

**FLUKE**®

**Biomedical**

# Operators Manual

- **IDA-4 Plus**  
*Infusion Pump  
Analyzer*



**FLUKE**®

**Biomedical**

# **IDA-4 Plus**

## **Infusion Pump Analyzer**

# **Operators Manual**

April 2005

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# Notices

**Fluke Biomedical**  
6920 Seaway Blvd.  
Everett, WA 98203  
USA

## Customer Support and Sales

USA and Canada: 800.648.7952  
Outside the USA: 775.883.3400  
Sales E-Mail: [sales@flukebiomedical.com](mailto:sales@flukebiomedical.com)  
Internet: [www.flukebiomedical.com](http://www.flukebiomedical.com)

## Service:

USA and Canada: 888.993.5853  
Outside the USA: 425.446.5560

For additional sales or service information, contact your local Fluke Biomedical Distributor or Fluke Electronics office

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## Restrictions and Liabilities

Information in this document is subject to change and does not represent a commitment by Fluke Biomedical. Changes made to the information in this document will be incorporated in new editions of the publication. No responsibility is assumed by Fluke Biomedical for the use or reliability of software or equipment that is not supplied by Fluke Biomedical, or its affiliated dealers.

## Claims

Our routine method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim.

If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact Fluke Biomedical or your local sales representative.

## Obtaining Assistance

If you have trouble operating the IDA-4 Plus, or just need some clarification on its operation, contact Fluke Biomedical's Technical Assistance Center at 800-648-7952.

## Returning the Instrument to Fluke

If it becomes necessary to return your instrument to Fluke, proceed as follows:

1. Every product returned to Fluke must have a Return Material Authorization (RMA) number. To obtain an RMA, contact Fluke through one of the following methods:

Phone: 888-99FLUKE (888-993-5853) or 425-446-5560  
Email: [service@fluke.com](mailto:service@fluke.com)

2. Pack the instrument carefully, using the original packing materials if available. Failure to pack the instrument properly could void your warranty and result in you paying for the instrument's repair.
3. Insure the unit for full retail value and ship to the address specified by Fluke

## Warnings

### Patient Circuit

This instrument has been designed for testing infusion devices but must **NEVER** be used while connected to a patient.

Tubing sets utilized to test infusion devices must never be used to administer fluids to patients.

Some older style infusion devices may have reusable components that could come in direct contact with the fluids being pumped. When testing these types of devices care must be taken to avoid possible contamination of reusable components due to backflow conditions.

### Contamination of the Measuring System

For best results use degassed water made up with detergent, as described under 'Test Fluid' on page 3-4.

High viscosity fluids cannot be used. Liquid containing oils (solvents, or strong chemicals) may also damage or contaminate the transducer. Do not use "Bleach" type of sterilizing agents, or alcohol's.

To extend the life of the transducer and to maintain accuracy it is recommended that periodically 20 ml of detergent solution be introduced into the fluid inlet port, left for 30 minutes, and then flushed out with 500 ml of clean water.

Care should be taken to prevent dirt, dust, metal swarf, or other debris from entering the measuring system since these are likely to damage the transducers.

### Explosion Risk

This instrument is not to be used in the presence of flammable anesthetic gases or vapors.

### Switching the Instrument **ON** or **OFF**

As is common with most other computing equipment, this instrument may be damaged by repeated interruption of the power supply, either by rapid switching **ON** or **OFF**, or by removing the line cord when the instrument is energized. After switching **OFF** allow at least 3 seconds before switching the unit **ON**. Never disconnect the line cord without first switching the unit **OFF**.

The **ON** / **OFF** switch is located on the rear panel of the unit.

### Connections

All external leads connecting to the **IDA-4 Plus** e.g. RS232 and Printer leads, must be no longer than 2.5 meters in length.

# Storage and Shipping

## Removing Internal Water before Shipping or Storage

Before long-term storage or shipping it is recommended that all-internal water be removed from the instrument. After manufacture and testing, internal water is removed by connecting the **FLUID OUT** ports to a (medical) suction pump for 2 minutes in the unit “**OFF**” condition. Users may wish to employ this method, which will not harm the unit.

Do not use compressed air to clear out internal water since pressures greater than 310 kPa (45 psi) may damage the pressure transducer.

## Storage and Packing

Remove as much internal water as possible (as described above).

Store away from sunlight.

Protect from frost (internal water may freeze and expand)

Protect from vibration and shock

The unit is a delicate electronic measuring instrument and as such should be cared for in the appropriate manner.

The unit should not be opened unless there is a facility to confirm the function and calibration of the unit afterwards.

There are certain types of keyboard that under ESD conditions can cease to function. Disconnecting the keyboard and reconnecting usually restores normal keyboard function. It is recommended a CE marked keyboard is used.

## Trademarks

All trademarks mentioned in this document are acknowledged.

## Manufacturing for:

**Fluke Biomedical**  
6920 Seaway Blvd  
Everett, WA 98203 USA  
775-883-3400  
800-648-7952

# Warranty

## Warranty and Product Support

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one full year from the date of original purchase. During the warranty period, we will repair or, at our option, replace at no charge a product that proves to be defective, provided you return the product, shipping prepaid, to Fluke Biomedical. This warranty does not apply if the product has been damaged by accident or misuse or as the result of service or modification by other than Fluke Biomedical. **IN NO EVENT SHALL FLUKE BIOMEDICAL BE LIABLE FOR CONSEQUENTIAL DAMAGES.**

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

Recalibration of instruments is not covered under the warranty.

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

## Warranty Disclaimer

Should you elect to have your instrument serviced and/or calibrated by someone other than Fluke Biomedical, 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 Fluke Biomedical for factory 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, you must first contact Fluke Biomedical's Technical Assistance Department at 775-883-3400. You will be required to provide 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.

# Chapter 1

## Introduction

*This chapter introduces the instrument and describes its features.*

### Thank you

Thank you for purchasing this instrument. It will allow you to verify the operation of your infusion devices providing measurements of volume delivered, flow rate and occlusion and backpressure.

### Introduction

There is now a reliable way to verify the condition and performance of infusion devices with various methods of delivery. This instrument has been provided to the medical and health industry so that the performance of most infusion devices currently on the market can be determined.

### Device Compatibility

The purpose of this unit is to quickly establish the state of any given infusion device and to determine the performance qualities of the device. This instrument can test and evaluate virtually any infusion device on the market today.

Because each infusion device manufacturer uses slightly different technology and delivery methods vary, provisions have been made to measure all currently used methods of delivery.

### About This Manual

The intent of this user's guide is to quickly instruct the new user on how to set up and operate this instrument. To this end, we've employed certain conventions to help you read and understand this manual.

The operation of this instrument is shown with LCD screen detail and text instructions and description, including which particular button to press, alongside the screen.

## **Features**

- ✓ Tests up to four Infusion Devices simultaneously (when four measuring Transducers fitted)
- ✓ Five button keypad operation
- ✓ Measurement of Volume Delivered
- ✓ Measurement of Flow Rate
- ✓ Measurement of Occlusion Pressure
- ✓ Measurement of Back Pressure
- ✓ Menu driven Utilities settings
- ✓ LCD (liquid crystal display) super twist Graphics with back light

## **Package Contents**

The contents of this package as shipped include:

- ✓ The main unit
- ✓ Line Cord
- ✓ 4 x 3 way Luer stopcock.
- ✓ 1 x 20 ml syringe
- ✓ 4 x Drain tubing
- ✓ 2 x Fuse
- ✓ Operator's Manual
- ✓ Calibration Certificate
- ✓ Certificate of Conformity
- ✓ Registration card

## Specifications

### Electrical Specification:

Supply Voltage	90 - 260 VAC.
Supply Frequency	50 - 60 Hz.
Supply Power	< 30 VA.
Fuse	20 mm 250 V, 1 A (T) (slow blow).
Earth Leakage Current	< 1.0 mA in single fault condition.

### Flow Rate Measurement

- Technique:** Flow is calculated by measuring a volume over time.
- Range:** 0.5 - 1000 ml/hr.
- Accuracy:** 1% of reading  $\pm$  1 LSD for flows of 16 - 200 ml/hr for volumes over 20 ml. Otherwise, 2% of reading  $\pm$  1LSD after delivery of 10 ml under laboratory conditions.

### Volume Measurement

- Technique:** Volume is measured directly by the transducer in minimum sample sizes of 60 micro-liters.
- Range:** 0.06 - 9999 ml.
- Accuracy:** 1% of reading  $\pm$  1 LSD for flows of 16 - 200 ml/hr for volumes over 20 ml. Otherwise, 2% of reading  $\pm$  1LSD after delivery of 10 ml under laboratory conditions.

### PCA Bolus Measurement

- Technique:** Volume is measured directly by the transducer in minimum bolus volumes of 0.5 ml. The measurement is made with a continuous rate between 0.0 and 30 ml/hr. The bolus flow rate should be at least four times the basal flow rate for reliable detection of boluses.
- Min Bolus:** 0.5 ml.
- Accuracy:** See volume measurement.

### Pressure Measurement

- Technique:** Direct occlusion of the infusion line and measurement of pressure prior to the glass transducer.
- Range:** 0 to 45 PSI and equivalents in mmHg and kPa.
- Accuracy:** 1% of Full Scale  $\pm$  1 LSD under laboratory conditions.

### **Physical**

- Dimensions:** ~19.05 cm x 18.11 cm x 30.18 (L x W x H)  
(for rear panel handle add 3.81cm)
- Weight:** 5.0 Kg (with 4 transducer fitted)
- Case:** Molded plastic front panel, metal rear housing.
- Color:** RAL 9002

### **Environmental**

- Operational:** 15-30 C up to 50% Relative Humidity
- Storage:** 0-40 C at 85% RH or less  
Do not leave for more than 48 hours at -20 C

### **Transportability**

If possible use the packaging supplied by the manufacturer. If this is not possible then enclose the instrument in a clear plastic bag, and place it in a cardboard box with plastic packing materials, with at least 5 cm (2 inches) between the instrument and the exterior of the box to protect against shock. Remove all water before packing.

## Chapter 2

# An Overview

*This chapter gives an overview of the instrument to help you understand the system.*

### Description of the Device and Intended Use

#### General

This is an instrument providing an automated system for measuring the Flow Rate, Volume Delivered and Occlusion (Stall) Pressure of Infusion Devices with various methods of delivery.

It is used to verify the performance of Infusion Devices and provides facilities for displaying results on the instrument's LCD, saving test results for subsequent printing and / or downloading to a PC.

#### Model Variations

There is one basic design which has provisions for one, two, three or four independent channels of measuring transducers within a common housing, providing options for testing up to four Infusion Devices simultaneously with one instrument.

#### Operational Modes

The unit can be used in a stand alone mode displaying results on the LCD and can subsequently print saved test results via a printer port and / or download saved test results to a PC via an RS232 port.

The unit may also be linked to, controlled by and display results via a PC using an external program, such as HydroGraph™ available from Fluke Biomedical.

#### Volume & Flow Measurement

Volume and flow measurements are achieved by using a calibrated burette and opto-sensors within each measurement transducer to accurately monitor the volume and time of the meniscus passing up the burette. This data is processed to provide Average Flow Rates, Bolus and Total Volume Delivered and Timing measurements.

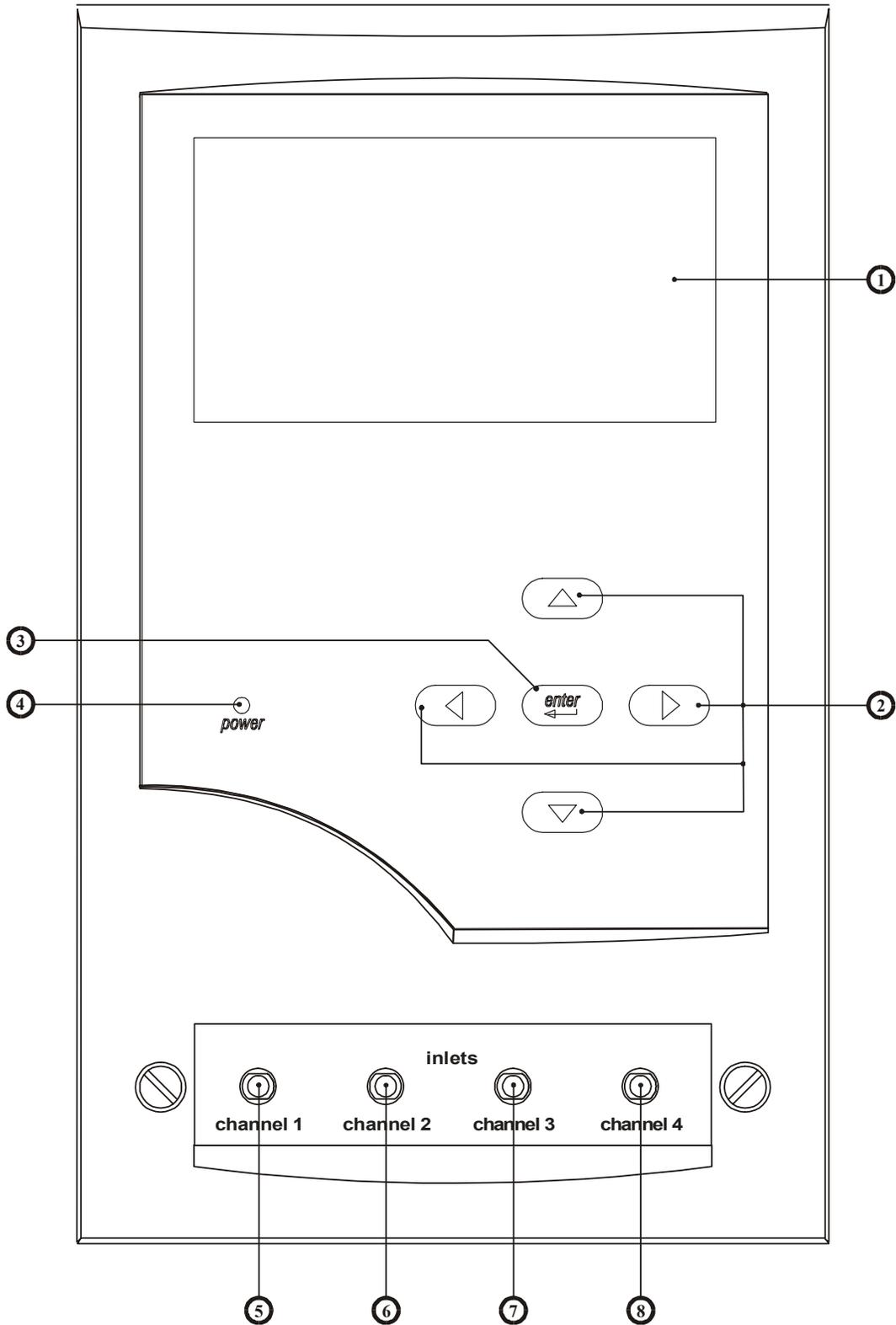
#### Occlusion & Back Pressure Measurement

A pressure transducer within each transducer performs pressure measurement. The output of the pressure transducer is fed to a conditioning amplifier then processed and the results displayed on the LCD and, if connected, on the PC screen. The user has the option to display Occlusion Pressure in psi, mmHg or kPa whereas Back Pressure measurement is set to default to mmHg only.

## **Front Panel Description**

1. Liquid Crystal Display-240 dot (W) x 128 (H). Graphic and Alphanumeric. With backlight.
2. Up, Down, Right and Left key-pad switches
3. Enter keypad.
4. Power 'ON' Indicator
5. Channel 1 Fluid 'IN' connector.
6. Channel 2 Fluid 'IN' connector.
7. Channel 3 Fluid 'IN' connector.
8. Channel 4 Fluid 'IN' connector.

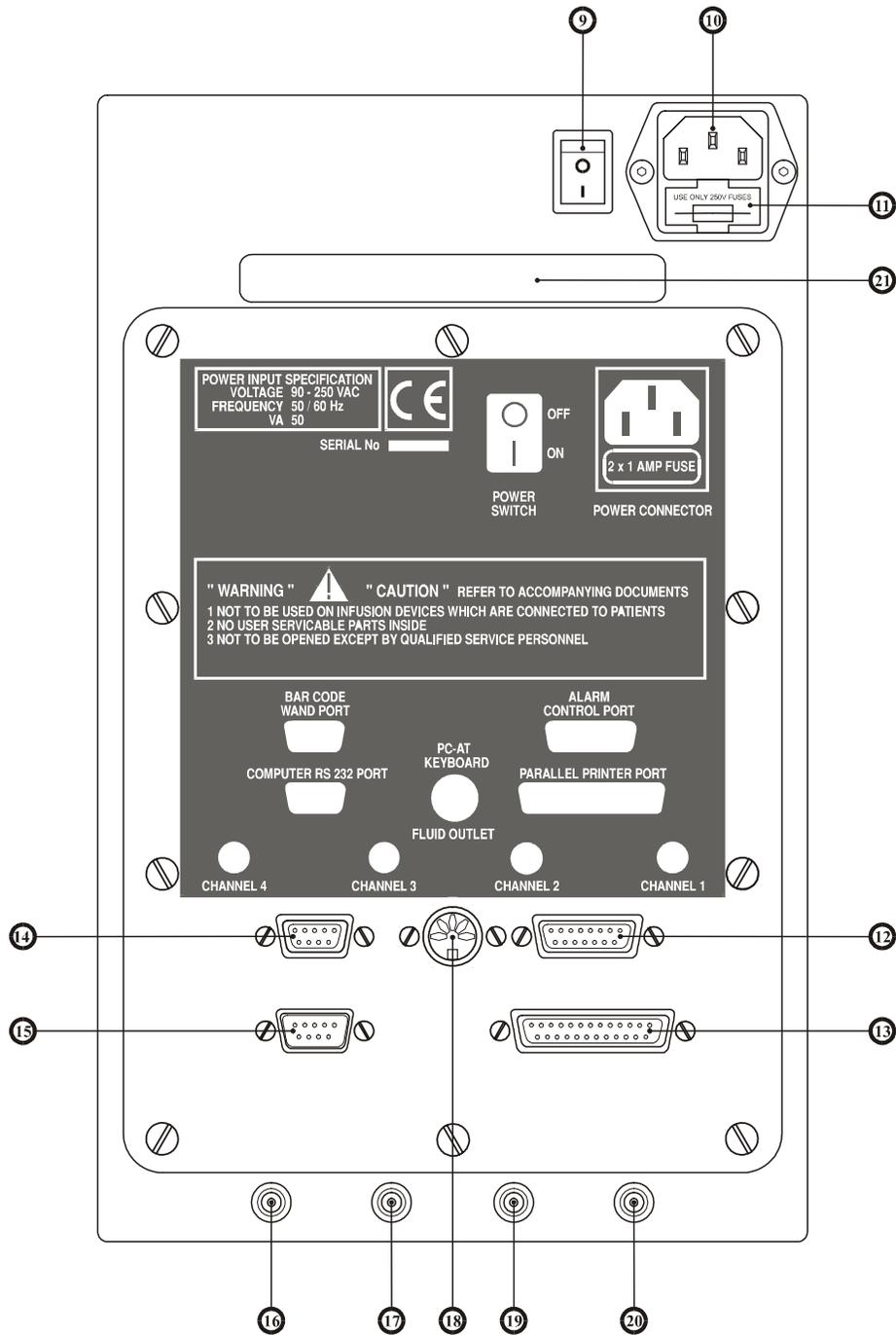
### Front Panel Layout Drawing



## **Rear Panel Description**

9. Mains ON / OFF switch.
10. Three pin IEC mains inlet connection.
11. Twin fuses integral with mains connector.
12. Alarm Control port. 15 way. (for optional trigger interface).
13. Parallel Printer Port. 25 way Female.  
Configured in the same way as a PC Printer Port.
14. Bar Code Wand Port. 9 way Female.  
Configured for HP Smart Wand (2400 Baud, n, 8, 1).
15. Computer RS232 Port. 9 way Female.  
Configured in the same way as PC COM Port.
16. Channel 4 Fluid 'OUT' connector.
17. Channel 3 Fluid 'OUT' connector.
18. PC AT keyboard Port.  
Configured for AT keyboards.
19. Channel 2 Fluid 'OUT' connector.
20. Channel 1 Fluid 'OUT' connector.
21. Carrying handle.

### Rear Panel Layout Drawing





## Chapter 3

# Operating Instructions

*This chapter discusses and illustrates the method of connecting units under test and the various operational modes.*

### Connecting Infusion Pumps under Test

*See Inlet Hose Connections and Outlet Hose Connections drawings.*

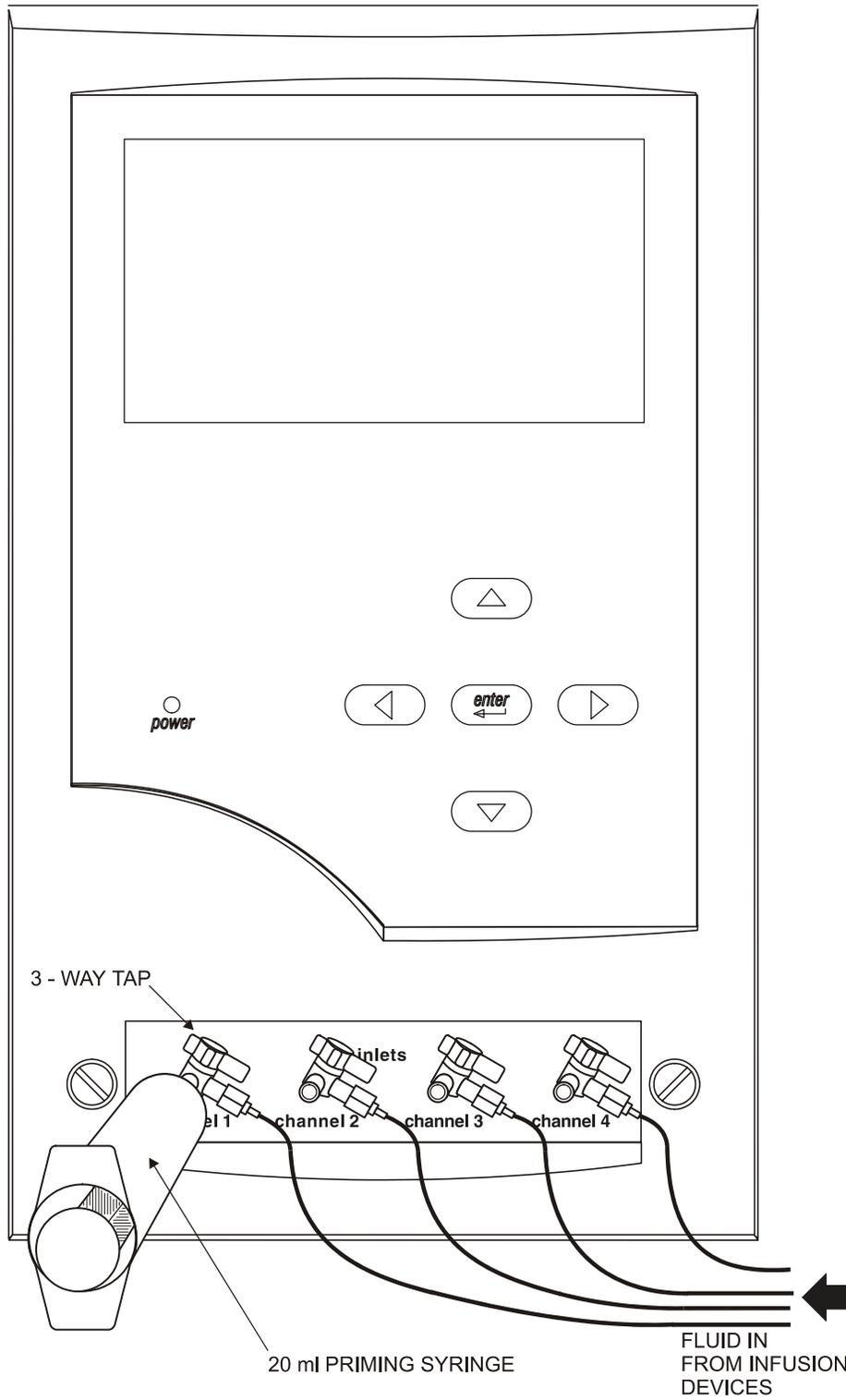
The Inlet Hose Connection drawing on the next page shows a method of connecting the inlets from units under test together with a priming syringe, both connected via a 3-way tap.

This method is the only method that should be employed with this instrument.

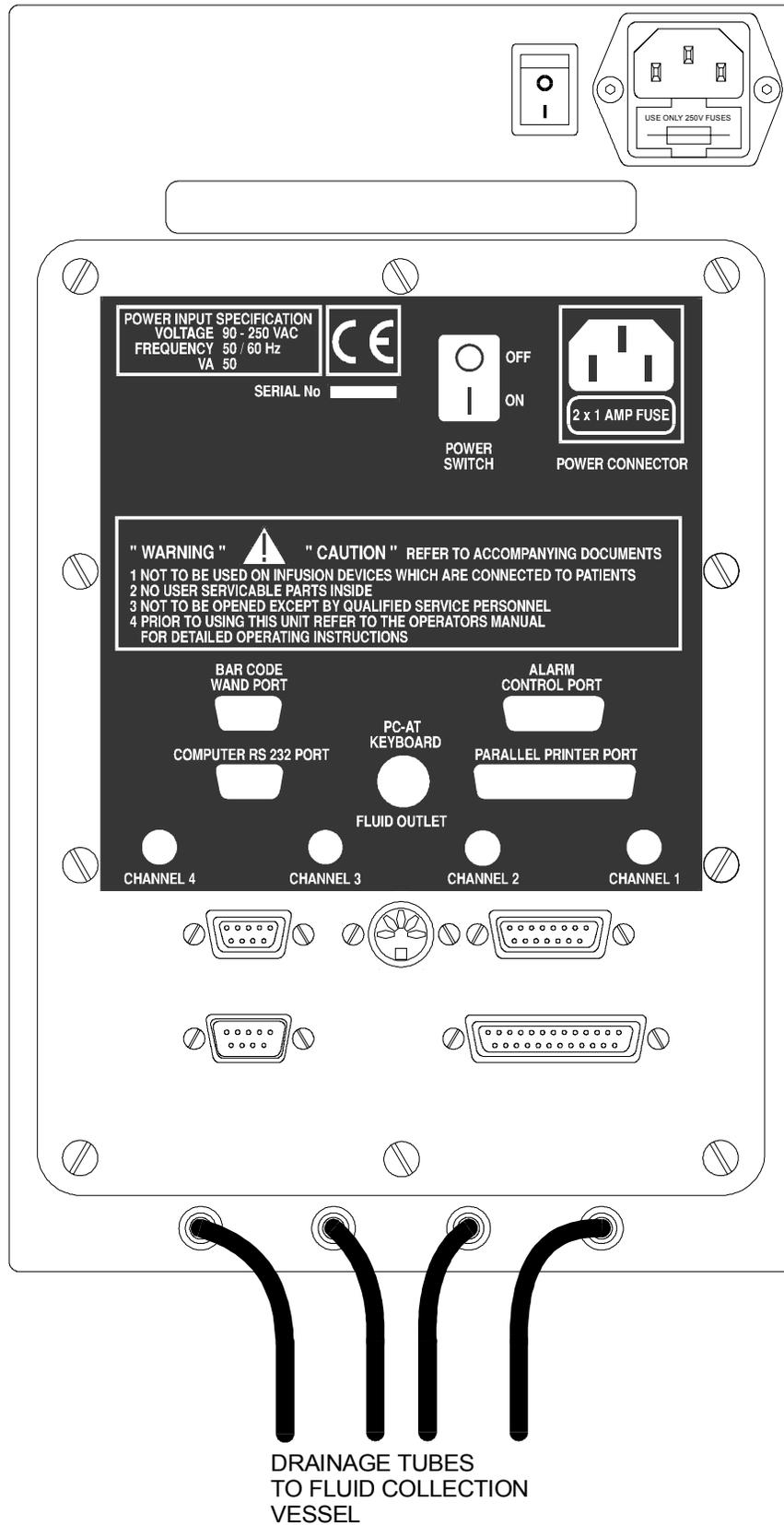
The Outlet Hose Connection drawing on page 3 shows the drain hose connections from the unit to an open drainage collection vessel. Please note that the drain Fluid Outlets should each have an independent hose to the drainage vessel and should not be joined in any way.

Note: Infusion device measurement accuracy is also affected by the compliance of the infusion device and delivery tubes. This is because there is a momentary blockage of flow when the measurement transducer is emptied. The back-pressure created by these events could cause some of the flow to be diverted into the compliance of the infusion device. For most infusion devices, the effect is trivial (less than 0.5%), but with very soft connecting tubing and large air pockets in the device or tubing, it could be significant. The tubing between the infusion device and the IDA-4 Plus should therefore be fairly rigid and all air should be removed before starting each flow test. At high flow rates it may be desirable to increase the compliance of the inlet tubing (longer or softer tube) if the back pressure interferes with the occlusion sensing alarms in the infusion device.

### Inlet Hose Connections Drawing



### Outlet Hose Connections Drawing



## **General Operating Notes**

The **IDA-4 Plus** is operated by four directional arrow buttons and an **ENTER** button on the front panel. These are used to operate a sequence of menus. An optional external keyboard can also be used to control the instrument and enter data. Any time data is prompted for, the bar code port is activated. The **ESC** key on the external keyboard will activate the **ESC** option from the menu without moving it.

If there is data in a field when it is initially selected, pressing **ENTER** will accept that data. When you type over the first character, any existing data will be wiped from the field and the newly typed data will replace it. The last character typed can be deleted using the backspace key. If **ESC** is pressed at any time during editing, the program will back up to the previous field or screen as appropriate.

If a data field is reached without an external keyboard, the up-arrow button on the front panel can be used as an **ESC** key,

## **First Time Use**

When first used the operator should set his or her own user preferences.

## **Report Header**

Set these three lines to suit your requirements. Refer to the **OPERATING INSTRUCTIONS / UTILITIES** section for details.

## **Set Clock**

Set the time & date to your time zone. The **IDA-4 Plus** contains a battery backed real-time clock device to maintain time and date when the instrument is switched off. This is used to time stamp the start of tests. It is not used to determine flow rate.

## **Test Parameters**

The preferred pressure units, Graph deviation and PCA pre-trigger time should be set.

## **Printer**

The **IDA-4 Plus** prints text reports only. To ensure compatibility with most printers no special control codes are used. If graphical reports are required the optional PC program HydroGraph™ is required.

## **Measuring Circuit**

It is advisable to ensure that the fluid circuits are flushed with at least 100ml of the test fluid before the first use.

## **Test Fluid**

The IDA-4 Plus Infusion Device Analyzer is intended for use with de-ionized water with added detergent. Fluids intended for use on patients, high viscosity, oily or corrosive substances will damage the transducer system. Tap water may contain contaminants which will also damage the transducer.

A suitable test fluid can be made using de-ionized water with a wetting agent such as MICRO-90. It is suggested that a 1-% stock solution of "MICRO-90" be prepared in volume using de-ionised water which may be kept up to 6 months in a closed vessel. This solution should then be diluted 10:1 with de-ionized water for daily use. Should the water you use cause too much foaming, then a 20:1 dilution is recommended for the daily solution.

MICRO-90 is available from:

International Product Corp.  
201 Connecticut Dr.  
P.O. Box 70  
Burlington, NJ 08016-0070 USA  
Tel 609 386 8770

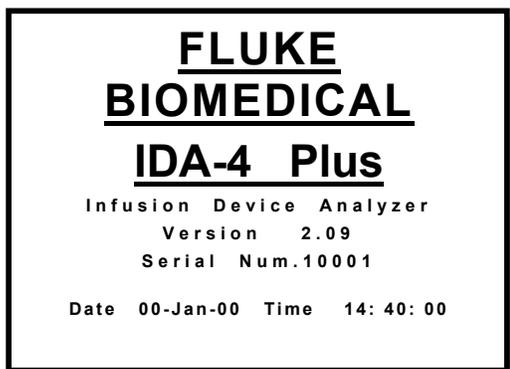
also

International Product Corp.  
1 Church Row  
Chislehurst, Kent BR7 5PG United Kingdom  
Tel. 0208 467 8944

### **Warning of Contamination**

Care should also be taken to prevent dirt, dust, metal swarf, or other debris from entering the measuring system since these are likely damage the transducers. When shipping or transporting, it is advisable to remove all water using a suction pump and enclose the unit in a plastic bag to prevent debris (such as polystyrene chips) entering the inlet or outlet connections.

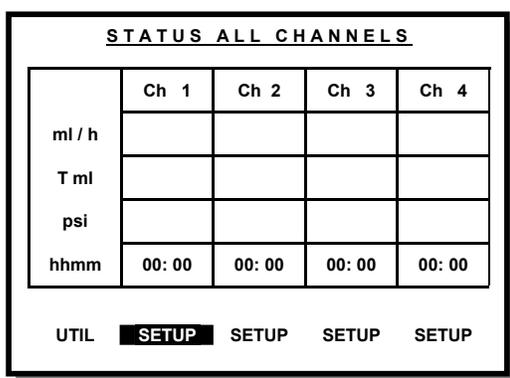
### Start-up Screen



When the unit starts, an introductory screen containing the name of the instrument, time, date and firmware version is displayed. After performing initialization procedures and self tests the instrument advances to the **STATUS ALL CHANNELS** screen.

Any errors detected are shown at the bottom of this screen. Fatal errors are indicated as such and inhibit progress. Non fatal errors give you the option to proceed.

### Status All Channels Screen



This is a dynamic screen that shows the current activity on all fitted channels. The designation **SETUP** indicates a channel fitted with a transducer and ready for operation. The upper case designation **N/O** indicates a channel that either does not have a transducer fitted, or is not operational. This is the 'home screen'; returned to after all operations except those entered from the utilities menu.

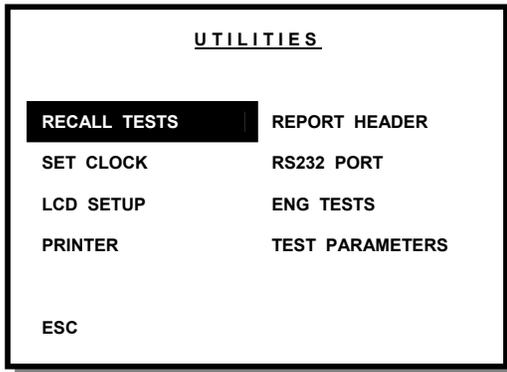
Moving the cursor to **UTIL** and pressing **ENTER** invokes the **UTILITIES** menu. Pressing the **ENTER** key with the cursor over **SETUP** invokes the **CHANNEL SETUP** menu for the appropriate channel.

The units of pressure displayed on this screen are the ones selected from the **TEST PARAMETERS SCREEN**.

When the screen is first displayed the cursor defaults to **SETUP** on the first operational channel. On subsequent occurrences the cursor should be on the last channel used. As a test progresses on an active channel the prompt for that channel changes to reflect the status of the channel.

When this screen is displayed on subsequent occasions, channels with operational transducers displays **SETUP** if they are not in use, or **VIEW** if a test is active. Active channels also show figures relating to the currently active test.

### Utilities

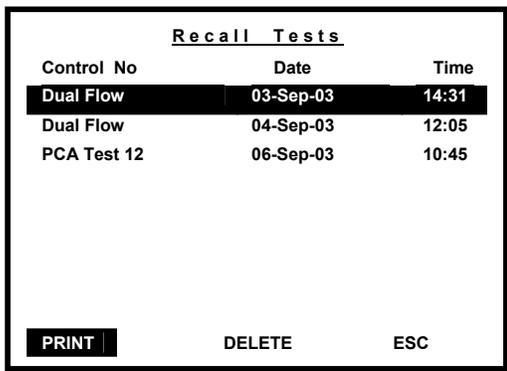


This screen is displayed whenever UTIL is selected.

Using the arrow keys to move the cursor to the required utility, in this case **RECALL TESTS** is selected, press **ENTER** and the set-up screen for the chosen utility is displayed.

Choosing **ESC** and pressing **ENTER** will default to the **STATUS ALL CHANNELS** screen.

### Recall Tests



The cursor is moved by pressing the up and down buttons. When the required stored test is selected, pressing **ENTER** brings up the menu selections shown at the bottom of the screen. User's then have the options to **PRINT** text data, **DEL** or **ESC** and return to **UTILITIES** main screen.



Note: If you select **DEL** and press **ENTER** a warning screen is displayed as shown. Selecting **YES** and pressing **ENTER** will **DELETE ALL** results. Make sure you have printed or downloaded any records that you need. Selecting **NO** returns to the **UTILITIES** menu.

### Set Clock

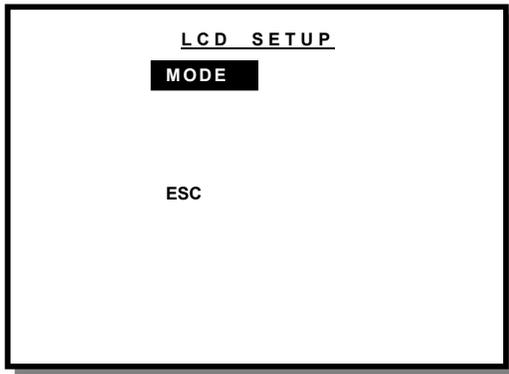


To Set the Clock use the left and right keys to select the item to be changed then the up and down keys to change to the required setting.

When correct settings are achieved press **ENTER** to accept these settings.

These settings cannot be altered once a test is in progress.

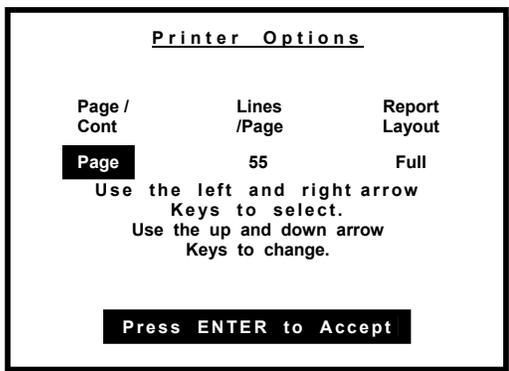
## LCD Set-up



Cursor defaults to **MODE** when this screen is selected, pressing **ENTER** changes the screen mode to black on white or white on black.

Choosing **ESC** and pressing **ENTER** accepts the mode and contrast as displayed and returns the screen to **STATUS ALL CHANN**

## Printer Options



To Set printer Left Margin, Form Feed and Layout use the left and right keys to select the item to be changed then the up and down keys to change to the required setting.

### *Page / cont*

When **'page'** printer is selected, a left margin is inserted and a form feed sent at the end of each page. (See lines / page). This is suitable for most printers that use single sheet or tractor feed paper.

When **'cont'** is selected, the left margin is not inserted and form feeds are not sent. This is suitable for most narrow paper strip printers.

### *Lines / page*

This allows the number of printed lines per page to be adjusted.

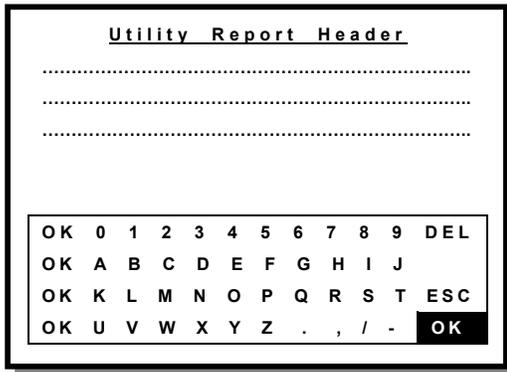
55 lines allow U.S. letter or European A4 paper to be used on most printers. There are some printers available that have a slightly shorter printing area. Adjust lines / page if the page size does not appear to be correct.

### *Layout*

**'Full'** prints all data points collected. **'Summary'** prints sample data points evenly distributed throughout the collected data, to fit the report on a single page.

When correct settings are achieved press **ENTER** to accept these settings. Last accepted entries are stored and can be changed as required via this screen

### Report Header



The **REPORT HEADER** of three lines and up to 28 characters on each line is entered via this screen. The entry is stored and will appear on all printouts, it should also be noted that this header can not be changed once a test is in progress. Entry is made via the alphanumeric matrix using the 5 button keypad, a bar code reader or if connected, via an external keyboard. On subsequent selection of this screen the existing stored entry is shown. This is stored in non-volatile memory and retained when the instrument is switched off.

To use the alphanumeric matrix, use the direction keys to move the cursor to the desired character, and select by pressing the **ENTER** key.

Continue until header is complete.

Moving the cursor to any **OK** position accepts the text, and move to the next field or screen. Selecting **DEL** deletes a character, and the **ESC** character escapes back to the previous field or screen

### RS232 Port



To set the **RS232** protocol, use the left and right keys to select the item to be changed then the up and down keys to change to the required setting.

The options are:

Speed: 150 - 38400 Baud

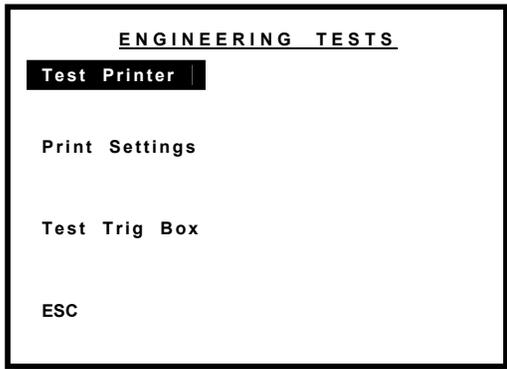
Parity: ODD - EVEN – NONE

Data: 7 or 8 bits

Stop: 1or 2 bits

When correct settings are achieved press **ENTER** to accept these settings which are stored until next changed via this screen.

## Engineering Tests



Using the arrow keys, move the cursor to the required selection and press **ENTER**.

### Test Printer

Checks the link to the printer by sending the serial number, software version and the three lines of report header to the printer.

### Print Settings

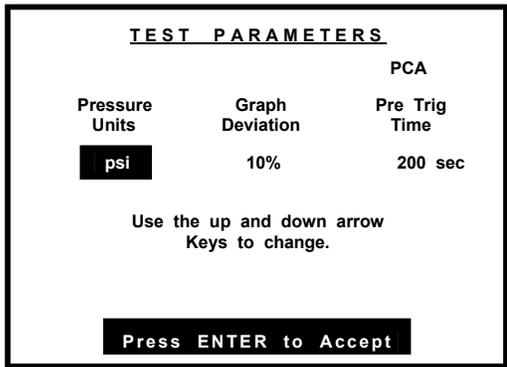
Prints the calibration factors for each transducer fitted.

### Test Trig Box

When entered, 2 rows of 4 zero's are displayed. The top row monitors the trigger buttons on the **PCA Trigger / Remote Call Interface**. The bottom row monitors the remote call inputs on the **PCA Trigger / Remote Call Interface**. When any of these are triggered, the appropriate '0' will change to a '1'. The left most digit represents channel 1 and the right most digit channel 4.

Choosing **ESC** and pressing **ENTER** will default to the **UTILITIES** Menu screen.

## Test Parameters



### Pressure Units

To cycle the pressure units between mmHg, kPa and psi, use the up and down keys to change then press **ENTER** to accept. The chosen units of pressure measurement are stored thereafter (until changed via this screen) and appear on all screens where pressure is indicated except on screens where back-pressure is indicated. This is displayed in mmHg for reasons of high resolution.

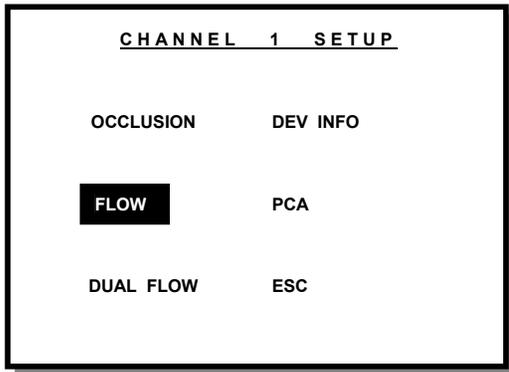
### Graph Deviation

This sets the upper and lower flow rate deviation lines on the graphs for Flow Rate and Dual Flow. If this is set to 0 (Zero) then a single line will be displayed at the set flow rate. If a flow rate is not entered when a test is set-up then no deviation lines will be displayed.

### PCA Pre Trig Time

When performing Lockout Time tests with PCA pumps, this sets the time prior to the expiry of the Lock-out time that the **IDA-4 Plus** will start attempting to trigger the pump.

## Channel Set-up Menu



This screen allows the operator to select the type of test to be performed as a rapid test or elect to enter further details before selecting the type of test. The layout of options on this menu has been optimized to reduce the number of key presses when using the rapid test options.

Using the arrow keys, move the cursors to the required selection and press **ENTER** to advance to the selected sub menu.

The following menu options are available:

### *Occlusion*

This advances to the **OCCLUSION TEST** screen where the operator will be prompted through the occlusion test. It will not be possible to save the test results.

### *Flow*

This advances to the **FLOW TEST** screen where the operator will be guided through Flow tests. It will not be possible to save the test results.

### *Dual Flow*

This advances to the **DUAL FLOW INFORMATION** screen, even for a rapid test as some information is required to perform this test. It will not be possible to save the test results.

### *Dev Info*

This advances to the **DEVICE INFORMATION** screen where information about the device being tested will be requested. If test results are to be saved, this option must be selected.

### *PCA*

This advances to the **PCA TEST INFORMATION** screen to request information required to perform a PCA test. It will not be possible to save the test results.

### *ESC*

This returns the operator to the **STATUS ALL CHANNELS** screen. The **ESC** key on an external keyboard will have the same effect.

## Device Information

```
Device Information Chan 1
Control No ██████████
Operator
Flow Rate

Manufacturer
Device Type
Serial Num.
Location

Press ENTER for next field
Press ESC for previous field
```

This screen prompts the operator for device and test information for the specific device under test. Data may be entered into the fields on this screen from the external keyboard or the optional bar code reader. The attributes for each field are described below.

When entering data into these fields the last character entered may be deleted using the backspace key. If there is data in the field and **ENTER** is pressed then that data is accepted. If the operator starts typing at the first position in the field then any existing data will be wiped from the field and the newly typed data will replace it. If **ESC** is pressed at any time during editing a field then the program will back up to the previous field, menu or screen as appropriate.

Note: If you enter this screen without an external keyboard connected, use the up arrow button to back out of the screen.

### *Control No*

**Control Number** is a mandatory field up to sixteen characters in length. If a test does not have a control number then it cannot be saved. This is usually a number or code that uniquely identifies the infusion device being tested. The cursor will be positioned in this field when the screen is first displayed.

When field is completed, pressing **ENTER** advances to the Operator field. Pressing **ESC** in this field returns the operator back to the **CHANNEL SETUP** menu.

### *Operator*

This is a mandatory field, up to sixteen characters in length. If a test is to be saved it should be possible to determine who performed the test.

Pressing **ENTER** at the end of this field advances the program to the Flow Rate field. Pressing **ESC** will return to the Control No field.

### *Flow Rate*

This is a mandatory field that only accepts numeric data. It can accept a maximum of six digits including a decimal point. This is the flow rate that the infusion device under test has been set to.

Pressing **ENTER** at the end of this field advances the program to a sub-menu as described in **SUB MENU 1**. Pressing **ESC** causes the program to step back to the Operator field.

### *Vol*

This is the volume you intend to deliver. If this volume is set, then when the volume is reached the instrument will give two long beeps and display a message.

Device Information Chan 1				
Control No	12345			
Operator	Your Name			
Flow Rate	10	Vol	20	
<b>MORE</b>	<b>FLOW</b>	<b>OCCL</b>	<b>PCA</b>	<b>DUAL</b>
Manufacturer				
Device Type				
Serial Num.				
Location				
Press ENTER for next field Press ESC for previous field				

## Sub Menu1

This menu is reached when all the mandatory fields have been entered. From this point is possible to go directly to a test or request further information. Each menu option is described below. The options on this menu can be selected by using the arrow keys followed by the **ENTER** key.

### *More*

Selecting this option advances to the Manufacturer field.

### *Flow*

This advances to the **FLOW TEST** screen where the operator will be guided through a flow rate test.

### *Occlusion*

This advances to the **OCCLUSION TEST** screen where the operator will be prompted through the occlusion test.

### *PCA*

This advances to the **PCA TEST INFORMATION** screen to request information required to perform a PCA test.

### *Dual*

This advances to the **DUAL FLOW RATE INFORMATION** screen.

### *Manufacturer*

This field is optional and is used to record the manufacturer of the device under test. This field has a maximum size of sixteen characters.

Pressing **ENTER** from this field advances to the **Device Type** field. Pressing **ESC** steps back to the Flow Rate field.

### *Device Type*

This optional field is used to record the type number (or model number) of the infusion device under test. It has a maximum length of sixteen characters.

Pressing **ENTER** from this field advances to the **Serial Num** field. Pressing **ESC** back tracks to the **Manufacturer** field.

### *Serial Num*

This optional field is used to record the serial number of the infusion device under test. A maximum of sixteen characters is allowed.

Pressing **ENTER** from this field advances to the **Location** field. Pressing **ESC** goes back to the **Device Type** field.

### Location

This is an optional field of sixteen characters in length. It is used to store the normal location of the device under test.

Pressing **ENTER** from this field advances to the **SUB MENU 2**. **ESC** goes back to the **Serial Number** field

### Sub Menu2

This menu allows you to select the type of test to perform after you have entered all the information about the device being tested.

#### ESC

This back tracks to the **Location** field. This gives the operator a chance to correct any of the preceding information that may have been entered incorrectly.

#### Flow

This advances to the **FLOW TEST** screen where the operator will be guided through a flow rate test.

#### Occlusion

This advances to the **OCCLUSION TEST** screen where the operator is prompted through the occlusion test.

#### PCA

This advances to the **PCA TEST INFORMATION** screen to request information required to perform a PCA test.

#### Dual

This advances to the **DUAL FLOW RATE INFORMATION** screen.

Device Information Chan 1			
Control No	12345		
Operator	Your Name		
Flow Rate	10	Vol	20
Manufacturer			
Device Type			
Serial Num.			
Location			
ESC	FLOW	OCCL	PCA DUAL
Press ENTER for next field			
Press ESC for previous field			

### Flow Test Screen (Prime Mode)

CHANNEL 1 FLOW		
FLOW	0.00	Avg ml/h
VOLUME	0.00	ml
ELAPSED TIME	00: 00: 00	
INST. FLOW	0.00 ml/h	
BACK PRESSURE	0 mmHg	
<b>PRIME</b>	STATUS	ESC

This is the screen that allows the operator to control the flow test. It has a menu across the bottom of the screen that changes to reflect the progress of the active test.

When this screen is first displayed the operator will be prompted to prime the channel. *This is essential to ensure the measuring circuit is filled with fluid.*

#### Prime

This prompt stays on the screen while there is any air in the measuring circuit. Pressing **ENTER** while the prompt displays **PRIME** will not have any effect. As the circuit is primed, the prompt will change to **START**. There may be some flickering between **PRIME** and **START** as bubbles are pushed through the system.

#### Status

This option takes you back to the main status screen. You may need to do this if you need to set-up more than one channel.

#### ESC

Selecting **ESC** or pressing the **ESC** key on the external keyboard will take the operator back to the **CHANNEL SETUP** menu.

### Flow Test Screen (Start Mode)

CHANNEL 1 FLOW		
FLOW	0.00	Avg ml/h
VOLUME	0.00	ml
ELAPSED TIME	00: 00: 00	
INST. FLOW	0.00 ml/h	
BACK PRESSURE	0 mmHg	
<b>AutoSTART</b>	START	STATUS ESC

#### Auto-Start

Pressing **ENTER** on this option puts the **IDA-4 Plus** into **AutoSTART** mode. The prompt will flash until the instrument detects that the fluid is flowing, then start the test.

#### Start

To manually start the test, move to the **START** selection and press **ENTER**. The **IDA-4 Plus** will immediately start analyzing the fluid flow once this is done.

#### Status

This will invoke the **STATUS ALL CHANNELS** screen.

#### ESC

Selecting **ESC** or pressing the **ESC** key on the external keyboard will take the operator back to the **CHANNEL SETUP** menu.

### Flow Test Screen (Measuring Mode)

<b>CHANNEL 1 FLOW</b>	
<b>FLOW</b>	<b>0.00</b> Avg ml /h
<b>VOLUME</b>	<b>0.00</b> ml
ELAPSED TIME	00: 00: 00
INST. FLOW	0.00 ml /h
BACK PRESSURE	0 mmHg
<b>STATUS</b>	<b>GRAPH</b> <b>FLOW</b> <b>OCCL</b> <b>END</b>

When the flow test is started the screen is advanced to the measuring mode as shown. This enables more menu options.

#### *Status*

This invokes the **STATUS ALL CHANNELS** screen.

#### *Graph*

This switches to the **FLOW GRAPH** screen for the current channel.

#### *Flow*

This ends the current test, clears the values from the screen and proceeds to the **FLOW TEST** screen in either **PRIME** or **START** mode, depending on the current state of the transducer. The results of the subsequent test will be appended to those of the test terminated by this option.

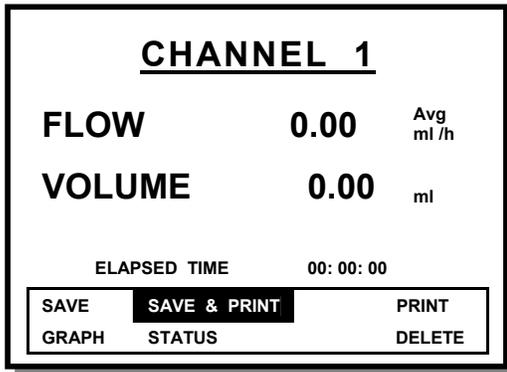
#### *Occlusion*

This ends the current test, clears the values from the screen and proceeds to the **OCCLUSION TEST** screen in Wait Mode. The results of the subsequent test will be appended to those of the test terminated by this option.

#### *End*

Ends the test, or sequence of tests, and advances the **FLOW TEST** screen to the **End of Test Mode**.

**Flow Test Screen (End of Test Mode)**



This view of the **FLOW TEST** screen allows the operator to save, print or delete the results of the test.

*Save*

This saves the results of the flow test, or series of tests, to non-volatile memory for later printing or transfer to a computer via the **RS232** port.

*Save & Print*

This saves the results as described above, then sends a report to a printer connected to the printer port on the instrument. The report will be in either full or summary format, as previously selected by the operator from the **UTILITIES / PRINTER** menu.

*Print*

This sends a report to a printer connected to the printer port on the instrument. The report will be in either full or summary format, as previously selected by the operator from the **UTILITIES / PRINTER** menu.

*Graph*

This switches to the **FLOW GRAPH** screen for the current channel to allow a graph of the results to be viewed before they are saved or printed.

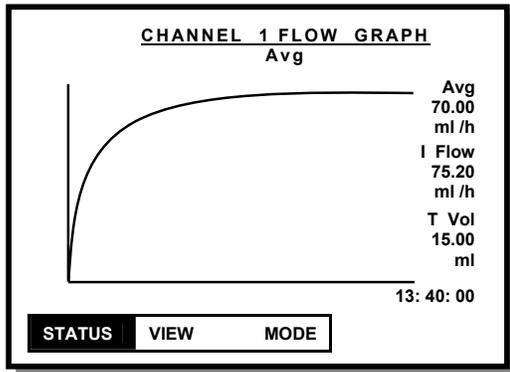
*Status*

This switches to the **STATUS ALL CHANNELS** screen to allow the operator to use another channel or change settings via the **UTILITIES** menu.

*Delete*

This deletes the current set of results from the operational memory of the instrument, without saving to the non-volatile memory. **CAUTION:** Once this option has been invoked there will not be any way to recover, view or print the results of this test.

## Flow Graph Screen



The **FLOW GRAPH** screen shown displays the average flow rate as a continuous line and instantaneous flow rate as a dashed line. A view of the Average, Instantaneous or both lines is available by selecting **MODE** from the menu.

Average flow rate, Latest Flow rate (instantaneous), Delivered Volume (T) and Time are displayed to the right of the graph. Two dashed lines represent  $\pm$  percentage deviation marks. The percentage can be set from the **TEST PARAMETERS SCREEN**.

### *Status*

This switches to the **STATUS ALL CHANNELS** screen to allow the operator to use another channel or change settings via the **UTILITIES** menu.

### *View*

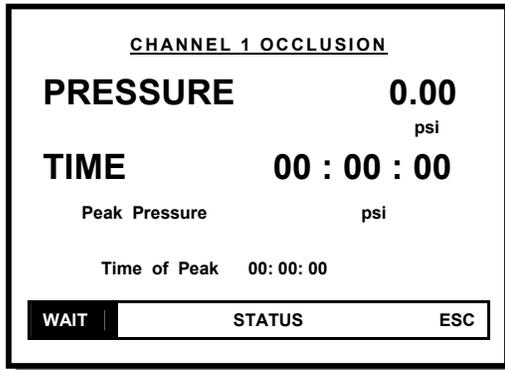
This returns to the **FLOW TEST** screen in either the Measuring Mode or the End of Test Mode, depending on which mode this screen was called from.

## Occlusion Test Screen

This is the screen that allows the operator to control the occlusion test. It has a menu across the bottom of the screen that changes to reflect the progress of the test. It is not necessary to prime the transducer to perform an occlusion test.

The operator sets the units of pressure displayed on this screen from the **TEST PARAMETERS SCREEN**.

### Occlusion Test Screen (Wait Mode)



When the **OCCLUSION TEST** screen is first entered it puts the transducer into a Tare measuring mode (i.e. subtracts the ambient pressure). While the transducer is in this mode the **WAIT** prompt is displayed.

#### *Wait*

This menu option is never active, it informs the operator to wait until the transducer has taken a tare reading. When the tare reading has completed this, the menu option changes to **START**, and the instrument advances to the start mode. The pump should be stopped or running very slowly during the wait period.

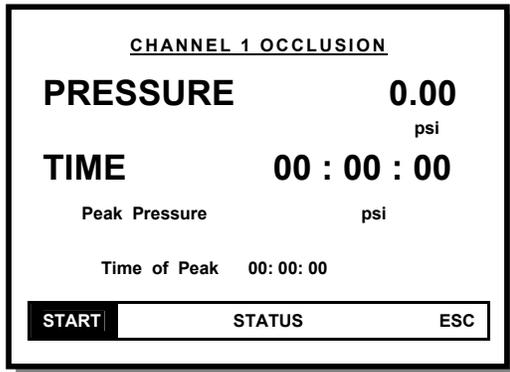
#### *Status*

This invokes the **STATUS ALL CHANNELS** screen.

#### *ESC*

Selecting **ESC** or pressing the **ESC** key on the external keyboard takes the operator back to the **CHANNEL SETUP** menu.

### Occlusion Test Screen (Start Mode)



When the transducer has completed its tare operation the screen changes as shown.

*Start*

When the transducer has completed its tare measurement the **START** option is enabled. Pressing **ENTER** while this option is selected will start the occlusion test and advances to the measuring mode.

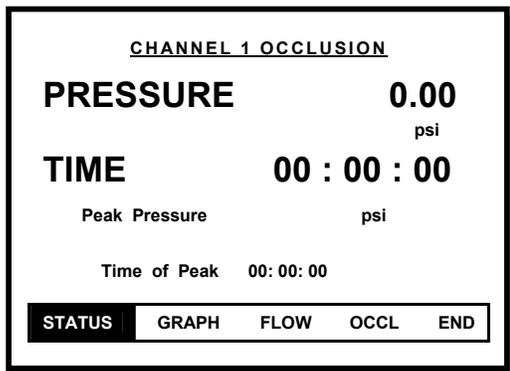
*Status*

This invokes the **STATUS ALL CHANNELS** screen.

*ESC*

Selecting **ESC** or pressing the **ESC** key on the external keyboard will take the operator back to the **CHANNEL SETUP** menu.

### Occlusion Test Screen (Measuring Mode)



When the test is started the screen enters the measuring mode as shown. This enables further menu options.

*Status*

This invokes the **STATUS ALL CHANNELS** screen.

*Graph*

This switches to the **OCCLUSION GRAPH** screen for the current channel.

*Flow*

This ends the current test, clears the values from the screen and proceeds to the **FLOW TEST** screen in either **PRIME** or **START** mode, depending on the current state of the transducer. The results of the subsequent test will be appended to those of the test terminated by this option.

*Occlusion*

This ends the current test, clears the values from the screen and proceeds to the **OCCLUSION TEST** screen in Wait Mode. The results of the subsequent test will be appended to those of the test terminated by this option.

*End*

Ends the test, or sequence of tests, and advances the **OCCLUSION TEST** screen to the End of Test Mode.

### Occlusion Test Screen (End of Test Mode)

<u>CHANNEL 1 OCCLUSION</u>							
Peak Pressure	0.00 psi						
Time of Peak	00: 00: 00						
Total Test Time	00: 00: 00						
Set Flow Rate	ml /h						
<table border="1"> <tbody> <tr> <td>SAVE</td> <td>SAVE &amp; PRINT</td> <td>PRINT</td> </tr> <tr> <td>GRAPH</td> <td>STATUS</td> <td>DELETE</td> </tr> </tbody> </table>		SAVE	SAVE & PRINT	PRINT	GRAPH	STATUS	DELETE
SAVE	SAVE & PRINT	PRINT					
GRAPH	STATUS	DELETE					

This view of the **OCCLUSION TEST** screen allows the operator to save, print or delete the results of the occlusion test.

#### *Save*

This saves the results of the occlusion test, or the series of tests, to non-volatile memory for later printing or transfer to a computer via the RS232 port.

#### *Save & Print*

This saves the results as described above, then sends a report to a printer connected to the printer port on the instrument. The report will be in either full or summary format, as previously selected by the operator from the **UTILITIES / PRINTER** menu.

#### *Print*

This sends a report to a printer connected to the printer port on the instrument. The report will be in either full or summary format, as previously selected by the operator from the **UTILITIES / PRINTER** menu.

#### *Status*

This switches to the **STATUS ALL CHANNELS** screen to allow the operator to use another channel or change settings via the **UTILITIES** menu.

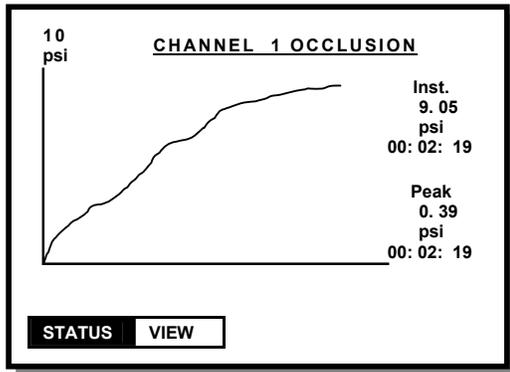
#### *Graph*

This switches to the **OCCLUSION GRAPH** screen for the current channel.

#### *Delete*

This deletes the current set of results from memory without saving to non-volatile memory. **CAUTION:** Once this option has been invoked there will not be any way to recover, view or print the results of this test.

## Occlusion Graph Screen



This graph displays the pressure value over time. It automatically adjusts its scale so that its maximum pressure and time are always within the axes.

The numerical data displayed at the right of the graph will include the current pressure and elapsed time.

Below this will be the peak pressure reached and the time that the peak was reached.

The pressure units are those selected from the **TEST PARAMETERS SCREEN**.

### *Status*

This switches to the **STATUS ALL CHANNELS** screen to allow the operator to use another channel or change settings via the **UTILITIES** menu.

### *View*

This returns to the **OCCLUSION TEST** screen in either the Measuring Mode or the End of Test Mode, depending on which mode called this screen.

### PCA Test Information Screen

Chan 1 PCA Test Information			
Basal Flow Rate (Continuous)		ml /h	
Total Volume		ml	
Bolus Volume	0.00	ml	
Lockout Time	Min	sec	
Loading Dose		ml	
0 1 2 3 4 5 6 7 8 9 .			OK
			ESC DEL

This screen is displayed whenever the operator elects to perform a **PCA TEST**.

#### *Basal Flow Rate*

This is a field must be completed to help the flow rate discriminate algorithms within the PCA analysis routines. If a flow rate has been entered on the **DEVICE INFORMATION** screen, then it will be displayed in this field. It can be accepted by pressing **ENTER** or it may be changed at this point, which will also change the Flow Rate.

Pressing **ENTER** at the end of this field advances the program to the **Total Volume** field. Pressing **ESC** will return to the **Channel Set-up Menu**.

#### *Total Volume*

This is the total volume to be infused during the test, as set on the PCA pump. When this volume has been delivered, two long beeps will be sounded and a message displayed.

Pressing **ENTER** at the end of this field advances the program to the **Bolus Volume** field. Pressing **ESC** will step back to the **Basal Flow Rate** field.

#### *Bolus Volume*

This is the bolus volume that the pump is set to deliver. This value is recorded for information purposes only.

Pressing **ENTER** in this field advances the program to the **Lockout Time** (minutes) field. Pressing **ESC** will step back to the **Total Volume** field.

#### *Lockout Time (minutes)*

This field and the **Lockout Time** (seconds) field set the time the device under test should inhibit requests for a bolus after the last bolus was delivered.

#### *Lockout Time (seconds)*

This field is used in conjunction with the **Lockout Time** (minutes) field as described above.

Pressing **ENTER** in this field advances the program to the **Loading Dose** field. Pressing **ESC** will step back to the **Lockout Time** (minutes) field. Lockout time is the time that the PCA pump is programmed to inhibit patient demands between boluses. This is used in combination with Pre Trigger Time, as set in the **TEST PARAMETERS SCREEN** to attempt to trigger the PCA pump.

#### *Loading Dose*

This is the volume expected to be delivered as the pump starts. It appears to the instrument as a bolus. If a non-zero value has been entered, and the first fluid detected is determined to be at a bolus flow rate, then the first

bolus will be reported as a loading dose, otherwise a loading dose will not be reported.

On completion of this field, the **PCA TEST** screen is invoked.

Note: When testing PCA pump performance it is essential that new syringes be used. It has been observed that syringe performance degrades rapidly after about 10 uses. The deterioration is particularly noticeable at the start of a bolus when the flow rate is increasing rapidly. It is characterized by a very high initial flow rate at the start of the bolus (4 to 5 times the bolus flow rate). This can cause the end of the bolus to be detected at the end of the spike.

### PCA Test Screen

This screen displays the measured output of the flow rate, volume and duration of the last bolus delivered, and the average flow rate, volume and duration of all boluses delivered. It will also display the measured basal rate, total delivered volume, total test time and time interval between the last two boluses delivered.

#### PCA Test Screen (Prime Mode)

Channel 1 PCA		
Last Bolus		Average
0.00	Volume ml	0.00
0.00	Flow Rate	0.00
0	Duration	0
	Interval	
Bolus Count	0	
Basal Flow Rate	0.00 ml /h	
Elapsed Time	00: 00: 00	
Total Volume	0.00 ml	
<b>PRIME</b>	<b>STATUS</b>	<b>ESC</b>

When the screen is first displayed, the operator is prompted to prime the channel. This is essential to ensure that the measuring circuit is filled with fluid. It is particularly important that the instrument is carefully primed when the loading dose is to be measured.

#### *Prime*

This prompt stays on the screen while there is any air in the measuring circuit. Pressing **ENTER** while this prompt displays **PRIME** will not have any effect. As the circuit is primed the prompt will change to **START** and advance to **Start Mode**. There may be some flickering between **PRIME** and **START** as bubbles are pushed through the system.

#### *ESC*

Selecting **ESC** or pressing **ESC** on the external keyboard takes the operator back to the **CHANNEL SETUP** menu.

### PCA Test Screen (Start Mode)

Channel 1 PCA		
Last Bolus		Average
0.00	Volume ml	0.00
0.00	Flow Rate	0.00
0	Duration	0
	Interval	
Bolus Count		0
Basal Flow Rate		0.00 ml /h
Elapsed Time		00: 00: 00
Total Volume		0.00 ml
<b>AutoSTART</b>	<b>START</b>	<b>STATUS</b> <b>ESC</b>

When the measuring circuit is primed successfully the screen changes as shown.

#### *Auto-Start*

Pressing **ENTER** on this option puts the **IDA-4 Plus** into **AutoSTART** mode. The prompt will flash until the instrument detects that the fluid is flowing, then start the test.

#### *Start*

When the measuring circuit is primed successfully the screen changes as shown. The following menu options are available:

#### *ESC*

Selecting **ESC** or pressing the **ESC** key on the external keyboard takes the operator back to the **CHANNEL SETUP** menu.

### PCA Test Screen (Measuring Mode)

Channel 1 PCA		
Last Bolus		Average
0.00	Volume ml	0.00
0.00	Flow Rate	0.00
0	Duration	0
	Interval	
Bolus Count		0
Basal Flow Rate		0.00 ml /h
Elapsed Time		00: 00: 00
Total Volume		0.00 ml
<b>STATUS</b>	<b>GRAPH</b>	<b>BOLUS / TRIG</b> <b>END</b>

When the **PCA TEST** is started the screen enters measuring mode as shown. This enables further menu options.

#### *Status*

This takes the operator to the **STATUS ALL CHANNELS** screen.

#### *Graph*

This selection displays the **PCA GRAPH** screen to view the bolus delivery verses time graph.

#### *Bolus / Trig*

This triggers a PCA Bolus request to the pump if the pump can be triggered electrically. *This requires the PCA Trigger / Remote Call Interface.* If the pump does not have an electrical trigger (e.g. pneumatic) then this button may be pressed simultaneously with the patient button on the pump to allow the request for bolus to be recorded.

#### *End*

This ends the test and advance to the End of Test Mode.

### PCA Test Screen (End of Test Mode)

Channel 1 PCA		
Last Bolus		Average
0.00	Volume ml	0.00
0.00	Flow Rate	0.00
0	Duration	0
	Interval	
Bolus Count		0
Basal Flow Rate		0.00 ml /h
Elapsed Time		00: 00: 00
Total Volume		0.00 ml
SAVE	SAVE & PRINT	PRINT
GRAPH	STATUS	DELETE

This view of the **FLOW TEST** screen allows the operator to save, print or discard the results.

#### Save

This saves the results of the PCA test to non-volatile memory for later printing or transfer to a computer via the RS232 port.

#### Save & Print

This saves the results as described above, then sends a report to a printer connected to the printer port on the instrument. The report will be in either full or summary format, as previously selected by the operator from the **UTILITIES / PRINTER** menu.

#### Print

This sends a report to a printer connected to the printer port on the instrument. The report will be in either full or summary format, as previously selected by the operator from the **UTILITIES / PRINTER** menu.

#### Status

This switches to the **STATUS ALL CHANNELS** screen to allow the operator to use another channel or change settings via the **UTILITIES** menu.

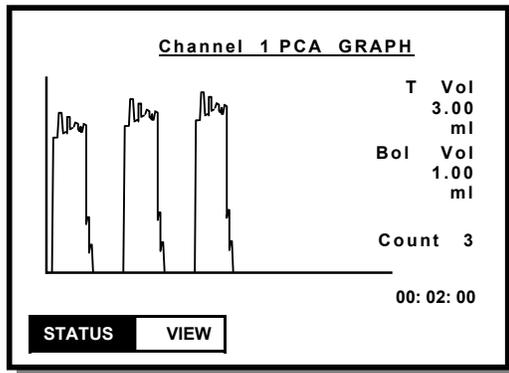
#### Graph

This switches to the **PCA GRAPH** screen for the current channel.

#### Delete

This deletes the current set of results from memory without saving to non-volatile memory. Once this option has been invoked there will not be any way to recover, view or print the results of this test.

## PCA Graph Screen



The **PCA GRAPH** screen displays the available data in a bar graph format. The amplitude of each spike represents the flow rate at which each bolus is administered. The width of each spike represents the time duration of that bolus. The gap between successive spikes will represent the time interval between boluses.

Numerical representation of the total volume delivered and the volume of the last bolus delivered will be displayed down the right of the graph.

### *Status*

This switches to the **STATUS ALL CHANNELS** screen to allow the operator to use another channel or change settings via the **UTILITIES** menu.

### *View*

This returns to the **PCA TEST** screen in either the Measuring Mode or the End of Test Mode, depending on which mode this screen was called from.

## PCA Bolus Trigger Methods

The **IDA-4 Plus** has two methods of operating with PCA bolus triggering; automatic and manual. Some PCA pumps provide a connector to allow the Patient Demand to be requested. The **IDA-4 Plus** enables this facility via the **PCA Trigger / Remote Call Interface**.

### *Automated Bolus Trigger*

With pumps that can be triggered electrically the bolus trigger signals are generated at one-second intervals, starting before the end of the lockout period.

The programmed period before lockout time expires is adjustable from the **TEST PARAMETERS SCREEN**.

### *Manual Bolus Trigger*

It is not possible to trigger some types of PCA pumps directly. Examples are ambulatory devices that have the trigger mounted on the pump case or pumps that use a pneumatic trigger. With these pumps the operator will have to press the **BOLUS / TRIG** prompt on the **PCA TEST** screen at the same time as pressing the bolus request button on the pump.

### *PCA Pump Testing Scenarios*

Various scenarios under which a PCA pump could be tested are considered in the following paragraphs. These scenarios may not be exhaustive and some parameters may have to be changed to satisfy the testing requirements of some pumps.

### *PCA Activity Only*

The basic test scenario would have the PCA pump set up to supply an initial loading or bolus, then deliver a series of boluses following a lockout period. The basal rate will be set to zero.

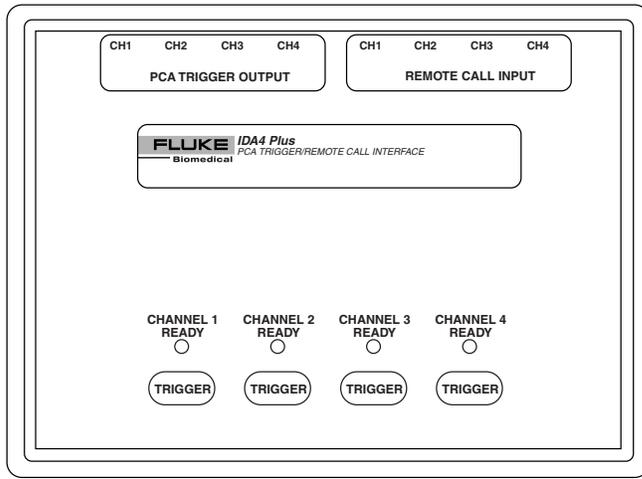
*PCA Activity with Basal Flow*

This will follow the PCA Activity Only scenario described above, but with a basal flow rate set. The basal flow rate should also be entered on the **IDA-4 Plus**.

*Basal Flow Only*

When a PCA pump is operated with the basal flow rate only, it should be tested using the normal single flow rate method.

**Optional PCA Trigger / Remote Call Interface**



The PCA Trigger / Remote Call Interface allows PCA pumps to be triggered by the IDA-4 Plus. It also has connections to allow alarm conditions of pumps to be monitored. It connects to the IDA-4 Plus via the 15 Way socket on the rear panel.

*Trigger*

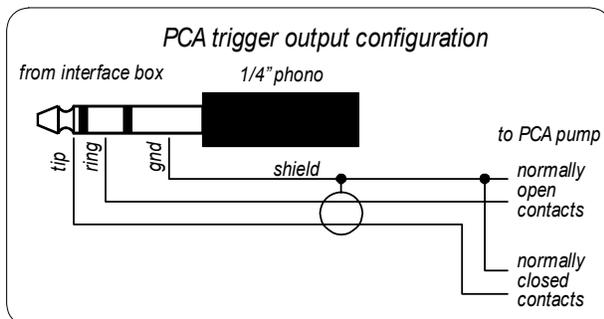
One trigger button is provided for each channel, to trigger a PCA pump via the PCA trigger output. This eliminates the need to ensure that the IDA-4 Plus is displaying the correct screen.

*Ready*

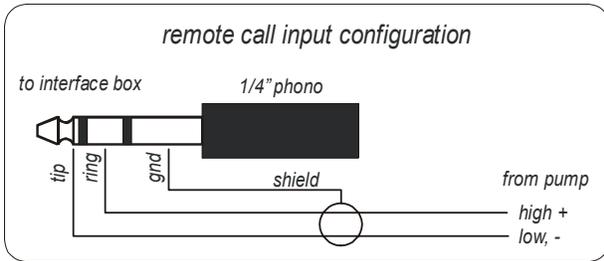
This LED will illuminate indicating that a bolus can be triggered on that channel. When a bolus is detected the LED will extinguish.

*PCA Trigger Output*

The PCA Trigger Output jacks (one for each channel) provide floating relay contacts. Normally open contacts are available between ring and shield. Normally closed contacts are available between tip and shield. (Refer to the pump manufacturer's service manual when preparing a PCA trigger cable).



*Remote Call Input*



Any change in the Remote Call Input jacks (one for each channel) will be detected by the IDA-4 Plus. For voltage output remote call, connect the higher potential to the ring and the lower potential or ground to the tip. For relay output remote call, the polarity does not matter. (Refer to the pump manufacturer's service manual when preparing a remote-call input cable).

## Dual Rate Test Information Screen

DUAL RATE TEST INFORMATION			
Secondary Rate	<input type="text"/>	ml /h	
Secondary Vol	<input type="text"/>	ml	
Primary Rate	<input type="text"/>	ml /h	
Primary Vol	<input type="text"/>	ml	
0 1 2 3 4 5 6 7 8 9 .		OK	
		ESC DEL	

This screen prompts the operator for information required to perform a dual rate flow test. As a minimum requirement the primary flow rate will be needed.

### *Secondary Rate*

This is the flow rate of the second part of the infusion. This is a mandatory field for dual flow rate measurement. It is used in conjunction with the primary flow rate to help the flow rate discrimination algorithms. Secondary will show as Flow 1.

Pressing **ENTER** in this field advances the program to the Secondary Volume field. Pressing **ESC** will step back to the Primary Volume field.

### *Secondary Volume*

This is the volume to be delivered at the secondary flow rate. This value is recorded for information only.

Pressing **ENTER** in this field advances to the **DUAL RATE TEST** screen. Pressing **ESC** will backtrack to the Secondary Rate field.

### *Primary Rate*

This is the flow rate of the first part of the infusion. If a Flow Rate has been entered on the **DEVICE INFORMATION** screen it is automatically entered into this field. This is a mandatory field for dual flow rate measurement. It is used in conjunction with the secondary flow rate to help the flow rate discrimination algorithms. Primary will show as Flow 2.

Pressing **ENTER** in this field advances the program to the Primary Volume field. Pressing **ESC** will return to the **CHANNEL SETUP** menu screen.

### *Primary Volume*

This is the volume to be delivered at the primary flow rate. This value is recorded for information only.

Pressing **ENTER** in this field advances the program to the Secondary Rate field. Pressing **ESC** will step back to the Primary Rate field.

## Dual Rate Test Screen

This is the screen that allows the operator to control the dual rate flow test. It has a menu across the bottom of the screen that changes to reflect the progress of the test.

### Dual Rate Test Screen (Prime Mode)

CHANNEL 1 DUAL FLOW			
<b>FLOW 1</b>		<b>0.00</b>	
			ml/h
<b>VOLUME</b>		<b>0.00</b>	ml
FLOW 2	0.00	VOLUME	
Elapsed Time		00:00:00	
Inst. Flow		0.00 ml/h	
Back Pressure		0.00 psi	
<b>PRIME</b>	<b>STATUS</b>		<b>ESC</b>

When the screen is first displayed the operator is prompted to prime the channel. This is essential to ensure that the measuring circuit is filled with fluid.

#### *Prime*

This prompt stays on the screen while there is any air in the measuring circuit. Pressing **ENTER** while this prompt displays **PRIME** will not have any effect. As the circuit is primed the prompt changes to **START**. There may be some flickering between **PRIME** and **START** as bubbles percolate through the system.

#### *Status*

This invokes the **STATUS ALL CHANNELS** screen.

#### *ESC*

Selecting **ESC** or pressing **ESC** on the external keyboard takes the operator back to the **CHANNEL SETUP** menu.

### Dual Rate Test Screen (Start Mode)

CHANNEL 1 DUAL FLOW			
<b>FLOW 1</b>		<b>0.00</b>	
			ml/h
<b>VOLUME</b>		<b>0.00</b>	ml
FLOW 2	0.00	VOLUME	
Elapsed Time		00:00:00	
Inst. Flow		0.00 ml/h	
Back Pressure		0.00 psi	
<b>AutoSTART</b>	<b>START</b>	<b>STATUS</b>	<b>ESC</b>

When the measuring circuit is primed successfully the screen advances to the Start Mode.

#### *Auto-Start*

Pressing **ENTER** on this option puts the **IDA-4 Plus** into **AutoSTART** mode. The prompt will flash until the instrument detects that the fluid is flowing, then start the test.

#### *Start*

When the channel is primed this option is displayed and enabled. Pressing **ENTER** while this item is selected starts the test and advances to the Measuring Mode.

#### *Status*

This invokes the **STATUS ALL CHANNELS** screen.

#### *ESC*

Selecting **ESC** or pressing **ESC** on the external keyboard takes the operator back to the **CHANNEL SETUP** menu.

### Dual Rate Test Screen (Measuring Mode)

CHANNEL 1 DUAL FLOW			
<b>FLOW 1</b>		<b>0.00</b>	ml/h
<b>VOLUME</b>		<b>0.00</b>	ml
FLOW 2	0.00	VOLUME	
Elapsed Time		00: 00: 00	
Inst. Flow		0.00 ml/h	
Back Pressure		0.00 psi	
<b>STATUS</b>	GRAPH	FLOW	OCCL END

When the test is started, the screen enters measuring mode for the primary flow rate (Flow 1) as shown. This enables further menu options.

As the test progresses the **IDA-4 Plus** detects the change in flow rate and changes the display to emphasize the secondary flow rate (Flow 2). The Instantaneous Flow Rate shall be displayed in this screen between the elapsed time and backpressure readings.

Status

This invokes the **STATUS ALL CHANNELS** screen.

Graph

This switches to the **DUAL FLOW GRAPH** screen for the current channel.

Flow

This ends the current test, clear the values from the screen and proceeds to the **FLOW TEST** screen in either **Prime** or **Start** mode, depending on the current state of the transducer.

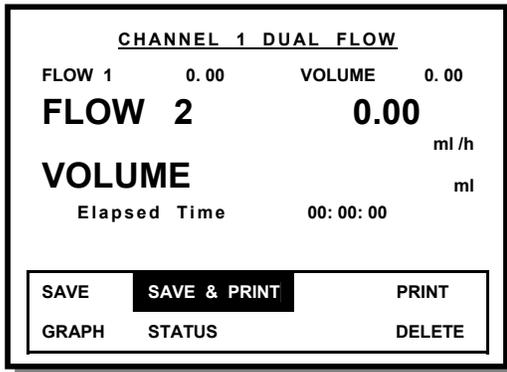
Occlusion

This ends the current test, clear the values from the screen and proceed to the **OCCLUSION TEST** screen in **Wait** mode.

End

Ends the test and advances to the **End of Test Mode**.

### Dual Rate Test Screen (End of Test Mode)



This view of the **DUAL FLOW TEST** screen allows the operator to save, print or discard the results.

#### *Save*

This saves the results of the dual flow test to non-volatile memory for later printing or transfer to a computer via the **RS232** port.

#### *Save & Print*

This saves the results as described above, then sends a report to a printer connected to the printer port on the instrument. The report will be in either full or summary format, as previously selected by the operator from the **UTILITIES / PRINTER** menu.

#### *Print*

This sends a report to a printer connected to the printer port on the instrument. The report will be in either full or summary format, as previously selected by the operator from the **UTILITIES / PRINTER** menu.

#### *Status*

This switches to the **STATUS ALL CHANNELS** screen to allow the operator to use another channel or change settings via the **UTILITIES** menu.

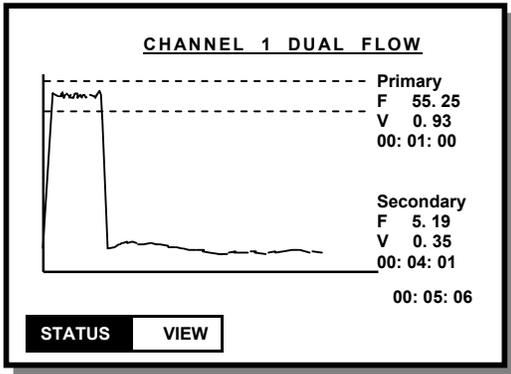
#### *Graph*

This switches to the **DUAL FLOW GRAPH** screen for the current channel to allow a graph of the results to be viewed before they are saved or printed.

#### *Delete*

This deletes the current set of results from memory without saving to non-volatile memory. Once this option has been invoked there will not be any way to recover, view or print the results of this test.

## Dual Rate Graph Screen



The **DUAL FLOW RATE** screen displays the average flow rate for the primary and for the secondary flows. Deviation marks as described in the single flow rate graph are shown for the primary flow rate only.

Text at the right of the graph displays the primary flow rate, volume delivered at that rate and the duration of the primary flow. This is followed by the secondary flow rate and volume delivered at the secondary flow rate.

### *Status*

This switches to the **STATUS ALL CHANNELS** screen to allow the operator to use another channel or change settings via the **UTILITIES** menu.

### *View*

This returns to the **DUAL RATE TEST** screen in either the Measuring Mode or the End of Test Mode, depending on which mode called this screen.

### **Measuring Flow-rate against Back-pressure**

Safety and performance standards for infusion devices expect manufacturers to state the flow characteristics under specified backpressure conditions. For instance, the flow rate might be quoted at zero output pressure, then subjected to backpressure of +300mmHg, and then -100mmHg. Some infusion devices (e.g. gastric feeding pumps) will not need to perform well against high back pressure, whereas other types (e.g. intravenous feeders) must deliver the stated flow rate against some back pressure.

This instrument can be subjected to backpressure within the range +300mmHg to -100mmHg to test the effect on delivered flow rate. Backpressure in this range will not affect flow measurement. Backpressures outside this range are not recommended.

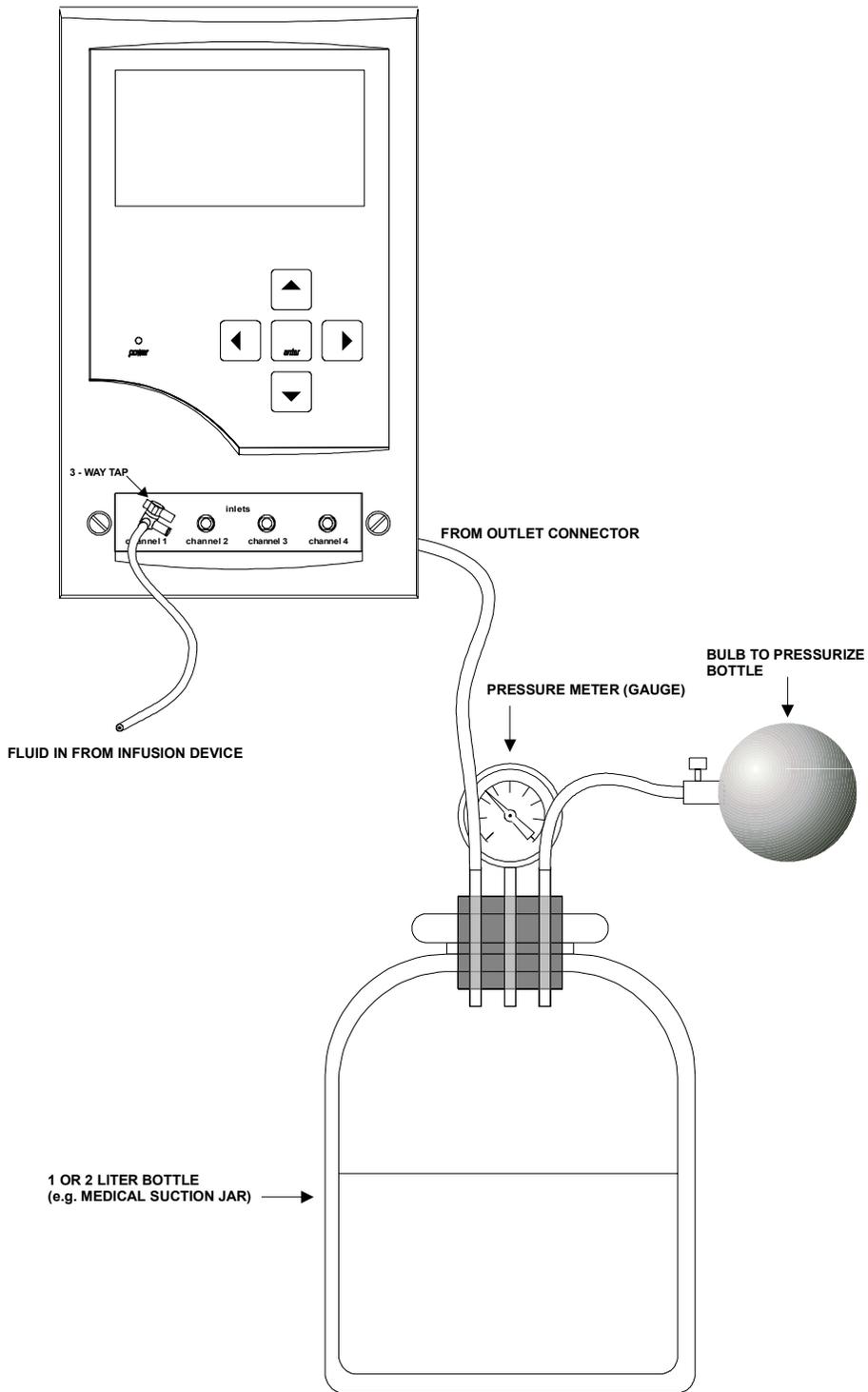
The following test arrangement is suggested for performing flow rate tests under back pressure. The pressure at the outlet must be returned to zero before performing an occlusion pressure test, and when changing infusion devices.

The recommended procedure is as follows:

1. Perform an initial prime.
2. Set outlet reservoir pressure to zero (open to air)
3. Blow AIR through the unit with a large syringe to ensure that there is practically no water in the outlet tube.
4. Connect to the infusion device to be tested.
5. Pressurize collection vessel to highest required (positive) test pressure
6. Allow infusion device to deliver at least 3 ml.
7. Conduct flow measurements.
8. Reduce pressure in collection vessel to next test value.
9. Repeat steps 6 and 7 as required.
10. Release pressure from collection vessel before disconnection is made.  
Remember that disconnecting the circuit under pressure may cause explosive release of water.

See:- Suggested Apparatus for Back Pressure Testing Drawing (Page 49).

### Suggested Apparatus for Back Pressure Testing Drawing



# Maintenance, Service and Calibration

*This chapter discusses routine maintenance and calibration procedures for the user.*

### User Care and Maintenance

#### Storage

Do not leave water inside the unit when storing or shipping. At the factory units are 'dried' before shipping by connecting a suction pump to each of the **FLUID OUTLET** connectors in turn for 2 minutes. This is performed with the unit switched off and disconnected from the supply. Connection to a medical suction pump will not harm the unit.

#### Handling

The equipment will be damaged if dropped or subjected to excessive shock.

#### Use

For best performance the unit should be regularly used, and may be left between test sessions with water inside.

#### Care of the Instrument Case

Clean using a damp cloth with a mild detergent. The molded front panel and rear housing can be damaged if an abrasive cleaner is used.

Do not use any type of solvent to clean the case.

#### Cleaning the Inside of the Instrument

Over a long period of use there may be some 'scaling' of the inside tubes etc. Also there may be organic growth inside the measuring system. We suggest occasional cleaning (e.g. every 3 months) as follows:

1. Inject 20 ml of warm detergent solution into each channel that is fitted with a measuring transducer and leave for at least 5 minutes. Then flush out with water.

Hypochlorite / Chlorine Bleach is not allowed, nor any alcohol based agent

## **User Performance Check**

The Calibration is set at the factory. For accurate Re-Calibration or resetting of Calibration the unit must be returned via the dealer.

Users may wish to check for faults after a period of use or after shock to the unit. We suggest the pressure measurement performance is checked by connecting an external pressure gauge and syringe to the fluid inlet connector of each channel fitted. Initiating an occlusion test on each channel in turn (each Fluid-inlet must be vented to atmosphere at the start of the test), and then raise the pressure to 1 Bar on each channel fitted and checking that the pressure readings are approximately as expected.

We suggest that flow measurement performance is checked using a syringe pump which has been calibrated with an accurate burette. We suggest checking each channel at 20 ml/hr. Please note that a new syringe must be fitted before performing this test, and the syringe pump must be allowed time to come up to speed before starting the Flow Test on each channel.

# Infusion Devices Delivery Methods

*This Appendix gives an overview of and discusses different types of Infusion Devices and Delivery Methods*

## Infusion Devices: An Overview

Infusion devices may be grouped into two types, gravity controllers and infusion pumps.

### Gravity Controllers

are powered devices which control the flow of the infusion to the desired rate by constricting the infusion line. There is no pumping action, i.e. they rely solely on the height of the fluid bag above the patient.

Regulators are a simple manual form of this device which do not rely on electronics and are generally single use.

This type includes:

### Drip-Rate Controllers

These are devices in which the desired flow is set in drops per minute. The electronic mechanism then counts the drops as they fall through a drop chamber and constricts the infusion line to achieve the desired flow.

### Volumetric Controllers

These are devices resembling the above, but in which the desired flow rate is set in milliliters per hour. The device calculates the conversion from drops per minute to milliliters per hour.

### Infusion Pumps

Infusion pumps are powered devices to provide the desired flow rate by a positive pumping action.

This type includes:

### Drip-Rate Pumps

These are devices in which the desired flow rate is set in drops per minute. The electronic mechanism then counts the drops as they fall through the drop chamber and the appropriate volume is infused into the patient, usually by a linear peristaltic pumping action.

### Volumetric Pumps

These are devices in which the desired flow rate is set in milliliters per hour. A variety of pumping means incorporating a known volume displacement are used (for example, a specified cassette mechanism). A drop sensor may be present for the purpose of indicating an empty infusion bag, or for the detection of inaccuracies in delivered volume.

### Syringe Pumps ('Syringe Drivers')

These are devices in which a syringe or cartridge containing the solution to be infused is secured in the pump and a plunger is driven forwards at a predetermined rate to achieve the desired infusion rate.

## **Patient Controlled Analgesia (PCA) Pumps**

These are devices in which the patient is able to initiate a dose of the infusion solution for the relief of pain. Access by the patient to the pump itself is prevented, pre-programmed restraints are placed on the parameters of the boluses and, in addition, a basal rate delivery of solution outside the control of the patient may be provided.

## **Pumps for Ambulatory Use**

These are small and light enough to be carried around by the patient without unduly interfering with everyday activities.

## **Anesthesia Pumps**

These are syringe pumps suitable for the administration of anesthetic agents and unsuitable for any other use.

## **Multi-Purpose Pumps**

These can be made to perform as one of the above listed pump.

## **Other Devices**

These include non-electrically powered devices, which do not have electrically generated alarm signals. Some of them are charged with a syringe and then deliver their output more or less continuously, with flow being controlled by a flow-regulating means, such as a capillary tube. This type of pumping device may use an elastomeric membrane, which, once expanded, provides sufficient force to drive the infusion. Applications include PCA and emergency situations.

The performance of non-electrically powered devices is generally inferior to those types mentioned above, but they may have other advantages, such as simplicity and the ability to operate in difficult environments.

Spring driven clockwork, and gas powered infusion devices are also available.

## **Flow Regulators**

which are manually set, non-powered, devices which appear in a variety of forms and which clamp onto, or are inserted in, the line. They usually have a rotary dial to give to give an indication of expected flow rate. Some of these devices claim to compensate for venous back pressure and maintain consistent flow.

The performance of non-electrically powered devices is generally inferior to those types mentioned, but they may have other advantages, such as simplicity and the ability to operate in difficult environments.

## **Infusion Devices: A More Detailed Look**

The previous section introduced the infusion devices that are generally to be found on wards, in intensive therapy units (ITUs) and theaters. In this section each device will be described with comments about safety, performance and suitability for application.

## **Gravity Controllers**

### **General**

Infusion controllers rely solely on gravity to provide the infusion pressure and consequently, the fluid container must be placed at an adequate height above the infusion site for the desired flow to take place. A drop sensor attached to the drip chamber of the administration set monitors the drip-rate. A variable mechanical clamp within the device, acting on the delivery tube, controls the flow and hence the drip-rate, to achieve the set rate.

Control against over-infusion is effective, but increased resistance to flow may result in under-infusion. The better controllers incorporate a flow status system in which users are provided with a visual indication of increased resistance to flow, which could mean that there is a 'positional IV' problem (catheter impinging on the vein wall) or even infiltration (extra-vascular infusion in which the catheter has punctured the vein and the infusion solution is infiltrating surrounding tissue). An alarm operates when there is a significant departure from the set drip-rate. No alarm should ever be regarded as being a nuisance.

Controllers are recommended for use in many lower risk applications, involving fluid replacement therapy where their low delivery pressure, early warning of problems at the infusion site, inability to pump air and the reduced risk of extra-vascular infusion (due to the low delivery pressure) are considerable advantages.

### **Drip-Rate Controllers**

use standard solutions sets and although they look much like a pump, they have no pumping mechanism. They are sometimes marked CONTROLLER. The flow rate is selected in drops per minute and controlled by battery or mains powered line occlusion valves. Controls tend to be few and simple to operate. More advanced models incorporate a flow status system, which gives a visual indication of resistance to flow. A drop sensor is always included.

Drip-rate controllers are suitable for the majority of lower risk infusions in which volumetric accuracy is of lesser importance, see below.

### **Accuracy of Drip Controlled Devices**

Because of the high accuracy of drop counting mechanisms used by gravity controllers, it is natural to assume that volume delivery will be correct according to the conversion used - it may not be.

The normal drops/ml for a set, or the value taken from a conversion chart, are approximate and the actual drops/ml may differ considerably. The volume of fluid in a drop depends on a number of variables: the composition of the fluid, its temperature and surface tension; the drip rate set; the size, shape and condition of the drop forming orifice. Most simple aqueous solutions of electrolytes, lactates or dilute sugars, give drop volumes fairly close to the expected nominal drops/ml, except at very low drip rates. However, total parenteral nutrition (fat-soluble vitamins, solutions containing alcohol and some amino-acid solutions) produce much smaller drops. The flow rate will therefore be lower than expected and the infusion time will be increased. With all fluids, the drops/ml value falls (drop volume rises) with increasing delivery rate.

For the majority of infusions, these variations are acceptable, but where volumetric accuracy is considered to be critical, the use of a volumetric pump (or a syringe pump if the volume to be infused is small) is essential.

### **Volumetric Controllers**

are calibrated in milliliters per hour, have a drop sensor, may have more controls and alarms than a drip-rate controller and may need a dedicated solution set or a disposable 'rate clip'.

Volumetric controllers include compensation for drop size. The main problem is knowing what compensation to apply, as drop size varies due to several factors. Volumetric accuracy is dependent upon the compensation being correct under all circumstances. With present technology, a number of compromises have to be accepted and a fluid code system is usually adopted which groups like infusates together. It is generally considered that the accuracy of delivery of these devices cannot be much better than  $\pm 10\%$  over a one-hour period.

The only advantage of using a volumetric controller, rather than a drip-rate controller, is that no calculations have to be made for the drip rate of the administration set and so this potential source of error is eliminated.

## **Infusion Pumps**

### **General**

Common to all pumps is the ability to overcome resistance to flow by increased delivery pressure. Pumps do not rely on gravity and can therefore be placed in almost any reasonable position relative to the infusion site (but not too high). The delivery pressure may rise to high values in some devices in the event of a catheter becoming occluded or displaced, with the danger of extra-vascular infusion. However, the default pressure is usually limited in modern pumps and some include a facility for setting very low occlusion alarm pressures.

Generally Speaking, the performance of pumps is predictable and the volume to be infused (VTBI) can be set in the confident knowledge that it will be delivered. Associated with this must come the understanding that these are electrically powered devices, having a number of risks. They must be used with full knowledge of these risks and thorough training in their operation.

Pumps are capable of accurate delivery of solution over a wider range of flow rates than controllers, at both the low and high ends of the delivery range, and may be designed for specialist applications, to which they must then be restricted.

### **Drip - Rate Pumps**

The flow rate is selected in drops per minute and this alone allows users to distinguish them from volumetric pumps. A drop sensor attached to the drip chamber counts drops and the pump then infuses the set drip rate into the patient.

Pumping is achieved either by the peristaltic action of rollers or, usually, by mechanical fingers (linear peristaltic) on deformable tubing. This latter type of pump uses a standard administration set, but rotary peristaltic pumps generally require softer tubing and special sets are provided with a pumping insert made of suitable material. Pumps that use drop sensing as their means of control do not normally compensate for variation in drop size.

Controls are few and simple, with only rudimentary alarms to warn of any departure from the set rate and some other malfunctions.

Air - in - line detection is rarely, if ever, provided and the occlusion response is poor, with high pressures being reached. These pressures are so high that in practice the alarm would probably never activate during extra - vascular infusion.

### **Volumetric Pumps**

These are the preferred pumps for medium and large flow rate and large volume infusions; although some are designed specially to operate at low flow rates for neonatal use. All are mains / battery powered, with rate being selected in milliliters per hour. Most use a linear peristaltic pumping mechanism, but other mechanisms are available, such as cassettes.

Volumetric pumps usually incorporate a wide range of features, required for neonatal and high-risk infusions, including air-in-line detector and comprehensive alarms. These features, if properly used, make intravenous (IV) infusion much safer. There are, however, some models either having, or which can be configured to have, a more basic specification, making them suitable for lower risk infusions only.

Some volumetric pumps incorporate a drop sensor, but only for monitoring and alarm purposes (such as empty container) and not as a primary control of delivery rate. Some are designed to be used with standard PVC gravity administration sets.

In common with all pumps, they have the capability of developing high delivery pressures (but not as high as drip-rate pumps) and due regard must be paid to this. However, in most pumps of this type, the pressure is limited to a pre-set value above which the pump will alarm.

Volumetric pumps generally incorporate the following features:

automatic alarm and shut down if air enters the system; pre-set control of total volume to be infused with digital readout of volume infused; automatic switching to keep vein open (KVO) rate at the end of the infusion; comprehensive alarm systems; automatic switch over to internal battery operation on failure of mains supply, with the facility to use the device on internal battery power only, if no mains power is available (for example during transportation); other features often available are micro and macro delivery modes, computer interface, operator-call alarm, primary and secondary ('piggyback') infusion capability and a technical memory log, which can record the last few hundred operations for incident analysis. Typically, most volumetric pumps will perform satisfactorily at rates down to 5 ml/h. If you wish to infuse at lower rates, you should check the trumpet graph. Below 1 ml/h, the performance should be checked by referring to the manufacturer.

## Syringe Pumps

These are low volume, high accuracy devices designed to infuse at low flow rates and are typically calibrated for delivery in milliliters per hour, typically 0.1 to 99 ml/h. Many pumps will accept different sizes and different brands of syringe (up to 50/60 or even 100 ml), but the pumps must be set up for a particular type and size of syringe in use, unless the pump detects the syringe size and type automatically. Total dose volume (without refilling) is limited to the size of the syringe used. They are mains and/or battery powered and tend to cost less than volumetric pumps.

Programming in units other than milliliters per hour may be possible, with some having a bolus facility whereby a given volume may be infused in a short time. In the past, syringe pumps had few alarms, but the trend has moved towards a comprehensive alarm system which guards against unsafe operation.

At low flow rates, delivery from a syringe pump is likely to be more uniform than that from a volumetric pump and the resultant short-term fluctuations are of much smaller magnitude. There have been problems with backlash (slackness which causes start-up and alarm delays) in the pump overcome by careful attention at the design stage. Following the manufacturer's instructions for priming the pump will reduce such problems. Features available vary so widely that each model must be separately assessed, but the more recent and more expensive models have much to offer, including delivery pressure displays.

Important points and advice for safe operation: the syringe barrel and plunger must be located securely in accordance with the manufacturer's instructions. Only by doing this will the instrument's safety features be fully operational and free-flow (siphonage) be avoided. Use the smallest syringe the pump will accept, and which is able to hold the required volume of drug. As in general, occlusion response times are decreased when using small syringes. Also, small syringes improve the consistency of the flow and reduce bolus volume when the occlusion is removed.

## PCA Pumps

Most of these pumps have the capability of mains or battery operation and are designed specifically for this application. They are typically syringe pumps, as the total volume of drug to be infused can usually be contained in a single-use syringe. Some PCA pumps are based on volumetric designs. The difference between a PCA pump and a normal syringe pump is the provision of a facility to enable patients to deliver a bolus dose themselves. A PCA pump may be programmed by clinical staff, to deliver a pre-set bolus on demand, with a pre-set lock-out time between boluses. In addition to the bolus delivered on patient demand, PCA pumps may also be programmed to deliver a basal rate (continuous low rate infusion). Examples of programming options are:

Loading dose; continuous infusion; continuous infusion with bolus on demand;

Bolus on demand only, with choice of units (ml or  $\mu\text{g/ml}$ , etc) and variable lockout time; drug concentration;

Once programmed, access to the control of the pump is usually only permitted by a key or software code but in some cases, limited patient access is allowed in order to change some parameters.

A feature of most PCA pumps is a memory log, which can be accessed either through the display, or downloaded via a printer or computer. This enables the clinician to determine when and how often, a demand has been made by the patient and what total volume of drug has been infused over a given time.

There is a range of miniature battery powered volumetric pumps designed for PCA applications and having disposable internal fluid reservoirs.

With PCA pumps, protection against free-flow is important, particularly as the patient may be unsupervised for some of the time.

## **Pumps for Ambulatory Use**

are of two types, miniature syringe drivers and miniature volumetric pumps. Because of the size of the devices, the available battery capacity is low and continuous pumping is not feasible. Most ambulatory pumps, therefore, give an output in the form of a small bolus delivered every few minutes. For the same reason, and because space is at a premium, very few alarms are provided. Usually, warning indicators are restricted to flashing light to show pump running and an audible alarm to indicate occlusion, or end of infusion.

Some non-electrically powered ambulatory pumps for PCA applications are appearing on the market, using, for example, elastomeric balloons as the energy source.

## **Miniature Syringe Pumps**

can easily be carried in a pocket or handbag, or worn by the patient. Most are battery powered (a few are spring-driven), have few controls and the minimum of alarms. They were developed from early syringe pumps accepting small volume syringes for intermittent bolus delivery via routes other than IV, typically subcutaneous infusion of insulin. However, pumps are now available that are specifically designed for IV infusions, and are useful in cytotoxic chemotherapy, pain relief and other applications where very small volumes are to be infused over periods of days, rather than hours, and where the patient is at home rather than in a hospital ward.

They can typically accept syringes between 2 and 10 ml and are able to achieve very low rates of delivery. Because of this ability to accept various sizes of syringe, these pumps may require the rate to be set in millimeters per day, that is, linear travel of syringe plunger against time. They will be able to achieve the linear rate with considerable accuracy. Calculations, which depend on the syringe used, may be required to convert from flow rate to linear travel per unit time.

The volumetric accuracy, however, can be variable, depending on the rate set, the fluid and syringe used and the type of tubing employed. At the very low infusion rates which can be selected (a few microliters per hour), some of the infusate may migrate through the walls of the tubing and never actually reach the patient.

## **Miniature Volumetric Pumps**

use removable reservoirs which contain the solution within the pump. Some may offer a large variety of programming options. Those pumps having bolus on demand, as well as basal rate, are also suitable for PCA pumps.

## **Anesthesia Pumps**

These are syringe pumps designed for use in anesthesia or sedation and must be used only for this purpose. They should be clearly labeled ANESTHESIA PUMP and should be restricted to operating and high dependency areas. They are designed so that the rate may be changed and other functions accessed immediately, whilst infusing. They need to infuse over a higher flow rate range than normal syringe pumps and have a high bolus rate facility, so that the induction dose may be delivered quickly, with a single operation. Because of their application, these pumps may have a number of specific features such as:

- Programming for body weight and drug concentration; drug specific
- smart-card system which automatically calibrates the pump for the drug

being infused; built-in drug libraries; interface for computer control and monitoring.

If these facilities are software enabled, by programming or smart card for example, in a pump that is otherwise suitable for other applications, they must be disabled before these pumps are used in any other application. Management must initiate policies to ensure that this is done. If these facilities cannot be locked out, in no circumstances should these pumps be used for any other application.



## Appendix B

# Computer Control Commands

*This Appendix gives an overview of computer commands necessary to control the IDA-4 Plus.*

### Overview

With the computer control feature, the user is provided more power and flexibility with the IDA-4 Plus. For example, automation of all channels can be achieved for a completely paperless approach to documentation.

When using computer control, the front keypad will be inoperable. The Status All Channels screen will be displayed and the menu prompts will guide the operator through the prime sequence and indicate the type of test in progress.

### Controlling the IDA-4 Plus with HydroGraph™

The IDA-4 Plus can be operated using a computer running HydroGraph™ software. Follow the steps below to get started:

- Power off the IDA-4. Connect the provided serial communications null modem cable or Fluke Biomedical's serial cable (PN 2392046) between the IDA-4 Plus serial port and the computer. Make a note as to which PC communications port the cable is connected to.
- Power up the IDA-4 Plus and wait for the status all channels screen to appear on the display.
- Make sure HydroGraph™ version 2.xx is installed on the computer.
- Once installed, start HydroGraph™ on the computer, connection should automatically occur. If not, refer to the HydroGraph™ Operators manual for further details.

## Controlling the IDA-4 Plus Using Serial Protocol

The IDA-4 Plus allows the operator full flexibility with regard to the RS232 port. Capabilities include receiving and sending data at baud rates of 300, 600, 1200, 2400, 4800, 9600, 19200 and 38400. The baud rate used for transmission is held in the IDA-4 Plus non-volatile memory and can be changed at any time by the operator. Other serial port parameters are Parity: even, odd and none; Data Bits: 7,8; Stop Bits: 1,2.

## Command Conventions

There are 2 types of commands used in the IDA-4 Plus. Commands that perform an action without returning data, and commands that return data to the host computer. The ASCII code commands are to be enclosed by square brackets. For example, to send a command to end a communication session, type [BYE]. All commands instructing to perform a test needs to have a channel number attached to the command. Some commands require more information in addition to channel number in the command line. For example the Dual Flow test requires definition of the primary rates and volume secondary rates and volume.

The following commands require only the channel number to execute:

[VOLn], [FLOWn], [PRESn], [PKPRESn], [PCATRIGn]

The following section describes the data pieces required to perform these tests via computer control.

## Perform a Flow Test [CnF,a,b,c]

This command starts a flow / volume test on the specified channel. The IDA-4 Plus status all channels screen will prompt the operator to prime the channel. Once primed, the operator will have to press the Start key on the IDA-4 Plus front panel or send the [CnF] command again.

Parameters:

a = control number of device under test  
b = technician name  
c = set flow rate

*n = channel number*

### Perform a Volume Test [CnV,a,b,c]

This command starts a flow / volume test on the specified channel. The IDA-4 Plus status all channels screen will prompt the operator to prime the channel. Once primed, the operator will have to press the Start key on the IDA-4 Plus front panel or send the [CnV] command again.

Parameters:

n = channel number

a = control number of device under test

*b = technician name*

c = set flow rate

### Perform an Occlusion Pressure Test [CnO, a,b,c]

This command starts an occlusion pressure test on the specified channel. The IDA-4 Plus status all channels screen will prompt the operator to start the test. The operator can either press the start key on the front panel or send the [CnO] command again.

Parameters:

n = channel number

*a = control number of device under test*

b = technician name

c = set flow rate

### Perform a PCA Test [CnPCA,a,b,c]

This command starts the PCA test on the specified channel. The IDA-4Plus status all channels screen will prompt the operator to prime the channel and start the test. Once primed, the operator can press the start key on the front panel or send the [CnPCA] command again.

Parameters:

n = channel number

a = control number of device under test

b = technician name

c = set basal flow rate

## Perform a Dual Flow Rate Test [CnD,a,b,c,d,e,f]

This command starts a Dual Flow rate test on the specified channel. The IDA-4 Plus status all channels screen will prompt the operator to prime the channel and start the test. Once primed, the operator can press the start key on the front panel or send the [CnD] command again.

Parameters:

a = control number of device under test  
b = technician name  
c = set primary flow rate  
d = set primary volume  
e = set secondary flow rate  
f = set secondary volume

*n = channel number*

## Fetch the Current Flow Measured on a Channel [FLOWn]

Returned to host:

[Flow, nnnn.nn, hh:mm:ss:mmm] <CR><LF>

Where:

nnn.nn is the flow rate in ml/hr

hh:mm:ss:mmm is the time since the start of the test, formatted as:

hh      Hours

ss      Seconds

mmm    Milli-seconds

*mmMinutes*

## Fetch the Current Volume Accumulated on a Channel [VOLn]

Returned to host:

[Vol, nnnn.nn, hh:mm:ss:mmm] <CR><LF>

Where:

nnn.nn is the vol in ml

hh:mm:ss:mmm is the time since the start of the test, formatted as:

hh      Hours

mm      Minutes

mmm    Milli-seconds

*ssSeconds*

### Fetch the Current Pressure on a Channel [PRESn]

Returned to host:

[PRES, pppp, hh:mm:ss:mmm] <CR><LF>

Where:

pppp is the pressure in the selected units

hh:mm:ss:mmm is the time since the start of the test, formatted as:

hh      Hours

ss      Seconds

mmm    Milli-seconds

*mmMinutes*

### Fetch the Peak Pressure on a Channel [PKPRESn]

Returned to host:

[PKF

Where:

pppp is the peak pressure in the selected units

hh:mm:ss:mmm is the time since the start of the test, formatted as:

hh      Hours

mm      Minutes

ss      Seconds

mmm    Milli-seconds

<b>ASCII Code</b>	<b>Function</b>	<b>Number of Parameters</b>	<b>IDA-4 Plus &lt;--&gt;</b>
BYE	Terminates Computer Control	0	-->
POLL	Returns # of channels installed	0	<-->
PRESUn	Sets the pressure units	n = Channel number	-->
CnF,a,b,c	Starts a Flow Test	3, n = Channel number	-->
CnV,a,b,c	Starts a Volume Test	3, n = Channel number	-->
CnO,a,b,c	Starts an Occlusion Test	3, n = Channel number	-->
CnPCA,a,b,c	Starts a PCA test	3, n = Channel number	-->
CnD,a,b,c,d,e,f	Starts a Dual Flow Test	6, n = Channel number	-->
END,n	End a Test	n = Channel number	-->
FLOWn	Fetches current flow rate	n = Channel number	<-->
VOLn	Fetches current volume	n = Channel number	<-->
PRESn	Fetches current pressure	n = Channel number	<-->
PKPRESn	Fetches the peak pressure	n = Channel number	<-->
PCATRIGN	Requests the start of a PCA trigger	n = Channel number	-->

**Table B-1:** ASCII Code Commands used in the Computer Control Protocol