding up to Module #6, as identified by removable adhesive labels on the front of each secondary Module. *Figure 3* through *Figure 10* below show the assembly of an example system providing three channels; assembly of an analyzer with fewer or more channels will be similar to what is shown in the figures. Note the Controller and each secondary Module provide an index line (shown in red in the figures) which indicates the starting position for the sliding motion.
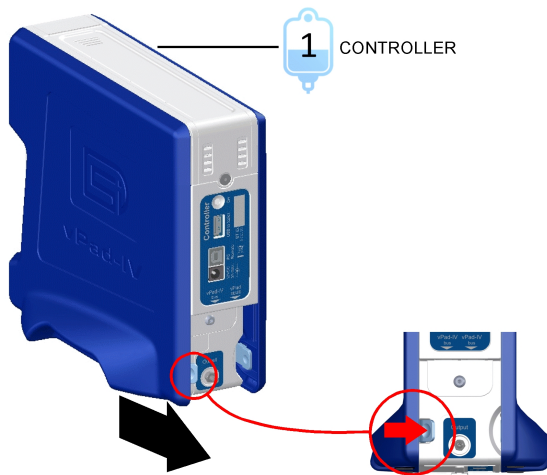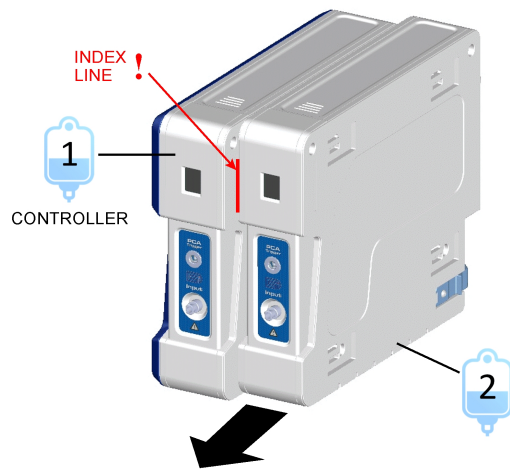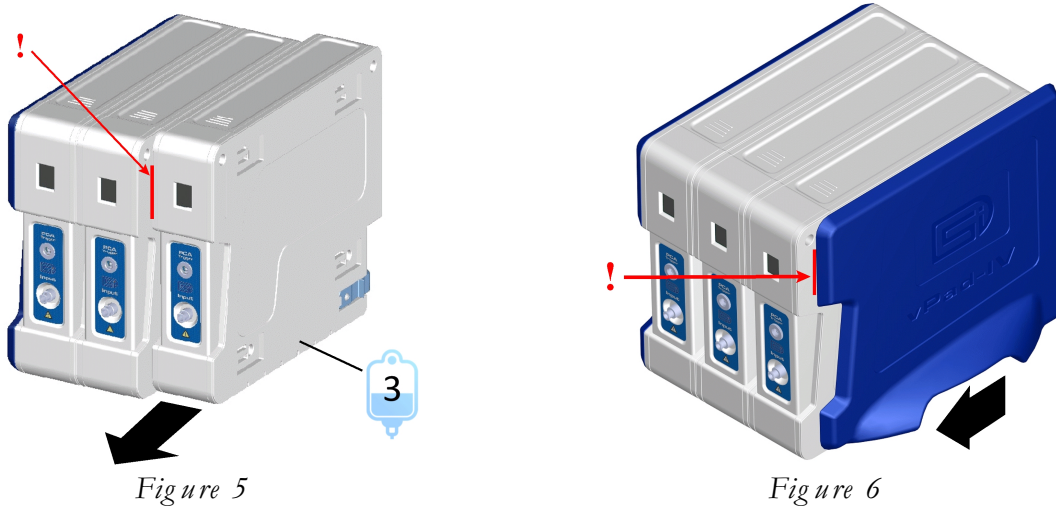
Figure 3

Figure 4

Once all secondary Modules have been attached (*Figure 5*), slide and lock the previously-removed side panel into place, so that the right side of the analyzer assembly is then covered (*Figure 6*). The temporary numeric label applied to the front of each Module may now be removed.

Figure 5

Figure 6

Check the completed assembly to verify that all components are fitted snugly and securely together.

3.2 Connect Cables and Power Supply

If you are assembling a multi-channel analyzer, use the interconnect cables provided with the Modules to connect the **vPad-IV bus** jacks at the rear of the assembly, for example as shown *Figure 7* for a three-channel setup.

Figure 7

As shown in *Figure 7*, the Controller provides a **vPad XBUS** input, which is not connected to other Modules but is intended for interface with a vPad Rugged safety analyzer or other vPad products. The **PC Remote** USB port on the Controller is used for remote control of vPad-IV from a PC.

If you prefer the vPad-IV tablet to control the analyzer via a wired connection, use the USB cable provided with the Controller to connect the **USB to tablet** port on the rear panel to the USB port of the tablet (*Figure 8* and *Figure 9*). If you prefer the tablet to control the analyzer via Bluetooth, then this USB connection is not needed. Note, however, the USB connection may be used to recharge the tablet when it becomes necessary to do so.
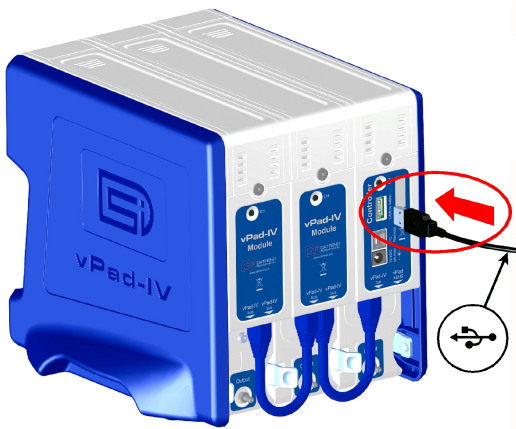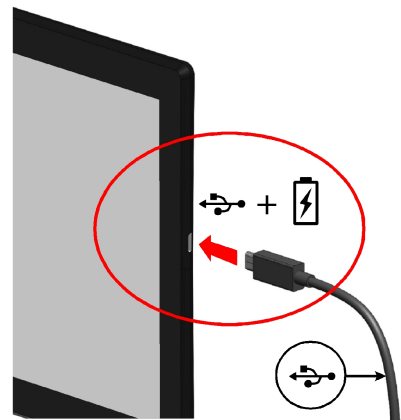
Figure 8   *Figure 9*

Connect the power supply provided with the Controller to the **12VDC** input on the rear panel (*Figure 10*), then use the line cord provided with the power supply to connect it to a nearby AC mains receptacle (*Figure 11*). The front panel of each Module should now display a unique channel number (1, 2, 3...).
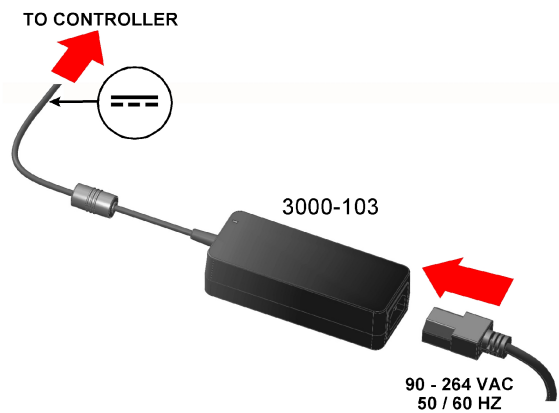
Figure 10   *Figure 11*

3.3 Check Tablet Communication

If the Vision Pad tablet is powered OFF, power it ON now. To do so, press and hold the ON/OFF button until the tablet vibrates and/or the screen becomes lit, then release the button (*Figure 12*).
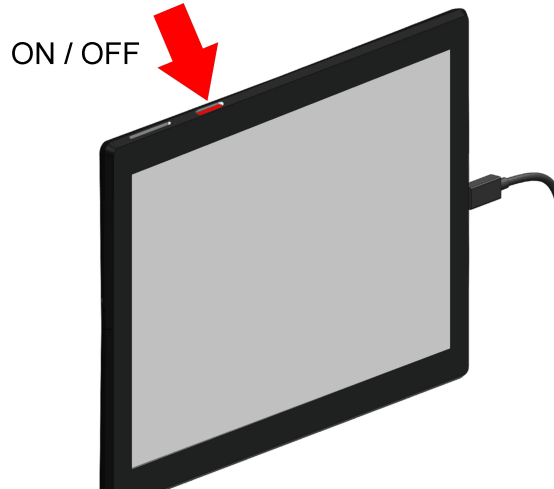

Figure 12

Once tablet startup is complete and the HOME screen is displayed, run the vPad Settings app ⬡ . Under "Device Setup" on the left, select "vPad-IV Pump Tester". Verify **Connected** status appears at the upper right corner of the tablet (*Figure 13*). Close vPad Settings after verifying the connection.

Figure 13

3.4 Powering OFF and Disassembly

To power OFF the tablet, press and hold the ON/OFF button (*Figure 12*) until a confirmation message appears on the tablet screen. Select the appropriate response to complete the Power Off sequence.

Note: Pressing and releasing the Power ON/OFF button momentarily will put the tablet in a 'sleep' mode. Press the ON/OFF button momentarily again to 'wake' the tablet. This is NOT the same as OFF.

If the analyzer is primed, it will be necessary to drain the water from each Module to enable full disassembly of the system. **DO NOT** drain by using a syringe to withdraw the water from the Luer input port as excessive or extreme suction may result in damage to internal sensors. Instead, use a syringe to inject *air* into the input until all water within the unit has been ejected, as observed at the output of the Module.

Disassemble the analyzer by reversing the assembly procedure. Power OFF the system, then disconnect all cables and tubing sets. Note that when input and output fluid connections are removed, if the Module is not already empty it will self-drain and release a small volume of water (about 3 ml).

Disassemble Modules by unlocking and then sliding Modules apart. To unlock, depress the thumb catch at the rear of each Module, beside the fluid Output port (see *Figure 14*). Note that for the left side panel (which appears on the right in *Figure 14*), the thumb catch is located *inside* the panel, as indicated by the figure.

Figure 14

| **CAUTION:** | Damage to vPad-IV caused by failure to observe the above instructions for proper draining and disassembly will not be covered under warranty. |

3.5 Fluids, Connections and Priming

3.5.1 Compatible Test Fluids

<div style="border:1px solid black">

CAUTION: use only distilled water or clean drinking water with vPad-IV

</div>

Distilled water is the preferred test fluid for vPad-IV. Bottled drinking water may also be used provided the water is demineralized and is not carbonated. Domestic water (i.e. "tap water") **should not be used** unless it is verified to be clean, transparent and low in mineral content. At a minimum, domestic water should be processed using a domestic water processing unit such as "Britta", "Rain Fresh" or "Vita Pure" (North America) or equivalent . Water processed with reverse osmosis is also acceptable.

Ideally the water should be de-gassed, or at minimum it should not contain visible air bubbles as such bubbles may interfere with the flow measurement process. Accordingly, if water is drawn from the cold faucet, it should be allowed to warm up to room temperature in an open container for a period of time so that any dissolved air is released. Warming the water while gently stirring can help release trapped air.

Store the water at room temperature in a closed container to prevent contamination with dust, mould and bacteria. Keep the storage container away from direct sunlight to avoid stimulation of algal growth.

DO NOT use a medical solution such as physiological saline, lactated Ringer's injection, dextrose in water (D5W or D50W), TPN solution and similar fluids with vPad-IV. **DO NOT** connect IV administration sets or other tubing which may have been contaminated with such solutions to vPad-IV. Viscous fluids and fluids which have a sticky or oily quality will prevent the flow sensor in vPad-IV from functioning correctly.

<div style="border:1px solid black">

Damage to vPad-IV caused by use of an incompatible fluid, or an IV set which has been contaminated by such fluid, is not covered under warranty.

</div>

Failure to observe these recommendations may result in inaccurate, intermittent or erratic measurements of flow and volume. The effects of contamination with a soiled or incompatible fluid can be overcome in some cases by cleaning the **glass flow sensor** which is internal to the affected Module. See Sections 5.3 and 5.4 in the maintenance chapter for further instructions.

Note: the quality of tap water can vary significantly from region to region throughout the world. Datrend can not comment on or verify the quality or cleanliness of your tap water with respect to its mineral or chemical content. *In an abundance of caution, it is recommended that you avoid the use of tap water as a testing fluid in vPad-IV.*

3.5.2 Fluid Connections

The fluid input to the vPad-IV Module is a female Luer connector located on the front panel (*Figure 15*).
The fluid output is a hose barb on the rear panel that is intended to fit 1/8" (3mm) inside diameter tubing.
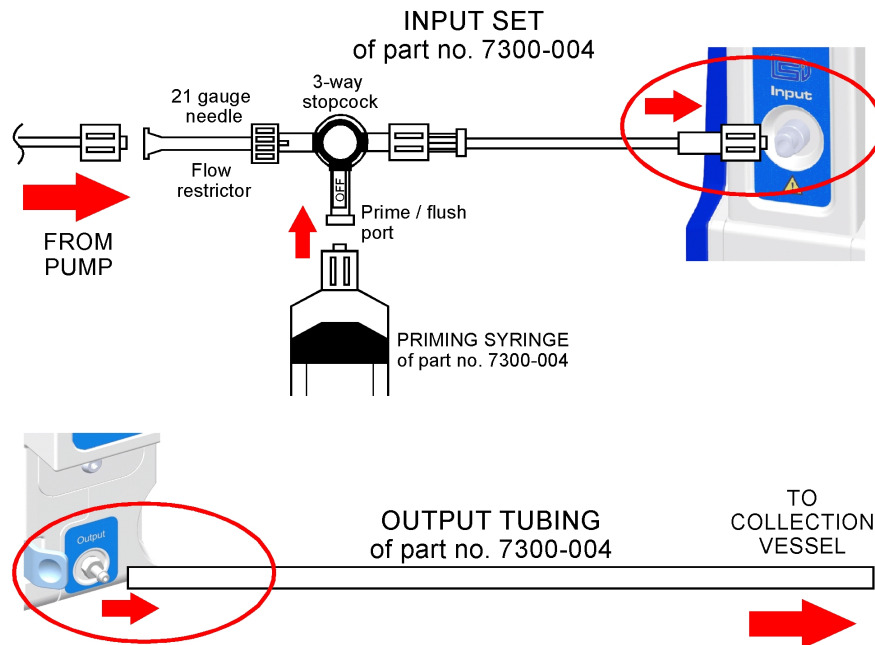

Figure 15

An input/output tubing kit (part number **7300-004**) is provided with each vPad-IV Module. Connect the
input tubing set to the Luer input port of the Module. Note the input set includes a 3-way stopcock and a 21
gauge needle. As shown in *Figure 15*, one port of the stopcock connects to the device under test while the
other port is used for priming or flushing the Module with the syringe included in the kit. The needle
attached to the stopcock is intended to provide a flow resistance and is a test requirement specified in the
IEC60601-2-24 standard for infusion devices. The needle may be removed if desired, although test results
may be accordingly affected. Use of the needle is recommended, particularly when testing infusion devices
that have an intermittent or "pulsatile" delivery characteristic.

Connect the 1/8" ID tubing to the barbed output port of the Module. Place the other end of the output
tubing in an open collection vessel having a volume of 500 mL or larger. To avoid an unintentional back
pressure or vacuum, situate the collection vessel at approximately the same elevation as the Module.

Testing with an applied back pressure requires connecting the Module output to a *closed* container. A
pressure or vacuum may be created by connecting the output to an IV bag and respectively elevating or
lowering the bag accordingly. In practise, this technique may be used to generate back pressures within a
range of ±100 mmHg, which will meet the test requirements of some infusion device standards. Generation
of a positive back pressure exceeding +100 mmHg, for example up to +300 mmHg (40 kPa) per IEC60601-

2-24, will require connection of a *rigid* closed vessel, such as a stoppered erlenmeyer flask, to the Module output (*Figure 16*). The flask is then pressurized or evacuated through a separate line to an external air pump or other source of compressed air. As shown in *Figure 16*, best results will be obtained when the applied air pressure is regulated with a suitable control valve or equivalent apparatus.
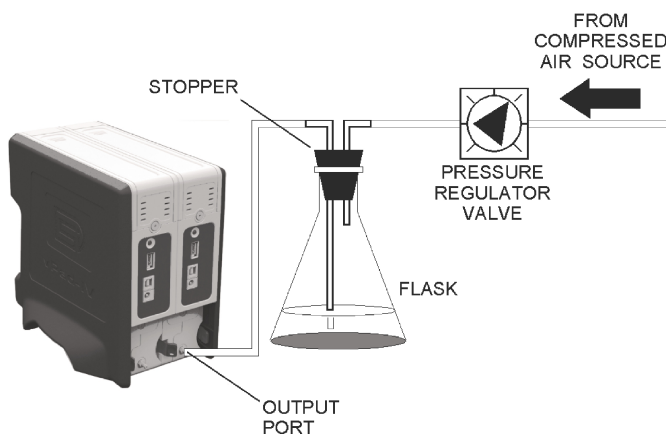

Figure 16

3.5.3 Channel Status

Start the vPad-IV app if it is not already running. When app startup is complete, check the channel status icons which are displayed on the lefthand side of the tablet screen. Channels that are ready to run a test will show the ⚙ icon ("setup and run"). Channels which are available but not ready show ⚠ icon ("alert"). Alert status usually means the channel requires *priming*; see below for further instructions.

3.5.4 Priming

**CAUTION: use only distilled water or clean drinking water with vPad-IV.
Refer to Section 3.5.1 for further instructions and warnings.**

Connect input and output tubing provided with vPad-IV to the Module (see *Figure 15*). Fill the syringe included in the tubing kit with distilled water or clean domestic (i.e. "tap") water. Connect the syringe to the stopcock of the input tubing, set the stopcock to the syringe port and then slowly inject at least **20 ml** of water to purge all air from the unit. Observe the output tubing while priming and stop injecting when both input and output tubes appear completely filled.

The vPad-IV app can assist with priming to ensure that trapped air is purged from the internal system. Run the app, and following startup, select a Module to be primed by pressing the corresponding "alert" icon ⚠ on the left.

The priming screen on the tablet (*Figure 17*) summarizes the above instructions and provides a video which will show you how to connect the input and output tubing and prime the system. After following the instructions, press the **Check Status** button to confirm the channel has been properly primed. If no air bubbles are detected in the Module flow sensor, you will then be permitted to set up and run a test. If air bubbles are detected during the status check, you will be instructed to prime the channel again.
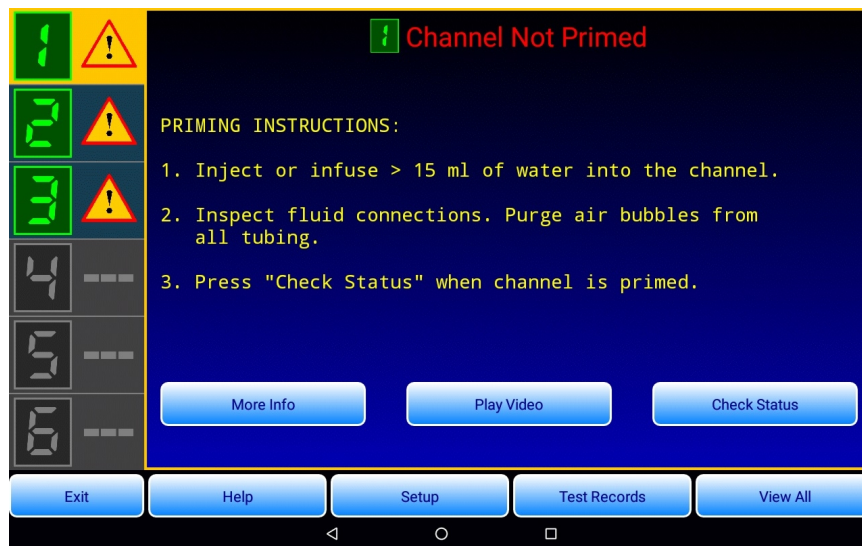

Figure 17

When priming or flushing a channel, always inject *into* the Module and **DO NOT** use the syringe to withdraw water from the input (*Figure 18*). Excessive or extreme suction applied at the input port of the Module may result in damage to internal sensors.
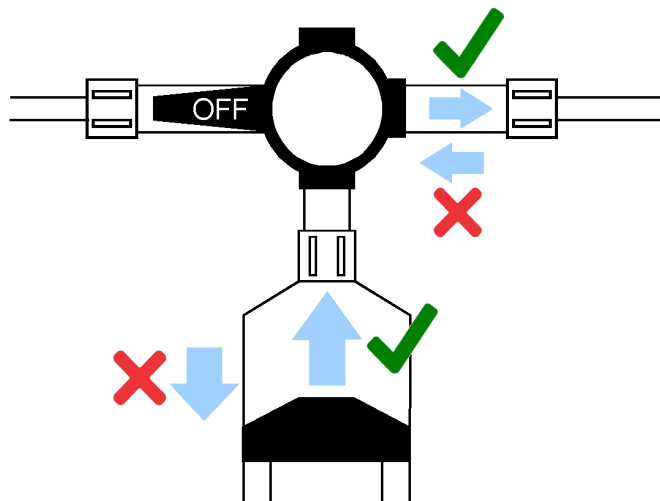

Figure 18

If it becomes necessary to drain vPad-IV for disassembly and/or shipment, per (*Figure 18*) **DO NOT** drain by using a syringe to withdraw the water from the Module input. Instead, use the syringe to inject *air* <u>into</u> the input until all water within the unit has been ejected, as observed at the output of the Module.

<u>CAUTION:</u>	Damage to vPad-IV caused by failure to observe the above priming and/or draining instructions will not be covered under warranty.

3.5.5 Wetting the Flow Sensor

vPad-IV may be used to test infusion devices immediately after priming. However, on initial receipt of the product, or after any period of dry storage which exceeds more than a week, best performance will be obtained if the Module's **flow sensor** is first "wetted" before performing any tests.

A vPad-IV Module may be "wetted" by priming the instrument as described in Section 3.5.4 and then running a Flow Rate Test at 400 ml/hr for approximately 10 minutes. See Section 4.3.4 on page 32 for instructions on setting up a Flow Rate Test.

An effective method of "wetting", which may be the preferred method if vPad-IV has spent a significant amount of time in dry storage, is to clean the instrument according to the instructions given in the maintenance chapter, specifically Section 5.3 on page 76. After cleaning, a Flow Rate Test at 400 ml/h for about one minute will prepare the flow sensor for subsequent tests to follow.

Once a vPad-IV Module has been primed and "wetted", it is preferable to leave the instrument filled with water between uses for as long as practical. While full, vPad-IV may be moved from one position to another (e.g. from test bench to storage shelf) provided input tubing sets are connected and Modules remain upright while the analyzer is being relocated.

3.5.6 Cleaning the Fluid System

The fluid system of vPad-IV should be cleaned on a regular basis. The frequency of cleaning will depend on the quality of water used with vPad-IV, ranging from about once every 6 months for distilled water up to once per month for ordinary "tap" water. A thorough cleaning will be necessary if vPad-IV becomes accidentally contaminated with an incompatible medical fluid such as dextrose (D50W) or TPN solution. Refer to the maintenance chapter on page 75 for complete instructions.

3.6 Troubleshooting

Problem	Solution

Missing or broken item	Contact your Datrend dealer and provide the part number of the item:
	Vision Pad tablet + stand: 7050-126 + 5550-105
	Tablet charger + blade set: 3000-087 + 7500-491
	vPad-IV Controller: 8000-201
	vPad-IV left side panel: 7400-004
	vPad-IV right side panel: 7400-005
	vPad-IV input/output tubing set: 7300-004
	Power supply: 3000-103
	AC power cord: According to region:
	    3000-471 (USA); 3000-004 (GBR);
	    3000-005 (AU/CN); 3000-006 (EUR);
	    3000-007 (IN/ZAF); 3000-013 (DNK);
	    3000-014 (ISR); 3000-473 (CHE);
	    3000-474 (BRA); 3000-475 (CHL)
	USB-A OTG adaptor: According to tablet model:
	    3140-390 (microUSB); or 3140-391 (USB-C)
	USB-A to tablet cable: According to tablet model:
	    3140-396 (microUSB); or 3140-500 (USB-C)
	Accessory bag: 7006-066
	
	<u>Per additional channel:</u>
	vPad-IV Module: 8000-200
	vPad-IV input/output tubing set: 7300-004
	Module interconnect cable: 3140-071

One or more Modules not powering up	Make sure the Module interconnect cables and the power supply are firmly plugged into their respective jacks at the rear of the analyzer (see *Figure 7*, *Figure 10* and *Figure 11*)
Some of my Modules show the same channel number	Reassign Module channel numbers so that they are unique: a. Apply power to the analyzer. If the analyzer is already powered up, disconnect the DC power cable at the back of the Controller Module and then reconnect the power to reboot the analyzer. b. Press and hold the "**CH**" button on the rear panel of the Module you want to change c. When the channel number starts blinking, release the button d. Quickly press and release the "CH" button to change the channel number. Repeat until the desired channel is reached. Typically, the Controller Module will be set to channel #1 and any other Modules are each set to unique channels in 2, 3, 4, 5, 6 order. e. Once the desired channel is reached, release the "CH" button and wait. When the channel number stops flashing, the number has then been stored in the Module's memory.

Problem	Solution
vPad-IV app or vPad Settings app says vPad-IV analyzer is not connected	Make sure the Controller Module has power, then: For wired (USB) connection: a. Make sure that the tablet USB communication cable is plugged into both the tablet and the **USB to tablet** jack on the rear panel of the Controller (see **Figure 8** and **Figure 9**). b. In vPad Settings app, select the USB option for "vPad-IV Pump Tester". c. If the above fails, restart the tablet. For wireless (Bluetooth) connection: a. In vPad Settings app, select the Bluetooth option for "vPad-IV Pump Tester". From the drop-down list, select the "BT ID" (Bluetooth ID) that you will find printed on the rear panel of the Controller Module. b. If the Controller's Bluetooth ID is not in the vPad Settings list, enter the Android Settings menu and pair the Controller with the tablet. When prompted by the tablet, enter Pass Code 1234 or 123456. c. If the above fails, restart the tablet.
Inaccurate flow measurements	Flow sensor may be dirty; see maintenance chapter on page 75 for cleaning instructions.

Chapter

4

4 Operation

This chapter explains how to use vPad-IV to perform infusion pump testing. Test Record management is also covered in this chapter.

4.1 HOME Screen

The Android HOME screen is displayed approximately 20 seconds after switching the tablet ON.

Figure 19

Initiate actions on the tablet by pressing the corresponding icon or button. For example:

Press to launch the vPad-IV application software, or "*app*". Use this app to perform infusion device testing.

Press to launch the vPad Record Manager app. Use this app to copy, print, convert or delete Test Records saved by vPad-IV. This app can be launched from the HOME screen, or from within vPad-IV by pressing the "Test Records" button.

Press to launch the vPad Settings app. Use this app to configure the USB or Bluetooth connection between the tablet and the vPad-IV Controller.

Press to access the Settings menu of the Android tablet. Use this menu to configure sound, display, touchscreen, and wireless setup of the tablet.

Near bottom center on the screen, press the **Apps** button to access more apps which are installed on the tablet. If this button is not shown by your tablet, try a swipe-up gesture from the bottom of the screen to view the Apps page.

At bottom center on the screen, press the **Home** button to return from an app to the Home screen.

Press the **Back** button to navigate back one step, from the app or screen currently being displayed, to a previous one. For some apps, this button's function may be disabled.

Press the **Recents** button to jump from the current app to a different app that was started earlier, but is currently on pause.

For more information on how to use the Android tablet, refer to the tablet operator manual supplied with vPad-IV.

4.2 Startup

Press the vPad-IV icon on the Android HOME screen to start the app. The app will connect to the Controller Module via USB, or alternatively by Bluetooth if wireless operation has been enabled in the vPad Settings app. After connecting with the Controller, the app will search for additional Modules which may be in the system (*Figure 20*).

Figure 20

Once connected channels have been found, they will be identified by number and displayed at left on the screen, along with their current status. The channel number on the screen will match the channel number displayed by the LED readout on the front of the Module.

Each Module incorporates a pressure transducer which will be zeroed at startup if the Module contains no water. An accurate zero reference is obtained if the Module input port is open to the atmosphere during the startup process. Refer to Section 4.3.3.6 on page 31 for more information on zeroing the pressure measurement.

If you have not *primed* the vPad-IV analyzer yet, you should do so before starting any tests. For further details, refer to Section 3.5 which begins on page 18.

4.3 Test Configuration
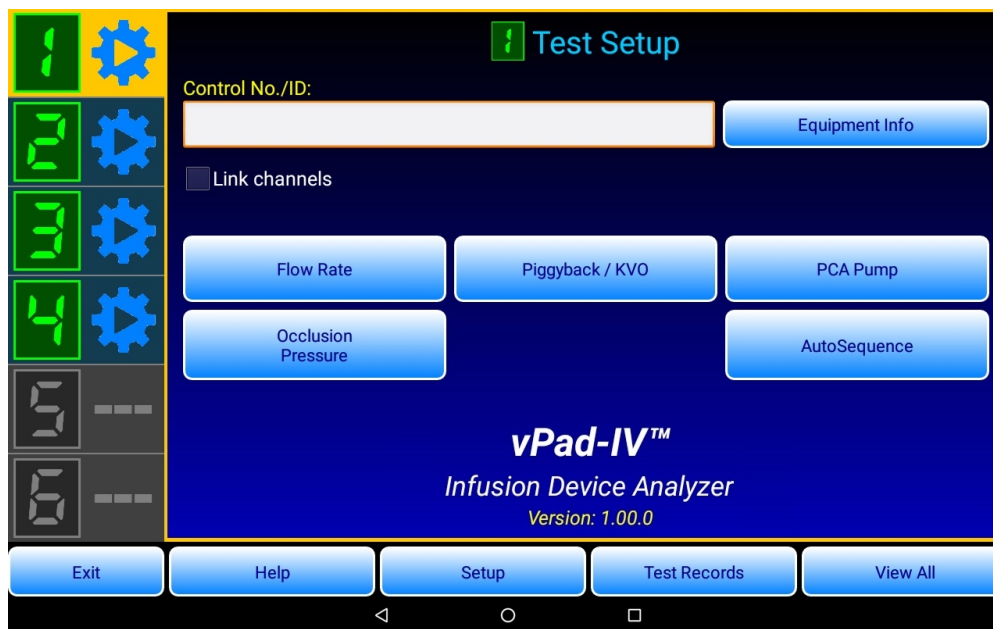
4.3.1 Test Setup and Device Recall

Figure 21

Begin a test by selecting an available channel that is displaying a 'setup and run' icon ⚙️ , then enter the control number or ID of the infusion device to be tested. The device ID, which must have three or more characters, is used as a primary identifier for Test Records and the on-tablet Equipment Record system. Enter equipment details you want to be saved in the Test Record by clicking the **Equipment Info** button. The Equipment Information menu enables you to input manufacturer, model, serial number and similar details, either by entering it with the on-screen keyboard or with a barcode scanner, or by selecting items from lists displayed by the **Choose** buttons on the menu. See Section 4.4.1 on page 41 for further information on the **Equipment Information Editor**.

If the entered device ID is known from a previous test, the app will prompt you to recall the Equipment Record. Recalling the Equipment Record will load the equipment information and test setup that was saved for the last test that was performed on the device.

4.3.2 Linking Channels

For testing of infusion devices that contain multiple pumps within a single unit, vPad-IV channels may be optionally linked during test setup. When the linked channels have completed their respective tests, the results from all such channels are combined into a single Test Record which is identified by the device ID.

To create linkages, first make sure that all required channels are primed and are ready to run a test (see Section 3.5 on page 18). Check the **Link channels** box, select one or more channels according to the number of pumps contained in the infusion device, then click **Apply**. A message in the Test Setup menu will indicate that the link is active.

Configuring a test on a linked channel will now apply the same test settings to all channels in the link. Before starting the test, equipment information may be optionally entered into one of the linked channels, which will later be saved to the combined Test Record. After the initial setup, each linked channel is then started individually, one after the other, as are the individual pumps which are connected to the vPad-IV channels.

4.3.3 Test Configuration Menus

Test configuration menus include controls for configuring each test type. Certain features and controls are common to all test configuration menus, as described below.
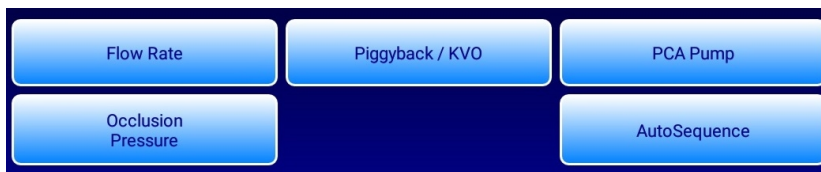
4.3.3.1 Test types

Figure 22

Flow Rate Test	This test measures the output of a single infusion or dose delivery. The Test Record will include the volume delivered on completion of the test and the average flow rate.
Piggyback / KVO Test	This test measures the output of an infusion having two distinct deliveries, which for a piggybacked infusion means delivery of a secondary dose followed by delivery of a primary dose at a lower rate. The Test Record includes the volume infused for each of the two deliveries and their respective average rates.
PCA Pump Test	This test measures the bolus output and lockout timing of a patient-controlled analgesia (PCA) pump. Additionally, the test may optionally measure the basal flow between bolus deliveries. The Test Record will include bolus and lockout measurements for each delivery infused over the course of the test.
Occlusion Pressure Test	This test measures the pressure developed by the infusion device when it pumps into an occluded line. The Test Record will include the peak pressure observed during the test, and the final pressure at the end of the test.

4.3.3.2 Automatic testing

All test types support an automatic mode, where vPad-IV will stop the test and evaluate the results when a user-defined stop condition is reached. While in progress, an automatic test can be stopped manually to obtain a result representative up to that point in time.

A Test Record for automatic test will include a percentage error between the measured value and the target rate or VTBI, as well as a pass/fail result which is based on the percentage tolerance defined in the test setup. See the following Sections for further instructions on how to configure an automatic test.

4.3.3.3 Manual testing

All test types support a manual mode, where the test will run indefinitely until stopped by the user. Other than selection of the test type, no further configuration is needed.

4.3.3.4 Monitoring pressure during test setup

Test configuration menus display a real-time reading of the pressure that is currently being sensed by the vPad-IV Module (*Figure 23*).

Figure 23

Prior to starting a Flow Rate, Piggyback or PCA Pump Test, the pressure display enables monitoring of a back pressure which may be optionally applied to the infusion device as part of the protocol.

Testing with an applied back pressure requires connecting the output of the vPad-IV Module to a *closed* container which can be pressurized or evacuated by an external air pump or other source of compressed air (see Section 3.5.2 and *Figure 16* on page 20 for further details). The pressure is adjusted while observing the real-time pressure display on the test configuration menu.

4.3.3.5 Pressure units

The **Units** button on test configuration menus (*Figure 23*) allows the pressure units of measure to be set to mmHg, psi, kPa and other units. The selected units of measure will be used by back pressure and occlusion pressure readouts and for results which are saved to the Test Record. This is a 'sticky' setting which is retained by the app once set.

4.3.3.6 Pressure zero

Referring to *Figure 23*, the **Zero** button on the test configuration menu enables the pressure measurement to be zeroed. This should be done only when pressures at the input and output of the Module are known to be zero. When a Module is in the primed state, it is best to set the zero when there is no infusion device connected to the input port and when input and output tubing sets are lying flat along the test bench so that hydrostatic pressure or vacuum applied to the Module is reduced as much as practical. This approach will improve accuracy of the zero calibration and thus accuracy of pressure measurements overall. Under no circumstances should the pressure be zeroed while an infusion device is actively pumping into the Module's input as such pumping is likely to cause the pressure at the Module input to be increased above zero.

The pressure zero offset of a Module is affected by altitude above sea level and to a lesser extent by the local weather. To accommodate use of vPad-IV over a wide range of geographic locations and environmental conditions, the app allows the zero to be adjusted over a range of -225 to +60 mmHg from the default sea-level reference. The app will display an error message if the user attempts to set the zero outside the permitted range of adjustment, in which case the user should carefully inspect the test setup to confirm no significant pressure or vacuum is being applied to the Module when the **Zero** button is pressed.

To assist the user in zeroing the Module appropriately, the app displays a confirmation dialog if the change in the zero offset will exceed ± 25 mmHg from its current setting. As previously stated, zeroing of the pressure measurement should be done only when pressures at the input and output of the Module are known to be zero, which is most accurately achieved with no infusion device connected to the input port and with input and output tubing sets lying flat along the test bench. If this is the case, press "OK" on the confirmation dialog to set the zero, or otherwise make adjustments to the test setup to reduce the pressure applied to the Module and repeat.

The most accurate zero calibration is obtained when the Module is completely empty of water and its input port is open to the atmosphere when the zero is taken. vPad-IV provides two different methods of obtaining such a zero reference: the channel's zero offset will be updated automatically if the Module is found to be completely empty at app startup, or alternatively, the Module may be drained during setup of an Occlusion Pressure Test and the **Zero** button pressed with the Module in this state. Respectively refer to Section 4.2 on page 27 and Section 4.3.7 on page 39 for further details.

Zero pressure offsets are stored for each channel individually. Previously-stored offsets can be individually or collectively reset via the app's **Setup** menu (see Section 4.8.7.2 on page 71).

4.3.4 Flow Rate Test Setup
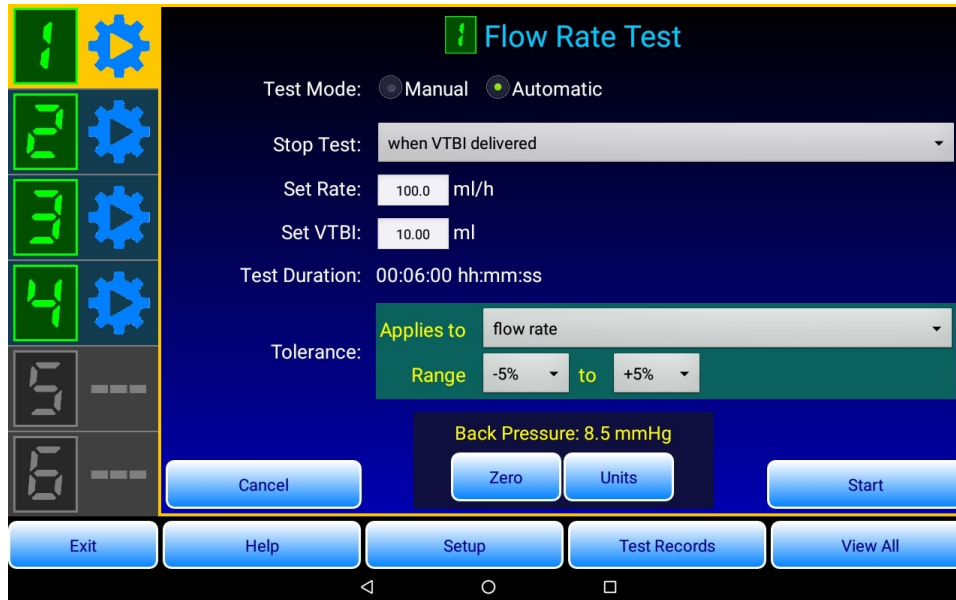
4.3.4.1 General setup

Figure 24

Use the **Flow Rate Test** to evaluate the ability of an infusion device to deliver a set volume-to-be-infused (VTBI) or dose in milliliters (ml) at a set rate in milliliters per hour (ml/h). An automatic test is preferred when the objective of the test is to evaluate the ability of the device to accurately infuse a Set VTBI or 'dose'. An automatic test may also be used if the test objective is to determine accuracy of the device in maintaining a Set Rate over a period of time.

Begin test setup by choosing the most suitable stop condition for the manufacturer's inspection procedure or other test protocol:

- stop the test when the pump's volume-to-be-infused (VTBI) is delivered
- stop the test when a set time limit or duration is reached
- stop the test when a target volume is reached
- stop the test when a target volume or time limit is reached, whichever happens first

Input the **Set Rate** and the **Set VTBI** that the infusion device will be set to for the test, or alternatively to the required duration of the test in hours, minutes and seconds. Depending on the stop condition, input of a Set Rate, VTBI or Duration causes the app to automatically recalculate and display the dependent test parameter. The app will alert you if you input an invalid setting or a value which is outside the measurement range of the analyzer.

Select a pass/fail **Tolerance** in percent from the pick-list according to the manufacturer's inspection protocol or alternatively per the performance specifications of the device under test. If the test is stopped when the **Set VTBI** has been delivered, then the tolerance may be applied to the flow rate measured at the end of the test, or to the volume delivered by the end of the test, or to both the measured rate and the delivered volume. For other stop conditions, the tolerance applies to flow only since the volume is either predetermined or the volume is not constrained by the test protocol.

Select the desired units of measure for **Back Pressure** and, if necessary, zero the reading if the pressure applied to the Module is in fact zero. Refer to Section 4.3.3.6 on page 31 for further details on zeroing. After zeroing, apply a back pressure to the DUT if this is required by the protocol, following instructions given in Section 3.5.2 on page 19.

Once the settings are input, run the test with the **Start** button. If the objective is to determine a *volume* as delivered from the device under test, start vPad-IV **first**, <u>then</u> start the infusion device. If the objective is to determine accuracy of the *flow* produced by the device under test, you may want to start the infusion device first, wait a period of time for the flow to stabilize, and <u>then</u> start vPad-IV after the delay. Refer to Section 4.5.3 on page 45 for more information on how the test begins after the **Start** button is pressed.

4.3.4.2 Windowed data analysis

Windowed analysis of the test results may be optionally enabled in a Flow Rate Test. *Figure 25* is an example which schematically illustrates the analysis performed on the acquired measurement data after the Flow Rate Test is completed.
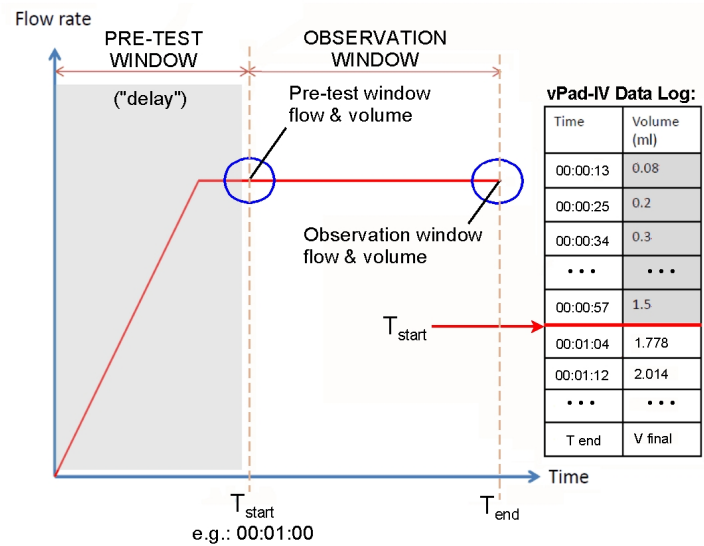

Figure 25

Windowed data analysis may be used when a manufacturer's inspection procedure or other test protocol requires the device under test (DUT) to run for a period of time before testing is performed. This "pre-test delay" allows the DUT to reach a stable operating condition before its output is tested. A disadvantage of the protocol, however, is that diagnostic information about the DUT's behaviour during the startup phase is lost.

vPad-IV is able to perform this test protocol without losing information by means of windowed data analysis. Referring to *Figure 25* , start time T_{START} corresponds to the "delay" defined in the test protocol. The "observation window" of *Figure 25* has a duration equal to the measuring time specified in the protocol. The **Test Duration** of the Flow Rate Test is then made equal to the sum of the required startup delay and the testing time or "observation time".

After the Flow Rate Test is completed, vPad-IV will determine the pass/fail result of the test based on the volume and flow measured from T_{START} to the end of the test. Optionally, the Flow Rate Test may be configured to include the "pre-test window" data in the Test Summary and assess these values to determine the pass/fail result.

Windowed analysis per *Figure 25* is enabled by a checkbox which is shown when the **Stop Test** condition is set to "when test duration is reached" (*Figure 26*).
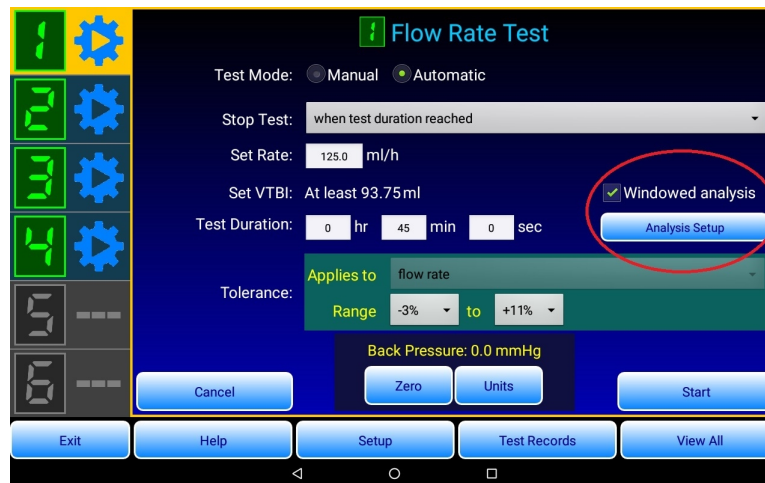
Figure 26

As previously described, the **Test Duration** is set equal to the sum of the startup delay and the testing time specified in the original protocol, after which the checkbox can be selected. After enabling windowed analysis, the analysis may be further configured by pressing the **Analysis Setup** button. The windowed analysis setup menu (*Figure 27*) enables the start of the observation window, or T_{START} of *Figure 25* , to be entered. Optionally, the test can be configured so that the reported results include the "pre-window" flow and volume measured from time $T = 0$ up to T_{START} , and for the flow measured at T_{START} to be passed or failed based on the tolerance settings of the test.
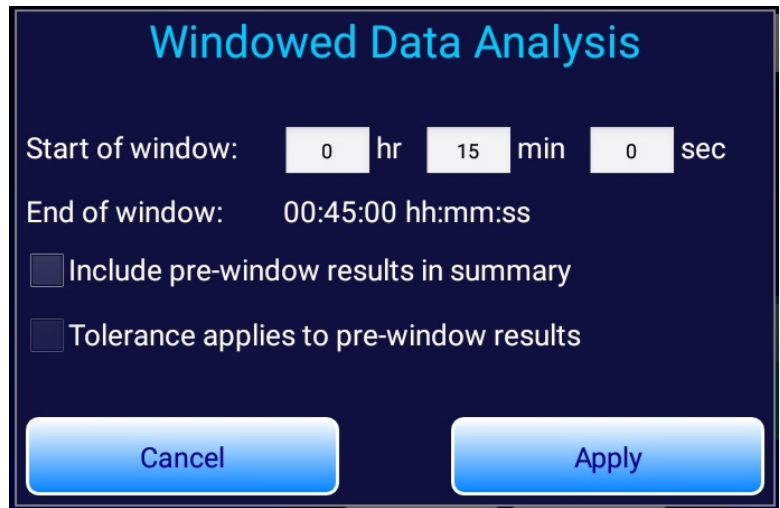
Figure 27

Example

A manufacturer's annual inspection procedure for an enteral feeding pump requires the device to be tested at a rate of 125 ml/h. According to the manufacturer's procedure, the DUT is run for 15 minutes after which the DUT output is then measured for 30 minutes. The DUT accuracy is specified as ±7%, however, when tested with water the DUT will over-deliver by +4%. There is no requirement to determine the flow during the startup phase.

The manufacturer's protocol is configured as shown in *Figure 26* and *Figure 27*. The **Set Rate** is 125 ml/h and the **Test Duration** is set to 15+30 = 45 minutes. T_{START} = 15 minutes is input via the menu of *Figure 27*. As shown in *Figure 26*, the pass/fail tolerance of the test is set to (-7+4) = -3% to (+7+4) = +11%, per the manufacturer's specifications. Also as shown in *Figure 26*, the VTBI of the DUT will need to be set to at least 93.75 ml to allow the test to be completed; in this example, setting the pump VTBI equal to 200 ml would guarantee sufficient fluid is delivered.

4.3.5 Piggyback / KVO Test Setup
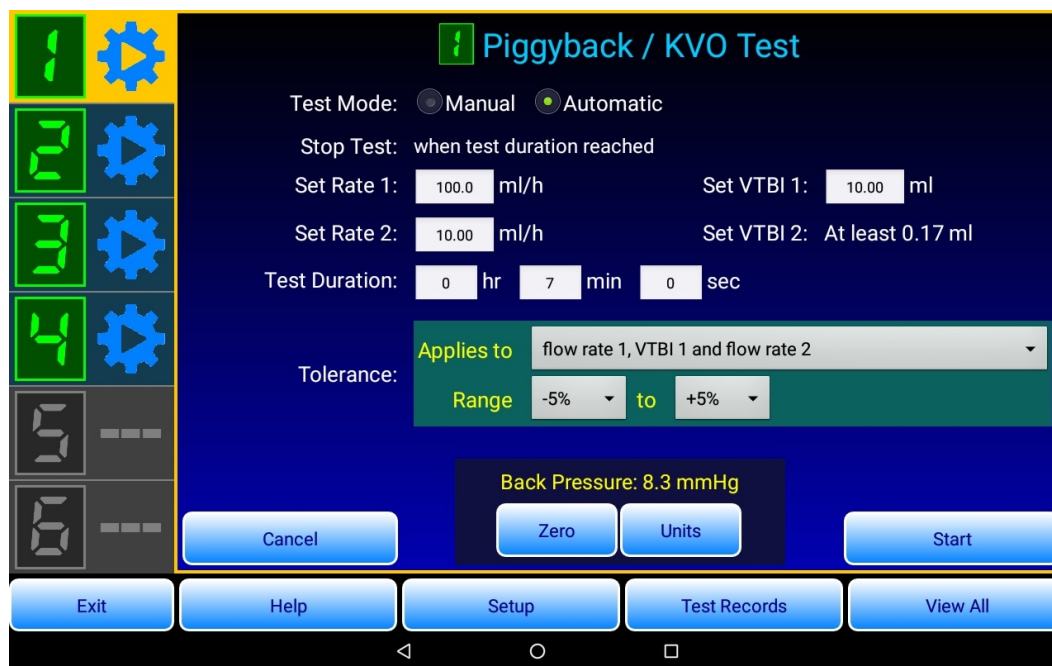

Figure 28

Use the **Piggyback / KVO Test** to evaluate the ability of an infusion device to deliver an initial volume-to-be-infused (VTBI) or 'dose' at a given rate, followed by a subsequent infusion which is delivered at a lower rate. This test may be used to evaluate piggyback medication delivery and keep-vein-open (KVO) capabilities of an infusion device.

In a piggybacked infusion, the device begins by delivering at the *secondary* or higher rate **first**. Once the secondary VTBI has been infused, the device under test reduces the flow to the *primary* rate and continues pumping until the primary VTBI is delivered. When KVO operation is enabled, the infusion device delivers at a set rate, then reduces the flow to the lower KVO rate once the set VTBI has been delivered. Piggyback and KVO tests are thus analogous and involve measurement of two different infusions, designated by vPad-IV as #1 and #2, within a single protocol.

Although a Piggyback / KVO Test may be run manually, an automatic test is preferred since the app will verify the test settings are valid before the test is started. Input **Set Rate 1** and **Set VTBI 1** for the first delivery of the infusion schedule; then **Set Rate 2** for the second delivery of the infusion; then finally a **Test Duration** which allows for both deliveries to be infused. The app will calculate and display a required minimum VBTI for the second delivery of the infusion schedule.

The app will require you to input a minimum VTBI 1 of 0.5 ml and a Rate 2 that is no more than one-fifth of Rate 1. Note vPad-IV does not rely on these test settings to determine when the change of rate occurs between the first and second deliveries. Instead, the vPad-IV Module detects the change from secondary to

primary infusion (or primary infusion to KVO) by direct realtime observation of the flow itself. Accordingly, the test settings must be configured within the specified limits to ensure the Module will reliably "see" the change in flow from Rate 1 to Rate 2 when this actually occurs during the test.

Choose a pass/fail **Tolerance** in percent according to specifications of the infusion device or per the manufacturer's inspection protocol. The tolerance may be applied to Rate 1; VTBI 1; Rate 1 and VTBI 1; or Rate 1, VTBI 1 and Rate 2 (default).

Once the settings are input, run the test with the **Start** button. With a piggyback or KVO test, always start vPad-IV **first**, <u>then</u> start the infusion device. Refer to Section 4.5.3 on page 45 for more information on how the test begins after the **Start** button is pressed.

4.3.6 PCA Pump Test Setup
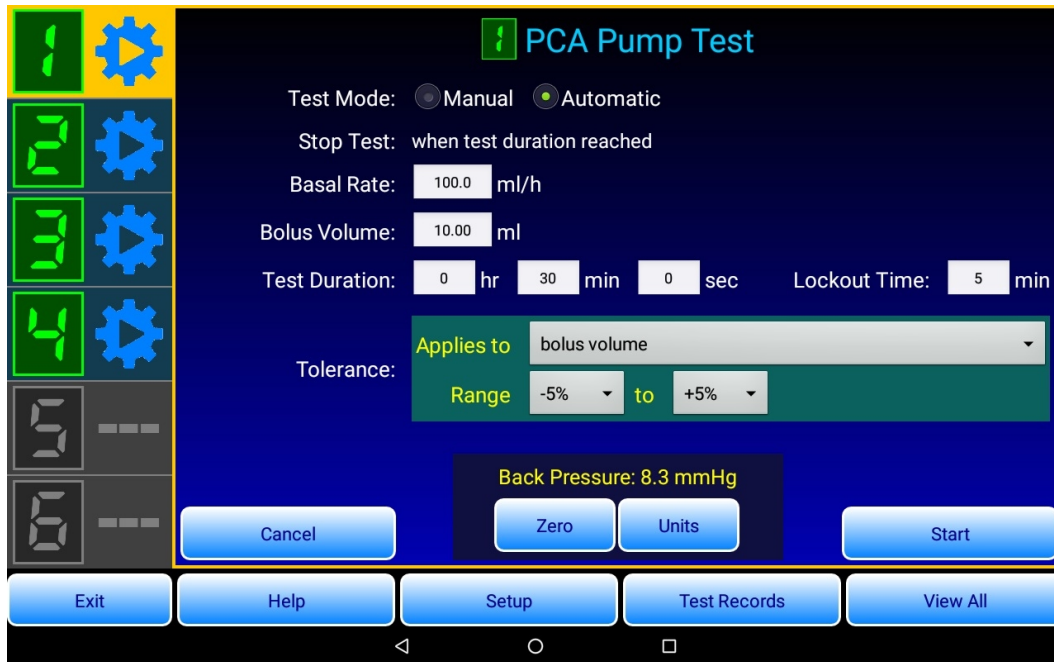
Figure 29

Use the **PCA Pump Test** to determine the ability of a patient-controlled analgesia (PCA) device to accurately infuse a set Bolus Volume or dose. The test also measures the lockout time and optional basal flow between the bolus deliveries. In this test, the PCA device is triggered automatically by vPad-IV to infuse each bolus during the protocol. Such triggering is accomplished by means of an accessory trigger cable which connects the vPad-IV Module to the device under test.

Set up for a PCA Pump Test as follows:

a. Connect the output of the PCA device to the fluid input of the vPad-IV Module. Prime all tubing and flush the Module.

b. Connect the **PCA Trigger** on the front of the vPad-IV Module to the input on the PCA device that would otherwise be used to connect a patient cable with pushbutton or similar control. Note that the Module's PCA trigger output is a 1/8" (3.2mm) monaural phono jack, providing a normally-open single-pole contact rated at 30V/0.3A (*Figure 30*).
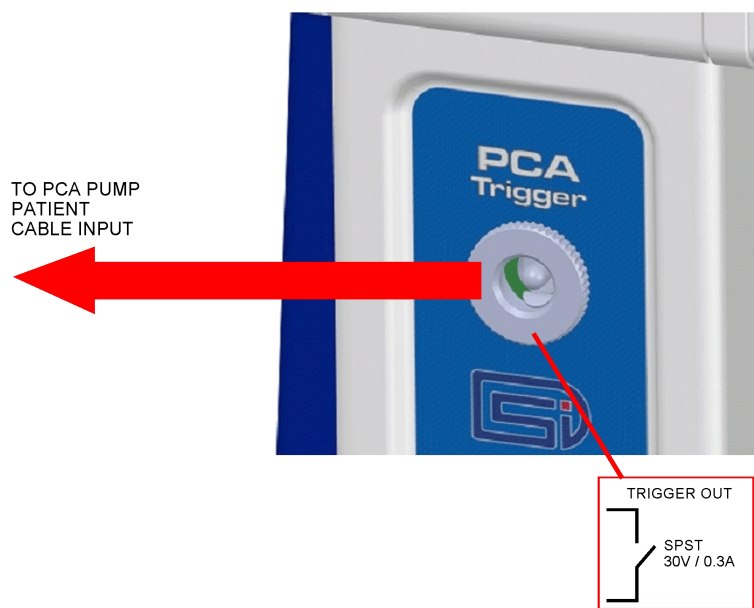
Figure 30

c. Program the PCA device with bolus volume, basal rate and lockout settings according to the manufacturer's inspection procedure or other protocol.

d. Select the channel in the vPad-IV app. Choose the PCA Pump Test and select manual or automatic testing. For an automatic test, enter the following test parameters:
   - **Basal Rate**, or input 0.0 ml/h for no basal infusion
   - **Bolus Volume** (minimum 0.5 ml)
   - **Lockout Time** between bolus deliveries (minimum 1 minute)
   - **Test Duration**. This setting must be at least 1 minute longer than the **Lockout Time**.
   - Select a pass/fail **Tolerance** in percent based on the test protocol or alternatively the performance specifications of the PCA device under test. The selected tolerance applies to the measured bolus volume and may be optionally applied to the lockout time and basal rate.

The app will require you to input a minimum **Bolus Volume** of 0.5 ml and a **Lockout Time** that is no less than one minute. Note vPad-IV does not rely on these test settings to determine when a bolus delivery actually begins and ends. Instead, the vPad-IV Module detects each bolus infusion based on direct realtime observation of the flow itself. Accordingly, the test settings must be configured as described to ensure the Module will reliably "see" the start and end of a bolus delivery when the infusion is triggered by the Module.

Once the settings are input, run the test with the **Start** button. vPad-IV will begin by outputting a trigger to the PCA device to initiate infusion of the first bolus. The PCA Pump Test proceeds automatically, with vPad-IV triggering delivery of each bolus and measuring the lockout interval between the bolus infusions.

4.3.7 Occlusion Pressure Test Setup
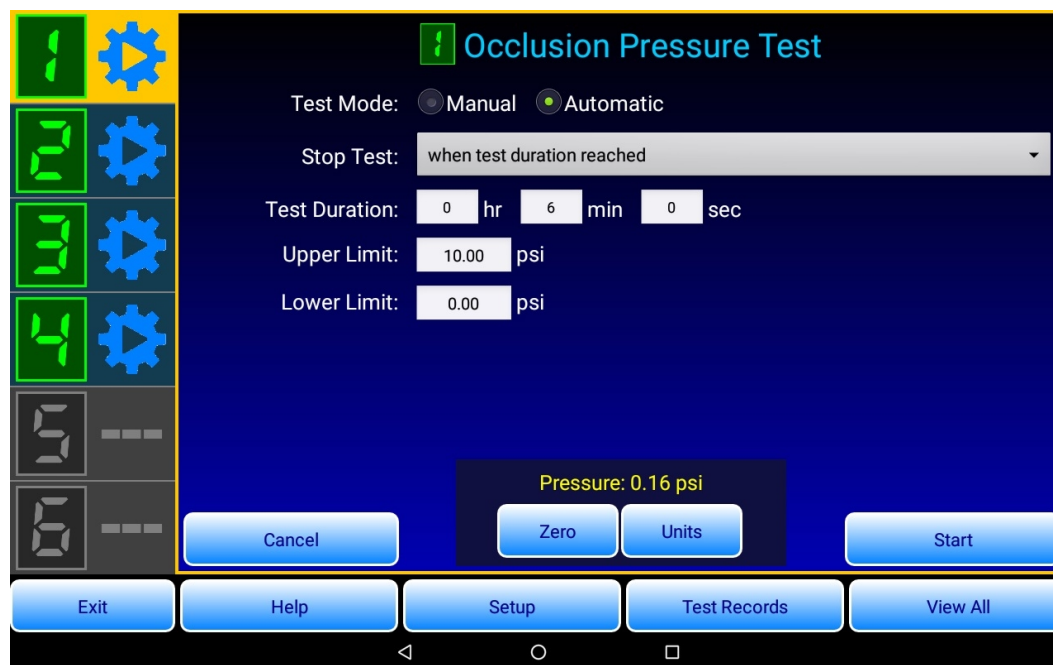
Figure 31

Use the **Occlusion Pressure Test** to measure the pressure developed by an infusion device when it pumps into an IV line that has been blocked at one end by the vPad-IV Module.

The Occlusion Pressure Test may be run manually or automatically. For automatic testing, select a suitable stop condition:

- stop the test when a time limit or duration in hours, minutes, seconds is reached; or
- stop the test when the pressure *drops* after having reached a peak, or when the set duration is reached, whichever happens first

Enter the upper pass/fail pressure limit of the test according to the manufacturer's inspection procedure or alternatively per the performance specifications of the device under test. Optionally, you may also enter a lower pass/fail limit for a *minimum* pressure that the infusion device must reach by the end of the test. Disable this minimum limit by entering zero, or otherwise refer to the manufacturer's protocol when inputting a value for the lower limit.

For best results, the pressure reading should be zeroed before the test is started. Follow the guidance specified in Section 4.3.3.6 on page 31 when zeroing the pressure. If the vPad-IV Module is primed, hydrostatic pressure or vacuum external to the unit may offset the zero calibration. Inaccuracy of the pressure zero can be eliminated by draining the Module and opening the input to the atmosphere while the setup menu for the Occlusion Pressure Test is being viewed. Once the Module has been emptied, and with the input port open to the air, press the **Zero** button on the menu to capture an accurate zero reference. After zeroing, the Module may be refilled and the test started. If the purpose of the test is to check the pressure transducer in the Module rather than test an infusion device, it is not necessary to refill the Module with water; in this case, verification of the Module's pressure measurement may be optionally performed with compressed air.

Users can stop an occlusion pressure test in progress at any time, even before the automatic stop condition is reached. Normally, you will stop the test when the infusion device senses the downstream occlusion and produces an audio-visual alarm. The peak pressure observed during the test, as well as the 'alarm' pressure observed when the test is stopped, are saved in the Test Record.

4.3.8 AutoSequence Test

A vPad-IV AutoSequence is a customizable series of user instructions, visual inspections or "checks", and one or more pre-configured tests of Flow Rate, Piggyback, PCA or Occlusion performance as described above. Choosing the AutoSequence option in the test setup menu will open a selector that lists all AutoSequences available on the tablet. Begin running an AutoSequence by clicking on its name in the list.

See Section 4.8.6 on page 67 for details on how to create or modify an AutoSequence with the **AutoSequence Editor**.

4.4 Editing Equipment Details

4.4.1 Equipment Information Editor

Figure 32

Information about the infusion device under test may be optionally entered with the **Equipment Information Editor**, which is displayed by the **Equipment Info** button of the Test Setup menu (see Section 4.3.1 and *Figure 21* on page 28). Details of a work order associated with the device may also be input. Entered data is copied to the Test Record which is saved on completion of the test. Equipment information and the work order *type* are also saved to an Equipment Record, enabling later recall of the information following input of the control number or equipment ID.

Most of the text-input fields of the Equipment Information have an associated pick list which is displayed by a corresponding **Choose** button. Pick lists are not intended to replace a database, but are meant to provide selectable "favourites" which may need to be entered frequently. Items may be added or removed from these pick lists by the **List Editor** of vPad-IV (see Section 4.8.5 on page 65).

Each text field of the information can be erased by a "long-press" gesture. A "long-press" means to touch the text field and hold it for a few seconds, until the field is cleared. The soft keyboard will then appear, enabling input of new information. In addition to the Equipment Information Editor, "erase on long-press" is implemented on almost all user interface menus of vPad-IV where such text fields appear.

4.4.2 Equipment ID or Control Number

The equipment ID or control number is important to vPad-IV since the ID will be used to create filenames for Test Records and Equipment Records that are saved on the tablet. You must input at least 3 characters for the ID to be accepted. Additionally, you must not use any of the following reserved characters in an ID:

$$\backslash \quad / \quad | \quad " \quad ? \quad * \quad < \quad >$$

4.4.3 Work Order Type

Some computerized maintenance management systems (CMMS) require a work order "type" to be specified, which corresponds to the activity to be performed. The use of two- or three-character codes to represent a work activity is common in managed systems. The default pick list installed with the vPad-IV app includes at least these items:

- PM (which means preventive maintenance inspection)
- CM (which means corrective maintenance or repair service)
- IE (which means incoming equipment inspection)

Additional codes as defined by a CMMS may be added to the above list via the **List Editor** of the app's **Setup** menu (see Section 4.8.5 on page 65).

4.4.4 Next Test Due Date

This text field is for input of a future date on or before which a scheduled maintenance inspection of the equipment should be performed. For example, you may choose a due date equal to today's date plus 12 months. Similar to other equipment information, if you input a due date, then it will then appear in the Test Record which is saved at the end of the test.

Although you could use the soft keyboard to type a due date, the best way to enter a date is to select it with the **Choose** button. This will ensure dates appear in the Test Record with a consistent format. Note that when a new test is being set up, the date selector control of vPad-IV will default to today plus the "default test interval" of the vPad system, which is set by means of the **vPad Settings** app (see Section 4.8.4 on page 62). If you enter or choose a due date at the start of a test, this initial input is maintained until a Test Record is saved. When you save a Test Record, you are given a second chance to select, modify or even clear the due date before the file is stored on the vPad tablet. See Section 4.7 on page 57 for further details on how Test Records are saved.

4.4.5 Recall Last Device

When you press the **Save** button of the Equipment Information Editor, a *backup* of some of the information fields on the menu is stored. This backup is independent of the test and will be maintained regardless of whether a test in progress is completed or cancelled. If a test is completed and a Test Record is saved, vPad-IV clears the equipment information to prepare for the next test, however, the information backup remains and may be restored with the **Recall Last** button after the next test is started. Thus, you can use **Recall Last** in incoming inspection activity which often involves testing of multiple devices of the same make and model but differing ID and serial number.

The following fields are restored by the **Recall Last** function:

- Description
- Manufacturer
- Model
- Facility
- Technician
- Next Test Due Date
- Work Order Type

The following fields are <u>not</u> modified by **Recall Last**:

- Control No./ID
- Serial Number
- Work Order

4.4.6 Equipment Records

Each time vPad-IV completes a test and saves a Test Record, an **Equipment Record** is also saved by the app. Equipment Records are identified by ID or control number and include all the text fields shown by the Equipment Information Editor, except for the work order. The Equipment Record also includes a *filename* for the test setup or AutoSequence that was used to test the device.

When you start a new test, input of an equipment ID or control number causes vPad-IV to search for a corresponding Equipment Record. If an Equipment Record is found, you can then open the Record and recall the equipment information and test setup which is stored in it. This saves time and effort in starting a new test for device which was tested in the past.

4.5 Running Pump Tests

4.5.1 Test Status

On the left side of the tablet screen, the vPad-IV app indicates the current status of each channel by means of icons.

	Channel ready / idle		Flow rate test in progress
	Piggyback / KVO **Rate 1** delivery in progress		Piggyback / KVO **Rate 2** delivery in progress
	PCA Pump **bolus** delivery in progress		PCA Pump **lockout** in progress
	Measurement of **Occlusion Pressure** or **Back Pressure** in progress		
	Automatic test done		Test encountered an error, or channel unprimed
	Test result PASS		Test result FAIL
	AutoSequence **INFORMATION** shown		AutoSequence **INSPECTION** required

4.5.2 Test Controls

vPad-IV shows the test screen immediately after a pump test is started on the channel. Tests in progress can be controlled with the following buttons which are found near the bottom of the tablet display:

Figure 33

Stop	Stop the test and generate a summary of the test results
Graph	Show a graph of acquired data up to and including the current elapsed time
Reset	Discard recorded data and restart the test
Cancel	Abort the test and return to test setup

4.5.3 Synchro-Start

All tests that measure flow enter a special "Synchro-Start" state at the beginning of a test, or when the test is reset. On the screen, the "Volume" and "Flow" displays initially appear grey, and the test timer remains frozen while waiting for the device under test to begin infusing (*Figure 34*).

Figure 34

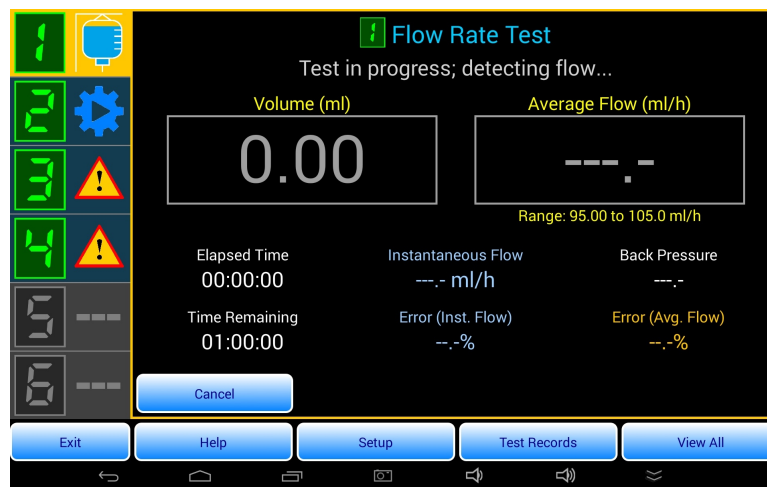After starting a test, the vPad-IV app will not measure flow, volume and time until the sensor in the vPad-IV Module detects fluid delivery. When accurate measurement of the infused volume is important, set the required VTBI or Dose on the infusion device, configure and start the vPad-IV test, and then start the infusion device *after* starting vPad-IV. If the purpose of the test is to measure the rate and not the volume

infused, the infusion device can be started first, after which vPad-IV may then be started. This second method is appropriate when the device under test should stabilize before measurement of the flow begins.

4.5.4 Measurement Readouts

The test screen shows the current test status and readouts for flow, volume, pressure and time. Each test typically features two large, principal readouts and other smaller readouts that provide supporting details, for example as shown in *Figure 35*.
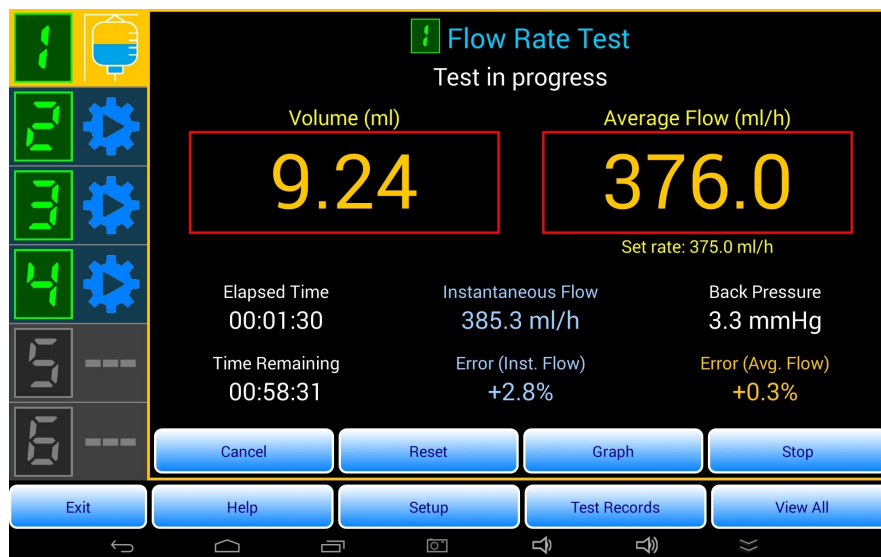
Figure 35

4.5.4.1 Flow test readouts

Volume and Flow
As shown in *Figure 35* , the principal readouts in tests which measure flow are the Volume delivered from the device under test, and the Average Flow which equals the indicated Volume divided by the Elapsed Time of the test
- The Flow Rate Test displays the Volume and Average Flow since the start of the delivery as detected by the *synchro-start* test feature (see Section 4.5.3, page 45)
- The Piggyback / KVO Test displays the Volume and Average Flow for the first or second delivery of the test (Rate 1 or Rate 2), as indicated near the top of the display
- The PCA Pump Test displays the Volume and Average Flow for the current Bolus delivery, or the Basal Volume and Flow during the PCA Lockout period, as indicated near the top of the display

Elapsed Time
Time since the start of the delivery as detected by the *synchro-start* test feature (see Section 4.5.3, page 45)

Instantaneous Flow	The incremental increase in volume ΔV divided by the amount time ΔT required to infuse the volume ΔV. The flow observation window ΔT may be set to 10, 30 or 60 seconds by means of the More Settings menu (see Section 4.8.7.1 on page 71).
Back Pressure	Pressure (or vacuum) detected in the IV line, which may oppose (or assist) the flow from the device under test; the source of such pressure or vacuum may be located at the Output port of the vPad-IV Module (see Section 3.5.2 on page 19 for further details)

4.5.4.2 Occlusion pressure readouts

Pressure	Occlusion tests display as <u>principal readout</u> the pressure developed by the infusion device into a blocked IV line
Elapsed Time	Time since the start of the occlusion test

4.5.4.3 Automatic test readouts

Setting and Range	When a tolerance is applied to the Volume and/or Flow measurement, the setting of the device under test (DUT) and the pass/fail acceptance range will be shown below the corresponding <u>principal readout</u>, alternating once every few seconds between the DUT setting and the pass/fail range.
Time Remaining	Time until the end of the test duration as defined in the AutoSequence
Flow Errors	Flow measurement error based on the ml/h rate setting of the device under test

4.5.4.4 Readout update interval

When testing flow, the frequency of display update will depend to some extent on the rate being measured. Above 7 ml/h, volume and average flow readings are updated once every two to ten seconds, depending on the rate. For rates less than 7 ml/h, the time required to measure volume and flow becomes inversely proportional to the rate. For example, a measurement at 1 ml/h will require approximately 70 seconds per reading.

The time required to measure volume and average flow is set by physical characteristics of the vPad-IV Module. Instantaneous flow, on the other hand, is calculated from the recorded volume data and will depend on the choice of flow observation window ΔT (10, 30 or 60 sec) that has been selected by means of the More Settings menu (Section 4.8.7.1, page 71).

When testing occlusion pressure, the reading is updated once every two seconds.

4.5.5 Graph Display

The **Graph** button as shown in *Figure 35* changes the test screen from numerical readouts to a realtime plot of acquired data. With the graph, users can view the fluctuations and overall trends of the infusion test (*Figure 36*).
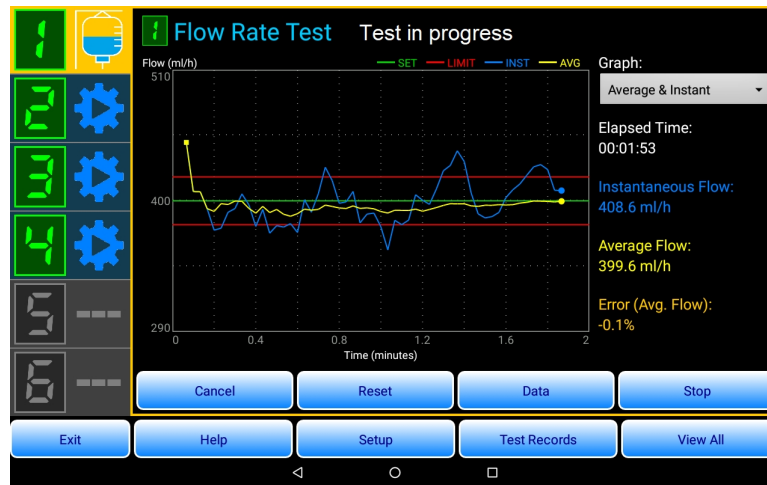
Figure 36

The measured value is plotted against the elapsed time of the test. As data is acquired, the horizontal time axis will automatically expand and the vertical axis will automatically scale so that the acquired data fits within the graph boundaries.

Graph options depend on the test in progress, as follows:

Graph Type	Applicable Tests	Graph Description
Instantaneous Flow	Flow Rate, Piggyback/KVO and PCA Pump Tests	Flow measured over short intervals ΔT ranging from 10 to 60 seconds, as set by the instantaneous flow window of the More Settings menu (Section 4.8.7.1, page 71).
Average Flow	Flow Rate Test	Ratio of the total volume delivered to the elapsed test time
Average & Instant.	Flow Rate Test	A combined graph of both instantaneous and average flow rates
Average % Error	Flow Rate Test	The error of the average flow as compared to the ml/h rate setting of the device under test
Pressure	Occlusion Test	Pressure developed by the device under test into a blocked IV line

4.5.6 AutoSequence Steps

A vPad-IV AutoSequence will proceed through each pre-programmed step in order, from first step to last. While an AutoSequence is running, the sequence title and progress (for example, "Step 1 of 5") is shown just below the channel display. Users can step through the AutoSequence with the control buttons at the bottom of the screen.
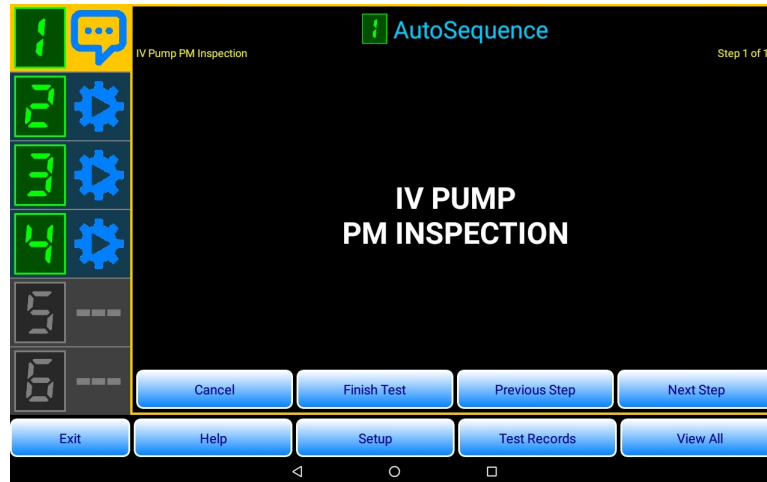
Figure 37

Referring to *Figure 37*, the sequence control buttons are:

Next Step   Proceed to the next step of the AutoSequence

Previous Step   Go back and repeat the previous step of the AutoSequence

Finish Test   End the AutoSequence before all steps are completed. A Test Record may be saved, but the Record will be assigned a "FAIL". This mode is intended for creating a record of a failed device inspection in a maintenance system (CMMS), where the failure could not be addressed at the time of inspection but must wait until the required maintenance and subsequent re-inspection can be completed at a later time.

Cancel   Abort the AutoSequence and return to test setup

AutoSequences are intended to follow the steps of an infusion device inspection or maintenance procedure ("PM"). Accordingly, an AutoSequence may include steps which display instructions to the user or which request a visual inspection of an item or feature of the infusion device. Autsequences may also include steps which measure flow, volume and occlusion pressure, as described below.

Information or prompt	💬	Displays test information or instructions for test setup
Inspection or check	🔍	Requires selection of an inspection result from the available options: PASS: inspected item is acceptable FAIL: inspected item is not acceptable Service: repair service or other work was performed to obtain an acceptable result N/A: inspection task does not apply to this device Info only: inspection records information only, which is not passed or failed
Back Pressure	⏲	Shows real-time pressure readings, enabling an externally-applied back pressure or vacuum to be adjusted to match a target which is specified in the AutoSequence (see also Section 3.5.2 and *Figure 16* on page 20)
Pressure Monitor	⏲	Similar to back pressure, the pressure monitor shows real-time pressure readings while displaying the average, maximum and minimum value of the pressure. The user may manually control whether the channel input is blocked or occluded, or otherwise remains open.
Pump Test		Runs a flow, piggyback, PCA or occlusion test according to a preset configuration which is defined in the AutoSequence

As users progress through the AutoSequence step-by-step, results of inspections and pump tests are added to the Test Record. At the end of the AutoSequence, the **Save Test Record** menu is shown in the same manner as a stand-alone Flow Rate or other test.

4.5.7 View All Channels

The **View All** button opens the analyzer overview, which provides a concise summary of status and measurement results for all channels (*Figure 38*).

Figure 38

Click on the row of an enabled channel to exit the analyzer overview and change the display to the selected channel.

4.5.8 Running Tests With Battery Power

If powered only by its internal battery, the tablet will enter **_doze mode_** if the screen is switched OFF with the power button. In doze mode, the tablet stops executing apps to save battery power.

Accordingly, when using Bluetooth communication and battery power, you should not switch the tablet screen OFF while running a vPad-IV test at the same time. Although a final test result will always be obtained and displayed when the tablet screen is switched back ON, while in doze mode the tablet may not log intermediate measurements to memory. This may affect results if the purpose of the test is to acquire data that is required for a IEC trumpet curve analysis.

Doze mode is inhibited when the tablet receives external power via its USB port. In this case, the vPad-IV app will continue to log data to memory even if the tablet screen is switched OFF while a test is running.

When Bluetooth communication is being used, and if a test will require several minutes to an hour or more to complete, consider powering the tablet with the battery charger provided with the vPad-IV system. This will ensure all intermediate measurements will be recorded to the data log even if the tablet screen is accidentally switched OFF during the test.

If the purpose of the test is to obtain a pass/fail result and there is no requirement to perform detailed analysis of recorded data after the test is completed, then there are no special requirements for battery-powered operation of vPad-IV. Users may switch the tablet screen OFF anytime under battery power, even while vPad-IV tests are running on multiple channels simultaneously, and the pass/fail result of each test will be shown after the tablet screen is switched back ON.

4.6 Test Summary

4.6.1 Test Results

At the end of every pump test, vPad-IV shows a summary which is based on analysis of the measurements observed during the test (*Figure 39*). After reviewing the summary, it may then be saved to a Test Record. Note a Test Record may include the displayed summary as well as additional summaries from tests completed with linked channels, or tests that were previously completed as part of an AutoSequence.
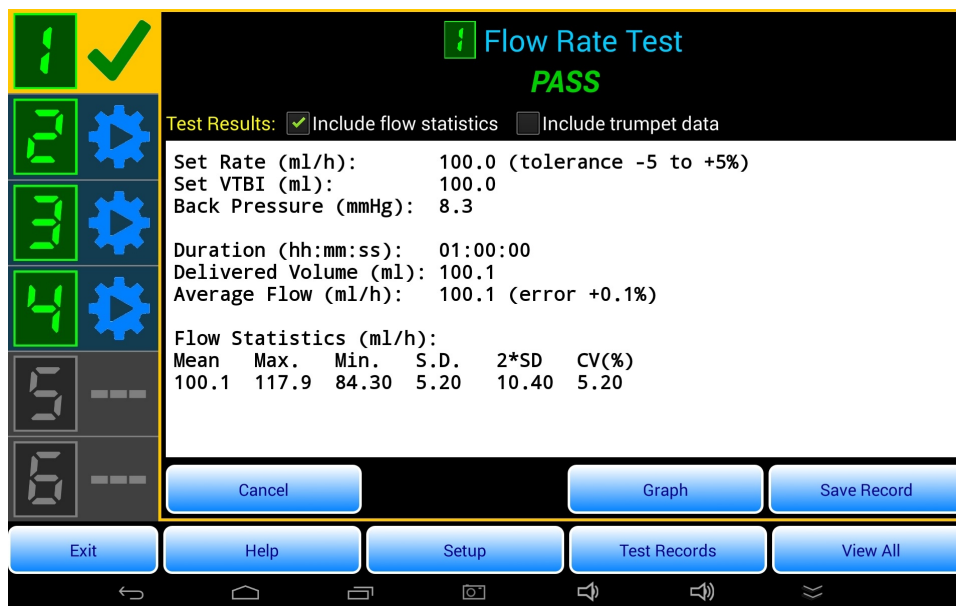
Figure 39

If the test was performed in manual mode, vPad-IV will not have sufficient information to evaluate the test results automatically. Users are asked at the end of the test to manually assign, at their discretion, a PASS or FAIL result before the summary is shown.

 For tests which measure flow and volume, vPad-IV requires the input of infusion device settings used in the manual test. The pump settings will be included in the Test Record, and may be used to calculate flow or PCA statistics as described in the following Sections.

4.6.2 Flow Test Summary

Summaries begin with the infusion device settings for rate and VTBI, and the average back pressure measured over the course of the test. Tolerances entered in automatic test mode are also shown next to the applicable setting. See Section 4.3.3.2 on page 30 for details on how to configure an automatic test.

4.6.2.1 Flow measurement results

Flow measurement results include the test duration, delivered volume, and average flow rate.

- Summary for a **Flow Rate Test** contains only one set of flow results
- Summary for a **Piggyback / KVO Test** contains two sets of flow results: one for Rate 1 and another for Rate 2
- Summary for a **PCA Pump Test** contains a separate result for each bolus delivery and for each lockout period observed during the test

4.6.2.2 Flow or PCA statistics

Summaries may optionally include a statical analysis of the measurement data recorded during the test. The analysis is enabled by the **Include statistics** checkbox near the top of the Summary screen (*Figure 39*).

Flow Statistics

Mean	Equivalent to average flow, or total volume infused divided by time required to deliver the volume
Max.	Maximum instantaneous flow (for definition of "instantaneous flow", see Section 4.5.4.1 on page 46)
Min.	Minimum instantaneous flow
S.D.	Standard deviation of instantaneous flow
2*SD	Standard deviation of instantaneous flow multiplied by two; encompasses 95% of normally distributed data
CV(%)	Coefficient of Variance (standard deviation of instantaneous flow normalized to the mean flow)

PCA Statistics

Bolus	Mean, Maximum and Minimum of all boluses delivered during the test
Basal	Mean, Maximum and Minimum rate whenever PCA device is in lockout
Lockout	Mean, Maximum and Minimum duration of all recorded lockouts

4.6.2.3 Trumpet data

This analysis is provided for the **Flow Rate Test** only and may be optionally enabled by the **Include trumpet data** checkbox near the top of the Summary screen (*Figure 39*). A trumpet curve analysis is performed over a time span which can be specified by the user.

A "*trumpet curve*" (*Figure 40*) is a method of statistical analysis specified in the IEC 60601-2-24 standard for infusion devices. The trumpet analysis attempts to illustrate the worst-case variability of the flow over specific intervals or "observation windows" which range from 2 minutes up to 31 minutes. As the observation window increases in duration, flow rate deviation from the overall mean is expected to decrease. The trumpet curve illustrates this convergence visually by plotting the errors of the largest and smallest calculated flow rates against the length of the observation window.
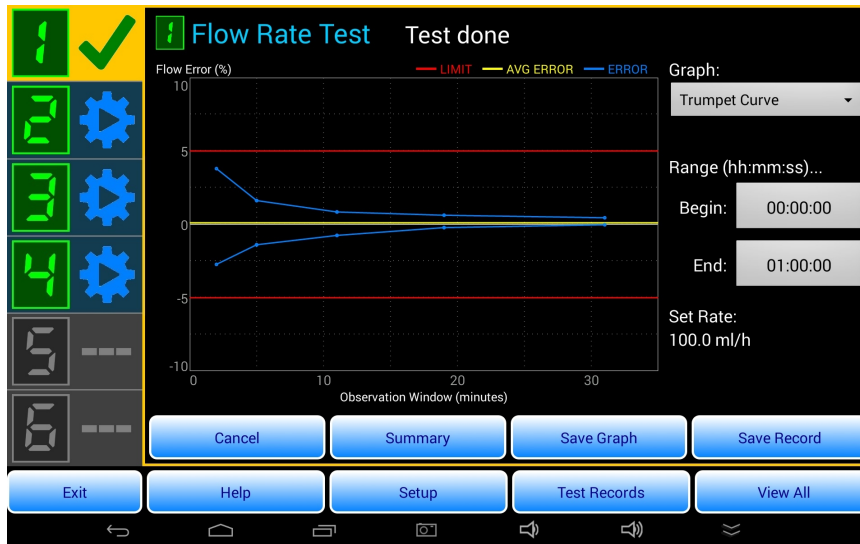

Figure 40

NOTE:	Trumpet analysis stops at the end of the specified analysis window (see *Figure 40* and Section 4.6.4) or the test duration, whichever comes first.

The inclusion of trumpet data in the summary is optional. Not all flow rate tests are eligible for trumpet analysis as there must be a sufficient amount of recorded data in memory to enable the necessary calculations. The IEC standard requires a minimum of one hour of data. A complete trumpet curve which includes results for all five observation windows will need at least 32 minutes of recorded data. If the selected period of analysis spans less than 5 minutes, the app will inform the user and will not proceed with the trumpet analysis. See Section 4.6.4 below for instructions on adjusting the trumpet time span.

Enabling the trumpet analysis will add the following details to the test summary:

Trumpet Data

Time span	The start and end time of trumpet analysis
Window size	Duration of moving observation window, as follows: 2 min 5 min 11 min 19 min 31 min
Window errors	Error of maximum flow rate calculated for the window size Error of minimum flow rate calculated for the window size
Overall error	Error of average flow rate over the entire test duration

4.6.3 Occlusion Test Summary

During an occlusion pressure test, vPad-IV monitors the fluid pressure in the IV line and records the peak measured value. The test summary therefore includes the peak pressure as well as the time at which it occurred. The summary also shows the pressure and time at the end of the test; depending on how the test was stopped, this may be simply the time and pressure at which the automatic test ended, or alternatively the time and pressure when the test was stopped manually in response to an audio-visual alarm from the device under test.

4.6.4 Graphical Summary

The **Graph** button of the test summary menu (*Figure 39* on page 52) shows a plot of all measurements recorded over the duration of the test, which is similar to the realtime plots described for test graph displays (see Section 4.5.5 and *Figure 36* on page 48).

Upon choosing a graph type, users can save a PNG image of the graph by clicking the **Save Graph** button (*Figure 41*). The button displays an image preview which includes a dialog that prompts for a filename. A default name is generated which has a similar format as a Test Record file. In addition to the device ID and date/time stamp, the default filename includes a suffix which identifies the type of graph and the vPad-IV channel it was obtained from. After editing the filename, if needed, click **Done** on the keyboard to save the graph.
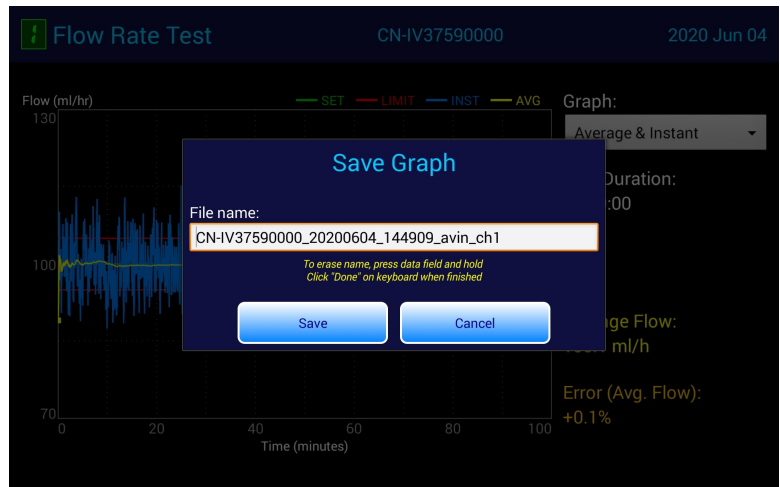
Figure 41

PNG images of graphs are saved to this folder on the vPad tablet:

Datrend/vPad-IV/Images/<*device_ID*>

where **<*device_ID*>** is the ID or control number of the infusion device that was entered at the start of the test. When PNG image files are saved, the filenames are added to the Test Record.

For **Flow Rate Tests**, a Trumpet Curve graph is a selectable option (see *Figure 40* on page 54). When the trumpet curve is selected, users can adjust the time span of trumpet analysis by clicking on the Begin or End time. When adjusting Begin or End times, the following should be noted:

- Time span must contain at least five minutes of data
- Time span should contain at least one hour of data for a full trumpet analysis per IEC 60601-2-24
- If trumpet end time exceeds the test duration, analysis will stop at the end of the test
- A new trumpet analysis is performed whenever the beginning and/or end times are changed. Depending on the amount of recorded data, the trumpet analysis may require a few seconds to complete.

If windowed data analysis has been enabled in the **Flow Rate Test**, the start time of the observation window will be indicated on summary flow graphs by a vertical line which is marked "Ts". Refer to Section 4.3.4.2 on page 33 for more information on windowed data analysis.

The **Summary** button of the graph display to returns the screen to the summary text. If PNG images have been saved, the filenames will appear at the end of the summary text.

4.7 Saving Test Records

4.7.1 Overview of Test Records

When a test is completed, a ***Test Record*** of the results may be saved. Test Records are text files which are stored by default in this folder on the vPad tablet:

Datrend/vPad-IV/Records

The above path may be changed via the **More Settings** menu of the app (see Section 4.8.7.4 on page 72 for further details).

Test Records are saved with the **Save Test Record** menu (*Figure 42*). In addition to saving the measurement results, this menu may be used to add work order information and labor-related information to the Test Record before it is saved.

Figure 42

In addition to saving the Test Record, the **Save Test Record** menu enables you to save the current test setup as an AutoSequence file on the tablet. The data log of the test may also be optionally saved. If label printing has been enabled in the **vPad Settings** app, then you will be prompted to print an inspection or "PM" tag after the Test Record is saved (see Section 4.8.4 on page 62 for more information on label printing setup).

4.7.2 Work Order Type

Some computerized maintenance management systems or CMMS require a work order "type" to be specified, which corresponds to the activity that was performed. If a work order type is entered into the text field or is chosen from the associated pick list, then it will be included with the results in the Test Record file.

The use of two- or three-character codes to represent a work activity is common in managed systems. The default "Choose" list for work order type includes at least these items:

- PM (which means preventive maintenance inspection)
- CM (which means corrective maintenance or repair service)
- IE (which means incoming equipment inspection)

Additional codes as defined by a CMMS may be added to the above list via the **List Editor** of the app's **Setup** menu. See Section 4.8.5 on page 65 for further details.

4.7.3 Completion Code

Some CMMS require Records to specify a completion code which enables an open work order to be closed. If a work completion code is entered into the text field or is chosen from the associated pick list, then it will be included with the results in the Test Record file.

The use of two- or three-character codes is common in managed systems. The default "Choose" list for completion code includes these items and numerous other examples:

- INI (which means incoming inspection has passed)
- PMP (which means preventive maintenance inspection has passed)
- PMR (which means PM inspection passed, with a repair)
- RFS (which means equipment removed from service)

Additional codes as defined by a CMMS may be added to the above list via the **List Editor** of the app's **Setup** menu. See Section 4.8.5 on page 65 for further details.

4.7.4 Labor Type

Some CMMS require technician labor to be recorded as regular time (RT) or overtime (OT). If a labor type is entered into the text field or is chosen from the associated pick list, then it will be included with the results in the Test Record file. The default "Choose" list for labor type includes RT and OT; other types as defined by a CMMS may be added to the list via the **List Editor** of the app's **Setup** menu. See Section 4.8.5 on page 65 for further details.

4.7.5 Labor Time

Technician labor time may be entered in hours, minutes or combination. If entered, the labor time will then be included with the results in the Test Record file. If you do not input a labor time, you will *not* be allowed to save the Test Record file if "Labor time is mandatory" has been set on the **More Settings** menu of the app (see Section 4.8.7.4 on page 72 for further details).

4.7.6 Next Test Due Date

This text field is for input of a future date on or before which a scheduled maintenance inspection of the equipment should be performed. For example, you may choose a due date equal to today's date plus 12 months. If you input a due date at the start of the test, or via the text field on the **Save Test Record** menu, then the date will be shown in the Test Record.

Although you could use the soft keyboard to type a due date, the best way to enter a date is to select it with the "Choose" button. This will ensure dates appear in the Test Record with a consistent format. Note that the date selector control of vPad-IV is reset to today's date every time you begin a new test. If you enter a due date at the start of a test, this setting is maintained until the end of the test and it will then appear in the due date field of the **Save Test Record** menu.

4.7.7 Test Report Title

Information shown by this text field is inserted at the beginning of each Test Record. The report title is shared by all vPad apps, so any changes made to this field in vPad-IV will be seen in other apps. Typically, the title is set to the name of an institution, organization or service provider and may include up to 10 lines of information such as address, phone number, email and so on.

4.7.8 Save Test Setup

When you save a Test Record, you can optionally save the test setup that was used as well. To save the test setup, check the **Save test setup...** checkbox of *Figure 42 before* pressing the **Save** button at the bottom of the menu. If you check the box and then press the **Save** button, vPad-IV will then prompt you to enter a name for the test. The name of the test will become the name of the AutoSequence file, which will be stored in this folder on the tablet:

Datrend/vPad-IV/AutoSequences

Once an AutoSequence file has been saved, you can then recall it for another test performed sometime in the future. Existing AutoSequences can also be opened and their settings reviewed or modified with the **AutoSequence Editor** menu. See Section 4.8.6 on page 67 for further details.

4.7.9 Save Data Log

A "data log" comprises all the individual measurements of time, volume, flow and/or pressure as acquired over the course of the test. To save such details, check the **Save data log** checkbox of *Figure 42 before* pressing the **Save** button at the bottom of the menu.

A data log file is identified by the control number or ID of the device and, similar to a Test Record, the filename will include a date-time stamp and will additionally specify the test type and channel number. The data log file is in standard comma-separated variables or "CSV" format, which is compatible with most spreadsheet programs. Data log files are stored in this folder on the tablet:

Datrend/vPad-IV/DataLogs

The data log recording function, controlled via the **Save data log** checkbox of *Figure 42*, is a 'sticky' setting which retains its state between tests. Once enabled by the menu of *Figure 42*, data log recording may be optionally disabled later on via the **More Settings** menu of the app, under the Test Record settings (see Section 4.8.7.4 on page 72).

When running an AutoSequence with data log recording enabled, you will be prompted to save a log file for each step in which a test is performed. Options are provided to bypass saving of the CSV file or otherwise disable data log recording altogether. For an AutoSequence, the **Save data log** checkbox of *Figure 42* is not shown since logs are optionally saved over the course of the sequence, as each test step is completed.

4.8 System Setup

The vPad-IV **Setup** menu (*Figure 43*), entered from the main menu of the app, enables users to access AutoSequence programming and additional device and app settings.
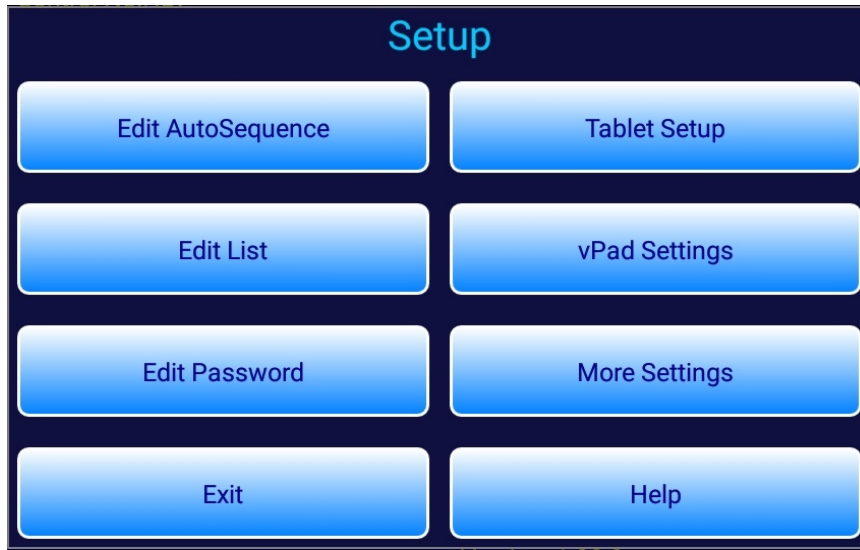
Figure 43

4.8.1 Password Setup

Access to the **Setup** menu may be optionally protected by a password. Department managers or institutions may require such security to prevent technicians from making changes to approved maintenance protocols. If a password has been created, then a user must enter the correct password before the **Setup** menu will be displayed.

To create or modify the password, press **Edit Password** on the **Setup** menu to display the "Edit Password" dialog. An active password can be disabled by clearing the password field on dialog then pressing **Save and Exit**. As indicated on the dialog, you can long-press on the text field to erase the password.

In the event a password is entered but is later forgotten, you can enter an override password which will grant access to the **Setup** menu. Once you gain access to the menu, the password can be erased or a new password entered. The override password is specific to each vPad unit. Contact Datrend Customer Service to obtain further instructions for the override password.

4.8.2 vPad Secure Support

vPad-IV is a security-aware app which can work with **vPad-Secure™**. Although the **Setup** menu password provides a basic level of security for vPad-IV alone, broader levels of security which govern operation of the entire tablet are possible when vPad-Secure is used.

If the **Setup** button on the main menu of vPad-IV appears disabled or greyed-out, this means vPad-Secure is installed on the tablet. To enable access to the **Setup** menu, it is necessary to enter the "app settings" password into *vPad-Secure* to release the lock on the **Setup** button. If desired, the vPad-IV password may still be used to provide a second tier of protection.

4.8.3 Tablet Setup

Press the **Tablet Setup** button of the **Setup** menu (*Figure 43*) to open the **Android Settings** menu. Use this menu for setup operations at the device level, for example:

- find a nearby WiFi wireless network and connect to it
- pair the tablet with a Bluetooth device such as a barcode scanner, printer or vPad analyzer
- change the Language and choose and/or configure Input devices, such as soft keyboards
- unmount a USB flash drive which has been connected to the tablet

Menu options and usage will depend on the Android version as specified under **About tablet**. Once the version is known, further information can be found by searching the web.

4.8.4 vPad Settings App

Press the **vPad Settings** button of the **Setup** menu (*Figure 43*) to launch the **vPad Settings** app. **vPad Settings** starts up by showing the General Settings tab. This tab is used to configure settings that are shared by several apps of the vPad family, including vPad-IV. For example, the "default test interval" setting on the General Settings tab will determine an initial date that is shown whenever a date selector menu is displayed by vPad-IV (initial date will be today, plus the "default test interval").

The most important settings for vPad-IV are those shown on the **Device Setup / vPad-IV** tab (see *Figure 44*).

Figure 44

These settings are associated with the *USB or Bluetooth connection* to the Controller Module of the vPad-IV system, which is the Module that is typically set to **channel one**.

To change the connection type from USB to Bluetooth (or visa versa), confirm the vPad-IV system is powered up and running. Select **vPad-IV** under **Device Setup** on the left of **vPad Settings**. If changing from Bluetooth connection to USB, make sure a USB cable is connecting the tablet to the Controller Module before continuing. If changing from USB connection to Bluetooth, confirm the "Bluetooth name" as shown by **vPad Settings** matches the Bluetooth ID of the Controller Module, which may be found on the rear panel of the Module. If the name shown by **vPad Settings** does not match that on the back of the Controller, press the selector to display a pop-up list of Bluetooth devices and change the name accordingly.

If the tablet's Bluetooth is OFF, or if the "Bluetooth name" of the Controller is not included in the pop-up list shown by **vPad Settings**, then press the **Bluetooth Settings** button. This will open the Bluetooth Settings menu of the tablet itself, from which you can enable the Bluetooth, and if necessary, pair the tablet with the Controller by performing a search for nearby Bluetooth devices.

Other settings include those listed under **Printers and Accessories** (*Figure 45*). At the end of a test, the vPad-IV app can print a maintenance inspection or "PM" tag for application to the infusion device. At minimum, such tags will include the equipment ID and the date of the test, and will often include a due date for the next inspection. To enable such printing, set **Enable label printing** in vPad Settings to "ON".

Figure 45

vPad-IV is compatible specific models of label printer. Each model may have various settings, including connectivity options and media type (i.e., size of label). Printer settings which may be configured in **vPad Settings** are:

Printer type	Selects make/model and corresponding connectivity option (WiFi or Bluetooth). Note the vPad-IV Controller is *not compatible* with label printers which require connection to a "XSC Smart Cable" interface, including **Brady TLS PC**, **Dymo SE300/450** and **Zebra GC420t** models. vPad-IV is compatible with label printers that work directly with the tablet through Bluetooth or WiFi connectivity, for example, **Brother PT-950NW** and **PT-750W** models.
Label media	Sets label size for those printers which accept a range of label stock
Label title	For printers which support a title, this will be printed at the top of the label in a larger font. Typically, this would be set to the name of the equipment owner, an institution, a service organization, or similar identification.
Print signature field	Enables printing of an underlined space where a technician may sign or initial the label
Barcode	Options are shown only if the selected printer supports barcodes. Select (linear) Code 128 or (two-dimensional) QR Code as desired.

Once the printer has been configured, press the **Test Printer** button to check connectivity.

Whether printed as a connectivity test or as an actual PM tag meant for application to an infusion device, vPad-IV will display a preview of the label before it is printed. Users may optionally cancel the printout or print multiple copies of the label if desired.

4.8.5 List Editor

Press the **Edit List** button of the **Setup** menu (*Figure 43*) to select and edit a pick list displayed by a "Choose" button on the **Equipment Information Editor** (see Section 4.4.1, page 41), or other user interface menu provided by vPad-IV. By means of the vPad-IV text editor, items may be added or deleted from any of the following pick lists:

- • Device manufacturers
- • Device models (model number and/or name)
- • Device descriptions (IV pump; PCA pump; enteral feeding pump; etc.)
- • Facilities (e.g. institutions, hospitals, clinics)
- • Facility locations (e.g. departments, wards, room numbers)
- • Technicians (e.g. names, initials, employee numbers)
- • Work order types (per CMMS, e.g. PM; CM; IE; etc.)
- • Labor types (also per CMMS, e.g. regular time; overtime; etc.)
- • Completion codes (also per CMMS: e.g. PMP (PM pass); etc.)

Figure 46 is an example which shows the list of device manufacturers being viewed in the Text Editor of vPad-IV.

Figure 46

Lists are text files which are stored in this folder on the vPad tablet:

Datrend/vPad-IV/Tables

Lists are not intended to replace a database but are meant to provide selectable "favourites" which may be entered frequently during use of the app. Accordingly, lists may be edited so that the most frequently-chosen items appear first.

4.8.6 AutoSequence Editor

Press the **Edit AutoSequence** button of the **Setup** menu (*Figure 43*, page 61) to create or modify an AutoSequence.

4.8.6.1 Create and edit

Before entering the **AutoSequence Editor**, users may select either of two editor options:

Edit Existing AutoSequence	Opens a browser which shows a list of AutoSequence files that are currently stored on the tablet. The AutoSequence to be edited is selected by pressing the corresponding row. While viewing the list, an undesired AutoSequence may be deleted by long-press gesture on the row.
Create New AutoSequence	Opens the editor with a generic AutoSequence template

After choosing an existing AutoSequence to edit, the editor will open the corresponding file and display the steps comprising the sequence. An example sequence which has 8 steps and which includes a flow test and an occlusion pressure test is shown in *Figure 47*. The steps of the sequence are executed in the same order they appear in the editor.
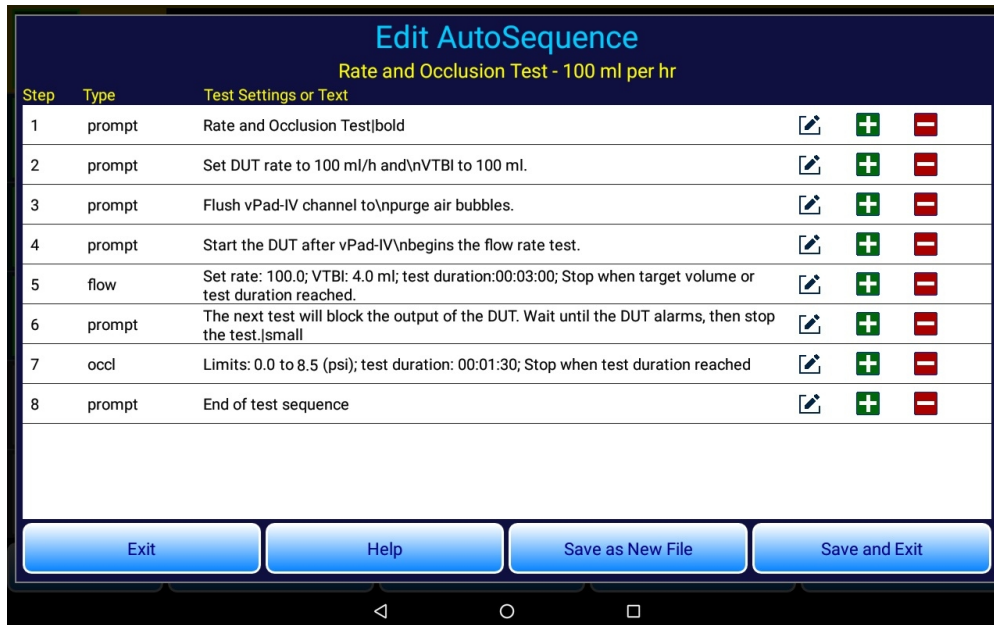

Figure 47

4.8.6.2 Editor actions

Referring to *Figure 47*, buttons on the editor screen provide these functions:

	Opens the step editor for the selected step
	Adds a new step below the selected step
	Removes the selected step from the sequence
Save and Exit	Saves changes to the AutoSequence file being edited and closes the editor
Save as New	Saves contents of editor to a new AutoSequence file; you will be prompted to enter a filename
Help	Displays the on-line user manual, AutoSequence Editor chapter
Exit	Closes the editor without saving changes

4.8.6.3 Step types

Referring to *Figure 47*, step "*types*" shown on the left of the editor screen invoke these operations during an AutoSequence:

|	
prompt	Displays instructions for test setup or other information
check	Intended for visual inspections of the infusion device. Requires user selection of a result chosen from the options, which is then saved to the Test Record: • PASS - Result is acceptable • FAIL - Result is not acceptable • SERVICE - Repair or other service was performed to obtain an acceptable result • N/A - Task does not apply to this device • INFO ONLY - Result is information rather than PASS or FAIL
flow	Runs a Flow Rate Test with settings for rate, VTBI and time as shown by the editor. On completion of the **flow** step, a summary of the measurement results is saved in the Test Record.
pigbk	Runs a Piggyback/KVO Test with settings for each infused dose of the test as shown by the editor. On completion of the **pigbk** step, a summary of the results for each dose is saved in the Test Record.

pca   Runs a PCA Pump Test with settings for bolus volume, basal rate and lockout as shown by the editor. On completion of the **pca** step, a summary of the measurement results is saved in the Test Record.

occl   Runs an Occlusion Pressure Test with settings for pressure limits and test duration as shown by the editor. Optionally, the test can be configured to maintain the pressure in the channel after the test is completed; this mode is useful for testing devices which may provide multiple occlusion pressure limits or thresholds. On completion of the **occl** step, a summary of the results is saved in the Test Record.

backpr   Displays real-time readings of pressure as measured by the channel, so that a back pressure or vacuum being applied externally to the infusion device can be adjusted before a Flow Rate or other test commences. The back pressure measured by this step is saved to the Test Record. For further details on back pressure setup, see Section 3.5.2 and *Figure 16* on page 20.

prmon   Similar to back pressure, the pressure monitor shows real-time pressure readings while displaying the average, maximum and minimum value of the pressure. The user may manually control whether the channel input is blocked or occluded, or otherwise remains open. Average, maximum and minimum pressures are saved to the Test Record when the step is completed.

Further details of the above step types, in particular how these steps will appear and function during execution of the sequence, are given in "Running Pump Tests" (Section 4.5, page 44) and "AutoSequence Steps" (Section 4.5.6, page 49).

When a new step is added to the sequence, the step is initilized to default settings. Clicking the **Edit** button opens the step editor to enable customization.

4.8.6.4 Step editors

Each step type has an associated editor that allows users to control appearance and behaviour of the step. Test-related step editors enable users to configure test settings such as rate, volume-to-be-infused (VTBI), stop condition and pass/fail tolerance.
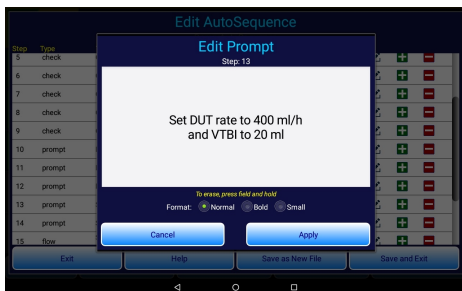

Prompt Editor

During sequence execution, a **prompt** step displays instructions to the user and/or other information. The prompt text can be freely customized, and formatted with **bold** type for emphasis or small type for longer messages or detailed instructions. The text is center-justified for normal and **bold** font, and left-justified for small font.

Check Editor

A **check** step typically displays a message which requests the user to inspect the infusion device and choose a result from the available options (PASS; FAIL; N/A; etc). Similar to a **prompt**, a **check** step optionally provides **bold** or small font.

Test Editors
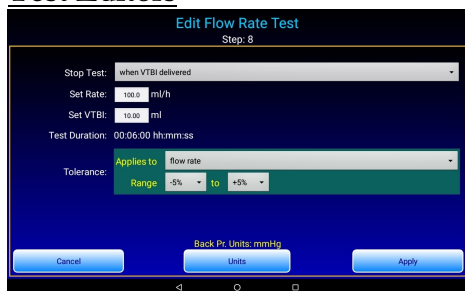
A test step executes an infusion device test in automatic mode as part of the AutoSequence. Flow Rate, Piggyback, PCA and Occlusion Tests are available. Users can add multiple tests of each type to the AutoSequence, limited only by practical considerations such as the total run time of the sequence. See Section 4.3.3 on page 29 for detailed instructions on configuring each type of test. Note that manual testing is not possible in an AutoSequence.

Back Pressure Editor

A **backpr** step in an AutoSequence enables users to monitor a back pressure or vacuum that has been externally applied to the infusion device via the output port of the Module. As the step is being executed, users may adjust the applied pressure or vacuum until a value required by the test protocol is reached. A back pressure step typically preceeds a Flow Rate Test where the response of the infusion device to the applied pressure or vacuum is evaluated. The back pressure editor requires input of the target back pressure or vacuum and the units of measure.

Pressure Monitor Editor

A **prmon** step in an AutoSequence is similar to **backpr** in that pressure in the channel is monitored during the step. Although there is no pressure target specified for the step, the editor allows the user to select the units of measure.

4.8.7 More Settings

Press the **More Settings** button of the **Setup** menu (*Figure 43*, page 61) to open the application settings menu (*Figure 50*).
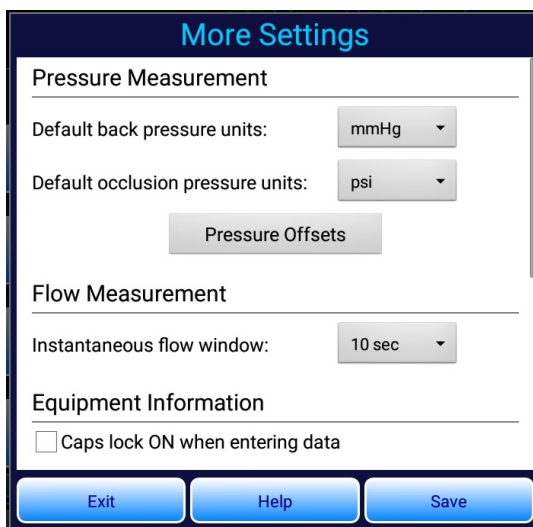

Figure 50

4.8.7.1 Pressure measurement settings

Use these controls to set the default units of measure for back pressure and occlusion pressure. These are default settings which are restored each time the app starts up, but which may be changed at test runtime as required to suit a specific protocol.

As described in Section 4.3.3.6 on page 31, the pressure measurement may be zeroed on each channel independently. Press the **Pressure Offsets** button to view a menu which displays the current zero offset for each channel. Via the **Pressure Offsets** menu, zero offsets may be reset individually or collectively.

4.8.7.2 Flow measurement settings

During a test, instantaneous flow is calculated from the incremental increase in volume ΔV which is observed over a preselected measurement time or "window" ΔT. The instantaneous flow window provides selections of 10, 30 or 60 seconds for ΔT, with 10 seconds being the default. Higher settings of the window reduce sensitivity of the instantaneous flow measurement to impulses and other short-term disturbances in an infusion. A setting of 30 or 60 seconds may be preferable when testing devices such as enteral feeding pumps, which may have a pulsatile or intermittent delivery characteristic.

4.8.7.3 Equipment information settings

Setting	Default	Description
Caps lock ON	Disabled	Affects data entry of equipment information via the soft keyboard, including ID or control number. If enabled, letters a-z will appear as uppercase A-Z. For this setting to take effect, you will need to enable the "Auto capitalization" text correction feature of the soft or "virtual" keyboard on the tablet. This is done via the Android Settings menu.

4.8.7.4 Test record settings

Setting	Default	Description
Save to:	`vPad-IV/Records`	Test Record files may be saved in any folder of the tablet; by default, the app saves them to `Datrend/vPad-IV/Records`. To save files in a different folder, such as `Datrend/vPad-Check/Records`, enter the full path of the folder in this box. Records should be stored somewhere within the `Datrend` folder, so that vPad Record Manager will be able to find them.
Disable signature/date	Disabled	By default, Test Records include an underlined space for a technician to sign and date when a paper copy of the Test Record is printed. Enable this setting to omit this line in the Test Record.
Omit next test due date	Disabled	By default, vPad-IV will include a "next test due" date in the Test Record, if such a date was input during the test. Enable this setting to prevent a due date from being included in Test Records. If enabled, the setting will also prevent users from entering such dates via the **Equipment Information Editor**.
Labor time is mandatory	Disabled	Technician labor time may be entered on completion of a test when the Test Record is saved. If this setting is enabled, the user cannot finish a test unless they enter their labor time.

Save data log	Disabled	The "data log" of a test comprises individual measurements of time, volume, flow and/or pressure acquired over the course of a test. This setting enables saving of such detailed data in CSV format when a Test Record is saved, or for an AutoSequence, as each test step of the sequence is completed.

4.9 Record Manager App

vPad Record Manager is an app which is installed on the Android tablet and which may be run independently of, or simultaneously with, the vPad-RF app.

Record Manager may be used to copy, print, and/or delete Test Record files saved by vPad-RF. Record Manager can also be used to convert Test Records to Adobe PDF documents. Note that PDF is a format which enables vPad Record compatibility with other Android apps, for example, e-book readers and document printing apps.

Press   on the Android HOME screen to launch the Record Manager app.

Figure 51

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

Chapter

5

5   Calibration and Maintenance

5.1   Calibration

Calibration of vPad-IV by a Datrend Authorized Service Center is recommended on an *annual* basis, and is *required* to extend the product warranty. The basic one (1) year warranty on the Modules 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 each Module to determine its calibration status.

5.2   General Maintenance

Except as specified in Section 5.4 below, vPad-IV contains no user serviceable parts. Maintenance of vPad-IV requires return of the Module(s) to a Datrend Authorized Service Center for repair. *Opening the case of a vPad-IV Module for any reason, other than according to the instructions of Section 5.4, will void the warranty and may compromise user safety.*

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

⚠️   Service must be performed by a factory trained, authorized service agent. Damage to internal flow and/or pressure sensors may result if Datrend service procedures are not followed.

⚠️   Safety of the operator may be compromised if the instructions in this manual are not followed, or if vPad-IV is used for a purpose not specified in this manual.

5.3 Routine Cleaning

Each vPad-IV Module should be cleaned once a month at a minimum when used with tap water, or once every four to six months when used with bottled drinking water or distilled water respectively. These recommendations apply to instruments which remain set up and primed at all times. If vPad-IV spends much of its time dry and in storage, cleaning should be conducted more frequently, ideally when dry Modules are primed for the first time during the initial setup (see Section 3.5.4 on page 20). Cleaning after a period of dry storage is the preferred method of "wetting" the fluid system prior to use (see Section 3.5.5 on page 22).

In the event vPad-IV is accidentally contaminated with dextrose, TPN solution or other incompatible fluid, the routine cleaning procedure described below should be adequate, provided such cleaning is performed immediately following the contamination. If repeated cleaning does not appear to improve test results, then refer to additional information in Section 5.4.

5.3.1 Cleaning Solutions

Cleaning solutions which are compatible with vPad-IV are listed below, ranked in terms of their relative effectiveness. The most effective cleaners for vPad-IV are strongly alkaline and have hydrophillic or water-attracting characteristics. Use only the cleaning agents specified below as others may have unintended side effects on operation of the instrument, or may cause damage to internal plastic components.

Cleaning solution	Rating	Preparation
Micro-90® in water	#1	Add 10 ml Micro-90® detergent to 190 ml distilled water. Mix gently to avoid foaming. Note Micro-90 is manufactured by International Products Corp. (www.ipcol.com) and is available in small quantities from Cole-Parmer (www.coleparmer.com).
Ammonia and liquid soap in water	#2	Add 20 ml concentrated pure ammonia household cleaner to 180 ml distilled water. Add 2 ml liquid dish soap (not dishwasher detergent) to the solution. Mix gently to avoid foaming. Note hazard warning below.
Sudsy Ammonia™ in water	#3	Where available, Sudsy Ammonia™ brand-name household cleaner may be used as an alternative to cleaning solution #2. Prepare by gently mixing 100 ml Sudsy Ammonia with 100 ml distilled water. Note hazard warning below.

Commercially-available cleaners which contain ammonia, although intended for home use, are toxic. Fumes may irritate eyes and nasal passages; direct contact may irrate the skin. **Use gloves and goggles** when preparing and using cleaning solutions that contain ammonia. In preparing a solution, always add liquid ammonia *to* water, not the other way around. Never mix ammonia cleaners with bleach as the combination will produce chlorine gas, which can be lethal.

⚠️ **DO NOT** use **window glass cleaners**, such as *Windex®* and similar household cleaners, with vPad-IV. Such cleaners include hydrophobic or water-repelling additives which can disrupt operation of the vPad-IV flow sensor.

5.3.2 Cleaning Procedure

a. Select a suitable cleaning agent as specified in Section 5.3.1, according to personal preference, local availability, and/or workplace guidelines. Prepare the cleaning solution in the concentration specified in the table of Section 5.3.1. When using Micro-90® in water, effectiveness of the cleaner may be increased by warming it in a microwave oven immediately prior to use; raise the solution temperature to 50°C or until the container is warm to the touch, and do not allow the solution to boil.

b. Fill a disposable 60 ml syringe with the cleaning solution and connect the syringe to the fluid input of the vPad-Module to be cleaned. Do not use the same syringe you use for vPad-IV priming because the cleaning solution will remove the syringe's lubricant.

c. Discharge the entire syringe into the Module at about 2 ml per second. Refill the syringe and then repeat. Under no circumstances should you quickly draw solution back into the syringe as the excessive suction may damage internal sensors.

d. Let the cleaning solution sit in the Module for about 10 to 15 minutes. **DO NOT** leave the cleaning solution in the unit for an extended period as prolonged exposure to the solution may cause damage to internal plastic components.

e. Flush the Module thoroughly with distilled water to remove all cleaning solution from the fluid system, as described in paragraph "c" above.

f. If the Module has been contaminated with a sticky liquid (e.g. dextrose (D50W), TPN solution, etc.), you may need to perform this procedure using a cleaning solution that has higher concentration. In such situations, use undiluted Sudsy Ammonia, or for other solutions, double the volume of the active agent (ammonia or Micro-90) in water. **DO NOT** allow the cleaning solution to remain in the Module for more than 10 minutes maximum, and be sure to thoroughly rinse the instrument with distilled water afterwards as described in paragraph "e" above.

5.4 Service Cleaning

Failure to observe test fluid recommendations as specified in Section 3.5.1 of this manual may result in inaccurate, intermittent or erratic measurements of flow and volume. When contamination by a soiled or incompatible fluid is minor, or is recognized immediately after the contamination occurs, the regular cleaning procedure described in Section 5.3 may be able to overcome the problem, although it may be necessary to repeat the procedure several times.

If an incompatible fluid such as dextrose (D50W) or TPN solution has been left in a Module for a period of time, and particularly if the Module has been allowed to dry out while such fluid was in the unit, then direct scrubbing of the **glass flow sensor** inside the Module will likely be necessary to remove the deposits on the glass. The vPad-IV Module has provisions which enable this repair procedure to be performed by an end-user in the field, potentially making it unnecessary for the user to return the damaged Module to an Authorized Service Center for repair.

The field repair procedure requires a Flow Sensor Cleaning Kit (part number **7500-155**), which contains the necessary tools and instructions. A single kit may be used to service multiple vPad-IV Modules. To request a 7500-155 kit, contact your Datrend distributor or Datrend Customer Service as specified in Section 5.5.

Do not disassemble the Module and attempt direct-contact cleaning of the internal glass flow sensor without a 7500-155 kit. Failure to use correct tools and procedure may result in irreversible damage to the Module or flow sensor which is not covered under warranty.

5.5 Service and Technical Assistance

For calibration, service assistance or technical support, contact:

Datrend Systems Inc.
Unit 130 - 4020 Viking Way
Richmond, BC • CANADA • V6V 2L4
Tel: 800.667.6557 (North America only) or
+1.604.291.7747 • Fax +1.604.294.2355
e-mail: **CustomerService@datrend.com**
www.datrend.com

For calibration and repairs, you will be given a Return Materials Authorization (RMA) number and the location of the nearest Service Facility.
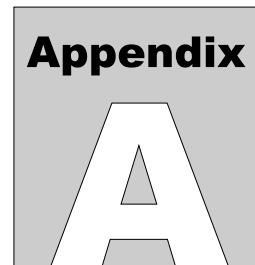
APPENDIX A. Sample Test Record

This appendix provides an example of a vPad-IV Test Record, illustrating the data representation for flow, volume, pressure and time. This Test Record was obtained by running the "IV Pump PM Inspection" AutoSequence, which includes visual inspection steps, a flow test, and an occlusion pressure test.

```
               Biomedical Engineering Dept.
                  St. Joseph's Hospital
                    1234 Main Street
                   MyTown MyState 98765
               Phone: 123-456-7890 Ext. 123


File: CN1234_20200910_144147_P.txt
Date: 2020 Sep 10
Time: 14:41:47
vPad-IV ID: My vPad-IV
Module SN:  IVM2020070138  Cal Date: 2020-07-23


Equipment Information...
Control No./ID:  CN1234
Description:     INFUSION PUMP
Manufacturer:   ABBOTT
Model:          PLUM XL
Serial Number:  78560-45221
Location:       ICU
Facility:       St Josephs Hospital


Work Order:     WO1234
Work Order Type: PM Preventive Maintenance
Completion Code: PMP Pm complete-Pass


Technician:     ZRS
Labor Type:     RT Regular Time
Tech Time (hrs): 2.00
          (min): 120


Overall Result:  PASS
Next Test Due:   2021 Sep 10


Signature:_____  Date:_____
```

```
DETAILED TEST DATA:
IV Pump PM Inspection, Channel 1
_____


Task:    Check DUT enclosure for damage
Data:    ----
Result: PASS
_____


Task:    Check power cord and plug
Data:    ----
Result: PASS
_____


Task:    Check fuse and ratings
Data:    ----
Result: PASS
_____


Task:    Check indicators and displays
Data:    ----
Result: PASS
_____


Task:    Check battery and battery charger
Data:    ----
Result: PASS
_____


Task:    Check air-in-line sensor
Data:    ----
Result: PASS
_____


Task:    Run Flow Rate Test
Data:    Set Rate (ml/h):        400.0 (tolerance -5 to +5%)
         Set VTBI (ml):          20.00 (tolerance -5 to +5%)
         Back Pressure (mmHg):   8.3

         Duration (hh:mm:ss):    00:03:00
         Delivered Volume (ml): 19.89 (error -0.5%)
         Average Flow (ml/h):    397.9 (error -0.5%)

         Flow Statistics (ml/h):
         Mean    Max.    Min.    S.D.    2*SD    CV(%)
         398.0   445.4   342.0   21.30   42.59   5.35
Result: PASS
_____
```

```
Task:    Run Occlusion Pressure Test
Data:    Time of peak pressure (hh:mm:ss):   00:00:46
         Peak Pressure (psi):    20.0 (limit 22.00 max)

         Pump alarm/test stopped (hh:mm:ss): 00:00:43
         Final Pressure (psi):   20.0
Result: PASS

END OF RECORD
```