ARCHIMEDE

User Manual

MOELCA s.r.l.

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CE

Manufacturer Responsibility

The instructions for use may contain a declaration that the Manufacturer, the Assembler, the Installer or the Importer consider themselves responsible for instrument safety, reliability and performance only if:

- assembling, extensions, adjustments, changes or repairs are performed by qualified service personnel under his authorization;
- the instrument is operated in a room whose electrical system applies with the relevant prescriptions;
- the instrument is operated according to the instructions for use.

The device complies with part 15 of the FCC Rules. Operation is subjected to the following 2 conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation"

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

COPYRIGHT

WARRANTY

MOELCA s.r.l. certifies that the instrument is free from any defect when shipped from factory. The warranty covers the instrument and all its parts for a period of 12 months from delivery date.

During the warranty period MOELCA s.r.l. will repair or replace free of charge (at its discretion and ex factory) the parts or units that prove to be defective. All parts or units replaced will become MOELCA s.r.l. property. The warranty is automatically voided in case of violations, changes, different use from that described in the instructions, wrong plugging in power mains, repairs performed by personnel not authorized by MOELCA s.r.l., accidental breakings due to transportation or falls, lack or deletion or modification of the serial number.

In case of repairs not covered by the warranty, MOELCA s.r.l. or its representatives will draw up a quotation and provide for repair upon written acceptance of the customer.

Service

During the warranty period the instrument should not be modified or repaired by personnel not authorized by MOELCA S.r.l. For information about service please contact:

Any repair **after the warranty period** should be performed by qualified personnel properly instructed by MOELCA s.r.l.

Manual Revision #	Software Revision #	Date	Author	Changes
1.00	1.00	01/03/2006	C. Milani	Original Document
1.01	1.08	21/07/2007	C. Milani	Change in separation procedures and WLAN.
1.02	1.12	03/03/2008	C. Milani	Modify like Fenwal suggestion.
1.03	2.00	06/06/2008	C. Milani	FCC ID rules-IP41
1.04	2.20	24/06/2008	C. Milani	Modify as PRS reference
1.05	2.25	10/01/2009	C. Milani	Change in troubleshooting.

The following list contains symbols and marks used in this manual.

Class I In this instrument the protection against direct and indirect contacts does not consist only of the basic insulation but, also of an additional safety measure.

Instrument with applied part type B.

CE mark certifying compliance with MDD 93/42 guideline.

SN Symbol for "SERIAL NUMBER".

Caution: please read attached documentation.

Caution: keep hands off this area.

Not ionized radiation.

Discard separately.

Manufacturer.

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1   INTRODUCTION

The present user manual describes functions, operation and using instructions of *Archimede*. Please read the present document before using the instrument, and keep it to hand for consultation in order to ensure proper system operation.

Archimede is an automatic extractor of emocomponents from whole blood. It allows to separate Erythrocytes, Buffy Coat, and Platelets from rich and poor plasma and platelet concentrate.

Both Standard and Top & Bottom bags can be used and, thanks to the high automatization one single operator can use several units at the same time. The laboratory productivity is therefore increased maintaining a high and standardized separation quality.

The separation procedure is continuously checked by a dedicated microcontroller. In case of alarm or if the preset parameter values are reached, the procedure is stopped.

1.1 Intended Use

Archimede should be used by <u>Qualified Personnel</u> only. It has been designed for the separation of emocomponents contained in hermetically sealed bags (bags containing whole blood and/or blood derivatives) consistent with the International Standard ISO 3826 and with the 93/42 MDD regulation. For optimum operation *Archimede* should be placed on a solid and stable surface, **preferably** away from direct heat sources.

1.2 Key features

- User-friendly interface.
- Graphic display of bags weight, force, and operation stages.
- Automatic delivery of Sag. M. through press.
- Variable speed separation movement, controlled by a stepper motor.
- Array of ten optical sensors for Buffy Coat level check.
- Optical detector of RBC, with electronic control of cover closure.
- Electronic control of the distance between plate and profile plate.
- Electronic control of the applied force with motor stop in case the safety limit is exceeded.
- Three scales with 2 Kg full-scale and 1 g resolution.
- Six clamps: four sealing-head clamps, one flow control clamp, one normal clamp.
- Mechanical buffy-coat separation system.
- Detection system of proper tubes positioning in each clamp.
- Can store up to 18 separation procedures, with approx. 40 parameters each.
- Self-tare and auto-calibration of the various measuring systems via software. Regulation trimmers have therefore been eliminated. The auto-calibration functions are managed directly by *ArchimedeLINK*.
- Can be used as a sealer and as a scale .
- Self-diagnosis program to make the solution of technical problems easier.
- Bi-directional data transmission via WLAN.
- PS2 port for barcode reader.
- Software update directly through PC.
- Built-in clock and calendar for traceability of the ongoing procedure.
- Optional RFID reader.
- Optional 2D bar code reader able to read multiple bar codes in one shot.

2 INSTALLATION

Archimede is a simple use highly versatile instrument allowing great automation.
It is supplied with preinstalled standard procedures that can be implemented and modified through *ArchimedeLINK*.

Picture 1: Parts included in the packing.

Upper bag holder   Barcode   WLAN antenna

Side scale holders   Magnetic filter holder

Profile plate   Support bar   Power cable

2.1 Unpacking Archimede

Remove *Archimede* from its packing. Take care not to crash the load cells.
Check that no part is damaged.

- *Archimede* is supplied with:
- Upper bag-holder plate and side scale-holders.
- Magnetic filter-holder. Pacemakers and floppy disk must keep away at least of 10 cm.
- WLAN antenna.
- Profile plate 2, 3, 4.
- Support bar.
- Power cable.
- Barcode reader.

2.2 Positioning Archimede

- Environmental conditions may affect *Archimede* operation. The following conditions should therefore be avoided or minimized:
- High temperatures, elevated humidity, proximity of free flames.
- Direct sunlight exposure.
- Elevated dust accumulation.
- Proximity of flammable substances.
- Unstable and non-flat surfaces or slippy.
- Separation distance of 20 cm must be maintained between the WLAN antenna and human bodies

2.3 Assembling scale, filter holders and antenna.

Lean the plastic plate on the upper scale holder. Screw the side scale holders paying attention to the load cells: the load cells are mechanically protected but, they should not be hit with force. Screw antenna and place it in vertical position. The filter holder is magnetic, and can be put in the most suitable position to support the filter during the procedures requiring filter use.

2.4 Switching on Archimede

The power cord must be plugged into a grounded power receptacle. When using an extension cord, make sure it is properly grounded. Any rupture of the ground lead inside or outside the instrument or a loose ground connection may result in hazardous operating conditions for the operating personnel. Intentional disconnection of the grounding is not permitted.

The correct value of line voltage and line fuses are indicated on the rear plate of the instrument.

Check that mains power switch on rear left is in **O** position. Then

plug the Barcode Reader into the socket marked with

Plug the power cord and turn the main switch on.
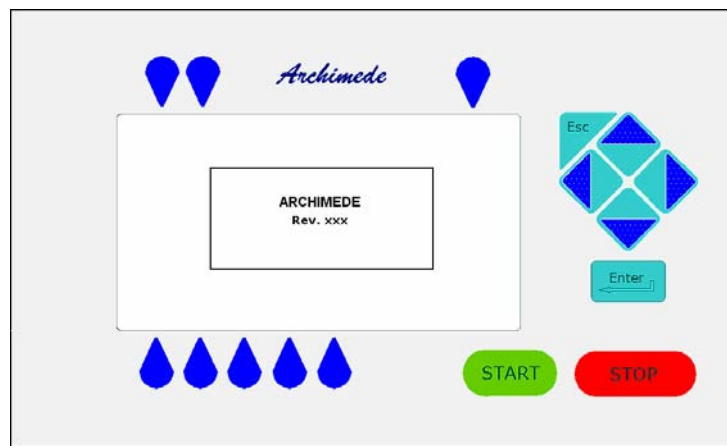
Picture 2: Archimede display

If Archimede is not in Stand Alone mode but is connected with ArchimedeLINK in WLAN, before proceed with the other controls it is necessary to set WLAN parameters. This configuration is described in the service manual at the paragraph configuration WLAN.

When the display lights on, instrument model and firmware software revision number should appear.

After verifying and initializing all data stored, *Archimede* performs a self-check of all measurement systems. In case of malfunction the display shows the problem detected and the possible remedy.
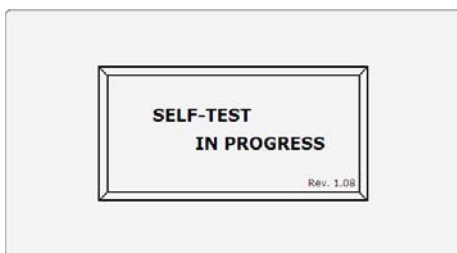
Picture 3: Screen shot "Self Test"

ATTENTION: DO NOT PUT YOUR HANDS IN THE FRONTAL PRESS PLATE WORKING AREA.

Press Plate Area

2.5 Instrument Setup

All sensitive data are preset in a non volatile RAM. They can be modified using *ArchimedeLINK*. Date and time are managed by a dedicated circuit that can operate for at least 60 days even without main power. However, if *Archimede* does not operate in stand alone mode, date and time are automatically updated when switching the instrument on, and get synchronized to *ArchimedeLINK*. When using the instrument for the first time, date and time need to be checked only if the system is not integrated with *ArchimedeLINK*.

2.5.1 Date and Time
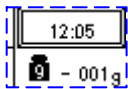
Using direction key-buttons highlight the display area indicating current date and time. Press to enter modify mode.
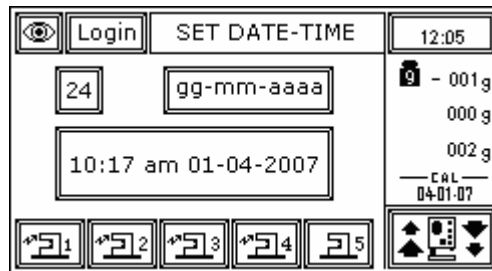
Picture 4: Date and time menu.

Set date and time using keys , up and down key to increase or decrease value, left and right to change the digit to modify and to confirm setting.

If you don't want to confirm the date and time change, press key .

FORMAT	READING
12	0-24
24	0-12 am/pm
dd-mm-yyyy	01-04-2008
mm-dd-yyyy	04-01-2008
yyyy-mm-dd	2008-04-01

Picture 5: Date and time format list.

Set current date and time, and confirm setting with key .

If you don't want to confirm the date and time change, press key .

2.5.2 Procedures Setup Check
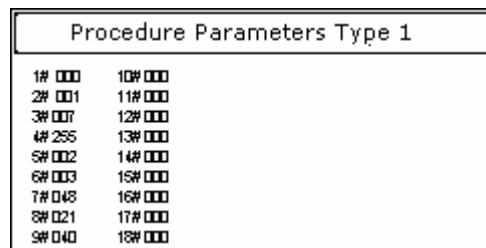
This check allows to verify all procedure parameters, and should be performed by the application specialist or service engineering. Procedure parameters and their meaning are described and can be set through *Archimede*LINK. The procedure is continuously displayed to enable users (above all those working in stand alone mode) to verify its correctness. To enter this menu press ▼ key-button above the icons 👁 and use direction key button ◆ to select PARAMETER LIST.

Picture 6: Utility menu.

Confirm setting with key Enter.

Using direction key-buttons ◆ it is possible to select the desired procedures.

Picture 7: Parameters procedures list

Archimedes due to its versatility enables automation combined with ease of use. It's setup with a minimum of standard procedures installed, implemented and modified through ArchimedeLINK with the help of a technical application.

3 GENERAL DESCRIPTION

Archimede consists of two parts:

- The electronic part includes a built-in microcontroller of the latest generation. Through this microcontroller the instrument can store the procedures data, control graphic display, drives motors, scales, sensors, clamps, sealer group and RFID reader.
- The mechanical part includes an axial system enabling movement of plate and buffy-coat separation system.
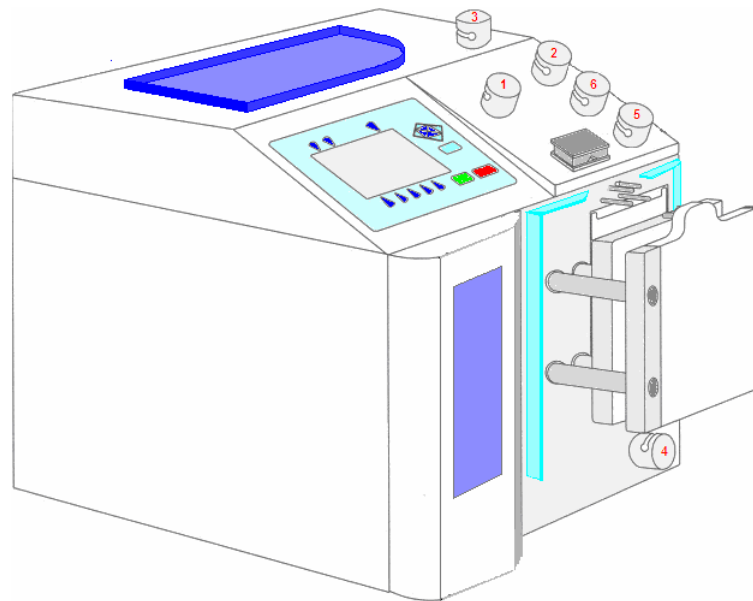
Picture 8: Global view

3.1 Upper Panel

The upper panel is designed to house tubes and collection bags. It includes:

- Upper scale, with removable plate; weight capacity 0-2000 grams with ± 1 g resolution.
- Photometer for red blood cells detection. It consists of a 540 nm optical system and a couple of IR sensors for air bubbles detection. A reflection optical systems detects cover state (open/closed) and tube presence.
- Three sealing head clamps: "Top", "Plasma", and "Buffy Coat"; one normal clamp for "Sag.M".
- One proportional valve for plasma flow control.
- Holder for additional bag.

3.2 Front Panel

The front panel is designed to hold the bag from which the emocomponents are to be extracted. It includes:

- Mobile separation plate controlled by one stepper motor and two sensors: the first sensor detects the distance between plate and profile plate, the second sensor detects the applied force.
- Fix plate provided with holders where the bag in use can be hanged.
- Primary bag support with bars for stainless-steel cannula breaking.
- Optical device for detection of buffy coat level. It consists of ten IR sensors linearity placed.
- Clamp "Bottom" with sealing head.
- Sensor for detection of the type of plate in use.

3.2.1 Keyboard

Some of the keyboard key-buttons are multifunction.
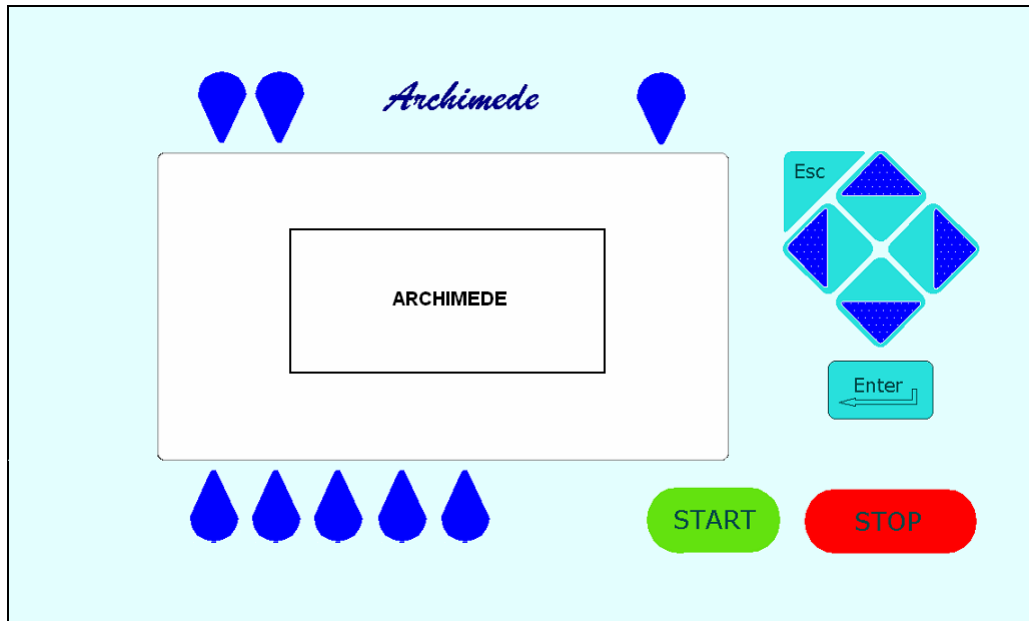
Picture 9: Keyboard

Allows to stop some functions and go back to the upper menu level**.**

Direction key-buttons: allow to move inside a menu and to change the value of the selected function.
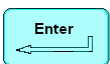
Allows to confirm the change or the selection.

Allows to start the separation procedure.

Allows to stop the ongoing procedure or application after confirmation.

Allows to start the displayed function.

3.2.2 Backlight Display

The screen is a wide LCD 240 x 128 graphic display. It is backlit to improve reading in poorly illuminated rooms.
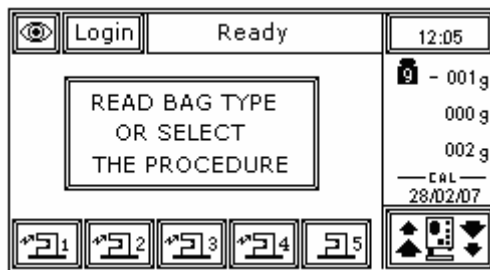
Picture 10: Main menu

Here is the meaning of the displayed functions:

	This menu allows to enter submenus to have parameters and maintenance actions displayed.
	Press to login operator by bar code reader.
	The instrument status is displayed in this area.
	Current time is displayed in this area.
	This menu allows to set the tare and to have front scale, upper scale and side weight displayed.
	Date of the last scales calibration is displayed in this area.
	This function allows to move back and forth the pressing plate.
	This function allows to open and close the selected clamp.
	The arrow appears when the sealing is activated.
	This function allows to enter the menu to select the desired procedure. The procedure can be selected manually or through BC reading of the type of bag.
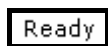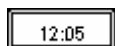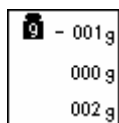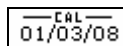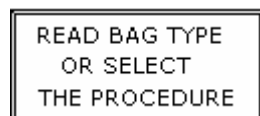
3.3 Rear Panel

The rear side includes the main power socket and two connectors that enable data exchange with the barcode reader and with a host computer.
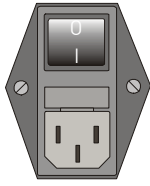
Power supply group including: power socket, On-Off switch, and fuse holder.

Antenna for WLAN connection to *ArchimedeLINK*.

PS2 connector. Allows connection to barcode reader.

Yellow led it is:.
- Lit; when *Archimede* is not connected in WLAN.
- Flash: when *Archimede* search WLAN.
- Off: when *Archimede* is connected in WLAN.

Green led. It is not activated.

Designed by manufacturer for exclusive connection to the instrument according to the prescriptions contained in the specific documentation of that instrument and to EN60950 Regulation.

3.4 Side Panel
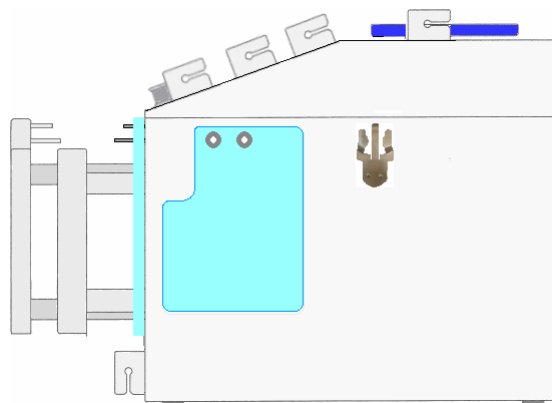
Picture 11: Lateral view

The right-side panel includes the support for lateral scale and the magnetic and removable filter support. The filter support is to be used if required by the selected procedure.

3.5 Meaning of Procedure Parameters

During the separation procedure *Archimede* operation is affected by several parameters. Some of these parameters are fix, that is, preset by the management program. Other parameters are variable, that is, settable by an application engineer through an external PC.

All variable parameters are factory preset and saved in a non-volatile memory with elevated retention capacity.

Fix parameters are used to monitor all the events with top priority alarm, i.e.: time necessary to enable all actuators very long, Sag. M dispensing time very long, etc.

In order to obtain a better management, procedure parameters are divided into group, defined by their meaning:

General control

Parameters for procedure security control activation.

1   **TUBES CHECK:**
During the procedure, checks that tubes are properly inserted into the clamps enabled for the ongoing procedure.

21   **Sag.M. quantity:**
Sag.M. amount already inside in the bag for RBC.

25   **Main bag weight:**
Weight of primary bag.

38   **PLT FILTRATE FLOW ALARM :**
Minimum flow that should pass through the filter. Below this value an alarm of obstructed filter is activated.

41   **Profile plate number:**
Number of profile plate use in the procedure.

43   **Primary Bag Positioning with Blade Ready for Weighing:**
Enables blade coming out to move primary bag away from front panel and allow correct weighing.

44   **Scale Stability Check:**
Enables check of weight stability as detected by enabled scales.

45   **Check Correlation Distance Weight:**
Check correlation between thickness bag and emocomponent weight.

46   **Enable scale reading:**
Must be inhibit in Archimede light version.

Initial phase

Parameters for Breaking Cannulas phase.

2   **CANNULAS BREAKING ENABLING:**
Enables the routine controlling breaking of the primary bag cannulas.

3   **CANNULAS BREAKING THRESHOLD:**
Force in xx.x Kg beyond which the plate stops and waits for cannulas breaking.

4   **MOTOR SPEED DURING CANNULAS BREAKING:**
Plate forward moving speed during cannulas breaking step.

5   **CANNULAS BREAKING HYSTERESIS:**
Value used to calculate the force value below which the system exits out of the cannulas-breaking routine. *V = (force measured at breaking position) – (current force).*

24   **MOTOR SPEED DURING FILTER PRIMING:**
Plate forward moving speed during filter priming.

Optical sensor management

Parameters for manage optical sensors of Archimede (IR and RBC).

6 NUMBER OF IR SENSOR USED TO ENABLE HB SENSOR:
Number identifying the IR sensor dedicated to RBC sensor activation.

RBC TARGET LEVEL: (PROCEDURE 8)
Value of IR - HB sensor to intercept the level of RBC.

7 MINIMUM OPTICAL GAP BETWEEN RBC AND PLASMA:
Value minimal of difference of reading between RBC and plasma with which it comes controlled the bag before and during the procedure.

8 HB SENSOR SENSIBILITY:
Sensibility HB sensor.

10 IR SENSOR ACTION THRESHOLD:
Threshold value for action of IR sensors.

15 NUMBER OF IR SENSOR USED FOR CHECK BUFFY COAT LEVEL:
Decimal number identifying the IR sensor buffy coat level position.

HAEMATOCRIT SELECTION: (PROCEDURE 13)
Allows you to set the desired level of haematocrit, based on this value system displays the number of IR LED concerned.

26 CLAMP CLOSURE DELAY TIME AFTER ERYTHROCITES LEVEL DETECTION
Delay time for clamp closure after detecting erythrocites level [0-25]s.

42 Air Elimination:
Allows to enable or inhibit the air elimination routine from plasma.

47 SELECTION OF IR CORRESPONDING TO UPPER AND LOWER BAG SIDE:
Allows to select the calibration sensors to be used to define the system's optical sensitivity. For optimum operation of the optical system, always select sensors within lower and higher reflection area of the label. If this is not possible because the label is on both sides, select so that the sensors can detect both plasma and RBCs.

Force management

Parameters for the force regulation system during the procedure.

9 MAXIMUM FORCE:
Value of the maximum force applied during the procedure; the plate stops if the force exceeds this limit.

13 MOTOR SPEED IN AUTOLEARNING PHASE:
Plate moving speed used in the first phase for the management of force .

Seal management

Parameters the select witch clamps will seal and how the selected clamp will seal.

11 SEALING MODE:
Selection of the sealing mode. In automatic mode, the system automatically seals the bags when the procedure is over. In manual mode, bags sealing must be confirmed.

12 SEALING CLAMPS SELECTION:
Selection of clamps to be used for sealing when the procedure is over. Clamps are numbered as follows: 1 Top, 2 Plasma, 4 Buffy, 8 Bottom. The value to be set in this position is the value corresponding to the sum of the clamps used: for example, if bottom and top are to be used, the value to be set is 9.

40 Clamps Number:
Value allowing to select the clamps to be used in the procedure.
Maximum flow of Sag. M. supplied, beyond which the dispensing force decreases.

Emocomponent volume

Parameters that define the Buffy Coat and the Sag.M. target volume.

18 RBCS NOT DETECTED FINAL DISTANCE WARNING:

Final distance value beyond which the system, after confirmation, stops the procedure if RBCs have not been detected.

BUFFY COAT VOLUME:

Desired buffy coat volume.

INSUFFICIENT DISPENSED VOLUMES FINAL DISTANCE WARNING:

Final distance value beyond which the system, after confirmation, stops the procedure if the set volumes have not been dispensed.

20 SAG. M. AMOUNT:

Sag. M. in [g] to be dispensed in the final step of the procedure.

22 BUFFY COAT AMOUNT WITHOUT BLADE SEPARATION:

Buffy coat [g] top be dispensed before mechanical blade separation.

23 BUFFY COAT ALARM DISTANCE:

Value of the distance beyond which the system, after confirmation, stops the procedure if the desired buffy coat amount has not been collected.

29 ALIQUOT WEIGHT 1: (UPPER SCALE)

Weight 1 desired for aliquot separation procedure.

14 ALIQUOT 2 WEIGHT: (UPPER SCALE)

Weight 2 desired for aliquot separation procedure.

30 PLASMA-PLT WEIGHT:

Value of the amount of plasma-plt to be separated.

37 BUFFY COAT TOTAL WEIGHT:

Total buffy coat weight.

39 ALIQUOT 3 WEIGHT: (LATERAL SCALE)

Weight 3 desired for aliquot separation procedure.

Secondary Emocomponent volume

Parameters that define the auto recover, wash or dilution and aliquot separation target volume.

19 EXCESS PLASMA FOR FILTER:

Excess plasma [g] to be collected after the system has detected the buffy coat.

MANUAL DISPENSING:

Enables manual platelets recovery after detecting RBCs.

32 SENSIBILITY OF FLOW VALVE:

Adjust sensitivity of flow valve feedback. (Clamp 6)

34 PLASMA FOR BC DILUTION:

Amount of plasma to be added to the buffy coat when its separator is enabled.

35 Delay for BUFFY COAT LINE CLEANING WITH SAG.M.:

Delay for cleaning deviation of Buffy Coat line with Sag.M.

36 PLASMA AMOUNT FOR BUFFY COAT TUBE CLEANING:

Amount of plasma to be dispensed by gravity in the buffy coat bag.

3.6 Procedure Parameters Display

Archimede is equipped with a long-retention internal memory. Up to 18 procedures can be stored, with up to 40 parameters each.
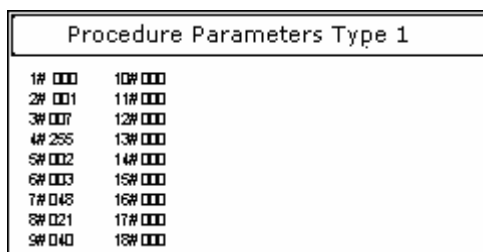
To display procedure parameter press ▼ key-button above the icons ▣ and use direction key button ◆ to select PARAMETER LIST.

UTILITY MENU

CALIBRATION
✓ PARAMETERS LIST
MAINTENANCE
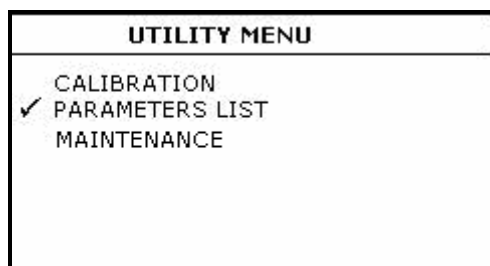
Picture 12: Utility menu.

Confirm setting with key ⌨.

Using direction key-buttons ◆ it is possible to select the desired procedures.

Procedure Parameters Type 1

1# ☐☐☐	10# ☐☐☐
2# ☐☐1	11# ☐☐☐
3# ☐☐7	12# ☐☐☐
4# 255	13# ☐☐☐
5# ☐☐2	14# ☐☐☐
6# ☐☐3	15# ☐☐☐
7# ☐48	16# ☐☐☐
8# ☐21	17# ☐☐☐
9# ☐40	18# ☐☐☐

Picture 13: Parameters procedures list

All procedures parameter values have been optimized in various testing centres. However, parameter values can be changed by the application engineer through *ArchimedeLINK* to improve the desired procedure.

3.7 Maintenance Display

Maintenance actions can be displayed only when *Archimede* is connected to *ArchimedeLINK*. In this case, maintenance actions can be managed reporting to *ArchimedeLINK* any information, including operator name and date of execution. It is also possible to schedule the desired maintenance actions according to the Blood Transfusional Centre protocol. To confirm the action performed, select maintenance type using the arrow ◆, confirm by pressing ⌨ and read the operator code.

MAINTENANCE LIST

⇒ Clean Display
Clean Clamp
Clean Sensors
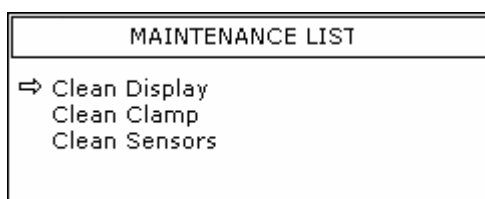
Picture 14: Maintenance list

3.8 Date and Time

Although the display normally shows only hours and minutes, *Archimede* is provided with a built-in calendar used to send to *ArchimedeLINK* procedure data, including date and time.
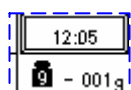
12:05
🔋 - 001g   Using direction key-buttons ◆ highlight the display area indicating

current date and time. Press [Enter] to enter modify mode.
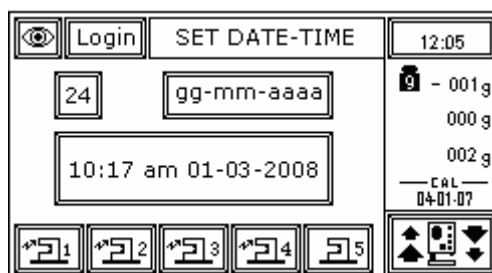
Picture 15: Date and time menu.

Set date and time using keys ◆ , up and down key to increase or decrease value, left and right to change the digit to modify and [Enter] to confirm setting.

If you don't want to confirm the date and time change, press key [Esc] .

FORMAT	READING
12	0-24
24	0-12 am/pm
dd-mm-yyyy	01-03-2008
mm-dd-yyyy	03-01-2008
yyyy-mm-dd	2008-03-01

Picture 16: Date and time format list.

Set current date and time, and confirm setting with key [Enter].

If you don't want to confirm the date and time change, press key [Esc] .

If the Blood Transfusional Centre uses *ArchimedeLINK,* date and time are automatically updated when the instrument is switched on or at the first connection of the day. The PC date and time are the reference data.

3.9   Scales

Archimede is provided with one front scale, one upper scale, and one side scale. All of them have a weighing capacity up to 2 Kg with ± 1 g resolution. The scales are electronically calibrated using a certified standard weight as a reference. The calibration date is highlighted in the lower display area dedicated to weights. Calibration is performed using *ArchimedeLINK.* The procedure is usually performed by a trained engineer authorized by the manufacturer.
Before using the system as a scale, it is necessary to set the tare value. Move the cursor using the arrows ◆ until the display shows "zero" in the scales area. Press [Enter] to zero all values.
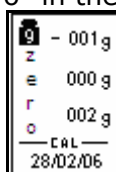
The bag or product you have to weight can be hanged to the front scale or to the side scale, or placed on the upper scale.

3.10   Manual Control of Plate Forward Moving

The plate can be manually moved forward and backward. This can be useful both if you want to press a bag manually, and if you want to check that the movement axial system is working correctly.

CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA.

To enter this mode, use the arrows ◆ to highlight the icon [icon], and then press [Enter]..
Now move the arrows up and down to move the plate in the desired direction. The forward moving is always controlled by the maximum applied force, while the backward moving is controlled by open plate limit switch. To stop the plate and keep the position press [STOP]; to exit and put the plate in standby position press ◢ .

This mode also allows to enable clamps by pressing ● ; if the clamp is closed and the tube is in position it is possible to seal by pressing [Enter].

Clamp number 5 of Sag. M. is not provided with sealing head, therefore cannot be used as a sealer.

3.11 Clamps Manual Control

All mounted clamps can be manually controlled with the exception of the flow clamp. This can be useful during the use of manual plate movement and to seal tubes to the bags.

The clamps positions change from open to closed and vice versa by pressing the ● key-button under the icon [icon] . If the highlighted clamp has to be used as a sealer, insert the tube to be sealed in the clamp and press [Enter]. The sealing cycle is inhibited in case the electronic protection implemented in the CSU detects the presence of moisture on the sealing clamp. Clamp 5 of Sag. M. is not provided with sealing head and therefore cannot be used as a sealer.

4 USING ARCHIMEDE

Using *Archimede* in separation mode is simple thanks to the built-in microcontroller. The microcontroller constantly checks the following parameters: buffy coat level, RBCs presence, weights, distance between plate and profile plate, separation speed, separation force, maximum settable force, correct program performance.

If connected to *ArchimedeLINK*, *Archimede* sends all sensor and procedure data, including those acquired by the barcode reader. In stand alone mode data are store into a FIFO memory and should be sent automatically to ArchimedeLINK on next connection.

4.1 Switching on

The switch on procedure includes a complete self-check of the system. Before switching *Archimede* on it is therefore necessary to remove any bag and check that the bags holders are free and correctly placed.
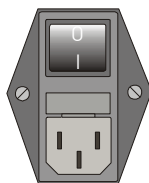
 After plugging the power cable, turn on the main switch on instrument rear.
The display should be back lighted and show "ARCHIMEDE". If not, check that the power cable is well plugged and that the power socket in use is powered.

If the display does not light up, please see Troubleshooting section.

4.2 System Self-check

Every time it is turned on, *Archimede* performs a self-check to verify proper system operation.
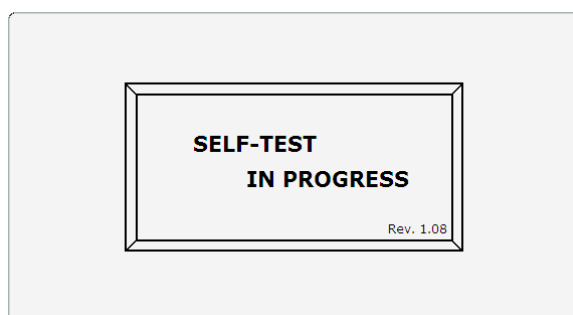
Picture 17: Screen shot "Self-Test in progress"

The actions performed following a negative check depend on the connection mode

 Stand Alone or *ArchimedeLINK.*

E^2prom Memory
Check of data integrity concerning calibration and procedure parameters.

 If data are incorrect, the system, after confirmation, will initialize them and restore the factory set values.

 Procedure data are restore to factory set values, while calibration data will require a new calibration.

Clock
Date and time check.

If date and time values are incompatible with the format, the system, after confirmation, will initialize them at 00:00:00 01/03/08.

Synchronization with data and time of *ArchimedeLINK* Server.

Scales
Tare check of all scales.

If the tare values are not within the preset limits, an error alarm will be sent and displayed.
If the problem persists, please see the Troubleshooting section.

Same as in stand alone mode.

Plate motor
Check of motor movement and limit switch.

If limit switches are not enabled within the preset travel limits, an error alarm will be sent and displayed. If the problem persists, please see the Troubleshooting section.

Same as stand alone mode.

Buffy-coat separation motor
Check of motor movement and limit switch.

If limit switches are not activated within the preset travel limits, an error alarm will be sent and displayed. If the problem persists, please see the Troubleshooting section.

Same as stand alone mode.

IR sensors
IR sensors check and self-calibration.

If IR sensors have an elevated dark current or a low sensibility, an error alarm will be sent and displayed. If the problem persists, please see the Troubleshooting section.

Same as stand alone mode.

Force sensor
Force sensor check.

If the force detected by the sensor is over the preset limits, an error alarm will be sent and displayed. If the problem persists, please see the Troubleshooting section.

Same as stand alone mode.

HB sensor
HB sensor check and self-calibration.

If the HB sensor has an elevated dark current or a low sensibility, an error alarm will be sent and displayed. If the problem persists, please see the Troubleshooting section.

Same as stand alone mode.

CSU

Check of sealing unit and tubes detector.

If the CSU state is not "ready", and if there are moisture or tubes within clamps, an error alarm will be sent and displayed. If the problem persists, please see the Troubleshooting section.

Same as stand alone mode

Flow control clamp

Actuator movement check.

If the limit switch is not activated within the preset travel limits, an error alarm will be sent and displayed. If the problem persists, please see the Troubleshooting section.

Same as stand alone mode.

4.3 Use as a scale

Archimede can be used as a weighing system thanks to its three load cells. The maximum measurable weight is 2 Kg with 1 g resolution.

Before using the system as a scale, it is necessary to calculate the tare. Move the cursor using the arrows ◆ until the word "zero" is displayed in the scales area of the screen and press ⏎ to zero the values.
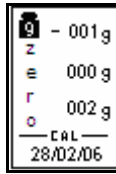
Picture 18: Scale tare

Now use the arrows to move the cursor to another option; this will avoid performing another tare by pressing ⏎ key-button unintentionally
Take the product you wish to weigh and hang it to the front or side scale, or put it on the upper scale.
Weights are displayed in the following order:

Front scale
Upper scale
Side scale
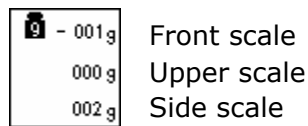
Picture 19: Reading scale area

4.4 Use as a sealing unit

Archimede can be used as a sealing unit thanks to its four built-in sealing heads.
Press ● key-button below the sealing head that you wish to use or highlight the sealing head using the arrows ◆ .

Location of the sealing heads is as follows:

[5] **NON-SEALING HEAD**

[4] **SEALING HEAD**

[3] **SEALING HEAD**

[2] **SEALING HEAD**
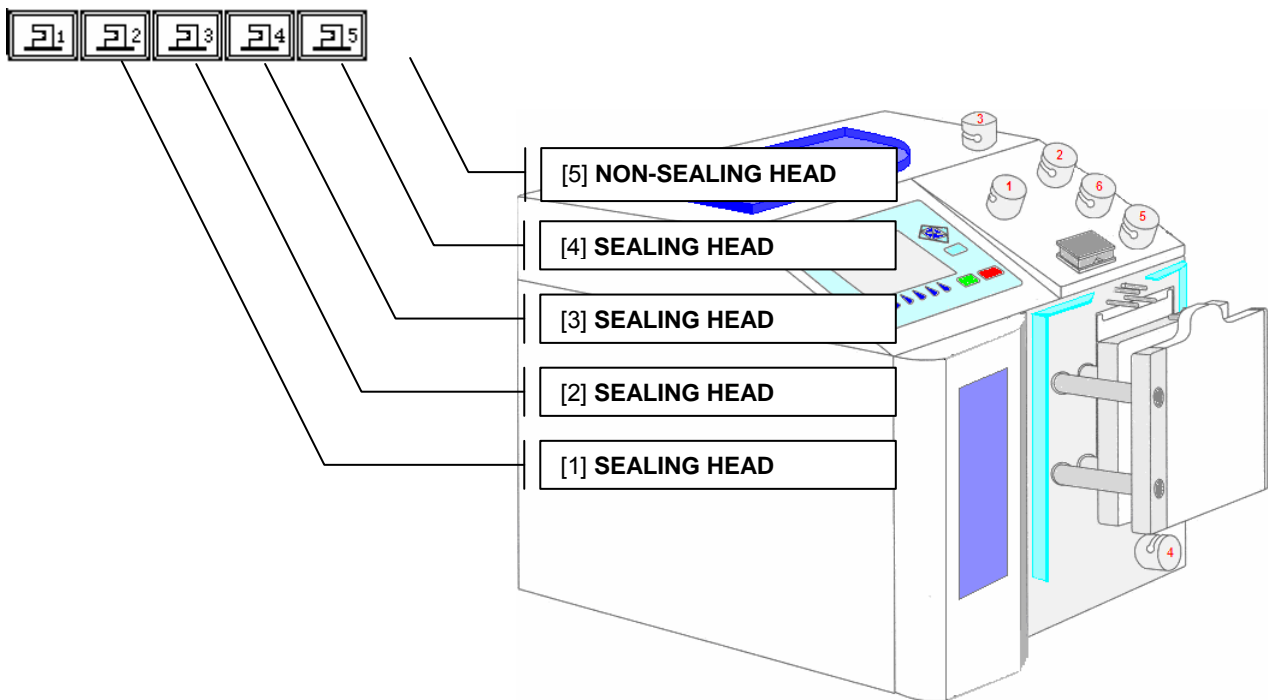
[1] **SEALING HEAD**

Picture 20: Archimede view

To perform sealing with the selected sealing head, press ⎗ key-button. If you don't want to seal but, you want to open or close the selected clamp, press 💧. Sealing operation will be shown on left side of the clamp by the symbol ↙ .

In case any error occurs, this will be displayed in the notice window of the screen:

- **Clean sealing head:** the CSU has detected some moisture; it is necessary to clean sealing head and tube and check for leakages.

- **Insert tube:** the tube sensor has detected that the tube is missing or incorrectly inserted in the sealing head clamp.

- **CSU busy:** the CSU is busy with a sealing cycle; retry after a few seconds.

4.5 Use as manual separator

Archimede can also be used as a manually controlled separator.
In this mode the enabled checks are the following:
- Position sensor determining the plate standby position.
- Force sensor determining plate stop if the applied force exceeds the set value. When the applied force decreases below the value calculated according to the hysteresis, the plate starts again. The values set for force and hysteresis are those set during the first active procedure.

ATTENTION: THE FORCE SENSOR IS ENABLED ONLY WHEN THE PLATE MOVES TOWARDS THE INSTRUMENT BODY.
CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA WHEN THE PLATE IS MOVING.

To enter this mode, use the arrows ✦ to highlight the icon and then press ⎗ . Now press the arrows up or down to move the plate in the desired direction, and press the arrows left or right to change the applied force with fix increments of 5 units.
To stop the plate and maintain the position press ⬤STOP ; to exit and move the plate to standby position press ◹Esc .
In this mode you can also enable the clamps by pressing 💧 key-button, and seal by pressing ⎗ key-button.
Clamp 5 of Sag. M. is not provided with sealing head and cannot be used as a sealer.

Picture 21: Manual movement window

4.6 Separation Procedure

Archimede can store up to 18 procedures. The operator can perform a manual selection or an automatic selection if the system is connected to *ArchimedeLINK*.

- **Manual mode**: To speed up procedures selection, the system can be configured to show only the procedures enabled. In this way, only the procedures most frequently used in the blood transfusional center will be displayed.

Using the arrows ◆ highlight the procedure you intend to use, then press [Enter] to start the procedure.

ENABLED PROCEDURES LIST

✓ *1 T&T triple PPP o PRP → RBC.
*2 T&T quad. PPP o PRP → BC → RBC.
*3 T&B triple PPP → BC → RBC.
*4 T&B quad. PPP → BC → RBC.
*5 PPP → PLT.
*6 PLT → BC residuo.
*7 PLT → BC residuo (con filtro).
*8 Separazione lavaggio emazie.
*9 PRP o gel piastrinico.
*10 Separazione cordone.
*11 Separazione in aliquote.
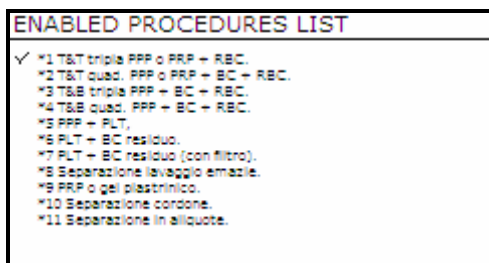
Picture 22: Enable procedures list

- **Automatic mode**: Using *ArchimedeLINK* it is possible to associate a bag type to a procedure type. In this way, from the main menu you will only have to read the bag type barcode and *ArchimedeLINK* will transmit to *Archimede* what type of procedure it has to run.

The separation procedures presently available are:

PRIMARY

- # 1 T & T triple PPP or PRP + RCC.
- # 2 T & T quadruple PPP or PRP BC + RCC.
- # 3 Top & Bottom triple PPP+BC+RCC.
- # 4 Top & Bottom quadruple PPP+BC+RCC.
- # 10 [a] Cord separation.
- # 11 [b] Aliquot separation.
- # 13 [d] Procedure Top & Top RBC with PPP + PPP.

SECONDARY

- # 5 PPP + PLT.
- # 7 PLT + residual BC with filter.
- # 8 Erythrocytes washing separation.

4.6.1 Questions

This mode (not available in stand alone mode) allows complete procedures traceability. With *ArchimedeLINK* it is possible to define a series of questions to be asked soon after choosing the procedure to be used. The replies will be checked according to various criteria: length, barcode type, character type, authorized operators IDs, donors IDs, bag lot validation.

Picture 23: Questions view

To reply to the question indicated by the arrow, read the barcode of the item concerned. If you need to read a reply again, move the arrow indicating the question using [icon] key-buttons.

Once the system has selected the type of procedure to be used, it is no longer possible to modify the reply to donor ID and operator ID. Actually, the choice criteria of the procedure take into consideration both operator's privileges and status of primary and secondary separation. Example: if a bag has already been processed as primary-secondary procedure, *ArchimedeLINK* will not allow the separation unless an operator having the due privileges forces it to do so.

To clear the series of questions and return to main menu, press [Esc icon] .

When all questions have been replied to, the initial display of the selected procedure will automatically appear.

4.6.2 PROCEDURE 1   T & T triple PPP or PRP + RCC.

This procedure is suitable for triple bags containing Sag. M. It allows erythrocytes separation (RCC) and platelets poor plasma (PPP).

Parameters used:

1   During the procedure, checks that tubes are properly inserted into the clamps enabled for the ongoing procedure.

2   Enables the routine controlling breaking of the primary bag cannulas.

3   Force in xx.x Kg beyond which the plate stops and waits for cannulas breaking.

4   Plate forward moving speed during cannulas breaking step.

5   Value used to calculate the force value below which the systems exits the cannulas breaking routine. *V =(force measured at breaking position) − (current force).*

6   Number identifying the IR sensor dedicated to RBC sensor enabling.

7   Value minimal of difference of reading between RBC and plasma with which it comes controlled the bag before and during the procedure

8   Sensibility HB sensor.

9   Value of the maximum force applied during the procedure; the plate stops if the force exceeds this limit.

11   Selection of the sealing mode. In automatic mode, the system automatically seals the bags when the procedure is over. In manual mode, bags sealing must be confirmed.

12   Selection of clamps to be used for sealing when the procedure is over. Clamps are numbered as follows: 1 Top, 2 Plasma, 4 Buffy, 8 Bottom. The value to be set in this position is the value corresponding to the sum of the clamps used: for example, if bottom and top are to be used, the value to be set is 9.

13   Plate moving speed used in the first phase for the management of force

18   Value of the distance beyond which the system, after confirmation, stops the procedure if no RBCs have been detected.

19   Excess plasma [g] to be collected after the system has detected the buffy coat.

20   Sag. M. amount [g] to be dispensed in the final step of procedure.

25 Tara sacca primaria. Valore utilizzato per calcolare la quantità di prodotto rimasto nella sacca primaria. [peso attuale-tara]

26   Threshold value used to detect air bubbles during procedures requiring its elimination.

40   Value allowing to select the clamps to be used in the procedure.

41   Number of the profile plate to be used with the ongoing procedure.

42   Enables the air elimination routine.

43   Primary bag positioning with blade ready for weighing.

44   Scale stability check.

45   Check Correlation Distance Weight.

46   Enable scale reading.

47   IR corresponding to higher and lower bag edge.

Position bags and tubes according to the below sequence. Be sure to avoid tensions and folds that might cause flow obstruction or weighing errors.
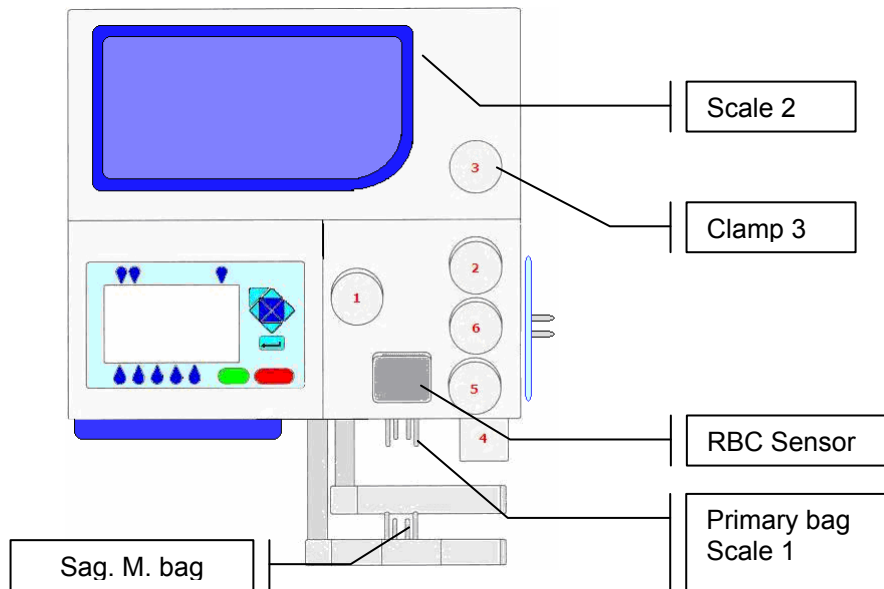
Picture 24: Kit installation procedure T/T triple

NOTE: Tubes in the various kits have different lengths. To simplify kits management, the firmware allows to configure which valves you wish to enable.
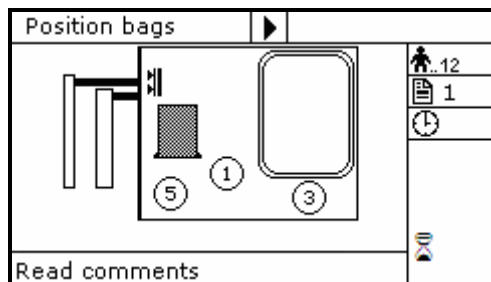
Picture 25: Position primary T/T triple bag.

- Hang the primary bag to the bag holders on the front panel. The label containing bag data should always be turned outside. After detecting the primary bag, the plate will move backword to make positioning of Sag.M. bag easier, and the display will show the bag icon.
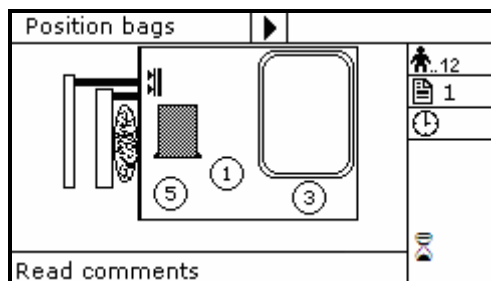
Picture 26: Position plasma and Sag.M. T/T triple bags.

- Hang the Sag. M. bag to the bag holders on the fix plate.
- Insert the Sag. M. tube firmly into clamp 5.
- Open the cover of HB sensor and insert the tube coming from the primary bag into the reading area. Close the cover.
- Insert the tube coming from the RBC sensor firmly into clamp 3.
- Position the plasma bag on upper scale.
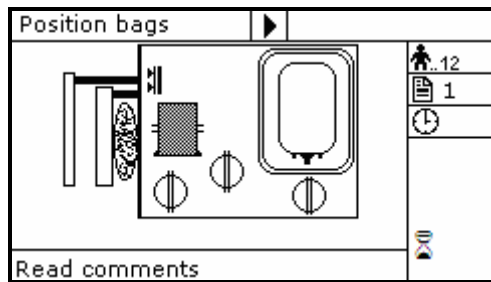
Picture 27: T/T Triple bags in position.

Archimede checks correct tubes positioning inside proper clamps by means of its optical sensors. The tube is correctly inserted when the clamp number is replaced by the icon ⊕.

Press [START] key-button to start the procedure.

If the primary bag expected weight check has been enabled through Archimede*LINK* and the detected weight does not fall within the set limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with [Enter] or press ◢ to leave the procedure. Furthermore, if the tube presence check is enabled the display will show the clamp numbers where tubes are not correctly inserted and the procedure will not start until all tubes are correctly inserted into the enabled clamps.

Now wait for the plate to get close to the bag. The plate will exert a force corresponding to the value set in the procedure parameters.

Parameters of the ongoing phase:

#13: Plate forward moving speed
#18: Action distance
#8:   RBC action threshold
#19: Excess plasma for filter
#20: Sag. M. amount
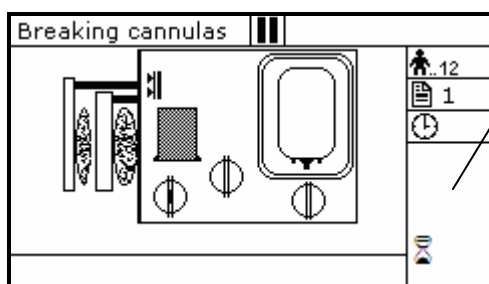
Picture 28: Break cannulas view T/T triple procedure.

Break the cannules by forcing on their side upper part, and wait a few seconds for positive pressure release. After detecting pressure decrease, Archimede automatically starts the separation cycle. If pressure does not decrease below the set value, due to tube obstruction or fluid clogging, it is anyway possible to force the cycle start by pressing [START] keybutton.

☞ During the procedure, possible comments can be read on the external part of the fix front plate.

The graphic interface will now show the current operating phase number, and the weight value of plasma collected. *Archimede* will check the erythrocytes level in the primary bag. When this level reaches the selected IR sensor, the display will show it in the area of the RBC-pressing plate. The photometer detecting the presence of erythrocytes will now check, in real time, the plasma flow. When the erythrocytes amount exceeds the value set in procedure parameters, the photometry will display "RBC" on the sensor cover icon and, if dispensation of excess plasma is not provided, the separation process will stop and the plate will move backwards to allow Sag. M. dispensing.

🚫 ATTENTION: THE FORCE SENSOR IS ENABLED <u>ONLY</u> WHEN THE PLATE MOVES TOWARDS THE INSTRUMENT BODY.
CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA WHEN THE PLATE IS MOVING.

If air elimination is enabled, the system will send the air contained in the primary bag into the Sag.M. bag both at the initial and final stage.

The sealing cycle depends on the value set in the procedure parameters;

Automatic sealing: sealing cycle of the selected clamps is performed automatically.

Manual sealing: press [START] keybutton to seal the enabled lines, or press [STOP] to continue, after confirming, without sealing.
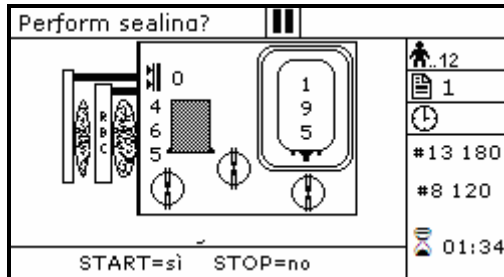
Picture 29: Sealing procedure T/T triple

Archimede will automatically send to Archimede*LINK* all events and data of the procedure performed.

At the end of the procedure the display will show the detected weights. If they are not the expected ones, because tubes are not correctly placed and distort scales' readings, the emocomponents can be weighed again after correcting tubes' position and the new weights can be sent to Archimede*LINK* again.

Correct weights: press [START] keybutton to continue with the same type of separation or press [Esc] to go back to the page listing the procedures.
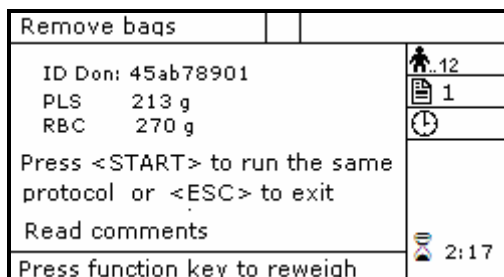
Picture 30: Viewing weights T / T triple.

Incorrect weights: press one of the 🔵 keybuttons to weigh emocomponents again. To accept the new values and send them to Archimede*LINK* press [Enter]
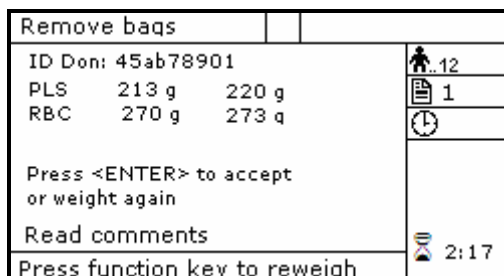
Picture 31: Reweigh T/T quadruple.

With Archimede*LINK* the normal limits check can be activated. If it is enabled and the detected weights do not fall within the set limits, the display will show the emocomponents' detected weights and the allowed limits. Press any key to continue.

ATTENTION

Emocomonents	val	min	max
RBC	221	232	333 g
BC	75	50	75 g
W.B no CPD	420	429	525 g

Picture 32: T/T quadruple with weight out of normal range.

Now remove tubes and bags and press START to continue with another separations of the same type or press ⬦ to exit.

If you need to interrupt the procedure either momentarily or definitively, press STOP keybutton.

Procedure finished?
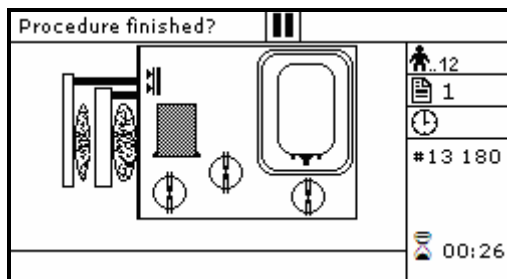
Picture 33: Pause or Stop procedure T/T triple.

Stop: press STOP or Enter. Archimede will display the sealing page and send data to Archimede*LINK*.

Pause: press START or ⬦ to continue the procedure.

4.6.3 PROCEDURE 2   T & T quadruple PPP or PRP BC + RCC.

This procedure is suitable for quadruple bags containing Sag. M. It allows to separate erythrocytes (RCC), platelets poor plasma (PPP) and buffy coat.

Parameters used:

1 During the procedure, checks that tubes are properly inserted into the clamps enabled for the ongoing procedure.

2 Enables the routine controlling breaking of the primary bag cannulas.

3 Force in xx.x Kg beyond which the plate stops and waits for cannulas breaking.

4 Plate forward moving speed during cannulas breaking step.

5 Value used to calculate the force value below which the systems exits the cannulas breaking routine. *V =(force measured at breaking position) – (current force).*

6 Number identifying the IR sensor dedicated to RBC sensor enabling.

7 Value minimal of difference of reading between RBC and plasma with which it comes controlled the bag before and during the procedure

8 Sensibility HB sensor.

9 Value of the maximum force applied during the procedure; the plate stops if the force exceeds this limit.

11 Selection of the sealing mode. In automatic mode, the system automatically seals the bags when the procedure is over. In manual mode, bags sealing must be confirmed.

12 Selection of clamps to be used for sealing when the procedure is over. Clamps are numbered as follows: 1 Top, 2 Plasma, 4 Buffy, 8 Bottom. The value to be set in this position is the value corresponding to the sum of the clamps used: for example, if bottom and top are to be used, the value to be set is 9.

13 Plate moving speed used in the first phase for the management of force.

16 Plasma to dilute Buffy Coat.

18 Value of the distance beyond which the system, after confirmation, stops the procedure if no RBCs have been detected.

19 Excess plasma [g] to be collected after the system has detected the buffy coat.

20 Sag. M. amount [g] to be dispensed in the final step of procedure.

22 Buffy coat amount [g] to be dispensed before mechanical separation.

23 Value of the distance beyond which the system, after confirmation, stops the procedure if the desired buffy coat amount has not been collected.

25 Tare of the primary bag. This value is used to calculate the product amount left in the primary bag. [current weight - tare]

34 Amount of plasma to be dispensed in the buffy coat bag.

35 Delay for cleaning deviation of Buffy Coat line with Sag.M.

36 Amount of plasma to be dispensed by gravity in the buffy coat bag.

40 Value allowing to select the clamps to be used in the procedure.

41 Number of the profile plate to be used with the ongoing procedure.

42 Enabling of the air elimination routine.

43 Primary bag positioning with blade ready for weighing.

44 Scale stability check.

45 Check Correlation Distance Weight.

46 Enable scale reading.

47 IR corresponding to upper and lower bag edges.

Position bags and tubes according to the below sequence. Be sure to avoid tensions and folds that might cause flow obstruction or weighing errors.
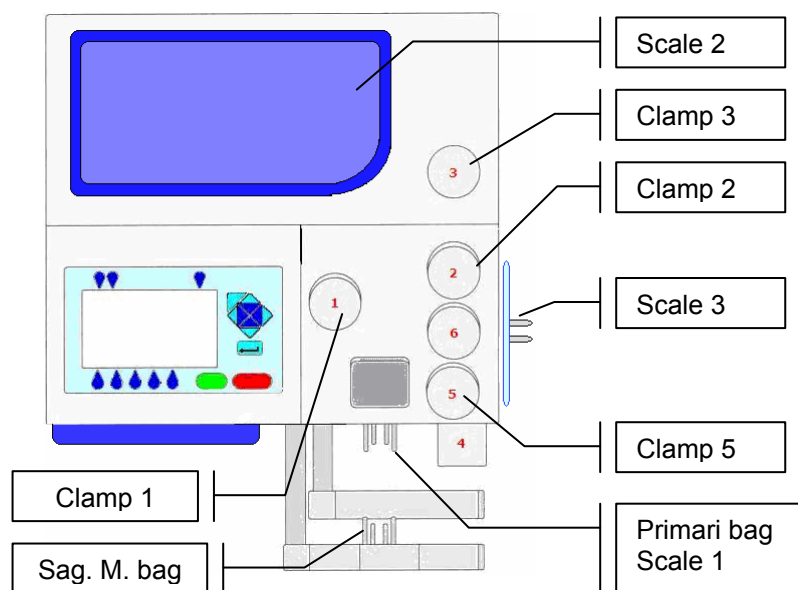
Picture 34: Kit installation T/T quadruple procedure.

NOTE: Tubes in the various kits have different lengths. To simplify kits management, the firmware allows to configure which valves you wish to enable.
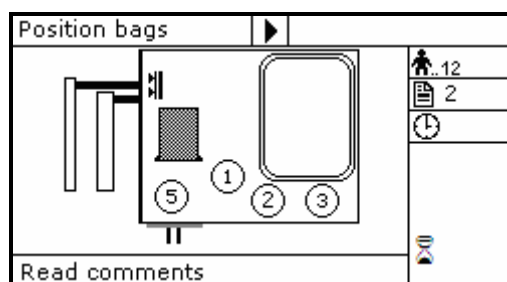

Picture 35: Position primary T/T triple bag.

▪ Hang the primary bag to the bag holders on the front panel. The label containing bag data should always be turned outside. After detecting the primary bag, the plate will move backword to make positioning of Sag.M. bag easier, and the display will show the bag icon.
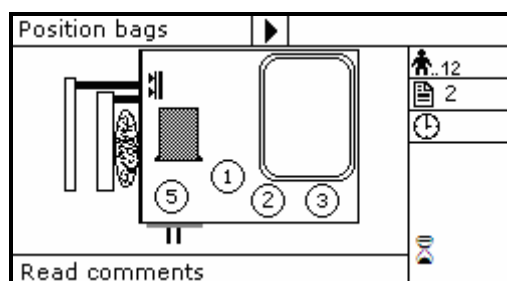
Picture 36: Position plasma, buffy coat and Sag.M. T/T quadruple bags.

▪ Hang the Sag. M. bag to the bag holders on the fix plate.
▪ Insert the Sag. M. tube firmly into clamp 5.
▪ Open cover of HB sensor and insert the tube coming from the primary bag into the reading area. Close the cover.
▪ Insert the tube coming from the HB sensor firmly into clamp 1.
▪ Insert buffy coat tube into clamp 3.
▪ Insert the plasma tube into clamp 2.

- Position the plasma bag on upper scale.
- Position the buffy coat bag on lateral scale.

Picture 37: T/T quadruple bags in position

Archimede checks correct tubes positioning inside proper clamps by mens of its optical sensors. The tube is correctly inserted when the clamp number is replaced by the icon ⊕.

Press **START** key-button to start the procedure.

If the primary bag expected weight check has been enabled through Archimede*LINK* and the detected weight does not fall within the set limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with **Enter** or press **Esc** to leave the procedure. Furthermore, if the tube presence check is enabled the display will show the clamp numbers where tubes are not correctly inserted and the procedure will not start until all tubes are correctly inserted into the enabled clapms

Now wait for the plate to get close to the bag. The plate will exert a force corresponding to the value set in the procedure parameters.

Parameters of the ongoing phase:

#8:   RBC action threshold
#22   Buffy coat amount
#19:   Excess plasma for filter

Picture 38: Break cannulas view quadruple T/T procedure

Break the cannulas by forcing on their side upper part. Wait for a few seconds that positive pressure is released. After detecting pressure decrease, Archimede automatically starts the separation cycle. If pressure does not decrease below the set value, due to tube obstruction or fluid clogging, it is anyway possible to force the cycle start by pressing **START** keybutton.

During the procedure, possible comments can be read on the external part of the fix front plate.

The graphic interface will now show the current operating phase number, and the weight value of plasma collected. *Archimede* will check the erythrocytes level in the primary bag. When this level reaches the selected IR sensor, the display will show it in the area of the RBC-pressing plate; the plasma line will be closed and the buffy coat line will be opened. When the buffy coat amount reaches the value set in the relevant procedure parameter, the system will enable the mechanical separation group and let the set plasma (PPP) amount flow to clean the line.
When cleaning is over, buffy coat will be dispensed in the bag, and the plate will move back words to allow Sag. M. dispensing.

ATTENTION: THE FORCE SENSOR IS ENABLED <u>ONLY</u> WHEN THE PLATE MOVES TOWARDS THE INSTRUMENT BODY.

CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA WHEN THE PLATE IS MOVING.

If air elimination is enabled, the system will send the air contanied in the primary bag to the Sag. M. bag both at initial and final stage.

The sealing cycle depends on the value set in the procedure parameters:

Automatic sealing: sealing cycle of the selected clamps is performed automatically.

Manual sealing: press [START] keybutton to seal the enabled lines, or press [STOP] to continue, after confirming, without sealing.
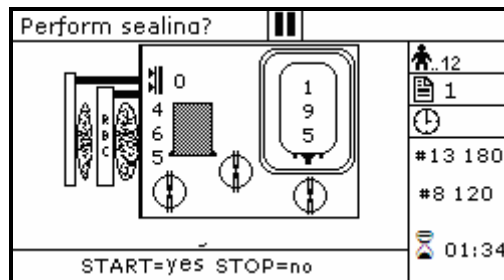
Picture 39: Sealing procedure T/T quadrupla

Archimede will automatically send to Archimede*LINK* all events and data of the procedure performed.

At the end of the procedure the display will show the detected weights. If they are not the expected ones, because tubes are not correctly placed and distort scales' readings, the emocomponents can be weighed again after correcting tubes' position and the new weights can be sent to Archimede*LINK* again.

Correct weights: press [START] keybutton to continue with the same type of separation or press [Esc] to go back to the page listing the procedures.
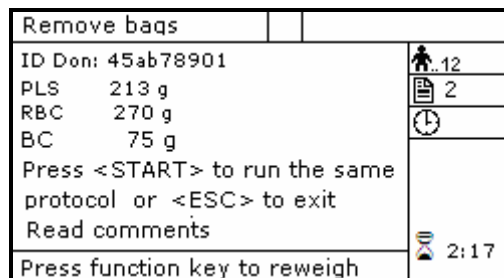
Picture 40: Viewing weights T / T quadruple.

Incorrect weights: press one of the 🔵 keybuttons to weigh emocomponents again. To accept the new values and send them to Archimede*LINK* press [Enter]
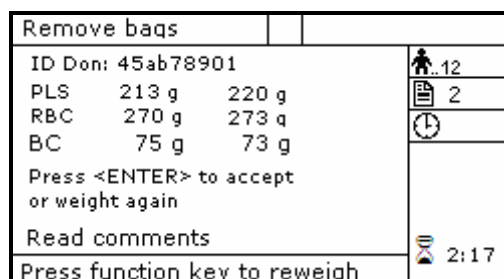
Picture 41: T/T quadruple with weight out of normal range.

With Archimede*LINK* the normal limits check can be activated. If it is enabled and the detected weights do not fall within the set limits, the display will show the emocomponents' detected weights and the allowed limits. Press any key to continue.


```
ATTENTION

Emocomponents   val   min    max
          RBC   221   232   333 g
         B.C.    43    50    75 g
   W.B no CPD   420   429   525 g
```

Picture 42: T/T quadruple with weight out of normal range

Now remove tubes and bags and press **START** to continue with another separation of the same type or press **Esc** to exit.

If you need to interrupt the procedure either momentarily or definitively, press **STOP** keybutton.
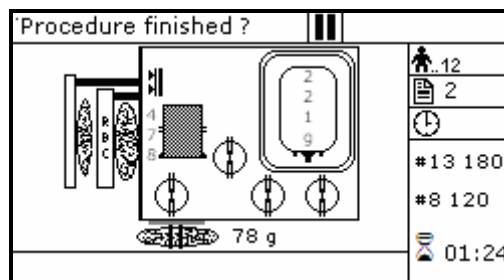
Picture 43: Pause or Stop procedure T/T quadruple

Stop: press **STOP** or **Enter** . Archimede will display the sealing page and send data to Archimede*LINK*.
Pause: press **START** or **Esc** to continue the procedure.

4.6.4 PROCEDURE 3   Top & Bottom triple PPP+BC+RCC.

This procedure is indicated for triple top & bottom bags to obtain buffy coat (BC), erythrocytes (RCC) and plasma (PRP).

Parameters used:

1 During the procedure, checks that tubes are properly inserted into the clamps enabled for the ongoing procedure.

2 Enables the routine controlling breaking of the primary bag cannulas.

3 Force in xx.x Kg beyond which the plate stops and waits for cannulas breaking.

4 Plate forward moving speed during cannulas breaking step.

5 Value used to calculate the force value below which the systems exits the cannulas breaking routine. *V =(force measured at breaking position) – (current force).*

7 Value minimal of difference of reading between RBC and plasma with which it comes controlled the bag before and during the procedure

8 Sensibility HB sensor.

9 Value of the maximum force applied during the procedure; the plate stops if the force exceeds this limit.

11 Selection of the sealing mode. In automatic mode, the system automatically seals the bags when the procedure is over. In manual mode, bags sealing must be confirmed.

12 Selection of clamps to be used for sealing when the procedure is over. Clamps are numbered as follows: 1 Top, 2 Plasma, 4 Buffy, 8 Bottom. The value to be set in this position is the value corresponding to the sum of the clamps used: for example, if bottom and top are to be used, the value to be set is 9.

13 Plate moving speed used in the first phase for the management of force

15 Number identifying the IR sensor dedicated to buffy coat level.

18 Buffy coat target value.

20 Sag. M. amount [g] to be dispensed in the final step of the procedure.

21 Sag.M. amount already present in RBC destination bag.

25 Tare of the primary bag. This value is used to calculate the product amount left in the primary bag. [current weight - tare].

32 Sensibility flow valve. (Clamp 6)

36 Plasma amount to be dispensed in the buffy coat bag.

40 Value allowing to select the clamps to be used in the procedure.

41 Number of the profile plate to be used with the ongoing procedure.

42 Enables the air elimination routine.

43 Primary bag positioning with blade ready for weighing.

44 Scale stability check.

45 Check Correlation Distance Weight.

46 Enable scale reading.

47 IR corresponding to upper and lower bag edges.

Position bags and tubes according to the below sequence. Be sure to avoid tensions and folds that might cause flow obstruction or weighing errors.
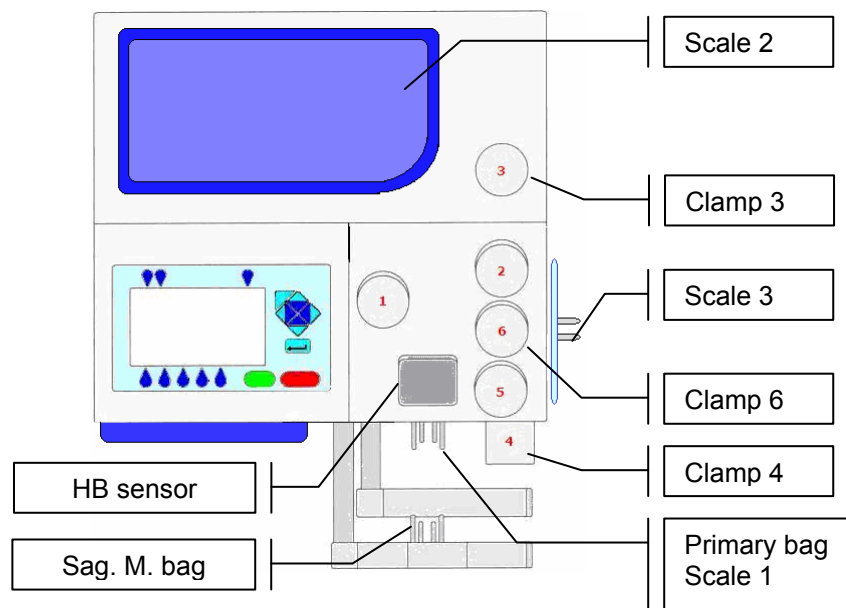
Picture 44: Kit installation T/B triple procedure.

NOTE: Tubes in the various kits have different lengths. To simplify kits management, the firmware allows to configure which valves you wish to enable.
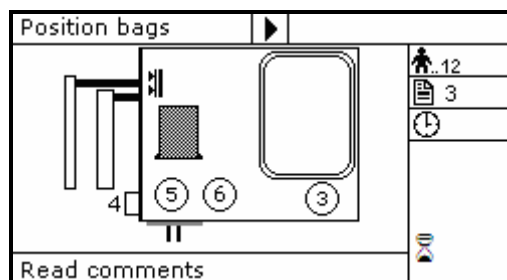
Picture 45: Position primary T/B triple bag.

- Hang the primary bag to the bag holders on the front panel. The label containing bag data should always be turned outside. After detecting the primary bag, the plate will move backword to make positioning of Sag.M. bag easier, and the display will show the bag icon.
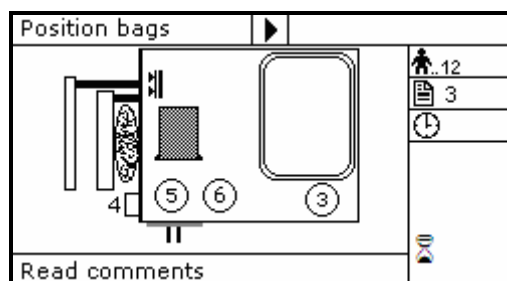
Picture 46: Position plasma, buffy coat and Sag.M. T/T triple bags.

- If required, hang the Sag. M. bag to the bag holders on the fix plate and insert the Sag. M. tube into clamp 5.
- Open cover of HB sensor and insert the tube coming from the primary bag into the reading area. Close the cover.
- Insert the plasma tube firmly into the flow-valve.
- Insert the tube coming from the flow-valve firmly into clamp 3.
- Insert RBC tube into clamp 4.
- Position the plasma bag on upper scale.

▪ Position the RBC bag on lateral scale.

Picture 47: T/B triple bags in position.

Archimede checks correct tubes positioning inside proper clamps by mens of its optical sensors. The tube is correctly inserted when the clamp number is replaced by the icon ⊕.

Press [START] key-button to start the procedure.

If the primary bag expected weight check has been enabled through Archimede*LINK* and the detected weight does not fall within the set limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with [Enter] or press [Esc] to leave the procedure. Furthermore, if the tube presence check is enabled the display will show the clamp numbers where tubes are not correctly inserted and the procedure will not start until all tubes are correctly inserted into the enabled clapms

Now wait for the plate to get close to the bag. The plate will exert a force corresponding to the value set in the procedure parameters.

Parameters of the ongoing phase:

#18: B.C target
#8: RBC action threshold
#20: Sag. M. amount

Picture 48: Break cannulas view T/B triple procedure.

Brake the cannulas by forcing on the side upper part of the cannula. Wait for a few seconds that positive pressure is released. After detecting pressure decrease, Archimede automatically starts the separation cycle. If pressure does not decrease below the set value, due to tube obstruction or fluid clogging, it is anywayt possible to force the cycle start by pressing [START] keybutton.

🖎 During the procedure, possible comments can be read on the external part of the fix front plate.

The graphic interface will now show the current operating phase number, and the weight value of plasma collected. *Archimede* will check the buffy coat level through IR sensors, flow valve and valves 3 and 4. The distance sensor will stop the separation process when the plate reaches the distance set in the procedure parameters. When this process is over, the plate will move back words to allow Sag. M. dispensing if required.

🚫 **ATTENTION: THE FORCE SENSOR IS ENABLED <u>ONLY</u> WHEN THE PLATE MOVES TOWARDS THE INSTRUMENT BODY.**
CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA WHEN THE PLATE IS MOVING.

Air elimination depends on procedure parameters setting:

Manual air elimination: press [START] keybutton to open clamp 3, put plasma bag in vertical position and remove air manually by pressing on the bag. When finished, press [STOP] keybutton to close clamp 3, and re-position plasma bag to detect weight.

The sealing cycle depends on the value set in the procedure parameters:

Automatic sealing: sealing cycle of the selected clamps is performed automatically.

Manual sealing: press [START] keybutton to seal the enabled lines, or press [STOP] to continue, after confirming, without sealing.

Picture 49: Sealing procedure T/B tripe

Archimede will automatically send to Archimede*LINK* all events and data of the procedure performed.

At the end of the procedure the display will show the detected weights. If they are not the expected ones, because tubes are not correctly placed and distort scales' readings, the emocomponents can be weighed again after correcting tubes' position and the new weights can be sent to Archimede*LINK* again.

Correct weights: press [START] keybutton to continue with the same type of separation or press [Esc] to go back to the page listing the procedures.
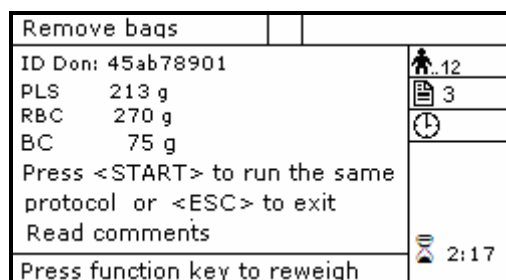
Picture 50: Viewing weights T / B triple.

Incorrect weights: press one of the 🔵 keybuttons to weigh emocomponents again. To accept the new values and send them to Archimede*LINK* press [Enter] keybutton.
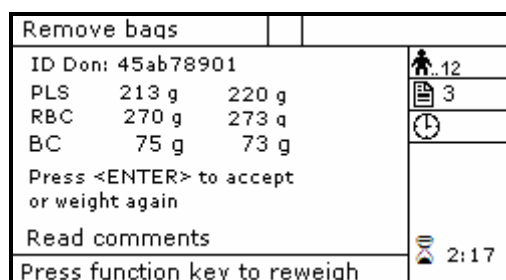
Picture 51: Reweigh T/B triple

With Archimede*LINK* the normal limits check can be activated. If it is enabled and the detected weights do not fall within the set limits, the display will show the emocomponents' detected weights and the allowed limits. Press any key to continue.

Picture 52: T/B triple with weight out of normal range.

Now remove tubes and bags and press 🟢 START to continue with another separation of the same type or press ◤ to exit.

If you need to interrupt the procedure either momentarily or definitively, press 🔴 STOP keybutton.
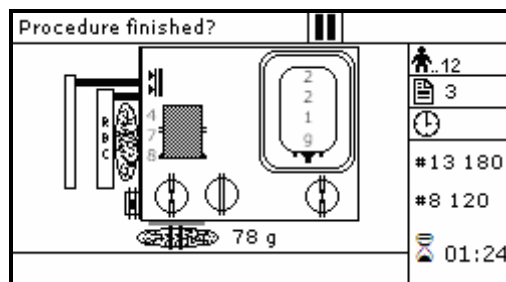
Picture 53: Pause or Stop procedure T/B triple

Stop: press 🔴 STOP or ⌨ Enter. Archimede will display the sealing page and send data to Archimede*LINK*.

Pause: press 🟢 START or ◤ to continue the procedure.

4.6.5 PROCEDURE 4   Top & Bottom quadruple PPP+BC+RCC.

This procedure is indicated for quadruple top & bottom bags to obtain buffy coat (BC), erythrocytes (RCC) and two plasma (PPP) one PPP for single buffy coat.

Parameters used:

1 During the procedure, checks that tubes are properly inserted into the clamps enabled for the ongoing procedure.

2 Enables the routine controlling breaking of the primary bag cannulas.

3 Force in xx.x Kg beyond which the plate stops and waits for cannulas breaking.

4 Plate forward moving speed during cannulas breaking step.

5 Value used to calculate the force value below which the systems exits the cannulas breaking routine. *V =(force measured at breaking position) – (current force).*

7 Value minimal of difference of reading between RBC and plasma with which it comes controlled the bag before and during the procedure

8 Sensibility HB sensor.

9 Value of the maximum force applied during the procedure; the plate stops if the force exceeds this limit.

11 Selection of the sealing mode. In automatic mode, the system automatically seals the bags when the procedure is over. In manual mode, bags sealing must be confirmed.

12 Selection of clamps to be used for sealing when the procedure is over. Clamps are numbered as follows: 1 Top, 2 Plasma, 4 Buffy, 8 Bottom. The value to be set in this position is the value corresponding to the sum of the clamps used: for example, if bottom and top are to be used, the value to be set is 9.

13 Plate moving speed used in the first phase for the management of force.

15 Number identifying the IR sensor dedicated to buffy coat level.

18 Buffy coat target value.

20 Sag. M. amount [g] to be dispensed in the final step of procedure.

21 Sag.M. amount already present in RBC destination bag.

25 Tare of the primary bag. This value is used to calculate the product amount left in the primary bag [current weight - tare].

32 Flow valve sensibility. (Clamp 6)

34 Plasma amount to be added to second plasma bag.

36 Plasma amount to be dispensed by gravity in the buffy coat bag.

40 Value allowing to select the clamps to be used in the procedure.

41 Number of the profile plate to be used with the ongoing procedure.

42 Enables the air elimination routine.

43 Primary bag positioning with blade ready for weighing.

44 Scale stability check.

45 Check Correlation Distance Weight.

46 Enable scale reading.

47 IR corresponding to upper and lower bag edges.

Position bags and tubes according to the below sequence. Be sure to avoid tensions and folds that might cause flow obstruction or weighing errors.
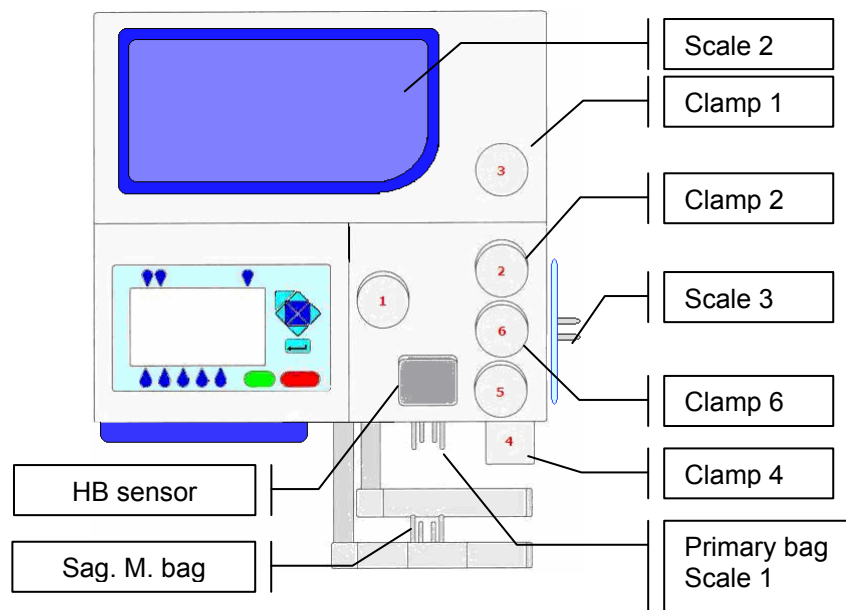
Picture 54: Kit installation T/B quadruple procedure

NOTE: Tubes in the various kits have different lengths. To simplify kits management, the firmware allows to configure which valves you wish to enable.
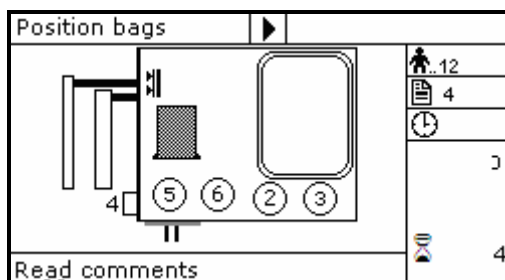
Picture 55: Position primary T/B quadrupla bag.

- Hang the primary bag to the bag holders on the front panel. The label containing bag data should always be turned outside. After detecting the primary bag, the plate will move backword to make positioning of Sag.M. bag easier, and the display will show the bag icon.
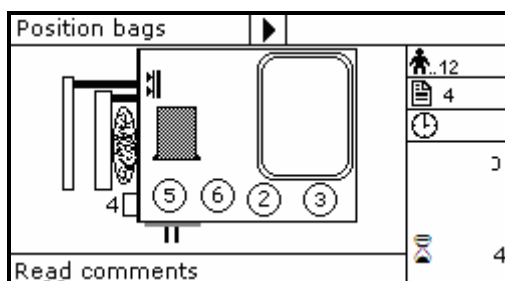
Picture 56: Position plasma, buffy coat and Sag.M. T/B quadruple bags.

- If required, hang the Sag. M. bag to the bag holders on the fix plate and insert the Sag. M. tube into clamp 5.
- Open cover of HB sensor and insert the tube coming from the primary bag into the reading area. Close the cover.
- Insert the plasma tube firmly into the flow-valve. (clamp 6)
- Insert the plasma tube coming from the flow-valve firmly into clamp 3.
- Position the plasma bag on upper scale.
- Insert the secondary plasma bag tube into clamp 2.

- Position the secondary plasma bag on upper scale.
- Insert RBC tube into clamp 4.
- Position the RBC bag on lateral scale.

Picture 57: T/B quadruple bags in position.

Archimede checks correct tubes positioning inside proper clamps by mens of its optical sensors. The tube is correctly inserted when the clamp number is replaced by the icon ⌀.

Press START key-button to start the procedure.

If the primary bag expected weight check has been enabled through Archimede*LINK* and the detected weight does not fall within the set limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with Enter or press Esc to leave the procedure. Furthermore, if the tube presence check is enabled the display will show the clamp numbers where tubes are not correctly inserted and the procedure will not start until all tubes are correctly inserted into the enabled clapms

Now wait for the plate to get close to the bag. The plate will exert a force corresponding to the value set in the procedure parameters.

Parameters of the ongoing phase:

#18: B.C. target
#8:   RBC action threshold
#20: Sag. M. amount

Picture 58: Break cannulas view T/B quadruple procedure.

Break the cannulas by forcing on their side upper part. Wait for a few seconds that positive pressure is released. After detecting pressure decrease, Archimede automatically starts the separation cycle. If pressure does not decrease below the set value, due to tube obstruction or fluid clogging, it is anyway possible to force the cycle start by pressing START keybutton.

During the procedure, possible comments can be read on the external part of the fix front plate.

The graphic interface will now show the current operating phase number, and the weight value of plasma collected. *Archimede* will check the buffy coat level through IR sensors, flow valve and valves 2, 3 and 4. The distance sensor will stop the separation process when the plate reaches the distance set in the procedure parameters. When this process is over, the plate will move back words to allow Sag. M. dispensing if required.

ATTENTION: THE FORCE SENSOR IS ENABLED ONLY WHEN THE PLATE MOVES TOWARDS THE INSTRUMENT BODY.
CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA WHEN THE PLATE IS MOVING.

Air elimination depends on procedure parameters setting:

Manual air elimination: press [START] keybutton to open clamp 3, put plasma bag in vertical position and remove air manually by pressing on the bag. When finished, press [STOP] keybutton to close clamp 3, and re-position plasma bag to detect weight.

The sealing cycle depends on the value set in the procedure parameters:

Automatic sealing: sealing cycle of the selected clamps is performed automatically.

Manual sealing: press [START] keybutton to seal the enabled lines, or press [STOP] to continue, after confirming, without sealing.

Picture 59: Sealing Procedure T/B quadruple

Archimede will automatically send to Archimede*LINK* all events and data of the procedure performed.

At the end of the procedure the display will show the detected weights. If they are not the expected ones, because tubes are not correctly placed and distort scales' readings, the emocomponents can be weighed again after correcting tubes' position and the new weights can be sent to Archimede*LINK* again.

Correct weights: press [START] keybutton to continue with the same type of separation or press [Esc] to go back to the page listing the procedures.
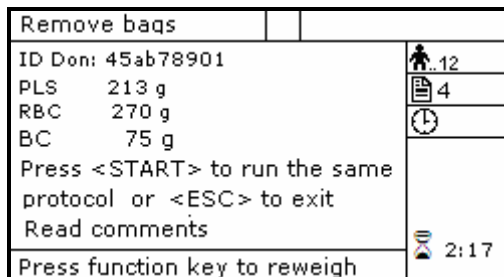
Picture 60: Viewing weight T/B quadruple

Incorrect weights: press one of the 🔵 keybuttons to weigh emocomponents again. To accept the new values and snd them to Archimede*LINK* press [Enter]

Picture 61: Reweight T/B quadruple

With Archimede*LINK* the normal limits check can be activated. If it is enabled and the detected weights do not fall within the set limits, the display will show the emocomponents' detected weights and the allowed limits. Press any key to continue.

Picture 62: T/B quadruple with weight out of normal range.

Now remove tubes and bags and press START to continue with another separation of the same type or press Esc to exit.

If you need to interrupt the procedure either momentarily or definitively, press STOP keybutton.

Picture 63: Pause or Stop procedure T/B quadruple.

Stop: press STOP or Enter. Archimede will display the sealing page and send data to Archimede*LINK*.

Pause: press START or Esc to continue the procedure.

4.6.6 PROCEDURE 5   Separation from PRP to PPP+PLT

This secondary procedure is for separate from PRP to result platelets poor plasma (PPP), and platelets concentrate.

Parameters used:

1 During the procedure, checks that tubes are properly inserted into the clamps enabled for the ongoing procedure.
2 Enables the routine controlling breaking of the primary bag cannulas.
3 Force in xx.x Kg beyond which the plate stops and waits for cannulas breaking.
4 Plate forward moving speed during cannulas breaking step.
5 Value used to calculate the force value below which the systems exits the cannulas breaking routine. *V =(force measured at breaking position) – (current force).*
9 Value of the maximum force applied during the procedure; the plate stops if the force exceeds this limit.
11 Selection of the sealing mode. In automatic mode, the system automatically seals the bags when the procedure is over. In manual mode, bags sealing must be confirmed.
12 Selection of clamps to be used for sealing when the procedure is over. Clamps are numbered as follows: 1 Top, 2 Plasma, 4 Buffy, 8 Bottom. The value to be set in this position is the value corresponding to the sum of the clamps used: for example, if bottom and top are to be used, the value to be set is 9.
13 Plate moving speed used in the first phase for the management of force.
18 Value of the final distance beyond which the procedure stops.
25 Tare of primary bag. This value is used to calculate the product amount left in the primary bag [current weight - tare].
30 Plasma-plt weight.
40 Value allowing to select the clamps to be used in the procedure
41 Number of the profile plate to be used with the ongoing procedure.
42 Enables the air elimination routine.
43 Primary bag positioning with blade ready for weighing.
44 Scale stability check.
45 Check Correlation Distance Weight.
46 Enable scale reading.
47 IR coresponding to upper and lower bag edge.

Position bags and tubes according to the below sequence. Be sure to avoid tensions and folds that might cause flow obstruction or weighing errors.
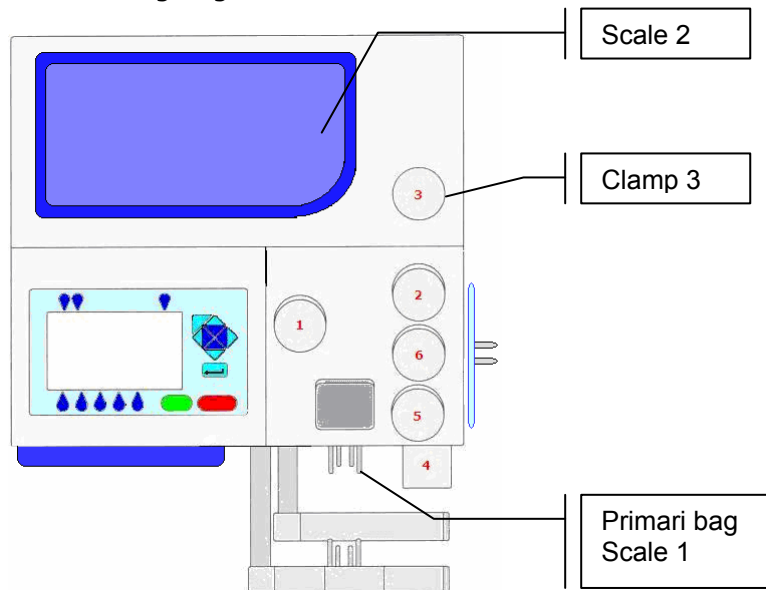
Picture 64: Kit installation procedure PRP to PPP+PLT

NOTE: Tubes in the various kits have different lengths. To simplify kits management, the firmware allows to configure which valves you wish to enable.
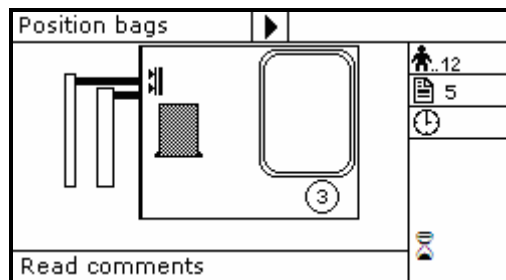
Picture 65: Position primary bag procedure PRP to PPP + PRP

▪ Hang the primary bag to the bag holders on the front panel. The label containing bag data should always be turned outside.
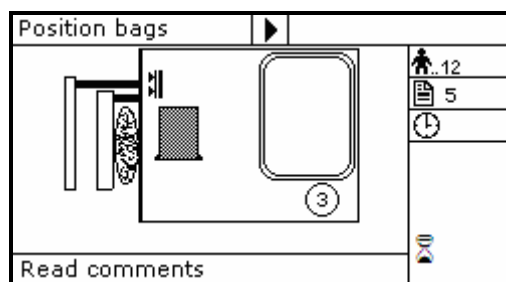
Picture 66: Position PLT bag procedure PRP to PPP + PRP.

• Open HB sensor cover and put the tube coming from primary bag inside the reading area. Close cover.
▪ Insert the plasma tube firmly into clamp 3.
▪ Position the plasma bag on upper scale.
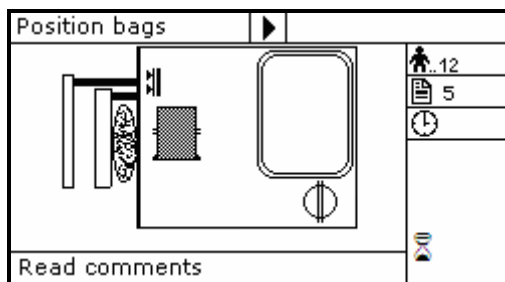
Picture 67: PRP to PPP + PRP bags in position.

Archimede checks correct tubes positioning inside proper clamps by mens of its optical sensors. The tube is correctly inserted when the clamp number is replaced by the icon ⊕.

Press [START] key-button to start the procedure.

If the primary bag expected weight check has been enabled through Archimede*LINK* and the detected weight does not fall within the set limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with [Enter] or press ◢ to leave the procedure. Furthermore, if the tube presence check is enabled the display will show the clamp numbers where tubes are not correctly inserted and the procedure will not start until all tubes are correctly inserted into the enabled clapms

Now wait for the plate to get close to the bag. The plate will exert a force corresponding to the value set in the procedure parameters.

Parameters of the ongoing phase:

#18:   Action distance between phases

Picture 68: Break cannulas view procedure PRP to PPP + PRP

Break the cannulas by forcing on their side upper part. Wait for a few seconds that positive pressure is released. After detecting pressure decrease, Archimede automatically starts the separation cycle. If pressure does not decrease below the set value, due to tube obstruction or fluid clogging, it is anyway possible to force the cycle start by pressing [START] keybutton.

The graphic interface will now show the current operating phase number, and the weight value of plasma collected. The operating phase depends on the distance set in the procedure parameters.
Archimede will check the plate distance. The distance sensor will stop the separation process when the plate reaches the distance set in the procedure parameters, and the plate will move back words to standby position.

✍ During the procedure, possible comments can be read on the external part of the fix front plate.

🚫 ATTENTION: THE FORCE SENSOR IS ENABLED ONLY WHEN THE PLATE MOVES TOWARDS THE INSTRUMENT BODY.
CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA WHEN THE PLATE IS MOVING.

The sealing cycle depends on the value set in the procedure parameters:

<u>Automatic sealing:</u>   sealing cycle of the selected clamps is performed automatically.

<u>Manual sealing:</u>   press [START] keybutton to seal the enabled lines, or press [STOP] to continue, after confirming, without sealing.
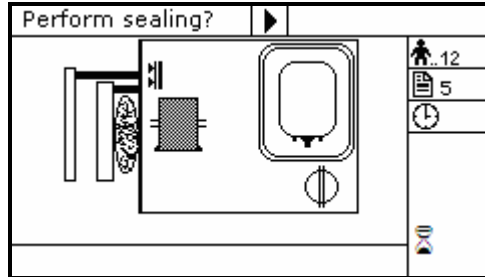
Picture 69: Sealing procedure PRP to PPP + PRP

Archimede will automatically send to Archimede*LINK* all events and data of the procedure performed.

At the end of the procedure the display will show the detected weights. If they are not the expected ones, because tubes are not correctly placed and distort scales' readings, the emocomponents can be weighed again after correcting tubes' position and the new weights can be sent to Archimede*LINK* again.

<u>Correct weights:</u> press [START] keybutton to continue with the same type of separation or press [Esc] to go back to the page listing the procedures.
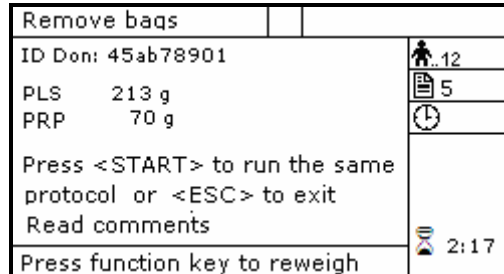
Picture 70: Viewing weight PRP to PPP + PRP.
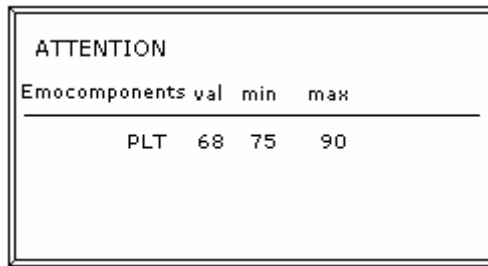
<u>Incorrect weights:</u>   press one of the ⬤ keybuttons to weigh emocomponents again. To accept the new values and send them to Archimede*LINK* press [Enter]
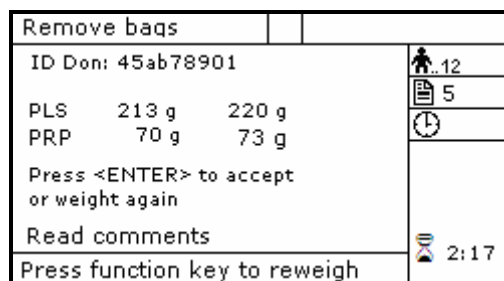
Picture 71: Reweight procedure PRP to PPP + PRP.

With Archimede*LINK* the normal limits check can be activated. If it is enabled and the detected weights do not fall within the set limits, the display will show the emocomponents' detected weights and the allowed limits. Press any key to continue.

Picture 72: Procedure PRP to PPP + PRP with weight out of normal range..

Now remove tubes and bags and press START to continue with another separation of the same type or press Esc to exit.

If you need to interrupt the procedure either momentarily or definitively, press STOP keybutton.
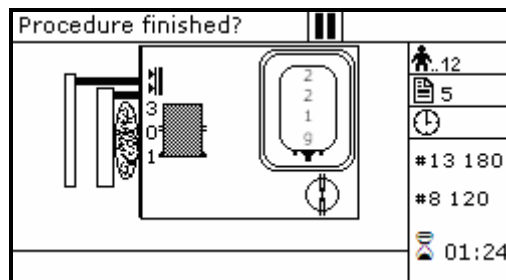
Picture 73: Pause or Stop procedure PRP to PPP + PRP.

Stop: press STOP or Enter. Archimede will display the sealing page and send data to Archimede*LINK*.

Pause: press START or Esc to continue the procedure.

4.6.7 PROCEDURE 7 Single or Pool of Buffy for PLT + residual BC with filter

This procedure allows to collect platelets and filtrate.

Parameters used:

1 During the procedure, checks that tubes are properly inserted into the clamps enabled for the ongoing procedure.
2 Enables the routine controlling breaking of the primary bag cannulas.
3 Force in xx.x Kg beyond which the plate stops and waits for cannulas breaking.
4 Plate forward moving speed during cannulas breaking step.
5 Value used to calculate the force value below which the systems exits the cannulas breaking routine. *V =(force measured at breaking position) – (current force).*
6 Number identifying the IR sensor dedicated to RBC sensor enabling.
8 Sensibility HB sensor.
9 Value of the maximum force applied during the procedure; the plate stops if the force exceeds this limit.
10 Threshold value for action of IR sensors.
11 Selection of the sealing mode. In automatic mode, the system automatically seals the bags when the procedure is over. In manual mode, bags sealing must be confirmed.
12 Selection of clamps to be used for sealing when the procedure is over. Clamps are numbered as follows: 1 Top, 2 Plasma, 4 Buffy, 8 Bottom. The value to be set in this position is the value corresponding to the sum of the clamps used: for example, if bottom and top are to be used, the value to be set is 9.
13 Plate moving speed used in the first phase for the management of force.
18 Value of the distance beyond which the system, after confirmation, stops the procedure if no RBCs have been detected.
19 Excess plasma [g] to be dispensed after the HB sensor has detected RBCs. If manual dispensing is enabled, the system allows manual product dispensing.
24 Motor speed during filter priming.
25 Tare of the primary bag. This value is used to calculate the product amount left in the primary bag [current weight - tare]
38 Minimum flow that should pass through the filter. Below this value an alarm of obstructed filter is activated.
40 Value allowing to select the clamps to be used in the procedure.
41 Number of the profile plate to be used with the ongoing procedure.
42 Enables the air elimination routine.
43 Primary bag positioning with blade ready for weighing.
44 Scale stability check.
45 Check Correlation Distance Weight.
46 Enable scale reading.
47 IR corresponding to upper and lower bag edge.

Position bags and tubes according to the below sequence. Be sure to avoid tensions and folds that might cause flow obstruction or weighing errors.
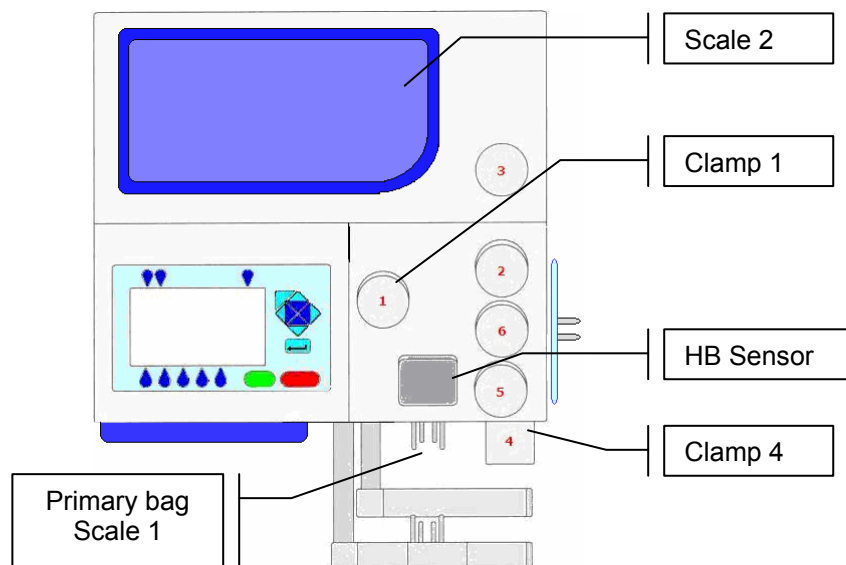
Picture 74: Kit installation procedure PLT with filter

NOTE: Tubes in the various kits have different lengths. To simplify kits management, the firmware allows to configure which valves you wish to enable.
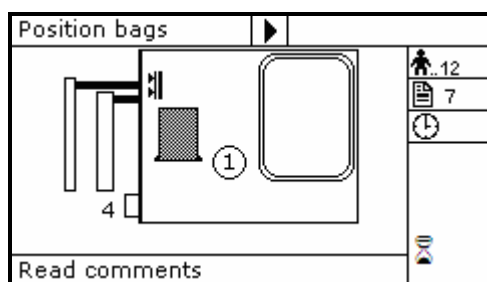
Picture 75: Position primary bag separation PLT with filter.

- Hang the primary bag to the bag holders on the front panel. The label containing bag data should always be turned outside.
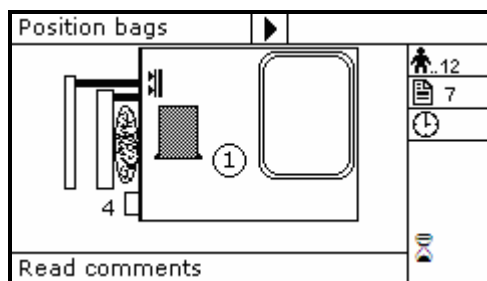
Picture 76: Position PLT bag separation PLT with filter.

- Insert the tube coming from the primary bag into clamp 4.
- Open cover of HB sensor and insert the tube coming from filter into the reading area. Close the cover.
- Insert the tube coming from the HB sensor firmly into clamp 1.
- Position the PLT bag on upper scale.
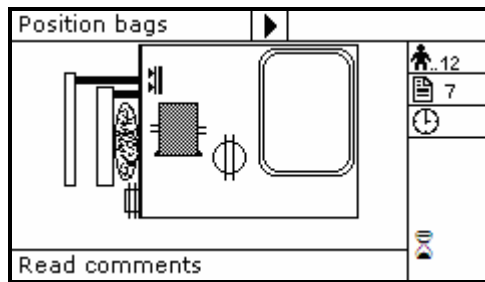
Picture 77: Bag PLT with filter in position.

Archimede checks correct tubes positioning inside proper clamps by mens of its optical sensors. The tube is correctly inserted when the clamp number is replaced by the icon ⏀.

Press [START] key-button to start the procedure.

If the primary bag expected weight check has been enabled through Archimede*LINK* and the detected weight does not fall within the set limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with [Enter] or press [Esc] to leave the procedure. Furthermore, if the tube presence check is enabled the display will show the clamp numbers where tubes are not correctly inserted and the procedure will not start until all tubes are correctly inserted into the enabled clapms

Now wait for the plate to get close to the bag. The plate will exert a force coresp0onding to the value set in the procedure parameters.

Parameters of the ongoing phase:

#13: Plate forward moving speed
#18: Action distance between phases

Picture 78: Break cannulas view procedure PLT with filter.

Break the cannulas by forcing on their side upper part. Wait for a few seconds that positive pressure is released. After detecting pressure decrease, Archimede automatically starts the separation cycle. If pressure does not decrease below the set value, due to tube obstruction or fluid clogging, it is anyway possible to force the cycle start by pressing [START] keybutton.

☛ During the procedure, possible comments can be read on the external part of the fix front plate.

The graphic interface will now show the current operating phase number, and the weight value of PLT collected. *Archimede* will check the flow and stop the plate in case of filter obstruction or RBC presence in the HB sensor. In case of filter obstruction, the operator can press [START] and continue until the new warning, while in case of RBC presence the system will stop the collection process and move the plate back to home position.

☛ During the procedure, possible comments can be read on the external part of the fix front plate.

🚫 ATTENTION: THE FORCE SENSOR IS ENABLED ONLY WHEN THE PLATE MOVES TOWARDS THE INSTRUMENT BODY.
CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA WHEN THE PLATE IS MOVING.

Air elimination depends on procedure parameters setting:

Manual air elimination: press [START] keybutton to open clamp 3, put plasma bag in vertical position and remove air manually by pressing on the bag. When finished, press [STOP] keybutton to close clamp 3, and re-position plasma bag to detect weight.

The sealing cycle depends on the value set in the procedure parameters:

Automatic sealing: sealing cycle of the selected clamps is performed automatically.

Manual sealing: press [START] keybutton to seal the enabled lines, or press [STOP] to continue, after confirming, without sealing.

Picture 79: Sealing procedure PLT with filter.

Archimede will automatically send to Archimede*LINK* all events and data of the procedure performed.

At the end of the procedure the display will show the detected weights. If they are not the expected ones, because tubes are not correctly placed and distort scales' readings, the emocomponents can be weighed again after correcting tubes' position and the new weights can be sent to Archimede*LINK* again.

Correct weights: press [START] keybutton to continue with the same type of separation or press [Esc] to go back to the page listing the procedures.
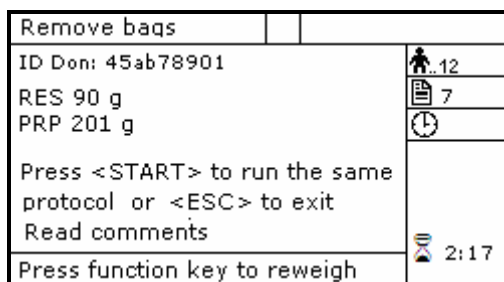
Picture 80: Viewing weight PLT with filter.
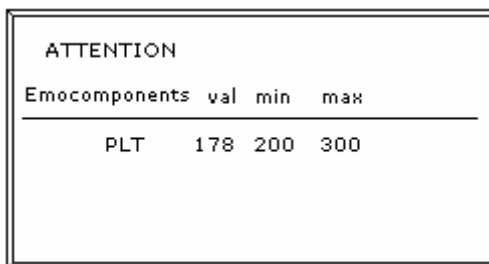
Incorrect weight: press one of the 🔵 keybuttons to weigh emocomponents again. To accept the new values and send them to Archimede*LINK* press [Enter]
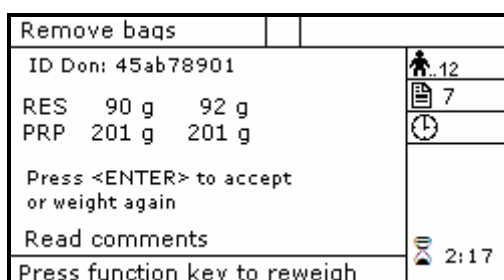
Picture 81: Reweight procedure PLT with filter.

USING ARCHIMEDE

With Archimede*LINK* the normal limits check can be activated. If it is enabled and the detected weights do not fall within the set limits, the display will show the emocomponents' detected weights and the allowed limits. Press any key to continue.


```
ATTENTION

Emocomponents  val  min   max
_____
       PLT    178  200   300
```

Picture 82: Procedure PLT with filter with weight out of normal range.

Now remove tubes and bags and press ⬤START to continue with another separation of the same type or press ◥ to exit.

If you need to interrupt the procedure either momentarily or definitively, press ⬤STOP keybutton.
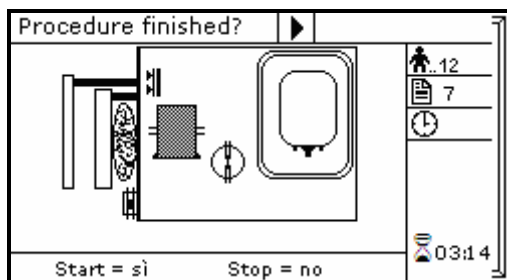
Picture 83: Pause or Stop procedure PLT with filter.

Stop: press ⬤STOP or ⌨Enter. Archimede will display the sealing page and send data to Archimede*LINK*.

Pause: press ⬤START or ◥ to continue the procedure.

4.6.8 PROCEDURA 8   Separation of Erythrocytes Washing

This procedure allows to separate the washing fluid from erythrocytes subjected to a washing procedure.

Parameters used:

1 During the procedure, checks that tubes are properly inserted into the clamps enabled for the ongoing procedure.

2 Enables the routine controlling breaking of the primary bag cannulas.

3 Force in xx.x Kg beyond which the plate stops and waits for cannulas breaking.

4 Plate forward moving speed during cannulas breaking step.

5 Value used to calculate the force value below which the systems exits the cannulas breaking routine. *V =(force measured at breaking position) – (current force).*

6 Number identifying the IR sensor dedicated to RBC sensor enabling.

7 Value minimal of difference of reading between RBC and plasma with which it comes controlled the bag before and during the procedure

8 Sensibility HB sensor.

9 Value of the maximum force applied during the procedure; the plate stops if the force exceeds this limit.

11 Selection of the sealing mode. In automatic mode, the system automatically seals the bags when the procedure is over. In manual mode, bags sealing must be confirmed.

12 Selection of clamps to be used for sealing when the procedure is over. Clamps are numbered as follows: 1 Top, 2 Plasma, 4 Buffy, 8 Bottom. The value to be set in this position is the value corresponding to the sum of the clamps used: for example, if bottom and top are to be used, the value to be set is 9.

13 Plate moving speed used in the first phase for the management of force.

18 Value of the distance beyond which the system, after confirmation, stops the procedure if no RBCs have been detected.

40 Value allowing to select the clamps to be used in the procedure.

41 Number of the profile plate to be used with the ongoing procedure.

43 Primary bag positioning with blade ready for weighing.

44 Scale stability check.

45 Check Correlation Distance Weight.

46 Enable scale reading.

47 IR corresponding to upper and lower bag edges.

Position bags and tubes according to the below sequence. Be sure to avoid tensions and folds that might cause flow obstruction or weighing errors.
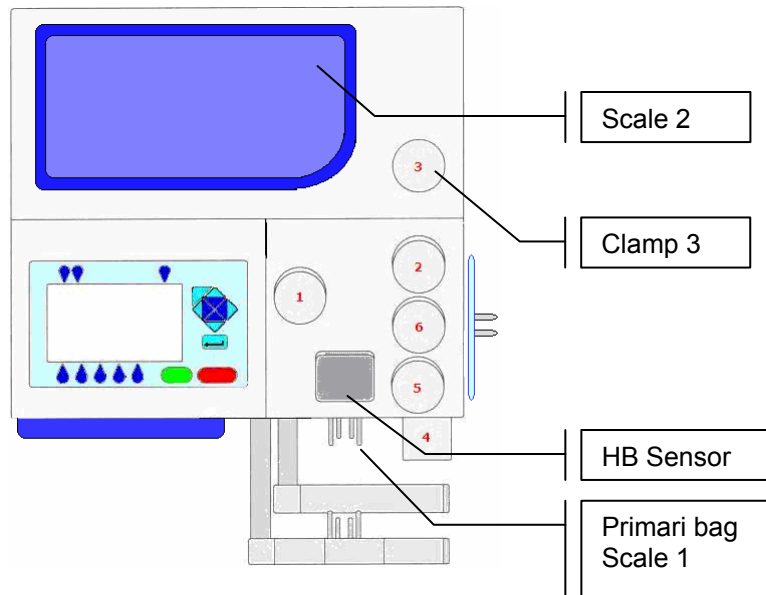
Picture 84: Kit installation procedure erythrocytes washing.

NOTE: Tubes in the various kits have different lengths. To simplify kits management, the firmware allows to configure which valves you wish to enable.
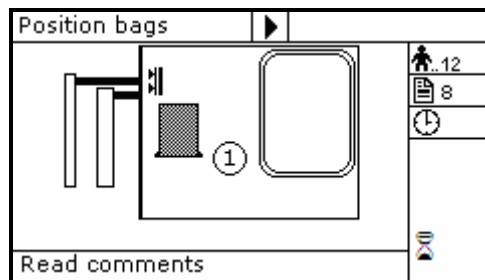
Picture 85: Position primary bag erythrocytes washing.

- Hang the primary bag to the bag holders on the front panel. The label containing bag data should always be turned outside.
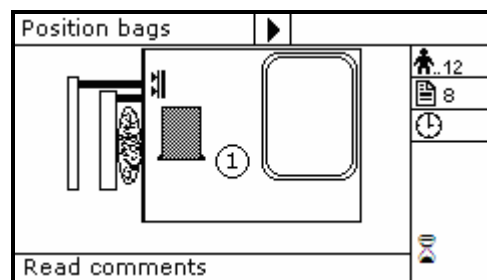
Picture 86: Position erythrocytes washing bag.

- Open cover of HB sensor and insert the tube coming from the primary bag into the reading area. Close the cover.
- Insert the tube coming from the HB sensor firmly into clamp 1.
- Position the washing fluid bag on upper scale.
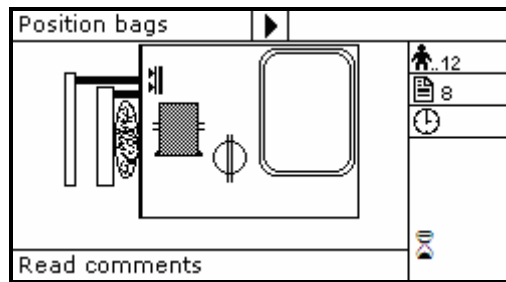
Picture 87: Erythrocytes washing bag in position.

Archimede checks correct tubes positioning inside proper clamps by mens of its optical sensors. The tube is correctly inserted when the clamp number is replaced by the icon ⬦.

Press [START] key-button to start the procedure.

If the primary bag expected weight check has been enabled through Archimede*LINK* and the detected weight does not fall within the set limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with [Enter] or press [Esc] to leave the procedure. Furthermore, if the tube presence check is enabled the display will show the clamp numbers where tubes are not correctly inserted and the procedure will not start until all tubes are correctly inserted into the enabled clapms

Now wait for the plate to get close to the bag. The plate will exert a force corresponding to the value set in the procedure

Parameters of the ongoing phase:

#13: Plate forward moving speed
#18: Action distance between phases
#8: RBC action threshold

Picture 88: Break cannulas view erythrocytes washing procedure

Break the cannulas by forcing on the side upper part of the cannula itself. Wait for a few seconds that positive pressure is released. After detecting pressure decrease, Archimede automatically starts the separation cycle. If pressure does not decrease below the set value, due to tube obstruction or fluid clogging, it is anyway possible to force the cycle by pressing [START] keybutton.

The graphic interface will now show the current operating phase number, and the washing solution weight collected. *Archimede* will check the erythrocytes level in the primary bag. When this level reaches the selected IR sensor, the display will show "RBC" in the pressing plate area.
The photometer detecting the presence of erythrocytes will now check, in real time, the washing liquid flow. When the erythrocytes amount exceeds the value set in procedure parameters, the photometry will display "RBC" on the sensor cover icon, the relative valve will stop, and the plate will move backwards to standby position.

During the procedure, possible comments can be read on the external part of the fix front plate.

ATTENTION: THE FORCE SENSOR IS ENABLED ONLY WHEN THE PLATE MOVES TOWARDS THE INSTRUMENT BODY.

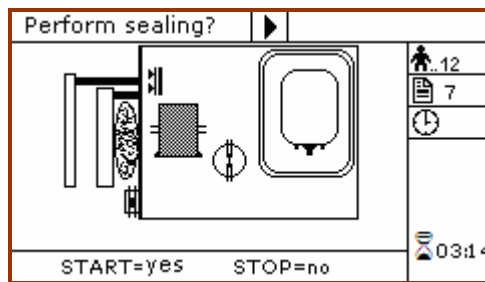**CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA WHEN THE PLATE IS MOVING.**

The sealing cycle depends on the value set in the procedure parameters:

Automatic sealing: sealing cycle of the selected clamps is performed automatically.

Manual sealing: press **START** keybutton to seal the enabled lines, or press **STOP** to continue, after confirming, without sealing.
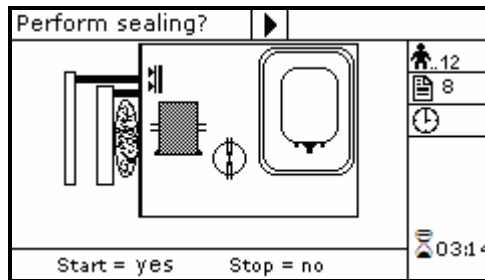
Picture 89: Sealing erythrocytes washing procedure.

Archimede will automatically send to Archimede*LINK* all events and data of the procedure performed.

At the end of the procedure the display will show the detected weights. If they are not the expected ones, because tubes are not correctly placed and distort scales' readings, the emocomponents can be weighed again after correcting tubes' position and the new weights can be sent to Archimede*LINK* again.

Correct weights: press **START** keybutton to continue with the same type of separation or press **Esc** to go back to the page listing the procedures.
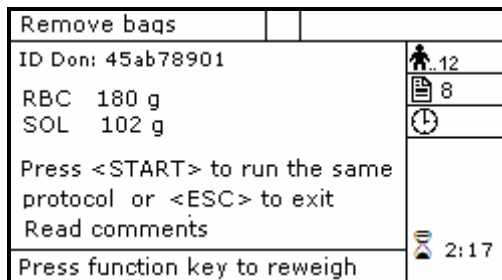
Picture 90: Viewing weight erythrocytes washing .

Incorrect weights: press one of the 🔵 keybuttons to weigh emocomponents again. To accept the new values and send them to Archimede*LINK* press **Enter**
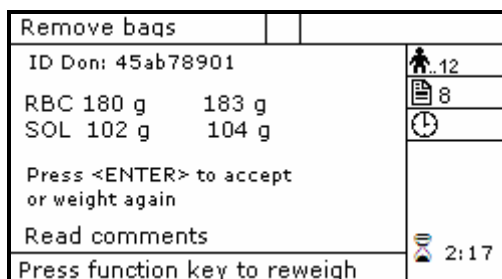
Picture 91: Reweight procedure erythrocytes washing.

Now remove tubes and bags and press ![START] to continue with another separation of the same type or press ![Esc] to exit.

![STOP]

If you need to interrupt the procedure either momentarily of definitively, press ![STOP] keybutton.
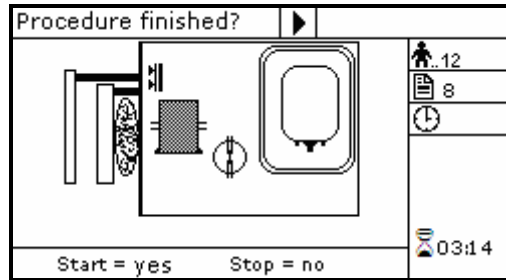
Picture 92: Pause or Stop in procedure erythrocytes washing .

Stop: press ![STOP] or ![Enter]. Archimede will display the sealing page and send data to Archimede*LINK*.

Pause: press ![START] or ![Esc] to continue the procedure.

4.6.9 PROCEDURE 10 [a]UMBILICAL CORD

This procedure is indicated for quadruple top & bottom bag to obtain erythrocytes (RCC), plasma (PPP), and buffy coat (BC) diluted with plasma added through a press.

Parameters used:

1 During the procedure, checks that tubes are properly inserted into the clamps enabled for the ongoing procedure.

2 Enables the routine controlling breaking of the primary bag cannulas.

3 Force in xx.x Kg beyond which the plate stops and waits for cannulas breaking.

4 Plate forward moving speed during cannulas breaking step.

5 Value used to calculate the force value below which the systems exits the cannulas breaking routine. *V =(force measured at breaking position) − (current force).*

7 Value minimal of difference of reading between RBC and plasma with which it comes controlled the bag before and during the procedure.

8 Sensibility HB sensor.

9 Value of the maximum force applied during the procedure; the plate stops if the force exceeds this limit.

11 Selection of the sealing mode. In automatic mode, the system automatically seals the bags when the procedure is over. In manual mode, bags sealing must be confirmed.

12 Selection of clamps to be used for sealing when the procedure is over. Clamps are numbered as follows: 1 Top, 2 Plasma, 4 Buffy, 8 Bottom. The value to be set in this position is the value corresponding to the sum of the clamps used: for example, if bottom and top are to be used, the value to be set is 9.

13 Plate moving speed used in the first phase for the management of force.

15 Number identifying the IR sensor dedicated to buffy coat level.

18 Buffy coat target value.

25 Tare of the primary bag. This value is used to calculate the product amount left in the primary bag [current weight - tare]

32 Sensibility flow valve. (Clamp 6)

40 Value allowing to select the clamps to be used in the procedure.

41 Number of the profile plate to be used with the ongoing procedure.

42 Enables the air elimination routine.

43 Primary bag positioning with blade ready for weighing.

44 Scale stability check.

45 Check Correlation Distance Weight.

**46** Enable scale reading.

47 IR corresponding to upper and lower bag edges.

Position bags and tubes according to the below sequence. Be sure to avoid tensions and folds that might cause flow obstruction or weighing errors.
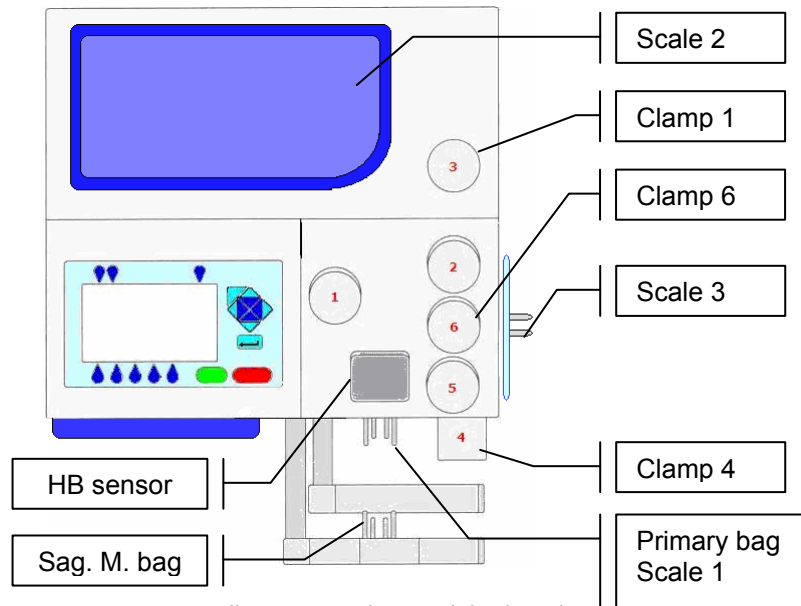

Picture 93: Kit installation procedure umbilical cord

NOTE: Tubes in the various kits have different lengths. To simplify kits management, the firmware allows to configure which valves you wish to enable.
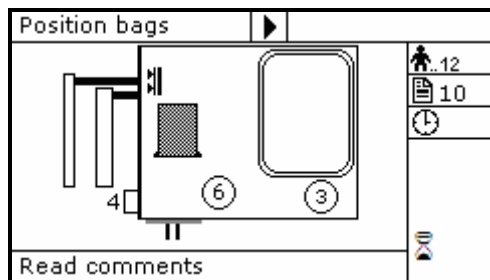

Picture 94: Position primary bag umbilical cord procedure.

▪ Hang the primary bag to the bag holders on the front panel. The label containing bag data should always be turned outside.
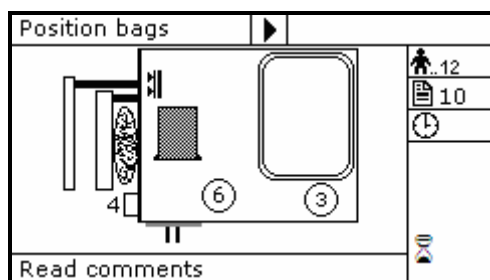
Picture 95: Position plasma, RBC bag of umbilical cord procedure.

▪ Open cover of HB sensor and insert the tube coming from the primary bag into the reading area. Close the cover.
▪ Insert the tube coming from HB sensor into clamp 6.
▪ Insert the tube coming from clamp 6 into clamp 3.
▪ Position the plasma bag on upper scale.
▪ Insert bottom tube into clamp 4.
▪ Position the RBC bag on lateral scale.
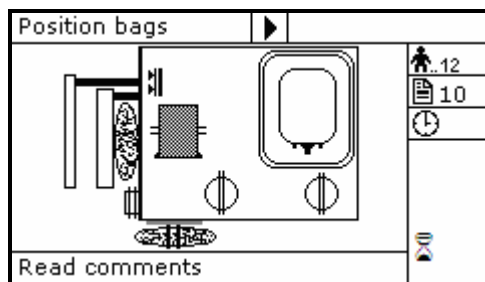
Picture 96: Erythrocytes umbilical cord in position.

Archimede checks correct tubes positioning inside proper clamps by mens of its optical sensors. The tube is correctly inserted when the clamp number is replaced by the icon ⨁.

Press [START] key-button to start the procedure.

If the primary bag expected weight check has been enabled through Archimede*LINK* and the detected weight does not fall within the set limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with [Enter] or press [Esc] to leave the procedure. Furthermore, if the tube presence check is enabled the display will show the clamp numbers where tubes are not correctly inserted and the procedure will not start until all tubes are correctly inserted into the enabled clapms

Now wait for the plate to get close to the bag. The plate will exert a force corresponding to the value set in the procedure parameters.

Parameters of ongoing phase:

#13:   Plate forward moving speed
#18:   Action distance between phases
#8:   RBC action threshold

Picture 97: Break cannulas view umbilical cord procedure.

Break the cannulas by forcing on their side upper part. Wait for a few seconds that positive pressure is released. After detecting pressure decrease, Archimede automatically starts the separation cycle. If pressure does not decrease below the set value, due to tube obstruction or fluid clogging, it is anyway possible to force the cycle start by pressing [START] keybutton.

During the procedure, possible comments can be read on the external part of the fix front plate.

The graphic interface will now show the current operating phase number, and the weight value of plasma collected. *Archimede* will check the buffy coat level through IR sensors, flow valve and valves 3, and 4. The distance sensor will stop the separation process when the plate reaches the distance set in the procedure parameters.

ATTENTION: THE FORCE SENSOR IS ENABLED <u>ONLY</u> WHEN THE PLATE MOVES TOWARDS THE INSTRUMENT BODY.
CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA WHEN THE PLATE IS MOVING.

The sealing cycle depends on the value set in the procedure parameters:

Automatic sealing: sealing cycle of the selected clamps is performed automatically.

Manual sealing: press [START] keybutton to seal the enabled lines, or press [STOP] to continue, after confirming, without sealing.
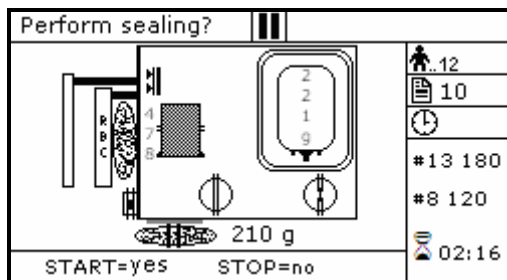
Picture 98: Sealing umbilical cord procedure.

Archimede will automatically send to Archimede*LINK* all events and data of the procedure performed.

At the end of the procedure the display will show the detected weights. If they are not the expected ones, because tubes are not correctly placed and distort scales' readings, the emocomponents can be weighed again after correcting tubes' position and the new weights can be sent to Archimede*LINK* again.

Correct weights: press [START] keybutton to continue with the same type of separation or press [Esc] to go back to the page listing the procedures.
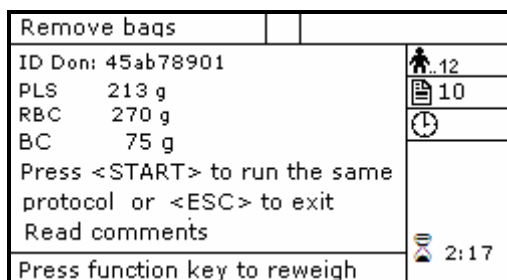
Picture 99: Viewing weight umbilical cord procedure

Incorrect weiths: press one of the 🔵 keybuttons to weigh emocomponents again. To accept the new values and send them to Archimede*LINK* press [Enter] .
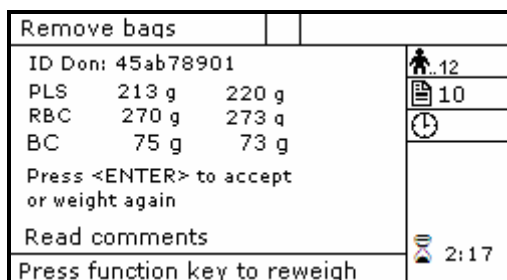
Picture 100: Reweight umbilical cord procedure.

Now remove tubes and bags and press [START] to continue with another separation of the same type or press [Esc] to exit.

If you need to interrupt the procedure either momentarily or definitively, press keybutton.
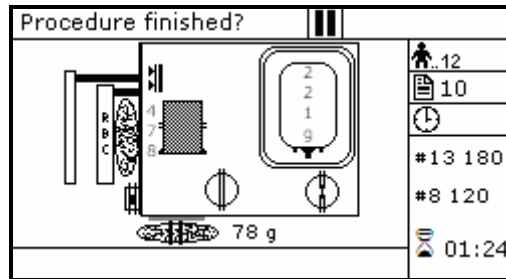
Picture 101: Pause or Stop procedure umbilical cord.

<u>Stop:</u> press or . Archimede will display the sealing page and send data to Archimede*LINK*.

<u>Pause:</u> press or to continue the procedure.

4.6.10 PROCEDURE 11 [b] ALIQUOT SEPARATION

This procedure allows to separate emocomponents in the four available bags by weighing them separately.

Parameters used:

1 During the procedure, checks that tubes are properly inserted into the clamps enabled for the ongoing procedure.
2 Enables the routine controlling breaking of the primary bag cannulas.
3 Force in xx.x Kg beyond which the plate stops and waits for cannulas breaking.
4 Plate forward moving speed during cannulas breaking step.
5 Value used to calculate the force value below which the systems exits the cannulas breaking routine. *V =(force measured at breaking position) – (current force).*
9 Value of the maximum force applied during the procedure; the plate stops if the force exceeds this limit.
11 Selection of the sealing mode. In automatic mode, the system automatically seals the bags when the procedure is over. In manual mode, bags sealing must be confirmed.
12 Selection of clamps to be used for sealing when the procedure is over. Clamps are numbered as follows: 1 Top, 2 Plasma, 4 Buffy, 8 Bottom. The value to be set in this position is the value corresponding to the sum of the clamps used: for example, if bottom and top are to be used, the value to be set is 9.
13 Plate moving speed used in the first phase for the management of force.
14 Weight of aliquot 2. (Upper scale)
18 Value of the distance beyond which the system, after confirmation, stops the procedure if the set volumes have not been dispensed.
25 Tare of the primary bag. This value is used to calculate the product amount left in the primary bag [current weight - tare].
29 Weight of aliquot 1. (Upper scale)
39 Weight of aliquot 3. (Lateral scale)
40 Value allowing to select the clamps to be used in the procedure.
41 Number of the profile plate to be used with the ongoing procedure.
42 Enables the air elimination routine.
43 Primary bag positioning with blade ready for weighing.
44 Scale stability check.
45 Check Correlation Distance Weight.
**46** Enable scale reading.
47 IR corresponding to upper and lower bag edges.

Position bags and tubes according to the below sequence. Be sure to avoid tensions and folds that might cause flow obstruction or weighing errors.
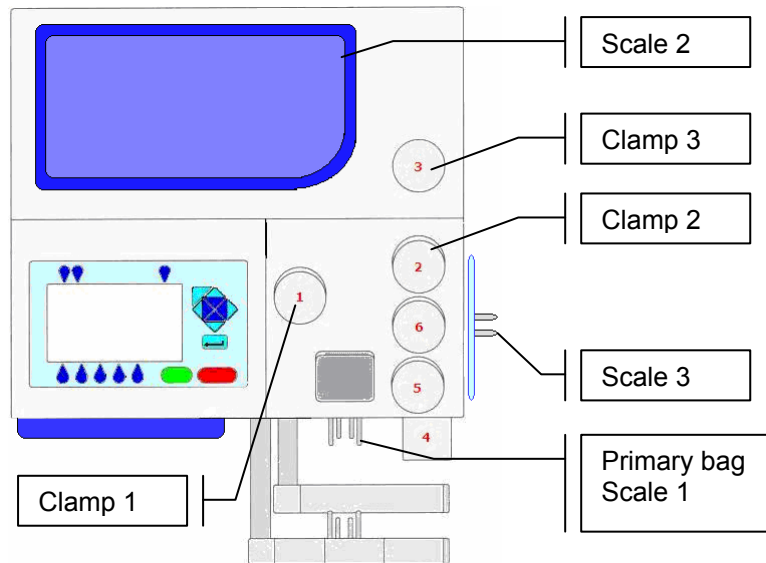

Picture 102: Kit installation aliquot separation procedure.

NOTE: Tubes in the various kits have different lengths. To simplify kits management, the firmware allows to configure which valves you wish to enable.
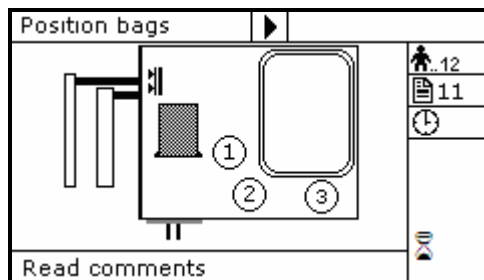

Picture 103: Position primary bag aliquot separation procedure.

▪ Hang the primary bag to the bag holders on the front panel. The label containing bag data should always be turned outside.
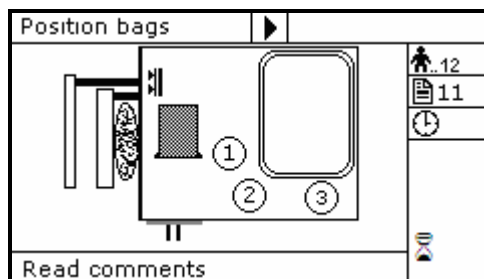
Picture 104: Position aliquot separation procedure. bag.

▪ Insert tubes from the bags on upper scale firmly into clamps 1 and 3.
▪ Insert tubes from the bags on lateral scale firmly into clamp 2.

Picture 105: Aliquot separation procedure bag in position.

Archimede checks correct tubes positioning inside proper clamps by mens of its optical sensors. The tube is correctly inserted when the clamp number is replaced by the icon ⌀.

Press [START] key-button to start the procedure.

If the primary bag expected weight check has been enabled through Archimede*LINK* and the detected weight does not fall within the set limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with [Enter] or press [Esc] to leave the procedure. Furthermore, if the tube presence check is enabled the display will show the clamp numbers where tubes are not correctly inserted and the procedure will not start until all tubes are correctly inserted into the enabled clapms

Now wait for the plate to get close to the bag. The plate will exert a force corresponding to the value set in the procedure parameters.

Parameters of the ongoing phase:

#13: Plate forward moving speed.

Picture 106: Break cannulas view aliquot separation procedure.

Break the cannulas by forcing on the side upper part of the cannula. Wait for a few seconds that positive pressure is released.

During the procedure, possible comments can be read on the external part of the fix front plate.

The graphic interface will now show the current operating phase number, and the weight value of plasma collected. *Archimede* will check the bags weights. When the desired volume is reached, the relevant clamp will be close. After the last aliquot the plate will move backwards to standby position.

ATTENTION: THE FORCE SENSOR IS ENABLED <u>ONLY</u> WHEN THE PLATE MOVES TOWARDS THE INSTRUMENT BODY.
CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA WHEN THE PLATE IS MOVING.

At the end of the procedure the display will show the detected weights. If they are not the expected ones, because tubes are not correctly placed and distort scales' readings, the

emocomponents can be weighed again after correcting tubes' position and the new weights can be sent to Archimede*LINK*.

Correct weights: press [START] keybutton to continue with the same type of separation or press [Esc] to go back to the page listing the procedures.

Picture 107: Viewing weight aliquot separation procedure.

Incorrect weights: prss one of the 💧 keybuttons to weigh emocomponents again. To accept the new values and send them to Archimede*LINK* press [Enter]
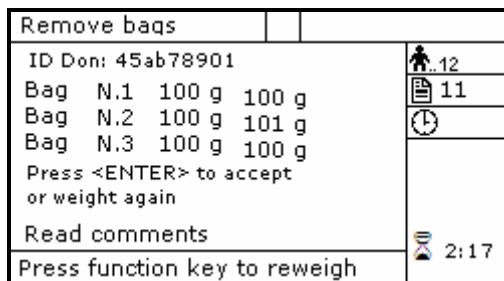
Picture 108: Reweight aliquot separation procedure.

The sealing cycle depends on the value set in the procedure parameters:

Automatic sealing: sealing cycle of the selected clamps is performed automatically.

Manual sealing: press [START] keybutton to seal the enabled lines, or press [STOP] to continue, after confirming, without sealing.
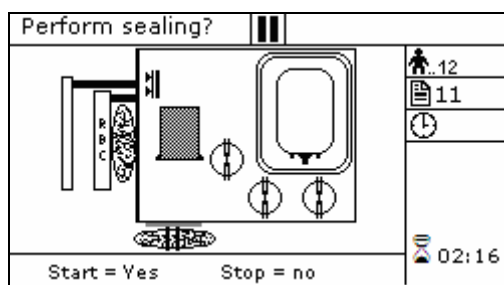
Picture 109: Sealing in aliquot separation procedure

Archimede will automatically send to Archimede*LINK* all events and data of the procedure performed.

Now remove tubes and bags and press [START] to continue with another separation of the same type ore press [Esc] to exit.

If you need to interrupt the procedure either momentarily or definitively, press keybutton.
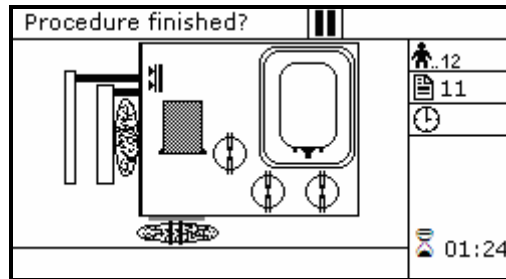
Picture 110: Pause or Stop aliquot separation.

Stop: press or . Archimede will display the sealing page and send data to Archimede*LINK*.

Pause: press or to continue the procedure.

4.6.11 PROCEDURE 13 [d] T & T for RCC diluted in Plasma + Predefined HCT.

This procedure is suitable for triple bags to obtain diluted RCC in plasma with predefined haematocrit (no additive solution) and PPP.

Parameters used:

1 During the procedure, checks that tubes are properly inserted into the clamps enabled for the ongoing procedure.

2 Enables the routine controlling breaking of the primary bag cannulas.

3 Force in xx.x Kg beyond which the plate stops and waits for cannulas breaking.

4 Plate forward moving speed during cannulas breaking step.

5 Value used to calculate the force value below which the systems exits the cannulas breaking routine. *V =(force measured at breaking position) − (current force).*

7 Value minimal of difference of reading between RBC and plasma with which it comes controlled the bag before and during the procedure

9 Value of the maximum force applied during the procedure; the plate stops if the force exceeds this limit.

11 Selection of the sealing mode. In automatic mode, the system automatically seals the bags when the procedure is over. In manual mode, bags sealing must be confirmed.

12 Selection of clamps to be used for sealing when the procedure is over. Clamps are numbered as follows: 1 Top, 2 Plasma, 4 Buffy, 8 Bottom. The value to be set in this position is the value corresponding to the sum of the clamps used: for example, if bottom and top are to be used, the value to be set is 9.

13 Plate moving speed used in the first phase for the management of force

15 Haematocrit target.

18 Value of the distance beyond which the system, after confirmation, stops the procedure if no RBCs have been detected.

25 Tare of the primary bag. This value is used to calculate the product amount left in the primary bag [current weight - tare]

40 Value allowing to select the clamps to be used in the procedure.

41 Number of the profile plate to be used with the ongoing procedure.

42 Enables the air elimination routine.

43 Primary bag positioning with blade ready for weighing.

44 Scale stability check.

45 Check Correlation Distance Weight.

46 Enable scale reading.

47 IR corresponding to upper and lower bag edges.

Position bags and tubes according to the below sequence. Be sure to avoid tensions and folds that might cause flow obstruction or weighing errors.
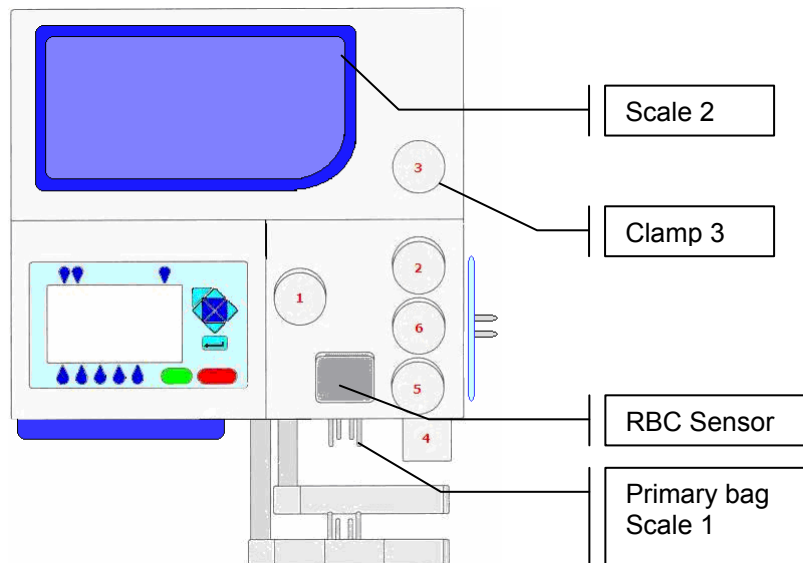

Picture 111: Kit installation procedure T & T with predefined HCT.

NOTE: .Tubes in the various kits have different lengths. To simplify kits management, the firmware allows to configure which valves you wish to enable.
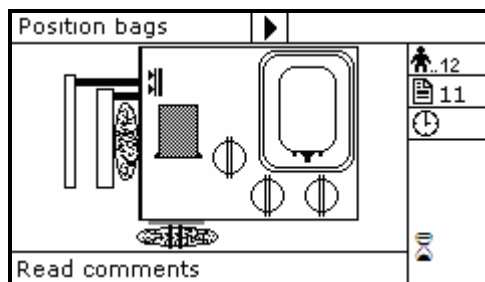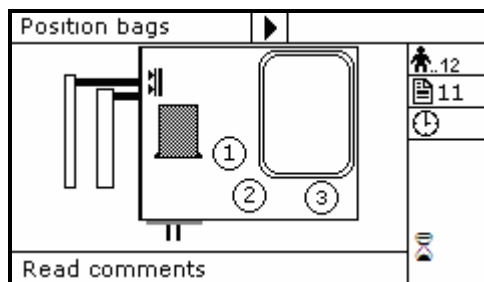

Picture 112: Position primary bag T & T with predefined HCT procedure.

▪ Hang the primary bag to the bag holders on the front panel. The label containing bag data should always be turned outside.
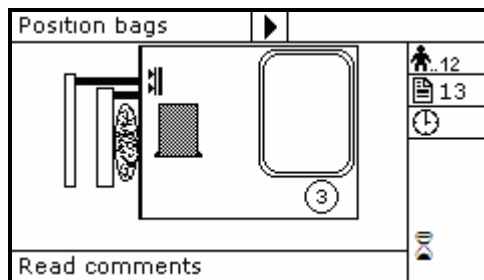
Picture 113: Position plasma bag T & T with predefined HCT procedure.

▪ Open the cover of HB sensor and insert the tube coming from the primary bag into the reading area. Close the cover.
▪ Insert the tube coming from the HB sensor firmly into clamp 3.
▪ Position the plasma bag on upper scale.
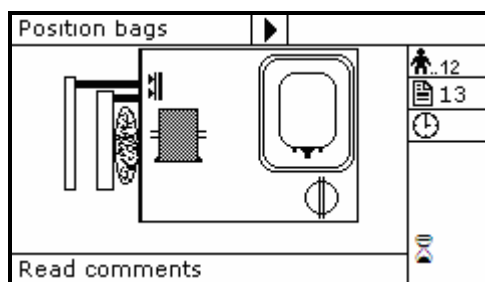
Picture 114: T & T with predefined HCT procedure bag in position.
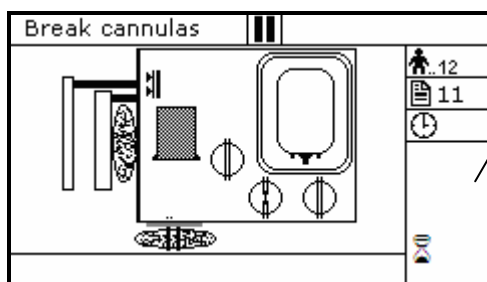
Archimede checks correct tubes positioning inside proper clamps by mens of its optical sensors. The tube is correctly inserted when the clamp number is replaced by the icon ⌀.

Press START key-button to start the procedure.

If the primary bag expected weight check has been enabled through Archimede*LINK* and the detected weight does not fall within the set limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with Enter or press to leave the procedure. Furthermore, if the tube presence check is enabled the display will show the clamp numbers where tubes are not correctly inserted and the procedure will not start until all tubes are correctly inserted into the enabled clapms

Now wait for the plate to get close to the bag. The plate will exert a force corresponding to the value set in the procedure parameters.

Parameters of the ongoing phase:

#13: Plate forward moving speed
#18: Action distance
#15: Haematocrit target

Picture 115: Break cannulas view procedure T & T with predefined HCT.

Brake the cannulas by forcing on the side upper part of the cannula. Wait for a few seconds that positive pressure is released. After detecting pressure decrease, Archimede automatically starts the separation cycle. If pressure does not decrease below the set value, due to tube obstruction or fluid clogging, it is anyway possible to force the cycle start by pressing START keybutton.

During the procedure, possible comments can be read on the external part of the fix front plate.

The graphic interface will now show the current operating phase number, and the weight value of plasma collected. *Archimede* will check the erythrocytes level and distance in primary bag. When this level reaches the HCT target will stop and the plate will move backwards.

ATTENTION: THE FORCE SENSOR IS ENABLED <u>ONLY</u> WHEN THE PLATE MOVES TOWARDS THE INSTRUMENT BODY.
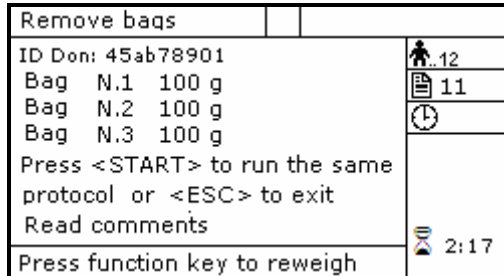**CAUTION: DO NOT PUT YOUR HANDS IN THE PLATE WORKING AREA WHEN THE PLATE IS MOVING.**

The sealing cycle depends on the value set in the procedure parameters:
<u>Automatic sealing:</u>   sealing cycle of the selected clamps is performed automatically.

Manual sealing: press [START] keybutton to seal the enabled lines, or press [STOP] to continue, after confirming, without sealing.
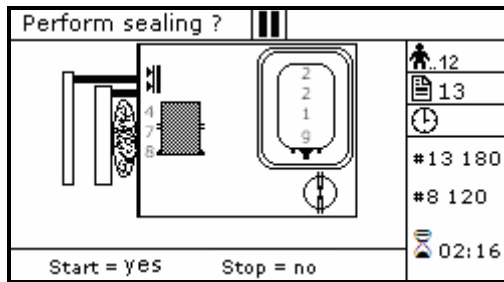
Picture 116: Sealing procedure RCC T & T with predefined HCT.

Archimede will automatically send to Archimede*LINK* all events and data of the procedure performed.

At the end of the procedure the display will show the detected weights. If they are not the expected ones, because tubes are not correctly placed and distort scales' readings, the emocomponents can be weighed again after correcting tubes' position and the new weights can be sent to Archimede*LINK* again.

Correct weights: press [START] keybutton to continue with the same type of separation or press [Esc] to go back to the page listing the procedures.
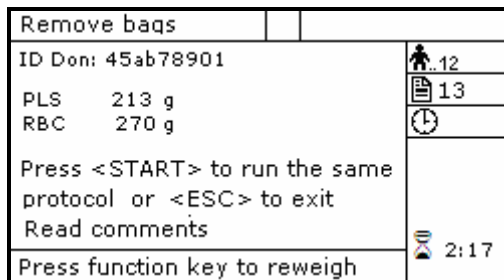
Picture 117: Viewing RCC T & T with predefined HCT procedure.

Incorrect weights: press one of the 🔵 keybuttons to weigh emocomponents again. To accept the new values and send them to Archimede*LINK* press [Enter]
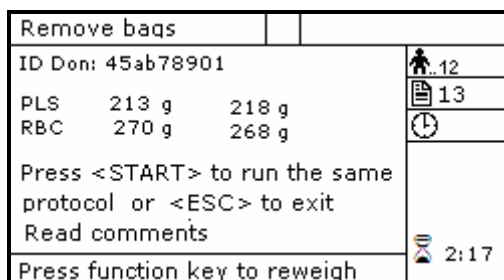
Picture 118: Reweight T & T with predefined HCT procedure.

With Archimede*LINK* the normal limits check can be activated. If it is enabled and the detected weights do not fall within the set limits, the display will show the emocomponents' detected weights and the allowed limits. Press any key to continue.

Picture 119: RCC T & T with predefined HCT procedure with weight out of normal range.

Correct weights: press keybutton to continue with the same type of separation or press to go back to the page listing the procedures.

Incorrect weights: press one of the keybuttons to weigh emocomponents again. To accept the new values and send them to Archimede*LINK* press

Now remove tubes and bags and press to continue with another separation of the same type or press to exit.

If you need to interrupt the procedure either momentarily or definitively, press keybutton.
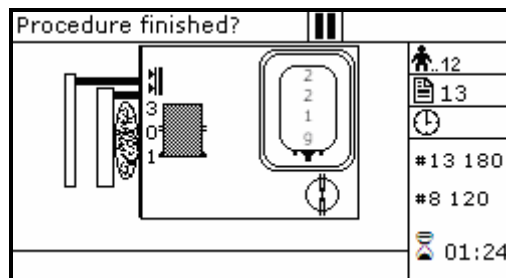
Picture 120: Pause or Stop procedure RCC T & T with predefined HCT.

Stop: press or . Archimede will display the sealing page and send data to Archimede*LINK*.

Pause: press or to continue the procedure.

5 SCALE CALIBRATION

Scale calibration can be performed only when Archimede has been switched on for a few minutes. This is necessary for measuring sensors to reach thermal stabilization. A set of certified sample weights is also necessary.

To enter calibration, press the ▼ keybutton above the 🔲 icon, and select CALIBRATION using 🔷 direction keybuttons.

```
       UTILITY MENU
 ✓ CALIBRATION
   PARAMETER LIST
   MAINTENACE
```
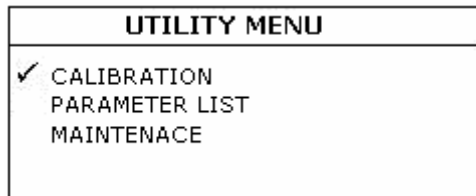
Picture 121: Calibration menu.

Confirm by pressing ⌨.

```
       CALIBRATION
 sample weight       500g
```
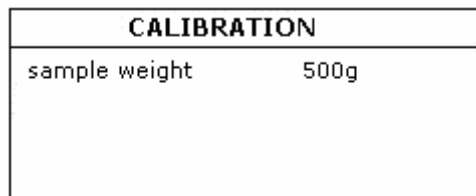
Picture 122: Calibration, sample weight setting.

Select the sample weight value you intend to use for calibration using 🔷 keybuttons, then confirm pressing ⌨.

```
       CALIBRATION
 Remove any weight from frontal scale

          << Press ENTER >>
```
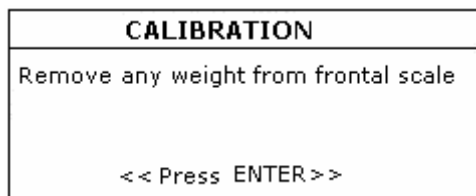
Picture 123: First step calibration.

To perform tare, remove any weight from the front scale and then confirm pressing ⌨.

```
       CALIBRATION
 Position        500 g
 on frontal scale
 Frontal reading   498 g
        << Press ENTER >>
```
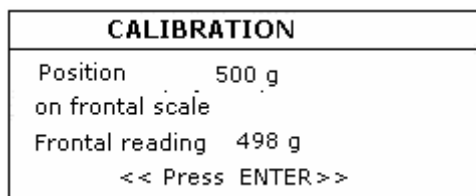
Picture 124: Second step calibration.

Position the selected sample weight. When the displayed value is stable ⌨ to confirm.

Repeat the above steps with upper scale (2) and lateral scale (3).

```
┌─────────────────────────────────────┐
│            CALIBRATION              │
├─────────────────────────────────────┤
│  K Prev        K Current            │
│  1.0050        1.0009    Scale 1    │
│  0.9890        1.0001    Scale 2    │
│  1.0563        1.1452    Scale 3    │
│                                     │
│  Press ENTER to accept              │
│  Press ESC to exit                  │
└─────────────────────────────────────┘
```

Picture 125: Calibration, calibration factors display.

Verify calibration factors calculated for front scale (1), upper scale (2), and lateral scale (3). Press [Enter] to confirm factors and save them, or press [Esc] to restore the previous calibration factors.

6   DATA TRANSFER

When the WLAN option is installed, *Archimede* can dialogue in bidirectional mode with *ArchimedeLINK.* This allows data transfer from more *Archimede* units, even if located several meters distant from the PC where *ArchimedeLINK* server is installed. The maximum possible distance is about 50 meters, depending on environment and disturbances that might be present.

6.1 WLAN

Picture 126: WLAN connection

A 802.11 b/g wireless LAN should be installed on the PC to be used. Communication takes place through the identification of Archimede's univocal serial number. This allows *ArchimedeLINK* to communicate with more units installed and switched on within a 50 meters distance.

⚠ Designed by manufacturer for exclusive connection to the instrument according to the prescriptions contained in the specific documentation of that instrument and to EN60950 Regulation.

6.2 Firmware Update and Procedures Protocols

- The use of *ArchimedeLINK* allows to:
- Update *Archimede*'s internal firmware. Firmware updating should preferably be performed by qualified engines authorized by manufacturer.
- Enter new procedures, up to a maximum of 18. New procedures creation should preferably be performed by application engineers having detailed knowledge of the various procedure parameters functions.
- Modify procedure parameters. This should be done by trained operators, or by application engineers in order to avoid entering unsuitable values for the regular bag press operation.
- Verify correct operation of all peripheral units connected to *Archimede.* This operation should be performed by qualified engineers authorized by manufacturer.

6.3 Data transmission and reception

Data concerning the ongoing procedure are sent both during the procedure and at the end of the procedure, with a round-up of all data acquired.

During the initial phase, *Archimede* sends *Archimede*'s univocal serial number, the procedure number and date and time of procedure beginning. In the final phase it sends all procedure data and events or errors, if any.
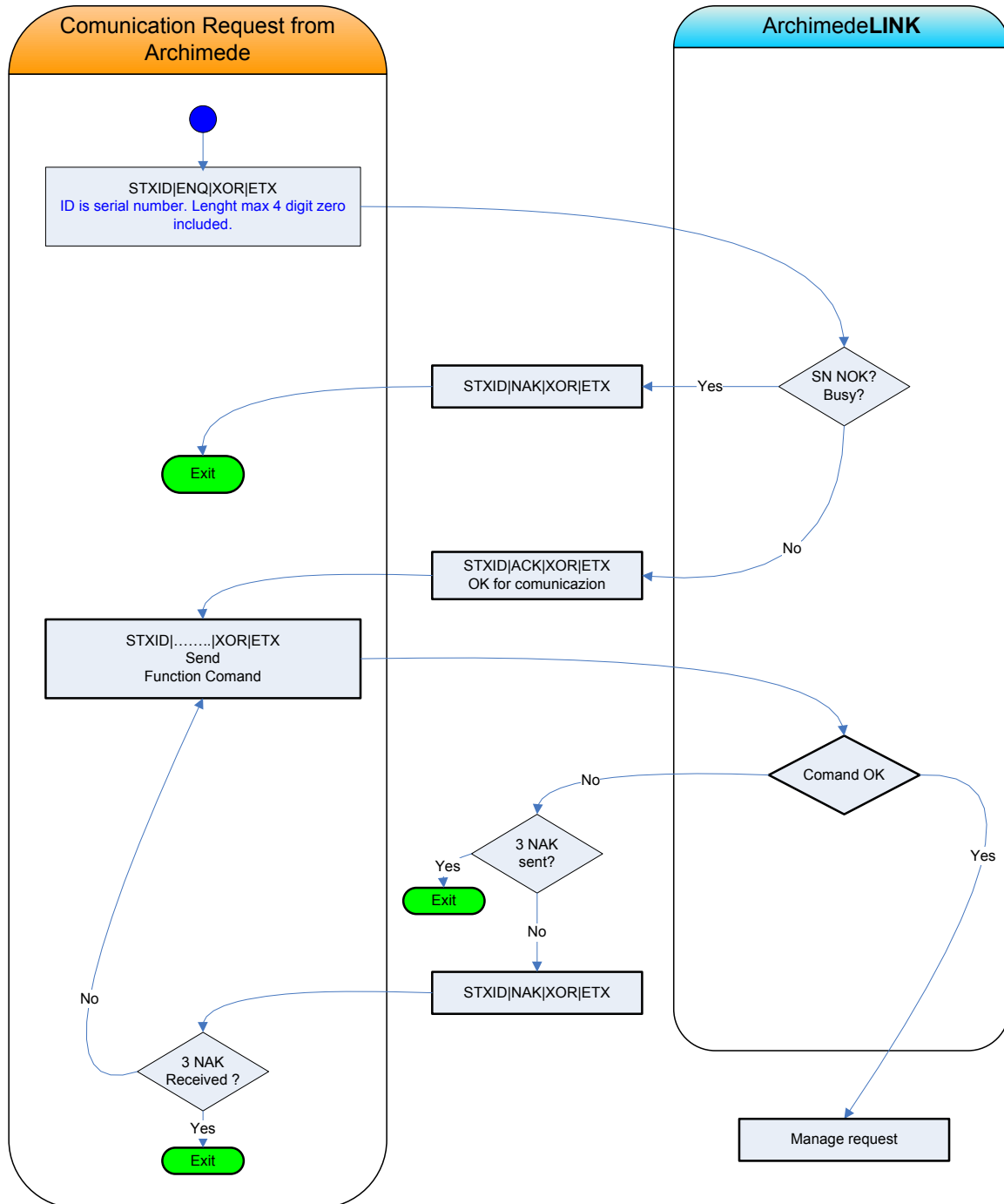
Picture 127: Communication request from Archimede
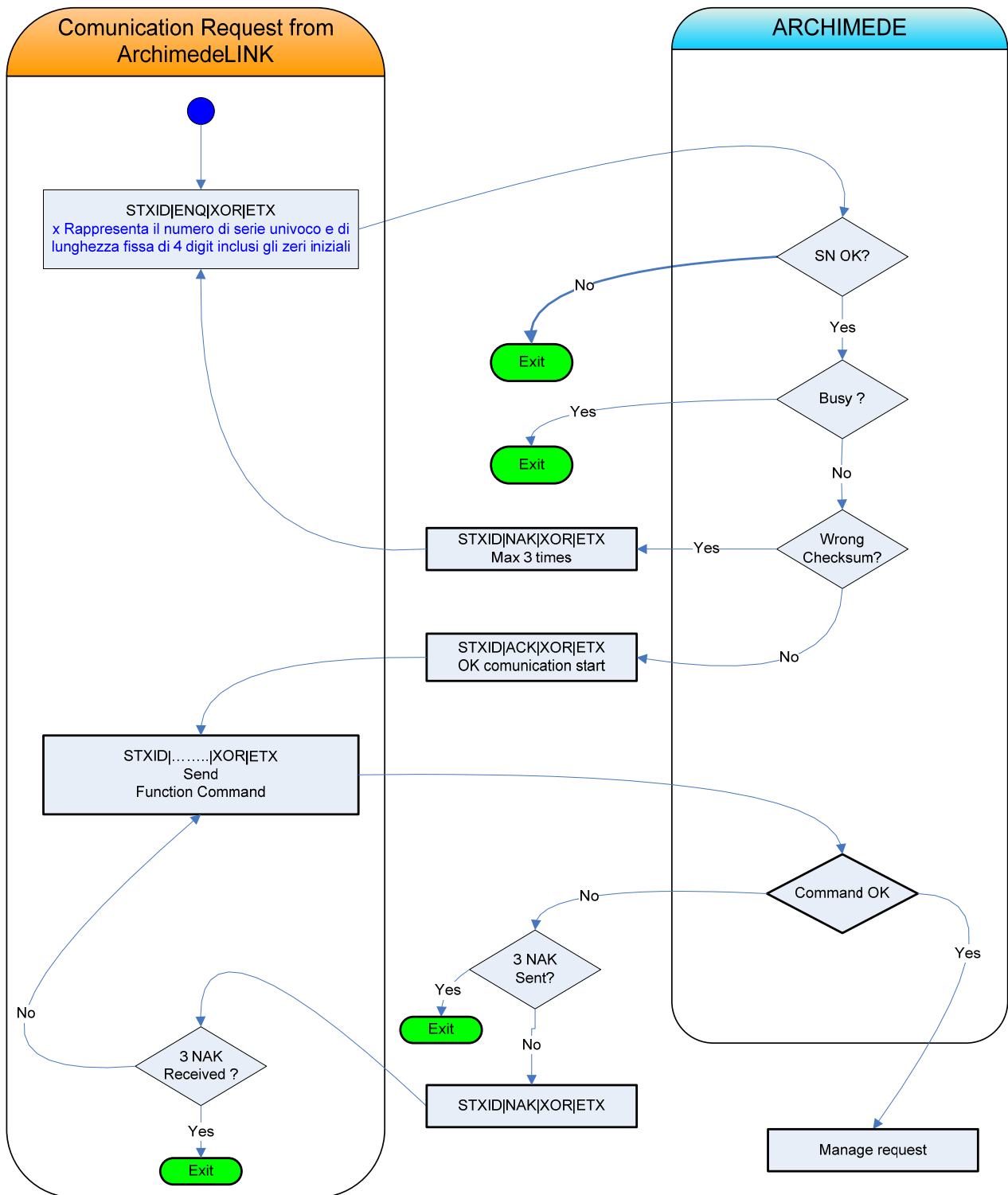
Picture 128: Communication request from ArchimedeLINK

DATA TRANSFER

6.3.1 Example of procedure data transmission:

Procedure preparation

⚒ STXxxxx|0d|yy|XOR|ETX
🖥 STXxxxx|ACK|XOR|ETX

Procedure start

⚒ STXxxxx|0e|yy|XOR|ETX
🖥 STXxxxx|ACK|XOR|ETX

Sealing in progress

⚒ STXxxxx|0f|yy|XOR|ETX
🖥 STXxxxx|ACK|XOR|ETX

Procedure run and relevant data

⚒ STXxxxx|0g|yy|OP|BC0|BC1|BC2|BC3|BC4|BC5|BC6|BC7|BC8|BC9|
hh:mm:ss|hh:mm:ss|hh:mm:ss|gg/mm/aa|
1111|2222|3333|cccc|ffff|ssss|hh:mm:ss|Events|Errors|XOR|ETX
🖥 STXxxxx|ACK|XOR|ETX

6.3.2 List of symbols used in the transmission protocol:

⚒	Data transmission from *Archimede* to PC.
🖥	Data transmission from PC to *Archimede*.
STX	Start of Text.
|	Unit separator
ACK	Acknowledge
XOR	String control byte
ETX	End of Text
xxxx	*Archimede*'s univocal serial number
0d	Data string ID: procedure preparation
0e	Data string ID: procedure start
0f	Data string ID: sealing in progress
0g	Data string ID: procedure run and relevant data
yy	Procedure number
OP	Operator code
BC	0,1,2,3,4,5,6,7,8,9 data read by barcode reader
hh:mm:ss	1st field procedure start time, 2nd field sealing start time, 3rd field time and date procedure end
▪	Weight of frontal scale
2222	Weight of upper scale
3333	Weight of lateral scale
cccc	Amount of plasma used for cleaning
ffff	Amount of plasma used for filter
ssss	Amount of Sag.M.
Events	Evens occurred during procedure
Errors	Errors occurred during procedure

7 TROUBLESHOOTING

Archimede checks continuously that the peripheral units connected work correctly. In case it detects an error that cannot be eliminated through the dedicated algorithms, the instrument displays the error.

7.1 Errors and Possible Solutions

Error 1A   **THE INSTRUMENT DOES NOT TURN ON**.

      Cause 1:   Main power is lacking.
      Remedy: Check that main voltage is present and that the power cord is correctly plugged.
      Cause 2:   Fuse blown
      Remedy: Replace burnt fuses with new ones of the type reported on data plate.

Error 2A   **DATE AND TIME LOSS**.

      Cause 1:   Reset of RTC circuit due to big conducted interferences.
      Remedy: Re-set date and time.
      Cause 2:   RTC backup capacitor is exhausted.
      Remedy: Call Authorized Service Center.

Error 3A   **THE DISPLAY SHOWS INCOMPREHENSIBLE CHARACTERS**.

      Cause 1:   Electronics interferences.
      Remedy: Turn Archimede OFF and ON.
                  Call Authorized Service Center.

Error 4A   **ARCHIMEDE DOES NOT CONNECT TO ARCHIMEDE*LINK***.

      Cause 1:   Archimede*LINK* is not enabled or Archimede network is disconnected.
      Remedy: Enable Archimede*LINK* server.
                  Connect to Archimede WLAN network.
                  Check that Archimede and Archimede*LINK* server subnets are correct.
                  Check firewall settings.

      Cause 2:   Noisy communication.
      Remedy: Check signal strength and ensure that Archimede's antenna is correctly screwed on and is not near metal objects.
                  Bring access point or server nearer Archimede units.
                  Change the WLAN module transmission channel.
                  Call Authorized Service Center.

7.2 Errors with Archimede codes

Error 1   **E^{2}PROM BUSY**.

      Cause 1:   E^{2}prom memory stuck or defective.
      Remedy: Turn *Archimede* OFF and ON.
      Cause 2:   Defective microcontroller E^{2}prom memory.
      Remedy: Call Authorized Service Center.

Error 2   **E^{2}PROM VERIFY**.

      Cause 1:   E^{2}PROM verify failed.
      Remedy: Turn *Archimede* OFF and ON.
      Cause 2:   Defective microcontroller E^{2}prom memory.
      Remedy: Call Authorized Service Center.

TROUBLESHOOTING

Error 3   **SPI TIMEOUT**

Cause 1:   One peripheral unit has unexpectedly interrupted the communication.

Remedy: Turn the instrument OFF and ON.

Cause 2:   Defective CPU or SO board.

Remedy: Call Authorized Service Center.

Error 4   **RFID TIMEOUT**

Cause 1:   Defective RFID label.

Remedy: Replace RFID label.

Cause 2:   RFID module is not responding.

Remedy: Turn the instrument OFF and ON.

Error 5   **RFID COMUNICATION ERROR**

Cause 1:   RFID data are corrupted.

Remedy: Turn the instrument OFF and ON.

Error 6   **CORRUPTED BOOT LOADER**

Cause 1:   Checksum of boot loader routine is not correct.

Remedy: Call Authorized Service Center.

Error 7   **CORRUPTED FIRMWARE**

Cause 1:   Checksum of firmware is not correct.

Remedy: Download firmware by ALNK.

Error 8   **WRONG CALIBRATION DATE**

Cause 1:   Data loss or corrupted.

Remedy: Run scales calibration.

Error 9   **PARAMETER OVER RANGE**

Cause 1:   During parameter check an error in parameter value has been detected.

Remedy: Run procedure update.

Error 10 (1-4)   **AD CONVERTER IS IN OVERFLOW.**

Cause 1:   Incorrect analog power

Remedy: Check that scale holders are correctly mounted and free from obstructions.
Turn *Archimede* OFF and ON.

Error 11 (1-4)   **AD CONVERTER TIMEOUT.**

Cause 1:   A/D converter stuck.

Remedy: Turn *Archimede* OFF and ON.

Error 12 (1-4)   **ADC UNDERFLOW DURING SCALE (X) TARE.**

Cause 1:   Scale holder is not in correct position.

Remedy: Check that scale holders are correctly mounted and free from obstructions.
Turn *Archimede* OFF and ON.

Error 13 (1-4)   **SCALE (X) TARE IS OVER LIMITS.**

Cause 1:   Scale holder is not in correct position.
AD input circuit not compensated.

Remedy:	Check that scale holders are correctly mounted and free from obstructions.
	Turn *Archimede* OFF and ON.

Error 14 (1-4)   **IN SEPARATION MODE TARE (X) VALUE IS OVER RANGE**.

Cause 1:	Weight detection circuit output $\geq$ 1000 mV.
Remedy:	Remove any extra weight from the cradle. Call Authorized Service Center.

Error 15 (1-4)   **K SCALES (X) VALUE OVERRANGE**.

Cause 1:	During calibration, the system has checked that scales calibration factor is over limit. The value of standard weight in use does not correspond to the value set during calibration..
Remedy:	Repeat calibration.
	Call Authorized Service Center.

Error 16 (1-10)   **LUMINOSITY**.

Cause 1:	There is too much light in the room. IR dark voltage > 500 mV.
Remedy:	Reduce environment luminosity.
Cause 2:	IR sensor is defective.
Remedy:	Call Authorized Service Center.

Error 17 (1-10)   **IR SENSOR SENSITIVITY TOO LOW**.

Cause 1:	IR sensor does not detect sufficient difference between lit and unlit led. Vtr < 4500mV with I led > 300 mA.
Remedy:	Clean IR sensors and yellow strip.
Cause 2:	IR sensors pair is defective.
Remedy:	Call Authorized Service Center.

Error 18 (1-10)   **IR SENSOR SENSITIVITY TOO HIGH**.

Cause 1:	IR sensor detects too much difference between lit and unlit led.
Remedy:	Reduce environment luminosity.
Cause 2:	IR sensors pair is defective.
Remedy:	Call Authorized Service Center.

Error 19   **HB SENSOR SENSITIVITY TOO LOW**.

Cause 1:	HB sensor does not detect sufficient variation between lit and unlit led.
Remedy:	Clean sensors.
Cause 2:	Green sensors is defective.
Remedy:	Call Authorized Service Center.

Error 20   **HB SENSOR SENSITIVITY TOO HIGH**.

Cause 1:	HB sensor detects too high variation between lit and unlit led.
Remedy:	Call Authorized Service Center.

Error 21 **PLATE OPENING MOVING TIME TO LIMIT POSITION >30 SECONDS.**

 Cause 1: Mechanical obstructions prevent the pressing plate from reaching open position. Time > 30 seconds.

 Remedy: Remove any obstruction. Clean support bars.

 Cause 2 Open position sensor defective.

 Remedy: Call Authorized Service Center.

Error 22 **PLATE CLOSING MOVING TIME TO LIMIT POSITION >30 SECONDS.**

 Cause 1: Mechanical obstructions prevent the pressing plate from reaching close position. Time > 30 seconds.

 Remedy: Remove any obstruction. Clean support bars.

 Cause 2: Force sensor defective.

 Remedy: Call Authorized Service Center.

Error 23 **BLADE MOVING TIME TO LIMIT POSITION >10 SECONDS.**

 Cause 1: Mechanical obstructions prevent the buffy coat separator from reaching open or close position within 10 seconds.

 Remedy: Remove any obstruction, Clean blade assy.

 Cause 2: BC position sensor defective.

 Remedy: Call Authorized Service Center.

Error 24 **PLATE POSITIONING TIME TO HOME POSITION >30 SECONDS.**

 Cause 1: Mechanical obstructions prevent plate movement from reaching home position within 30 seconds..

 Remedy: Remove any obstruction.

 Cause 2: Home position sensor defective.

 Remedy: Call Authorized Service Center.

Error 25 **POSITIONING TIME OF IR CALIBRATION POSITION SENSOR > 10 SECONDS.**

 Cause 1: Mechanical obstructions prevent plate movement from reaching IR calibration position within 10 seconds..

 Remedy: Remove any obstruction.

 Cause 2: IR cal position sensor defective.

 Remedy: Call Authorized Service Center.

Error 26 **PLATE ZERO-POSITION SENSOR OVER RANGE.**

 Cause 1: Mechanical obstructions prevent plate movement from reaching zero position.

 Remedy: Remove any obstruction.

 Cause 2: Distance sensor defective.

 Remedy: Call Authorized Service Center.

Error 27 **FORCE SENSOR HAS DETECTED STRESS >1 WITH PLATE FREE.**

 Cause 1: Mechanical obstructions prevent to correlate values between distance and force during self-check.

 Remedy: Remove any obstruction.

 Cause 2: Force sensor is defective.

 Remedy: Call Authorized Service Center.

Error 28 **CALIBRATION POSITION DISTANCE SENSOR VOLTAGE > 4600 mV.**

 Cause 1: Mechanical obstructions prevent plate movement.

	Remedy:	Remove any obstruction.
	Cause 2:	Defective linear sensor.
	Remedy:	Call Authorized Service Center.

Error 29 (1-4) **WET OR DIRTY ELECTRODES IN SEALING HEAD**.

            Cause 1: Sealing heads wet or dirty.

            Remedy: Clean and dry sealing heads' electrodes. Press 🔵 keybutton to open the clamp in error; insert tube again and press ⌨ to perform sealing again. If a procedure is ongoing, press **START** to continue.

            Cause 2: Defective sealing head or CSU.

            Remedy: Call Authorized Service Center.

Error 30 **SEALING UNIT BUSY**.

            Cause 1: CSU cable disconnected.

            Remedy: Check and connect cable.

            Cause 2: Defective CSU.

            Remedy: Call Authorized Service Center.

Error 31 **TUBE IN THE CLAMP**.

            Cause 1: Tubes are inserted to clamps during self-diagnosis.

            Remedy: Remove tubes from clamps and repeat self-diagnosis cycle.

            Cause 2: Defective tube sensor.

            Remedy: Call Authorized Service Center.

Error 32 (1-4) **ELEVATED LOAD CELLS OFFSET**.

            Cause 1: Bags or weights positioned on the scales during self-diagnosis.

            Remedy: Remove any bags or weights from the scales during self-diagnosis cycle.

            Cause 2: Defective offset digital system.

            Remedy: Call Authorized Service Center

Error 33 **ELEVATED FLOW-VALVE CHECK CYCLE**.

            Cause 1: Valve-actuator movement is locked.

            Remedy: Remove tubes or any obstruction from the actuator and retry. Check if cable is inserted correctly. Replace flow valve assy.

            Cause 2: Defective position sensor.

            Remedy: Call Authorized Service Center.

Error 34 **STEP NUMBER UNSUITABLE FOR COMPLETING ONE FLOW-VALVE CYCLE**.

            Cause 1: Valve-actuator movement is locked.

            Remedy: Remove tubes or any obstruction from the actuator and retry. Check if cable is inserted correctly. Replace flow valve assy.

            Cause 2: Defective motor.

            Remedy: Call Authorized Service Center.

TROUBLESHOOTING

Error 35 (1-3)   **CELL K OVER RANGE**.

    Cause 1:   In self test phase, during calibration factors check an error has been detected.

    Remedy: Ricalibrate all scales.

Error 36   **FORCE SENSOR K OVER RANGE**.

    Cause 1:   In self test phase, during calibration factor check an error has been detected.

    Remedy: Ricalibrate force sensor.

Error 37   **INSUFFICIENT PLASMA-PLT**.

    Cause 1:   The plasma amount set in the procedure is higher than the amount collected.

    Remedy: Verify actual value.

    Cause 2:   Scale not calibrated.

    Remedy: Calibrate scale.

Error 38   **INSUFFICIENT PLASMA WEIGHT**.

    Cause 1:   During separation plasma weight is not adequate.

    Remedy: Check that the cannula has broken and that there are no obstructions; then go on.

Error 39   **INSUFFICIENT BUFFY-COAT**.

    Cause 1:   The buffy-coat amount set in the procedure is higher than the amount collected.

    Remedy: Verify actual value.

    Cause 2:   Scale not calibrated.

    Remedy: Calibrate scale. (see scale calibration)

Error 40   **INSUFFICIENT SAG-M WEIGHT**.

    Cause 1:   Sag-M amount is insufficient to complete the procedure.

    Remedy: Check actual amount and confirm.

    Cause 2:   Scale not calibrated.

    Remedy: Calibrate scale (see scale calibration).

Error 41   **CHECK SAG-M FLOW**.

    Cause 1:   Sag-M tube folded or collapsed.

    Remedy: Adjust bag tube and remove obstructions.

    Cause 2:   Clamp 5 closed.

    Remedy: Unlock clamp 5.
    Call Authorized Service Center.

    Cause 3:   Scale not calibrated.

    Remedy: Calibrate scale (see scale calibration).

Error 42   **LIMIT SWITCH REACHED WITH INSUFFICIENT SAG-M**.

    Cause 1:   Sag-M bag lacking. The system has detected the all-opened-plate sensor without dispensing Sag-M.

    Remedy: Position Sag-M bag.

    Cause 2:   Defective open-plate sensor.

    Remedy: Call Authorized Service Center.

Error 43   **RBCS NOT DETECTED**.

Cause 1:	Wrong action threshold.
Remedy:	Check value of parameters 8.
Cause 2:	Wrong distance threshold.
Remedy:	Check value of parameters 18.
Cause 3:	Insufficient erythrocytes amount.
Remedy:	Repeat procedure.
Cause 4:	Defective HB sensor.
Remedy:	Call Authorized Service Center.

Error 44   **CHECK FLOW**.

Cause 1:	Obstructed filter.
Remedy:	Retry with a new bags set.
Cause 2:	Tubes poorly positioned.
Remedy:	Relocate tubes.
Cause 3:	Scale not calibrated.
Remedy:	Calibrate scale (see scale calibration).

Error 45   **NOT IN USE**.

Error 46   **UNEXPECTED WEIGHT**.

Cause 1:	Scale weight has had a sudden variation due to an external agent.
Remedy:	Check that foreign objects are not on the scales and remove it.
Cause 2:	Scale unstable.
Remedy:	Check if scale holder don't touch against metal plate. Call Authorized Service Center.

Error 47   **BARCODE TOO LONG**.

Cause 1:	Barcode not compatible with the system. The maximum possible length is 20 characters including the control character.
Remedy:	Read a compatible code.
Cause 2:	Barcode reader set improperly.
Remedy:	Reconfiguration of barcode (see Datalogic barcode configuration).

Error 48   **PROCEDURE HAS BEEN INTERRUPTED BY THE OPERATOR**.

Cause 1:	The operator has pressed key-button and confirmed interruption with key-button.
Remedy:	Repeat procedure.

Error 50   **ERROR DISTANCE-WEIGHT**.

Cause 1:	The plate is in position where weight measured must be more.
Remedy:	Verify any obstructions that may create false weight readings. Check bag setting parameters.

Error 51   **ERRORE PESATA-DISTANZA**.

Cause 1:	The plate is in position where weight measured must be less.

Remedy:	Verify any obstructions that may create false weight readings. Check bag setting parameters.

Error 52   **TIMEOUT PLATE.**

Cause 1:   The distance detected did not change over the last 18 seconds.

Remedy: Verify any obstructions of the tubes and proper breaking of cannula.

Error 53 (1-6)   **HIGH SENSOR TUBE LIGHT.**

Cause 1:   Ambient light detected by the sensor tube x is too high.

Remedy: Reduce ambient light. Change tube sensor (x).

8   Maintenance

Archimede requires very little maintenance. It simply consists in keeping clean case, clamps, flow valve, optical sensors and the weighing system calibration control.

8.1   Daily Maintenance

8.1.1 Cleaning

Clean upper scale tray and holder with detergent or disinfectant; avoid hitting the mechanical device supporting the tray and do not pour liquids inside the central gap.
Clean clamps hollow and its actuator with a wet cotton wad.
Clean *Archimede* case with disinfectant. Keyboard and optical sensors should be cleaned only with a cloth dampened with water.

Never use alcohol, acetone, trichloroethylene or any solvents.

8.1.2 Decontamination

Remove the upper scale tray and decontaminate both tray and holder with bleach or disinfectant. Do not hit the mechanical device supporting the tray and do not pour liquids inside the central gap. Decontaminate also flow-valve actuator, clamps actuators and optical sensors with a cotton fioc dampened with bleach or disinfectant. Rinse with water all parts treated with bleach or disinfectant.

Never use alcohol, acetone, trichloroethylene or any solvents.

8.1.3 Monthly Maintenance

Monthly maintenance simply consists of checking scales calibration. The check should be performed by a certificate centre with certified weights. If the reading does not fall within the allowed range, please contact the authorized technical service centre.

8.2   *Yearly Maintenance*

Yearly maintenance is performed by qualified engineers authorized by manufacturer.

> ⚠️   **Before cleaning with any liquid, turn *Archimede* off and disconnect the power cable.**

8.3   *Maintenance Recording*

This function is enabled only when *Archimede* is connected to *ArchimedeLINK*. In this case, all maintenance operations can be stored sending to *ArchimedeLINK* data relevant to maintenance, operator, and date of performance.

To confirm the action done, select the desired maintenance using the arrows ◆ , confirm with ⬜ and read the operator code.

```
┌──────────────────────────────┐
│       MAINTENANCE LIST        │
│                               │
│  ⇨ Clean Display              │
│    Clean Clamp                │
│    Clean Sensors              │
│                               │
└──────────────────────────────┘
```

Picture 129: Maintenance view

9   ACCESSORIES

Archimede can be supplied with:

- ▪ RFID reader for labels or cards type RFID ISO15693. Supported tags are I.CODE SLI and Tag_it.
- ▪ Omnidirectional bar code reader.

OPTIONAL ACCESSORIES

10 DISPOSAL

When disposing materials, please observe the following recommendations:

10.1 Packing Material Disposal

- Throw packing materials in the proper separate collection containers.
- In case of doubts, please ask the blood centre chief for information about proper separate collection.

10.2 Archimede Disposal

- If *Archimede* is no longer usable, please bring it to the area separate collection centre

<p align="center">or</p>

- Ask the nearest Technical Service authorized centre.

Separate waste collection.

Discard separately.

DISPOSAL

11 TECHNICAL FEATURES

- Painted metal case.

- Graphic backlight display 240 x 128.

- N° 3 load cells for 2 kg: non linearity 0,02% F.S., repeatability 0,02% F.S., resolution ± 1 g.

- Detection system of force exerted by the plate.

- N° 4 sealing head clamps, 1 normal clamp, and one flow valve.

- N° 10 optical sensor to detect buffy coat level.

- Optical device to detect red blood cells presence.

- Many separation procedures stored, up to a maximum of 18.

- WLAN for bi-directional data transfer of procedure and configuration data.

- PS2 port for external barcode-reader connection.

- Adjustable sealing time from 0.5 to 4 seconds, frequency 40.68 MHz.

- <u>Environmental requirements:</u>   Temperature between 5°C and 45°C Humidity lower than 80% without condensation.

- <u>Power supply:</u>   90 VAC 84 W 1A, 230 VAC 81 W 0.4A, fuses 2.0 AT.

- <u>Dimensions</u>   Width 435, depth 500, height 425 [mm].

- <u>Weight:</u>   40Kg

- <u>Transport and storage temperature</u>   From –20°C to +70°C. Relative humidity from 20% to 90% without condensation.

    - In accordance with: EN60601-1-2 (2001-11)
      IEC60601-1-2 (2001-09)
      EN60601-1:1990-08+ EN60601-1/Ec :1994-07 +
      EN60601-1/A1:1993+EN60601-1/A1/Ec:1994-07 +
      EN60601-1/A2:1995-06 + EN60601-1/A13:1996-01.
      EN60950-1(2001) + A1
      EN301 489-17 V1.2.1 (2002-08).
      EN301 489-1 V1.6.1 (2005-09).

- Electrical safety: Class I – Instrument with applied part Type B.

    Rule 12 MDD 93/42 – Device belonging to Class I without measurement function.
    Instrument not suitable for use in the presence of flammable anaesthetic mixtures with air or oxygen or nitrous oxide. Instrument for continuous working.

- Instrument in compliance with MDD 93/42 EEC requirements.
- International protection: IP41.
- FCC ID: V991504.