BC Biomedical
A UNIT OF BC GROUP INTERNATIONAL, INC.

INFUSION PUMP ANALYZER

IPA-1000 SYSTEM

USER MANUAL

BC BIOMEDICAL
IPA-1000 SYSTEM
TABLE OF CONTENTS

This User Manual covers the following units:

- IPA-1000
- MC3.5-1000
- MC35-1000

WARNING - USERS

The IPA-1000 System is for use by skilled technical personnel only.

WARNING - USE

The IPA-1000 System is intended for testing only and should never be used in diagnostics, treatment or any other capacity where they would come in contact with a patient.

WARNING - CONNECTIONS

All connections to patients must be removed before connecting the DUT to the IPA-1000 System. A serious hazard may occur if the patient is connected when testing with the unit. Do not connect any leads from the patient directly to the unit or DUT while it is powered by the System.

WARNING - LIQUIDS

Do not submerge or spill liquids on the IPA-1000 System. Do not operate the IPA-1000 System if internal components not intended for use with fluids may have been exposed to fluid, as the internal leakage may have caused corrosion and be a potential hazard.

WARNING - MODIFICATIONS

The IPA-1000 System is intended for use within the published specifications. Any application beyond these specifications or any unauthorized user modifications may result in hazards or improper operation.

CAUTION - FLUID

Only Distilled Water should be used in the chambers with the IPA-1000 System. Do not use tap water, glucose or any other fluid; this will cause the tubing to become contaminated.

CAUTION - SERVICE

The IPA-1000 System is intended to be serviced only by authorized service personnel. Troubleshooting and service procedures should only be performed by qualified technical personnel.

CAUTION - ENVIRONMENT

Exposure to environmental conditions outside the specifications can adversely affect the performance of the IPA-1000 System. Allow the IPA-1000 System to acclimate to specified conditions for at least 30 minutes before attempting to operate it.

CAUTION - CLEANING

Do not immerse. The IPA-1000 System should be cleaned by wiping gently with a damp, lint-free cloth. A mild detergent can be used if desired.

CAUTION - INSPECTION

The IPA-1000 System should be inspected before each use for wear and should be serviced if any parts are in question.

NOTICE – SYMBOLS

Symbol	Description
	**Caution** (Consult Manual for Further Information)
	**Center Negative**
	Per European Council Directive 2002/95/EC, do not dispose of this product as unsorted municipal waste.

NOTICE – ABBREVIATIONS

ANSI	**American National Standards Institute**
C	**Celsius**
°	**degree(s)**
DUT	**Device Under Test**
Euro	**European**
F	**Fahrenheit**
FS	**Full Scale**
hr	**hour(s)**
Hz	**hertz**
kg	**kilogram(s)**
µA	**microampere(s)**
mA	**milliampere(s)**
mL	**milliliter(s)**
mm	**millimeter(s)**
min	**minute(s)**
NEDA	**National Electronic Distributors Association**
Lbs	**Pounds**
RH	**Relative Humidity**
USA	**United States of America**
VDC	**Volts Direct Current**

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NOTICE – CONTACT INFORMATION

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BC BIOMEDICAL
IPA-1000 SYSTEM
INFUSION PUMP ANALYZER

The Model IPA-1000 System is a Microprocessor based High Precision Infusion Pump Analyzer (IPA). It tests the flow rate of Intravenous (I.V.) Infusion Pumps. The flow rates are displayed in milliliters per hour. The unit can test two volumetric pumps for output flow rate simultaneously using two volumetric chambers.

The following are highlights of some of the main features.

IPA-1000 SYSTEM (BASIC FEATURES):

- LARGE GRAPHICS DISPLAY WITH CURSOR SELECTION OF OPTIONS AND SETUP OF PARAMETERS
- ± 1% OF READING FLOW ACCURACY
- STANDARD MILLILITERS PER HOUR RANGE
- DIGITAL CALIBRATION – NO POTS TO TURN
- SELECTABLE DISPLAY OPTIONS AND DIGIT SIZES
- BATTERY LIFE DISPLAY (0 TO 100%)
- SOFTWARE ADJUSTABLE CONTRAST
- USES ANY COMBINATION OF CHAMBERS
- 3.5 mL & 35 mL CHAMBERS AVAILABLE
- SIMPLE TO MAINTAIN AND CLEAN (NO VALVES)
- REPLACEABLE TUBES
- SEALED LEVEL SENSORS
- AUTOMATIC DETECTION OF CONNECTED CHAMBER TYPE
- PROGRAMMABLE END OF TEST AUDIO
- PROGRAMMABLE AUTO OR MANUAL TEST START
- OPTIONAL BATTERY ELIMINATOR

AVAILABLE MODELS:

The base unit plus one of the volumetric chambers are required to test Infusion Pumps.

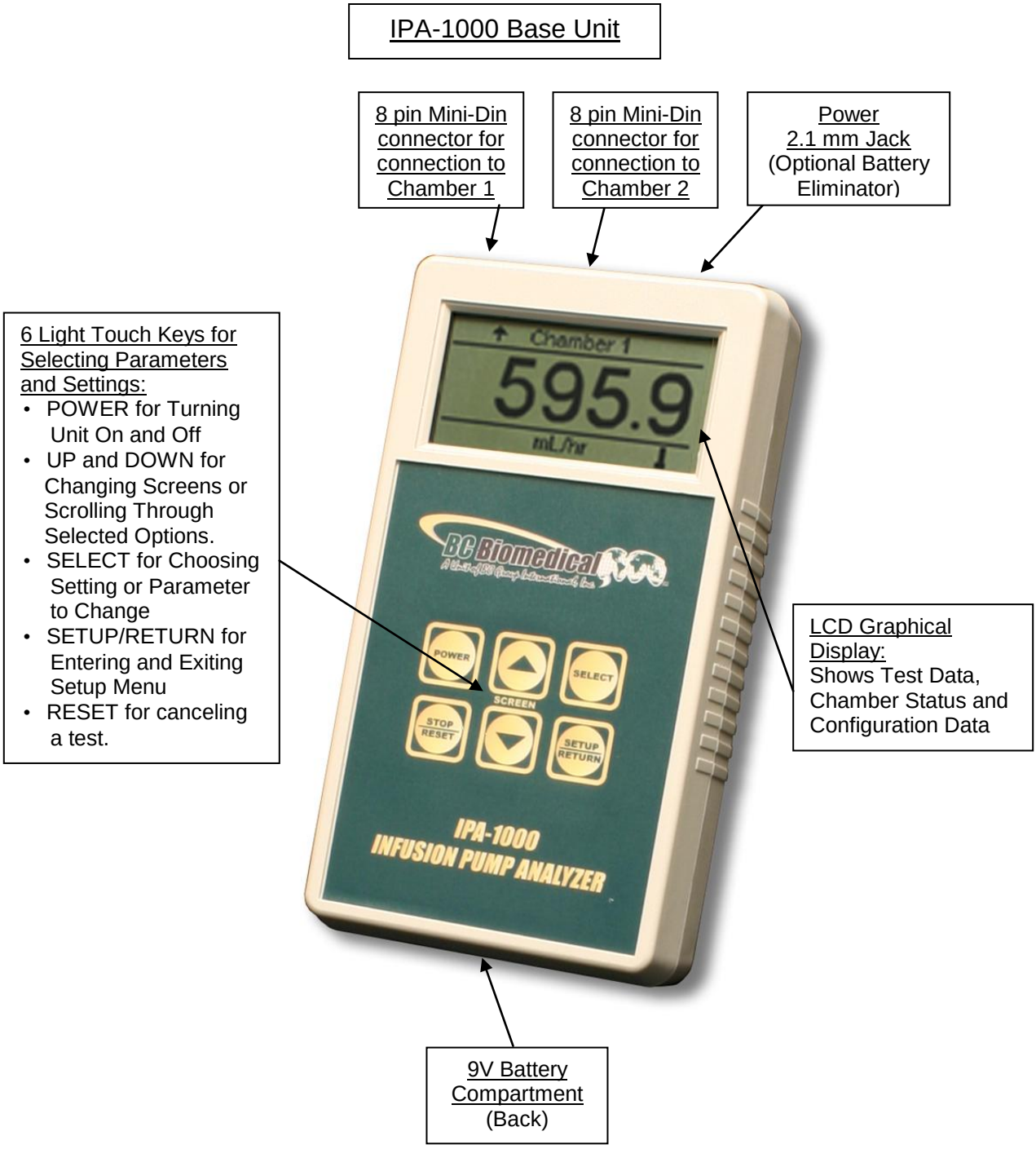
- IPA-1000 INFUSION PUMP ANALYZER BASE UNIT
- MC3.5-1000 3.5 mL VOLUMETRIC CHAMBER
- MC35-1000 35 mL VOLUMETRIC CHAMBER

OPTIONAL ACCESSORIES:

- BC20-21100 BATTERY ELIMINATOR, USA version
- BC20-21101 BATTERY ELIMINATOR, EUROPE version
- BC20-30109 SOFT CARRYING CASE
- BC20-40631 OVERFLOW ASSEMBLY KIT 3.5 mL
- BC20-40632 OVERFLOW ASSEMBLY KIT 35 mL
- BC20-40607 CHAMBER INTERCONNECT CABLE

OVERVIEW

This section looks at the layout of the IPA-1000 System, including the Base Unit and the Chambers and gives descriptions of the elements that are present.



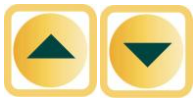
3.5 mL Chamber
MC3.5-1000

35 mL Chamber
MC35-1000

KEYS

Six tactile-touch keys are provided for system operation:

– This key turns the unit off and on. The unit will return to the screen that was active when it was turned off.



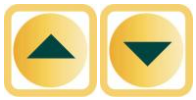
– In the DISPLAY MODE, these keys toggle the display through the available main screens. In the SELECT MODE, if a parameter has been highlighted, these keys with scroll through the available settings.

– On the Setup screen, there are a number of parameters that may be selected and changed. This key sequences the cursor (Highlight) through those parameters.

– This key is used to STOP any of the running flow tests or to manually reset the system if Auto Test Reset is set to NO. (See Setup Section for more details.)

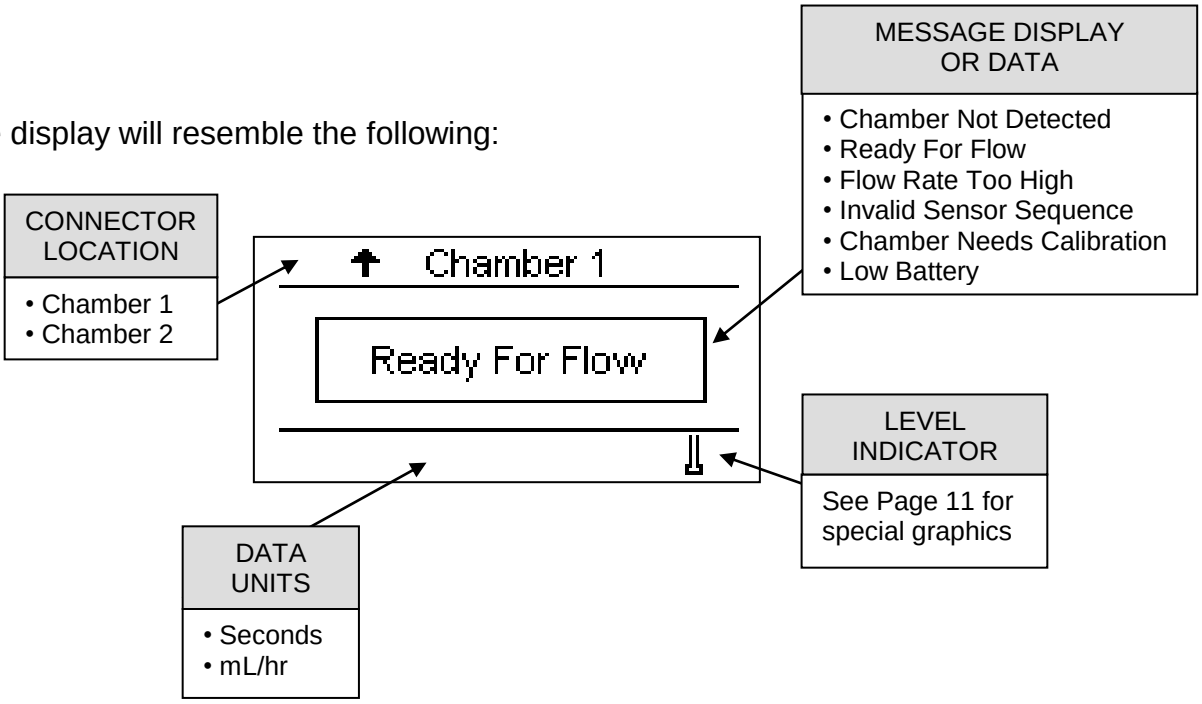
– This key toggles the unit into and out of the Setup Mode. Depressing this key will enter the Setup screen where the configuration can be viewed and adjusted. Depressing the key again will exit the Setup Mode and return to the previously viewed main screen.

SCREENS

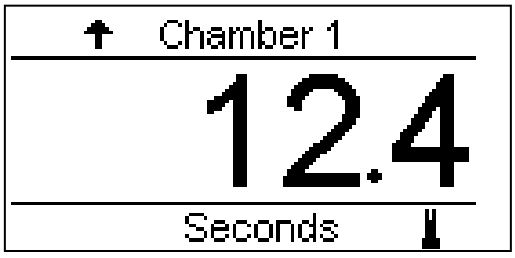
MAIN SCREENS – There are four main screens: Chamber 1, Chamber 2, DUAL and CONNECTORS. The available screens can be toggled using  .

CHAMBER SCREENS – The Chamber 1 and Chamber 2 screens have a large time and flow rate display, as shown below. The arrow at the top of the screen indicates the connector used for that Chamber. The level indicator at the bottom of the screen identifies the level of Distilled Water in the Chamber.

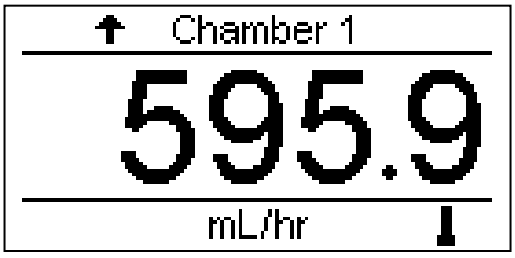
The display will resemble the following:



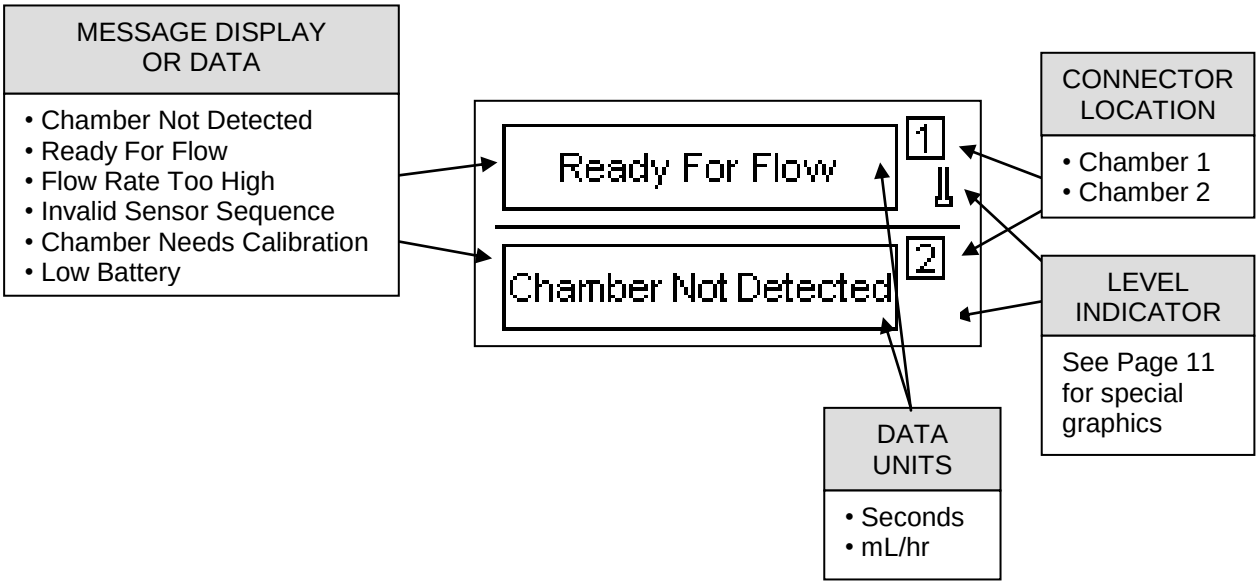
TYPICAL SCREEN DURING TEST



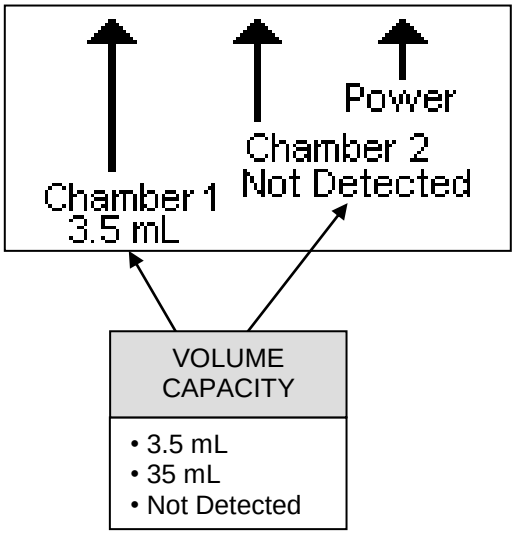
TYPICAL RESULTS SCREEN



DUAL SCREEN – The DUAL screen shows the status of both Chambers at the same time.



CONNECTORS SCREEN – The connectors screen indicates the layout of the connectors at the top of the IPA-1000. Also shown is the volume capacity of any connected Chambers.



MESSAGES

Several status messages are available to indicate the present state of the system. The following is a brief description of the available messages:

CHAMBER NOT DETECTED – This message indicates that a Chamber has not been detected.

READY FOR FLOW– This message indicates that the Chamber is reset and waiting for fluid to be detected at the bottom sensor. As soon as fluid is detected, the timer will begin running and the test will begin. The test ends when the fluid reaches the top sensor or when the Reset key is depressed.

FLOW RATE TOO HIGH – This message indicates that the flow rate is higher than the resolution of the meter.

INVALID SENSOR SEQUENCE– This message indicates that Distilled Water is detected at the top sensor but not at the bottom sensor. This could be caused by either a bad sensor or a bubble in the tube.

CHAMBER NEEDS CALIBRATION– This message indicates that a Chamber has been detected, but the calibration data stored in the Chamber is invalid. The Chamber should be serviced.

LOW BATTERY– This message indicates that the batteries are low and should be replaced.

LEVEL INDICATOR

A special graphic has been incorporated into the display to identify the level of Distilled Water in each Chamber. The graphic is located at the lower right corner of the display for each Chamber.

This graphic indicates that Distilled Water is not present at the lower or upper sensor.

This graphic indicates that fluid is present at the lower sensor.

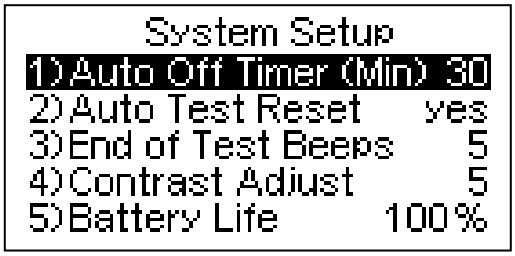
These graphics are displayed sequentially to indicate that a test is running.

This graphic indicates that Distilled Water is detected at the top and bottom sensor.

This graphic indicates that Distilled Water is present at the top sensor, but not the bottom. This is an invalid condition, indicative of either a bubble at the bottom sensor or a faulty sensor.

SETUP

The Setup Mode allows the user to adjust the configuration of the meter. The Setup screen can be entered using the SETUP RETURN key. The parameters can be changed by using SELECT key to highlight the line and ▲ ▼ to toggle the available options. The Setup screen can be exited using the SETUP RETURN key.



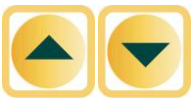
The following is a breakdown of the parameters available in the configuration of the unit and their available options:

System Setup Configuration		
Parameter	**Description**	**Range**
Auto Off Timer	Determines the period of inactivity before the unit is turned OFF. A timer is started when the unit is turned ON and is reset each time a key is pressed. When the timer reaches the value set in this parameter, the power is automatically turned OFF. (NOTE: Setting this parameter to 0 disables the Auto Off timer. When running from line power, the unit does not automatically shut off. Auto Off timer is inactive during a test.)	0-30 Minutes
Auto Test Reset	The auto reset mode automatically resets the system for a new flow test when the tube is emptied. If Auto Test Reset is set to NO, the user must manually press the RESET key to configure the system for another test.	YES/NO
End of Test Beeps	This determines the number of times that the unit will beep at the completion of a test. If set to zero, the unit will not beep.	0-15
Contrast Adjust	Sets the contrast of the display screen.	0-20
Battery Life	Displays current life of the battery. At 10%, a warning screen will appear. At 0%, the unit will power down automatically.	0-100% (Read Only)
Software	Displays current software version.	(Read Only)

OPERATIONS

Chambers are connected to the base unit using the Chamber Interconnect Cable (BC20-40607). Chambers can be connected or disconnected at any time. Disconnecting a chamber while a test is running will cancel the test.

As a chamber is connected or disconnected, the display will change to display the available chambers. For example, if a test is running on Channel 1 and a second Chamber is plugged into Channel 2, the display will automatically change to the dual display mode. If both chambers are connected and Chamber 1 is removed, the display will automatically change to the large screen displaying Chamber 2.

NOTE: The screen can always be manually changed by using the  keys.

THEORY OF OPERATIONS

Infrared sensors are used to detect the presence of Distilled Water in the chamber. There are two sensors in each chamber. As Distilled Water is detected at the bottom sensor, an internal timer is started. The timer runs internally in hundredths of seconds but is only displayed in tenths of seconds. The test automatically ends when Distilled Water is detected at the top sensor. A buzzer will sound to indicate that the test is complete. The buzzer can be programmed to sound for a specific number of beeps (0-15 beeps, see setup).

The flow rate is calculated based on the volume of the chamber and the time required to fill the tube. The chamber rating (3.5 mL or 35 mL) represents the nominal volume between the two sensors. For maximum accuracy, the precise volume of each individual chamber is calibrated and digitally stored in the chamber memory. Since the calibration data is stored in the chamber, they are interchangeable with any base unit.

A test in progress can be aborted by pressing the 

key, by disconnecting the chamber or by Distilled Water not being detected at the bottom sensor.

RUNNING A TEST

To run a flow test, the chamber must be Ready for Flow, as indicated in the base unit display (see Messages). When the base unit is setup for Manual Reset, the 

key must be used to manually reset the unit after each test. When the base unit is setup for Automatic Reset, the chamber will be automatically reset when the Distilled Water level drops below the bottom sensor.

A flow test can be started whenever the display indicates “Ready for Flow”. The flow test is started by Distilled Water being detected at the bottom sensor. Before initiating the flow on the Infusion Pump under test, ensure that the Infusion Pump is programmed to deliver a sufficient amount of Distilled Water to fill the chamber to the top sensor.

NOTE: The chamber volumes of 3.5mL and 35mL are nominal; it is advised that delivery volume should be about 4 mL and 40 mL respectively.

CAUTION - FLUID

Only Distilled Water should be used in the chambers with the IPA-1000 System. Do not use tap water, glucose or any other fluid; this will cause the tubing to become contaminated.

OPTIMIZING MEASUREMENTS

To optimize the performance of the IPA-1000 System, it is recommended that a wetting agent be used to minimize the surface tension of the test solution. The recommended wetting agent is “MICRO-90 ®”, available from Cole-Parmer ® (www.coleparmer.com).

To prepare the test solution, mix 1 mL of “MICRO-90 ®” per 1 Liter of Distilled Water. If foaming becomes a problem, change the ratio to 0.5 mL of “MICRO-90 ®” per 1 Liter of Distilled Water.

The sheeting action of the test solution has a minor effect on test results. It is recommended to discard the results of the first test and only record data from the second test of the DUT.

Any droplets remaining in the chamber after a test run will affect the accuracy of the test results. Adjust the drain rate to minimize the droplets.

MANUAL REVISIONS

Revision #	Program #	Revisions Made
Rev 01	DT7312CA	Preliminary Manual
Rev 02	DT7312CA	Page Numbers Adjusted
Rev 03	DT7312CA	Accessories Updated
Rev 04	DT7312CD	Cautions, Notices, Misc. Edits
Rev 05	DT7312CD	Photos Updated, Specifications Updated, Misc. Edits
Rev 05	DT7312CD	Misc. Edits

LIMITED WARRANTY

WARRANTY: BC GROUP INTERNATIONAL, INC. WARRANTS ITS NEW PRODUCTS TO BE FREE FROM DEFECTS IN MATERIALS AND WORKMANSHIP UNDER THE SERVICE FOR WHICH THEY ARE INTENDED. THIS WARRANTY IS EFFECTIVE FOR TWELVE MONTHS FROM THE DATE OF SHIPMENT.

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SPECIFICATIONS

IPA-1000 BASE UNIT

FLOW	
RANGE	0.0 to 9999.9 mL/hr (Dependent on Chamber)
RESOLUTION	0.1 mL/hr
ACCURACY	± 1% Reading, ± 1 Digit
TIME RESOLUTION	0.01 Seconds
CONNECTIONS	8-pin Female Mini-DIN Receptacle

ELECTRICAL		
POWER	BATTERY	9V Alkaline Battery (ANSI/NEDA 1604A or equivalent)
	BATTERY ELIMINATOR	9 VDC, 200 mA  BC20-21100 (USA Version) BC20-21101 (Euro Version)
POWER CONSUMPTION	ON	8 mA (No Chambers) 12 mA (1 Chamber) 16 mA (2 Chambers)
	OFF	< 60 µA
BATTERY LIFE	CONTINUOUS	> 24 Hours
	OFF	12 Months

PHYSICAL & ENVIRONMENTAL		
DISPLAY	128 x 64 Graphical LCD, Non-Backlit	
MEMORY	SETUP	EEPROM, All Parameters
	RETENTION	10 Years w/o Power
CONSTRUCTION	ENCLOSURE	ABS Plastic
	FACE PLATE	Back-printed Lexan
SIZE	7.09 x 3.97 x 1.80 Inches (180.1 x 100.8 x 45.7 mm)	
WEIGHT	< 1 Lbs (0.45 kg)	
OPERATING RANGE	15 to 30 °C (59 to 86 °F) 10% to 80% RH, Non-Condensing	
STORAGE RANGE	-40 to 60 °C (-40 to 140 °F)	

MC3.5-1000 & MC35-1000 CHAMBERS

FLOW		
RANGE	3.5 mL Chamber	0 to 999.9 mL/hr
	35 mL Chamber	15.0 to 9999.9 mL/hr
MEDIA	Distilled Water	
MEDIA CONNECTION	Luer Lock Fitting	

ELECTRICAL	
POWER	Powered by IPA-1000 Unit
CONNECTIONS	8-pin Female Mini-DIN Receptacle Connects to IPA-1000 Base Unit using BC20-40607 Mini-DIN Straight-Thru Interconnect Cable

PHYSICAL & ENVIRONMENTAL		
CONSTRUCTION	ENCLOSURE	ABS Plastic
	FACE PLATE	Back-printed Lexan
SIZE	14.00 x 5.00 x 3.50 Inches (355.6 x 127.0 x 88.9 mm)	
WEIGHT	< 2.2 Lbs (1.00 kg)	
OPERATING RANGE	15 to 30 °C (59 to 86 °F) 10 to 80% RH, Non-Condensing	
STORAGE RANGE	-40 to 60 °C (-40 to 140 °F)	

NOTES

NOTES

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