PURPOSE

To define the procedure to manufacture aliquots of apheresis platelets.

POLICY

An aliquot is a portion of apheresis platelets prepared from a donor unit and is used when patients require transfusion of small volumes of platelets. The Department of Pathology Transfusion Services prepares aliquots of platelets based on a physician's order. Transfusion Services maintains a stock inventory of aliquots of apheresis platelets.

PRINCIPLE

- Certain patient populations require only small volumes of platelets during transfusion. This includes neonates and patients at risk for volume overload. Aliquots may be prepared from an apheresis platelet unit with the use of a sterile connecting device. A donor unit of apheresis platelets is connected to an empty platelet bag using a sterile connecting device. A portion of the apheresis platelet is transferred to the empty bag to achieve an aliquot volume. The aliquot is weighed on a calibrated scale and the volume is calculated based on the weight. The appropriate steps to aliquot and label the product in the blood bank laboratory information system are followed.

EQUIPMENT AND MATERIALS

- Donor unit of apheresis platelets
- Empty platelet bag
- Sterile connecting device (SCD)
- Scale
- Hemostats
- Sterile connecting device log
- ISBT labels
- Digitrax label printer
- Sebra heat sealer

QUALITY CONTROL:

- Documentation of the SCD, lot number of transfer bag and whether the weld quality control is acceptable (A) or unacceptable (U) must be entered into the sterile connecting device log worksheet at the time of product division.

PROCEDURE

- Select the apheresis platelet to be divided into part A and part B.
  - Volume of the apheresis platelet must be >200 ml but less than 340 ml.
- Document the following information on the sterile connecting device log:
  - Donor unit number
  - Blood type
  - Expiration date of the unit
  - Original volume of main platelet bag
  - Original volume of anticoagulant
  - Lot number of the transfer bag

- Gently agitate the unit to ensure the product is well mixed.
- Using the sterile tube welder, connect the tubing from the main bag to the transfer bag. Refer to the Genesis RapidWeld STW Model:GRW-430 Operator's manual for instructions on how to use the sterile tubing welder.
- Open the weld by squeezing the flared edges between your thumb and forefingers and slightly rolling it.
- Inspect for the integrity of the seal by visually inspecting for leakage.
  - A satisfactory weld does not leak.
  - An unsatisfactory weld has evidence of leaking. Discontinue the process. Any blood products exposed to leaking welds should be considered contaminated and discarded according to Blood Bank procedure 2371.A. Refer to Operator's Manual, The Genesis Rapidweld STW Model :GRW-430, p.19.
  - Document inspection and any actions taken on the sterile connecting device log worksheet.
- Place the empty platelet bag on the scale and tare the scale to zero.
- Calculate the volume of platelets to be transferred from the parent bag. 1 ml of apheresis platelets is equivalent to 1.03 gram weight.
- Place the unit to be divided at a level above the transfer bag.
- Transfer the calculated volume of platelets from the parent bag to the empty platelet transfer bag +/- 10 mls.
  - For specific volumes requested by the physician, transfer the calculated volume plus an additional 15 mls into the transfer bag to compensate for the platelets lost in the filter and tubings used during transfusion.
- Clamp the hemostat leading from the parent bag to aliquot bag.
- Seal the tubing near the transfer bag using the Sebra tube sealer.

- Complete computer documentation for aliquoting platelets with satisfactory inspection.
  - Refer to attached LIS attachment # 1 for LIS exhibits on how to aliquot platelets in the laboratory information system.
- Print labels from the blood bank computer system for both parts A and B.
- Re-label the main bag as part A
- Label the transfer bag as part B.
- List the anticoagulant volume for each divided platelet on the aliquot label.
- Anticoagulant volume is half the volume of the original platelet bag.
- Perform ISBT label verification with a second CLS.
- Separate the aliquot from the main bag by cutting the heat sealed segment.
- Part B of the split platelets should be issued before part A.

RESPONSIBILITY

- Trained and competent staff will prepare aliquots.

EXCEPTIONS

- There are no exceptions to this policy

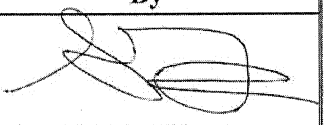
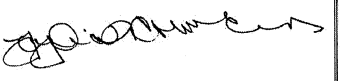
REFERENCES

- AABB, Technical Manual, current edition, Bethesda MD.
- AABB, Standards for Blood Banks and Transfusion Services, current edition, Bethesda MD.
- Modern Blood Banking & Transfusion Practices, sixth edition , Denise M. Harmening
- Genesis Rapid Weld Operator's Manual

APPENDICES AND EXHIBITS

- **Rapid weld Operators manual**
- **Guide on how to aliquot platelet in Meditech**
- **Sterile Connecting device log worksheet**

PROCEDURE HISTORY

Date	Written/ Issued by	Revision/ Review	Approved Date	Approved By
02/17	A. Olario B.Thomas T.Cox	New Policy	2/21/17	 Sarah Barnhard MD
02/17		New Policy -CLIA director	2/21/17	 Lydia Howell MD
02/17		New Policy- Medical Director	2/21/17	Hanne M. Jensen Hanne Jensen MD

Month/Year:________________
Instrument ID/SN:___________

Example #1
BB2957.T

University of California Davis Health
Department of Pathology and Laboratory Medicine, Transfusion Services
Sterile Connecting Device Log

Date	Staff Performing Weld	Main Platelet Bag	Platelet Transfer Bag	Weld Integrity (A/U)	Label Verified by CLS	Comments
		Unit #:________ Blood Type:________ Unit Expiration Date:________ Original Volume:________ New Volume:________ New Volume of Anticoagulant:________	Unit #:________ Blood Type:________ Unit Expiration Date:________ Lot# of Transfer Bag:________ Exp. Date of Transfer Bag:________ Volume of Unit:________ Volume of Anticoagulant:________			
		Unit #:________ Blood Type:________ Unit Expiration Date:________ Original Volume:________ New Volume:________ New Volume of Anticoagulant:________	Unit #:________ Blood Type:________ Unit Expiration Date:________ Lot# of Transfer Bag:________ Exp. Date of Transfer Bag:________ Volume of Unit:________ Volume of Anticoagulant:________			
		Unit #:________ Blood Type:________ Unit Expiration Date:________ Original Volume:________ New Volume:________ New Volume of Anticoagulant:________	Unit #:________ Blood Type:________ Unit Expiration Date:________ Lot# of Transfer Bag:________ Exp. Date of Transfer Bag:________ Volume of Unit:________ Volume of Anticoagulant:________			
		Unit #:________ Blood Type:________ Unit Expiration Date:________ Original Volume:________ New Volume:________ New Volume of Anticoagulant:________	Unit #:________ Blood Type:________ Unit Expiration Date:________ Lot# of Transfer Bag:________ Exp. Date of Transfer Bag:________ Volume of Unit:________ Volume of Anticoagulant:________			

A: Acceptable if no leaks observed by visual inspection.
U: Unacceptable if leaking is observed.
Unit label verification must be a CLS. This CLS must not be the same CLS performing the welding and labeling the bags.

Reviewed By:________________
Date:________________

University of California Davis Health System

Department of Pathology and Laboratory Medicine

Transfusion Services

Manufacturing Blood Product Aliquots

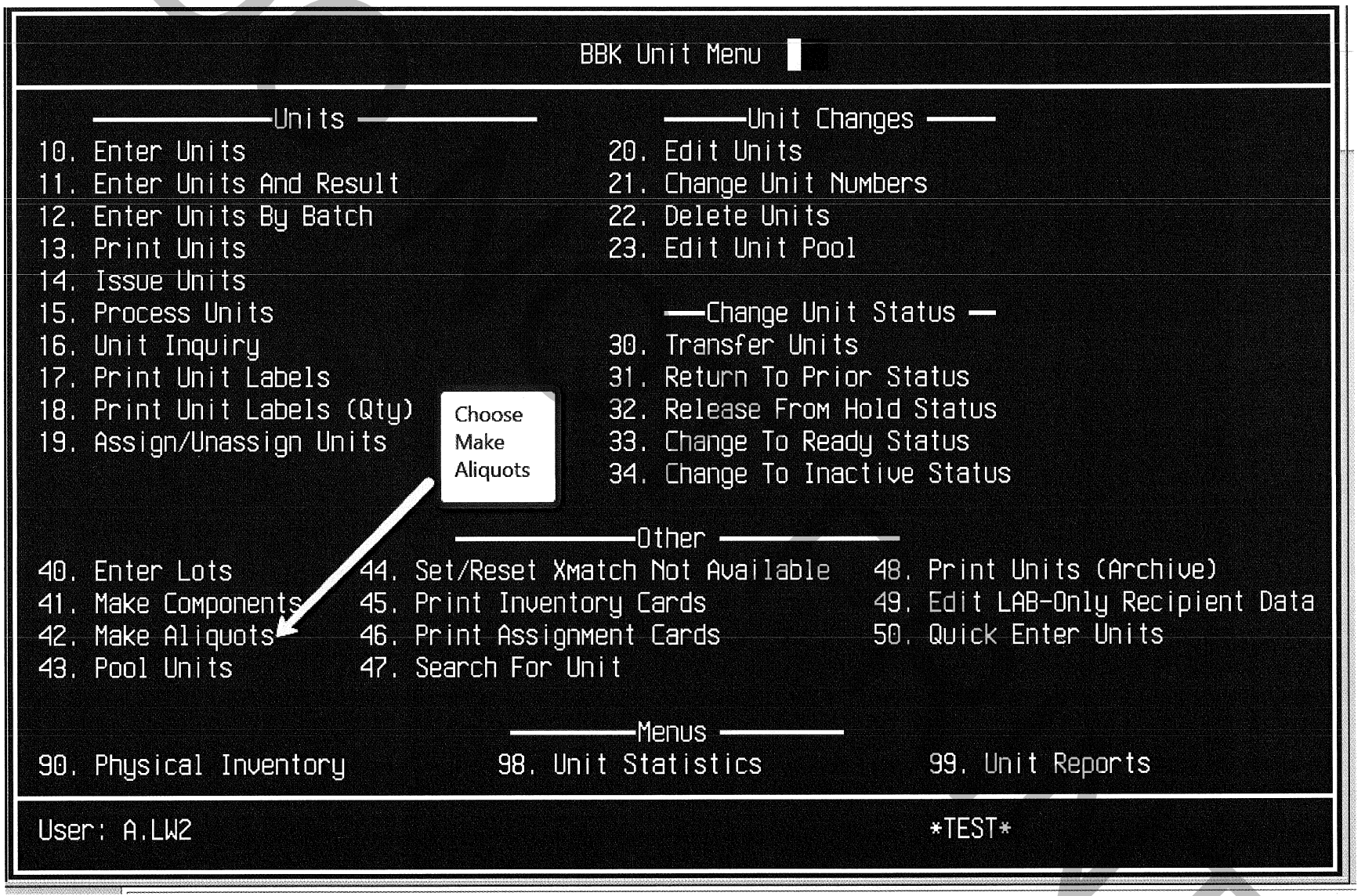
Technical Procedure BB2957.T

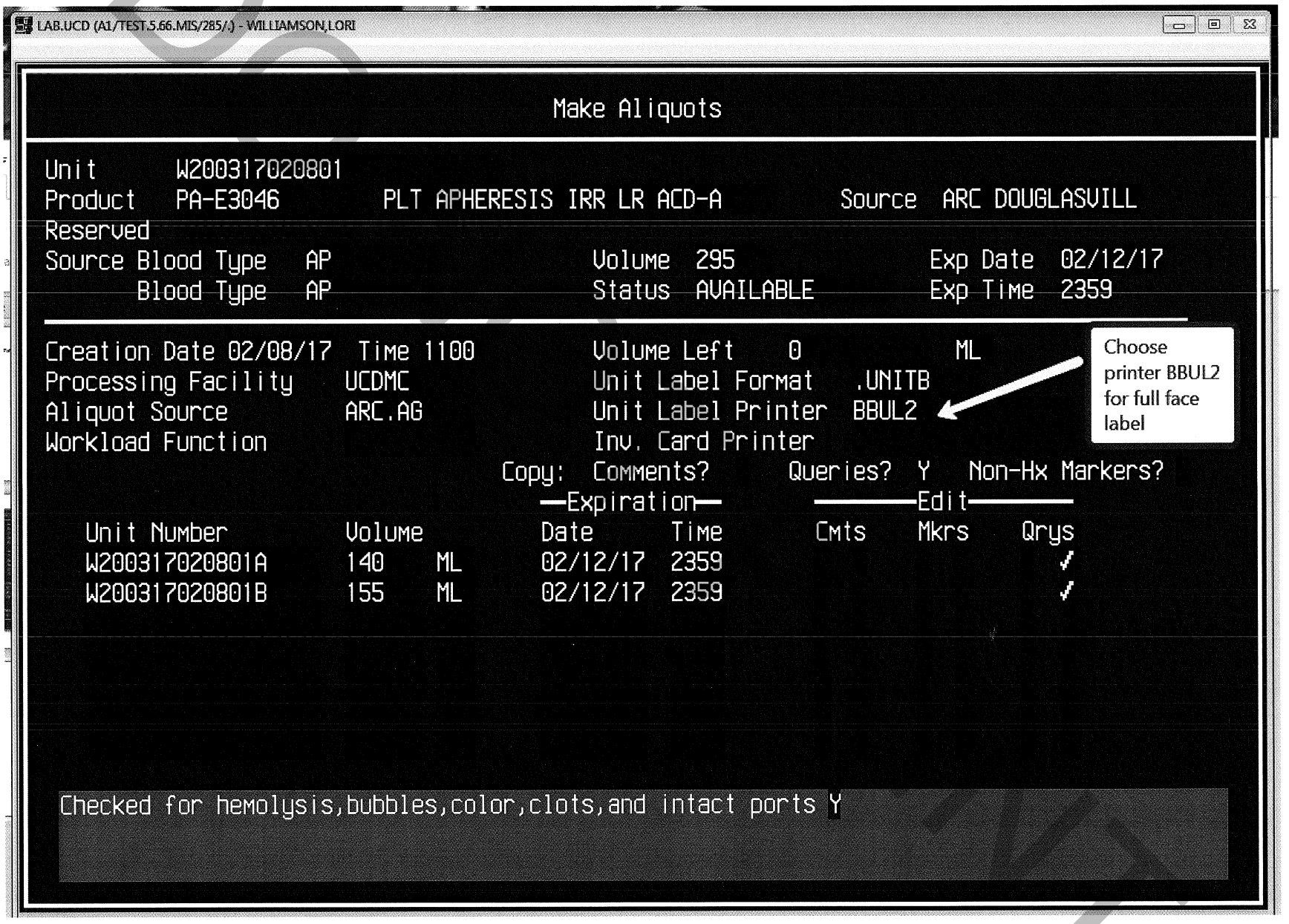
ATTACHMENT # 1

MEDITECH GUIDE ON HOW TO SPLIT PLATELETS

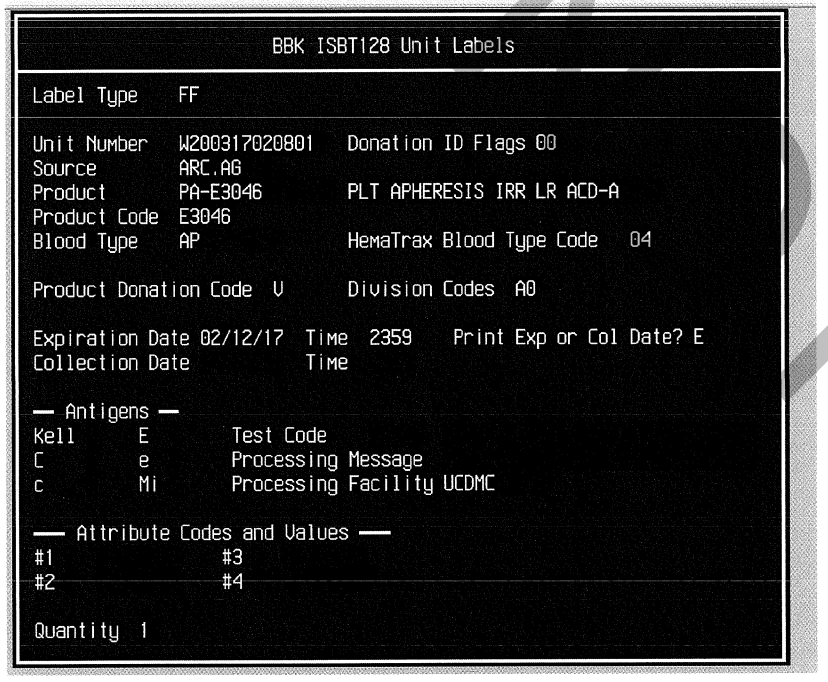
Platelet Products that can be Aliquoted

Mnemonic	Name	Abbrev	Make Aliquots?
PA-E3046	PLT APHERESIS IRR LR ACD-A	PLT.APH.IR.LR	Y
PA-E4647	PLT APHERESIS IRR LR ACD-A	PLT.APH.IR.LR	Y
PA-U3046	PLT APHERESIS IRR.U LR ACD-A	PLT.APH.IR.LR	Y
PA-U4647	PLT APHERESIS IRR.U LR ACD-A	PLT.APH.IR.LR	Y
PA-E3056	PLT APHERESIS IRR LR ACD-A.1	PLT.APH.IR.LR1	Y
PA-E4648	PLT APHERESIS IRR LR ACD-A.1	PLT.APH.IR.LR1	Y
PA-U3056	PLT APHERESIS IRR.U LR ACD-A.1	PLT.APH.IR.LR1	Y
PA-U4648	PLT APHERESIS IRR.U LR ACD-A.1	PLT.APH.IR.LR1	Y
PA-E3057	PLT APHERESIS IRR LR ACD-A.2	PLT.APH.IR.LR2	Y
PA-U3057	PLT APHERESIS IRR.U LR ACD-A.2	PLT.APH.IR.LR2	Y
PA-E3058	PLT APHERESIS IRR LR ACD-A.3	PLT.APH.IR.LR3	Y
PA-U3058	PLT APHERESIS IRR.U LR ACD-A.3	PLT.APH.IR.LR3	Y
PA-E3077	PLT APHERESIS LR ACD-A	PLT.APH.LR	Y
PA-E4643	PLT APHERESIS LR ACD-A	PLT.APH.LR	Y
PA-E3087	PLT APHERESIS LR ACD-A.1	PLT.APH.LR1	Y
PA-E4644	PLT APHERESIS LR ACD-A.1	PLT.APH.LR1	Y
PA-E3088	PLT APHERESIS LR ACD-A.2	PLT.APH.LR2	Y
PA-E3089	PLT APHERESIS LR ACD-A.3	PLT.APH.LR3	Y

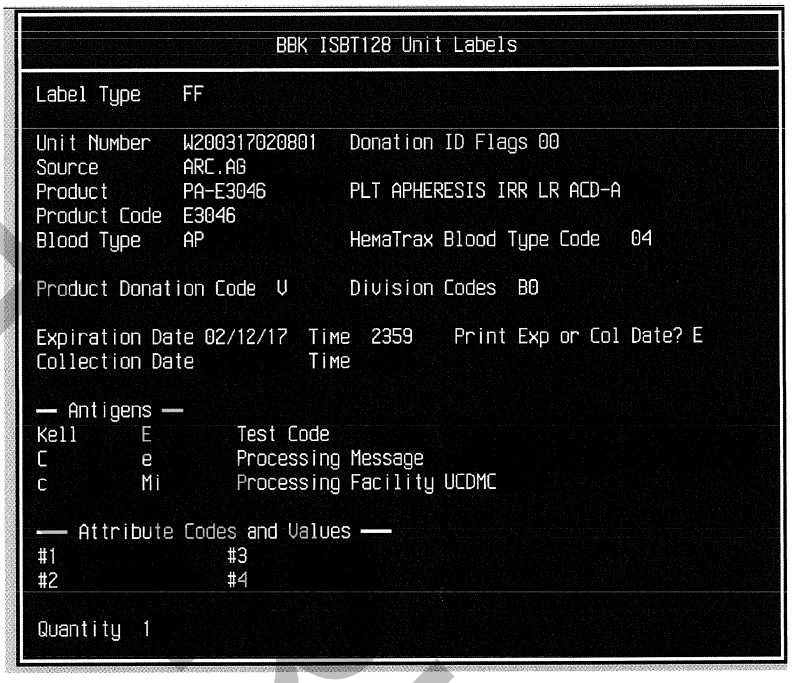

BBK Unit Menu
Units
10. Enter Units
11. Enter Units And Result
12. Enter Units By Batch
13. Print Units
14. Issue Units
15. Process Units
16. Unit Inquiry
17. Print Unit Labels
18. Print Unit Labels (Qty)
19. Assign/Unassign Units
Unit Changes
20. Edit Units
21. Change Unit Numbers
22. Delete Units
23. Edit Unit Pool
Change Unit Status
30. Transfer Units
31. Return To Prior Status
32. Release From Hold Status
33. Change To Ready Status
34. Change To Inactive Status
Choose
Make
Aliquots
Other
40. Enter Lots
41. Make Components
42. Make Aliquots
43. Pool Units
44. Set/Reset Xmatch Not Available
45. Print Inventory Cards
46. Print Assignment Cards
47. Search For Unit
48. Print Units (Archive)
49. Edit LAB-Only Recipient Data
50. Quick Enter Units
Menus
90. Physical Inventory
98. Unit Statistics
99. Unit Reports
User: A.LW2
TEST


LAB.UCD (A1/TEST.5.66.MIS/285/) - WILLIAMSON,LORI
Make Aliquots
Unit W200317020801
Product PA-E3046 PLT APHERESIS IRR LR ACD-A Source ARC DOUGLASVILL
Reserved
Source Blood Type AP Volume 295 Exp Date 02/12/17
Blood Type AP Status AVAILABLE Exp Time 2359
Creation Date 02/08/17 Time 1100 Volume Left 0 ML
Processing Facility UCDMC Unit Label Format .UNITB
Aliquot Source ARC.AG Unit Label Printer BBUL2
Workload Function Inv. Card Printer
Copy: Comments? Queries? Y Non-Hx Markers?
Expiration Edit
Unit Number Volume Date Time Cmts Mkrs Qrys
W200317020801A 140 ML 02/12/17 2359 /
W200317020801B 155 ML 02/12/17 2359 /
Checked for hemolysis,bubbles,color,clots,and intact ports Y
Choose printer BBUL2 for full face label

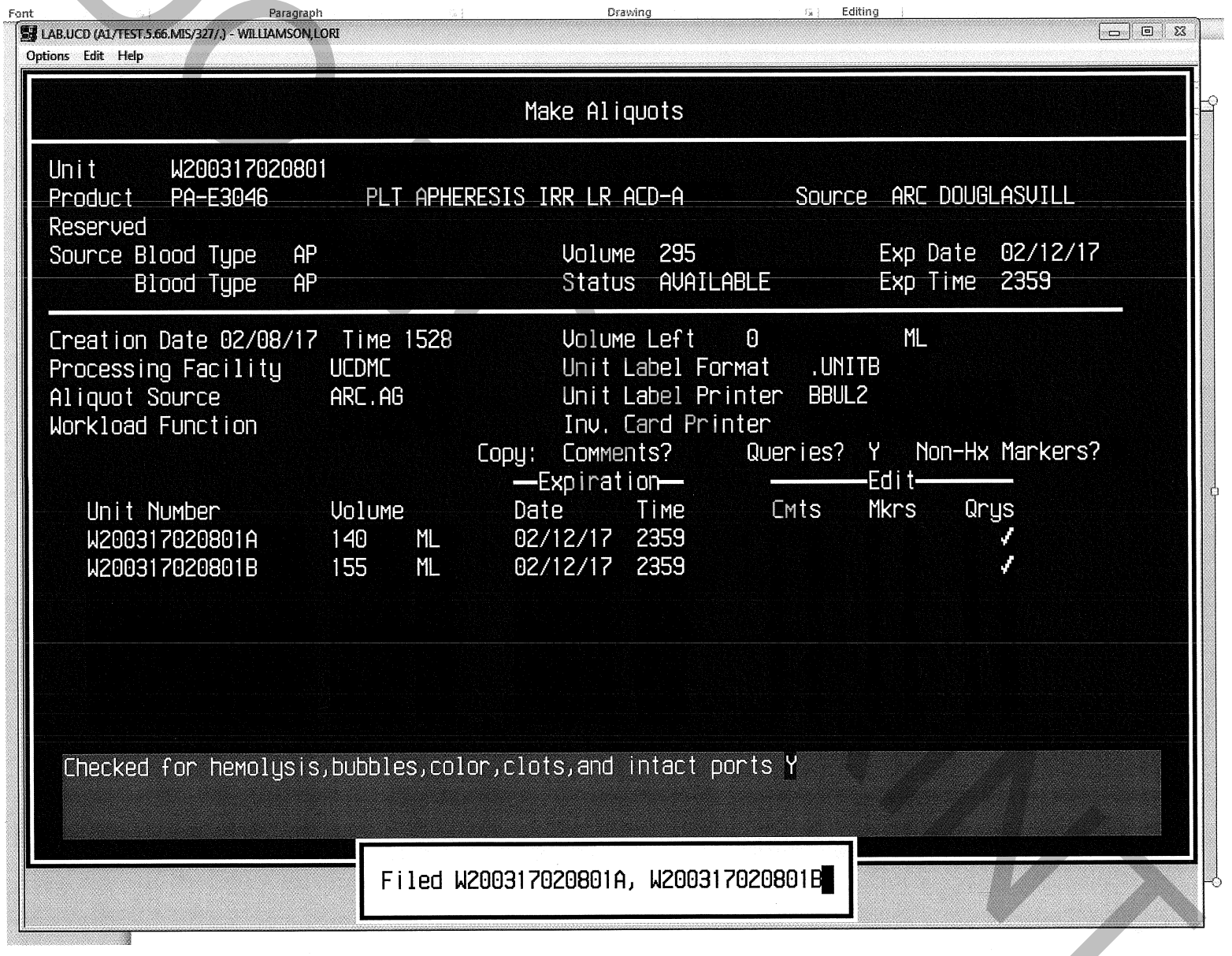
Label type = FF
Both A & B labels will print



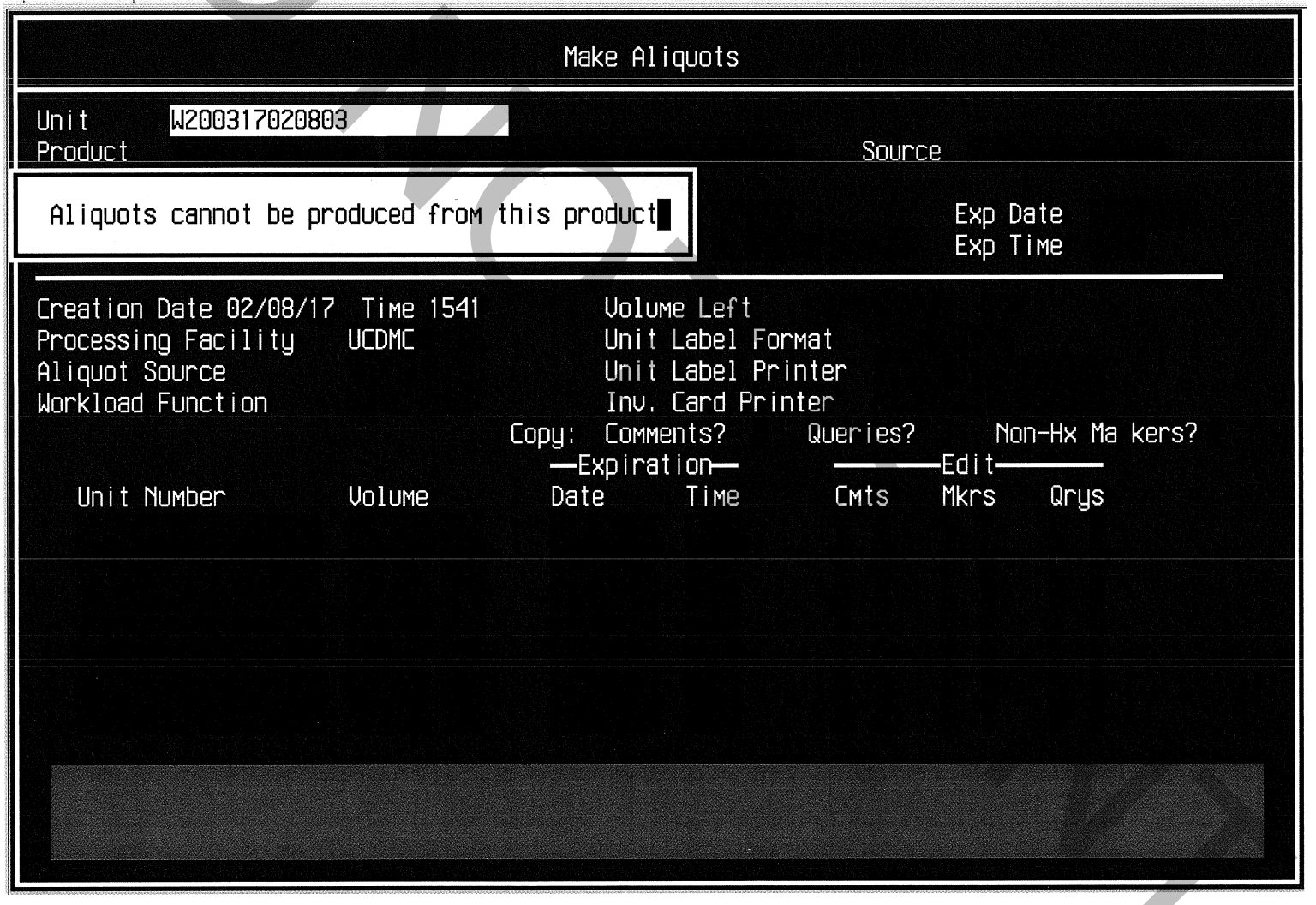
Place A label on main bag



Place B label on transfer bag

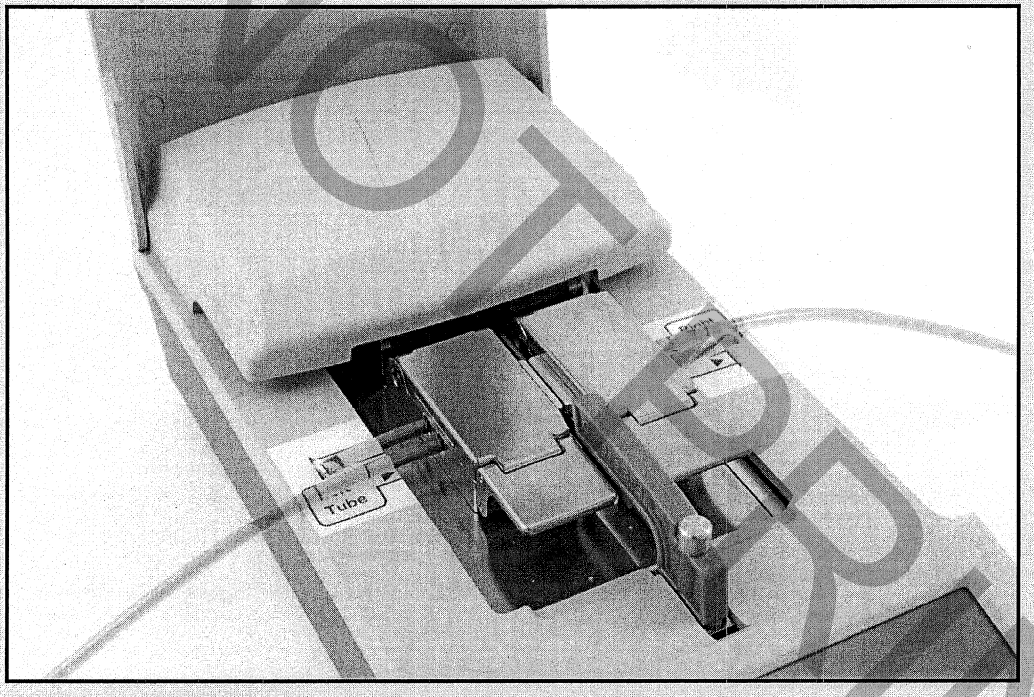

Font
Paragraph
Drawing
Editing
LAB.UCD (A1/TEST.5.66.MIS/327/.) - WILLIAMSON,LORI
Options Edit Help
Make Aliquots
Unit W200317020801
Product PA-E3046 PLT APHERESIS IRR LR ACD-A Source ARC DOUGLASVILL
Reserved
Source Blood Type AP Volume 295 Exp Date 02/12/17
Blood Type AP Status AVAILABLE Exp Time 2359
Creation Date 02/08/17 Time 1528 Volume Left 0 ML
Processing Facility UCDMC Unit Label Format .UNITB
Aliquot Source ARC.AG Unit Label Printer BBUL2
Workload Function Inv. Card Printer
Copy: Comments? Queries? Y Non-Hx Markers?
Expiration Edit
Unit Number Volume Date Time Cmts Mkrs Qrys
W200317020801A 140 ML 02/12/17 2359 ✓
W200317020801B 155 ML 02/12/17 2359 ✓
Checked for hemolysis,bubbles,color,clots,and intact ports Y
Filed W200317020801A, W200317020801B

If you choose a platelet product that is NOT eligible for aliquots, you will get this message.



THE GENESIS RAPIDWELD™ STW

Model: GRW-430



OPERATOR'S MANUAL

Contents

1 Description of Safety Symbols

□ WARNING

"Warning" indicates inappropriate use of the device may result in serious injury to the user and damage the device. User must follow the procedures as specified in this manual.

□ CAUTION

"Caution" indicates the presence of a hazard that could result in an adverse event on the user and potentially damage the device if ignored.

☞NOTICE

"Notice" informs the user in the event of a failure to follow the instructions described in this manual. "Note" also informs the user a specific function may or may not be executed or will not produce the desired effect if the instructions are not followed accordingly.

2 Warnings, Service and Cleaning

This manual will provide the information necessary to operate and maintain the **GENESIS RAPIDWELD™ STERILE TUBE WELDER (STW).**

It is very important for the operator to read and follow all procedures outlined in this manual. If the procedures are not followed the device may not perform to manufacturer's specifications and could result in leaking non-sterile welds or other non-anticipated outcomes. If a problem is encountered and not addressed in this manual, or if there are additional questions pertaining to the use or maintenance of this device, the operator should contact Genesis BPS Technical Support Staff at 1-866-712-5663 or send an e-mail to info@genesisbps.com.

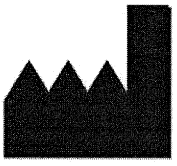
☞NOTICE The **GENESIS RAPIDWELD™ STW** has been designed for making sterile connections of PVC tubing for blood processing applications. The device, tube holders and clamps have been designed to accommodate and weld medical PVC tubing within the range specified in this manual. (See section 5.1) Tubing of same diameter should be used to result in a leak free, sterile weld. Medical PVC tubing complying with the ISO standard 3826-1:2013 and having the dimensions specified in this manual can be used. Genesis BPS validated the device's ability to perform welds on medical PVC tubing with the following dimensions: OD 4.26mm/ ID 2.99mm/ WT .63mm. Users should carefully check the welds according to the instructions in this manual. If, for any reason the weld is leaking, the sterility of the system may be compromised resulting in possible contamination. The operator should follow locally established procedures to avoid contamination.

☐ CAUTION When this device is introduced into a new blood bank setting the new operators should conduct an in house validation study to demonstrate the device works as intended in that particular setting by conducting 30 practice welds with appropriate tubing and confirm the welds are fully functional.

☐ CAUTION The **GENESIS RAPIDWELD™ STW** is an electro-mechanical device designed for rugged performance and routine usage. However, spillage of liquid into the device may cause irregular performance and could result in leaking, non-sterile or weaker welds. In the event of a spill into the device, operations must be discontinued. The device should be placed into a sealed plastic bag. Contact Genesis BPS Technical Support Staff at 866-712-5663 or 201-708-1400 or send an e-mail to info@genesisbps.com for further instructions.

WARNING While operating the **GENESIS RAPIDWELD™ STW**, do not attempt to connect to external communications circuits. USB Ports should only be connected to listed UL 60950 (ITE) equipment or listed UL 61010 equipment. The Ethernet Port should only be connected to equipment with a maximum 60 V DC output/connection to the equipment. The Barcode Port should be connected to listed equipment or equipment that has a maximum 60 V DC output/connection to the equipment.

WARNING Genesis BPS does not recommend opening the device or any other attempts to service the **GENESIS RAPIDWELD™ STW.** This could result in possible injury and will void any and all warranties. This device must be serviced by manufacturer authorized service technicians. The operator should contact:



Genesis BPS LLC
465 Route 17 South
Ramsey, NJ 07446, USA
Tel. 201 708 1400
Fax 201 708 1104

Genesis BPS Technical Support Staff
USA:866-712-5663 or 201-708-1400 or send an e-mail to info@genesisbps.com.
International Customers e-mail: info@genesisbps.com

NOTICE The operator should not use solvents or abrasives to clean the **GENESIS RAPIDWELD™ STW**. A 10% solution of commercial bleach or a 70% solution of isopropyl alcohol is recommended to clean the surface of the device only. If used properly and no blood spills are encountered, the device requires limited maintenance. Implementing a surface cleaning regimen (daily, weekly, monthly) is at the discretion of the end user based on the overall usage. The operator should not submerge the device in water or allow any fluid to seep into the device.

3 Introduction

The **GENESIS RAPIDWELD™ STW** is a bench top, portable device protected by three device specific patents. The **GENESIS RAPIDWELD™ STW** is intended for use by appropriately trained and qualified personnel in hospitals, laboratories, and/or clinical settings for the purpose of making sterile connections of polyvinyl chloride (PVC) tubing in blood processing applications.

The **GENESIS RAPIDWELD™ STW** provides sterile connection technology developed for the purpose of connecting sterile blood product containers without opening the system and compromising the sterility of the contained fluids. The **GENESIS RAPIDWELD™ STW** is used in blood processing applications to enable the user to make sterile connections between two tubes of PVC tubing. This allows the blood processing system to remain functionally closed. Tubing may be attached to bags, needles, filters, apheresis, infusion, aliquot or collection sets. The **GENESIS RAPIDWELD™ STW** welds wet to wet, wet to dry and dry to dry tubing combinations.

- The unique patented CLAMPS use technology designed to STRIP fluid away from the weld site, simulating a tube stripper, thus eliminating blood cell necrosis in the blood product.
- Parallel tube loading is simple and easy.
- The **GENESIS RAPIDWELD™ STW** is a waferless device that does not require the use of a consumable wafer for each weld.
- Weld time is extremely fast, creating a sterile weld in approximately 14/15 seconds making it ideal for high volume sterile tube welding processes.
- The portability and small size makes the **GENESIS RAPIDWELD™ STW** easy to use, move, and store.
- The device is designed for indoor use only

3.1 Features Summary

The **GENESIS RAPIDWELD™ STW** mechanisms are housed within a case. The hinged case lid must be closed for the device to operate.

- **Locking Safety Cover**: provides protection for the operator while the weld operation is in progress. It also serves to inhibit accidental or unintentional interruption of the weld process and the removal of the PVC tubing prior to the weld cycle completion. The clear viewing window enables the operator to observe the weld cycle while in progress.

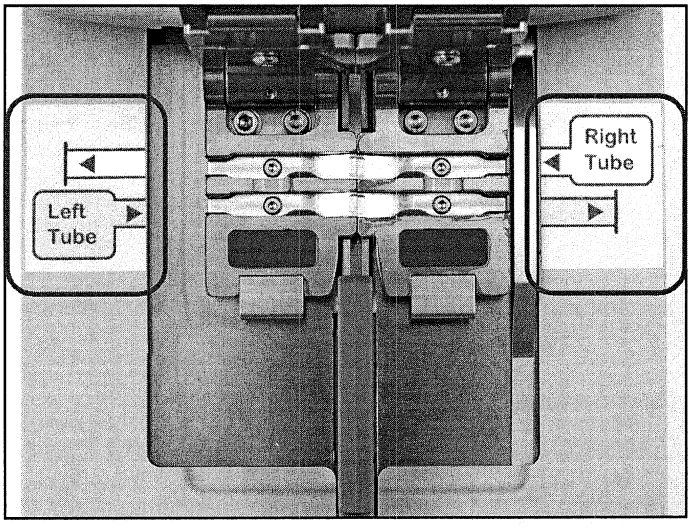
4.5 Operator Control Panel

The **GENESIS RAPIDWELD™ STW** is controlled by a color touch screen control panel located at the front of the device. Audio and visual indications are provided to the operator for information on the **GENESIS RAPIDWELD™ STW** status, operation, operator input requirements, fault conditions and operator error warnings.

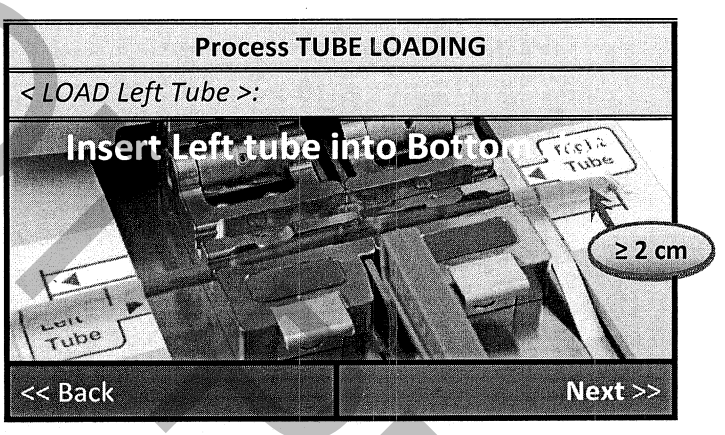
4.6 Power Supply

The power supply provides a regulated 12 volt direct current to the **GENESIS RAPIDWELD™ STW** via an interconnecting cable. The power supply input cord is fitted with a hospital grade plug, which must be connected to a hospital grade receptacle in order to achieve grounding reliability. Positive locking features are provided on the interconnecting cable to avoid accidental disconnecting of the **GENESIS RAPIDWELD™ STW** during operation. A red dot on the power supply output cable connector illustrates the correct orientation into the device's rear power receptacle.

NOTICE Tubes must be placed in the slots according to the labels located on the sides of the tube holder clamps. This will ensure the Top Right main line is welded to the Bottom Left main line. Reversed tube loading will result in heat sealed stub ends, but the main lines will not be welded together.



5. **LEFT TUBE LOADING** – Follow instructions for "Tube Loading" as they appear on the screen.

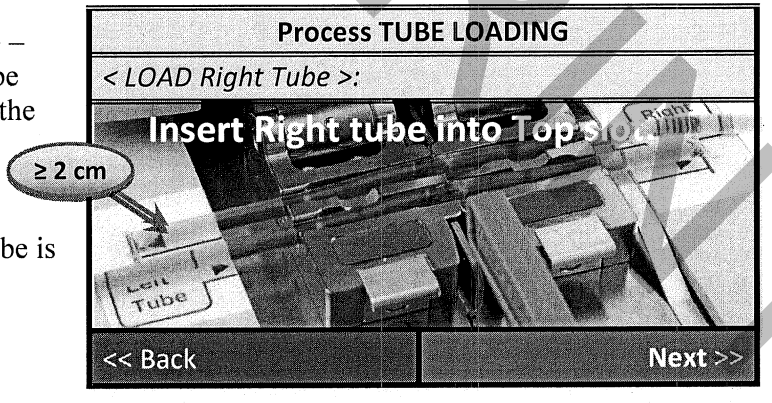


NOTICE Allow at least **2 cm** (3/4 inch) of tubing to overhang outside of the clamps.

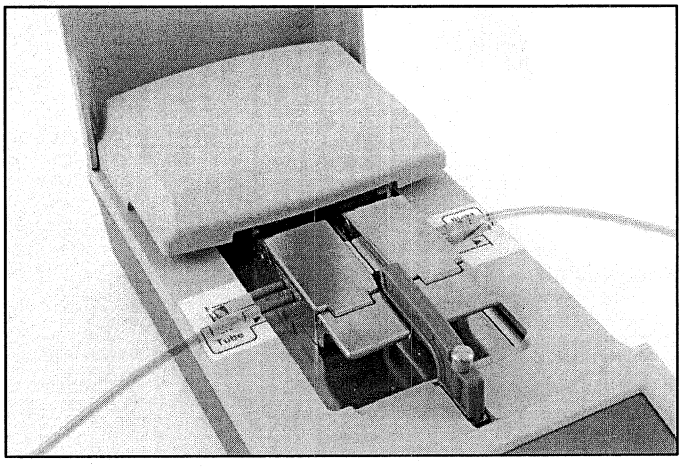
6. Press "Next" after left tube is properly loaded.

7. **RIGHT TUBE LOADING** – Follow instructions for "Tube Loading" as they appear on the screen.

8. PRESS "Next" after right tube is properly loaded.

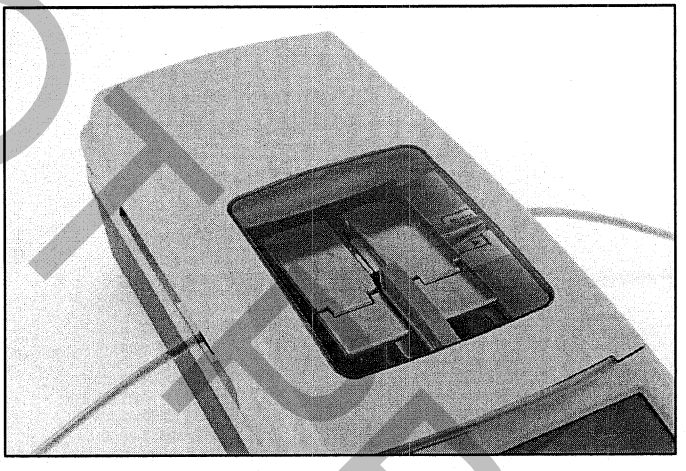


9. Once tubes are properly loaded close and latch the tube holder clamps.



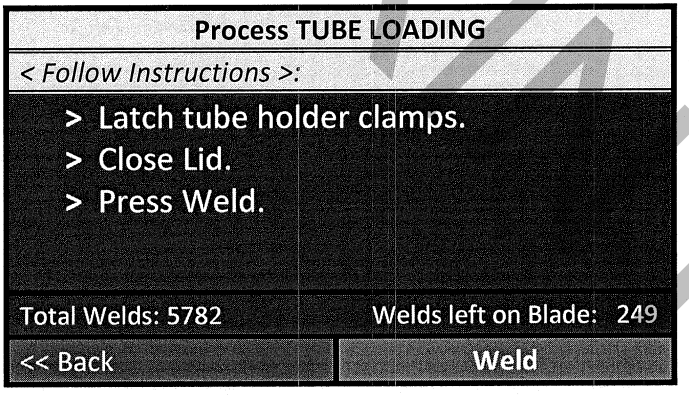
NOTICE Before closing the tube holder clamps, both the bottom and top slots must be loaded with tubing

10. Close the Case Locking Lid

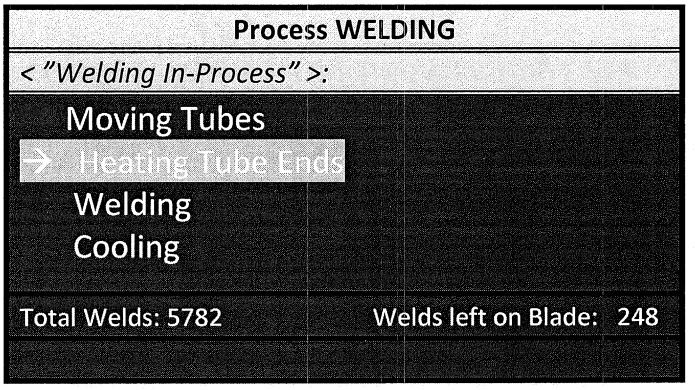


WARNING Make sure the case Locking Lid is closed before pressing WELD on the display screen.

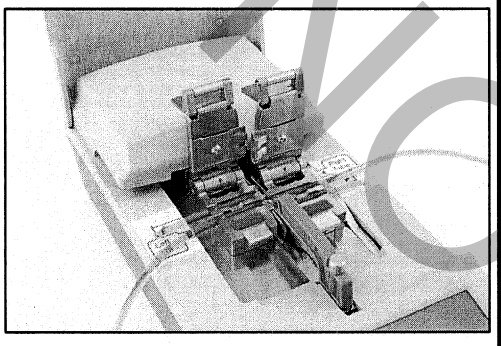
11. Press "WELD". The Case Locking Lid will lock and the weld process will proceed.

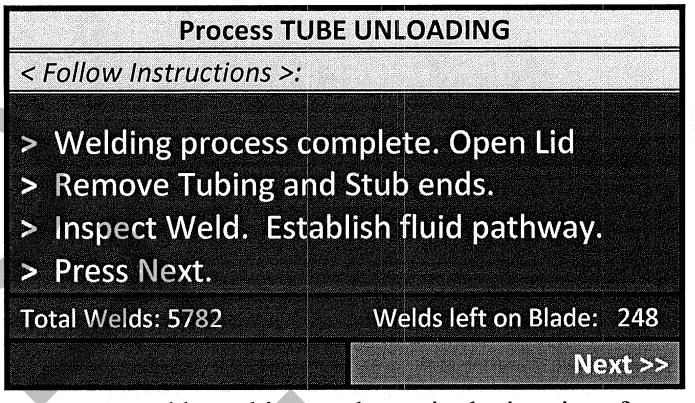


12. **Weld Cycle**: During the weld cycle the display screen displays each individual process.



13. **Tube Unloading:** The display screen displays "**Welding Process Complete**. The Lid Case unlocks to allow removal of tubing. Remove excess tubing (stub ends). Remove welded tubing.

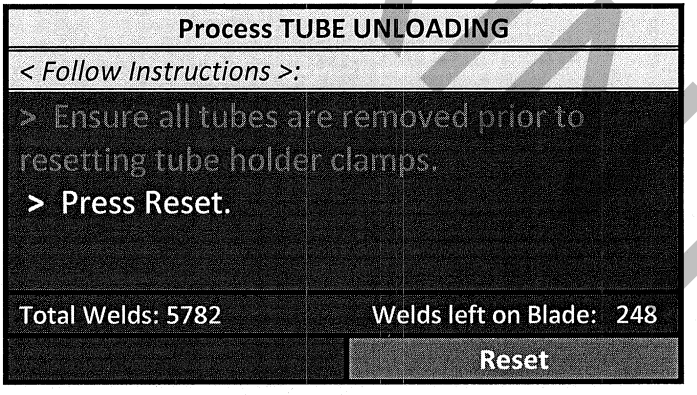




14. **Weld Opening:** The welded tubes are separated by a thin membrane in the interior of the weld site. This thin membrane must be opened manually to establish a fluid pathway after completion of the welding process. (Reference Weld Inspection section 5.4 below.)

NOTICE Although the stub ends are heat sealed, the seal is not strong. Therefore do not subject the ends to excessive force. Use a commercial tube sealer if a strong permanent seal is required.

15. **RESET:** Press "RESET" to reposition tube holder clamps for the next weld cycle. The Main Menu appears and the device is ready for another weld cycle. To perform another weld cycle, the operator should repeat instructions (1-13)



5.4 Weld Inspection

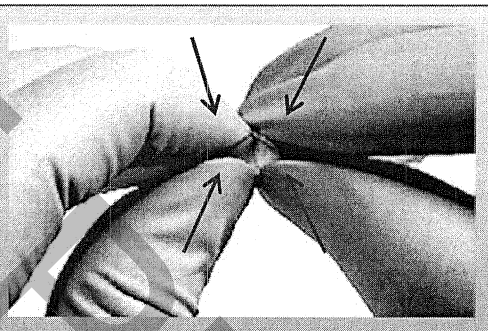
The **GENESIS RAPIDWELD™ STW** was designed to produce strong, leak-free welds if used in accordance with this operation manual. The following section details the process for examining the quality and strength of welds prior to the opening of the fluid pathway in the blood processing system.

1. Examine the weld for leaks by visual inspection of the weld area.
   a. If the weld is leaking without any stress being placed on the tubing, operation should be discontinued.

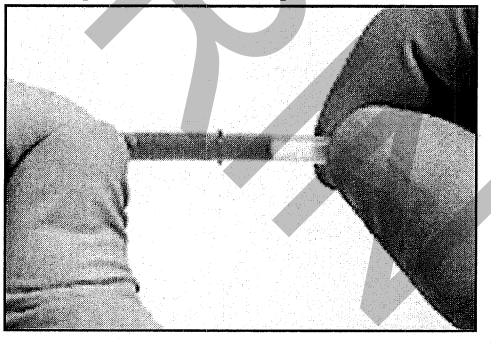
WARNING **Any blood products exposed to leaking welds should be considered contaminated and processed according to established procedures.**

   b. Ensure all steps in the operation manual have been followed.
   c. If it is determined that operator error **is not** the cause of the poor weld and leaks continue to be a problem, discontinue operations and contact Genesis BPS Technical Support Staff at 866-712-5663 or 201-708-1400 or send an e-mail to info@genesisbps.com.

2. ***Opening the weld:*** Position your fingers close to the left and right side of the the weld site. Open the weld by squeezing the flared edges of the weld between your thumbs and forefingers and slightly rolling it.



3. Rolling the tubing between the fingers will restore the original tubular shape.



4. Squeeze the contents past the weld and pull on the tubing.

WARNING The operator should avoid excessive or abusive handling of the welded tubing. Excessive pulling or bending of the weld could result in a leak. As with non-welded tubing, welded tubing should not be exposed to any solvents or excessive stress such as heat or cold. Such exposure could compromise the integrity of the weld.

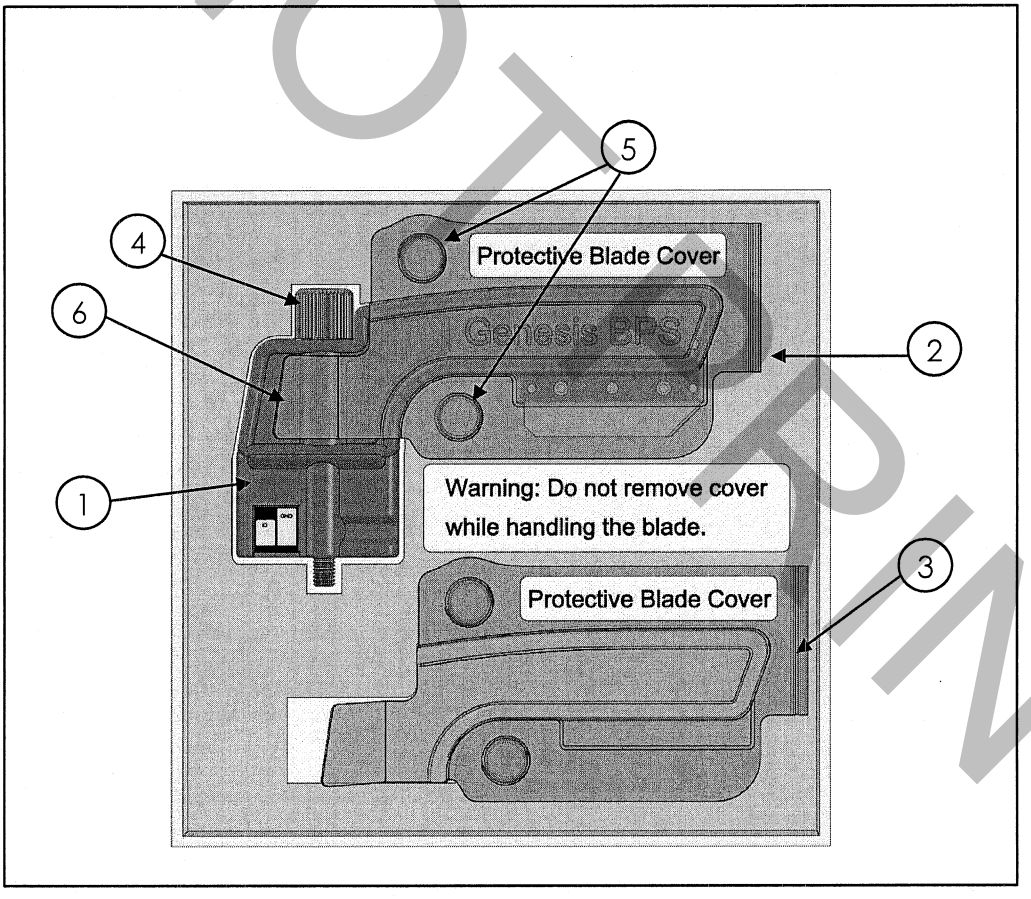
6 Blade Module Replacement

6.1 Description Blade Module

The **GENESIS RAPIDWELD™ STW** is designed with a built in service meter to record the number of welds performed on the device. This feature monitors the usage endured by the Blade Module. The operator is warned when the Blade Module is nearing required replacement. If the operator fails to respond to the warning message, the **GENESIS RAPIDWELD™ STW** will not operate. You can restart and continue using the device once a new blade module is installed.

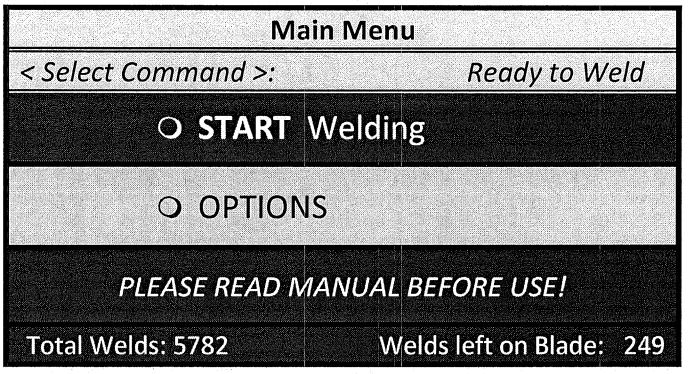
Photo of Blade Module Replacement Kit Identifying Key Components

1. Replacement Blade Module
2. Protective Blade Cover
3. Spare Protective Blade Cover (Install over used Blade Module prior to removal.)
4. Thumb Screw
5. Plastic Snaps
6. Wing Tabs

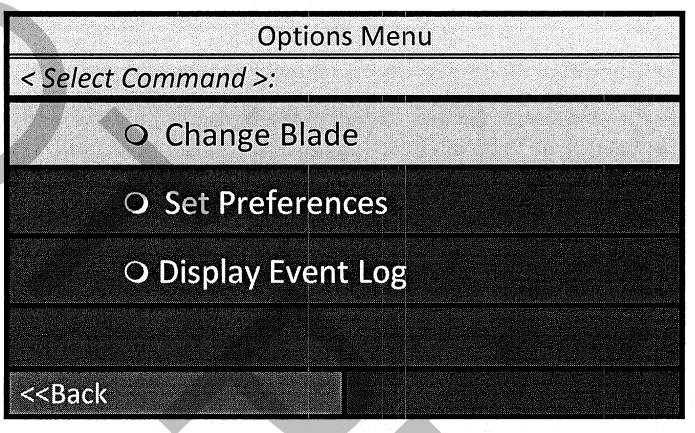


6.2 How to replace the Blade Module

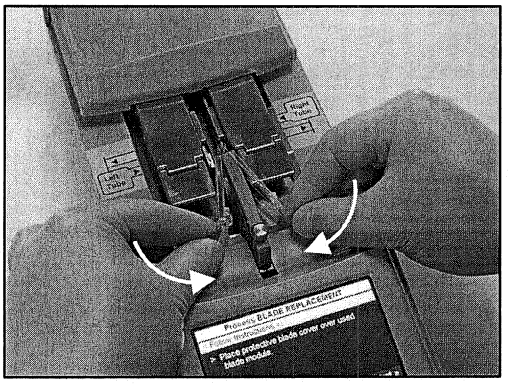
1) Select "OPTIONS" on the Main Menu.

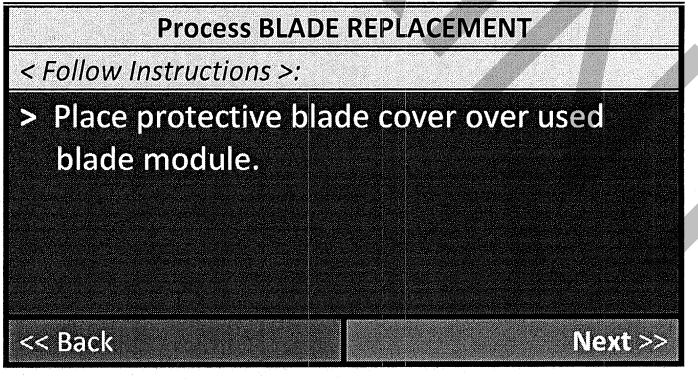


2) Select "Change Blade" on the Options Menu.



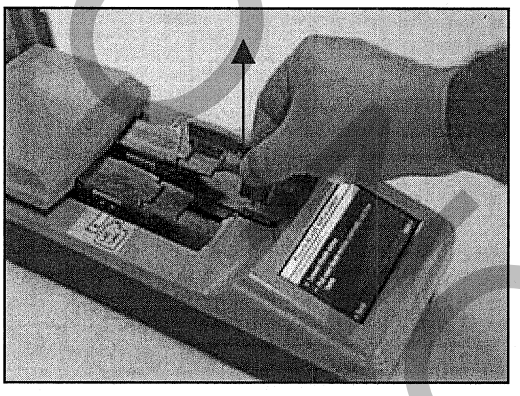
Clamps are repositioned to allow blade replacement. Included in the package is a protective blade cover. Place protective blade cover over used blade module. Close plastic snaps. Press "Next".

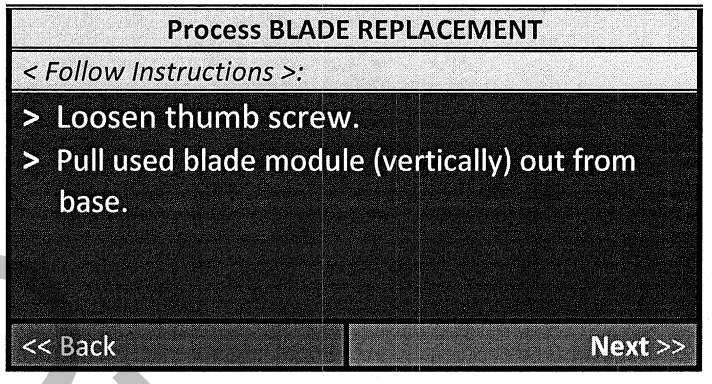




3) Loosen thumb screw (Counter Clockwise).

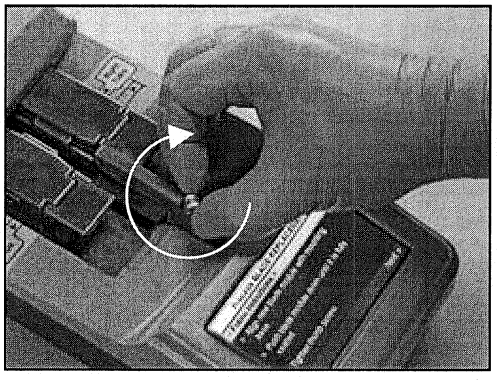
4) Pull blade module (vertically) out from the blade module mounting base. Discard according to internal procedures. Press "Next".

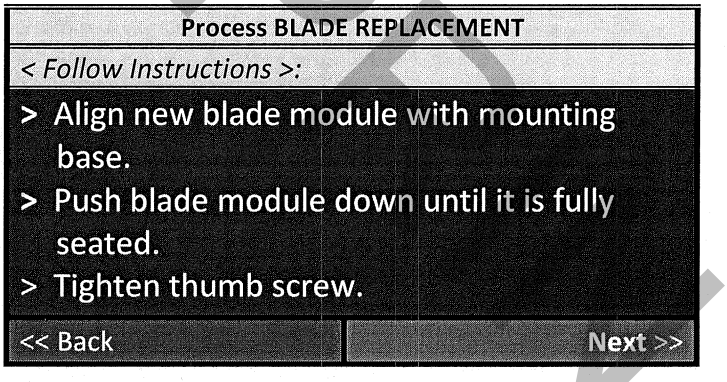




5) Remove new blade module from package. **Do not remove protective cover until blade module is fully installed.**

6) Carefully align the new Blade Module with mounting base. **Push blade module down until it stops moving and is fully seated in place.**

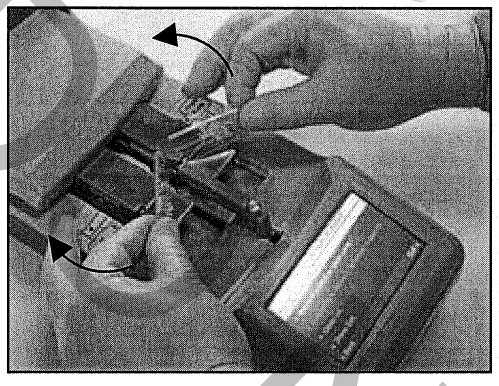


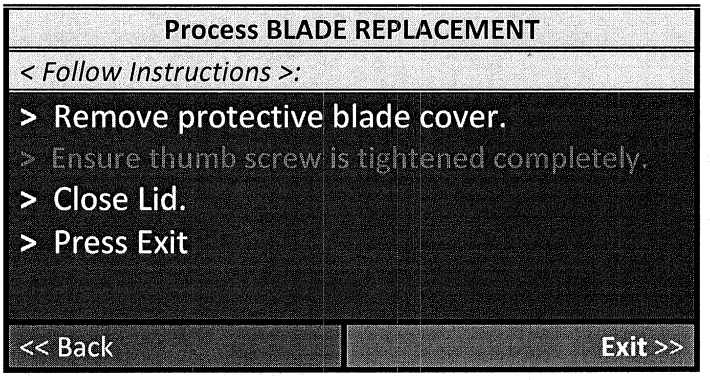


7) Tighten thumb screw to secure and lock blade module in place. Press "Next".

NOTICE Make sure blade module is locked in place.

8) Remove protective blade cover by pulling wing tabs apart.

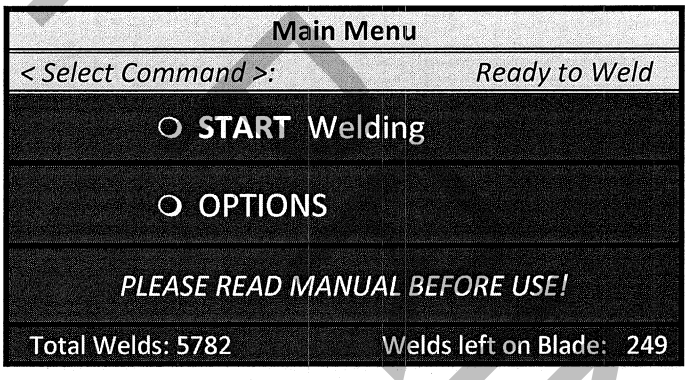




9) Close Lid and Press "Exit" on display screen to return to MAIN MENU.

NOTICE Device will only exit Blade Replacement process when Lid is closed.

10) The **GENESIS RAPIDWELD™ STW** is now reset to resume a weld cycle.



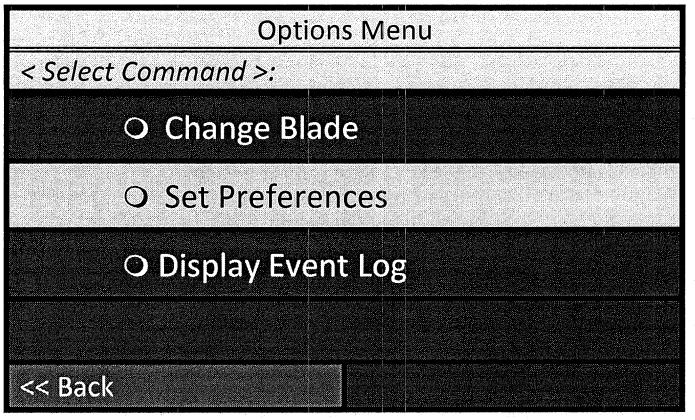
NOTICE Software will not allow operation to resume until new blade is installed.

7 Set Preferences

The Set preferences menu allows users to set the date and time, and change miscellaneous device settings.

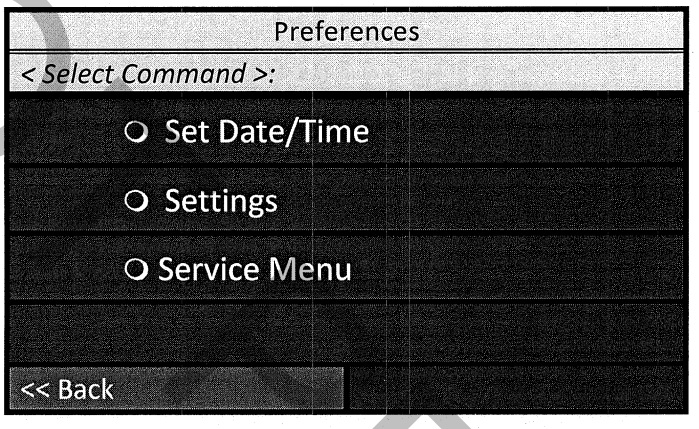
7.1 Set Date/Time

The Set Date/Time menu allows users to set the date and time for the device. Time is entered using the 24 hour format. Date formats can be selected using the Settings menu screen.



7.2 Settings

The Settings screen allows the user to change various device settings. Pressing the "↑" button cycles through the available settings.



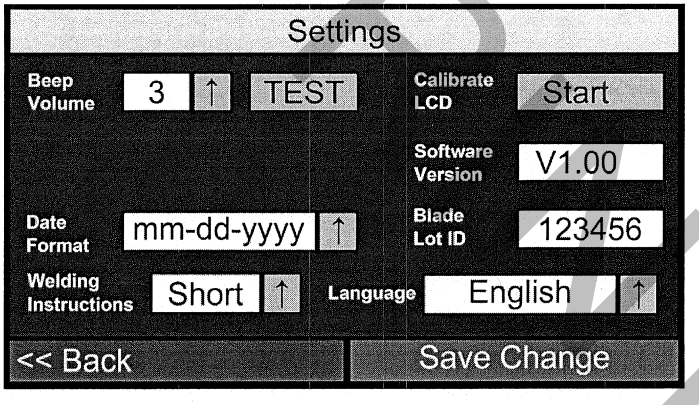
Beep Volume sets the volume of touchscreen beeps. Pressing the "TEST" button will play a preview of the new beep volume.

Date Format changes the formatting standard used by the device.

Calibrate LCD runs the touch screen calibration routine. Follow the on-screen instructions to calibrate the touch screen. Calibration may be needed if touches are not being accepted or activating the wrong items.

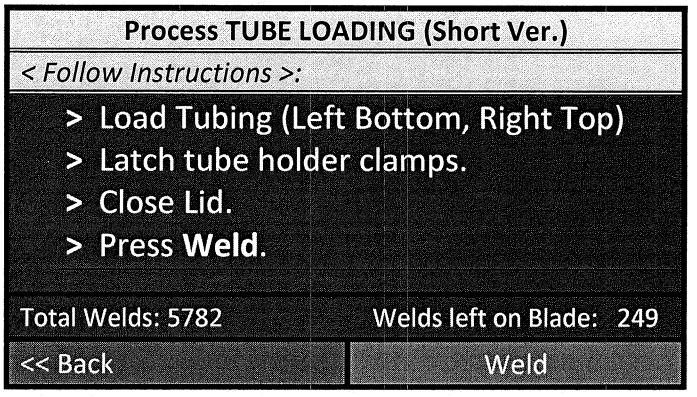
Software Version displays the installed software version number.

Blade Lot ID displays current blade module lot number.



Language toggles between device language options. Press the toggle button until the desired language is selected. Then press save change to apply the language.

Welding Instructions toggles between long or short versions of the loading instructions. Long instructions are the default mode and displays detailed, guided directions for tube loading before each weld cycle. The Short version, intended for experienced users, reduces instructions to one screen, allowing for faster tube loading.



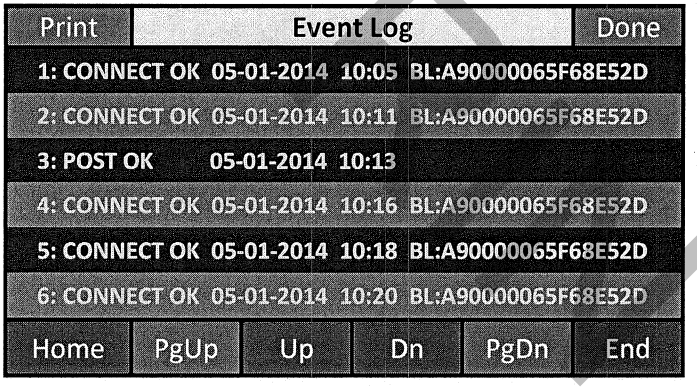
Press the **Save Change** button to accept or the **Back** button to cancel changes.

7.3 Service Menu

The service menu is used only for diagnostic purposes and is not accessible by the user.

8 Display Event Log

The Event log allows the user to review the operational history of the device. A rolling log of the last 2,000 events is saved. The most common events recorded are the Power-On Self-Test (POST) results and weld connections. Every time a weld connection is successfully completed the date, time, and blade serial number are recorded. Additionally, the firmware continuously monitors the performance of the heater, fan, and motors; any errors detected will be recorded in the event log.



The **Up** and **Dn** buttons scroll through the log, one record at a time. The **PgUp** and **PgDn** buttons scroll through an entire page at one time. The **Home** button jumps to the beginning of the log starting with the oldest record. The **End** button jumps to the end of the log displaying the latest record. The **Done** button will exit the event log.

The Print button outputs the event log through the front Mini USB COM port. The current software version requires the use of a Windows terminal program to capture the event log output.

9 Troubleshooting Guide

The **GENESIS RAPIDWELD™ STW** monitors each weld cycle for operation errors and instrument faults. If an error is detected, an appropriate error message and instruction will be displayed on the color touch screen display panel.

9.1 Device Fault Detection

The **GENESIS RAPIDWELD™ STW** monitors the status of the device beginning with a short diagnostic routine. Before each weld cycle, the **GENESIS RAPIDWELD™ STW** tests for sufficient voltage and whether the memory and heater are functioning within specifications. During a weld cycle the heaters are continually monitored for various error conditions. This monitoring is performed to ensure proper operating conditions are maintained during a weld cycle. Key mechanical functions are also monitored to identify mechanical problems requiring service.

In order to ensure the safety and efficacy of the device, the **GENESIS RAPIDWELD™ STW** prevents continued operation when a device fault is detected. The device fault alarm message appears on the display screen in a RED pop-up window. The device displays the Error Message continuously until the pop-up message is dismissed by pressing the "OK" button or the device times out and powers down. The following table summarizes the device Event Log Codes, fault conditions and messages. The Event Log is viewable in the OPTIONS/Display Event Log menu. If an error is detected, contact Genesis BPS for technical support.

WARNING Precautionary measures are required if the device fails to complete a weld cycle. The tubes will likely be cut but NOT SEALED if the device failed to reach the heating position. In the event of a stalled motor the device will attempt to move the tube holders back to the Unload position to allow removal of the tubes. Prior to releasing the tube holder clamps, it is recommended that hemostats or other appropriate tube clamps be used near the tube holders to reduce spillage.

9.2 Device Fault Event Code Table:

If the **GENESIS RAPIDWELD™ STW** detects any of the error conditions below, the device will shut down disabling all functions. Please contact your local Genesis BPS representative for service. All error or alarm events are Date and Time stamped and saved in an Event Log.

Event Log Code	Displayed Message	Description	Corrective Action
LOW POWER	-STARTUP FAULT- Low System Power OK	Power supply voltage below lower limit.	Check power connections. Restart.
AMB SENSOR	-STARTUP FAULT- Ambient Sensor Failed OK	Internal ambient temperature sensor not communicating.	If error persists contact Genesis BPS for technical support.
HtSink Snsr	-STARTUP FAULT- Heat Sink Temp Sensor Failed OK	Heat Sink temperature sensor not communicating.	If error persists contact Genesis BPS for technical support
LOW FAN RPM	-START UP FAULT- Low Fan RPM OK	Fan Speed below lower limit.	If error persists contact Genesis BPS for technical support.
NO BLADE	-START UP FAULT- Blade Missing OK	Blade Module not detect during startup.	Install Blade Module
HEATER OPEN	-STARTUP FAULT- Heater Open OK	No measurable heater current flow.	Contact Genesis BPS for technical support.
HTR RES LOW	- STARTUP FAULT - Heater Resistance Low OK	Heater resistance below lower operating threshold limit.	Contact Genesis BPS for technical support.
HTR RES HI	- STARTUP FAULT - Heater Resistance High OK	Heater resistance above upper operating threshold limit.	Contact Genesis BPS for technical support.

NO CUTS REM	-DEVICE FAULT- No blade cuts remaining OK	Blade Module weld count has reached zero.	Run Change Blade routine. Follow instruction to install new Blade Module.
ClampNtOpen	-DEVICE FAULT- Clamp failed to Open OK	Clamp Lock motor exceed current limit during release move.	Contact Genesis BPS for technical support.
ClampNtClsd	-DEVICE FAULT- Clamp failed to Close OK	Clamp Lock motor exceed current limit during locking move.	Contact Genesis BPS for technical support.
CARG MTR I	- DEVICE FAULT- Carriage motor overcurrent OK	Carriage Motor exceeded current limit.	If error persists contact Genesis BPS for technical support.
STLD->BKOFF	STALLED: Carriage failed to reach target Backoff position OK	Time limit exceeded for programed move.	Press OK to shut down. If error persists contact Genesis BPS.
STLD->HOME	STALLED: Carriage failed to reach target Home position OK	Time limit exceeded for programed move.	Press OK to shut down. If error persists contact Genesis BPS.
STLD->LOAD	STALLED: Carriage failed to reach target Load position OK	Time limit exceeded for programed move.	Press OK to shut down. If error persists contact Genesis BPS.
STLD->XCHNG	STALLED: Carriage failed to reach target Blade Change position OK	Time limit exceeded for programed move.	Press OK to shut down. If error persists contact Genesis BPS.
FltRecFail	- FAULT RECOVERY FAILED – Following user manual, try to unload tubes, then press OK. OK	Move to reposition clamps after weld cycle fault failed to reach target.	Press OK to shut down. Tube holders may not be in a position to remove tubes. Use external tube clamps to shut off tubes.

9.3 Operator Warning Event Code Table:

If a fault is detected during the weld process the software will interrupt the weld cycle and give appropriate instructions to handle the fault. In the case of a stalled carriage motor, the device will attempt to recover from the fault condition and move the tube holders back to the load position to allow access to the tubing. All weld process fault events are Date and Time stamped and saved in an Event Log.

Event Log Code	Displayed Message	Description	Corrective Action
LOAD TUBES	LOAD TUBES Press OK OK	Tube Sensor Bar is not detecting tubes loaded in the tube holder clamps prior to initiating the weld cycle.	Ensure Bottom Left and Top Right tube holder slots are properly loaded. Press OK.
CLOSE LID	CLOSE LID Press OK OK	Lid Sensor is detecting the Lid is not closed as requested.	Ensure the Lid is seated completely closed. Press OK.
UNLOAD TUBES	UNLOAD TUBES Press OK OK	Tube Sensor Bar is detecting the tubes have not been removed as requested.	Ensure all tubing has been removed from the tube holder clamps. Close clamps and press OK.
AMB COLD	Process HANDLE FAULT ~ < Follow Fault Instructions >: > Device too cold for welding due to low Internal temperature reading. > Close Lid and press Continue to enable Warming cycle. (Reference Manual) Continue	Internal ambient temperature sensor below operating limits. Device may have been stored in a cold environment.	Close Lid and press Continue. The device will turn on the heaters and enter a warming cycle. Allow the GENESIS RAPIDWELD™ STW to warm up above 10 °C (50 °F).
AMB HOT	Process HANDLE FAULT ~ < Follow Fault Instructions >: > Device too hot for welding due to high Internal temperature reading. > Close Lid and press Continue to enable cooling cycle. (Reference Manual) Continue	Internal ambient temperature sensor above operating limits.	Close Lid and press Continue. The device will turn off the heaters and enter a cooling cycle. Allow the GENESIS RAPIDWELD™ STW to cool.
BOGUS XCHNG	Process HANDLE FAULT~ < Follow Fault Instructions >: > Invalid blade exchange detected. Please use full Change Blade Option in the future. Continue	Blade Module changed without using the proper programed Change Blade routine.	Use the Change Blade routine under the Option Menu.
HtSink HOT	Process HANDLE FAULT ~ < Follow Fault Instructions >: > Device too hot for welding due to high Internal temperature reading. > Close Lid and press Continue to enable cooling cycle. (Reference Manual) Continue	Internal Heat Sink temperature sensor above operating limits.	Close Lid and press Continue. The device will turn off the heaters and enter a cooling cycle. Allow the GENESIS RAPIDWELD™ STW to cool.
Mov2Ht<5MM	Process HANDLE FAULT < Follow Fault Instructions >: > Device failed to completely cut tubing. > Warning! Tubes are open! > Press Continue, wait for tube reset, then follow prompt.	Weld cycle failed to reach cut position. Tube Holders will attempt to return to Load position.	Tubes may be open! Use external tube clamps to seal tubes prior to releasing clamp latches.

PARTIAL CUT	Process HANDLE FAULT < Follow Fault Instructions >: > Device failed to completely cut tubing. > Warning! Tubes are open! > Press Continue, wait for tube reset, then follow prompt. Continue	Weld cycle failed to reach final cut position. Tube Holders will attempt to return to Load position.	Tubes may be open! Use external tube clamps to seal tubes prior to releasing clamp latches.
Move2Ht<Load	Process HANDLE FAULT ~ < Follow Fault Instructions >: > Device failed to reach Heat position. > Warning! Tubes may be open! > Press Continue, wait for tube reset, then follow prompt. Continue	Weld cycle failed to reach heat position. Tube Holders will attempt to return to Load position.	Tubes may be open! Use external tube clamps to seal tubes prior to releasing clamp latches.
Move2ht<5MM	Process HANDLE FAULT ~ < Follow Fault Instructions >: > Device failed to reach Heat position. > Warning! Tubes are sealed but not welded! > Press Continue, wait for tube reset, then follow prompt. Continue	Weld cycle failed to reach final heat position. Tube Holders will attempt to return to Load position.	Tubes may be sealed but not welded. Unload Tubes. Press OK.
Mov2WeldBad	Process HANDLE FAULT < Follow Fault Instructions >: > Device failed to reach Weld position. > Warning! Tubes sealed but not welded. > Press Continue, wait for tube reset, then follow prompt. Continue	Weld cycle failed to reach final weld position. Tube Holders will attempt to return to Load position.	Tubes are sealed but not welded. Unload Tubes. Press OK.
Mov2UnldBad	Process HANDLE FAULT < Follow Fault Instructions >: > Device failed to reach Unload position but tubes should be properly welded. > Press Continue and follow instructions. Continue	Weld cycle failed to reach final unload position. Tube Holders will attempt to return to Load position.	Tubes are welded. Unload Tubes. Press OK.
ShutDn2Cut	Process HANDLE FAULT ~ < Follow Fault Instructions >: > Abnormal shutdown detected during last move to CUT. > Warning! Tubes may be open! > Press Continue, wait for tube reset, then follow prompt. Continue	Initial Startup routine detected that the previous weld cycle was interrupted during tube cutting move.	Tubes may be open! Use external tube clamps to seal tubes prior to releasing clamp latches.
ShutDn2Heat	Process HANDLE FAULT < Follow Fault Instructions >: > Abnormal shutdown detected during last move to HEAT. > Warning! Tubes may be open! > Press Continue, wait for tube reset, then follow prompt. Continue	Initial Startup routine detected that the previous weld cycle was interrupted during the move to heat position.	Tubes may be open! Use external tube clamps to seal tubes prior to releasing clamp latches.
ShutDn2Weld	Process HANDLE FAULT ~ < Follow Fault Instructions >: > Abnormal shutdown detected during	Initial Startup routine detected that the previous weld cycle was	Tubes may be open! Use external tube clamps to seal tubes prior to

	last move to WELD. > Warning! Tubes may be open! > Press Continue, wait for tube reset, then follow prompt. Continue	interrupted during the move to weld position.	releasing clamp latches.
ShutDn2Unld	Process HANDLE FAULT ~ < Follow Fault Instructions >: > Abnormal shutdown detected during last move to UNLOAD. > Warning! Tubes may be open! > Press Continue, wait for tube reset, then follow prompt. Continue	Initial Startup routine detected that the previous weld cycle was interrupted during the move to unload position.	Tubes may be open! Use external tube clamps to seal tubes prior to releasing clamp latches.

9.4 Normal Operation Event Code Table:

The CONNECT OK event is recorded every time a successful weld is completed. The Date, Time and Blade Module serial number are saved in the Event Log.

Event Log Code	Displayed Message	Description	Corrective Action
CONNECT OK	No Message Displayed	Weld cycle successfully completed. Date and Time of weld recorded in Event Log	None
BLADE XCHNG	No Message Displayed	Blade module exchange serial number Date and Time stamped in Event Log	None
POST OK	No Message Displayed	Power On Self-Test passed. Date and Time of test recorded in Event Log	None

10 Specifications

10.1 Mechanical Specifications

Characteristics	Values	
	GENESIS RAPIDWELD™ STW	**Power Supply**
Length	33 cm (13 in.)	18 cm (7.1 in.)
Width	14.2 cm (5.6 in.)	5.8 cm (2.3 in.)
Height	9.9cm (3.9 in.)	3.9 cm (1.5 in.)
Weight	2.5 kg (5.5 lbs)	0.69 kg (1.52lbs)
Power Cord	Power supply output cord length: 1.3m (4ft)	Power supply inlet: IEC 60320-C13 North American and International cord sets are available.

10.2 Electrical Specifications

Characteristics	Values
Power Supply Input Voltage	AC 100-240V
Operating Current	~ 1.0A
Frequency	50/60Hz
Power Supply Output	DC 12 V, 7.08A max, 85W max
Power Consumption	70 Watts max

10.3 Other Specifications

Characteristics	Values
Optimal Operating Temperature	10°C – 40°C ambient (50°F – 104°F)
Storage Temperature	10°C – 40°C preferred (50°F – 104°F)
Relative Humidity	10% - 90% (avoid condensing atmosphere)
Altitude	≤ 2000 meters (6560 feet)
Nominal Weld Cycle Interval	14/15 seconds

11 Regulatory Compliance Statements

The **GENESIS RAPIDWELD™ STW** is UL, Class 1.
The device should only be used with the power supply delivered with the **GENESIS RAPIDWELD™ STW** device.
The device should not be used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
The device should not come in direct contact with the patient during normal use.
The device does not require sterilization.
The device should be cleaned per manufacturer instructions.
A hospital-grade receptacle must be used to achieve grounding reliability.

CE Marking
The device is in compliance with applicable requirements of directive 93/42/EEC (Class 1 device).

UL Classification Mark
Electrical equipment for measurement, control, and laboratory use UL 61010-1, IEC/EN 61010-1.

The symbol  on the product indicates this product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard incorporating the same level of test requirements.

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Protected by U.S. Patent No. 7,398,813 8,066,269 8,708,019

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