

Floor-Standing Platelet Incubator Model FS100, FS100-2 Operating Instructions

Model Number _.	
Serial Number	

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1. Safety

The following symbols marked on the equipment mean:



Caution: Please read and understand all necessary installation and operating instructions prior to operating the system.

Always observe the following safety precautions:



- Use only as specified by the operating instructions or the intrinsic protection may be impaired.
 - 1. WARNING: Do not modify the system or its components. Any alterations or modifications to the Platelet Incubator may be dangerous and will void the warranty.
 - 2. WARNING: Do not attempt to modify the system's firmware or attempt to install 3rd party firmware. Only use firmware provided by Boekel Scientific. Any alterations or modifications to the firmware may be dangerous and will void the warranty.



- WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Connect only to a power supply with a voltage corresponding to that on the serial number label.



- Connect only to a power supply that provides a safety ground terminal.
- After transport or storage in humid conditions, dry out the unit before connecting it to the supply voltage. During drying out, the intrinsic protection may be impaired.



- Disconnect power before servicing, moving, or cleaning.
 - 1. Remove all bags of platelets before attempting to move, service, or clean the system.
 - 2. Do not position system where it is difficult to reach the power inlet or power switch.
 - 3. Do not block or restrict ventilation slots. Allow at least 3" clearance around the entire unit.



- Do not reach into the incubator until the agitation has completely stopped.
- It is the user's responsibility to carry out appropriate decontamination per their SOP if platelets or other hazardous material is spilled on or inside the equipment. Refer to Section 7.1 for a general guideline on how to proceed with decontamination.
- Before using any cleaning or decontamination method, users should verify that the method of cleaning will not damage the unit.
- If liquid is spilled inside the unit, disconnect it from the power supply and follow your SOP for cleaning spilled platelets.
- Do not use with flammable, corrosive, or hazardous material.
- If the temperature displayed is more than 2°C off from a calibrated independent thermometer, the unit requires service and should not be used.
- Electromagnetic interference could affect the operation of the system if it is used in the vicinity of devices that have not been evaluated to the relevant EMC standard/s.

1.1. EMF Interference

This system may cause interference to radio and television reception or to equipment sensitive to electromagnetic fields. When installed properly, the system has been designed to minimize this effect. However, there is no guarantee that electromagnetic interference will not be caused by the system.

If the system does cause interference to radio, television, or other equipment, which can be determined by turning the instrument off and on, the user may attempt to correct the interference by one or more of the following measures:

- Increase the distance between the system and the radio/TV receiver.
- Connect the system to an outlet on an electrical circuit different from that which the radio/TV receiver is connected.

If this system is used near an intense electromagnetic source, interference noise may cause an adverse effect on the system performance or functionality.

The system is designed to minimize possible interference from external electromagnetic fields; however, there is no guarantee that external electromagnetic fields will not have an effect on this instrument.

If the system does incur electromagnetic interference, which can be determined by turning on and off possible source(s) of electromagnetic interference nearby, the user may attempt to correct the interference by one or more of the following measures:

- Reorient the instrument.
- Increase separation between the instrument and possible source(s) of electromagnetic interference.
- Connect the instrument to an outlet on a different electrical circuit from the possible source(s) of electromagnetic interference.
- Check that any other device connected to the system is not affected by electromagnetic interference.

1.2 Default Passcode

To change advanced settings of the incubator, a passcode is required. The passcode can be changed via the setup menu.

The default passcode is: 1234

2. Product Information

2.1 Introduction

The Boekel Scientific Platelet Incubator offers bidirectional controlled temperature and the continuous agitation necessary to properly store platelets to maintain product quality. The system uses thermoelectric devices to maintain temperature; there is no refrigerant or compressor. The easy-to-program, color, touchscreen interface allows for printing of temperature and event logs to an inkless thermal printer, viewing of the temperature and data log, alarms to protect the integrity of the product and the unit, network communications for remote monitoring, and a patented inventory management system.

2.2 Indications for Use of the Boekel Platelet Incubator

The Boekel Scientific Platelet Incubator is intended for use in hospitals, blood banks and laboratories where it is required to store Pooled Platelets and Apheresis Platelets for future infusion into a patient. This device is not intended for the storage of, but not limited to, Red Blood Cells, Whole Blood, Hematopoietic Progenitor Cells, Umbilical Cord Blood, Fresh Frozen Plasma, Cryoprecipitate AHF or Plasma Frozen Within 24 Hours after Phlebotomy.

3. Assembly

3.1 Unpacking

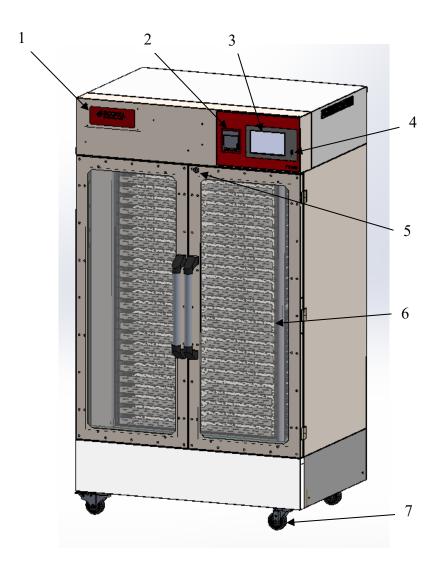
- Remove packing materials carefully and retain for future shipment or storage of the unit.
- Inspect for damage. Report all shipping damage to the carrier immediately. Shipping damage is covered by the carrier and repair/replacement for shipping damages must be coordinated through the carrier.
- Complete and return the Warranty Registration Card or scan the QR code and submit the Information Online
- Package contents:
 - (1) Boekel Scientific Floor-Standing Platelet Incubator
 - (1) Power Cord
 - (1) Operating instructions
 - (2) Rolls of Thermal Printer Paper (one roll installed in printer, one roll extra)
 - (2) Door Keys

3.2 Installation

- Place the Platelet Incubator on a flat and stable surface, making certain the sides and back have at least 3 inches of clearance for proper airflow.
- 2. Once the equipment is in position, the two front casters must be locked prior to powering on.
- 3. Do not move the equipment while fully loaded. To reposition the equipment, remove all bags of platelets from the shelves, then unlock the casters. Once repositioned, ensure the front casters are again locked prior to powering on.
- 4. Fit the power line cord into the IEC power socket on the back of the unit and plug the power cord into a properly grounded outlet.
- 5. Power on the unit using the switch above the power cord inlet
- 6. Upon startup, a temperature alarm may sound. This alarm can be silenced by pressing the alarm icon and pressing the green confirmation check mark. The alarm will resolve when the incubator nears target temperature. This is normal.
- 7. Once the system boots up, it will immediately begin controlling temperature to the default setting of 22°C. No operator intervention is required for this.

4. System Overview

4.1 Major Components

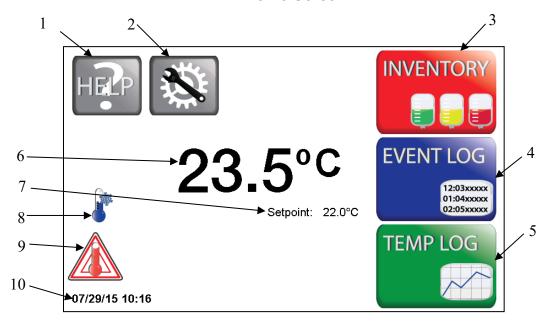


- 1. Alarm Visual Indicator Will illuminate when an alarm is active.
- 2. On Board Thermal Printer Prints temperature and/or event log for selected timeframe.
- 3. User Interface Color touch screen display.
- 4. USB port Used to download system data and upload new firmware, if required.
- 5. Door Lock Locks both doors. Physical key required to open.
- 6. Agitation Unit Used to keep bags of platelets in motion, contains 25 removable shelves.
- 7. Swivel Casters Four swivel casters support the machine with the front pair being lockable.

5. Operation

5.1 Controls and Displays – Home Screen

Below is a picture of the **Home Screen**. If the unit has entered the screen saver mode touch the screen to view the **Home Screen**.



- Help Button Provides information on how to operate the system.
- 2. Settings Button Used for advanced configuration of the system.
- Inventory Button This button is part of the inventory management system. This button is pressed in order to view or modify the inventory status of the unit.
- 4. Event Log Button This displays the event log menu. The event log menu can print the event data and download the system data to USB.
- 5. Temperature Log Button This displays the temperature log menu. The temperature log menu can print the temperature data, download the data to USB, and display the temperature data in graphical format.
- 6. System Temperature Displays the temperature in Celsius inside the chamber.
- 7. System Setpoint Shows the current temperature setpoint in Celsius.
- 8. Heating/Cooling Icon Displays whether the unit is heating or cooling to maintain the setpoint temperature. The Heating Icon is red in color and the Cooling Icon is blue in color.
- 9. Alarm/Notification Button System alarms and notifications are displayed in the lower left hand corner of the Home screen. These can be temporarily silenced by touching the active alarm button. It is not recommended to temporarily silence alarms without fully investigating the reason for the alarm and addressing any issues.
- 10. System Date/Time Displays the current date in MM/DD/YY format and the current time in 24-hour format.

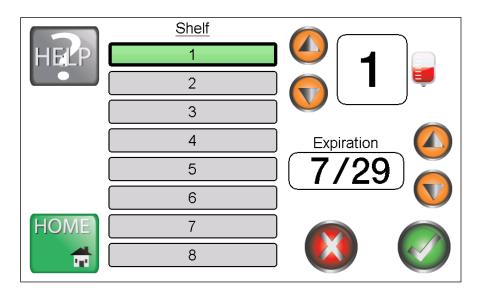
5.2 The Inventory Management System

The inventory management system consists of a series of countdown timers initiated by pressing the Inventory Button on the home screen. These countdown timers help the operator track the amount of time the various inventory pieces have been in the incubator. The system uses a color-coded pictorial of the agitator shelves and alarms to alert the operator of pending inventory expiration. These timers can be configured in the *Settings Menu > Inventory Timer Setup*. More information on the timer configuration is located in the <u>Setup Menu</u>. This section will describe the inventory timers and how the inventory management system is operated.

The pictorial is a visual representation of the platelet agitation unit. It shows which shelves have inventory (by green/yellow/red coloring) and which are empty (gray coloring). To the right of each shelf are the corresponding expiration dates and numbers of bags currently loaded on the shelf.

To load or unload inventory from a shelf, the user first touches which shelf's inventory will be changed (1 - 25).

The following image will appear if shelf 1 is selected:



With no inventory on a shelf the user can select the number of total bags on the shelf and the expiration date. Shelves change color based on the amount of time left before expiration. Bags expire at 11:59:59 PM on the day of expiration.

The operator uses the *Up/Down Buttons* to set the amount of inventory that will be on the selected shelf. Another set of *Up/Down Buttons* are used to set the expiration date of the inventory on the shelf. The *Green Check Button* confirms the timer initiation. The *Red X* and *Home Buttons* exit the screen without initiating the timer.

Note: Any changes made in the inventory management system require the operator to manually reconcile the amount of physical inventory on the selected shelf with the amount shown on the screen.

- A Gray-colored shelf indicates that there is no inventory on this shelf.
- A Green-colored shelf indicates that there is inventory with a shelf life of greater than 36 hours. (Note: this time is *not* configurable in the setup menu)
- A Yellow-colored shelf indicates that there is inventory with a shelf life of 36 to 18 hours. (Note: this time is configurable in the setup menu)
- A Red-colored shelf indicates that there is inventory with a shelf life of less than 18 hours. (Note: this time is configurable in the setup menu)
- A Blinking Red-colored shelf indicates that inventory has expired.

5.3 Data Acquisition System

The Platelet Incubator logs temperature data and system event data to ensure product quality during operation. This data is available in four different ways.

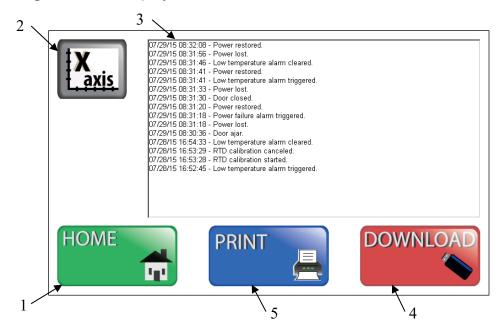
- Screen Saver The temperature trend graph is displayed as one of the rotating screen savers.
- Print The system can print the temperature log graph for up to thirty days from the **Log Menus**.
- Download The system can download the temperature data and system data for up to thirty days from the **Log Menus** in .CSV format to a USB drive from the USB port located on the front of the unit.
- System Log Download From the USB Button in the Settings Menu the system can download to a USB drive all of the data in the internal memory.

- Viewing the Event Log

From the **Home Screen**, the system event log is accessed by pressing the *Event Log Button*.



The Log Screen is displayed:



- 1. Home Button Returns the operator to the *Home Screen*.
- 2. X Axis Button This button is used to change the time settings (X Axis on the graph.) The settings range from one to thirty days. The set timeframe will also be used for the *Download Button* and the *Print Button*.
- 3. Event Log Table Active logs of system events/alarms.
- 4. Download Button The *Download Button* initiates log download to a USB drive plugged into the front of the unit to the right of the touch screen. The timeframe of the download is established in the *X Axis Button* settings (1 30 days). The file is in CSV format and it can be viewed in Microsoft Excel and most spreadsheet or text programs. The USB drive should be FAT32 formatted; common for USB drives, and have ample free space (at least 500KB).
- 5. Print Button This button prints the alarm data in graphical format to the on board printer. The printer is an inkless, thermal printer. The data range is established in the *X Axis Button* settings.

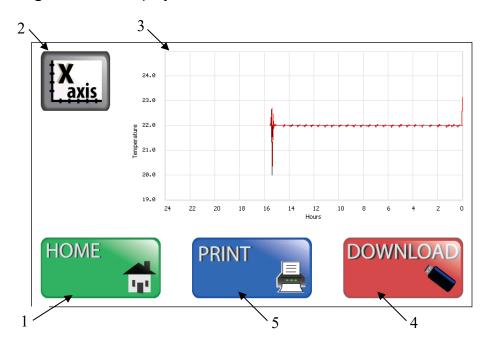
- Viewing the Temperature Log

From the **Home Screen**, the system temperature log is accessed by pressing the *Temp Log Button*.





The **Log Screen** is displayed:



- 1. Home Button Returns the operator to the *Home Screen*.
- 2. X Axis Button This button is used to change the time settings (X Axis on the graph.) The settings range from one to thirty days. The set timeframe will also be used for the *Download Button* and the *Print Button*. The default setting is 7 days.
- 3. Temperature Log Graph Active logs of temperature versus time. Temperature data is logged every minute.
- 4. Download Button The Download Button initiates log download to a USB drive plugged into the front of the unit to the right of the touch screen. The timeframe of the download is established in the X Axis Button settings (1 30 days). The file is in .CSV format and it can be viewed in Microsoft Excel and most spreadsheet or text programs. The USB drive should be FAT32 formatted; common for USB drives, and have ample free space (at least 500KB).
- 5. Print Button This button prints the data in graphical format to the onboard printer. The printer is an inkless, thermal printer. The data range is established in the *X Axis Button* settings.

On-Board Printing System

The on-board thermal printer does not require ink. The printed paper is removed from the printer by pulling in an up-and-across motion.

- Replacing Printer Paper

Paper is easily replaced by opening the tray door by pushing the black button. This will open the door to reveal the empty paper reel. Remove the paper reel by gently pulling the empty reel away from the unit. New paper is placed in the unit in the reverse manner. The printer requires 50mm wide thermal printer paper.



Figure 5.3.6

Place printer paper roll in the orientation shown in figure 5.3.6. Once in this orientation, lift printer door to close. Incubator is now ready to print.

For ordering additional printer paper please use Boekel part number: 932-0025

- Printer Notifications

If the system detects a printer error the error will be displayed on the screen such as "paper jam" or "printer door open". Fix the displayed error to use the printer.

5.4 Battery Backup

If power is lost because of a power failure, or the power switch has been turned off without shutting down the system, the incubator will enter a Battery Backup Mode of operation.

In a battery backup situation, the system continues data logging of the temperature probe values only. Temperature control, touchscreen interface, and printer functionality *will not* be available in Battery Backup Mode.

Should power be lost, it is recommended to transfer the platelet inventory to another temperature controlled location as soon as possible. The incubator chamber will get warmer due to residual heat generated by the agitator motor.

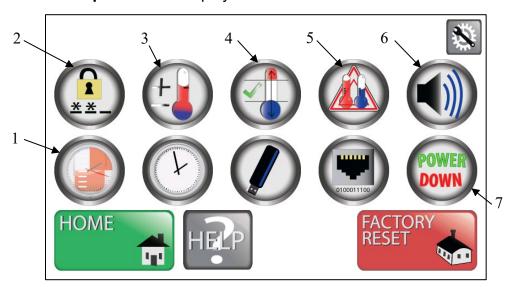
5.5 Setup Menu

The **Setup Menu** is accessed by pressing the *Setup Button* and entering the passcode. The Default Passcode is "1234".

Setup Button:

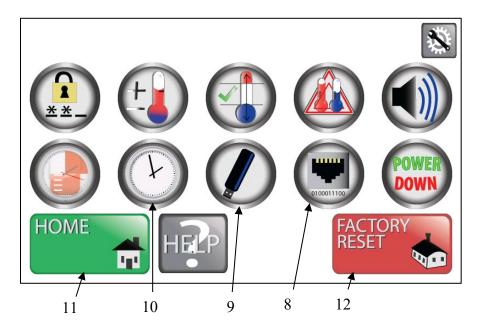


The **Setup Screen** is displayed:



- 1. Inventory Timer Button This button is used to change the timing of the inventory notifications and expiration. (See Inventory Timer Setup for additional information)
- 2. Password Button This button is used to change the password for the setup menu. The default password is 1234. If the password is lost, please contact Boekel Scientific for assistance.
- 3. Setpoint Temperature Button This button is used to change the incubator temperature setpoint. The default setpoint temperature is 22°C.
- 4. Temperature Calibration Button This button is used to calibrate the incubator temperature reading. (See the <u>Calibration Section</u> 5.6 for additional information.)
- 5. High / Low Temperature Alarm Button This button is used to set the high and low temperature alarm setpoints. Default temperature setpoints are 23.5°C for the high alarm and 20.5°C for the low alarm. This menu also has functionality to automatically test that each alarm operates as intended. For more details, refer to Section 5.7.
- 6. Alarm Speaker Button This button is used to change the volume of the system alarms.
- 7. Power Down Button This button is used to disconnect the power from the incubator safely. The power down button stops all data logging and shuts down the battery backup.

Setup Screen (continued)



- 8. Network Button This button is used to enable and configure a remote network connection.
- 9. USB Button This button is used to Upload Firmware or Download the system log.
- 10. Time/Date Button This button is used to set the time and date.
- 11. Home Button This button is used to return to the **Home Menu**.
- 12. Factory Reset Button This button resets all settings to factory defaults, including calibration settings. This also resets the password to the factory default "1234". Please note that the unit must be recalibrated after performing a factory reset.

- Inventory Timer Setup

The inventory timer settings are established in the **Setup Screen**.

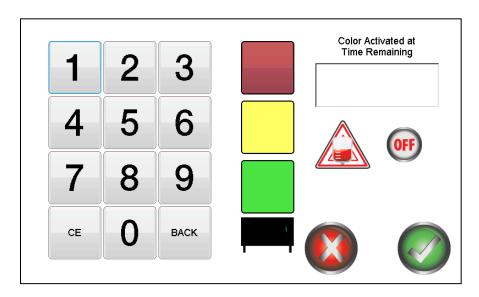
Setup Button:



Inventory Timer Button:



The **Inventory Timer Screen** is displayed:



The **Inventory Timer Screen** changes the timers and notifications associated with the agitator shelf color. To change the timer or notifications, first touch the Red or Yellow Icon.

This icon is pictured below:



Inventory Timer Setup (continued)

The visual notification for a specific color state is turned off and on with the "OFF" or "ON" button. There are no audible or logged notifications for this. This icon is pictured below.

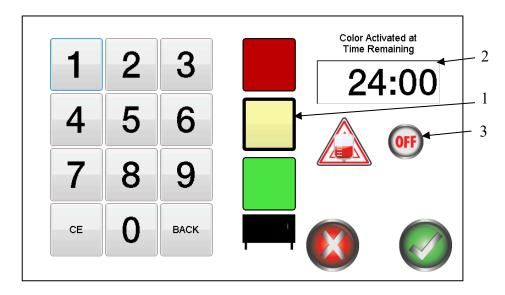
To change the timing of this color state, touch the "Color Activated at Time Remaining" Box. Use the keypad to enter the amount of time remaining before the notification/color change is activated. Touch the "Green Confirmation Check" to save the changes to the inventory timers. The default timer settings are listed below.

Shelf Color	Time Remaining (HH:MM:SS)	Alarm Status	User Configurable
Blinking Red	00:00:00	ON	NO
Red	18:00:00	ON	YES
Yellow	36:00:00	OFF	YES
Green	>36:00:00	OFF	NO

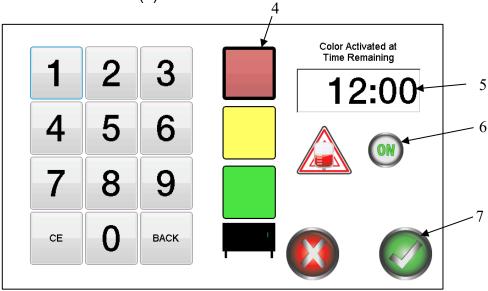
Example:

The lab where the Platelet Incubator is placed typically receives inventory with only two days left before expiration. They want to configure the inventory management system to have a notification one day before the inventory expires and 12 hours before the inventory expires. To configure the notification in this manner, they would follow this procedure:

To obtain the first notification, or yellow notification, a day before the inventory expires they would touch the Yellow Button (1) and set the activation time at 24 hours before expiration (2). They would also turn the notification state to "ON" (3).



To obtain the second notification, or red notification, at 12 hours before the inventory expires, they would then touch the Red Button (4) and set the activation time at 12 hours before expiration (5). They would also turn the notification state to "ON" (6). To save the changes, they would then touch the "Green Confirmation Check" (7).



5.6 Calibration

It is recommended to perform calibration annually or if the unit is moved or being returned to service after maintenance.

The platelet incubator has a simple, two-point method for calibrating the displayed temperature. Using a precision calibrated temperature device with an accuracy of $\pm 0.2^{\circ}\text{C}$ is recommended. The calibration device is placed inside the chamber in the center of a middle agitator shelf. During the calibration procedure, the agitator should not contain any inventory or other objects that may impair airflow, and it should be running in the chamber for at least 30 minutes prior to starting the calibration process. The temperature read by the calibration device is used to adjust the displayed reading on the incubator. The sequence will take at least 2 hours and requires the operator to interact with the incubator during the process.

- Low Point Calibration

The calibration sequence is located in the setup menu.



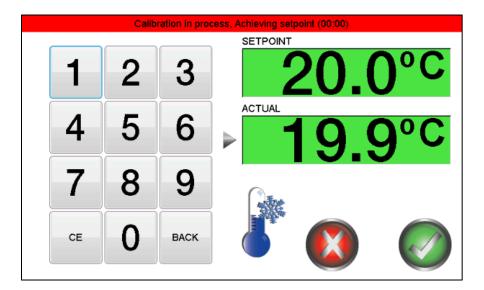


The Low Point Calibration Screen is displayed:



During the calibration sequence, a timer will start, and the incubator will achieve and stabilize at a low temperature of 20°C. During this time, the "ACTUAL" temperature box will be *red* and will not be editable.

Low Point Calibration Temperature Stabilized:

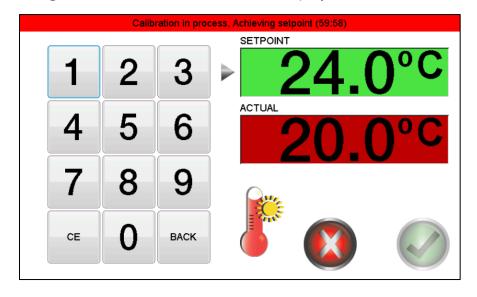


Once the calibration timer has elapsed, the "ACTUAL" temperature box turns *green*, and values can be entered. The user then enters the value of the calibration device in the "ACTUAL" temperature box and touches the "Green Confirmation Check".

This will initiate the High Point Calibration Sequence.

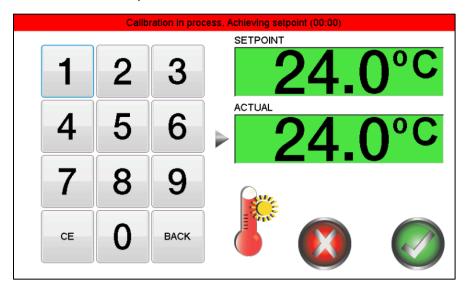
- High Point Calibration

The **High Point Calibration Screen** is displayed:



During the calibration sequence, a timer will start, and the incubator will achieve and stabilize at a high temperature of 24°C. During this time, the "ACTUAL" temperature box will be *red* and will not be editable.

High Point Calibration Temperature Stabilized:



Once the calibration timer has elapsed, the "ACTUAL" temperature box turns *green*, and values can be entered. The user then enters the value of the calibration device in the "ACTUAL" temperature box and touches the "Green Confirmation Check" to confirm the calibration. The device will return to the setup menu and is now calibrated.

Notes: The high and low calibration temperature setpoints can be changed by touching the "SETPOINT" box and inputting a new value. The operator will enter the value of the calibration device once the timer expires. This is indicated by a *green* "ACTUAL" temperature box.

Also, upon completion of the calibration process, the unit may be at a temperature that causes the high temperature alarm to trigger. This is normal, and the alarm can be silenced, if desired. The alarm will soon clear as the Incubator begins cooling to the setpoint.

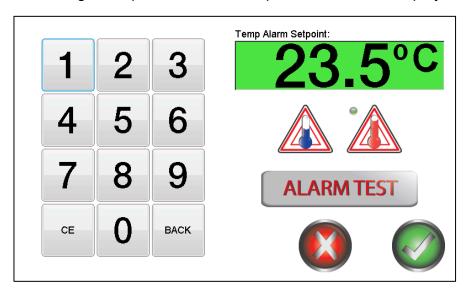
5.7 High/Low Temperature Alarm Test

It is recommended to perform the High/Low temperature alarm test annually or if the unit is moved or being returned to service after maintenance. The Boekel Platelet Incubator provides a fully automated test for each alarm. From the Setup Menu, these tests can be accessed through the High/Low Temperature Alarm Button.

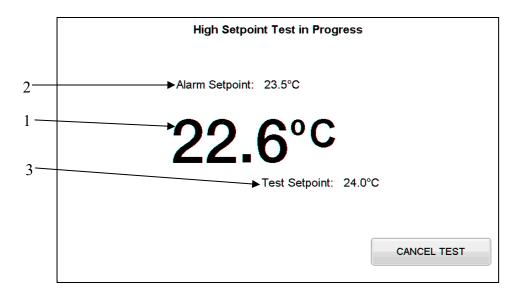
Before starting, it is recommended to remove all inventory from the Agitator shelves and store them temporarily in another suitable location. During this test, the temperature of the Incubator chamber may exceed the recommended guidelines for proper platelet storage.

To test the High Temperature Alarm:

- 1. From the Main Menu, press the Setup Button.
- 2. Enter the Passcode and press the green confirmation check mark.
- 3. From the Setup Menu, press the High/Low Temperature Alarm Button.
- 4. Select the High Temperature Alarm Icon. Unless previously modified, the default High Temperature Alarm Setpoint of 23.5°C is displayed.



- 5. If desired, enter a new High Temperature Alarm Setpoint (between 15°C -29°C) and press the green confirmation check mark. Note: This will exit to the Setup Menu. Repeat Steps 3-4 to continue.
- 6. Ensuring the High Temperature Alarm icon is already selected, press the Alarm Test Button.
- 7. A dialog box appears for confirmation. Press the green confirmation check mark to continue.
- 8. The screen changes to the High Temperature Alarm Test Screen and displays the following: The current temperature reading (1), the current High Temperature Alarm Setpoint (2), and a Test Setpoint (3) (which is always 0.5°C above the High Temperature Alarm Setpoint).



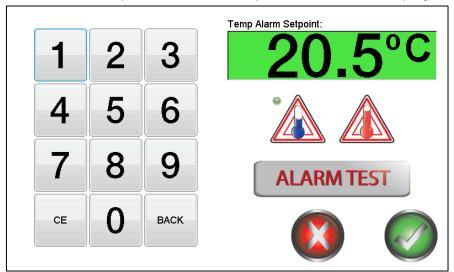
- 9. The incubator automatically begins heating to the Test Setpoint.
- 10. Once the current temperature reading reaches the High Temperature Alarm Setpoint the alarm is triggered. The High Temperature Alarm icon is displayed on the screen and the alarm sounds. The alarm can be silenced, if desired, by pressing the Alarm icon and pressing the green confirmation check mark in the dialog box that appears.
- 11. Once the Alarm has been triggered, the Test Setpoint changes to the system Temperature Setpoint (default value of 22°C), and the system begins cooling. The current temperature reading may continue to increase for a short period of time while the system reacts to this change.
- 12. Once the current temperature reading falls below the High Temperature Alarm Setpoint, the High Temperature Alarm icon disappears and the alarm turns off.
- 13. The system will continue cooling to achieve the Temperature Setpoint.
- 14. The High/Low Temperature Alarm screen is displayed with a dialog box that reads "Setpoint Test Complete. Returning to Normal Operation." Press the green confirmation check mark to continue.
- 15. The dialog box disappears and the system resumes normal heating/cooling and data logging operations.

While resuming normal operation, it is possible that the Low Temperature Alarm may be triggered as the system compensates for the test that was just run. This is normal and the alarm can be silenced.

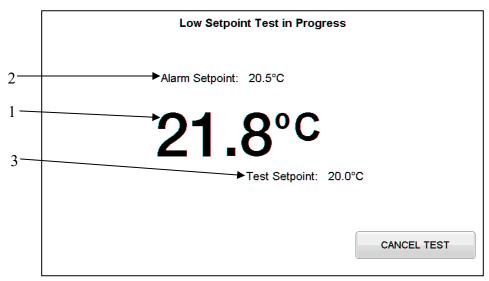
Please allow at least 30 minutes for the system to stabilize at the temperature setpoint before adding inventory to the Agitator shelves.

To test the Low Temperature Alarm:

- 1. From the Main Menu, press the Setup Button.
- 2. Enter the Passcode and press the green confirmation check mark.
- 3. From the Setup Menu, press the High/Low Temperature Alarm Button.
- 4. Select the Low Temperature Alarm Icon. Unless previously modified, the default Low Temperature Alarm Setpoint of 20.5°C is displayed.



- 5. If desired, enter a new Low Temperature Alarm Setpoint (between 15°C 29°C) and press the green confirmation check mark. Note: This will exit to the Setup Menu. Repeat Steps 3-4 to continue.
- 6. Ensuring the Low Temperature Alarm icon is already selected, press the Alarm Test Button.
- 7. A dialog box appears to ensure you want to run the test. Press the green confirmation check mark to continue.
- 8. The screen changes to the Low Temperature Alarm Test Screen and displays the following: The current temperature reading (1), the current Low Temperature Alarm Setpoint (2), and a Test Setpoint (3) (which is always 0.5°C lower than the Low Temperature Alarm Setpoint).



- 9. The incubator automatically begins cooling to the Test Setpoint.
- 10. Once the current temperature reading reaches the Low Temperature Alarm Setpoint the alarm is triggered. The Low Temperature Alarm icon is displayed on the screen and the alarm sounds. The alarm can be silenced, if desired, by pressing the Alarm icon and pressing the green confirmation check mark in the dialog box that appears.
- 11. Once the Alarm has been triggered, the Test Setpoint changes to the system Temperature Setpoint (default value of 22°C), and the system begins heating. The current temperature reading may continue to decrease for a short period of time while the system reacts to this change.
- 12. Once the current temperature reading rises above the Low Temperature Alarm Setpoint, the Low Temperature Alarm icon disappears and the piezo buzzer turns off.
- 13. The system will continue cooling to achieve the Temperature Setpoint.
- 14. The High/Low Temperature Alarm screen is displayed with a dialog box that reads "Setpoint Test Complete. Returning to Normal Operation." Press the green confirmation check mark to continue.
- 15. The dialog box disappears and the system resumes normal heating/cooling and data logging operations.

While resuming normal operation, it is possible that the High Temperature Alarm may be triggered as the system compensates for the test that was just run. This is normal and the alarm can be silenced.

Please allow at least 30 minutes for the system to stabilize at the temperature setpoint before adding inventory to the Agitator shelves.

5.8 Alarms

The platelet incubator has a variety of alarms and notifications to protect the product quality and the system itself. These are listed below. All audible alarms can be silenced by pressing the alarm icon but will reactivate in five minutes if the alarm condition is not fixed/cleared. It is not recommended to temporarily silence alarms without fully investigating the reason for the alarm.

Agitation Alarm

The agitation system is equipped with a detection system to detect unintended stoppage. This is communicated to the incubator, and any errors are displayed on-screen. This alarm is silenced by pressing the alarm icon and cleared by fixing the issue. This alarm is signaled visually, audibly, and networked; and it will be recorded in the event log.



Agitation Alarm Icon

- General Equipment Alarm

The platelet incubator is equipped with a detection system to detect equipment failures and warnings. The General Equipment Alarm will be triggered if an equipment failure or warning is detected in the thermoelectric module fans. This alarm is silenced by pressing the alarm icon and cleared by fixing the issue. This alarm is signaled visually, audibly, and networked; and it will be recorded in the event log.



General Equipment Alarm

- Door Alarm

The platelet incubator is equipped with a door alarm. If either or both incubator doors are open for an extended amount of time (greater than 2 minutes) the door alarm will be triggered. This alarm is silenced by pressing the alarm icon and cleared by closing the door. This alarm is signaled visually, audibly, and networked; and it will be recorded in the event log.



Door Alarm

- Network Alarm

The platelet incubator is equipped with a network alarm. If the incubator is connected to a central monitoring system and has an issue maintaining a connection to the remote network, the network alarm will be triggered. This alarm is silenced by pressing the alarm icon and cleared by re-establishing a connection. This alarm is signaled visually, audibly, and networked (if using the relay connection); and it will be recorded in the event log.



Network Alarm

- High / Low Temperature Alarms

The platelet incubator is equipped with high and low temperature alarms. These alarm setpoints are configurable in the Setup Menu. These alarms are silenced by pressing the alarm icon and cleared when the temperature is within the High Temperature and Low Temperature Alarm limits. These alarms are signaled visually, audibly, and networked; and they will be recorded in the event log.



High Temperature Alarm



Low Temperature Alarm

Battery Alarm

The platelet incubator is equipped with a battery backup system to support data logging in the event of a power failure. The control system monitors the health of the rechargeable batteries. If the control system detects an issue with the batteries or the unit has unexpectedly lost power, it will trigger a battery alarm. The battery alarm will also appear if the unit is powered down without using the *Power Down* button in the setup menu. This alarm is silenced by pressing the alarm icon and cleared by fixing the issue. This alarm is signaled visually, audibly, and networked; and it will be recorded in the event log.



Battery Alarm

- Expiration Warning Notification

The platelet incubator is equipped with an inventory management system based on system timers. If the unit detects inventory that is about to expire, denoted by a Red or Yellow shelf color, it will trigger the Expiration Warning Notification. This notification is configured in the Setup Menu. This notification is silenced by pressing the notification icon and cleared by removing the inventory. This notification is signaled visually and networked only, and will not be recorded in the event log.



Expiration Warning Notification.

5.9 Help Menu – Icon Descriptions

The Help Menu icon offers a description of all icon functionality. Icons are described below:



The Help Button is used to access the Help Menu. The Help Menu indicates the functions of all icons.



The Setup Button is used to access the Setup Menu. The Setup Menu is password protected and allows advanced configuration of the Incubator.



The Heating Icon indicates that the incubator is heating to achieve the temperature setpoint.



The Cooling Icon indicates that the incubator is cooling to achieve the temperature setpoint.



The Event Log Button accesses the log settings and allows for printing and downloading of system logs.



The Inventory Button accesses the Inventory Overview Screen. This screen displays the inventory and the time left before expiration.



The Temperature Log Button accesses the graphical temperature log settings and allows for printing and downloading of system logs.



The Alarm Test Button is accessed from the High/Low Temperature Alarm Setting Screen. This provides a fully automated test of the High or Low Temperature Alarm functionality.



The Home Button will take you to the Home Screen.



The Print Button prints the temperature log for the predetermined mode and time. The predetermined time is set by the X Axis button.



The Download Button downloads the temperature and event log to a USB drive.



The Confirm Button confirms the settings and exits out of the screen.



The Cancel Button exits out of a screen without saving changes.



The X Axis button sets the time frame for the displayed graph and printed graph.



The Password Button is used to change the current password. The Password is used to change settings in the Settings Screen. The Default Password is 1234.



The Temperature Setpoint Button is used to change the temperature setpoint. The default temperature is set to 22.0°C.



The Calibration Button is used to calibrate the incubator temperature.



The Temperature Alarm Button is used to set the setpoints for the High and Low Temperature Alarms. This menu also has functionality to automatically test that each alarm operates as intended (detailed in Section 5.7).



The Volume Button changes the volume of the incubator alarm.



The Inventory Timer Button changes the timers and notifications associated with the inventory management system.



The Time Button sets the Time and Date of the unit.



The USB Button allows for a complete system log download or the uploading of firmware.



The Network Button allows for enabling and configuration of the network settings.



The Power Down button initiates a power down sequence so that the unit can be removed from power. This stops all data logging and alarms and disables the battery backup.



Agitation Alarm Icon – The system has detected that agitation is not taking place.



General Equipment Alarm – The System has detected a general equipment alarm with the thermoelectric module fans.



Door Alarm – The system has detected that the door has been opened for an extended period of time.



Network Alarm - The system has detected an external network issue.



High Temperature Alarm – The temperature has risen above the high temperature alarm setpoint.



Low Temperature Alarm – The temperature has dropped below the low temperature alarm setpoint.



Battery Alarm – The system has detected an issue with the batteries in the battery backup system or the system has lost main power and has used the battery backup to log data.



Expiration Warning Notification - There is inventory in the unit that is close to expiring. This is configurable to appear whenever an inventory shelf turns red and/or yellow in the inventory management system.

5.10 Network Connection

The platelet incubator is supplied with the hardware and software required for integration into a building or hospital management system.

Protocols Available: MODBUS via RS-485 MODBUS TCP/IP via Ethernet RJ45

MODBUS TCP/IP CONNECTIVITY DETAILS

Static or Dynamic IP available.

TCP/IP Port: 502

MODBUS RS-485 CONNECTIVITY DETAILS

Settings: 19,200 baud, 8 Data bits, 1 Stop bit, Even Parity

Exceptions

A Modbus exception will be returned if an unused register is addressed.

Registers

Coils (Read/Write)

00113 (110	ad/vviito)		
Block	Name	Description	Size
Index			(bits)
1		Reserved for future use	1
65535		Reserved for future use	

Discrete Inputs (Read Only)

Block Index	Name	Description	Size (bits)
1	IN1	Power On	1
2	IN2	Agitator Alarm Signal	1
3	IN3	Door	1
4	OUT1	Alarm Relay (Alarm Active)	1
5	OUT2	Light (Light On)	1
6	OUT3	Agitator (Door Closed and No Agitator Alarm)	1
7	OUT4	Battery Charging (Charge Current > 0)	1
8	OUT5	Battery On (Shutdown Mode Disabled)	1
9		Reserved for future use	
65535		Reserved for future use	

Inputs (Read Only)

Block Index	Name	Description	Size (Bytes)
1	Firmware Version	Firmware Version (ASCII)	8
5	RTD1	RTD1 Temperature (1/1,000 th °C)	2
6	Peltier Percentage	Percentage of heating or cooling (1/1,000 th %)	2
7	Alarm Code	Alarm Condition Error code Bit 0 = Reserved Bit 1 = High Temperature Bit 2 = Low Temperature Bit 3 = Network Bit 4 = Power Failure Bit 5 = Agitator Bit 6 = Service Bit 7 = Door Bit 8 = Inventory Bit 9 = Battery	2
8		Reserved for future use	
65535		Reserved for future use	

Holding (Read/Write)

Block Index	Name	Description	Size (Bytes)
1		Reserved for future use	
65535		Reserved for future use	

6. Specifications & Operating Conditions

Platelet Incubator:	Model number FS100	Model number FS100-2	
Electrical:	115V, 60 Hz, 7A Peak, 4A Steady State, 500 Watts	230V, 50Hz, 4A Peak, 2A Steady State, 500 Watts	
Temperature Range:	20°C – 24°C		
Alarms:	Door, Printer, Inventory, Low Temperature, High Temperature, Agitation, General Equipment, Network, and Battery Alarms		
Printer:	50mm thermal printer		
Temperature Control Method:	Thermoelectric		
Inventory Management System:	Time Based		
Ambient Temperature Range:	16°C – 30°C Ambient		
Temperature Accuracy:	±0.3°C between 20°C and 24°C		
Connectivity:	USB, Ethernet, RS485, Dry-contact Relay		
Product Dimensions:	40" W x 28" D x 70" H		
Shipping Weight:	575 lbs.		
Transport and Storage Temperature Range:	10°C – 50°C		
Humidity (operation, transport, or storage):	25-90% (non-condensing)		
Altitude:	0 - 2,000 m above sea level		

6.1 Default Settings

Temperature Setpoint	22°C
High Temperature Alarm	23.5°C
Low Temperature Alarm	20.5°C
Product Shelf Life Timer (Green)	>36 hours (not configurable)
Product Shelf Life Timer (Yellow)	36-18 hours
Product Shelf Life Timer (Red)	<18 hours
Log X-Axis	7 days
Alarm Volume	On – High Volume
Passcode	1234

7. Maintenance and Service

7.1. Cleaning

Before using any cleaning or decontamination method, users should verify that the method of cleaning will not damage the unit.

- 1. Power down unit with the *Power Down* function in the setup menu.
- 2. Turn power switch to the off (O) position.
- 3. Remove mains power supply cord.
- 4. Remove all removeable equipment and/or shelves from the incubator.
- 5. Inspect incubator chamber for damage and corrosion and repair if necessary.
- 6. Inspect the incubator door seal for damage and repair if necessary.
- 7. If the incubator is soiled it will first need to be cleaned with an alkaline liquid detergent.

The following detergent trade names are alkaline liquid detergents. Prepare the cleaning solution in accordance with the manufacturer's instructions:

- a) Micro-90®
- b) Stan-Bio Bioclean®
- c) Contrad®

The following cleaners are not recommended and could damage the equipment:

- a) Hypochlorite Solutions
- b) Corrosive Detergents
- c) Acidic Solutions
- d) Salt Solutions
- 8. Clean: Use a lint-free cloth to clean the interior of the incubator, the door, and the incubator door gasket. Remove all visible dirt from surfaces.
- 9. Clean: Use a lint-free cloth to clean shelves or equipment associated with the incubator. Remove all visible dirt from surfaces.
- 10. Remove Cleaner: Use a lint-free cloth and sterile deionized water to wipe the interior of the incubator, the door, and the incubator door gasket. Perform this action twice to remove all cleaner.
- 11. Remove Cleaner: Use a lint-free cloth and sterile deionized water to wipe shelves or equipment associated with the incubator. Perform this action twice to remove all cleaner. Do not submerse any equipment or shelves with deionized water.
- 12. Disinfect: Use a lint-free cloth and a 70% isopropyl alcohol solution to clean the interior of the incubator, the door, and the incubator door gasket.

- 13. Disinfect: Use a lint-free cloth and a 70% isopropyl alcohol solution to disinfect shelves or equipment associated with the incubator.
- 14. Return removeable equipment and / or shelves to the incubator.

7.1.1. Cleaning Spilled Platelets

In the event that a bag leaks or tears and platelets are spilled in/on the unit, special considerations must be made to decontaminate the unit.

- 1. As soon as evidence of a leak is discovered, immediately power down unit with the *Power Down* function in the setup menu.
- 2. Turn power switch to the off (O) position.
- 3. Remove mains power supply cord.
- 4. Per your SOP, remove the leaking/spilled bag of platelets and dispose of it properly.
- 5. Per your SOP, remove all remaining bags of platelets from the system and either temporarily store them in an alternate suitable location or dispose of the bag(s) properly.
- 6. Clean and decontaminate the inner chamber of the incubator per your SOP.
- 7. Clean and decontaminate the incubator door per your SOP.
- 8. Inspect the system for evidence that platelets have leaked through any seams in the interior of the incubator chamber. If platelets have leaked through the seams, contact Boekel Scientific for additional instructions.
- 9. Per your SOP, clean and decontaminate the outside of the incubator.
- 10. Inspect the system for evidence that platelets have leaked through any seams or holes on the exterior of the incubator chamber. If platelets have leaked into these areas, contact Boekel Scientific for additional instructions.
- 11. Once the entire unit has been verified to be decontaminated and the unit is completely dry, reassemble the unit by installing the components in reverse order.

7.2. Calibration

1. Refer to section 5.6 for performing temperature calibration.

7.3. Replacement of Fuses

To change the main incubator fuses:

- 1. Enter the setup menu and press the *Power Down* button.
- 2. Turn power switch to the off (O) position.
- 3. Disconnect the unit from the power supply.
- 4. Remove the line cord from the power entry module on the back of the unit
- 5. Pull back on the fuse drawer catch (located on top of power entry module).
- 6. Pull out the fuse drawer.

- 7. Check and replace with the correct fuses if necessary
- 8. 115V unit fuses must be 5mm x 20mm, fast acting, rated at 8A 250V.
- 9. 230V unit fuses must be 5mm x 20mm, fast acting, rated at 4A 250V
- 10. Push the drawer back in and reconnect the unit to the power supply.

7.4 Preventative Maintenance

The following actions are recommended on an annual basis (dependent upon ambient conditions) to ensure efficient continued operation of the equipment:

- 1. Remove covers and vacuum any accumulated dust off the heatsink fins on both heatsinks of the thermoelectric assembly.
- 2. Remove and clean both condensate drip trays.
- 3. Clean all interior surfaces of the incubator and allow to dry before reconnecting power.

8. Troubleshooting

Symptoms	Possible Cause	Corrective Action
Power		
The unit does not power on.	Power cord not connected to Electrical receptacle on Unit, and/or Wall outlet	Fit the power line cord into the IEC power socket on the rear of the unit and verify if plugged into a properly grounded outlet
	Power supply failure	 Verify that power source is active and regulated
	A fuse has blown	Replace fuse
	Malfunctioning Power Key	Contact Boekel Scientific for Service
	Malfunctioning Control System	Contact Boekel Scientific for Service
Temperature Control		
The temperature does not stabilize	Not enough clearance around incubator	Confirm there is 3 inches of clearance around the incubator
	Faulty Temperature Sensor	Contact Boekel Scientific for Service
	Confirm Ambient Temperature is within the recommended range	
The displayed temperature does not match a calibrated	Unit is in need of calibration	Refer to Calibration Section
temperature measuring device	Faulty Temperature Sensor	Contact Boekel Scientific for Service
Alama Failum		
Alarm Failure	A1 / 15 11 1	
Audible alarm does not sound	Alarm/notification does not generate an audible alarm	Check Alarms section of this document to ensure the alarm is supposed to be audible for the particular event
	Buzzer volume has been turned off Facility arising business.	Turn on the alarm volume through the settings menu
	Faulty piezo buzzer	Contact Boekel Scientific for Service

9. Warranty and Service

9.1. Warranty

When used in the appropriate laboratory conditions and in accordance with these operating instructions, Boekel Scientific warrants this product to be free of defective parts, material and workmanship for a period of two years from the date of shipment. The liability of Boekel Scientific for any defective equipment during the warranty period shall be limited to the repair of defective equipment or replacement thereof without charge for parts or labor.

9.2. Service

If service is required, contact Boekel Customer Service at 1-800-336-6929. A Decontamination Certificate must be completed, signed by the user, and returned to Boekel Scientific prior to receiving the RMA number.



Boekel Scientific 855 Pennsylvania Blvd. Feasterville, PA 19053

Phone: (215) 396-8200 or (800) 336-6929

Fax: (215) 396-8264

Email: Boekel-info@boekelsci.com

If the unit is located in the European Community, then contact our EC Authorized Representative for service.

EC REP

Ducit Medical
The Chase, Level 1
Carmanhall Road
Sandyford, Dublin D18 Y3X2
Ireland
+353-86-8120451