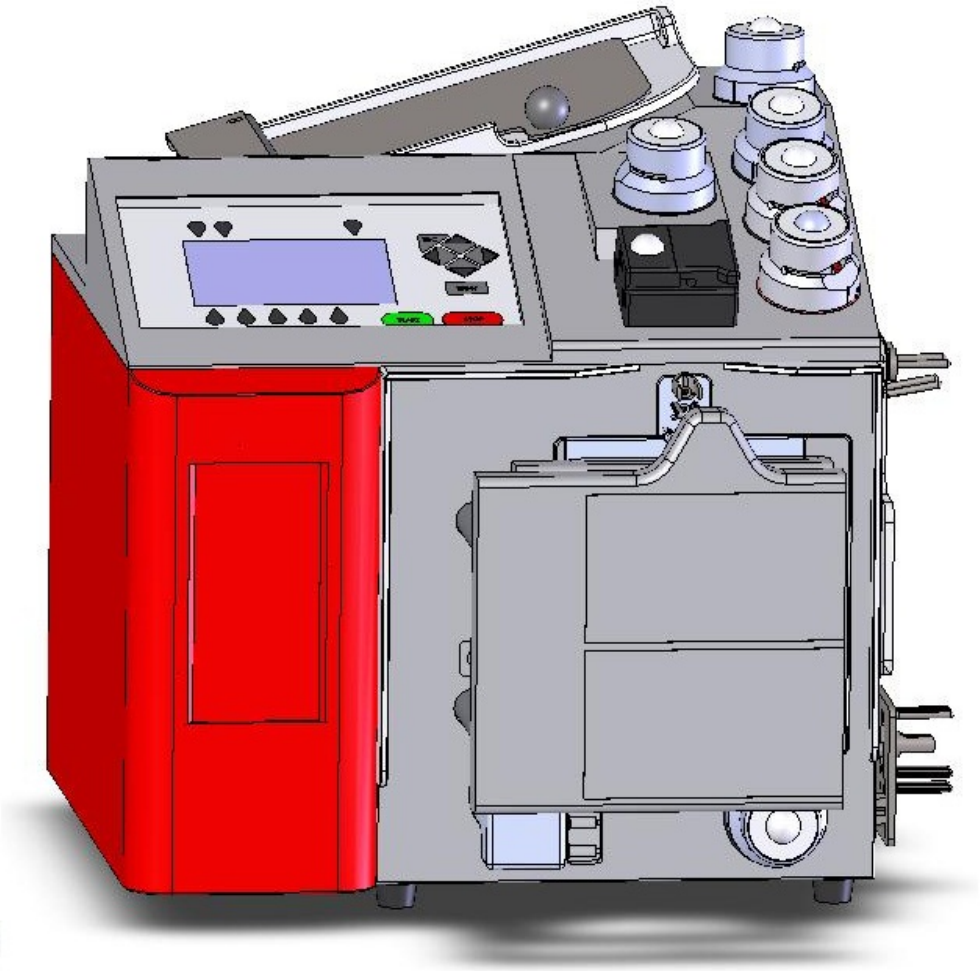
ARCHIMEDE

REF **MOE1504**

Automatic Blood Component Extractor
Operator's Manual



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CE 0681

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 operating in a room whose electrical system applies with the relevant prescriptions;
- the instrument is operating 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 avoid the user's authority to operate the equipment.

COPYRIGHT

MOELCA s.r.l. certifies that the instrument is free from any defects 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 any repairshould be performed by personnel instructed by trainers. The trainers have always to be qualified by MOELCA S.r.l.

For information about technical service please contact local representative.

Any repair **after the warranty period** should be performed only by personnel instructed by qualified trainers.

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MARKINGS

List of the symbols and marks used in this manual:

Class I	Equipment in which protection against electrical shock does not rely on basic insulation only, but which includes an additional safety precaution in the form of a means for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation (EN 60601-1 Regulations)
IP41	Protection against objects >1.0 mm diameter touching internal parts. Vertically falling water will not have any harmful effect
CE	The marking reflects compliance with the Council Directive 93/42/EEC on Medical Devices
CE 0681	The marking reflects compliance with the Council Directive 1999/5/EC on radio equipment and telecommunications terminal equipment.
SN	Symbol for "SERIAL NUMBER" according to the European Standard – EN 980
	Symbol for "CAUTION, CONSULT ACCOMPANYING DOCUMENTS" according to the European Standard – EN980
	Bar code reader.
	**Disposal of Electrical and Electronic Equipment** In the European Union, electrical and electronic equipment must not be disposed of with other household-type waste. It must be collected separately. Please observe the relevant legal regulations effective in Your Country.
	Symbol for the "MANUFACTURER" (EN980 Stds)
	Symbol for "CATALOGUE NUMBER" according to the **European Standard – EN 980**.

MARKINGS

List of the symbols and marks used on the device:

Class I	Equipment in which protection against electrical shock does not rely on basic insulation only, but which includes an additional safety precaution in the form of a means for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation (EN 60601-1 Regulations)
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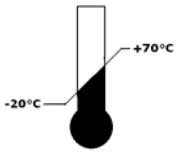
	Symbol for the "MANUFACTURER" (EN980 Stds)
	Ensure that hand(s) and/or finger(s) are not between or too close to the plates during compression
	Symbol for "CATALOGUE NUMBER" according to the **European Standard – EN 980**.

List of the symbols and marks used on the carton box:

Symbol used to indicate that the product should be kept dry



Symbol for "temperature limitation." The upper and lower temperature limits will be indicated on either side of the symbol

CE

The marking reflects compliance with the Council Directive 93/42/EEC on Medical Devices

CE 0681 ⓘ

The marking reflects compliance with the Council Directive 1999/5/EC on radio equipment and telecommunications terminal equipment.

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1 INTRODUCTION

The present operator 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 blood components 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 Destination

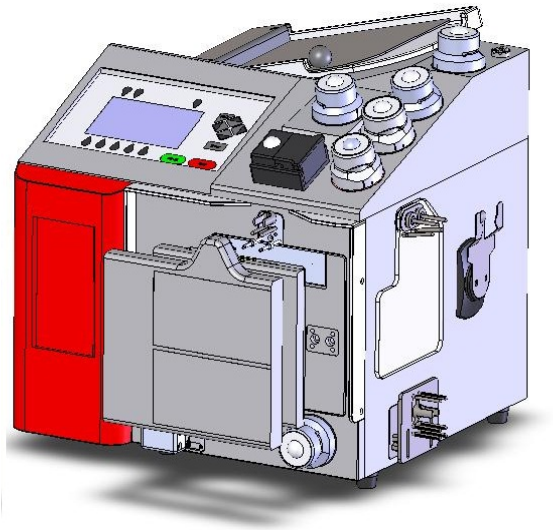
Archimede should be used by Qualified Personnel only. It has been designed for the separation of blood components contained in hermetically sealed bags (bags containing whole blood and/or blood derivatives) consistent with the International Standard ISO 3826 and with the 93/42 MDD regulation and following modifications (2007/47/EU of 21/03/2010).
For optimum operation *Archimede* should be placed on a solid and stable surface, away from direct heat sources.
Archimede as to be placed in such a way to permit at the Operator to switch it off and disconnect it from the electrical plug.
WARNING !: to avoid the risk of the shock hazard, this device has to be exclusively connected with a plug with ground protection!

1.2 Key features

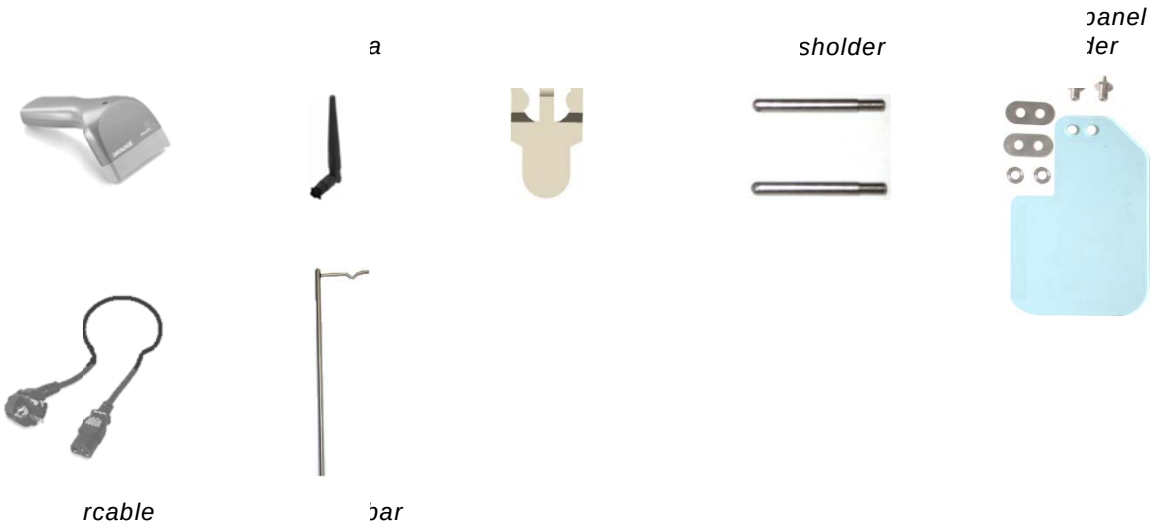
- User-friendly interface.
- Graphic display of bags weight, force, and operation stages.
- Automatic delivery of Red Cell Additive Solution through press.
- Variable speed separation movement, controlled by a stepper motor.
- Array of 18 optical sensors for Buffy Coat level check.
- Optical detector 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 weight scales with 2 Kg full-scales 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. The auto-calibration functions are managed directly by *ArchimedeLINK*.
- Can be used as a sealer and as a weight scale.
- Self-diagnosis program to make the solution of technical problems easier.
- Bi-directional data transmission via LAN and 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.



2.1 Unpacking Archimede

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

- *Archimede* is supplied with:
- Side weight scale-holders.
- Magnetic filter-holder. Pacemakers and floppy disk must keep away at least of 10 cm.
- WLAN antenna.
- 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:

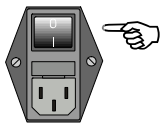
- High temperatures, elevated humidity (See Chapter 13 Technical features of this manual)
- Proximity of free flames.
- Direct sunlight exposure.
- Elevated dust accumulation.
- Proximity of flammable substances.
- Unstable and non-flat surfaces or slippy.
- Separation distance of 20 cm must be maintained between the WLAN antenna and human bodies

2.3 Assembling weight scale, filter holders and antenna.

Screw the two hexagonal screws in the holes that are on *Archimede* left side, place one of the plates with holes and then the plexiglas panel, put the other plate and screw the knurl metal parts. Screw the side weight scales 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.

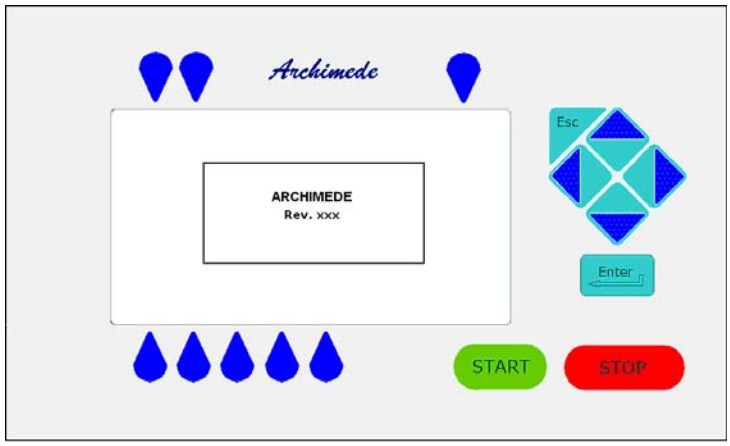
2.4 Switching on Archimede

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 **0** position. Then plug the Barcode Reader into the socket marked with 

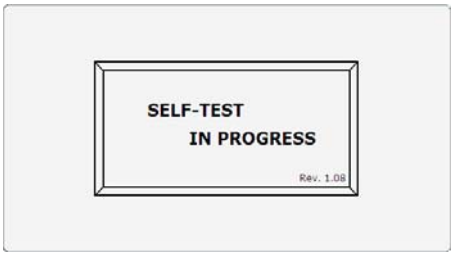
Plug the power cord and turn the main switch on (position 1).



Picture 2: Archimede display

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

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

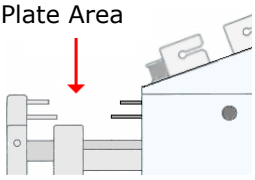


Picture 3: Screen shot "Self Test"

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.

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

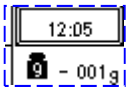
Press Plate Area



2.5 Instrument Setup

All sensitive data are stored and saved in a non volatile RAM. They can be modified using *ArchimedeLINK*. Date and time are managed by a dedicated rtccircuit. If without main power, it may operate for about 60 days. 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 edit mode or directly with the key  over the time.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 4: Date and time format list.

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.Confirm setting with key  .

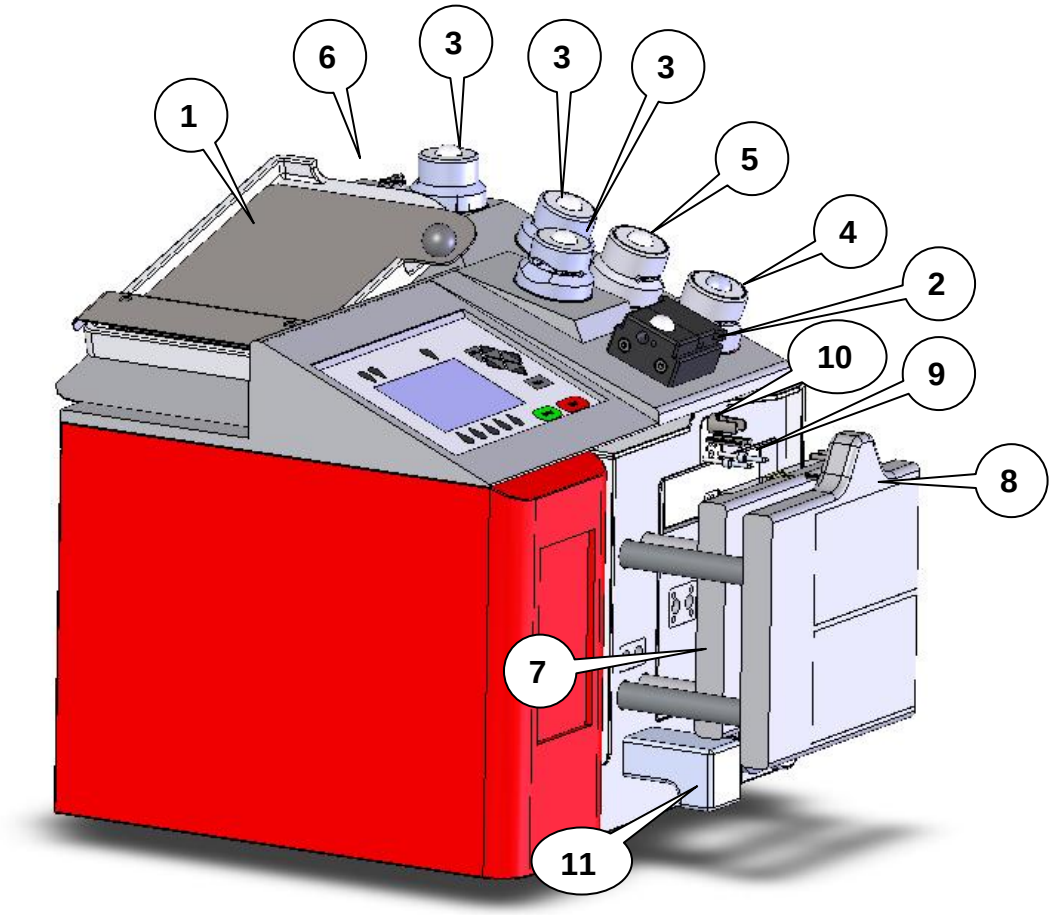
Using direction key-buttons  it is possible to select the desired procedures.

Archimede 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 *Archimede*LINK with the help of an application specialist.

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, weight scale, sensors, clamps, sealer group and RFID reader.
- The mechanical part includes an axial system enabling movement of plate and buffy-coat separation system.



Picture 5: Global view

3.1 Upper Panel

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

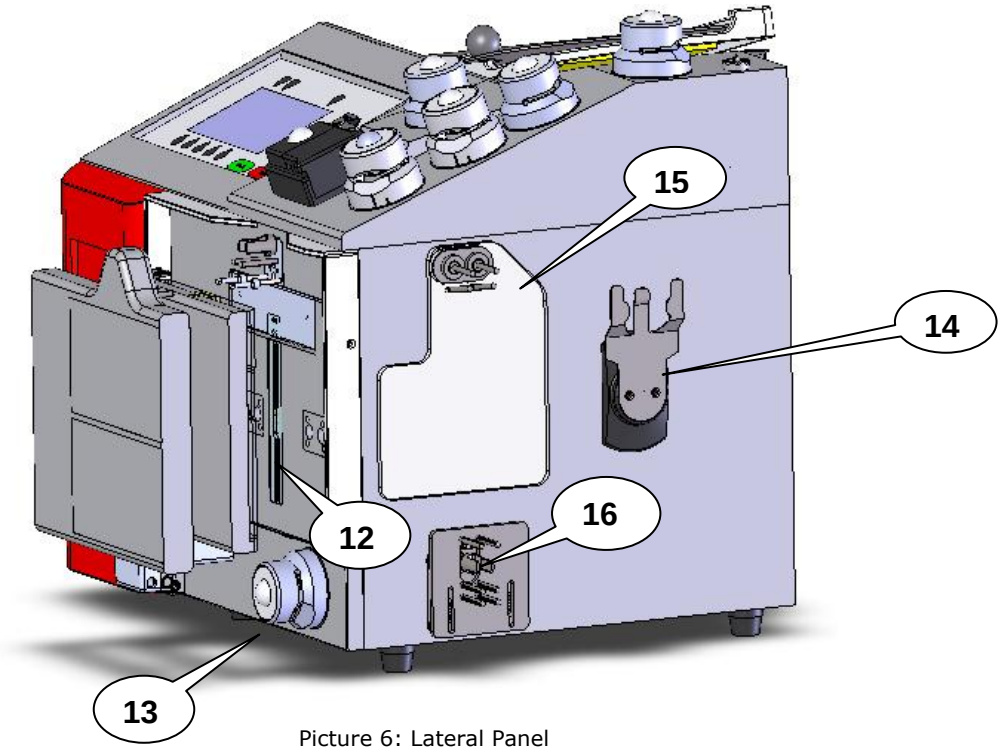
1. Upper weight scales with weight capacity 0-2000 grams with ± 1 g resolution.
2. Photometer for red blood cells detection. It consists of a 540 nm optical system and a couple of IR sensors for air bubbles detection. A reflection optical systems detects cover state (open/closed) and tube presence.
3.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

3.2 Front Panel

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

7. 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.
8. Fix plate provided with holders where the bag in use can be hanged.
9. Primary bag support with pins for stainless-steel cannula breaking with weight scales with weight capacity 0-2000 grams with ± 1 g resolution.
10. Frontal cannula breaker (W.B. C.B.) actuator that provides to break automatically the cannula of the primary bag hangs on frontal support (optional).
11. Magnetic sensors(Hall effect) for detection of the type of profile plate in use.
12. Optical device for detection of buffy coat level. It consists of 18 IR sensors linearly placed.
13. Clamp "Bottom" with sealing head.

3.3 Lateral Panel



Picture 6: Lateral Panel

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

14. Filter holder.
15. Lateral weight scales with plexiglass plate.
16. Lateral cannula breaker (R.C. C.B.) actuator that provides to break automatically the cannula of the lateral bag hangs on lateral support. (optional)

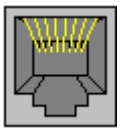
3.4 Rear Panel

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 inlet including: power socket, On-Off switch, and fuse holder.

Antenna for WLAN connection with *ArchimedeLINK*.

PS2 connector.Allows connection of barcode reader.



LAN connector with yellow and green led.
Yellow led is:

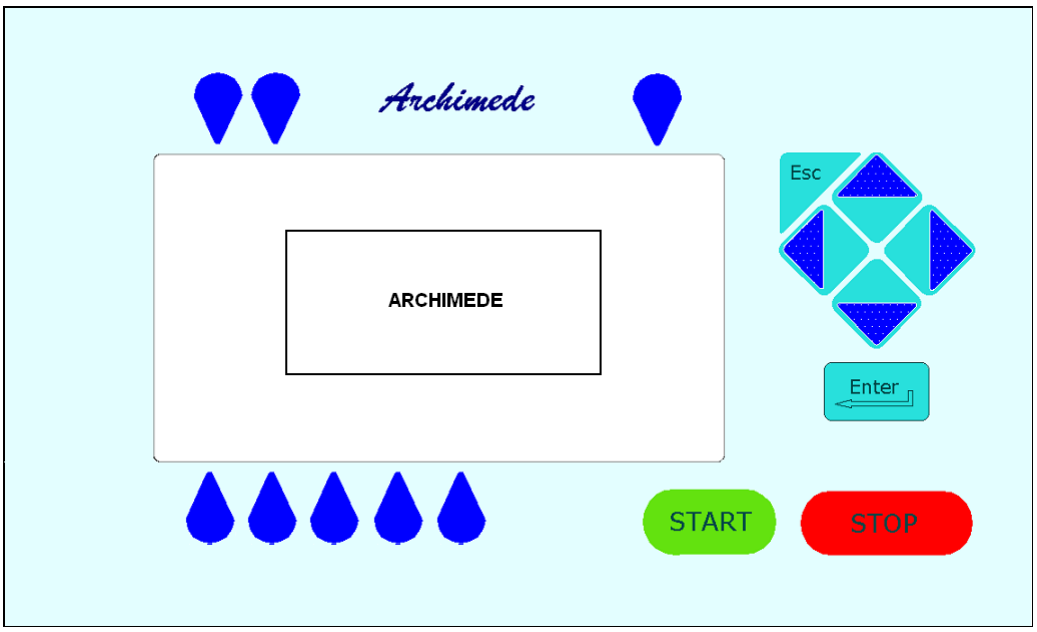
- Flashing: in case of errors.
- Off: in normal condition.

Green led lit if there is Ethernet activity.

Caution:
Consult accompanying documents according to the European Standard – EN980

3.5 Keyboard

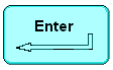
Some of the keyboard key-buttons are multi-functions.



Picture 7: 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 select the displayed function.

3.6 Backlight Display

The screen is a wide LCD 240 x 128 graphic display. It is backlit to improve reading in low illuminated rooms.

3.6.1 Main Menu.

READ BAG TYPE OR SELECT THE PROCEDURE

This function allows to enter the menu to select the desired procedure. The procedure can be selected manually by pressing key START or through BC reading of the type of bag.

3.6.2 Enable procedure list.

ENABLED PROCEDURES LIST

---

1 T&T triple PPP or PRP+RBC
2 T&T quad PPP or PRP +BC+RBC
3 T&B triple PPP+BC+RBC

Picture 8: Enable procedures list

Using the arrows  highlights the procedure you intend to use, then press  to start the procedure selected by ✓.

3.6.3 Utility menu.

To enter this menu press key-button above the icons  and use direction key button  to select the desired function.

UTILITY MENU

-

CALIBRATION
√ PARAMETER LIST
OPERATOR LIST
CONTRAST
MAINTENANCE

Firmware x.xx

Picture 9: Utility menu.

CALIBRATION: Allows to calibrate the three weight scales of *Archimede* by choosing the desired weight.

PARAMETER LIST: Allows to display the numerical values of all parameters of the procedures established.

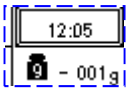
OPERATOR LIST: Allows you to view the list of codes associated with the use of authorized operators *Archimede*.

CONTRAST: Allows to adjust display contrast.

MAINTENANCE: Allows you to view the list of active maintenance and execute them. (only when connected to *Archimede*LINK).

3.6.4 **Date and Time**

Although the display normallyshows only hours and minutes, *Archimede* is provided with built-in calendar used to send to *ArchimedeLINK* procedure data, including date and time.



Using direction key-buttons  highlight the display area indicating current date and time. Press  to enter modify mode.

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	01-06-2011
mm-dd-yyyy	06-01-2011
yyyy-mm-dd	2011-06-01

Picture 10: Date and time format list.

Note: If the Blood Transfusion 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.

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 *Archimede*LINK on next connection.Archimede can store up to 300 procedure data before start to overwrite the oldest ones.

4.1 Switching on

While switching on the device a complete self-check of the system is performed. 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 will 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 11: Screen shot "Self-Test in progress"

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

 Stand Alone  *ArchimedeLINK.*

E²prom 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. In this case, weight scales calibrations are required.

 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 01/06/11.


Synchronization with data and time of *ArchimedeLINK* Server.

Tube Sensors
Check non presence of tubes and autocalibrate the sensors.


If the calibration values are out of limits an error will be sent and displayed.If the problem persists consult the Troubleshooting section.


Same as in stand alone mode.

CSU (Central Sealing Unit)
Check sealer unit.


If the CSU is not in the state of "ready" and detect the presence of moisture,an error will be sent and displayed. If the problem persists, consult the Troubleshooting section.


Same as in stand alone mode.

CB system (Cannula Breaker system)
Check cannula breaker system.


If the cannula breaker 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 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.

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.

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.

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.

Proportional clamp
Check movement actuator.

 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 in stand alone mode.

Weight scales
Tare check of all weight 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.

4.3 Main Display

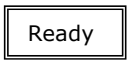
To access the various functions, there are two different ways:

- With the arrow keys moves the selection, visible through the highlight of the frame of the icon.
- With the function keys , you select the function below or above the key.

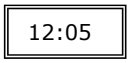
Here is the meaning of the displayed functions:

This menu allows to enter submenus to have; calibration, parameters list, operator list and maintenance actions displayed.

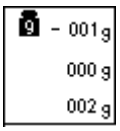
Press to login operator by bar code reader.



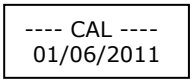
The instrument status is displayed in this area.



Current time is displayed in this area. If upper function key is pressed allows to change the date and time.



This menu allows to set the tare and to have front weight scale, upper weight scales and side weight displayed.

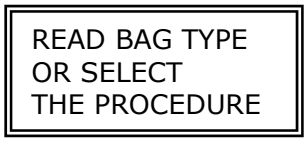


Date of the last weight scales calibration is displayed in this area.

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.

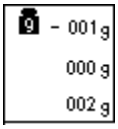


This function allows to enter the menu to select the desired procedure. The procedure can be selected manually or through BC reading of the type of bag.

4.4 Use as a weight 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 weight scale, it is necessary to calculate the tare. Move the cursor using the arrows until the word "zero" is displayed in the weight scales area of the screen and press to zero the values.
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 weight scale, or put it on the upper weight scale.
Weights are displayed in the following order:



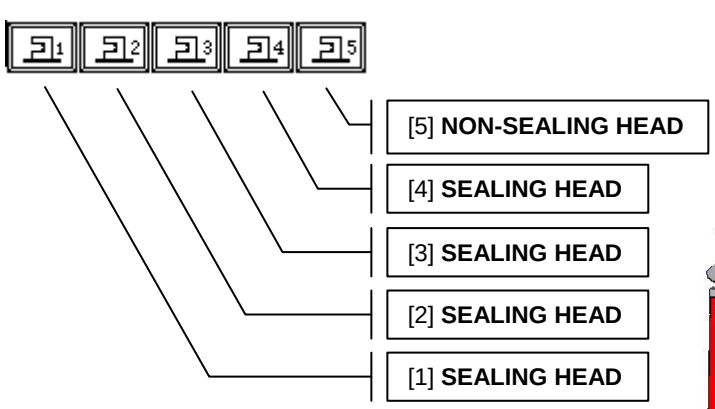
Front scale
Upper scale
Side scale

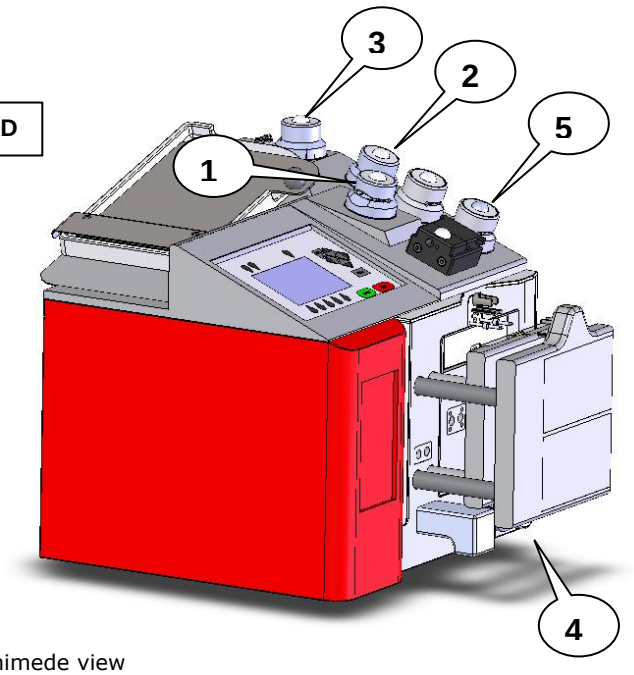
Picture 12: Reading weight scales area

4.5 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:





Picture 13: 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.

4.6 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  ; to exit and move the plate to standby position press  .
In this mode you can also enable the clamps by pressing  key-button, and seal by pressing  key-button.
Clamp 5 of Red Cell Additive Solution is not provided with sealing head and cannot be used as a sealer.

5 Separation Procedures

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 transfusion center will be displayed.

READ BAG TYPE OR SELECT THE PROCEDURE

if this icon is highlighted, press the START button to see installed procedures list

Using the arrows  highlight the procedure you intend to use, then press  to start the procedure.

ENABLED PROCEDURES LIST
1 T&T triple PPP or PRP+RBC 2 T&T quad PPP or PRP +BC+RBC 3 T&B triple PPP+BC+RBC

Picture 14: 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. If information of a bag type is not sufficient to select the type of procedure, other questions can be asked or you can select from a reduced list the procedures associated with that type bag in case they were more than one.

The separation procedures presently available are:

PRIMARY

TYTE	NAME
1	T&T triple PPP or PRP + RBC
2	T&T quadruple PPP or PRP + BC + RBC
3	Top & Bottom triple PPP+BC+RCC.
4	Top & Bottom quadruple PPP+BC+RCC.
6	Top & Bottom triple PPP or PRP with BC.
10	Cord separation
11	Aliquot separation
13	Top & Top RBC with PPP + PPP.

SECONDARY

TYPE	NAME
5	Separation from PRP to PPP + PLT
7	PLT + residual BC with filter
8	Erythrocytes washing separation
12	PLT from single BC.

5.1 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.
There are two possible ways to set *Archimede*LINK:

- Manual association answer-question: Questions will be displayed with an arrow that indicates the code to read. After reading the barcode the code will be display and the arrow will move to the next question.
- Auto association of answer-question: Question will be displayed without the arrow because the operator will read any of the codes desired, and the system will recognize, through the characteristics of the code, what is the correct answer association. So the operator can read in any sequence take the codes to be read.

In manual association if necessary you can read the answers by moving with the arrow keys  to select a target question, while in automatic association just read again the code and it will be automatically reported in the right position.

Once the system has selected the type of procedure to be used, it is not longer possible to modify the answer to donation 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 appropriate privileges forces it to do so.

To clear the series of questions and return to main menu, press  .
When all questions have been replied to, the initial display of the selected procedure will automatically appear.

5.2 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 and *Archimede*Link.
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, Red Cell Additive Solution dispensing time very long, etc.
In order to obtain a better management, procedure parameters are divided into group.For a detailed explanation see service manual.

5.3 Procedures description.

Common Operations to all procedures.

Initial screen show the following information:

The status of the procedure: separation or pause.

The clamp visible are those actually used for the separation and sealing.

The sensor HB with its status (open or closed, with or without tube).

The force read by the sensor.

Last 4 digits of the operator code (if you read above).

On the left the number that indicates the type of procedure while on the right the number of sequential procedures

Estimated percentage of time.

The time of separation from breaking cannula to end of sealing.

'Read comments' you can read comments if connected to *Archimede*LINK. The comments labels are available on the outside of the front plate in place.

BCL (Buffy Coat Level)

SET Buffy coat set level.

ACT Actual buffy coat level.

STOP

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

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

Pause: press START or Esc to continue the 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.

Sealing

The sealing cycle depends on the value set in the procedure parameters #11 and #12;

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

Manual sealing: press START key button to seal the enabled lines, or press STOP then START to continue without sealing.

NOTE: Tubes in the various kits have different lengths. To simplify kits management, the firmware allows to configure which clamps you wish to enable by parameter #40.

Sending data

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

At the end of the procedure the display will show the measured weights. If they are not the expected ones, because tubes are not correctly placed and distort weight scale' readings, the blood components can be weighed again after correcting tubes' position and the new weights can be sent to *ArchimedeLINK*again.

Correct weights

If you remove all the tubes and all the bags, *Archimede* will automatically start a procedure of the same type. You can force the process by pressing the START button to continue with the same type of separation. To go back to the procedures list page press Esc button.

Incorrect weights:

Press one of the key buttons below the display to weigh blood components again. To accept the new values and send them to *ArchimedeLINK* press Enter

Normal limits

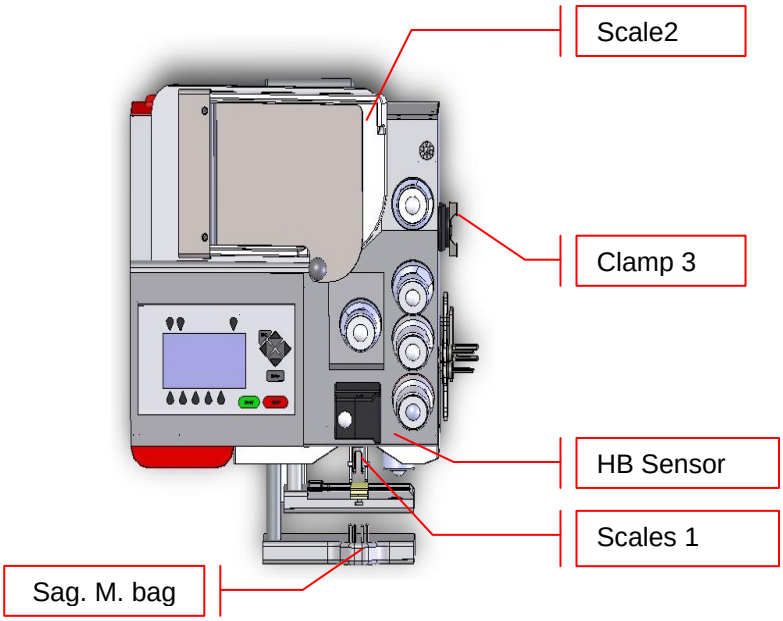
With *ArchimedeLINK* the normal limits check can be activated. If it is enabled and the detected weights do not fall within the defined limits, the display will show the blood components' detected weights and the allowed limits. Press any key to continue.

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

5.3.1 PROCEDURE 1: T & T triple PPP or PRP + RCC.

This procedure is suitable for triple bags with or without Red Cell Additive Solution It allows erythrocytes separation (RCC) and platelet-poor plasma (PPP) or platelet-rich plasma (PRP), weighing the plasma and red blood cells.

Separation Description:



Picture 15: Kit installation procedure T/T triple

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

- Hang the primary bag on the bag holders of the front panel. The label containing bag data should always be turned outside. After detecting the primary bag, the plate will move backward to make positioning of Sag.M. bag easier, and the display will show the bag icon.

- Hang the Red Cell Additive Solution bag to the bag holders on the fix plate.
- Insert the Red Cell Additive Solution 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 HB sensor firmly into clamp 3.
- Position the plasma bag on upper weight scale.

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 , (only with tube control enable). When all the bags and tubes are in position the text at the top right will be changed to START and the procedure start automatically.

Press START key-button to start the procedure if the autostart doesn't happen.

If the "primary bag expected weight check"has been enabled through *ArchimedeLINK*and the measured weight does not fall within the defined limits,a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with 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 clamps. In also, if a bags is not recognized an error will be displayed.

Now wait for the plate to get close to the bag. The plate will apply a force corresponding to the value set in the procedure parameters (# 3).

If the automatic breaking cannula (#45) is active the *Archimede*breakes automatically the cannulas and starts the separation cycle, it is available only if this optional is installed.

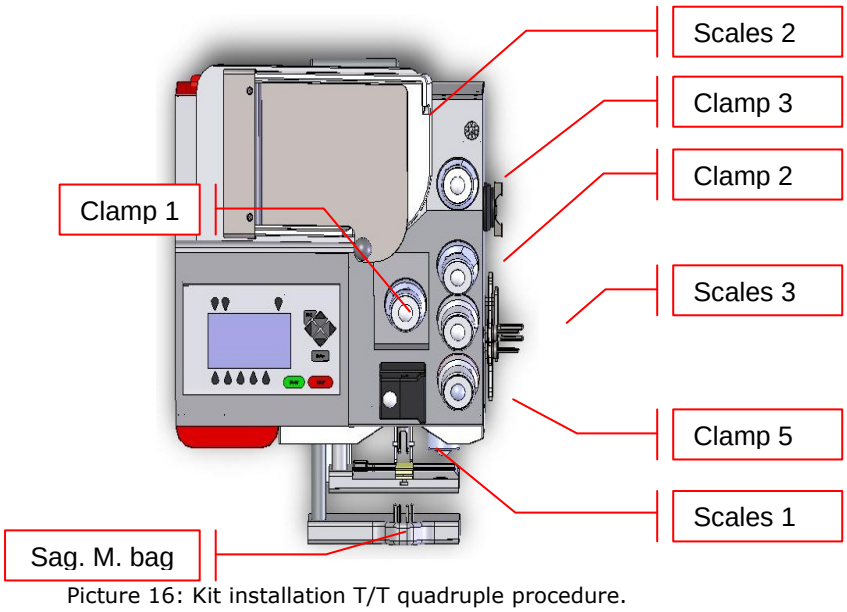
If the cannula breaking is active (# 2) the message "Break cannulas" will be displayed. Break the cannulas by forcing on their side upper part, and wait a few seconds for pressure reduction. After detecting pressure decrease, *Archimede* automatically starts the separation cycle. If, due to obstructions or tube kinks pressure circuit is not reduced below the threshold set, it is anyway possible to force the cycle start by pressing START key button. If the cannula breaking is not active (# 2) *Archimede* automatically starts the cycle of separation.
The graphic interface will now show the current operating phase number, and the weight (value) of plasma collected. *Archimede* will check if the parameter # 6 is active, the level of red blood cellsin 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 (#19) is not provided, the separation process will stop and the plate will move backwards to allow Red Cell Additive Solution dispensing.
If air removal is enabled, the system will send the air contained in the plasma bag into the selected bag.

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

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

This procedure is suitable for top and top standard quadruple bags containing Red Cell Additive Solution It allows to separate erythrocytes (RCC), platelet-poor plasma (PPP) and buffy coat or platelet-rich plasma (PRP) and buffy coat platelets with weighing the plasma, buffy coat and red blood cells.

Separation Description:



Picture 16: Kit installation T/T quadruple procedure.

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

- Hang the primary bag on the bag holders of the front panel. The label containing bag data should always be turned outside. After detecting the primary bag, the plate will move backward to make positioning of Red Cell Additive Solution bag easier, and the display will show the bag icon.
- Hang the Red Cell Additive Solution bag to the bag holders on the fix plate.
- Insert the Red Cell Additive Solution 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 weight scale.
- Position the buffy coat bag on lateral weight scale.

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 (only with tube control enable).When all the bags and tubes are in position the text at the top right will be changed to START and the procedure start automatically.

Press START key-button to start the procedure if the autostart doesn't happen.

If the "primary bag expected weight check"has been enabled through *ArchimedeLINK* and the measured weight does not fall within the defined 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 clamps. In also, if a bags is not recognized an error will be displayed.
Now wait for the plate to get close to the bag. The plate will apply a force corresponding to the value set in the procedure parameters (#3).

If the automatic breaking cannula (#45) is active the *Archimede*breakes automatically the cannulas and starts the separation cycle, it is available only if this optional is installed.

If the cannula breaking is active (# 2) the message "Break cannulas" will be displayed. Break the cannulas by forcing on their side upper part, and wait a few seconds for pressure reduction. After detecting pressure decrease, *Archimede* automatically starts the separation cycle. If, due to obstructions or tube kinks pressure circuit is not reduced below the threshold set, it is anyway possible to force the cycle start by pressing START key button. If the cannula breaking is not active (# 2) *Archimede* automatically starts the cycle of separation.

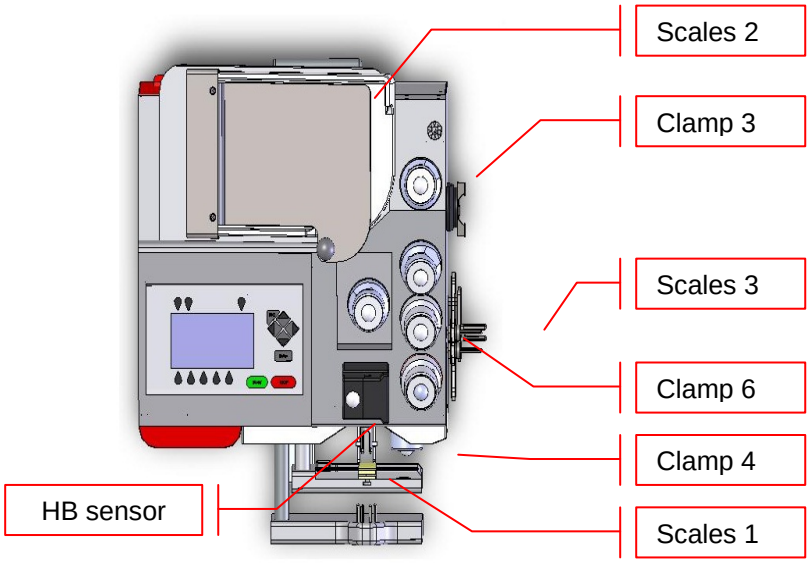
The graphic interface will now show the current operating phase number, and the weight (value) of plasma collected. *Archimede* press a plasma quantity in the bag of Buffy Coat equal to the value of the parameter # 34. Afterwards if parameter #6 is active *Archimede* will check the erythrocytes level 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 photometric group that detects the presence of red blood cells will now, in real time check the flow of blood components and when the concentration of red blood cells exceed the threshold set in parameter # 8, the display show inside of sensor area RBC. If is not active the dispensing of an excess of plasma (# 19) 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 procedure parameter #22, the system will enable the mechanical separation group until the quantity of buffy coat set in the parameter #37 is reached. After the plate will return in open postion, if parameter #36 is set a quantity of plasma will be dispense by gravity in the Buffy Coat bag. If parameter # 35 is set, before dispensing the Red Cell Additive Solution into RBC bags will be kept open the Buffy Coat clamp to clean the BC line. Afterward, the remaining quantity of Red Cell Additive Solution will be released into RBC bag.

If air removal is enabled, the system will send the air contained in the primary bag to the Red Cell Additive Solution bag both at initial and final stage.
Now remove tubes and bags and press START to continue with another separation of the same type or press Esc to exit.

5.3.3 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 (PPP).

Separation Description:



Picture 17: Kit installation T/B triple procedure.

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

- Hang the primary bag on the bag holders of the front panel. The label containing bag data should always be turned outside. After detecting the primary bag, the plate will move backward to make positioning of Red Cell Additive Solution bag easier, and the display will show the bag icon.
- 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 tube coming from the flow-valve firmly into clamp 3.
- Insert RBC tube into clamp 4.
- Position the plasma bag on upper weight scale.
- Position the RBC bag on lateral weight scale.

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 (only with tube control enable).When all the bags and tubes are in position the text at the top right will be changed to START and the procedure start automatically.

Press START key-button to start the procedure if the autostart doesn't happen.

If the "primary bag expected weight check"has been enabled through *ArchimedeLINK* and the measured weight does not fall within the defined limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with 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. In also, if a bags is not recognized an error will be displayed.

Now wait for the plate to get close to the bag. The plate will apply a force corresponding to the value set in the procedure parameters (#3).

If the automatic breaking cannula (#45) is active the *Archimede*breakes automatically the cannulas and starts the separation cycle, it is available only if this optional is installed.

If the cannula breaking is active (# 2) the message "Break cannulas" will be displayed. Break the cannulas by forcing on their side upper part, and wait a few seconds for pressure reduction. After detecting pressure decrease, *Archimede* automatically starts the separation cycle. If, due to obstructions or tube kinks pressure circuit is not reduced below the threshold set, it is any way possible to force the cycle start by pressing 

key button.If the cannula breaking is not active (# 2) *Archimede* automatically starts the cycle of separation.

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 equivalent to buffy coat volume set in the parameters #18. After the plate will back, if parameter #36 is set a quantity of plasma will be dispense by gravity in the Buffy Coat bag. Now if parameter #20 is set the Red Cell Additive Solution is dispensed into RBC bag.

Air removal depends on procedure parameters #42 setting :

Manual air removal : put plasma bag in vertical position, press 

key button to open clamp 3, and remove air manually by pressing on the bag. When finished, press 

key button to close clamp 3, and re-position plasma bag to detect weight. The process will continue automatically.

Now remove tubes and bags and press 

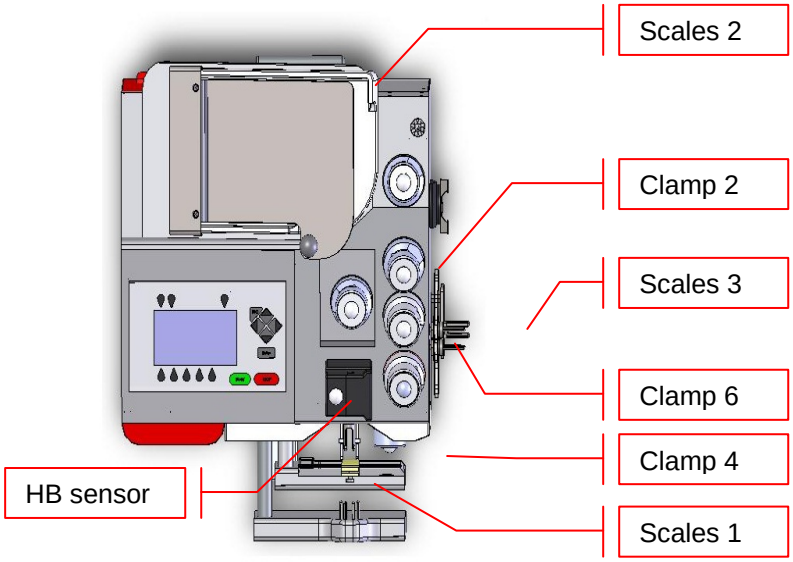
to continue with another separation of the same type or press 

to exit.

5.3.4 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) with one PPP for single buffy coat.

Separation Description:



Picture 18: Kit installation T/B quadruple procedure

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

- Hang the primary bag on 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 backward to make positioning of Red Cell Additive Solution bag easier, and the display will show the bag icon.
- Open cover of HB sensor and insert the tube coming from the primary bag into the reading area. Close the cover and 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 weight scales and i
- Insert the secondary plasma bag tube into clamp 2.
- Position the secondary plasma bag on upper weight scale.
- Insert RBC tube into clamp 4 and position the RBC bag on lateral weight scale.

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 (only with tube control enable).When all the bags and tubes are in position the text at the top right will be changed to START and the procedure start automatically.

Press START key-button to start the procedure if the autostart doesn't happen.

If the "primary bag expected weight check"has been enabled through *ArchimedeLINK* and the measured weight does not fall within the defined limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with 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. In also, if a bags is not recognized an error will be displayed.

Now wait for the plate to get close to the bag. The plate will apply a force corresponding to the value set in the procedure parameters (#3).

If the automatic breaking cannula (#45) is active the *Archimede*breakes automatically the cannulas and starts the separation cycle, it is available only if this optional is installed.

If the cannula breaking is active (# 2) the message "Break cannulas" will be displayed. Break the cannulas by forcing on their side upper part, and wait a few seconds for pressure reduction. After detecting pressure decrease, *Archimede* automatically starts the separation cycle. If, due to obstructions or tube kinks pressure circuit is not reduced below the threshold set, it is any way possible to force the cycle start by pressing START key button.If the cannula breaking is not active (# 2) *Archimede* automatically starts the cycle of separation.

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 equivalent to buffy coat volume, set in the parameters #18. After the plate will back, if parameter #36 is set a quantity of plasma will be dispense by gravity in the Buffy Coat bag. Now if parameter #20 is set the Red Cell Additive Solution is dispensed into RBC bag.

Air removal depends on procedure parameters #42 setting :

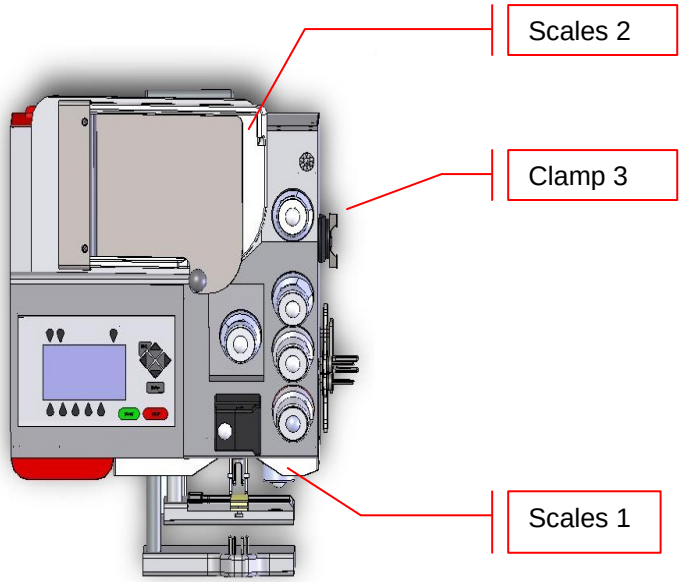
Manual air removal : put plasma bag in vertical position, press START key button to open clamp 3, and remove air manually by pressing on the bag. When finished, press STOP key button to close clamp 3, and re-position plasma bag to detect weight. The process will continue automatically.

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

5.3.5 PROCEDURE 5: Separation from PRP to PPP+PLT

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

Separation Description:



Picture 19: Kit installation procedure PRP to PPP+PLT

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

- Hang the primary bag on the bag holders of the front panel. The label containing bag data should always be turned outside.
- Insert the plasma tube firmly into clamp 3.
- Position the plasma bag on upper weight scale.

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 (only with tube control enable).When all the bags and tubes are in position the text at the top right will be changed to START and the procedure start automatically.

Press START key-button to start the procedure if the autostart doesn't happen.

If the "primary bag expected weight check"has been enabled through *ArchimedeLINK* and the measured weight does not fall within the defined limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with 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 clamps. In also, if a bags is not recognized an error will be displayed.

Now wait for the plate to get close to the bag. The plate will apply a force corresponding to the value set in the procedure parameters (#3).

If the automatic breaking cannula (#45) is active the *Archimede*breakes automatically the cannulas and starts the separation cycle, it is available only if this optional is installed.

If the cannula breaking is active (# 2) the message "Break cannulas" will be displayed. Break the cannulas by forcing on their side upper part, and wait a few seconds for pressure

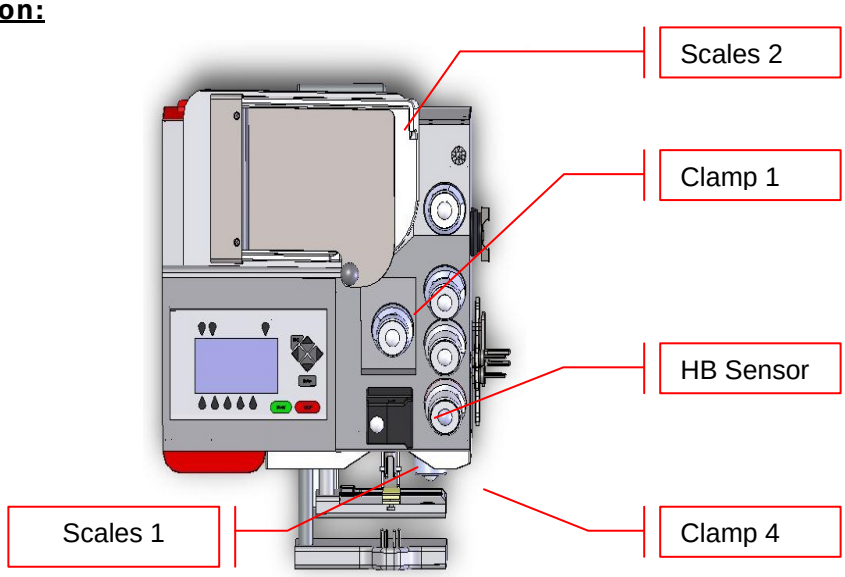
reduction. After detecting pressure decrease, *Archimede* automatically starts the separation cycle. If, due to obstructions or tube kinks pressure circuit is not reduced below the threshold set, it is any way possible to force the cycle start by pressing START key button.If the cannula breaking is not active (# 2) *Archimede* automatically starts the cycle of separation.
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 parameters #18 or the quantity set in the parameter # 30. Then the plate will move backword to standby position.

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

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

This procedure allow to use double bags for the collection of platelets from single or pools of Buffy Coat with filter for platelets (PLT) and Buffy Coat residue (Res).

Separation Description:



Picture 20: Kit installation procedure PLT with filter

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

- Hang the primary bag on the bag holders of the front panel. The label containing bag data should always be turned outside. After detecting the primary bag, the plate will move backward to make positioning of Red Cell Additive Solution bag easier, and the display will show the bag icon.
- 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 weight scale.

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 (only with tube control enable).When all the bags and tubes are in position the text at the top right will be changed to START and the procedure start automatically.

Press START key-button to start the procedure if the autostart doesn't happen.

If the "primary bag expected weight check"has been enabled through *ArchimedeLINK* and the measured weight does not fall within the defined limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with 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 clamps. In also, if a bags is not recognized an error will be displayed.

Now wait for the plate to get close to the bag. The plate will apply a force corresponding to the value set in the procedure parameters (#3).

If the automatic breaking cannula (#45) is active the *Archimede*breakes automatically the cannulas and starts the separation cycle, it is available only if this optional is installed.

If the cannula breaking is active (# 2) the message "Break cannulas" will be displayed. Break the cannulas by forcing on their side upper part, and wait a few seconds for pressure reduction. After detecting pressure decrease, *Archimede* automatically starts the separation cycle. If, due to obstructions or tube kinks pressure circuit is n 

duced below the threshold set, it is any way possible to force the cycle start by pressing key button.If the cannula breaking is not active (# 2) *Archimede* automatically starts the cycle of separation.

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 

and continue until a new warning.While in case of RBC presence if parameter # 19 is set, the system will asked if you want to end the procedure or continue in manual mode, if #19 is disable the procedure will end automatically.

Air removal depends on procedure parameters #42 setting:

Manual air removal : put plasma bag in vertical position, press 

key button to open clamp 3, and remove air manually by pressing on the bag. When finished, press 

key button to close clamp 3, and re-position plasma bag to detect weight. The process will continue automatically.

Now remove tubes and bags and press 

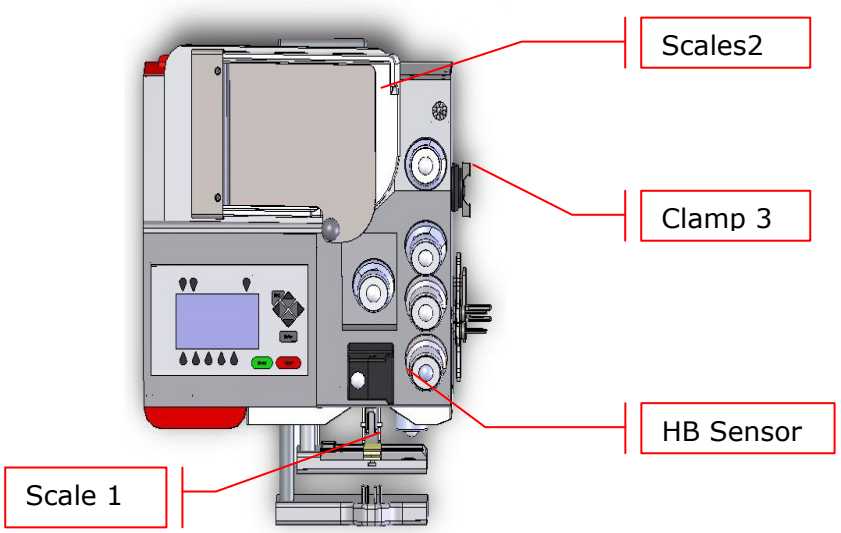
to continue with another separation of the same type or press 

to exit.

5.3.7 PROCEDURE 8: Separation of Erythrocytes Washing

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

Separation Description:



Picture 21: Kit installation procedure erythrocytes washing.

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

- Hang the primary bag on the bag holders of the front panel. The label containing bag data should always be turned outside. After detecting the primary bag, the plate will move backward to make positioning of Red Cell Additive Solution bag easier, and the display will show the bag icon.
- 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 weight scale.

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 (only with tube control enable).When all the bags and tubes are in position the text at the top right will be changed to START and the procedure start automatically.

Press START key-button to start the procedure if the autostart doesn't happen.

If the "primary bag expected weight check"has been enabled through *ArchimedeLINK* and the measured weight does not fall within the defined limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with 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 clamps. In also, if a bags is not recognized an error will be displayed.

Now wait for the plate to get close to the bag. The plate will apply a force corresponding to the value set in the procedure (# 3).

If the automatic breaking cannula (#45) is active the *Archimede*breakes automatically the cannulas and starts the separation cycle, it is available only if this optional is installed.

If the cannula breaking is active (# 2) the message "Break cannulas" will be displayed. Break the cannulas by forcing on their side upper part, and wait a few seconds for pressure reduction. After detecting pressure decrease, *Archimede* automatically starts the separation cycle. If, due to obstructions or tube kinks pressure circuit is not reduced below the threshold set, it is any way possible to force the cycle start by pressing 

key button.If the cannula breaking is not active (# 2) *Archimede* automatically starts the cycle of separation.

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 IR sensor selected in #6, the clamp will be close with a delay equal to that set in parameter # 26. Otherwise if the sensor HB in parameter # 6 is flagged, the display will show on the HB lid the reading RBC when erythrocyte are detected. The plate will move backwards and a surnatant fall down by gravity with a quantity equal to that set in parameter # 26.

Now remove tubes and bags and press 

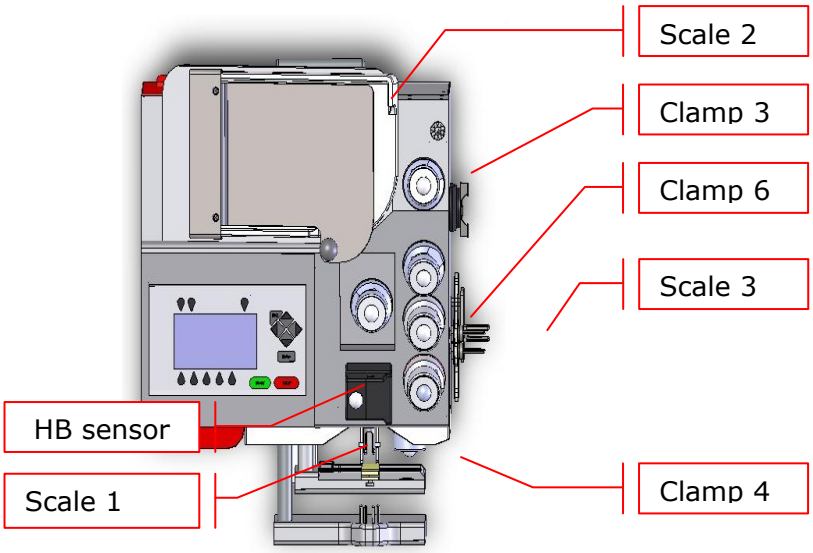
to continue with another separation of the same type or press 

to exit.

5.3.8 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.

Separation Description:



Picture 22: Kit installation procedure umbilical cord.

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

- Hang the primary bag on the bag holders of the front panel. The label containing bag data should always be turned outside. After detecting the primary bag, the plate will move backward to make positioning of Red Cell Additive Solution bag easier, and the display will show the bag icon.
- 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 weight scale.
- Insert bottom tube into clamp 4.
- Position the RBC bag on lateral weight scale.

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 (only with tube control enable).When all the bags and tubes are in position the text at the top right will be changed to START and the procedure start automatically.

Press START key-button to start the procedure if the autostart doesn't happen.

If the "primary bag expected weight check"has been enabled through *ArchimedeLINK* and the measured weight does not fall within the defined 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 clamps. In also, if a bags is not recognized an error will be displayed.

Now wait for the plate to get close to the bag. The plate will apply a force corresponding to the value set in the procedure parameters (#3).

If the automatic breaking cannula (#45) is active the *Archimede*breakes automatically the cannulas and starts the separation cycle, it is available only if this optional is installed.

If the cannula breaking is active (# 2) the message "Break cannulas" will be displayed. Break the cannulas by forcing on their side upper part, and wait a few seconds for pressure reduction. After detecting pressure decrease, *Archimede* automatically starts the separation cycle. If, due to obstructions or tube kinks pressure circuit is not reduced below the threshold set, it is any way possible to force the cycle start by pressing 

key button.If the cannula breaking is not active (# 2) *Archimede* automatically starts the cycle of separation.

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 VOLUME OF Buffy coat reaches the value set in parameter #18.

Now remove tubes and bags and press 

to continue with another separation of the same type or press 

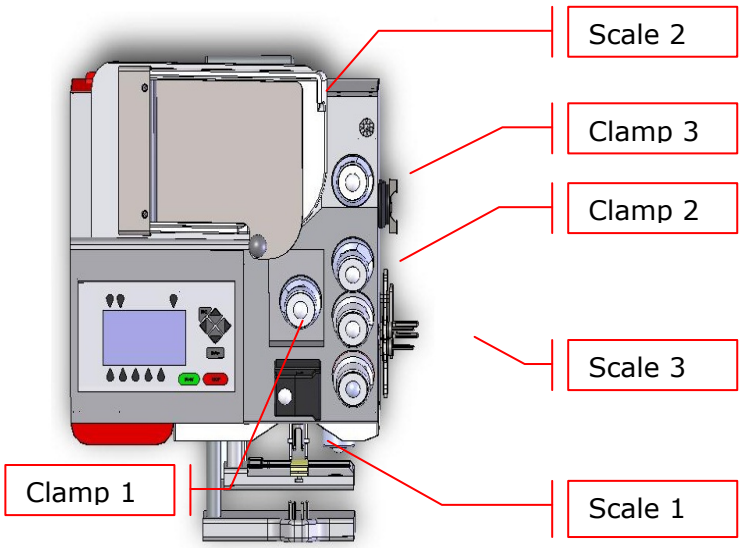
to exit.

5.3.9 PROCEDURE 11[b]: ALIQUOT SEPARATION

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

Separation Description:

First the volumes are loaded from the parameters # 14, # 29 and # 39. If the volumes shown are those you want, press START to proceed with the positioning of the bags. Otherwise if you want to change the volume setting press arrows up and down . To change the bag selection press the left and right arrows , while to disable a bag just reset the volume or press .



Picture 23: Kit installation aliquot separation procedure.

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

- Hang the primary bag on the bag holders of the front panel.
- Insert tubes from the bags on upper weight scales firmly into clamps 1 and 3.
- Insert tubes from the bags on lateral weight scales firmly into clamp 2.
- If selected position the bag 1 on upper weight scale.
- If selected position the bag 2 on upper weight scale.
- If selected position the bag 3 on lateral weight scale.

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 (only with tube control enable).When all the bags and tubes are in position the text at the top right will be changed to START and the procedure start automatically.

Press START key-button to start the procedure if the autostart doesn't happen.

If the "primary bag expected weight check"has been enabled through *ArchimedeLINK* and the measured weight does not fall within the defined limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with 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. In also, if a bags is not recognized an error will be displayed.

Now wait for the plate to get close to the bag. The plate will apply a force corresponding to the value set in the procedure parameters (#3).

If the automatic breaking cannula (#45) is active the *Archimede*breakes automatically the cannulas and starts the separation cycle, it is available only if this optional is installed.

If the cannula breaking is active (# 2) the message "Break cannulas" will be displayed. Break the cannulas by forcing on their side upper part, and wait a few seconds for pressure reduction. After detecting pressure decrease, *Archimede* automatically starts the separation cycle. If, due to obstructions or tube kinks pressure circuit is not reduced below the threshold set, it is any way possible to force the cycle start by pressing START key button.If the cannula breaking is not active (# 2) *Archimede* automatically starts the cycle of separation.

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.

Archimede will automatically send to *ArchimedeLINK* 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 weight scale' readings, the blood components can be weighed again after correcting tubes' position and the new weights can be sent to *ArchimedeLINK*.

Correct weights: if you remove all the tubes and all the bags, *Archimede* will automatically start a procedure of the same type. You can force the process by pressing the START button to continue with the same type of separation. To go back to the procedures list page press Esc button.

Incorrect weights: press one of the key buttons below the display to weigh blood components again. To accept the new values and send them to *ArchimedeLINK* press Enter

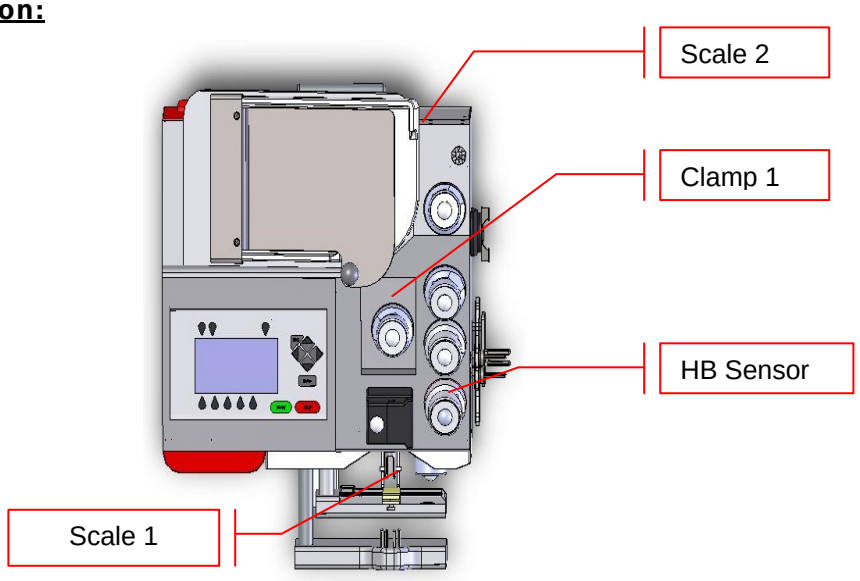
Archimede will automatically send to *ArchimedeLINK* all events and data of the procedure performed.

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

5.3.10 PROCEDURE 12[c]: PLT + BC from single Buffy Coat.

This procedure allow to use double bags for the collection of platelets from single or pools of Buffy Coat with filter for platelets (PLT) and Buffy Coat residue (Res).

Separation Description:



Picture 24: Kit installation procedure PLT +BC.

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

- Hang the primary bag on the bag holders of the front panel. The label containing bag data should always be turned outside. After detecting the primary bag, the plate will move backward to make positioning of Red Cell Additive Solution bag easier, and the display will show the bag icon.
- 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 weight scale.

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 (only with tube control enable).When all the bags and tubes are in position the text at the top right will be changed to START and the procedure start automatically.

Press START key-button to start the procedure if the autostart doesn't happen.

If the "primary bag expected weight check"has been enabled through *ArchimedeLINK* and the measured weight does not fall within the defined limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with 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 clamps. In also, if a bags is not recognized an error will be displayed.
Now wait for the plate to get close to the bag. The plate will apply a force corresponding to the value set in the procedure parameters (#3).

If the automatic breaking cannula (#45) is active the *Archimede*breakes automatically the cannulas and starts the separation cycle, it is available only if this optional is installed.

If the cannula breaking is active (# 2) the message "Break cannulas" will be displayed. Break the cannulas by forcing on their side upper part, and wait a few seconds for pressure reduction. After detecting pressure decrease, *Archimede* automatically starts the separation cycle. If, due to obstructions or tube kinks pressure circuit is n 

duced below the threshold set, it is any way possible to force the cycle start by pressing key button.If the cannula breaking is not active (# 2) *Archimede* automatically starts the cycle of separation.

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 

and continue until the a warning, while in case of RBC presence if parameter # 19 is set, the system will asked if you want to end the procedure or continue in manual mode.

Air removal depends on procedure parameters setting #42:

Manual air removal : put plasma bag in vertical position, press 

key button to open clamp 3, and remove air manually by pressing on the bag. When finished, press 

key button to close clamp 3, and re-position plasma bag to detect weight. The process will continue automatically.

Now remove tubes and bags and press 

to continue with another separation of the same type or press 

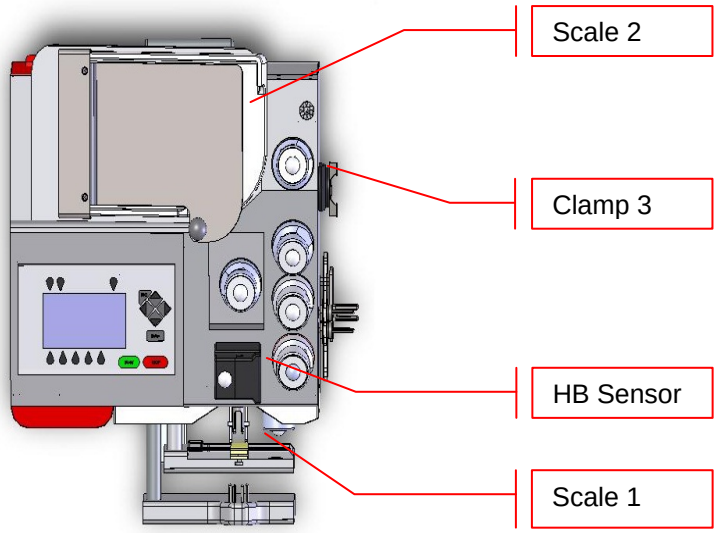
to exit.

5.3.11 **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.

Separation Description:

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



Picture 25: Kit installation procedure T & T with predefined HCT.

- Hang the primary bag on the bag holders of the front panel. The label containing bag data should always be turned outside.
- 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 weight scale.

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 (only with tube control enable).When all the bags and tubes are in position the text at the top right will be changed to START and the procedure start automatically.

Press START key-button to start the procedure if the autostart doesn't happen.

If the "primary bag expected weight check"has been enabled through *ArchimedeLINK* and the measured weight does not fall within the defined limits, a warning will be displayed showing both limits and current weight. After verifying the cause of the problem, confirm weight with 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 clamps. In also, if a bags is not recognized an error will be displayed.
Now wait for the plate to get close to the bag. The plate will apply a force corresponding to the value set in the procedure parameters (#3).

If the automatic breaking cannula (#45) is active the *Archimede*breakes automatically the cannulas and starts the separation cycle, it is available only if this optional is installed.

If the cannula breaking is active (# 2) the message "Break cannulas" will be displayed. Break the cannulas by forcing on their side upper part, and wait a few seconds for pressure reduction. After detecting pressure decrease, *Archimede* automatically starts the separation cycle. If, due to obstructions or tube kinks pressure circuit is n 

duced below the threshold set, it is any way possible to force the cycle start by pressing key button.If the cannula breaking is not active (# 2) *Archimede* automatically starts the cycle of separation.

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.
Now remove tubes and bags and press 

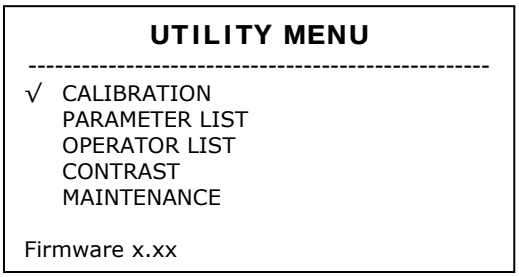
to continue with another separation of the same type or press 

to exit.

6 WEIGHT SCALE CALIBRATION

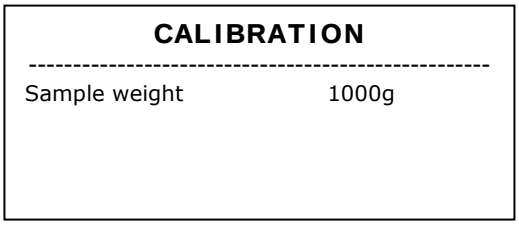
Weight scales calibration can be performed only when *Archimede* has been switched on for a few minutes. This is necessary for measuring sensors to reach thermal stabilization. A set of certified weights is also necessary.

To enter calibration, press the key button above the icon, and select CALIBRATION using direction key buttons.



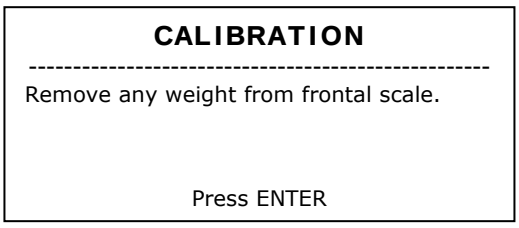
Picture 26: Calibration menu.

Confirm by pressing Enter.



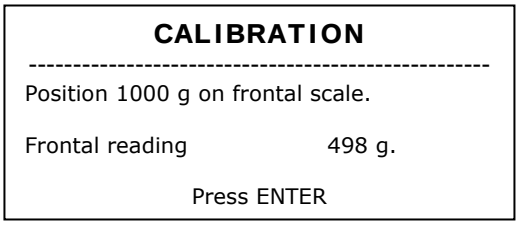
Picture 27: Calibration, sample weight setting.

Select the sample weight value you intend to use for calibration using key buttons, then confirm pressing Enter.



Picture 28: First step calibration.

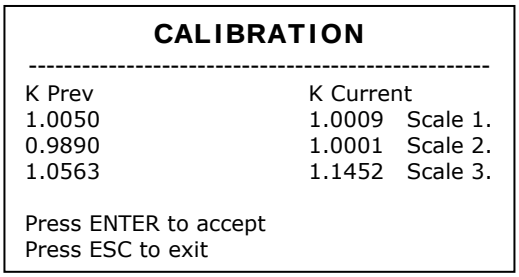
To perform tare, remove any weight from the front weight scales and then confirm pressing Enter.



Picture 29: Second step calibration.

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

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



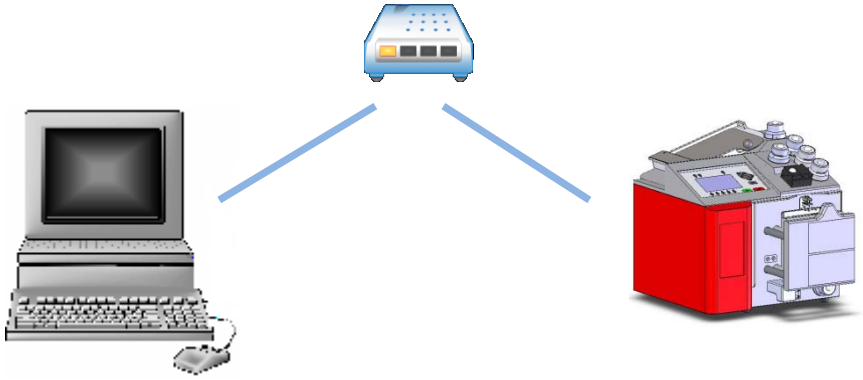
Picture 30: Calibration factors display.

Verify calibration factors calculated for front weight scales (1), upper weight scales (2), and lateral weight scales (3). Press  to confirm factors and save them, or press  to restore the previous calibration factors.

7 DATA TRANSFER

With LAN or WLAN, *Archimede* can dialogue in bidirectional mode with *ArchimedeLINK.* This allows data transfer from several*Archimede* units, even if located several meters distant from the PC where *ArchimedeLINK* server is installed.

7.1 LAN



Picture 31: LAN connection

Every *Archimede* connected to an IP network must have a unique IP address, and if DHCP mode is enable IPaddress is automaticallyassigned. Communication takes place through the identification of *Archimede*'sunique serial number.

7.2 WLAN

Picture 32: 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*'sunique serial number. This allows *ArchimedeLINK* to communicate with more units installed and switched on within a 50 meters distance aroung the computer.

Caution:
Consult accompanying documents according to the European Standard – EN980

7.3 Firmware Update and Procedures Protocols

- The use of *ArchimedeLINK* allows to:
- Update *Archimede*'s internal firmware. Firmware updating should preferably be performed by qualified engineers 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 device components connected to *Archimede.* This operation should be performed by qualified engineers authorized by manufacturer.

8 TROUBLESHOOTING

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

8.1 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: Archimede has been switch off for a long period.
Remedy: Leave Archimede on for some hours.
Cause 2: RTC backup capacitor is exhausted.
Remedy: Call Authorized Service Center.

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

Cause 1: Electronics interferences.
Remedy: Press ESC.
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 closerArchimede units.
Change the WLAN module transmission channel.
Call Authorized Service Center.

8.2 Errors with Archimede codes

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

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

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

Cause 1: E^2PROM verify failed.

Remedy: Turn *Archimede* OFF and ON.
Cause 2: Defective microcontroller E^2prom memory.
Remedy: Call Authorized Service Center.

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 scales 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 SCALES (X) TARE.**

Cause 1: Scales holder is not in correct position.
Remedy: Check that scales holders are correctly mounted and free from obstructions.
Turn *Archimede* OFF and ON.

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

Cause 1: Scales holder is not in correct position.
AD input circuit not compensated.
Remedy: Check that scales 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 ≥ 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 (1-18) **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 (1-18) **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 (1-18) **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: Forcesensor 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 calposition 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: Distancesensor 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 isdefective.

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 key button 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.

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

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

Remedy: Recalibrate 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: Recalibrate 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: Scales 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: Scales not calibrated.

Remedy: Calibrate scale. (see scales 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: Scales not calibrated.

Remedy: Calibrate scales (see scales 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: Scales not calibrated.
Remedy: Calibrate scales (see scales 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: Scales not calibrated.
Remedy: Calibrate scales (see scales calibration).

Error 45 **NOT IN USE.**

Error 46 **UNEXPECTED WEIGHT.**

Cause 1: Scales 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: Scales unstable.
Remedy: Check if scales 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: Reconfigure barcode (see Datalogic barcode configuration).

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

Cause 1: The operator has pressed STOP key-button and confirmed interruption with Enter 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 50 **ERRORE WEIGHT-DISTANCE**

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).

Error 54 **NOT IN USE.**

Error 55 **NOT IN USE.**

Error 56(1-4) **TIMEOUT CANNULA BREAKER MOTOR.**

Cause 1: Mechanical obstructions prevent CB movement.

Remedy: Remove any obstruction.

Cause 2: CBposition sensor defective.

Remedy: Call Authorized Service Center.

9 Maintenance

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

9.1 Daily Maintenance

9.1.1 Cleaning

Clean upper weight scales 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.

Warning: Never use alcohol, acetone, trichloroethylene or any solvents.

9.1.2 Decontamination

Remove the upper weight scales 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 dubs dampened with bleach or disinfectant. Rinse with water all parts treated with bleach or disinfectant.

Warning: Never use alcohol, acetone, trichloroethylene or any solvents.

9.1.3 Monthly Maintenance

Monthly maintenance simply consists of checking the calibration of all weight scales using certified weights. If the readings don't fall within the allowed ranges, please contact the authorized technical service centre.

9.2 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.

9.3 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.

10 ACCESSORIES

Archimede can be supplied with:

- RFID reader for labels or cards type RFID ISO15693. Supported tags are I.CODE SLI and Tag_it.
- Omni directional bar code reader.
- Cannula breaker for W.B. cannula and for R.C. cannula.

11 DISPOSAL

When disposing materials, please observe the following recommendations:

11.1 Packing Material Disposal

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

11.2 ArchimedeDisposal

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

or

- Ask the nearest Technical Service authorized centre.

Separate waste collection.

Symbol (WEEE 2002/96/EC)

For product disposal, ensure the following:

- Do not dispose of this product as unsortedmunicipal waste.
- Collect this product separately.
- Use the collection and return systems availableto you.

For more information on return, recovery orrecycling of this product, please contact yourlocal service representative.

12 ELECTROMAGNETIC COMPATIBILITY

The following information needs to be provided according to IEC 60601-1-2:2007
Archimede as well as all medical electrical equipment, needs special precautions regarding EMC (electromagnetic compatibility) and needs to be installed and put into service according to the following information.
Because the intensity of electromagnetic energy is greatest near the source of a transmitting antenna, portable and mobile RF communications equipment can affect medical electrical equipment.

Archimede has been designed to withstand the effects of EMI (electromagnetic interference) and meets the most current EMC standards that apply to the instrument. However, extremely high levels of electromagnetic energy (above the levels of IEC 60601-1-2) may still produce interference.

To reduce the risk of EMI, follow these recommendations:

-Do not turn on or use hand-held personal communications devices, such as mobile two-way radios or cellular phones, near the instrument.
-If these devices need to be used, follow the "recommended separation distance" as shown in the following tables.
-In the case of unexplained EMI, consider the locations of nearby transmitters, such as radio or TV stations. You may have to move the instrument or place shield material between the transmitter and the instrument.
- Be aware that modifying the instrument or adding accessories or components, not specifically authorized by MOELA, may make the instrument more susceptible to interference from radio waves.

Table 1

Guidanceandmanufacturer'sdeclaration–electromagneticemissions		
TheModel*Archimede*isintendedforuseintheelectromagneticenvironment specifiedbelow.Thecustomer orthe userofthe Model*Archimede*should assurethatitisusedinsuchanenvironment.		
Emissionstest	**Compliance**	**Electromagneticenvironment–guidance**
RFemissions CISPR11	Group1	TheModel*Archimede*usesRFenergyonlyforitsinternal function.Therefore, itsRFemissionsareverylowand arenotlikelytocause anyinterferenceinnearby electronicequipment.
RFemissions CISPR11	ClassB	TheModel*Archimede*issuitableforuseinallestablishments, includingdomesticestablishmentsandthosedirectly connectedtothepubliclow-voltage powersupply networkthatsupplies buildings usedfordomestic purposes.
Harmonicemissions IEC61000-3-2	ClassA	
Voltagefluctuations/ flickeremissions IEC61000-3-3	Complies	

Table 2

Guidanceandmanufacturer'sdeclaration–electromagneticimmunity			
The*Archimede*isintendedforuseintheelectromagneticenvironmentspecifiedbelow.The customer ortheuserofthe*Archimedes*houldassurethatitisusedinsuchanenvironment.			
IMMUNITYtest	**IEC60601testlevel**	**Compliancelevel**	**Electromagneticenvironment– guidance**
Electrostatic discharge(ESD) IEC61000-4-2	☐6kVcontact ☐8kVair	☐6kVcontact ☐8kVair	Floorsshouldbewood,concreteor ceramictile.Iffloorsarecoveredwithsyntheticmaterial,therelativehumidity shouldbeatleast30%.
Electricalfast transient/burst IEC61000-4-4	☐2kVforpower supplylines ☐1kVforinput/output lines	☐2kVforpower supplylines ☐1kVforinput/output lines	Mainspowerqualityshouldbethatofa typicalcommercial orhospital environment.
Surge IEC61000-4-5	☐1kVline(s)to line(s) ☐2kVline(s)toearth	☐1kVdifferential mode ☐2kVcommonmode	Mainspowerqualityshouldbethatofa typicalcommercial orhospital environment.
Voltagedips,short interruptionsand voltagevariations onpowersupply inputlines IEC61000-4-11	<5%*U*T (>95%dipin*U*T) for0,5cycle 40%*U*T (60%dipin*U*T) for5cycles 70%*U*T (30%dipin*U*T) for25cycles <5%*U*T (>95%dipin*U*T)	<5%*U*T (>95%dipin*U*T) for0,5cycle 40%*U*T (60%dipin*U*T) for5cycles 70%*U*T (30%dipin*U*T) for25cycles <5%*U*T (>95%dipin*U*T)	Mainspowerqualityshouldbethatofa typicalcommercial orhospital environment.Iftheuseroftheh *Archimede*requires continuedoperationduringpower mainsinterruptions,itisrecommended thattheh*Archimede*be poweredfromanuninterruptiblepower supplyorabattery.
Powerfrequency (50/60Hz) magneticfield IEC61000-4-8	3A/m	NOT applicable : the apparatus does not contain any device susceptible to power frequency magnetic fields.	-
NOTE *U*T isthea.c.mainsvoltagepriortoapplication ofthetestlevel.			

Table 4

Guidanceandmanufacturer'sdeclaration–electromagneticimmunity			
The*Archimede*isintendedforuseintheelectromagneticenvironmentspecifiedbelow.Thecustomer ortheuserof the*Archimede*shouldassurethatitisusedinsuchanenvironment.			
IMMUNITYtest	**IEC60601TEST LEVEL**	**Compliancelevel**	**Electromagneticenvironment–guidance**
ConductedRF IEC61000-4-6 RadiatedRF IEC61000-4-3	3Vrms 150kHzto80MHz 3V/m 80MHzto2,5GHz	3Vrms 10V/m	PortableandmobileRFcommunicationsequipment shouldbeusednoclosertoanypartofthe*Archimede*,includingcables,thantherecommended separationdistancecalculatedfromtheequation applicable tothefrequency ofthetransmitter. **Recommendedseparationdistance** d=0,35P $^{1/2}$ d= 0,35 P ^{½} (80 MHz to 800 MHz) d= 0 , 7 P ^{½}(800 MHz to 2,5 GHz) where*P*isthemaximumoutputpowerratingofthe transmitter inwatts(W)accordingtothetransmitter manufacturerand*d*istherecommendedseparation distanceinmetres(m). Fieldstrengths fromfixedRFtransmitters, asdetermined byanelectromagneticsitesurvey,[a] shouldbe lessthanthecompliance levelineachfrequency range.[b] Interferencemayoccurinthevicinityofequipment markedwiththefollowingsymbol:
NOTE1 At80MHzand800MHz,thehigherfrequency rangeapplies. NOTE2 Theseguidelinesmaynotapplyinallsituations.Electromagneticpropagationisaffectedbyabsorption andreflectionfromstructures,objectsandpeople.			
[a] Fieldstrengthsfromfixedtransmitters,suchasbasestationsforradio(cellular/cordless)telephonesandland mobileradios,amateurradio,AMandFMradiobroadcastandTVbroadcastcannotbepredictedtheoretically withaccuracy.Toassesstheelectromagneticenvironmentduetofixed RFtransmitters,anelectromagneticsite surveyshouldbe considered.If the measuredfieldstrengthin the locationin whichthe Model*Archimede*is used exceeds the applicable RF compliance level above, the Model *Archimede*should be observed to verify normal operation.Ifabnormalperformanceisobserved,additionalmeasuresmaybenecessary,suchasre-orientingor relocatingtheModel*Archimede*. [b] Overthefrequency range150kHzto80MHz,fieldstrengthsshouldbelessthan3V/m.			

Table 6

Recommendedseparationdistancesbetween portableandmobileRFcommunicationsequipmentandtheModel			
The *Archimede*is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.Thecustomerortheuserofthe*Archimede*canhelppreventelectromagneticinterferencebymaintaining aminimumdistancebetweenportableandmobileRFcommunicationsequipment(transmitters)andthe*Archimede*			
Ratedmaximumoutputpower oftransmitter W	**Separationdistanceaccordingtofrequency oftransmitter**		
	150kHzto80MHz $d=0,35P^{1/2}$	**80MHzto800MHz** $d=0,35P^{1/2}$	**800MHzto2,5GHz** $d=0,7P^{1/2}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmittersrated at a maximumoutputpowernot listed above, the recommendedseparationdistance*d* in metres(m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximumoutputpowerratingofthetransmitterinwatts(W)according tothetransmittermanufacturer. NOTE1 At80MHzand800MHz,theseparation distanceforthehigherfrequency rangeapplies. NOTE2 These guidelinesmaynotapplyinall situations.Electromagnetic propagationisaffectedby absorptionand reflectionfromstructures,objectsandpeople.			

13 TECHNICAL FEATURES

- Painted metal case.
- Graphic backlight display 240 x 128.
- 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.
- 4 sealing head clamps, 1 normal clamp, and one flow valve.
- 18 optical sensors to detect buffy coat level.
- Optical device to detect red blood cells presence.
- Many separation procedures stored, up to a maximum of 18.
- LAN and WLAN for bi-directional data transfer of procedure and configuration data.
- PS2 port for external barcode-reader or keyboard connection.
- Adjustable sealing time from 0.5 to 4 seconds, frequency 40.68 MHz.
- Latex free.
- Environmental requirements: Temperature between 5°C and 45°C Humidity lower than 80% without condensation.
- Power supply: 90 VAC 84 W 1A, 250 VAC 81 W 0.4A, N.2 fuses T2 AT 250 VAC
- Dimensions Width 435, depth 500, height 425 [mm].
- Noise Level < 65 dBA
- Weight: 39Kg, without any optionals.
- Transport and storage temperature From –20°C to +70°C, relative humidity from 20% to 90% without condensation.
- British Thermal Unit ~300 BTU/h

MANUFACTURER:

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14 ARCHIMEDE APPLICABLE STANDARD REGULATION LIST AND CERTIFICATIONS

- The *Archimede* is a non sterile accessory (MDD 93/42/EEC, article 1, §2 (b)) to the Blood-Pack Units which are medical devices in the scope of the 93/42/EEC Directive.

- Without measuring function: the *Archimede* is typically used in a laboratory environment, with no patient connected to the instrument. The *Archimede* is not intended by the manufacturer to measure a quantitatively a physiological or anatomical parameter, or a quantity or a qualifiedly characteristic of energy or of substances delivered to or removed from the human body. The instrument is not intended to display a measurement from which an operator is required to make a diagnostic or interpretative decision affecting the patient's health and safety.

- Class I, non-sterile accessory without measuring function to a medical device according to the Council Directive 93/42 EEC and following modifications (2007/47/EU of 21/03/2010)

- International protection: **IP41**

Released by	DocumentRef. Number	Title	Date
MOELCA S.r.l.		EC Declaration of Conformity Archimede Version 3.1 (Medical Device Directive)	31/08/2011
MOELCA S.r.l.		EC Declaration of Conformity Archimede 3.1 (R&TTE directive) *	19/09/2011
MOELCA S.r.l.	E7M-1109-1374-C	Expert Opinion the Notified Body based on the Conformity Assessment according to Annex IV of the R&TTE Directive 1999/5/EC	19/09/2011
P. R. & S. (Notified Body)	11_022_REV1	(Prima Ricerca & Sviluppo) "Archimede Certificate of Conformity"	30/05/2011
P. R. & S. (Notified Body)	EMCTR_110232-4	Compliance: EN 60601-1-2 (2007) EN 301 489-1 V.1.8.1 (2008-04) EN 301 489-17 V.2.1.1 (2009-05)	18/05/2011
P. R. & S. (Notified Body)	MACTR_ 110482_0A	Compliance: EN ISO 12100-1:2003 + A1:2009 EN ISO 12100-2:2003 + A1:2009 EN ISO 13857:2008 - EN 349: 1993	12/05/2011
P. R. & S. (Notified Body)	MPETR_110481-0	Compliance: EN 62311: 2008	31/05/2011
P. R. & S. (Notified Body)	SAFTR_110233-1	Compliance: EN 60601-1:2006-10	14/03/2011
P. R. & S. (Notified Body)	ETSTR_110479-0	Compliance: EN 300 328 V1.7.1 (2006-10)	14/06/2011
P. R. & S. (Notified Body)	ETSTR_110480-0	Compliance: EN 300 330-1 V 1.7.1 (2010-02) EN 300 330-2 V 1.5.1 (2010-02)	10/05/2011
Ministero della Salute	DGFDM/III/P I.5.I.e.1/2010/610	Free Sales Certificate	24/02/2011
MOELCA S.r.l.		Declaration of Origin	23/02/2011

***Please contact info@moelca.it to request this latest EC declaration of conformity**