

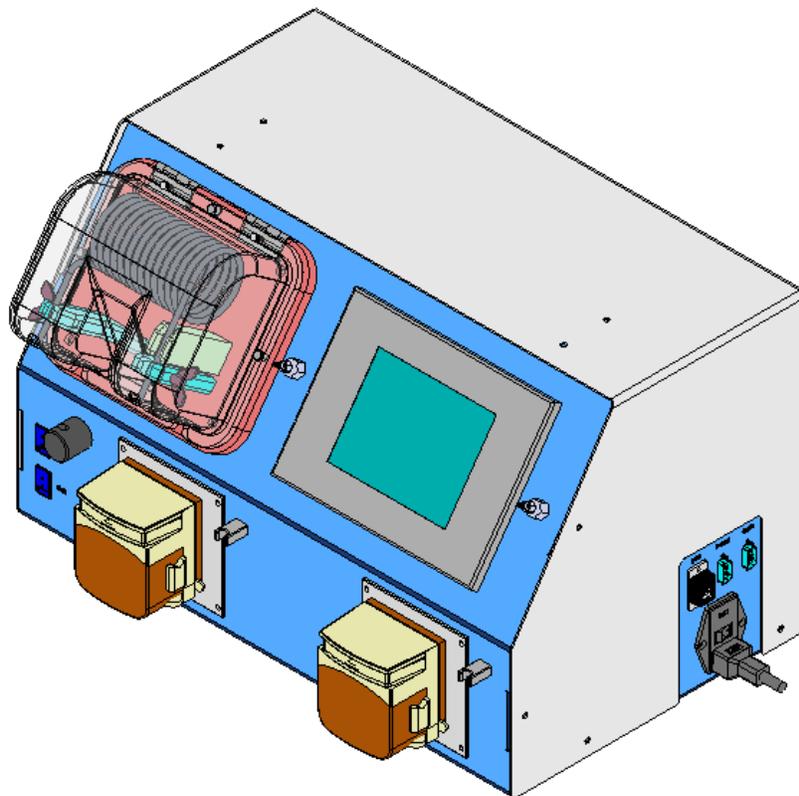
# PERFUSION APPARATUS

MODEL No: PER-5.2

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## USER MANUAL

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## 1 Getting Started



### 1.1 Symbols Used in this Manual



The lightning flash with arrowhead symbol, within an equilateral triangle, is intended to alert the user to the presence of dangerous voltage within the machine's enclosure that may be of sufficient magnitude to constitute a risk of electric shock.



The exclamation point within an equilateral triangle is intended to alert the user to the presence of important information in the literature that accompanies the device.



This symbol warns of moving parts may cause personal injury.



This symbol is used when two people are needed to do the task.

### 1.2 Machine Information

In the spaces provided below, record the Model and Serial No. located on the rear panel of this machine.

Model No. \_\_\_\_\_

Serial No. \_\_\_\_\_

**Retain this information for future reference.**

### 1.3 Contact Information

**Biorep Technologies, Inc.**

3225 NW 112<sup>th</sup> Street

Miami, FL 33167

info@biorep.com

[www.biorep.com](http://www.biorep.com)

Tel: 305-687-8074

Fax: 305-688-8029

## 1.4 Safety Information



PLEASE READ AND OBSERVE ALL WARNINGS AND INSTRUCTIONS GIVEN IN THIS USER'S MANUAL AND THOSE MARKED ON THE UNIT. RETAIN THIS BOOKLET FOR FUTURE REFERENCE.



DO NOT REMOVE THE MACHINE'S COVER OR YOU MAY BE EXPOSED TO DANGEROUS VOLTAGE. REFER SERVICING TO QUALIFIED PERSONNEL ONLY.



TO REDUCE THE RISK OF FIRE OR ELECTRIC SHOCK, DO NOT EXPOSE THIS DEVICE TO RAIN OR MOISTURE. DANGEROUS HIGH VOLTAGES ARE PRESENT INSIDE THE ENCLOSURE.



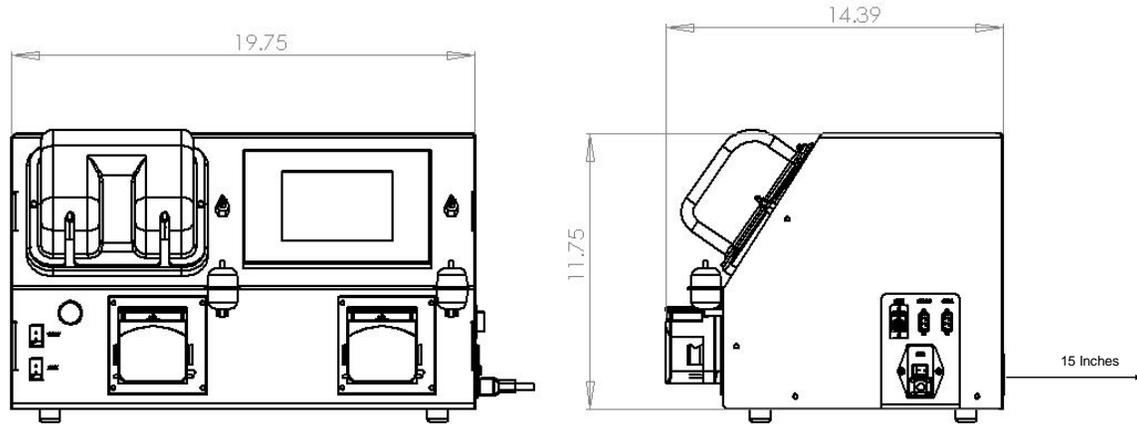
READ AND UNDERSTAND HOW MOVING PARTS ARE CONTROLLED BEFORE OPERATING THE MACHINE. KEEP YOUR FINGERS AWAY FROM MOVING PARTS; NEGLECTING TO DO MAY CAUSE PERSONAL INJURY.

### READ AND FOLLOW THESE INSTRUCTIONS:

1. Keep these instructions for future reference and heed all warnings stated in this manual.
2. Do not block any ventilation openings. Install the machine in accordance with the manufacturer's instructions. See Site Preparation in section 1.5 for details.
3. Do not defeat the safety purpose of the polarized or grounding-type plug. A polarized plug has two blades with one wider than the other. A grounding-type plug has two blades and a third grounding prong, which is provided for your safety. If the provided plug does not fit into your outlet, consult an electrician for replacement of the obsolete outlet or contact Biorep Technologies, Inc. at (305) 687-8074.
4. Protect the power cord and the plug from being damaged. Avoid walking on or pinching the cord or plugs.
5. Refer all servicing of the machine to qualified personnel. Servicing is required when the apparatus has been damaged in any way, for example: the power-supply cord or plug is damaged, liquid has been spilled or objects have fallen into the apparatus, or if the apparatus has been exposed to rain or moisture, has been dropped, or does not operate normally for any reason.

### 1.5 Site Preparation

This machine is intended to be used in a controlled laboratory environment. Please refer to the figure below for proper installation of the machine. The machine has one ventilation opening in the rear. A 15 inches clearance is recommended between the back of the machine and the wall.



**Figure 1: Dimensions of the Perfusion Apparatus 5**

### 1.6 Unpacking Instructions



Remove the top 2 pieces of blue foam and the items that are located on top of the machine. Then, carefully remove the foam that surrounds the machine. It is suggested that the machine be removed from the box by two people, one on each side. To lift the Perfusion Apparatus, place your hands underneath the machine and remember to bend at the knee. Please, keep the box and all the foam pieces in storage, in case the machine needs to be shipped in the future.

### 1.7 Packing List

The following items are included with the purchase of a Perfusion Apparatus:

Qty	Reference	Description
1	PER-05-115	Perfusion Apparatus
1	PER05-TUBHC-01	Disposable Perfusion Tubing Set with Coil (Sterile)
1	PERTRAY-MABS-01	Disposable Perfusion Tray (Sterile)
1	TC-02	Biorep Thermoprobe
1	86610610	Medical-Rated Power Cord
1	PER05-UM	User Manual
1	PER05-DAQ	CD with Software & User Manuals

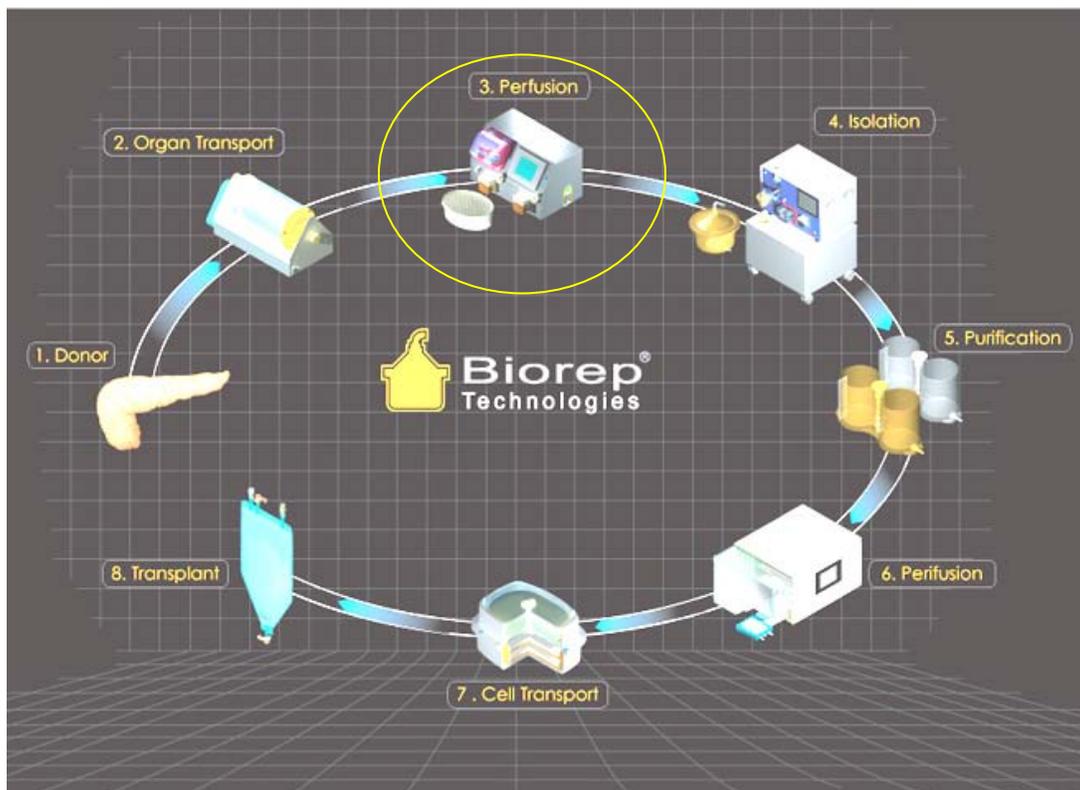
## 2 Introduction

This manual is intended to be used by doctors, researchers, and technicians who have already been trained in islet isolation procedures and technologies. This document contains the necessary information for unpacking, installing, and operating the machine.

The Perfusion Apparatus has been developed to assist in and allow automation of the pancreas perfusion step of the islet isolation process. The machine accurately regulates flow, pressure, and temperature in two separate perfusion loops. In addition, the machine has the ability to store a time-lapse record of every parameter during the procedure. The Perfusion Apparatus enables the researcher not only to analyze each perfusion, but to refine the procedure into a repeatable and efficient protocol by creating custom recipes for the machine to execute automatically.

The apparatus consists of two pumps, two pressure sensors, one heater, and one touch screen. This apparatus is used in conjunction with the Biorep Perfusion Tray (PERTRAY-MABS-01), the Biorep Thermoprobe (TC-02), and the disposable perfusion tubing set (PER05-TUBHC-01). One of each is included with your new Perfusion system, and replacements are sold separately.

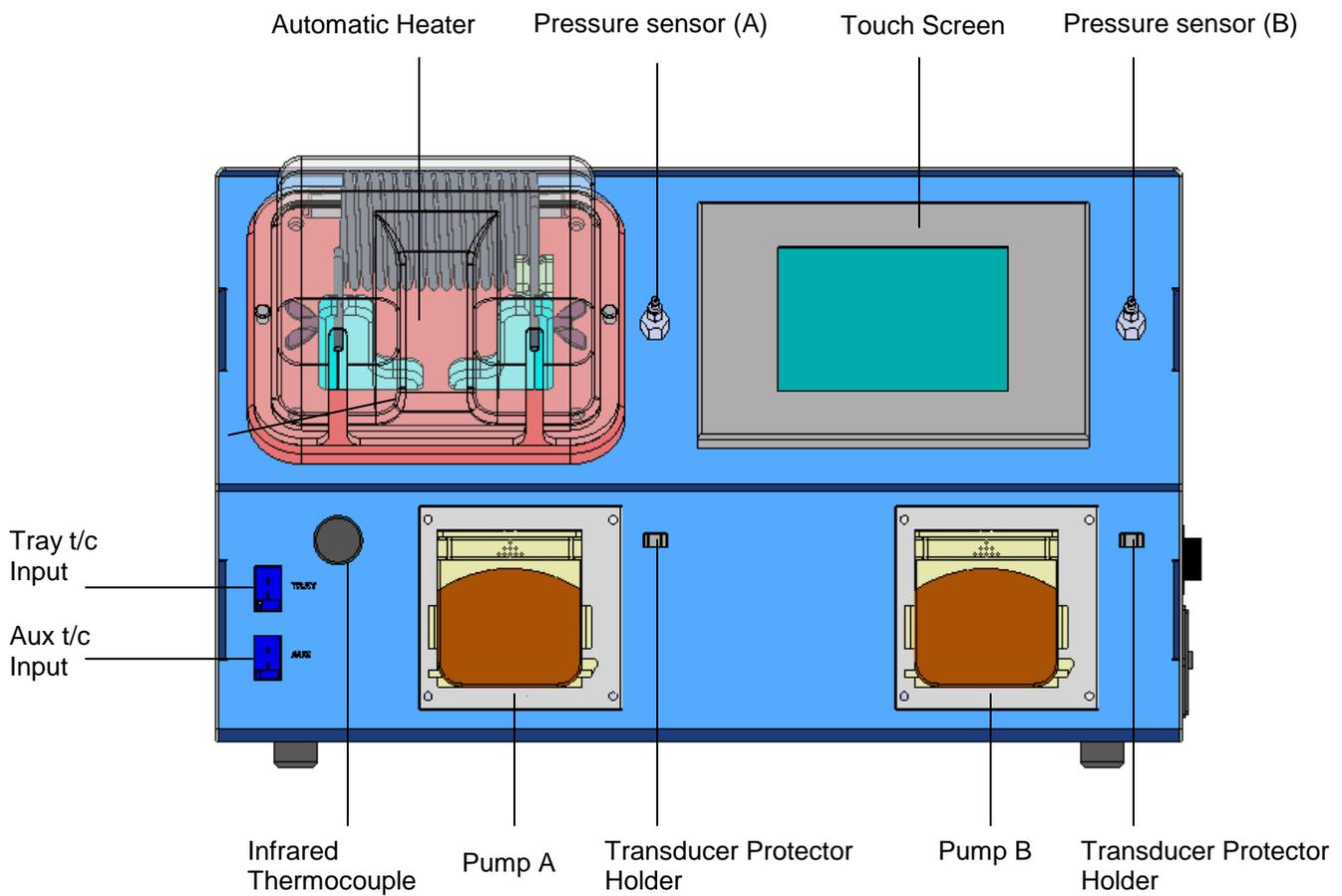
The Perfusion Apparatus is used to automatically distend the organ by pumping fluid at a constant regulated pressure. The machine automatically adjusts the flow rate to maintain a constant pressure, therefore minimizing the risk of tissue damage.



**Figure 2: Perfusion Machine in the Islet Isolation Process**

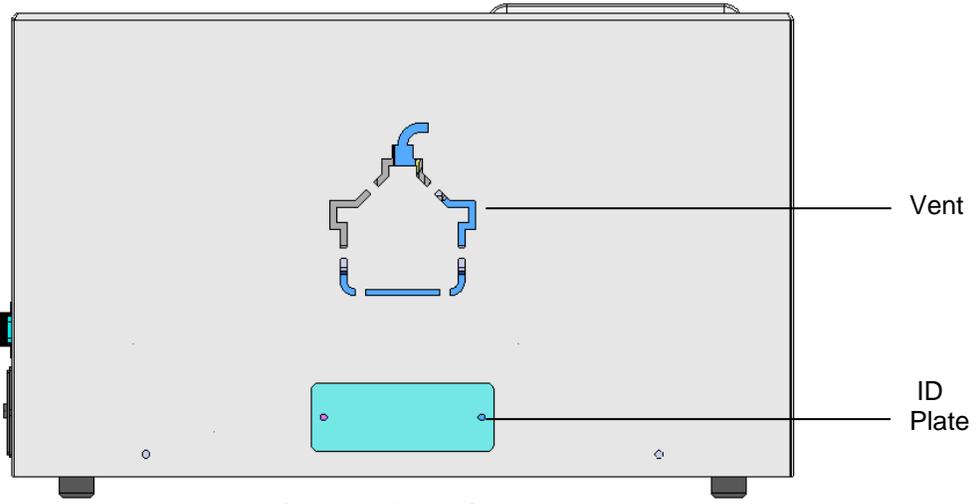
### 3 Machine Parts Identification

#### 3.1 Front View



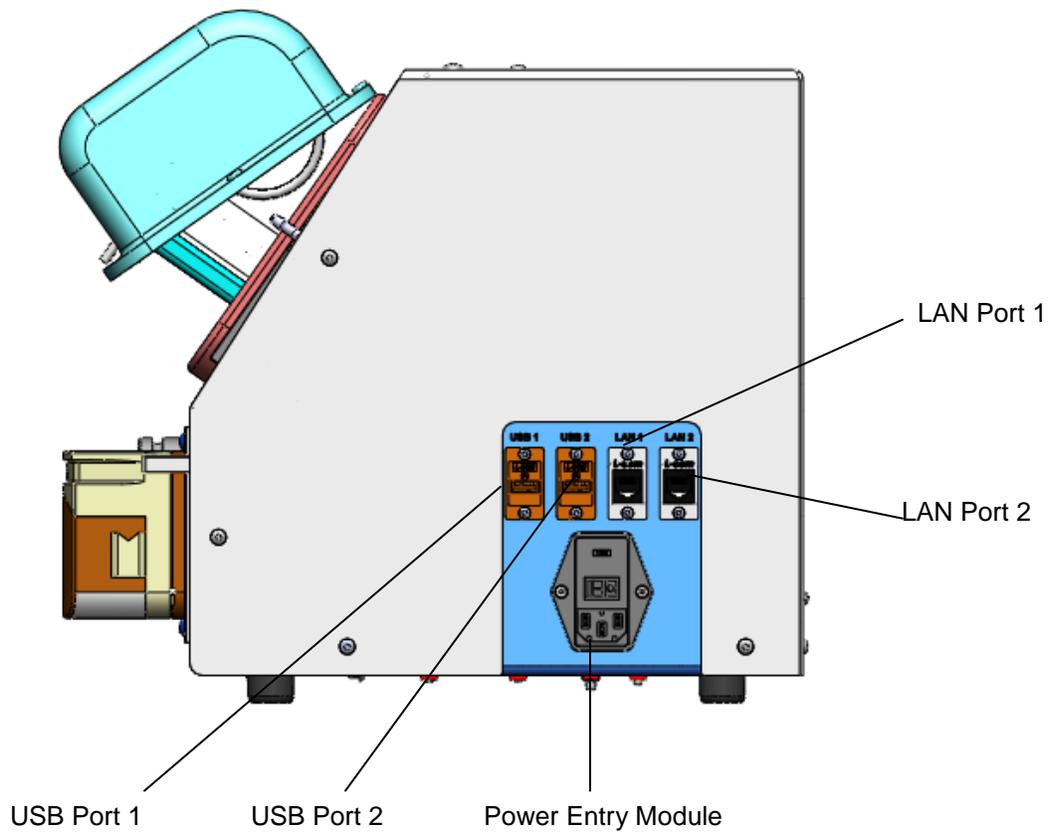
**Figure 3: Front View**

**3.2 Rear View**



**Figure 4: Rear View**

**3.3 Right View**



**Figure 5: Right Side View**

## 4 Accessories

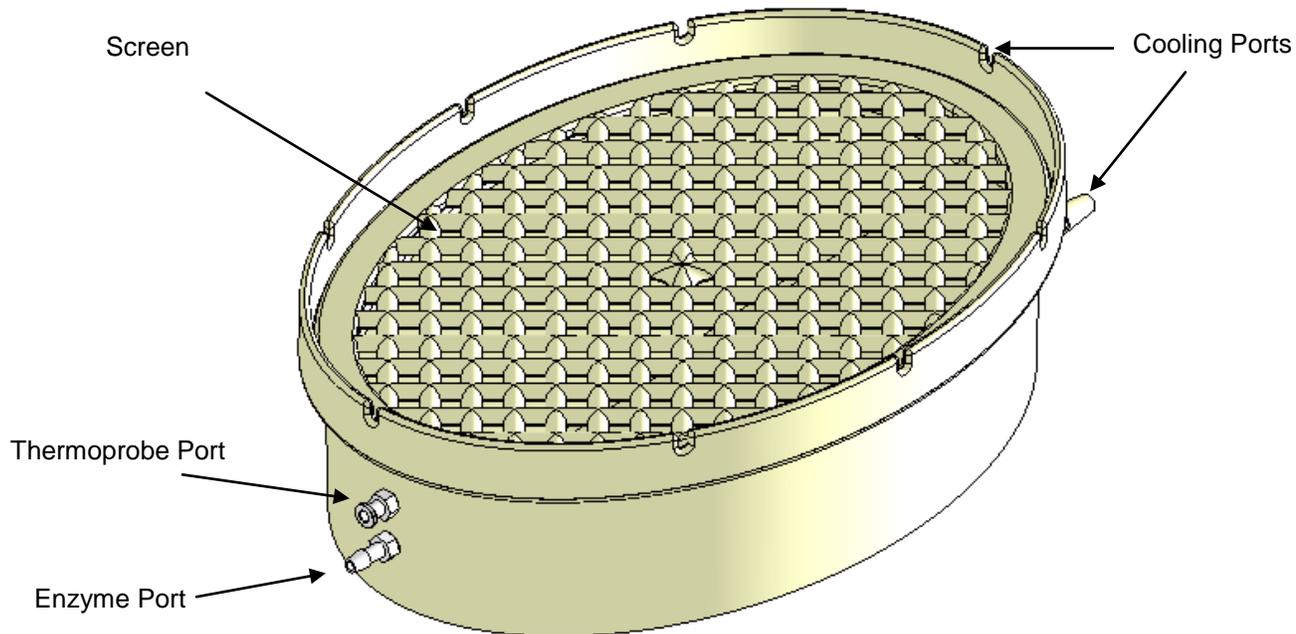
The following disposable accessories are included with the Perfusion Apparatus. For ordering information, please consult our webpage [www.biorep.com](http://www.biorep.com) or contact one of our sales representatives at (305) 687-8074.

### 4.1 Perfusion Tray (PERTRAY-MABS-01)

The **Perfusion tray** has a removable mesh. Below the mesh, the tray has a funnel shape to direct all the fluid to the **Enzyme Port**. The **Thermoprobe Port**, is used to attach a Biorep Thermoprobe to monitor the enzyme temperature. The two horizontal ports on the opposite side are available to re-circulate cold water or a suitable coolant to cool the enzyme if desired.

The Perfusion Tray is available in disposable and autoclavable versions. The included disposable plastic tray is made from ABS plastic, and it is intended to be a single use disposable device. Note that use of alcohol based coolants may promote crack formation on the ABS. The autoclavable perfusion tray is made of stainless steel.

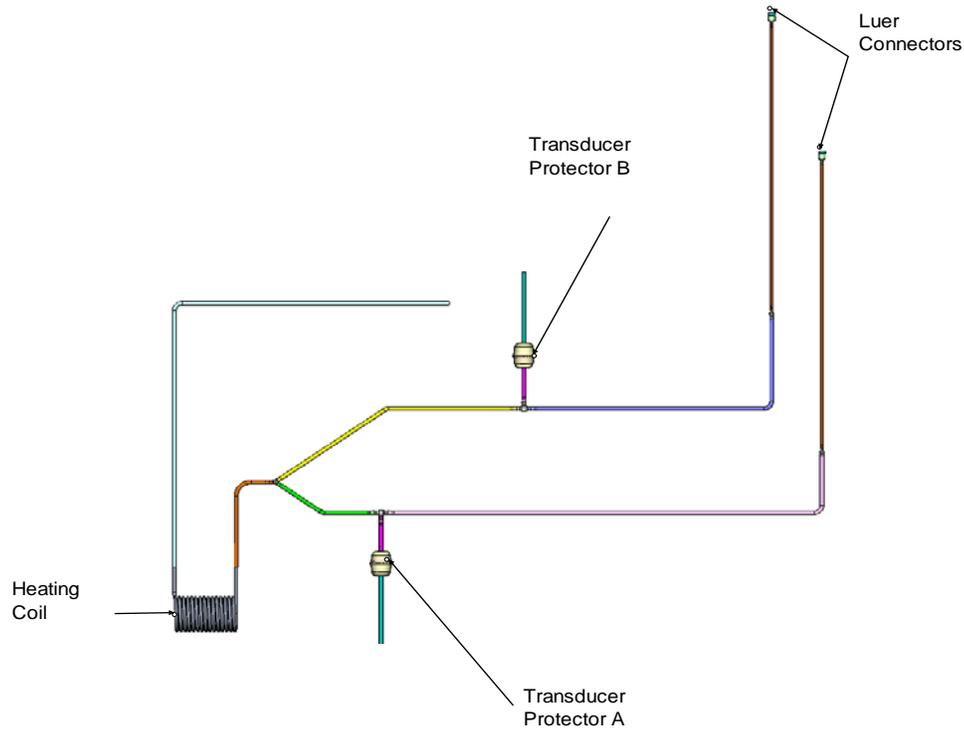
To lower the enzyme temperature, connect 0.25" ID (6.3mm) tubing to the cooling ports and re-circulate cold water. Do not restrict flow on the coolant output port as this may cause damage to the tray.



**Figure 6: Disposable Perfusion Tray**

#### 4.2 Disposable Tubing Set with Coil (PER05-TUBHC-01)

For information about how install the tubing set please refer to Section 5.1.



**Figure 7: Perfusion Apparatus Tubing Set (PER05-TUBHC-01)**

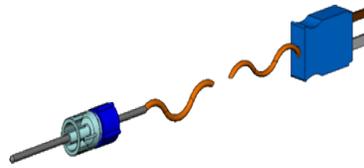


**Important:** If silicone tubing remains inside a closed peristaltic pump head for extended periods, there may be permanent tubing profile deformation.

#### 4.3 Biorep Thermoprobe (TC-02)

The Biorep Thermoprobe is a sterile, disposable type-T Thermocouple. It has a universal mini-plug connector that measures temperature at the site of any female Luer connection.

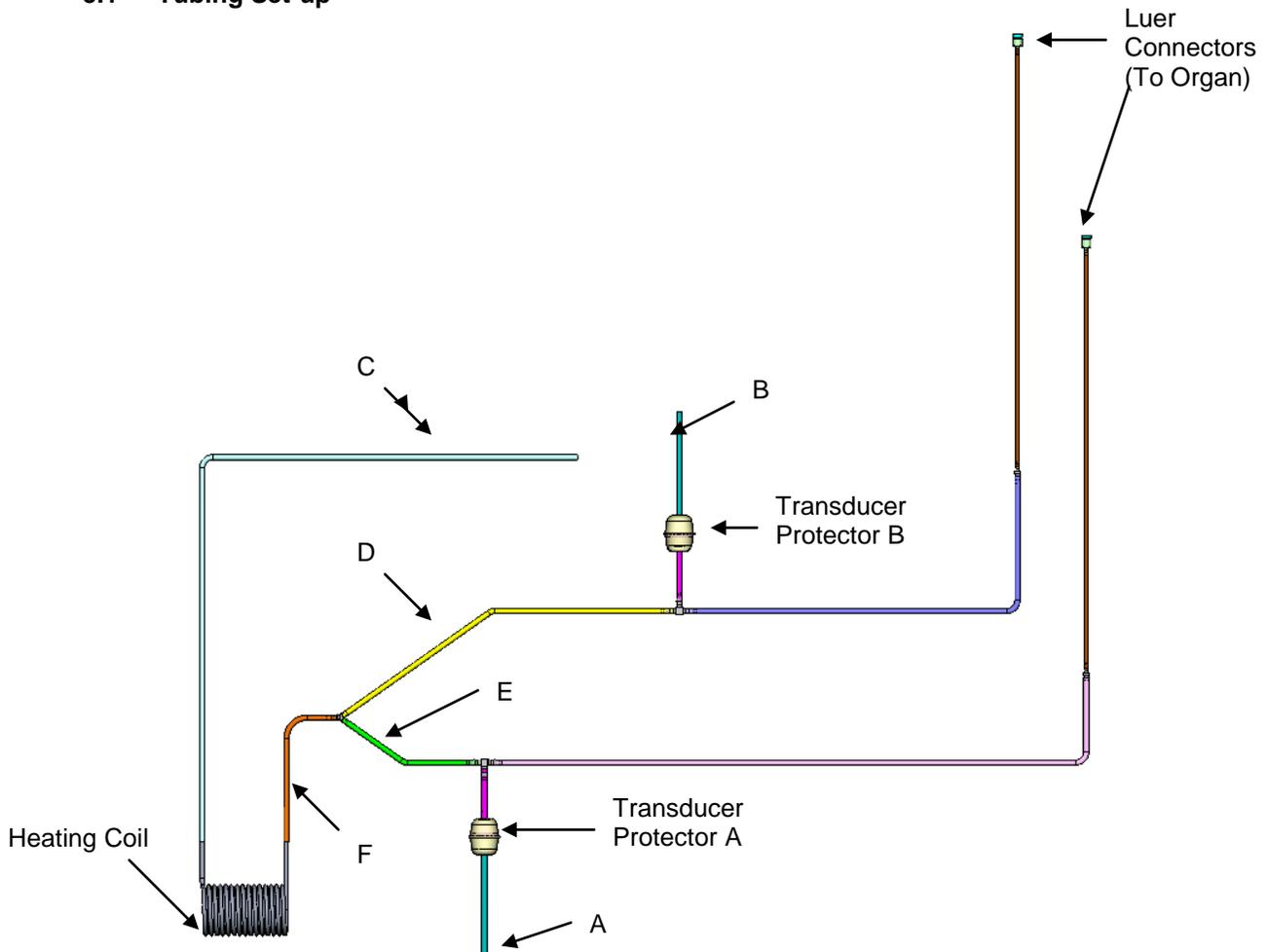
***Directions:*** Connect the Thermoprobe to the Perfusion Tray Thermocouple Port (see Figure 6) and use it to measure the collected perfusion fluid temperature inside the perfusion tray.



**Figure 8: Biorep Thermoprobe**

## 5 Perfusion Machine Set-up

### 5.1 Tubing Set-up



**Figure 9: Tubing Set Installation**

#### Tubing Set-up Directions (also see photograph on the following page):

- 1) Place the heating coil inside the automatic heater. Make sure there is good contact between the stainless steel coil and the aluminum arms. Also, make sure there is good contact between the coil and the spring loaded thermocouple. See Heater Set-up (5.2).
- 2) Connect tube "C" to the **Enzyme port** on the perfusion tray.

- 3) Place tube sections “D” and “E” in the appropriate peristaltic pump. Make sure the tubing is not being pinched on the inlet or outlet.
- 4) Connect Tubes “A” and “B” to the appropriate pressure sensor fittings.
- 5) Secure both “Transducer Protector A” and “Transducer Protector B” to their respective holders.
- 6) Use both Luer connections for the catheters that go to the pancreas.

### **Tubing Set and Tray Installation**



**Figure 10: Tubing Set and Tray Illustration**

## 5.2 Heater Set-up

A heating element is a coiled stainless steel tube. It has a large heating surface area to provide precise and non-localized heat to the fluid that circulates through it. The temperature of the fluid is constantly being monitored and controlled by the Infrared Thermocouple immediately after the heater's outlet. Follow the instructions below and see the figure below to properly connect the Heating Element.

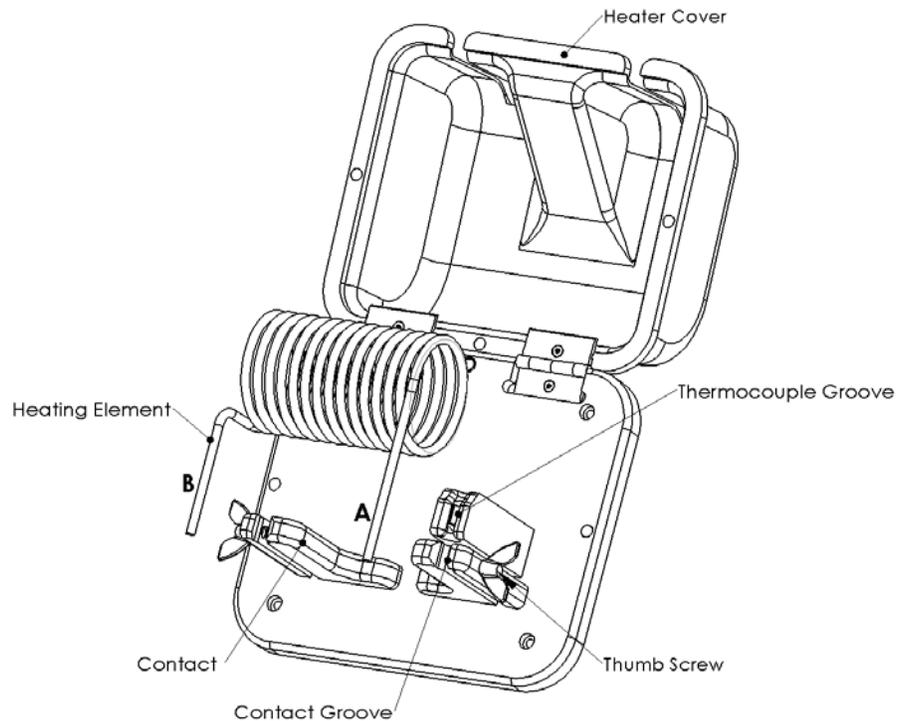
Loosen the thumbscrews to open the clamps enough to fit the heating element's ends into the contact grooves.

The heating element terminations (A and B) are different. Identify each one by their shape. Be sure that end **B** of the heating element is inserted into the contact groove on the left, and that end **A** fits completely into the thermocouple groove on the right. Then, tighten the thumbscrews.

Close the heater cover carefully. The heating element must not touch the heater cover. If the coil touches the cover, loosen the thumbscrews and adjust the heating element as necessary.



If the heating coil is not properly connected, and the heater is ENABLED, an audible alarm will sound. The error message "Check Heating Coil Connections" will appear. Verify all steps above.



**Figure 11: Heater Set-up**



**IMPORTANT: At least one peristaltic pump has to be ON (flow rate > 15ml/min), AND the heater cover needs to be closed for the heater to operate.**

## 6 Perfusion Apparatus Operation

The main operation of the Perfusion Apparatus is done through the touch-screen interface. This type of interface eliminates the need for an external keyboard or mouse device and provides a visual and intuitive interaction with the user. The operator should familiarize himself/herself with the different screens, features, and controls of the interface before attempting to operate the machine during an actual isolation.



Anyone who will operate and/or supervise the use of this machine should read and understand this section in its entirety.



This machine has been designed with alarm features that will help the user identify and correct potential problems. Alarm messages will be displayed at the bottom of the screen.



**Close the protective covers of the peristaltic pumps while working. The moving rollers that are beneath the covers can cause injuries.**

**ICON/BUTTON CONVENTIONS.** The touch-screen interface of this machine has virtual buttons, represented by icons, to activate and deactivate the different features of the machine. Care was taken at the time of designing these icons, so that there is minimal ambiguity between on and off states (active and inactive). However, to avoid confusion please read this section of the manual carefully. Every button icon has two display states: a “gray-scale” state and a “colored” state. When the button icon is “gray-scale” it represents an inactive or “OFF” condition. When the icon is colored, it represents an active or “ON” condition. If a “gray-scale” icon is pressed, the icon will change to “colored” icon and the controlled feature will turn on. If a colored icon is pressed, the controlled element will turn off and the icon will be grayed out.

### 6.1 Power-Up

The machine’s main power switch is located in the right side of the machine, above the power entry module. Connect the power cord to the power entry module and then plug it into a 115 or 230 VAC outlet (check voltage rating on red window).

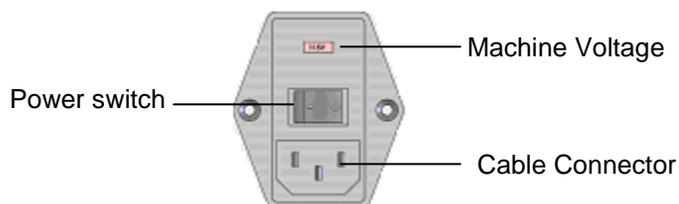


Figure 12: Power Entry Module  
**Power Entry Module**

## 6.2 Power-up Page



This will be the first page that appears after the system has completed the boot-up process. In this page you will be prompted to touch anywhere to begin. Do not touch the screen or enter any commands via keyboard or mouse until you see this screen.

## 6.3 Login Page



The Login Page allows you to Log into your password protected user account. The user account saves the preferences of your experiments, and saves time by pre-filling some frequently used fields during the experiment process and during reporting.

The first step is creating a user account. To create a new user account, press the **Add User** Button.

### 6.3.1 Add Users



When the “Add User” button is pressed, the “New User Account” fields on the right of the screen will be enabled. Upon clicking on any field a pop-up keyboard will appear. Enter a unique username and password using the keyboard and press “Accept”. Click Save to create the user.

### Login Page



Now you will be able to find your User name on the drop down list at the top left. The next time you do a perfusion experiment, just select your user from the list, enter your password and press “Login”.

## 6.4 Main Menu

### Main Menu



Once logged in, you will arrive at the Main Menu page. On this page you can select the operation mode of the machine.

“**Manual Mode**” will take you to a control panel interface where you can manually manipulate the machine parameters during an experiment session. These sessions can be recorded for later analysis, reporting or playback in the “**Data Viewer**” mode. You can think of Manual Mode as the experiment “composer”, and the data viewer as the experiment “player/editor”.

On the Data Viewer mode, you can monitor the various parameters of a perfusion session, and re-create or edit previous sessions step-by-step.

In this page you will also see the User account, the Software Version installed in your perfusion machine, and the machine **Status Bar** at the bottom. The Status Bar will display any alarms or important messages related to the function of the machine.

You can also end the session from this page either by logging out of your user account or by turning the system off. PLEASE DO NOT TURN THE MACHINE OFF FROM THE POWER ENTRY MODULE BEFORE BEING PROMPTED TO DO SO.

## 6.5 Manual Mode

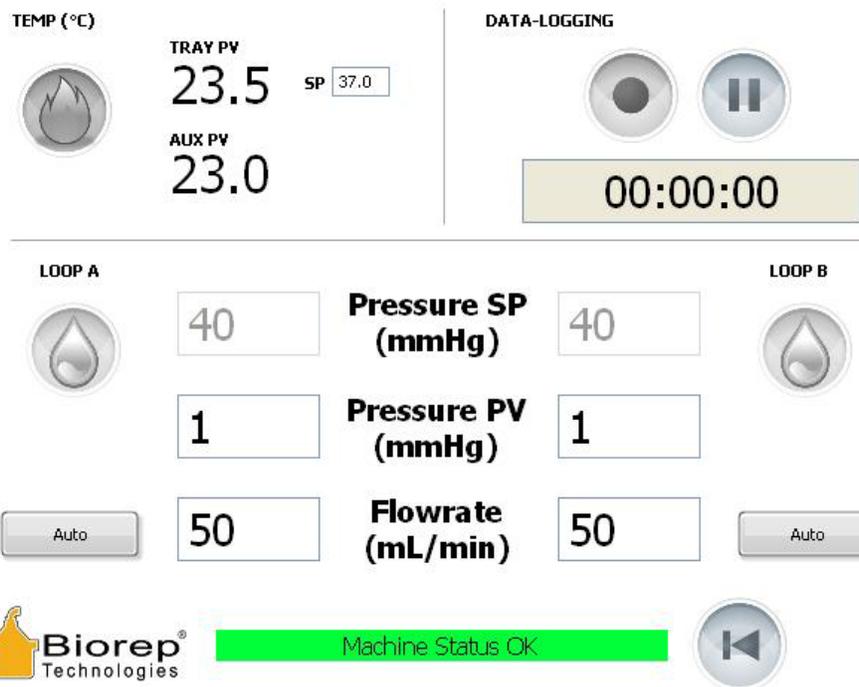
### 6.5.1 Experiment Data



Selecting manual mode will take you to the screen below, where you will be required to fill out a form type page with all the relevant data of the donor, the organ and the Operator. Most of the fields include drop-down menus for quick selection. The drop down list can be edited to include any other options not in the default list.

Once the data is filled, you can continue to the Control Panel by clicking the NEXT arrow on the bottom right.

## 6.5.2 Control Panel



**TEMP (°C)**

TRAY PV 23.5 SP 37.0

AUX PV 23.0

**DATA-LOGGING**

00:00:00

**LOOP A**

40 Pressure SP (mmHg) 40

1 Pressure PV (mmHg) 1

Auto 50 Flowrate (mL/min) 50 Auto

**LOOP B**

40 Pressure SP (mmHg) 40

1 Pressure PV (mmHg) 1

Auto 50 Flowrate (mL/min) 50 Auto

**Biorep**<sup>®</sup> Technologies Machine Status OK

All the controls required to operate the machine during a Manual Mode experiment are located in this single interface. In this control panel you will be able to change the Temperature parameters, the Flow/Pressure parameters and control the recording of your experiment for use in the Data Viewer mode. For reference, the term “**indicator**” will be used for fields that are “read-only”. This means that they are not editable, and only provide measurement data or other information to the user. A “**control**” is the term used for a field that is editable by clicking. These are usually variables set by the user to control the machine.

### 6.5.2.1 Temperature Control



**TEMP (°C)**

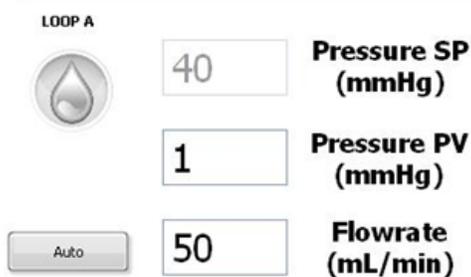
TRAY PV 23.5 SP 37.0

AUX PV 23.0

The temperature control section of the control panel has the following functionality: The icon on the left is the Heater **ON/OFF** button. The **TRAY PV** is an indicator of the temperature “**Present Value**” measured by the perfusion tray thermoprobe. The **AUX PV** is also an indicator of temperature measured by the auxiliary thermoprobe. The **SP** stands for “**Set Point**”. The **SP** is a control of the target temperature you want your system to reach and maintain. When the heater is turned **ON**, the heater will gradually heat the fluid up to the **SP** you specify. You will get constantly refreshing temperature readings from both **TRAY** and **AUX PV** indicators.



### 6.5.2.2 Flow control



There are two independent flow loops labeled LOOP A and LOOP B. Both loops operate the same way, so we will describe the controls in LOOP A only.

The “drop” icon on the top left is the ON/OFF button for the peristaltic pump.

The AUTO button on the bottom left toggles the pump operation between two modes: Flow and Pressure control.

The default mode (**Auto OFF**) is a “Flow” control mode, in which the user determines the exact flow delivered by the pump in mL/min. The user sets the desired flow rate by clicking on the **Flowrate** control field. The pump will maintain that flow regardless of the pressure (within safety limits); the pressure will be displayed on the **Pressure PV** indicator. **Pressure SP** is disabled.

When the **Auto** mode is activated, the pump will enter a “Pressure” control mode, in which the user determines the pressure to be maintained in the system in mmHg. The user sets the desired pressure by clicking on the **Pressure SP** field. The machine will automatically regulate flow to reach and maintain the specified pressure in the loop. The loop pressure is constantly measured and displayed by the **Pressure PV** indicator. In Auto mode the **Flowrate** field on the bottom becomes an indicator of the current flow rate and can't be edited.

### 6.5.2.3 Data-Logging



The Data logging section records your perfusion experiment for later analysis, reproduction or edition in the Data Viewer mode.

Press the Record button at any point during your experiment to start logging all the parameters and their changes over time. You can use the Pause button to suspend the data-logging in case you want to make a change or two “off-the-record”.

When you want to stop logging, just depress the Record button. The session will be added to the end of the Reports list in the Data-Viewer section.

### 6.5.2.4 Taskbar



The taskbar at the bottom of the screen has the following functions: On the left, the Biorep Logo is a shortcut to the Main Menu screen. On the right, there will be navigation arrows that will take you to the next or previous screens when applicable. The most important feature is the **Status Bar** on the center, which provides the user with visual feedback on any errors or important messages from the system. A more detailed discussion on errors is found in section 7.

## 6.6 Data-Viewer Mode

### Data Viewer

Experiment 2/8/2012 2:03 PM

Reports | Report Info | Temperature | Loop A | Loop B | Deleted Reports

Operator: All [v] [Playback] [Export Data] [Delete]

Date/Time	Donor Unos #	Organ ID	Operator
11/4/2011 4:05 PM			Biorep
11/4/2011 4:29 PM			Biorep
11/7/2011 11:04 AM			Biorep
11/7/2011 11:06 AM			Biorep
11/7/2011 11:08 AM			Biorep
11/9/2011 7:32 AM			Biorep
12/29/2011 1:51 PM			Biorep
2/8/2012 2:03 PM	2459	568	John Smith



Machine Status OK



The Data Viewer screen is where all recorded experiments can be analyzed, replayed or deleted. Each experiment recording is called a Report. A list of all reports can be found in the first tab of the Data-Viewer page. They are listed in chronological order, so the last experiment will be found last on the list. Click on an experiment to select it. All data displayed on the following tabs will relate to the selected experiment.

#### Data Viewer

Experiment 2/8/2012 2:03 PM

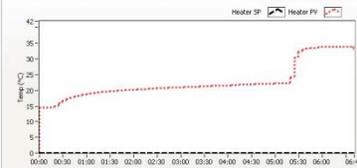
Reports | Report Info | Temperature | Loop A | Loop B | Deleted Reports

Data Type	Property name	Property value
Operator Data	User Account	John Smith
	Date	2/8/2012
	Time	1:53 PM
Donor Data	Enzyme ID	9076
	Experiment Type	Research
	Donor Unos #	2459
	Height	1.9
	Age	23.0
	ABO/Rh	O-
	Cause of Death	na
Species	Human	
Notes	no notes	

#### Data Viewer

Experiment 2/8/2012 2:03 PM

Reports | Report Info | Temperature | Loop A | Loop B | Deleted Reports



#### Data Viewer

Experiment 2/8/2012 2:03 PM

Reports | Report Info | Temperature | Loop A | Loop B | Deleted Reports



You can export all experiments of a particular user to an external device by selecting your user account from the **Operator** drop down and selecting **Export Data**. A windows explorer pop-up will appear. Navigate to the folder you want to save the data to and click on "Current Folder". The file will be saved with the name: **ManualReports.tdms**. This file can then be opened in your personal PC with the supplied report reader application.



You can delete a report from the list by highlighting it and clicking on **Delete**. All deleted reports can be found on the last tab “Deleted Reports” and can be recovered from there.

The most valuable feature of the Data-Viewer is the ability to replay an experiment. To do this, select the experiment you wish to replay and click on Playback.

### 6.6.1 Experiment Playback

**Playback Mode**



00:01:06

HEATER TEMP (°C)    PRESSURE A (mmHg)    PRESSURE B (mmHg)

22.0    66    1
Manual Mode Override

Time Stamp	Heater SP	Pump A Flowrate SP	Pump A Pressure SP	Pump B Flowrate SP	Pump B Flowrate SP
00:03	0.0	50.0	0.0	0.0	0.0
00:26	0.0	100.0	0.0	0.0	0.0
00:40	0.0	150.0	0.0	0.0	0.0
01:00	0.0	0.0	25.0	0.0	0.0
01:18	0.0	0.0	50.0	0.0	0.0
01:47	0.0	0.0	50.0	50.0	0.0
01:55	0.0	0.0	50.0	200.0	0.0
02:51	0.0	0.0	50.0	150.0	0.0
02:57	0.0	0.0	100.0	150.0	0.0



00:00    00:30    01:00    01:30    02:00    02:30    03:00    03:30    04:00    04:30    05:00    05:30    06:00    06:40

Time (minutes:seconds)


Machine Status OK


Playback mode will provide you with an interface in which you can replay a previously recorded experiment; you can also make modifications on-the-fly if required. All the steps of the experiment are listed in a tabular manner. The beginning of a step is defined as the moment where the user changes any variable of the experiment. The end of a step is when the next change occurs, which also marks the beginning of the next step and so on. The time completion bar at the bottom shows you the experiment elapsed time in relation to the total time of the experiment.

To begin replaying the selected experiment press the **Play** icon on the top. The experiment will start and continue through the steps as recorded. To pause and un-pause the experiment press the Play button.

If you need to perform an on-the-fly modification of any of the parameters, click the **Manual Mode Override** button. This will bring you to the manual Control Panel (see Section 6.5.2). In here you can make all necessary adjustments. When ready to resume your experiment, press the **Back** button and you will return to the Playback Screen. Once in the playback screen, press the **Play** button to resume where you left off.

The **Restart** button is the circular arrow button to the right of the Play button. Pressing it will reset the experiment from the beginning.

To return to the Playback main screen press the Back button.

## 7 Troubleshooting

### 7.1 Safety Alarms

Audible safety alarms are in place for your prompt response to a safety hazard, or an irregular condition of the machine that can affect the experiment outcome. The machine will generate an audible alert and/or a notification in the status bar for the following situations:

#### 7.1.1 Temperature Alarms

1. **Tray temperature too high.** This is abnormal condition, which can be found if the machine is not controlling temperature properly. This may happen if the tubing is not properly attached to the infrared tubing. If this is not the cause of the problem, a faulty controller may be the cause and you should contact customer service.
2. **Infrared sensor temperature too high.** This is an abnormal condition that may occur if the tubing is inserted in the IR sensor after it has been improperly inserted. The heater will be automatically deactivated until the temperature normalizes. If the problem persists, contact customer service.
3. **Heating coil temperature too high.** This may happen if flow is obstructed at any point in the system, leading to a lack of flow in the heater. Check for obstructions in the system and re-establish normal flow, for the heat exchange to occur.

#### 7.1.2 Hazardous conditions

1. **Heater cover open:** Machine will disable the heater if it doesn't detect a closed cover. To prevent exposure of hot surfaces, make sure to close the cover properly before activating the heater
2. **Heater enabled – Pump off (no flow).** This alarm is triggered when the heater is on, but there is no flow. The machine will disable the heater to prevent an unsafe overheating condition. Turn the pump on before activating the heater.
3. **Check infrared sensor.** This alarm appears when the machine detects an unusual pattern of temperature change in the IR sensor. Most of the time it indicates that the tubing is not properly inserted in the sensor.

#### 7.1.3 Malfunctioning hardware

1. **Tray temperature sensor error.** Check that Biorep Thermoprobe connected to the tray is properly inserted in the Tray t/c input (See Figure 3).
2. **Infrared temperature sensor error.** This may be caused by a loose sensor in the interior of the machine. Please contact customer service for instructions.
3. **Heating coil temperature sensor error.** This may be caused by a loose sensor in the interior of the machine. Please contact customer service for instructions
4. **Check heating coil connections.** This alarm occurs when the heater does not perform as expected. Check that the heater is in good contact with the electrode arms and that it they are screwed properly.

**If problems persist or you encounter any other problems or have additional questions regarding the operation of the perfusion apparatus, please contact customer support at:**

**Biorep Technologies, Inc. [info@biorep.com](mailto:info@biorep.com); Tel: 305-687-8074**