

MACOPRESS® Smart

AUTOMATIC BLOOD COMPONENTS SEPARATOR



USER MANUAL

en

an Rev 3.0 ENG July 2011

Index of Contents

| | |
|--|-----------|
| INDEX OF CONTENTS | 2 |
| PREFACE | 5 |
| TECHNICAL SUPPORT AND SALES OFFICE | 5 |
| CERTIFICATIONS | 6 |
| MANUFACTURER RESPONSABILITY | 6 |
| COPYRIGHT AND TRADEMARKS | 6 |
| SYMBOLS AND CONVENTIONS | 7 |
| REVISION HISTORY | 9 |
| SPECIAL WARNINGS | 10 |
| CAUTION! | 10 |
| WARNINGS FOR STAFF SAFETY | 11 |
| ELECTROMAGNETIC EMISSION WARNINGS | 12 |
| ENVIRONMENTAL RISKS AND WASTE DISPOSAL | 16 |
| WARRANTY | 17 |
| INTRODUCTION | 18 |
| PURPOSE OF USE OF MPS EVO | 18 |
| FEW CONCEPTS ABOUT THE PREPARATION OF BLOOD COMPONENTS | 18 |
| <i>THE MAIN BLOOD COMPONENTS THAT CAN BE PREPARED WITH MPS EVO</i> | 19 |
| <i>BUFFY COAT PRODUCTS</i> | 19 |
| DESCRIPTION OF THE PARTS | 20 |
| <i>Keyboard</i> | 20 |
| <i>Display</i> | 21 |
| <i>Back panel</i> | 21 |
| <i>Optical sensors</i> | 21 |
| <i>Clamps and optical sensor panel</i> | 21 |
| <i>Sealer Clamps</i> | 22 |
| <i>Scales</i> | 22 |
| <i>Main Press</i> | 22 |
| <i>Lateral Press</i> | 22 |
| FUNCTIONAL DESCRIPTION | 23 |
| COMPUTER CONNECTIONS | 27 |
| CONNECTING MPS EVO TO THE COMPUTER | 27 |
| INSTALLATION | 29 |
| <i>Removing MPS EVO from its packaging</i> | 29 |
| <i>Where to install MPS EVO</i> | 29 |
| <i>Installing the parts supplied</i> | 30 |
| <i>Follow the instructions described in this paragraph:</i> | 30 |
| <i>Switching on MPS EVO</i> | 30 |
| <i>Before everything else, check that the mains and power line are correctly earth wired. If the earth cable is damaged this may reduce the effectiveness and or the safety: in case, NEVER switch on the machine and solve the problem first.</i> | 30 |
| <i>Switching off MPS EVO</i> | 31 |

| | |
|--|-----------|
| MODE OF USE | 32 |
| STAND-ALONE MODE | 32 |
| BIDIRECTIONAL MODE | 32 |
| <i>Preparation List</i> | 32 |
| REMOTE PROGRAM START FROM DMSPLUS | 33 |
| SECURITY | 33 |
| SEPARATION'S PROGRAMS | 34 |
| STANDARD SEPARATION PROCEDURES | 34 |
| EXTRACTION FROM WHOLE BLOOD USING STANDARD TOP-TOP BAGS | 34 |
| EXTRACTIONS FROM WHOLE BLOOD USING TOP & BOTTOM BAGS | 36 |
| HOW TO USE A PROGRAM | 39 |
| HOW TO GENERATE A NEW PROGRAM | 39 |
| DISPLAY MENU..... | 40 |
| HOW TO USE THE DISPLAY MENU | 40 |
| HOW TO CHANGE THE PROGRAM'S SETTINGS | 41 |
| PROGRAM HEAD | 41 |
| DESCRIPTION OF PHASES | 43 |
| PHASE A: Extraction of a single blood component or air using the main press | 43 |
| PHASE B: Transfer by gravity or by lateral press of a single blood product or air..... | 44 |
| PHASE C: Extraction of PL by differential weight from PRP or PPP for preparation of PLTS or cryoprecipitate..... | 45 |
| PHASE D: Simultaneous extraction of two components (Top and Bottom bags) | 45 |
| EXAMPLES: | 48 |
| FINAL NOTES ABOUT THE CREATION OF A NEW PROGRAM | 48 |
| HOW TO LOAD THE BAGS..... | 49 |
| TUBE POSITIONING MASK | 49 |
| IF YOU ARE USING A RBC ADDITIVE SOLUTION BAG, REMEMBER TO BREAK ITS BREAK AWAY CANNULA TOO. | 50 |
| YOUR MPS EVO MACHINE IS NOW READY TO PERFORM THE FIRST EXTRACTION WITH STANDARD BAGS. | 50 |
| LOADING A SET OF TOP & BOTTOM BAGS | 50 |
| NOTICES, ALARMS AND ANOMALIES | 52 |
| MAINTENANCE..... | 56 |
| DAILY MAINTENANCE (OPERATOR) | 56 |
| WARNING FOR CLEANING AND DISINFECTION! | 56 |
| CLEANING | 57 |
| DECONTAMINATION | 57 |
| SIX-TWELVE MONTH'S MAINTENANCE | 57 |
| CHECKING THE SCALES | 58 |
| CHECKING THE SEALER CLAMPS | 58 |
| TECHNICAL DATA..... | 60 |
| DESCRIPTION OF AVAILABLE VERSIONS OF MPS EVO..... | 62 |
| Cod. 9MPSEVO485 | 62 |
| Cod. 9MPSEVOLAN | 62 |
| Cod. 9MPSEVOWIFI..... | 62 |

| | |
|--|-----------|
| CONFIGURATION OF MPS EVO FOR NET CONNECTION | 63 |
| CONFIGURATION OF MPS EVO WITH RS485 NETWORK | 63 |
| <i>RS485 CONNECTION DRAWING</i> | 63 |
| CONFIGURATION OF MPS EVO WITH ETHERNET NETWORK | 65 |
| <i>ETHERNET CONNECTION DRAWING</i> | 65 |
| CONFIGURATION OF MPS EVO WITH WIFI NETWORK | 68 |
| <i>Wi-Fi CONNECTION DRAWING</i> | 68 |
| CONVERSION FROM WIFI OR ETHERNET NETWORK TO RS485 | 71 |
| <i>Temporary Conversion</i> | 71 |
| <i>Permanent Conversion</i> | 72 |
| OPTIONAL ACCESSORIES | 74 |
| <i>Cod. 9MPS040</i> | 74 |
| <i>Cod. 9MPS050</i> | 74 |
| <i>Cod. 9MPS060</i> | 74 |
| <i>Cod. 9MPS060L</i> | 74 |
| <i>Cod. 9MPS080</i> | 74 |
| <i>Cod. 9MPS080L</i> | 74 |
| <i>Cod. STR.DB.00</i> | 75 |
| <i>Cod. 9MPS090</i> | 75 |
| WiFi NET ACCESSORIES | 75 |
| <i>Cod. 9MPSWIFI_AP</i> | 75 |
| LAN NET ACCESSORIES | 75 |
| <i>Cod. 9MPSHUB_PC</i> | 75 |
| <i>Cod. 9MPSLAN_CAB</i> | 75 |
| RS485 ACCESSORIES | 75 |
| <i>Cod. 9MPS311</i> | 76 |
| <i>Cod. 9MPS070</i> | 76 |

PREFACE

This manual is written to provide information about the use of the blood components separator MACOPRESS EVO.

TECHNICAL SUPPORT AND SALES OFFICE



| | | |
|--|-----------------------|---|
| | Address Headquarter | Delcon s.r.l Via Matteucci 25/27 20862 Arcore (MB) Italy |
| | Telephone Headquarter | +39-039617670 |
| | Fax Headquarter | +39-039617677 |
| | Address Factory | Delcon s.r.l Via Zanica 19/I/F 24050 Grassobbio (BG) Italy |
| | Telephone Factory | +39-0354522336 |
| | Fax Factory | +39-0354233203 |
| | Business e-mail | info@delcon.it |
| | Service e-mail | service@delcon.it |
| | Website | www.delcon.it |

Manufactured exclusively for:



| | | |
|--|-----------------------|---|
| | Address Headquarter | MACOPHARMA S.A. Rue Lorthiois 59420 MOUVAUX (FRANCE) |
| | Telephone Headquarter | +33 (0) 3 20 11 84 30 |
| | Fax Headquarter | +33 (0) 3 20 11 84 86 |
| | Business e-mail | contact@macopharma.com |
| | Service hotline | 0049 (0) 6103 9008 99 |
| | Website | www.macopharma.com |

CERTIFICATIONS

Quality System in conformity with **ISO 9001:2008, ISO13485:2003**



MANUFACTURER RESPONSABILITY

The instructions may contain a declaration of responsibility regarding safety and correct use of this device only if:

- The operations of assembly, setting, change, and repair must be performed by authorised personnel.
- The electrical installation has been carried out in conformity with the instructions.
- The device is used in accordance with this manual.

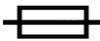
Delcon s.r.l. reserves the right to make corrections, modifications, enhancements, improvements, and other changes to its products, manuals and services at any time without notice.

COPYRIGHT AND TRADEMARKS

All rights reserved. No part of this document can be reproduced, stored, or transmitted in any form without the prior written permission of Delcon s.r.l. Despite every care has being adopted during the preparation of this document, Delcon s.r.l. shall not assume any responsibility for atrocities or negligence. Nor shall they assume any responsibility for damages caused by use of the information contained herein. These same rights are reserved for any person(s) or company involved in the creation and production of this manual. All trademarks mentioned in this manual are property of their respective owners.

SYMBOLS AND CONVENTIONS

The list below is a summary of the symbols and conventions used in this handbook.

| | |
|---|---|
|  | Please read carefully |
|  | Watch your hands, risk of crushing! |
|  | Ground connection point (earth) |
|  | General warning sign or “Consult accompanying documents” |
|  | Refer to instruction manual/booklet. Before use the equipment, read carefully the manual. "Follow instructions for use" |
|  | Medical equipment includes RF transmitters for WiFi Communication comply to International Standards IEEE 802.11b/g transceiver FCC approved |
|  | Indicates Device serial number |
|  | Postal address Manufacturer |
|  | Date of manufacture |
|  | Fuses |
|  | Complies with (USA) Federal Communications Commission regulations |
|  | TÜV Rheinland Product Safety and Quality Certification (US and Canadian electrical safety standard) |
|  | Device tested in accordance with standard CAN/CSA-C22.2 NO. 61010-1 2 nd Edition, including Amendment 1 |
| PL | Any Plasma product |
| RBC | Any Red Blood Cell product |
| BC | Buffy-Coat |
| PLTS | Platelets Concentrate |
| PRP | Platelets Rich of Plasma |
| Cryo | Cryoprecipitate (Factor VIII) |
| WB | Whole Blood |
| RBC additive solution | Solution for RBC storage |
| T&B or TAB | Top and Bottom bags |
| PC | Personal computer |
| DMSPlus | DMSPlus (Data Management Software Plus). It's the Windows® software application described in this manual |

| | |
|-------------------------|---|
| PRG | A separation program of MPS EVO |
| User or Operator | Person that uses the MPS EVO machine |
| ID Donation | Code that identifies the donation |
| Machine or MPS | MPS EVO blood components separator |
| Protocol | All instructions related to the use of barcodes or RFID Tag with one specific PRG |
| Barcode | A written barcode label |
| Tag Code | A specific field in the RFID memory tag. It's defined by the position within the TAG and its length |
| RFID Tag | Radio Frequency ID. Re-writable electronic memory used to carry information on bag |
| OPT1 | Top Main optical sensor |
| OPT2 | Main Press optical sensor (made of 8 single optical sensors) |
| P1 | Main press or Press P1 |
| P2 | Lateral Press or Press P2 |
| MPS EVO | MacoPress EVO |
| OPT3 | Clamp1 optical sensor |

REVISION HISTORY

| DATE | DESCRIPTION OF REVISION |
|-------------|--|
| Sep-21-2010 | Revision 2.0 Initial release for MPS EVO with firmware version revision FWR:2.xx and DMSPlus software support. |
| July-2011 | Revision 3.0 Add new technical table, Add new standard for Europe and US CSA market Modifications for the firmware revision FWR:2.xx and DMSPlus software support V2.x. |
| | |
| | |
| | |

SPECIAL WARNINGS

CAUTION!

Before using the equipment, read this manual carefully.

This instrument is not designed for use in the presence of flammable mixtures, such as anaesthetics, oxygen, or nitrous oxide with air.

Avoid water or other liquids from entering the equipment: this can cause short circuits and corrosion with subsequent damages.

Before cleaning or overhauling MPS EVO , always disconnect the power supply cable. For cleaning see the detailed instruction for the product to use.

MPS EVO must only be used for the purposes for which it is designed, as described in this manual.

Macopharma and Delcon s.r.l. shall not assume any responsibility in the following cases:

1. Any use of MPS EVO different from those described in this manual.
2. Damages to the operator or patient due to incorrect installation, use, or maintenance or carried out by personnel not authorised by Macopharma.
3. Electrical or mechanical changes carried out during or after installation and not authorised by Macopharma.
4. Use of the press system for purposes different from those indicated in this manual.
5. Improper use of the sealer heads (for ex. Sealing plastic materials other than the bag's tube).
6. Improper use of the optical systems for any purpose different than the one written in this manual.

Only personnel authorised by Macopharma are authorised to remove the machine's exterior safety guards and carry out maintenance.

NOTE: Upon request Macopharma will provide diagrams of the circuits, component list, instruction about calibration process and other useful information to Technical Assistance Service.



WARNINGS FOR STAFF SAFETY

MPS EVO can be dangerous should you fail to take into consideration several precautions for use:

1. **Never insert anything other than a disposable bag** for storing blood or its derivatives inside the press system.
2. Before inserting a bag containing blood or its derivatives inside the MPS EVO press system, make sure that the bag is intact: **never process bags that show signs of damages, it is dangerous for you and the machine.**
3. **Watch your fingers!** Both press systems (main and lateral press) can generate enough force to crush the fingers. **While MPS EVO is working NEVER insert your hands or fingers between the press plates.**
4. The machine weighs approx. 38Kg: never attempt to move the machine alone, you may damage your spine and drop the machine down! At least two people are required and use the special handles on the base of the machine: one hand on the handle and the other one on top to counterbalance the weight.
5. Quality is guaranteed only with the use of original spare parts and original accessories.
6. **MPS EVO should be used by skilled and trained operators with a basic knowledge of blood bank components preparation and management. Mental and physical disabilities of operators are advised against.**



ELECTROMAGNETIC EMISSION WARNINGS

Manufacturer's guide and declaration – Electromagnetic emissions

The MPS EVO automatic blood component separator can be used in electromagnetic environments as specified on the following page. The customer or user of the MPS EVO automatic blood component separator must make sure the equipment is used in this environment.

NOTE: Portable and mobile RF communications could affect MPS EVO during its functioning. Pay attention.

| Guidance and manufacturer's declaration – Electromagnetic Emission | | |
|---|-------------------|--|
| The MPS EVO automatic blood separator is intended for use in the electromagnetic environment specified below. The customer or the user of the MPS EVO automatic blood separator should assure that it is used in such an environment. | | |
| Emissions Test | Compliance | Electromagnetic environment – Guidance |
| RF Emissions CISPR11 | Group 1 | The MPS EVO automatic blood component separator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| Emissions Radiated /Conducted CISPR11 | Class B | The MPS EVO automatic blood component separator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC/EN 61000-3-2 | Class A | |
| Voltage fluctuations / flicker emissions IEC/EN 61000-3-3 | Complies | |

Guidance and manufacturer's declaration – Electromagnetic Immunity

The MPS EVO automatic blood separator is intended for use in the electromagnetic environment specified below. The customer or the user of the MPS EVO automatic blood separator should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic environment - Guidance |
|---|---|---|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 2,4,6 kV contact ± 2,4,8 kV air | ± 2,4,6 kV contact ± 2,4,8 kV air | Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines ± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruption and voltage variations on power supply input lines IEC 61000-4-11 | <5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (> 95% dip in U_T) for 5 s | <5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (> 95% dip in U_T) for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the MPS EVO automatic blood separator requires continued operation during power mains interruptions, it is recommended that the MPS automatic blood separator be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location on a typical commercial or hospital environment. |
| NOTE: U_T is the a.c. mains voltage prior to application of the test level. | | | |

Guidance and manufacturer's declaration – Electromagnetic Immunity

The MPS EVO automatic blood separator is intended for use in the electromagnetic environment specified below. The customer or the user of the MPS EVO automatic blood separator should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic environment - Guidance |
|--|--|-----------------------------|--|
| <p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p> | <p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p> | <p>[3] V</p> <p>[3] V/m</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the MPS EVO automatic blood separator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$d = \sqrt{\frac{P}{4\pi f^2}} = 0.28m$ 0.150 MHz to 80 MHz</p> <p>$d = \sqrt{\frac{P}{4\pi f^2}} = 0.28 m$ 80 MHz to 800 MHz</p> <p>$d = \sqrt{\frac{P}{4\pi f^2}} = 0.56 m$ 800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^c should be less than the compliance level in each frequency range.^d</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

-
- ^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MPS EVO automatic blood separator is used exceeds the applicable RF compliance level above, the MPS EVO automatic blood separator should be observed, additional measures may be necessary, such as re-orienting or relocating the MPS EVO automatic blood separator.
- ^b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.
- ^c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MPS EVO automatic blood separator is used exceeds the applicable RF compliance level above, the MPS EVO automatic blood separator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MPS automatic blood separator.
- ^d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

ENVIRONMENTAL RISKS AND WASTE DISPOSAL

MPS EVO contains materials, which at the end of the working life of the apparatus, must be disposed at one of the recycling centres nominated by your Local National Health Department.

For US market, please follow all applicable federal state and local laws regarding disposal of Waste Electrical and Electronic Equipment (WEEE). Electronic products must not be disposed of as unsorted municipal waste.

Please dispose this products by returning it to the point of sale or to your local municipal collection point for recycling.

In particular, the apparatus contains the following materials:

- Iron
- Copper
- Aluminium
- Non-biodegradable plastics
- Fibres glass for printed circuits
- Ferrite
- Lithium batteries



When this crossed-out wheeled bin symbol is attached to a product or its packaging it means the product is covered by the European Directive 2002/96/EC for Waste electrical and electronic equipment (WEEE) and by the European Directive 2002/95/EC for equipment containing hazardous materials.

This electrical and electronic device cannot be disposed of in a normal landfill.

Instead the equipment must be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.

In order to eliminate any health hazards to the employees of the recycling companies, the device must be free from toxic, infectious, radioactive or organic substances. This is responsibility of the Users.

Illegal disposal of the product by the holder includes the application of administrative sanctions provided by national law in force

WARRANTY

Macopharma guarantees the MPS EVO equipment for 24 months from the date of sale. The guarantee is free only at Macopharma premises both for spare parts and labour included. The guarantee covers only the parts that might result defective during the validity period. The guarantee does not include any damage caused by negligence, tampering or by any intervention executed by person not authorised and not qualified by Macopharma. **The LCD display and the load cells of the scales are not covered by the guarantee.**

To use the guarantee service, the customer must abide by the following rules:

1. MPS EVO should be delivered for repair to Macopharma or to your nearest authorised Technical Assistance Centre possibly in its original packaging.
2. Transports are always at care, risk and charges of the customer.
3. Macopharma reserves the right to refuse the machine if delivered with transport costs collect.
4. **The equipment must be delivered clean and disinfected. Any trace or organic material such as blood products, will be ground for product refusal.**
5. MPS EVO should be delivered with a letter describing all data of the customer, a person to get in contact for any question and a short description of the claim.

For further information on the guarantee procedure, contact Macopharma.

INTRODUCTION

Purpose of use of MPS EVO

MPS EVO should be used by skilled and trained operators with a basic knowledge of blood bank components preparation and management. Mental and physical disabilities of operators are advised against.

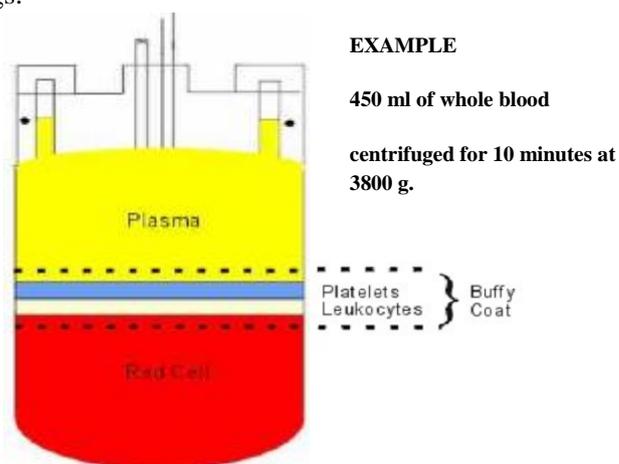
MPS EVO is an automatic separator designed to prepare blood components from centrifuged blood prepared in single use plastic bags. MPS EVO is designed to work in combination with blood bags manufactured upon the International Standard ISO 3826 and the European Directive no. 93/42MDD. Within these conditions, MPS EVO can prepare blood components with any kind of commercially available bag, either conventional or TOP & BOTTOM type.

Few concepts about the preparation of blood components

Irrespective to the technical choice for the preparation of blood components, the principle that allows you to reach the final result is the same: a quick and controlled sedimentation of whole blood through centrifugation. The centrifuges are used to separate the blood components into fractions. Following a suitable centrifugation curves and knowing the mean density of the blood cells, it is possible to arrange the blood components in proper fractions inside common blood bags.

Density of blood parts

| | |
|--------------------|-------------------|
| Plasma | 1.026 g/ml |
| Platelets | 1.058 g/ml |
| Monocytes | 1.062 g/ml |
| Lymphocytes | 1.070 g/ml |
| Basophils | 1.075 g/ml |
| Neutrophils | 1.082 g/ml |
| Eosinophils | 1.087 g/ml |
| Red Cells | 1.100 g/ml |



MPS EVO is a machine that, after the bags of WB are duly centrifuged, automatically and quickly prepares most blood components using the most common blood bags available on the market, both standard and Top & Bottom types. By means of the controlled movement of a press used to press the bag of centrifuged whole blood, a network of clamps fitted with sealer heads, three or more weighing scales (depends by the chosen configuration) and a series of optical sensors, MPS EVO automatically and accurately extracts and transfers blood fractions from the main bag to the satellite bags and in some cases vice versa. Even RBC additive solution if available, can be transferred. This manual also describes the many other possibilities this system offers.

The best performance in terms of component quality and quantity can only be reached by means of an optimum relation between the centrifugation curve and the MPS EVO settings: two closely connected parameters.

As a general indication for the most common preparations using 450ml bags, the following page summarises some figures regarding the G-forces of centrifugation applicable to whole blood:

| TYPE OF PROCEDURES | MEAN VALUE IN Gxs (integral force or AFC) |
|---|---|
| PRP 1 st centrifugation with standard bag | 550,000 |
| PRP 2 nd centrifugation | 3,000,000 |
| BC 1 st centrifugation with standard bag | 1,500,000 |
| BC 2 nd centrifugation with single BC standard bag | 100,000 |
| BC 2 nd centrifugation POOL of 3 BC | 180,000 |
| BC 2 nd centrifugation POOL of 6 BC | 240,000 |
| BC 1 st centrifugation Top & Bottom bag | 2,700,000 |

The above figures are only approximation but they might be useful to define a starting point. Some centrifuges can automatically calculate the integral force. It is always advisable to have an acceleration and a very low deceleration, irrespective to the type of centrifuge, to avoid re-suspension or remixing of the layers.

THE MAIN BLOOD COMPONENTS THAT CAN BE PREPARED WITH MPS EVO

After the first centrifugation of WB:

PLASMA PRODUCTS

1. Platelet-poor plasma (PPP)
2. Plasma from filtered whole blood (PPP)
3. Platelet-rich plasma (PRP)
4. Filtered platelet-rich plasma (PRP)

BUFFY COAT PRODUCTS

1. Dry Buffy Coat
2. Buffy Coat with Platelets
3. Buffy Coat with Platelets for subsequent preparation of PLTS from single BC.

RBC PRODUCTS

1. RBC with RBC ADDITIVE SOLUTION
2. RBC BC depleted with RBC ADDITIVE SOLUTION
3. RBC BC depleted with added Plasma
4. RBC with RBC ADDITIVE SOLUTION from filtered WB

After the second centrifugation of the fractions:

PLASMA PRODUCTS

1. Platelets Concentrate from PRP
2. Cryoprecipitate

BUFFY COAT PRODUCTS

1. Platelets Concentrate from single Buffy Coat unit
2. Platelets Concentrate from pool of Buffy Coat

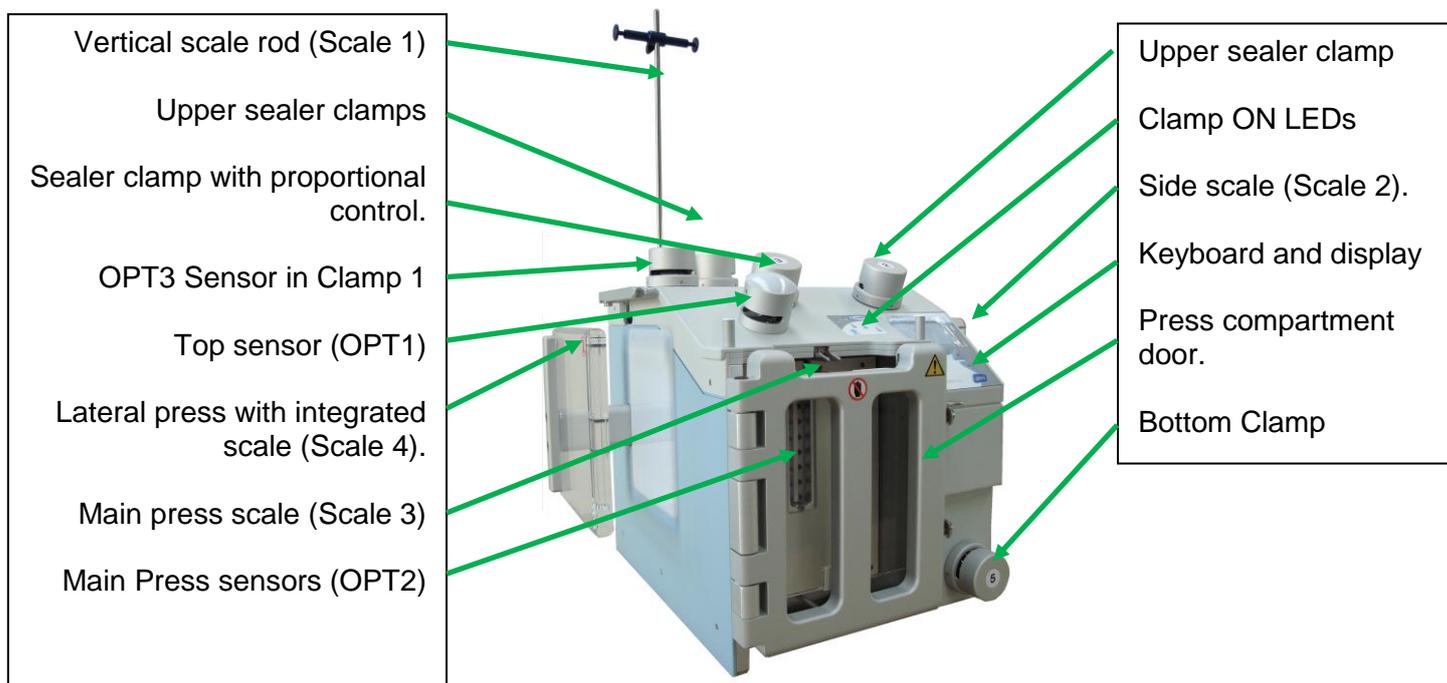
RBC PRODUCTS

Removal of the washing solution for washed Red Cells concentrate

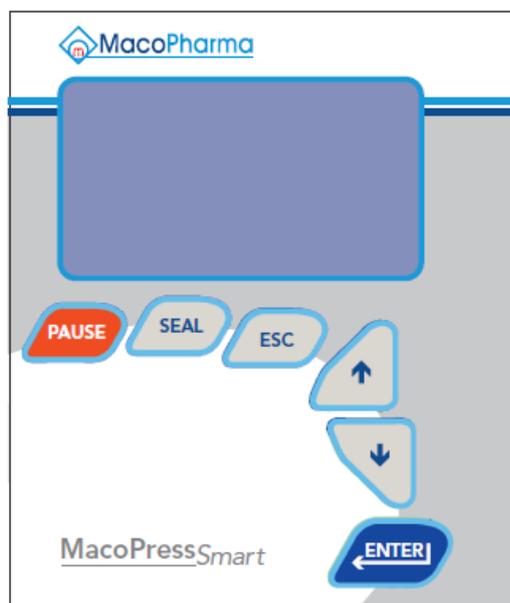
In addition it is also possible to use MPS EVO to:

- a) Divide a blood component stored in one bag into other satellite bags. This function is useful for example when preparing paediatric doses.
- b) Remove excess air from one bag and transfer it to another bag.

DESCRIPTION OF THE PARTS



Keyboard



The keyboard has six multifunction keys:

1. **PAUSE:** to pause the extraction procedure
2. **SEAL:** to manually enable the sealer/clamps from main menu.
3. **ESC:** to exit the function or procedure in progress.
4. **UP Arrow:** to move upward for Menu selection.
5. **DOWN Arrow:** to move downward for Menu selection.
6. **ENTER:** to confirm the selected parameter or function or start/continue a separation procedure.

Clamps and optical sensor panel



- Includes six LEDs, five of which are numbered for each clamp and one is for the main optical sensor.
- The LEDs have three positions: OFF, ON green, ON red.
- When the program is started, the LED corresponding to the clamps enabled for that specific program will light-up RED. The tubes should be inserted appropriately, inside the devices indicated by the LED.
- When the tubes are correctly placed inside the devices, the corresponding LEDs will light-up GREEN.

Display

LCD display with BLUE – WHITE graphics and back lighted. All the menus are visible on screen. Follow the instructions to easily access work protocols and use or program the machine.

Back panel

The back panel is fitted with the following elements:

- Main switch with safety fuses and voltage selector
- Network connectors RS485
- Additional external scale connector
- Radio frequency output connector for optional sealer handgun
- Connector for barcode reader or for COMBO reader and writer (barcodes and RFID Tags)
- Wi-Fi or LAN module (depend by the version)
- Machine data plate.

Optical sensors

MPS EVO is equipped with eight optical sensors situated vertically on the main press (OPT2) in addition to two top sensors (OPT1 and OPT3) situated on the upper part of the machine, one inside Clamp N°1 and one near clamp number 3.

Upper main sensor OPT1

This sensor can also be programmed for each type of separation. Its function is to identify the approaching of a fraction different from the previous one and therefore detect a change in the state of the fluid flowing inside the tube: from air to plasma or from plasma to Buffy Coat. There is a series of red-coloured LEDs on the cover of the main sensor that automatically light up when the separation has ended or when an error occurs. The sensitivity of the sensor can be programmed from 1 to 999.

Press sensors OPT2.

For each program, it is possible to set any of the eight sensors as reference level for buffy coat while approaching also determining its sensitivity: number 1 is the first on top. In this way, you can set the exact

point to stop the buffy coat layer, or use the sensor to determine the moment in which the press must switch to the next velocity profile. You can also define the sensitivity of each sensor (1 – 999).

Sealer Clamps

MPS EVO is equipped with five sealer clamps where one (the number 3), it is with proportional control. These clamps are electromechanical components with double function: clamping and /or sealing tubes. According to the program in progress, the clamps can be activated to automatically or manually seal at the end of process. **Each clamp has a tube control sensor that checks the correct positioning of the tube:** this avoids performing incorrect operations due to wrongly tubes insertion.

Clamp no.3 situated immediately after the upper optical sensor (OPT1) is with proportional movement. This clamp is useful mainly while working TOP & BOTTOM bags. The proportional regulation allows the system to accurately control the position of buffy coat, regulating the upper outflow from the T&B bag. Clamp no.3 is slower compared to the other clamps, and therefore **should not be used to quickly close a tube**. The clamp n°3 can be used also with standard bag to partially close the tube during the plasma extraction.

Scales

Electronic scales are used to weigh the blood components. These scales, although are designed to withstand forces up to 5 kg are delicate parts: **avoid overloading, do not pull scales and do not apply any excessive force while touching.** The weight reading by the scales can be the net or the gross upon the running procedure and settings: see program PHASES for that.

Main Press

The main press is electronically controlled and motioned. It moves by PHASES connected together according to the program combination. Inside each one of these PHASES, it is possible to set the velocity profile of the press (up to 5 profiles according to the PHASE) and manage up to four essential parameters:

- 1) movement speed (0-120 rpm of motor)
- 2) maximum upper pressure to be applied on bag (50 – 600 millibar)
- 3) final press position (0-650 in tenths of millimetres where 0 = completely closed)
- 4) position where switching the speed to next profile (0-650 expressed in tenths of a millimetre)
- 5) OPT2 optical sensor number to be engaged (both to change profile or end the PHASE)

Lateral Press

The lateral press is also electronically controlled and motioned. It moves by PHASES connected together according to the program combination but does not include any optical sensor. Inside each one of these PHASES, it is possible to set the velocity profile of the press (up to 5 speed profiles according to the PHASE) and manage up to four essential parameters:

- 1) movement speed (0-120 rpm of motor)
- 2) **maximum upper pressure to be applied on bag (50 – 400 millibar)**
- 3) **final press position (0-650 in tenths of millimetres where 0 = completely closed)**
- 4) position where switching the speed to next profile (0-650 expressed in tenths of a millimetre)

FUNCTIONAL DESCRIPTION

SYSTEM

1. MPS EVO is compatible with the majority of the commercially available blood bags even from different manufacturers. The equipment should be used with certified bags with collect volume between 200-600 ml and with standard tubes between 3.5-6.0 mm OD.
2. Never use blood freeze.
3. Smart system to extract contemporary PL and RBC during the T&B procedures with precise control of BC layer positioning.
4. Automatic adjustment of final BC volume and Hct to leave inside the bag either during the T&B or Standard bags preparations.
5. Automatic extraction of exceeding air from WB or PL bags (to prepare air free PL)
6. MPS EVO can manage up to 800 code labels as barcode or RF-ID tag for up the 50 programs with possibility of automatic cross-matching among codes.
7. As standard it's possible to work with machine on stand-alone or with the DMS Plus application on-line.
8. Bidirectional function all time on-line available.
9. Fast execution time is of 1.30 minute for a quadruple Top – Top bags and 2.30 minutes for a quadruple Top – Bottom.
10. MPS EVO can works as stand-alone or in bidirectional mode with DMSPlus software on line.
11. Automatic auto-zero of all optical sensors.

PROCESS CONTROL

MPS EVO has user- friendly software named DMSPlus (Data Management Software). DMSPlus is designed for remote controls of MPS and for collection & handling of separation data. **DMSPlus must be installed on a computer with Windows® XP, VISTA or 7 (computer and Windows® not included).**

By using DMSPlus you can do the following remote operations on all available MPS:

- modify any existing Program of MPS EVO,
- generate new Programs of separations and upload them on the MPS EVO,
- upgrade the firmware of machines (reserved to service people only),
- download the data of each single procedure of separation executed by the MPS EVO.
- activate a full bidirectional control: at reading of a specific code from MPS EVO, the machine will start automatically a pre-determinate PRG from a Working List arranged by the Operator or automatically generated by the exclusive SMART PREPARATION list or delivered by the Blood Bank software.
- prepare proper cross-matching filters for each PRG to be applied on both type of read codes, either as barcode label than Tag RFID,
- set the working program to be used on one or more separators.
- Generate Reports based on all recorded separations even applying customizable filters per blood component type, ID donation and much more. The Reports can be printed directly by network printer (not included) or saved as .csv o Word file (it is necessary a valid license of Microsoft Office for exporting on Word format: not included).
- DMSPlus can deliver automatically (cycling) or manually, all separations data to any path available on the Windows Network: this can be done as single file, periodic file, multiple files and formatted as needed by the host computer.

-
- DMSPlus can print the label of each blood component with the following value (ID code, components weight, date ...). The value printed on the label can be configured. Optional printer is needed for this purpose.

Data transmitted from MPS EVO to DMSPlus for each procedure:

- 1) Serial number of MPS EVO
- 2) Description of the performed Program
- 3) Number of the performed Program
- 4) Net weight of Plasma extracted
- 5) Net weight of Buffy Coat
- 6) Net weight of whole blood
- 7) Net weight of Plasma transferred into BC bag
- 8) Net weight of transferred RBC ADDITIVE SOLUTION
- 9) Net weight of PL transferred back into the main bag
- 10) Net weight of PL extracted into other satellite bags
- 11) Net weigh of Platelets Concentrate
- 12) Net weight of packed RBC
- 13) Separation date
- 14) Time of separation
- 15) Duration of separation
- 16) Error codes if any
- 17) Tens of different and customizable codes, either as barcode labels or RFID Tags are available too.

To use and enter in the DMSPlus application software is necessary to have a personal Account and a PASSWORD. DMSPlus has five access levels with different privileges. Upon the level given to each Operator, the privileges are defined. The level Administrator has full control and power and it's the only one that may add new Account (Operators). The lowest level is for the Machine's Operator: can use all functions of the machine but cannot modify any settings or parameters. DMSPlus includes a LOG module that automatically records all operations and modifications done for statistical purposes and quality controls.

NOTES about the data and their handling!

- the list above represents the whole list of data delivered to DMSPlus or stored onto the internal memory of MPS EVO.
- MPS EVO can store up to 1000 separations data: after this limit, it will delete automatically starting from the older one (cyclic memory).
- The code labels can be completely configured one by one as: enable / disable, position, reading order, description, cross-matching with specific mask to be arranged upon customer need,
- The availability of each data depends by the running Program, hence some of them can or cannot be present in the data base of DMSPlus.

-
- With DMSPlus is also possible to enable or disable one by one each of those data as well it is possible to define a customizable saving MODE. This feature is useful to save the data in a proper format of TXT file, easy to use by any external software.
 - The weight collected from MPS EVO can be viewed and or exported in [ml] or in [g] from DMSPlus.

STRUCTURE OF A SEPARATION PROGRAM

1. Each Program of extraction is always made of a **DESCRIPTION**, a Program **HEAD**, a certain number of **PHASES**, a **WEIGHTS mapping** and a **CODES protocol** (either barcode or tag RFID).
 - a. The **DESCRIPTION** is the name the User has chosen for the Program,
 - b. The Program **HEAD** defines all hardware parts used by the machine from the beginning to the end of a Program such as the clamps-sealers to use, the scales and the type of press movement for example,
 - c. A **PHASE** is a complete sequence of instructions given to MPS EVO to move one or more blood product from one bag to another one. A Program may include a single PHASE or more PHASES depending by the type of preparation to perform. **MPS EVO has five type of PHASES, independent each other but chainable together:**
 - i. **PHASE A:** single component or air extraction using main press,
 - ii. **PHASE B:** single component transfer by gravity or by lateral press,
 - iii. **PHASE C:** differential extraction at fixed weight of a component by main press (typically for preparation of the PLTS from PRP after second centrifugation)
 - iv. **PHASE D:** contemporary extraction of two components by main press (Top and Bottom bags).
 - v. **PHASE E:** preparation of aliquots of same or different volumes starting from a primary bag inside main press.
 - d. **First available PHASE of a Program begin automatically after START.**
 - e. **The end of a PHASE depends by several events;** the first of those events that chronologically occurs terminates the PHASE. Whenever a further PHASE is available, the next one will start automatically and hence when all PHASES are executed the Program itself is terminated.
 - f. **Typically, the events that may terminate a PHASE are the following:**
 - i. The main optical sensor OPT1 has detected the approaching of a new component (air, PL, BC),
 - ii. The main press optical sensor OPT2 has detected the approaching of the BC layer,
 - iii. The scale has reached the target weight forecasted for that PHASE,
 - iv. The press has reached the target STOP positioning forecasted for that PHASE.
 - g. The **WEIGHTS mapping** defines the final composition of the weights to be recorded: if net, gross, if some tare has to be deducted or added. In some cases is also possible to define a tare that might be added or deducted from the read weight like for example, add the SAGM weight onto the weight of RBC.
 - h. The **CODES protocols** defines how many labels to read and/or write with that specific PRG and eventually if they must be compared with a set of MASTER filters from a prearranged List of Codes for cross- matching. **To one specific CODE is also possible to associate a exclusive action. In example: when read code XXX execute PRG n. YYY.**

DATA MANAGEMENT & ON BOARD SOFTWARE

1. When MPS EVO works as stand-alone without the DMSPlus software, it is always possible to know the net weights of the components that are displayed at the end of the separation.
2. When MPS EVO works with DMSPlus on line, it is simple to download and organize the data of each separation as well the management of new Programs.
3. The creation of a new Program of extraction is possible only by using DMSPlus.
4. For safety reasons, it is possible to lock one or more Programs to prevent tampering or manipulation from MPS EVO keyboard.

COMPUTER CONNECTIONS

MPS EVO is supplied complete with the DMSPlus software. Despite MPS EVO can be used as stand-alone, best control and performance can be reached only by using the DMSPlus application. ***Before install the DMSPlus application, please be sure that your computer has at least the following minimum requirements:***

- Intel Pentium 4 processor or higher version
- One RS232 and one USB ports free or two USB ports (may require a USB/RS232 converter in this last case)
- 1 GB RAM
- 100MB of free space on Hard-Disk
- 1024x768 minimum resolution monitor, 16 million colors
- Free Ethernet card (whenever LAN or Wi-Fi connection should be used between computer and separators)
- Additional Ethernet card if the computer must be connected to a second net (in example the one of blood bank)
- **Operating System Windows™ XP or Vista or 7**
- **Microsoft Office®** if you wish to export data as Word or Excel file.

CONNECTING MPS EVO TO THE COMPUTER

The connection of one or more separators to the computer can be done in three different ways depending by the available version MPS EVO: RS485, Ethernet or Wi-Fi. All machines must have same communication system. See Section **CONFIGURATION OF MPS EVO FOR NET CONNECTION**.

When the MPS EVO network is active and the machine is on line with DMSPlus, on all menus that appear at display, on top left corner will appear a small logo as shown on figure below:

```
-----  
<  MPS R: xxx >  
< date and time >  
< 1- Programs >  
< 2- Balances >  
< 3- Settings >  
< 4- Tech Service >  
< 5- Send Data to PC >  
<Select: >  
-----
```

For proper setting of your MPS EVO network, please refer to the DMSPlus Operator manual.

In the above green circle you can have the following symbols to indicate the network status:



The WiFi network is enabled/selected but not active.



The WiFi network is active.



The Ethernet network is enabled/selected but not active.



The Ethernet network is active.



The RS485 network is enabled/selected but not active



The RS485 network is active

INSTALLATION

Removing MPS EVO from its packaging



CAUTION!

MPS EVO weighs approximately 38Kg; never attempt to lift the machine alone; you may damage your spine or back muscles! Be at least two people while moving MPS EVO and use the extractable handles situated underneath the machine to do it easily: one hand on the handle and the other one on top of machine to counterbalance the weight.

**Remove the machine carefully from its packaging with all the other parts.
Check that all parts of machines are intact.**

The standard MPS EVO equipment is composed of:

- Power supply cable
- Support for left scale with hexagonal fixing key
- Rod for vertical scale
- User Manual
- Any accessory if purchased.

Where to install MPS EVO

WARNING: To avoid the risk of electric shock, this equipment must be only connected to a supply mains with protective earth.

To achieve the best performance in complete safety it is important that MPS EVO is positioned on a flat and stable surface or a stable table without wheels, capable to hold at least 50Kg/m². Should you have more than one machine to install on the same table, leave enough space around the machines to work easily.

Never position MPS EVO on an unstable surface. Vibrations can compromise the weight readings of the scales and the machine may fall down with consequent danger for the people around.

Never position MPS EVO too close to centrifuges for blood bags. The vibrations generated by the large centrifuges can create operational problems and if they are old type, they can also create electromagnetic disturbance.

It is advisable to position MPS EVO in a dry place, free from humidity and away from direct sunlight, radiators or other heat and ignition sources.

MPS EVO must be placed in blood bank laboratory far away from life support equipment.

Installing the parts supplied

Follow the instructions described in this paragraph:

- Insert the vertical rod of top scale inside the threaded hole on top of machine and gently screw it down. If necessary turn the upper up to reach the right position.
- Install the support of lateral right scale by screwing until the end the two rods inside the threaded holes available on right wall of the machine. **Gently tight the two upper security dowels, taking care that the transparent pan MUST BE LEFT at a distance of at least 2 cm from the side panel: it's scale and must be free to move.**

WARNING: No modification of the equipment is allowed

Switching on MPS EVO

Before everything else, check that the mains and power line are correctly earth wired. If the earth cable is damaged this may reduce the effectiveness and or the safety: in case, NEVER switch on the machine and solve the problem first.



CAUTION!

**MPS EVO requires a supply voltage of 100-240V 50-60Hz 300VA
Check if you available power voltage is inside of above declared range.**

Make sure the main switch at the back of the machine is switched OFF before connect the machine to power line.

Without any bags loaded on MPS EVO, with the door firmly closed and without touching the scales, insert the power supply cable and switch on the machine using the main switch on back side.

MPS EVO will start the initialization and calibration procedure of all its components.



ATTENTION!

The start-up procedure may last few minutes. During the initial start-up NEVER TOUCH any part of MPS EVO: it's dangerous for your fingers and you might easily false the calibration procedure!

After start-up the MPS EVO screen will display:

```
                MAIN MENU
-----
<           MPS R: xxx >
<   date and time   >
< 1- Programs      >
< 2- Balances      >
< 3- Settings      >
< 4- Tech Service  >
< 5- Send Data to PC >
<Select:          >
-----
```

Each menu contains sub-menus relating to the selected context. The controls are intuitive and will not be listed any further in this paragraph.

In order to improve the heat stability of MPS EVO and therefore the accuracy of the scale readings, it is advisable to wait at least 30 minutes before starting first separation.

Switching off MPS EVO

You may switch off MPS EVO at any time using the main switch situated at the back.

In case of emergency the power supply of MPS EVO can be interrupted by disconnecting the mains plug or by disconnecting the mains connector from appliance inlet.

MODE OF USE

Stand-alone mode

On stand-alone mode the machine can work independently by the DMSPlus Software. In this case is the Operator that chose the PRG directly from the machine keyboard. Main functions of DMSPlus remain as remote programming of MPS EVO, collection and handling of separations results.

Bidirectional mode

On bidirectional mode MPS EVO must work all time on-line with DMSPlus . Same capacity of programming and data collection of STANDALONE mode are kept but in addition, it controls and starts automatically an extraction PRG by cross-matching an ID Donation with a Preparation List: the one who match together let start the correct PRG.

The communication link between DMSPlus and all machines is always required and must be fixed: they must be in condition to communicate at any time.

Preparation List.

If the read ID Donation is available inside the memorized list or anyway if available by DMSPlus manual preparation list, the corresponding PRG associated to that ID will be automatically executed on the machine.

The Preparation List can be either Standard or Smart.

Standard Preparation List

A standard Preparation List is created externally as TXT file without any action of DMSPlus. The list is imported by DMSPlus from an external source. Typically it's a file released by the Blood Bank Software.

Smart Preparation List

A Smart Preparation List is much more performing than a Standard Preparation List and it may include several automatic operations inside. A Smart Preparation List must begin from a Donation File. The Donation File is generated by the blood collection monitors or mixers/scale and normally includes all data related to the donations. To generate a Preparation List from a Donation File you should define the Donation Smart Filters too. The Donation Smart Filters define the rules or conditions that have to match together, to let a PRG being associated to a specific ID: one filter for each PRG.

NOTE: Either if you use the Smart or the Standard Preparation List you have the possibility to add or remove manually one or more ID from the list, see the DMSPlus Operator manual for more details.

PAY ATTENTION!

The use of MPS EVO on bidirectional mode requires the Wi-Fi or the Ethernet connection with the computer. RS485 serial connection has a limited communication capacity and thus cannot support all necessary data flow for the bidirectional controls: as upper limit, NEVER connect to same computer more than four MPS EVO together if RS485 network is in place.

Remote Program start from DMSPlus

From DMSPlus you can send to all or some MPS EVO the Program you wish to run. In this way for example, you may set at once all machines to run same Program.

SECURITY

Only authenticated USERS can access the functionality of the DMS Plus application. Each user according to its role is associated with a level of privileges that allow the access only to those Sections granted for his level. There are five different levels, from the one with all privileges (administrator) to the one with the lowest level of access (standard operator). See the Configuration/Users section for details about the access levels described on the DMSPlus User manual.

For further information on Mode of Use of MPS EVO with DMSPlus, please make reference to the DMSPlus User Manual.

SEPARATION PROGRAMS

Standard separation procedures

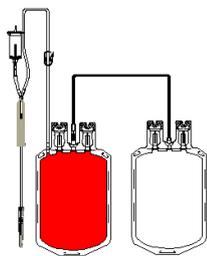
MPS EVO offers several extraction possibilities upon the type of available bags and procedures to perform. Sixteen Programs are factory installed. They can be partially modified from the machine or completely handled by using the specific software application DMSPlus (see DMSPlus User Manual for more info on the application).

Here below is the list of the 16 factory-loaded Programs:

EXTRACTION FROM WHOLE BLOOD USING STANDARD TOP-TOP BAGS

DESCRIPTION OF THE BASIC PROCEDURES:

Program 1: Double bags.



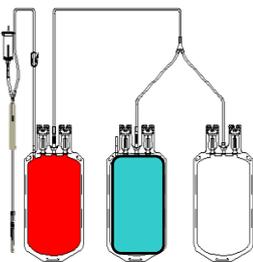
Procedure:

1. Extraction of Plasma.
2. Reinsertion of Plasma by weight in WB bag (enabled or disabled) for Red cells dilution.

Final result:

- Plasma
- Red Cells with BC diluted in Plasma.

Program 2: Triple bags with RBC ADDITIVE SOLUTION.



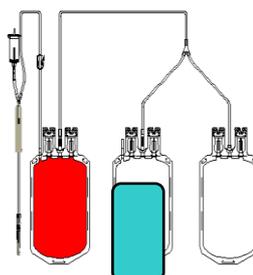
Procedure:

1. Extraction of Plasma.
2. Possibility to transfer extra Plasma (enabled or disabled) after optical sensors detect BC.
3. Transfer of RBC ADDITIVE SOLUTION in the Red Cells.

Final result:

- Plasma with or without platelets.
- Red Cells with BC diluted in RBC ADDITIVE SOLUTION.
- Possibility of subsequent processing of PLTS from PRP.
- Possibility of subsequent processing of cryoprecipitate.

Program 3: Triple bags with RBC ADDITIVE SOLUTION (with air removed).



Procedure:

1. Extraction of air from WB bag to RBC ADDITIVE SOLUTION bag.
2. Continues as per PROGRAM 2.

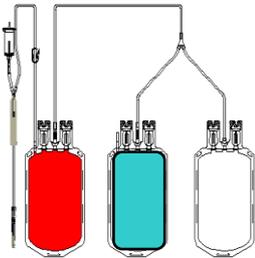
Final result:

- Plasma with or without platelets in air-free bags.
- Red cells with BC diluted in RBC ADDITIVE SOLUTION.

- Possibility of subsequent processing of PLTS from PRP.
- Possibility of subsequent processing of cryoprecipitate.

Program 4:

Triple bags with RBC ADDITIVE SOLUTION (Plasma of predetermined weight)



Procedure:

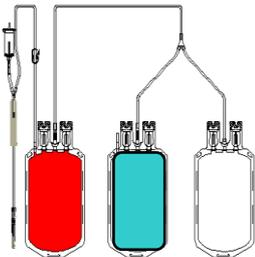
1. Extraction of Plasma by weight (stops at xx grams).
2. Extraction will stop before the set weight is reached if the optical sensors detect the approach of BC.
3. Transfer of RBC ADDITIVE SOLUTION.

Final result:

- Plasma
- Red Cells with BC diluted in RBC ADDITIVE SOLUTION.
- Possibility of subsequent processing of cryoprecipitate.

Program 5:

Triple bags with RBC ADDITIVE SOLUTION (Plasma of predetermined weight + air removal)



Procedure:

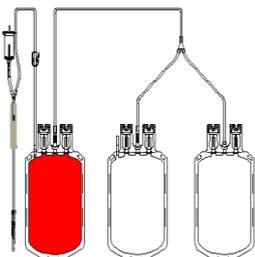
1. Extraction of air from WB bag and transfer to RBC ADDITIVE SOLUTION bag.
2. Continues as per PROGRAM 4.

Final result:

- Plasma in an air-free bag.
- Red Cells with BC diluted in RBC ADDITIVE SOLUTION.
- Possibility of subsequent processing of cryoprecipitate.

Program 6:

Triple bags without RBC ADDITIVE SOLUTION.



Procedure:

1. Extraction of Plasma.
2. Extraction of dry BC by weight.
3. Return by weight of Plasma in WB for Red Cells dilution.

Final result:

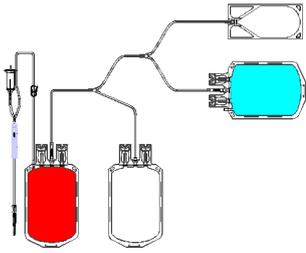
- Plasma
- Red cells without BC diluted in Plasma.
- Possibility of subsequent processing of PLTS from PRP.
- Possibility of subsequent processing of cryoprecipitate.

Program 7:

Quadruple bags with Plasma free BC.

Procedure:

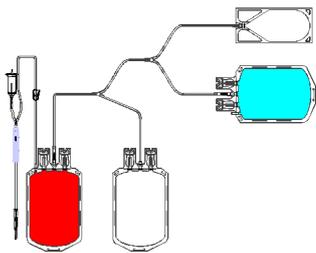
1. Extraction of Plasma.
2. Extraction of dry BC or with platelets.
3. Possibility to return Plasma to WB bag for line washing by weight.
4. Transfer of RBC ADDITIVE SOLUTION in Red Cells.



Final result:

- Plasma with or without platelets.
- BC with or without platelets.
- Red cells stripped of BC and diluted in RBC ADDITIVE SOLUTION.
- Possibility of subsequent processing of PLTS from PRP.
- Possibility of subsequent processing of PLTS from BC pool.
- Possibility of subsequent processing of cryoprecipitate.

Program 8: Quadruple bags with Plasma free BC (with air removed).



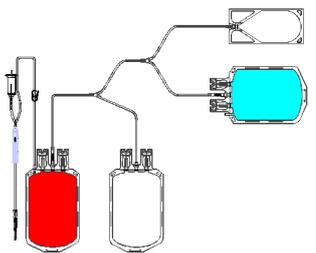
Procedure:

1. Extraction of air from WB bag and transfer to RBC ADDITIVE SOLUTION bag.
2. Continues as per PROGRAM 7.

Final result:

- As per PROGRAM 7 but with Plasma in air-free bags.

Program 9: Quadruple bags with BC and added Plasma.



Procedure:

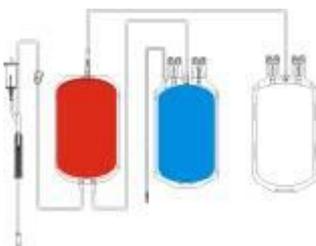
1. Extraction of plasma.
2. Extraction of BC by weight.
3. Dilution of BC with Plasma by weight.
4. Possibility to return Plasma to WB bag for line washing by weight.
5. Transfer of RBC ADDITIVE SOLUTION in Red Cells.

Final result:

- Plasma
- BC with added Plasma.
- Red Cells stripped of BC and diluted in RBC ADDITIVE SOLUTION.
- Possibility of subsequent processing of PLTS from single BC.

EXTRACTIONS FROM WHOLE BLOOD USING TOP & BOTTOM BAGS

Program 10: Triple T&B bags



Procedure:

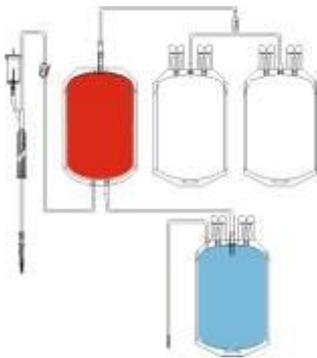
1. Extraction of N g of PL.
2. Extraction of Plasma and Red Cells.
3. Regulation of residual BC haematocrit with sensors and press position.
4. Possibility to reinsert Plasma in WB bag (enabled or disabled) for line washing or for further BC dilution.

Final result:

- Plasma
- Dry BC or with PL
- Red Cells without BC diluted in RBC ADDITIVE SOLUTION.
- Possibility of subsequent processing of PLTS from BC pool.

Program 11:

Quadruple T&B bags



Procedure:

1. Extraction of N g of PL in the satellite bag containing PLTS (after agitating the single BC, used to wash the tube and valve: reducing RBC contamination)
2. Extraction of Plasma and Red Cells.
3. Regulation of residual BC haematocrit in WB bag with sensors and press position.
4. Possibility to reinsert Plasma in WB bag (enabled or disabled) for line washing or for extra BC dilution for subsequent processing of platelets from BC.

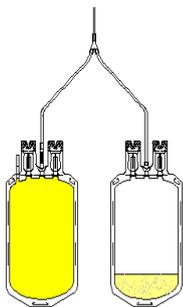
Final result

- Plasma
- Dry BC, with platelets, with or without added Plasma.
- Red cells without BC diluted in RBC ADDITIVE SOLUTION.
- Possibility of subsequent processing of PLTS from PRP.
- Possibility of subsequent processing of PLTS from single BC or BC pool.
- Possibility of subsequent processing of cryoprecipitate.

EXTRACTIONS AFTER 2nd CENTRIFUGATION

Program 12:

Preparation of PLTS or cryoprecipitate (from PRP or PPP)



Procedure:

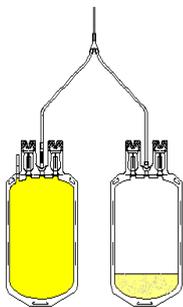
1. Weighing of initial bag gross weight.
2. Automatic subtraction of the tare (tare value to be entered in advance)
3. Extraction of Plasma by weight difference.
4. Procedure ends upon reaching weight set for the PLTS or cryoprecipitate.

Final result:

- Plasma
- Platelet concentrate or cryoprecipitate at predetermined weight.

Program 13:

Preparation of PLTS or cryoprecipitate from PRP or PPP by pre-defined end point position of main press (press always stops at same position).



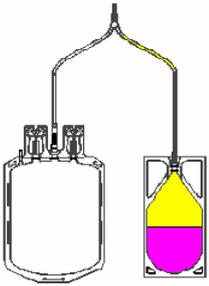
Procedure:

1. Extraction of Plasma until pre-set press position is reached.

Final result:

- Plasma
- Platelet concentrate or cryoprecipitate.

Program 14: Extraction of PLTS from single BC (bag 100ml)



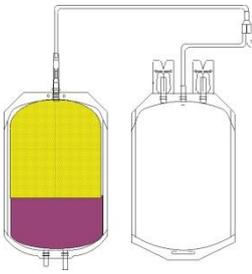
Procedure:

1. Extraction of platelet concentrate until optical sensors detect BC.
2. Possibility to transfer by weight extra xx g to PLTS bag (enabled or disabled) after optical sensor has detected the BC layer.

Final result:

- Platelet concentrate from single BC
- Dry BC

Program 15: Extraction of PLTS from single BC (bag 450ml)



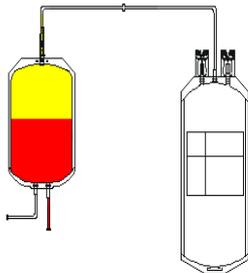
Procedure:

1. Extraction of PLTS until optical sensor OPT1 detects the BC.
2. Possibility to transfer by weight extra xx g to PLTS bag (enabled or disabled) after optical sensor has detected the BC layer.

Final result:

- PLTS from single BC
- Dry BC

Program 16: Extraction of PLTS from pool of BC



Procedure:

1. Extraction of PLTS until optical sensor OPT1 detects the BC.
2. Possibility to transfer by weight extra xx g to PLTS bag (enabled or disabled) after optical sensor has detected the BC layer.

Final result:

- PLTS from pool of BC.
- Dry BC

How to use a Program

From the Main Menu, Select *1 – Programs* and press ENTER. Use the arrows to select the Program and press ENTER to confirm. Follow the instructions on screen.

IMPORTANT NOTES:

1. All factory loaded Programs have the following functions disabled: tube sealing all OFF, barcode reading NONE, automatic sending of data to the computer NO, initial and final component weighing NO.
2. Open the breakable valves on the bags ONLY when requested by the machine.
3. Follow the instructions on screen and NEVER touch the scales or the tubing during the processing.
4. Once started program is no longer possible to change the PRG settings.
5. If you make a mistake press PAUSE to suspend the PRG and then ESC to abort the procedure or ENTER to resume the procedure again.
6. At the end of the PRG the alarm sounds and warns that the program is finished.
7. In case of program failure the Operator can easily restore the device operation by the main switch placed in the rear panel of the ME equipment; the user can turn off everything and the only side effect is the loss of the blood bag under process.

To change the Program's parameters see [How to change the program setting](#).

How to generate a new program

It is not possible to generate a new separation program from the machine: please refer to the DMSPlus manual for further information about that.

DISPLAY MENU

How to use the Display MENU

Main menu:

```
-----  
<      MPS  R: xxx >  
<  date and time  >  
< 1- Programs    >  
< 2- Balances    >  
< 3- Settings    >  
< 4- Tech Service >  
< 5- Send Data to PC >  
<      Select:   >  
-----
```

1. **Programs:** to access the programs stored in the memory and hence start a procedure. The programs are stored on the Non-volatile equipment internal memory and all modifications are not delete when you switch on and off the equipment
2. **Balances:** to access the menu to use and check scales functionality.
3. **Settings:** to access the menu of machine's settings to set the language, date and time, enable-disable the network and **change the parameters of each Program available in the machine.**
4. **Tech Service:** to access several functions pertaining exclusively to the technical service people.
5. **Send Data to PC:** to send manually to computer the separations data stored in the memory.

NOTES:

- **If the NETWORK is disabled, the machine will not record the separation data.**
- Most of the main menu functions are intuitive and easy-to-understand therefore no further details are required.

Bidirectional status

When the equipment works in Bidirectional way in the first position of the above "main menu" instead of the label "*programs*" you find "*bidirectional*", select it only one time in order to enter in Bidirectional mode activity.

Local Mask List status

When the equipment works in Local Mask List way in the first position of the above "main menu" instead of the label "*programs*" you find "*Local Mask List*", select it only one time in order to enter in Local Mask List mode activity.

HOW TO CHANGE THE PROGRAM'S SETTINGS



To modify a Program without any problems, you must have acquired a good knowledge of all processing procedures as well as a good skill about the structure and functional logic of MPS EVO. Incorrect setting of parameters can worsen the final result or even compromise the entire procedure. Before apply any modification, carefully read this Section and make one change by one, so that you can reset the initial conditions in case the result are not the one forecasted.

To change a Program from the INITIAL menu, use the arrows to select **3 – Settings** then press ENTER to confirm. The following window will appear:

```
-----  
< 1- Language           >  
< 2- Date and Time     >  
< 3- Enable data Net  >  
< 4- Programs Settings>  
<                       >  
<Select:  --  --     >  
<ENTER to Continue.  >  
<ESC to Exit         >  
-----
```

Use the arrows to select **4 – Programs settings** and press ENTER to confirm. **Default Password to change the PRG settings is: 000000.** To enter the default PWD just press Enter for each 0 to confirm the digit.

Use the arrows to identify the Program you want to change and press ENTER to confirm.



From MPS EVO you can only change a part of the Program's parameters whereas for complete access, you must use the software application DMS Plus.

The parameters of a specific Program that you can change from the MPS EVO keyboard are:

- the program **HEAD** that determines the general functions from start to finish
- the Program **PHASES** (1 – n) that determine the movements of the blood components.

To access the Program HEAD, press ENTER again.

PROGRAM HEAD

Legend: 0 = disabled, 1 = enabled, or enter a value from 1 to xxx by arrows

```
-----  
<Modify Prg Head:      >  
< Plate Type           : - >      - type of reduction plate (not supplied as standard)  
< Tube check Enab.:   >      - enable tube control in the clamps + optical sensor  
<                       >  
<                       >  
<                       >  
<                       >  
<                       >  
<ENTER to Continue.  >  
-----
```

```

-----
<Modify Prg Head:      >
<                      >
<  Automatic Sealing  >
< CL1: -      CL2: -  >      - selects and enables auto - sealing of clamps
< CL3: -      CL4: -  >      at the end of PRG: sealing occur automatically
< CL5: -          >
<                      >
<ENTER to Continue.  >
-----

```

```

-----
<Modify Prg Head:      >
<                      >
<  Manual Sealing     >
< CL1: -      CL2: -  >      - selects and enables manual sealing
< CL3: -      CL4: -  >      at the end of PRG : sealing occur upon
< CL5: -          >      Operator confirmation
<                      >
<ENTER to Continue.  >
-----

```

```

-----
< Modify Prg Head :    >
<                      >      - defines the clamps that have to be automatically
<Clamp auto opening   >      opened after PRG termination
< CL1: -      CL2: -  >
< CL3: -      CL4: -  >
< CL5: -          >
<                      >
<ENTER to continue.  >
-----

```

Once you have checked and confirmed the Program HEAD, you may now access the PHASES.



The sequence and number of PHASES available in a Program are not fixed but depend by the routine of that specific PRG. From MPS EVO it is not possible to cancel or add a PHASE, this can only be performed via DMSPlus software.

Remember there are five types of PHASES and each one can be interlinked together:

- Phase A: Extraction of a single component or air (use main press only)
- Phase B: Transfer of a single component by weight or even air if the optional side press is installed (do not use the main press).
- Phase C: Extraction of a component by differential weight (initial weight known)
- Phase D: Simultaneous extraction of two components (T&B processing)
- Phase E: aliquots preparations (divide the bag in N smaller volumes upon set availability).

DESCRIPTION OF PHASES

PHASE A: Extraction of a single blood component or air using the main press

This phase manages the **extraction of a single blood component or air from the main bag to a satellite bag; it uses the main press.** A PHASE A ends when one of the following conditions appear, the first one that occurs in chronological order:

1. The operator has set a fixed weight to extract and this weight has been reached on the selected scale.
2. The main sensor OPT1, if enabled, has switched ON due to the BC approaching.
3. The sensor OPT2 (Sensor selected on the main press), if enabled, has switched on due to the approach of BC.
4. The press has reached the final position set in the last velocity profile of the program.
5. Max allowed time to perform the PHASE elapsed.

When a PHASE ends, the machine automatically proceeds to next one otherwise if no more phases are available, the program will be terminated itself.

```
-----
<Phase Ext. : PL      >
<Fixed weight  : -    >
<Ph Max Time   : -    >
< V1: -        D1: -  >
< L1: -        S1: -  >
< V2: -        D2: -  >
< L2: -        S2: -  >
<               >
<ENTER to Continue. >
-----
<Phase Exc.: xx      >
< V3: -          D3: - >
< L3: -          S3: - >
< V4: -          D4: - >
< L4: -          S4: - >
< V5: -          D5: - >
< L5: -          S5: - >
<ENTER to Continue. >
-----
<Phase Ext.: xx      >
< Weight OPT1: -     >
< Sens_OPT1  : -     >
< Delay_OPT1 : -     >
< Weight_OPT3: -     >
< Sens_OPT3  : -     >
< Delay_OPT3 : -     >
<ENTER to Continue. >
-----
< Extr.phase:       >
< Pos_BC_end  : --- >
< Sen_OPT2_BC : --- >
< End Ph time  : -   >
<               >
<               >
<               >
<ENTER to Continue. >
-----
```

Fixed Weight=ends the PHASE when the enabled scales measures the weight entered in this field (0-400)

Ph max Time: set time out for alarm or terminate the Phase

V1 = press motor velocity in rpm (1 - 120)

L1 = enable sensor 1 of OPT2 to end first speed profile (1 = first sensor from the top)

D1 = Distance between door and press in tenths of mm to end the first velocity profile (0-650)

S1 = sensitivity of sensor 1 of OPT2 (300-700)

Subsequent velocity profiles (up to 5)

V2, L2, D2, S2 ...: repeat same controls as above but for further speed profiles.

NOTE:

- The end of a velocity profile is determined by few different events, the first that chronologically occur:
 - o LED on press get ON (BC intercepted)
 - o Set distance has been reached

When a Speed profile ends, the machine automatically jump to next profile if available otherwise terminate the PHASE.

- Define the weight to read on scale before perform the auto-zero of OPT1 (0-200)
- Define the optical sensitivity to switch ON OPT1 (0-999)
- Define the delay in seconds from Phase start to perform the auto-zero of OPT1 (0-100)

- Select one OPT2 sensor to be used to terminate the Phase (1-8): when BC arrives to that sensor phase end.
- Define the optical sensitivity of selected OPT2 (400-800)
- Define a time out that when elapsed terminate the Phase. (0-999)

NOTES:

1. MPS EVO is equipped with an auto-zero system for the optical sensor OPT1. Every time that a PHASE A begins, the auto-calibration of the sensor occurs. This is used to zeroing the optical differences among the various tubes of bags or simply to compensate the differences of absorbance provided by Plasma from different donors: this is called automatic linearization of the process and it allows high reproducibility at any time.
2. **The correct timing to perform the auto-zeroing can be defined by one of the two following events:**
 - a. **By weight, when the scale has reached the weight entered on field *Weight_OPT1* (normally used).**
 - b. **By time, when xx seconds as defined by *Delay_OPT1* – have elapsed.**
3. The two options for the auto-zero engagement of OPT1 (a. and b.) are mutual excluding and cannot be both enabled.
4. **When the PHASE is used to extract AIR, it is necessary that the zero of OPT1 is activated on the air and therefore immediately, so you must enter zero as set for the *OPT1_Weight: 0* (zero).**

PHASE B: Transfer by gravity or by lateral press of a single blood product or air

The PHASE B manages the transfer **of a component from one satellite bag to another**. The transfer may occur by gravity or by lateral press either by weight or by OPT1 engagement. **A PHASE B ends for one of the following conditions, first one that occurs in chronological order:**

1. The weight to transfer has been reached on the scale (typical example PL in BC).
2. The maximum execution time of the PHASE has been reached (if function is enabled).
3. The scales have read the total transferred weight of the RBC solution (RBC ADDITIVE SOLUTION).
4. The scale has read the total transferred weight of the generic blood component from one bag to another one.
5. The lateral press has reached the final speed profile without any previous events.
6. The lateral press is completely closed without any previous events.
7. The main optical sensor OPT1 has detected the interface between air and plasma, during the air extraction.

When the PHASE B ends, the machine automatically proceeds to the next one in the program, otherwise if there are no more phases the program will terminate.

```
-----  
<Transf.Phase: xx      >  
<                      >  
< Weight to trans: -  >  
<                      >  
< End Ph Max Time: -  >  
< Phase End Time : -  >  
< Manual reinsert: -  >  
<ENTER to Continue.  >  
-----
```

- *Weight to transf:* define the target weight of the product to transfer(0 - 400)
- *End Phase Max Time:* if you enter 1, the Phase is terminated if the time defined by next function is reached (0-1)
- *Max Phase Time:* define time out before alarm or timeout to terminate the Phase if function above is enabled. 0-9999)(multiple of 100 ms, if you set 10 mean 1 sec, while 1 means 100ms)
- *Manual reinsert:* if you enter 1, before perform the transfer the machine will ask you for confirmation while entering 0, transfer occur automatically

```

-----
< Tran.Phase: xx      >
< Lateral Press...   >
< V1: -      D1: -   >
< V2: -      D2: -   >
< V3: -      D3: -   >
<                   >
<                   >
<ENTER to Continue. >
-----

```

Function enabled only if (optional) side press installed.

```

- V1,D1: velocity and distance profile 1 (1-120RPM, 0-650 in tens of mm)
- V2,D2: velocity and distance prof.2 (1-120RPM, 0-650 in tens of mm)
- V3,D3: velocity and distance prof.3 (1-120RPM, 0-650 in tens of mm)

```

PHASE C: Extraction of PL by differential weight from PRP or PPP for preparation of PLTS or cryoprecipitate

PHASE C must always be used as the first PHASE of a PRG and Manual Weighting of centrifuged bag must be done before START. A PHASE C can be used to extract PL after a second hard centrifugation of PRP or PPP, hence leaving on bottom part of the bag a pre-defined quantity of product that can be PLTS or CRYO.

The procedure is as follows

1. The centrifuged bag should be first loaded on the active scale as requested by the display.
2. The scale read the total weight by showing the grams on display and hence, the software automatically deducts the entered tare value and stores the data.
3. A residual volume you wish to leave inside the original bag is entered (W_residual).
4. The bag should be loaded in the main press if not already done and the door closed.
5. the bag is pressed until the **top** scale reads the weight by difference: $W_{diff.} = [(W_{Tot} - W_{Tare}) - W_{residual}]$

When the PHASE ends, the machine automatically proceeds to the next phase in the program, otherwise if there are no more phases the program will end.

```

-----
<Transf.Phase: PL    >
<                   >
< PLTS              >
<                   >
< T.max Phase : 200 >
<                   >
< Residual Wei: 60  >
<                   >
<ENTER to Continue. >
-----

```

```

- T. Max Phase: define the time out before alarm (0-999)
- Residual Wei: define the final weight (10 - 300) you want to leave inside the mother bag (the on inside the press)

```

PHASE D: Simultaneous extraction of two components (Top and Bottom bags)

This PHASE is used only to process **TOP & BOTTOM bags where simultaneous extraction of PL and RBC should occur.** A PHASE D ends when the press reaches the position entered in the panel of last active speed profile or, when the OPT1 reads the approaching of BC (if function enabled).

When the PHASE ends, the machine automatically proceeds to the next one in the program, otherwise if none other phase is available the program terminates itself.

```

-----
<Extr.phase: PL      >
<          RBC      >
< LED BC Posit.: 5  >
< BC Pos. Sens.:700 >
<                   >
<                   >
<                   >
<ENTER to Continue. >
-----

```

- LED BC Posit.: define the Led to be used to stop the BC position (1-8)
- BC Pos.Sens.: define the optical sensitivity of active LED (400-800)

```

-----
<Extr. phase.:  PL  >
<          RBC    >
< T.max Phase: 300 >
< OPT1 weight:  10 >
< OPT1 Sens. : 880 >
< Delay_OPT1 : --  >
<                   >
<                   >
<ENTER to Continue. >
-----

```

- T. Max Phase: define the time out in seconds to activate the alarm (0 - 999)
- OPT1 Weight: define the weight in grams to be reached on the scale to perform the auto-zero of OPT1,
- OPT1 Sens: define the optical sensitivity of OPT1 (0 - 999%)
- Delay_OPT1: define the time out to perform the auto-zero of OPT1 (to be used in place of OPT1_weight)(0 - 100)

NOTES:

1. MPS EVO is equipped with an auto-zero system for the optical sensor OPT1. Every time that a PHASE D begins, the auto-calibration of the sensor occurs. This is used to zeroing the optical differences among various tubes of bags or simply to compensate the differences of absorbance provided by Plasma from different donors: this is called automatic linearization of the process and it allows high reproducibility at any time.
2. **The correct timing to perform the auto-zero can be defined by one of the two following events:**
 - a. **By weight, when the scale has reached the weight entered on field *Weight_OPT1* (normally used).**
 - b. **By time, when xx seconds as defined by *Delay_OPT1* – have elapsed.**
3. The two options for the auto-zero engagement of OPT1 (a. and b.) are mutual excluding and cannot be both enabled.

```

-----
<Extr.Phase:      PL >
<          RBC    >
< V1: 120  D1: 200 >
< V2:  30  D2:  80 >
< V3:   2   D3:  28 >
< V4: -    D4: -    >
< V5: -    D5: -    >
<ENTER to Continue. >
-----

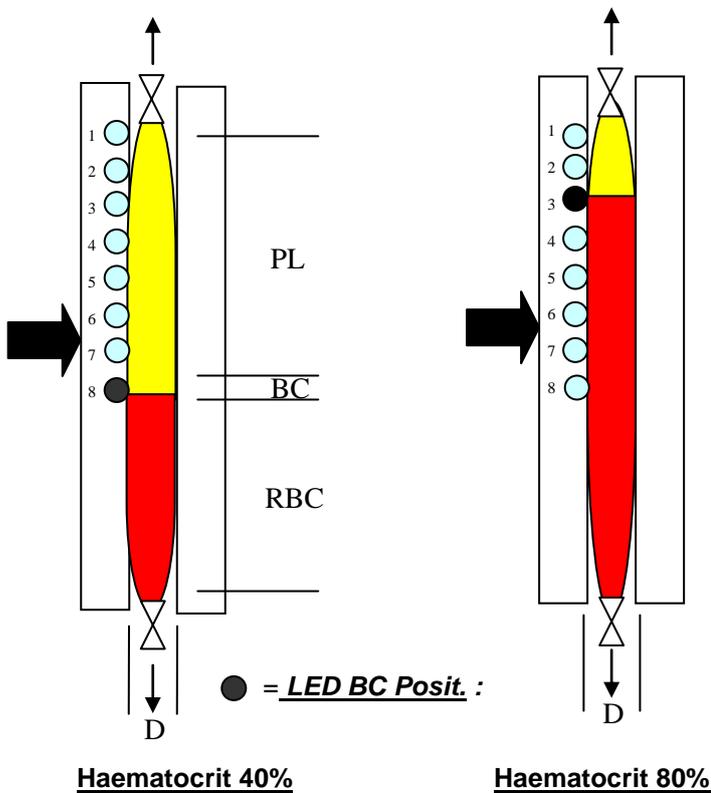
```

- V1,D1: velocity and distance of speed Profile 1 (0-120RPM, 0-650 in tens of mm)
- V2,D2: velocity and distance prof.2 (0-120RPM, 0-650 in tens of mm)
- V3,D3: velocity and distance prof.3 (0-120RPM, 0-650 in tens of mm)
- V4,D4: velocity and distance prof.4 (0-120RPM, 0-650 in tens of mm)
- V5,D5: velocity and distance prof.5 (0-120RPM, 0-650 in tens of mm)



IMPORTANT NOTE: last valid Distance (D3 on the example above) determines the end of the PHASE and thus the final volume of product inside the bag (the main inside the press). If you need to adjust the hematocrit and thus the PL / BC ratio inside the bag, you must select an upper or lower LED by the command *LED BC Posit.* where: 1 = first LED on top, 8 = last LED at bottom. This sensor is used by MPS EVO to hold the BC layer at corresponding position of same LED and hence, it defines the final Hct of the bag.

See drawing ahead for better understanding.



How to adjust the final total volume and the haematocrit (PL / BC ratio) inside the bag:

1. The final total volume is defined by the distance D* on the drawing.
2. D* is ALWAYS defined by last enabled speed profile (D3 = 28 in the example above that means, press stop when reach the gap of 2,8 mm),
3. PL / BC ratio or the haematocrit is defined by the LED BC Posit. : higher is the LED and higher is the Hct or vice versa, lower is the LED and lower will be the Hct but in any case without changing the final total volume of the bag.

The PL / BC ratio is crucial in order to achieve the desired results while preparing PLTS concentrates. Hct may vary if PLTS are produced from single or pool of BC too.

 **IMPORTANT NOTES FOR ALL TOP & BOTTOM PROCEDURES!**

1. The machine is supplied with two factory-loaded PRG for Top and Bottom bags: PRG No. 10 and the PRG no. 11.
2. **Both PRG before starts the PHASE D include a PHASE A.** The PHASE A is available as standard for the following reasons:
 - a. By letting pass through some PL, we can be sure the frangible glass valve of WB bag is properly broken and the line is free and open,
 - b. Load some clean PL onto the satellite bag might be useful, to be used as cleaning solution after overnight mixing of the Buffy-coats.
3. ALWAYS remember that a PHASE D ends when the last Distance entered is reached

EXAMPLES:

PROGRAM 10 – TRIPLE BAGS:

1. **First - PHASE A:** 20 grams of PL are extracted onto the top satellite bag before moving to next PHASE D.
2. **Second - PHASE D:** simultaneous extraction of PL and RBC. The procedure ends when the press reaches the last Distance.
3. **Third - PHASE B (option: not included on factory loaded PRG 10):** transfer of a single component by weight. If necessary, it can be used to transfer a part of the previously extracted PL back into the BC. This is useful for washing the PL line or to transfer additional PL inside the BC bag for further Hct adjustment.

PROGRAM 11 – QUADRUPLE BAGS:

PROCESSING FOR SUBSEQUENT PLTS FROM SINGLE BC

1. **First - PHASE A:** used for the same reason described for triple bag but with an additional aim. Since the BC are not processed immediately but agitated for several hours before perform the second centrifugation, it often happens that part of the BC may raises the tube dirtying the glass valve and hence increasing the risk of PLTS contamination. To remedy this problem and at the same time to check if the breakable valve opens correctly, before starting the PHASE D we use a PHASE A to move a small quantity of PL (20-30 grams) into the second satellite bag (not in the final PL bag). In this way even if during the agitation the valve and tubing are full of RBC, before loading the bag on the centrifuge, we just can use that PL positioned on the satellite to wash the valve and hence get the line completely clean. This process can considerably reduce the contamination of RBC inside PLTS.
2. **Second - PHASE D:** simultaneous extraction of PL and RBC. The procedure is the same as the one describe above for triple bags.
3. **Third - PHASE B (option: not included on factory loaded PRG 11):** transfer of a single component by weight. If necessary, it can be used to transfer a part of the previously extracted PL back into the BC. This is useful for washing the PL line or to transfer additional PL inside the BC bag for further Hct adjustment.

FINAL NOTES ABOUT THE CREATION OF A NEW PROGRAM

REMEMBER THAT:

1. The HEAD of a Program determines how and which hardware must be used from the START to the END of a Program.
2. Every single movement of blood component from one bag to another always requires the execution of an exclusive PHASE.
3. The extraction of air from a bag inside main press must be managed as an exclusive PHASE A.
4. The extraction of air from a bag loaded on lateral press must be managed as an exclusive PHASE B.
5. It is possible to move contemporary two components only by using TOP & BOTTOM bags and only by using a PHASE D.

HOW TO LOAD THE BAS

Once you have chosen the separation program, the machine will ask you to load the bags.

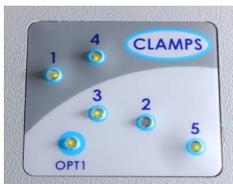


Once it happens, make sure that:

1. The bags and tubes are correctly positioned.
2. The tubes have no bindings and are not stretched.
3. The tubing do not pull the scales,
4. Once the procedure is started **AVOID TOUCHING** the tubing or bags or scales: you may compromise the normal functionality and precision of weight reading.
5. If you see some mistakes while the procedure is already running press **PAUSE**, solve the problem and then press **ENTER** to restart the procedure or **ESC** to abort the PRG.

There are several ways to position the bags onto the machine. It depends on the type of procedure you wish to perform and on the type of bag available but always remember that **ANYWAY THE BAG THAT STAY INSIDE THE PRESS MUST ALWAYS HAVE THE LABEL FACING TO THE DOOR!**

Tube positioning mask



In order to help the Operator to correctly positioning the tubes, MPS EVO is equipped with a LED panel. When a Program is selected, the LEDs matching with same number of clamps to be used with that PRG will light-up to RED. When the Operator has correctly inserted the tubes in place, the LEDs become GREEN.

Loading a set of STANDARD BAGS

This paragraph describes the correct way to load the bags on the system (example with standard quadruple bags).



1. The bag containing centrifuged whole blood must be inserted in the press compartment with **the label facing the door.**
2. If the tubing with needle is facing upward, push it through the top otherwise if it is facing downward through the bottom.
3. The bag of plasma is normally hanged on the left on the vertical scale though clamp no.1, while the bag of RBC additive solution is hanged on the vertical rod through clamp no.4.
4. The bag of BC is hung on the right side scale using clamp no.2.
5. Thread the tube of the main bag inside the optical sensor and the remaining part inside the proper clamps.

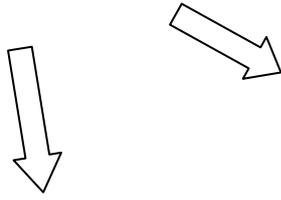
Remember that:

- The example shows a standard quadruple bag.
- Arrangement of bags positioning may vary according to the type of procedure and bag available.



CAUTION !

When inserting the tubes, check that they are correctly positioned into the clamps and optical sensor ! The photo shows the correct procedure to insert the tube into the OPT1 sensor



Close the press door and follow the instructions on screen.



Open the frangible valve(s) of the bag(s) ONLY when requested by the machine!

To open the frangible valve of the main bag, hold it firmly, pull gently upwards and by whilst moving to right and left break the valve.

If you are using a RBC ADDITIVE SOLUTION bag, remember to break its break away cannula too.

Your MPS EVO machine is now ready to perform the first extraction with standard bags.

Loading a set of TOP & BOTTOM BAGS

The same recommendations for positioning standard bags and tubes are also valid for Top & Bottom bags.



1. The bag of whole blood must be inserted in the press compartment with the label facing the door.
2. The bag of plasma is normally hang on to the left part of the vertical scale using clamp n°.1, whereas if you are using a second satellite bag this should be placed on the right using clamp n°.4
3. The bottom bag must be hanging on to the right scale with the tube into the lower clamp n.5.
4. Thread the main bag tube inside the upper optical sensor and the remaining tube(s) in the relevant clamp.

Remember that:

- The example shows a triple bag.
- Arrangement of the bags can vary according to the type of procedure and bag available.



IMPORTANT NOTES

-
1. The use of the optical sensor depends by the type of procedure adopted and the settings for that program. For example, if you are preparing PLTS from PRP, the sensors are irrelevant because the quantity of PLTS concentrate is determined either by weight or by the press stopping at a predefined position.
 2. **THE BAG INSIDE THE PRESS MUST ALWAYS BE POSITIONED WITH ITS LABEL FACING OUTWARDS!!**

NOTICES, ALARMS AND ANOMALIES

MPS EVO controls all actions performed by the program in progress. When the machine recognises an unforeseen condition it will generate a warning message. These warnings are classified in three types: WARNINGS, ERRORS and ANOMALIES.

- **NOTICES** are part of the normal interaction between operator and machine: procedure in progress, on-line weight reading, other information.
- **ERRORS** inform the operator about a problem that has occurred during the processing of a bag. For example the impossibility to transfer the component X from one bag to another or the accidental escape of tubing from a clamp. Some errors may include a suggested solution to the Operator, a corrective action to take while others might cause the interruption of the Program. In rare cases, you may require the help of the Technical Assistance Service.
- **ANOMALIES** inform the operator that a possible failure has been detected and that the machine is not able to perform the planned operation. The help of the Technical Assistance Service is often necessary.



Each screen message is preceded by an alarm tone characterized by a single or repetitive impulse (it depends on device settings).

Press ENTER/ESC or the key indicated on display to silence the sonorous alarm.

The table below contains a list of possible system or error warnings and their short description.

| Warning | Description | Warning | Description |
|--|--|---|---|
| <pre>//----- [N:3] < < There are NO < active programs! < < < < <ESC to EXIT. //-----</pre> | <p>No program are installed on MPS EVO. Press ESC to exit.</p> | <pre>//----- [N:11] < ANOMALY ! < < DOOR OPEN ! < < Close the door < OR < <ESC to terminate. //-----</pre> | <p>The system indicates an anomaly because the door is opened. Please close the door to continue or press ESC to stop the procedure.</p> |
| <pre>//----- [N:15] < PROGRAM IN PAUSE ! < < < < < <ENTER to continue. <ESC to EXIT. //-----</pre> | <p>The program is in pause mode. Press ENTER to continue (the procedure) or ESC end the program.</p> | <pre>//----- [N:16] < PROGRAM IN PAUSE ! < < WRONG position of < tubing in Clamp X ! < < <ENTER to continue. <ESC to EXIT //-----</pre> | <p>This alert appears when the program is running. The program pauses because the tube in clamp X is not correctly positioned. To continue insert the tube correctly and then press</p> |

| | | | |
|---|--|--|--|
| | | | ENTER to continue the procedure; press ESC to end the program. |
| <pre>//----- [N:22] < PROGRAM IN PAUSE > < FOR TIME OUT ... > < > < > < > < > <ENTER to continue. > <ESC to EXIT. > //-----</pre> | The program is in pause because the maximum time for that phase has been exceeded. Press ENTER to continue the procedure or ESC to end the program. | <pre>//----- [N:23] < PROGRAM IN PAUSE > < FOR OPERATOR > < REQUEST.... > < > < > < > <ENTER to continue. > <ESC to EXIT. > //-----</pre> | This sentence appears when the operator decides to pause the program. Press ENTER to continue the procedure or ESC to end the program. |
| <pre>//----- [N:24] < PRESS ERROR ! > < Program Terminated > <for Press end of Run > < > < > < > < > <ENTER per TERMINATE. > //-----</pre> | The system indicates that the program is terminated because the press reaches its end of run. Press ENTER to end the program. | <pre>//----- [N:27] < PRESS ERROR ! > < Program in pause > < for blocked press. > < > < > < > <ENTER to continue. > <ESC to EXIT. > //-----</pre> | The system shows that the program is in pause because the press is blocked. Press ENTER to continue the procedure or ESC to end the program. |
| <pre>//----- [N:54] < Please check for > < tube occlusion for > < > <Component : X > < > < > <ENTER to continue. > <ESC to EXIT > //-----</pre> | The system informs the operator that the tube in clamp X is occluded. Press ENTER to continue the procedure or ESC to end the program. | <pre>//----- [N:64] < ERRORE of > < communication > < with server. > < > < Trying to recover > < the connection > < Please Wait... > < > //-----</pre> | An error is occurred during the communication with server. MPS EVO is trying to recover the connection. The operator must wait until the end of the operation. |
| <pre>//----- [N:65] < > < PAUSE > <for Optical detection> < > < > < > < > <ENTER to Continue > <ESC open clamp > //-----</pre> | The system stops the Phase D because the top main optical sensor (OPT1) has intercepted red cells in the tube. Press ENTER to continue the procedure or ESC to open the clamp. | <pre>//----- [N:67] < Clamp module > < NOT ready ! > < > < > < > < > <ENTER to try again. > <ESC to skip. > //-----</pre> | The system warns that the clamp module is not ready to work. Press ENTER to retry the operation or ESC to skip. |

| | | | |
|---|---|--|--|
| <pre>//----- [N:68] < < <Wet head on Clamp: x > < < < <ENTER to try again. > <ESC to EXIT > //-----</pre> | <p>The system indicates that during the sealing procedure there is residual moisture on the head clamp. Press ENTER to try again or ESC to exit.</p> | <pre>//----- [N:73] < SERVER > < not available. > < < Waiting for server > < connection... > < < ESC prg manual sel. > < ENTER to continue > //-----</pre> | <p>MPS EVO can't connect to server and it's working to connect. Press ESC to choose the program manually or ENTER to continue.</p> |
| <pre>//----- [N:75] < <Initialization ERROR > < of net module! > < <Net NOT available > < <ESC to try again. > <ENTER to continue. > //-----</pre> | <p>An error occurs during the initialization of Ethernet or WiFi module: the Network is not available. Press ESC to try again or ENTER to continue.</p> | <pre>//----- [N:76] < < System ANOMALY > < opto of Press ! > < < < <ENTER to try again. > <ESC to EXIT > //-----</pre> | <p>A system anomaly is occurred in the main press optical sensor (OPT2). Press ENTER to try again or ESC to exit from the program.</p> |
| <pre>//----- [N:77] < < System ANOMALY > < main opto ! > < < < < <ENTER to try again. > <ESC to EXIT > //-----</pre> | <p>A system anomaly is occurred in the top main optical sensor (OPT1). Press ENTER to try again or ESC to exit from the program.</p> | <pre>//----- [N:89] < < ERROR ! > < < Wrong code > < < < <Please Wait... > //-----</pre> | <p>The system warns that the read code is wrong. Please wait.</p> |
| <pre>//----- [N:166] < < The clock battery > < < is discharged ! > < < < < <ENTER to Continue. > //-----</pre> | <p>The battery of the inside real time clock is discharged. Press ENTER to continue the procedure.</p> | <pre>//----- [N:167] < Date and Time are > < WRONG ! > < < New Date and Time! > <Date 01:01:06 > <Time 00:00:00 > < <ENTER to Continue. > //-----</pre> | <p>The set date and time are wrong. MPS EVO sets the date and time format automatically, then the operator can set current date and current time. Press ENTER to continue.</p> |
| <pre>//----- [N:169] < ERROR > < < Closing PRESS ! > < < < < < <ENTER to Continue. > //-----</pre> | <p>The system indicates that an error is occurred during the closure of the press. Press ENTER to continue the program.</p> | <pre>//----- [N:170] < ERROR > < < Opening PRESS ! > < < < < <ENTER to Continue. > //-----</pre> | <p>The system indicates that an error is occurred during the opening of the press. Press ENTER to continue the program.</p> |

| | | | |
|--|---|--|--|
| <pre>//-----[N:171] < ERROR > < > < PRESS Calibration !> < > < > < > < > < > <ENTER to Continue. > //-----</pre> | <p>The system indicates that an error is occurred during the calibration procedure of the press. Press ENTER to continue the program.</p> | <pre>//----- [N:175] < ERROR > < > < Control Door and > < Plate Type ! > < > < > < > <ESC to EXIT. > //-----</pre> | <p>The system warns that the door is opened or the installed plate type is wrong. Press ESC to exit.</p> |
| <pre>//-----[N:176] < ERROR > < > < WRONG PLATE ! > < > <Reques. Plate N: X > <Read Plate N: Y > < > <ESC to EXIT. > //-----</pre> | <p>The system detects a discrepancy between the selected plate (X) and the detected one (Y). Press ESC to end the program.</p> | <pre>//----- [N:177] < ERROR > < > < PROPORTIONAL VALVE > < > < > < > < > <ENTER to Continue. > //-----</pre> | <p>The system signals an error in the control system of proportional valve, which regulates the flow in the tube. Press ENTER to continue the procedure.</p> |
| <pre>//-----[N:211] < > < Error to > < communicate > < with the reader! > < > < > < ESC to cancel > < ENTER to retry > //-----</pre> | <p>MPS EVO can't communicate with the COMBO reader. Press ESC to cancel or ENTER to retry the operation.</p> | <pre>//----- [N:212] < > < ERROR ! > < > < Wrong Tag Bag > < > < > < > <Please wait... > //-----</pre> | <p>This warning indicates that during the reading of R-FID tag the system detects a wrong tag bag.</p> |
| <pre>//-----[N:213] < > < No program to run > < > < > < > < > < > < ENTER to continue > //-----</pre> | <p>The system informs the operator that the barcode number doesn't match any installed programs. Press ENTER to continue .</p> | | |

MAINTENANCE

The maintenance of MPS EVO is very limited. Essentially the job required to the Operator is to keep the machine clean, to verify the scales and optical systems efficiency. At least once a year, it should be performed a complete control and system's calibration by a qualified service engineer.

NOTE: For missing good maintenance, the quality of product could be affected.

Daily maintenance (Operator)

WARNING FOR CLEANING AND DISINFECTION!

Please pay attention while cleaning and disinfecting your MPS EVO, some solutions may attack the materials damaging the surfaces of the unit. Warranty void if wrong solutions are used to clean the units.

SOLUTIONS CONTAINING THE FOLLOWING PRODUCTS MUST NOT BE USED ON PLEXIGLAS PARTS (sliding adapter of door, side press plate, right hand scale holder, press sensors covers and top part of top optical sensor)

Alcohols

- Amyl Alcohol > 3%
- Benzyl Alcohol > 3%
- Butanol > 20%
- Ethyl Alcohol > 20%
- Methyl Alcohol > 20%
- Propyl Alcohol > 20%

Disinfectants and cleaning solutions

- Peroxide 90 volumes
- Ammonia concentrated
- Bleach > 25% chlorine
- Iodine tincture

ACCEPTABLE SOLUTIONS FOR CLEANING AND DISINFECTION

Alcohols

- Ethanol slightly conc. < 10%
- Ethanol < 20% (but request fast rinsing after application with wet clean cloth)
- Methyl Alcohol < 20% (but request fast rinsing after application with wet clean cloth)

Disinfectants and cleaning solutions

- Peroxide 40 volumes
- Ammonia diluted < 1%
- Benzalkonium chloride < 2% even mixed with clorexidine 0.5 - 1%
- Formalin < 5% (but this one is heavily toxic)
- Bleach < 10%
- Merbromin

It is recommended after disinfection and cleaning **to rinse all parts with a clean cloth or gauze slightly wet with water** to remove any trace of used solutions that long term, might anyway affect the surfaces.

No water or other liquid should be spilled onto any part or inside the machine.

Cleaning

Remove all bags and clean the front panel and press compartment using a soft clean cloth dampened with detergent or disinfectant. Avoid **to spill any liquid inside the machine or scratching the transparent window of the optical sensors**.

Before restarting the machine rinse the parts with a clean slightly wet cloth and then dry it.

NEVER use abrasive products, acetone, trichloroethylene or other solvents.

Decontamination

NOTE: decontamination is an emergency procedure and must only be performed when strictly necessary.

Generally, decontamination is only necessary after blood leakage for bag or tubing breaking.

In these cases:

- Switch off the machine and disconnect the power cable.
- Carefully remove the bags wearing protective clothing (gloves, overalls, protective glasses, etc.)
- Using a proper disinfectant solution, clean the entire exterior of machine, the press compartment all contaminated parts **taking care of not to spill liquid inside the electronic equipment.**
- Using a slightly dampened cloth with water, rinse the machine parts and then dry it.

If a tube breaks inside a clamp:

- Remove the protective cap by pressing down and rotating counter clockwise at same time: carefully extract it from the housing.
- Carefully clean the electrodes and all the surrounding area, taking care not to spill any liquid inside the clamp: use damp pieces of gauze and if necessary cotton buds.
- Dry and check to make sure there is no dirt left inside the clamp.
- Pay attention to remove any part of gauzes or cloth from the clamps.
- Before switching on the machine, wait at least 30 minutes to let the parts drying completely.
- Before using MPS EVO again, check the clamps functionality as described in Checking the Sealer Clamps.

 **Never use acetone, trichloroethylene or other strong solvents. Remember that bleaching solutions tarnish most of metal parts: use it as lowest than possible and always rinse the parts by using a clean cloth dampened with water, better distilled water.**

Six-twelve month's maintenance

Every six – twelve months is recommended to control the status of the scales and of the clamps: these operations can be done by the Users (some calibration material should be provided).

Checking the scales

To check the scales, you need a calibrated weight of 500g (+/- 0.1g).

This control **should be performed after 30 minutes from machine switch on** to permit a good thermal stabilization of the system.

From the main menu indicated below:

```
-----  
<  MPS  R: xxx  >  
<  date and time  >  
< 1- Programs    >  
< 2- Balances    >  
< 3- Settings    >  
< 4- Tech Service >  
< 5- Send Data to PC >  
<   Select:      >  
-----
```

Select *2-Balances*+ ENTER:

```
-----  
< Menu balances handl.>  
<                               >  
< B1= ---- g          >  
< B2= ---- g          >  
< B3= ---- g          >  
< B4= ---- g          >  
< B5= ---- g          >  
<ESC to EXIT.        >  
-----
```

Now load the sample weight on the scales one by one and check if reading is correct.

Checking the sealer clamps

Items necessary for this operation:

- One of your standard PVC bags **with tubing filled with water or physiological solution.**

From the main menu indicated below:

```
-----  
<  MPS  R: xxx  >  
<  date and time  >  
< 1- Programs    >  
< 2- Balances    >  
< 3- Settings    >  
< 4- Tech Service >  
< 5- Send Data to PC >  
<   Select:      >  
-----
```

Press the key SEAL:

```
-----  
< Manual Sealing  >  
<                               >  
< CLAMP:          >  
<                               >  
<                               >  
<UP/DOWN Selection. >  
<ENTER to Seal.   >  
<ESC to EXIT.    >  
-----
```

Use the arrows to select a clamp. Insert the tube into the corresponding clamp and then use ENTER to seal and ESC to exit: repeat the operation for all clamps.

Should any test fails, please get in contact with the Technical Assistance Service.

TECHNICAL DATA

| | |
|---|---|
| Trade name: | MACOPRESS® <i>Smart</i> |
| Product code: | 9MPSEVOLAN, MAC.DB.WIFI (9MPSEVOWIFI), MAC.DB.485 (9MPSEVO485). |
| Manufacturer: | DELCON s.r.l. Via Matteucci, 25/27 20862 Arcore (MB) - Italy |
| Manufacturer for: | MACOPHARMA S.A. Rue Lorthiois 59420 MOUVAUX (FRANCE) |
| Reference standard: | IEC/EN 60601-1, 3rd Ed. “Safety of Medical Electrical Equipment. General Requirement”. IEC/EN 61010-1, 2nd Ed. “Safety Requirements for Electrical Equipment for measurement, control and laboratory use. General Requirements”. UL 61010-1, 2nd Ed. CAN/CSA C22.2 No.61010-1+GI1, 2nd Ed. EN 62304, 1st Ed. “Medical Device Software – Software Life-Cycle processes”. Dir. 2006/42/EC “Directive on Machinery”. |
| CE Classification: | Class 1 Medical Device according to Directive 93/42 MDD and 2007/47 MDD . |
| Electrical supply: | 100-240 VAC 50/60 Hz |
| Power consumption: | 300 VA |
| Fuses: | Two of 4 AT - 230V |
| Supply cable: | Detachable power supply cord |
| Ambient operational conditions: | Temperature: +10° ~ +35°C Relative humidity: 30 ~ 85% non-condensing |
| Storage conditions: | Temperature: +10° ~ + 40° C Relative humidity: 10 ~ 95% non-condensing |
| Weighing scale accuracy: | ± 2% on read value ±3 grams |
| Optical sensors: | Class 1 equipment with LED, invisible infrared radiation. Maximum power emitted: <1 mW Wave length λ : 880 nm Reference standard: CEI EN 60825-1:2003 |
| Average separation time of quadruple bag: | 1.30 min in standard bag 2.30 min T&B bag |
| Alarms: | Acoustic and Optical |
| Error and alarm codes: | Shown on the graphic LCD with reference code |
| Languages: | Italian, English, Spanish, German ,French (other on demand) |

| | |
|------------------------------------|---|
| Data communication | Serial RS485 Ethernet LAN WiFi 822.11 b/g LAN (FCC approved) |
| In case of an electrical blackout: | System reset (cancellation of single operation in progress) |
| Measurements: | mm. 400 H (+250 mm for rod of upper scale), mm. 330 D and mm 400 L |
| Net weight: | ~ 38 Kg |
| Size and weight with packaging: | 560H x 520D x 500L mm, 45-48 Kg. |

DESCRIPTION OF AVAILABLE VERSIONS OF MPS EVO

Cod. 9MPSEVO485

MPS EVO double press 485: same as basic version 485 plus an additional lateral press. The lateral press can be used for some automatic procedures such as air extraction, priming of in-line filters, fast RBC additive solution transfer and some more. **This version has an internal module for serial connection RS485 with computer.** The DMS Plus is included as standard. See ahead for further accessories needed for SERIAL connection to the computer.

Cod. 9MPSEVOLAN

MPS EVO double press Ethernet: same as basic version Ethernet LAN plus an additional lateral press. The lateral press can be used for some automatic procedures such as air extraction, priming of in-line filters, fast RBC additive solution transfer and some more. **This version has an internal module for serial connection RS485 with computer plus an additional Ethernet module.** The DMS Plus is included as standard. See ahead for further accessories needed for ETHERNET connection to the computer.

Cod. 9MPSEVOWIFI

MPS EVO double press Wi-Fi: same as basic version Wi-Fi plus an additional lateral press. The lateral press can be used for some automatic procedures such as air extraction, priming of in-line filters, fast RBC additive solution transfer and some more. **This version has an internal module for serial connection RS485 with computer plus an additional Wi-Fi module.** The DMS Plus is included as standard. See ahead for further accessories needed for Wi-Fi connection to the computer.

CONFIGURATION OF MPS EVO FOR NET CONNECTION

All versions of MPS EVO can be exclusively connected to the computer **ONLY** if the DMS Plus application just designed for that has been already installed and correctly configured. For more details about the installation, configuration and use of the software DMS Plus, it is recommended to read carefully its User Manual.

All machines have as standard the hardware to support the serial net connection RS485 but upon the available version of MPS EVO might also be installed the Ethernet LAN or Wi-Fi Wireless LAN modules. The Network Type enabled at the factory is ALWAYS the one who refers to the purchased version hence:

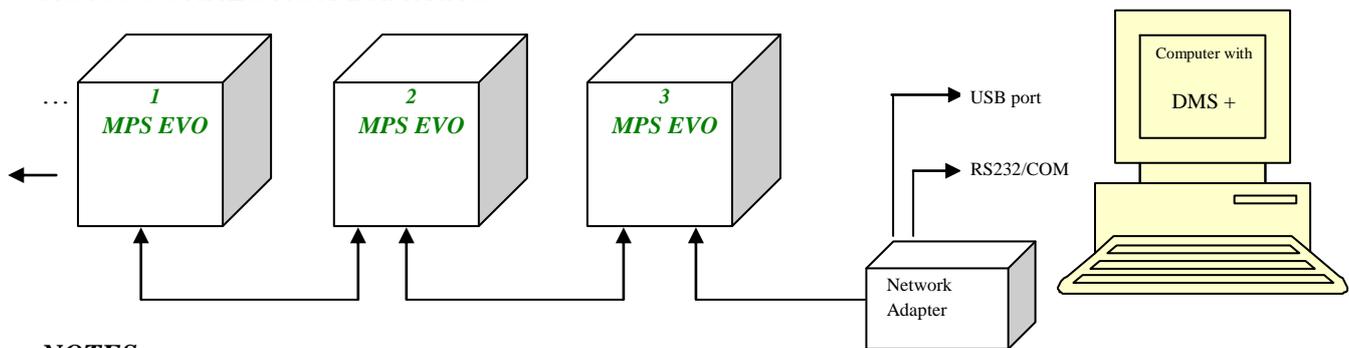
1. Version 9MPSEVO485 RRS485 net is enabled.
2. Version 9MPSEVOLAN: Ethernet net is enabled with same IP address for all new machines (IP: 10.0.5.4)
3. Version 9MPSEVOWIFI: Wi-Fi Wireless net is enabled with same IP address for all new machines (IP: 10.0.5.4)

For all machines with Ethernet or Wi-Fi modules, it is also possible to temporary or finally switches the net to serial RS485: once the network type is defined, anyone else available is contemporary disabled. At any time is possible to modify back the network type.

CONFIGURATION OF MPS EVO WITH RS485 NETWORK

To let the machines working on RS485 net, it is necessary to connect it together with a serial cable cod. 9MPS070 (**to be purchased separately**) while last one must be connected to the Net Adapter – converter cod. 9MPS311 (**to be purchased separately**). The Net Adapter must also be connected to the computer both to RS232 and USB ports where DMS Plus has been installed.

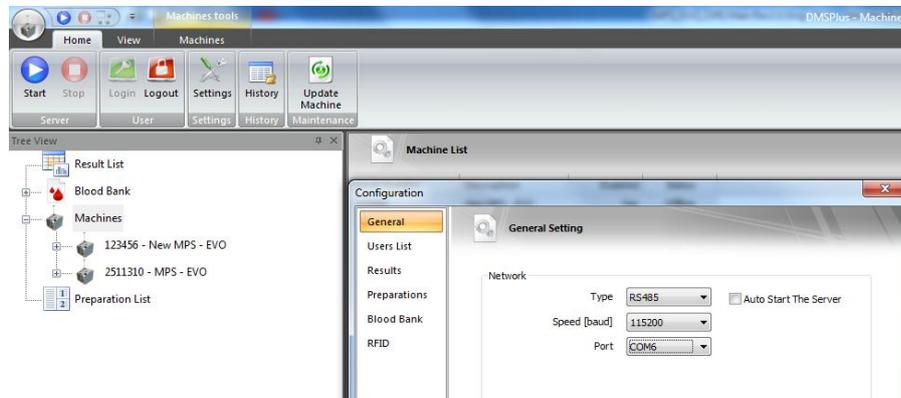
RS485 CONNECTION DRAWING



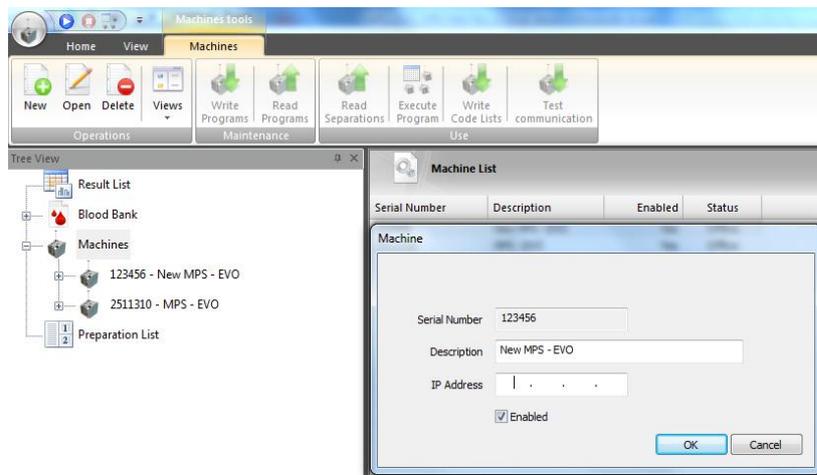
NOTES:

- 1) Both connectors RS232 and USB of the Net Adapter cod.9MPS311 **MUST BE connected to the computer.**
- 2) If the computer does not have any serial port RS232, it is possible to use a RS232/USB converter. Upon the available version of Windows and converter type, it might be necessary to install a specific driver to use it (normally available on internet): please refer to the Windows and converter's documentation for proper installation of the driver. Once the RS232/USB has been installed, Windows creates a new serial COM port with number 1, 2, 3...): please refer to the Windows documentation on how to identify the "System peripherals" to understand which COM port has been activated.
- 3) **Let's do an example with COM port 6 activated by Windows:**

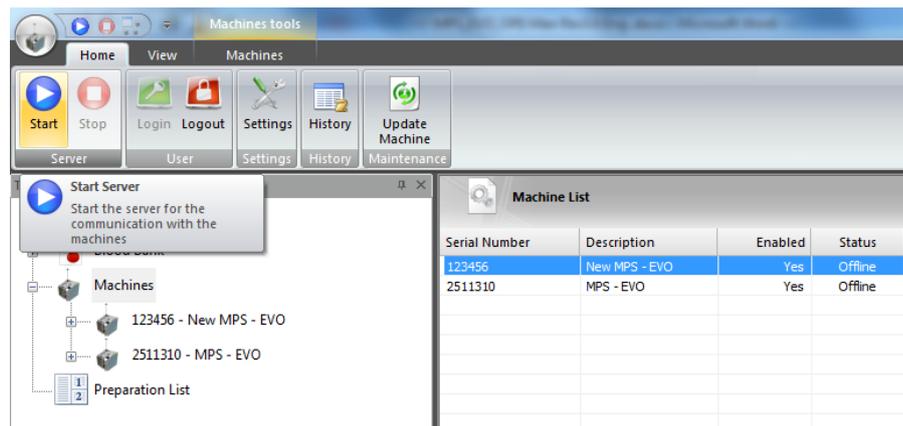
- a. Install the software DMS Plus on your computer,
- b. Launch DMS Plus and then login (default user and password is “service”)
- c. From DMS Plus menu *Home* → *Settings* → *General* set *Network Type* as RS485 and the *Port COM* at same value as shown by your computer: **absolutely NEVER change the baud rate that must remain at 115200**. (On the example we are using the COM 6).



- d. From left tree select *Machines* and then from the top Ribbon button select *Machines*. Click on *New* and then enter the serial number of the machine (can be found on back data label of the machine) and a description if necessary. Repeat and enter with *New* all serial numbers of machines to be used.



- e. Switch ON all machines and wait for the end of the start-up procedure until the Main menu appears on the display.
- f. From the DMS Plus start the communication server as follow: *Home* → *Start*. All lines of the area *Machines List* of various machines that are ON, should switch from *Status Offline* to *Online* in green colour. If it does not happen, verify that all machines are ON, properly connected and that all serial numbers have been correctly entered: serial numbers can be also found from the machine menu *Tech Service* → *diagnostic*, (default pwd is 000000) *Show label data menu*.



- g. Now the machines can communicate with the computer and it is possible to read/write the *Machine HEAD*, the Programs, the separation data and so on: see DMS Plus User Manual for more details on how to change the machine settings or the Programs parameters.

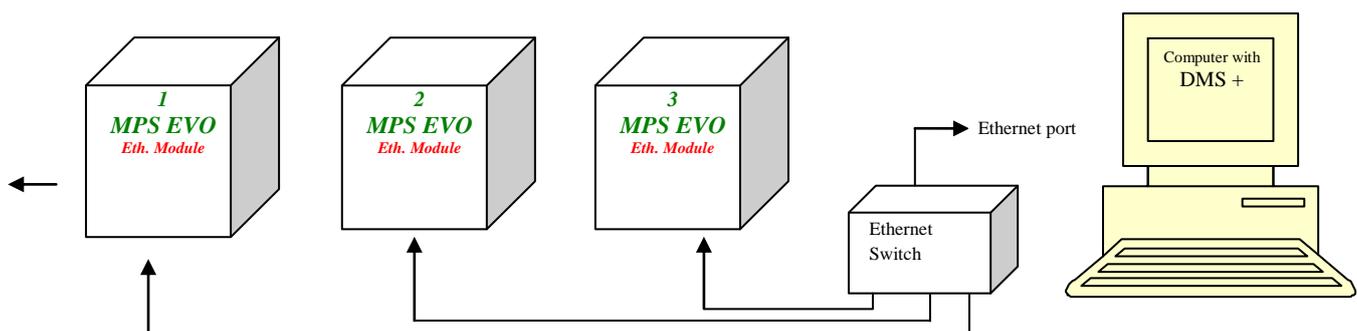
NOTE: at any new start of DMS Plus software it will be necessary to manually start its server to permit the communication with the machines, unless the function on *Home* → *Settings* → *General* → *Auto Start the Server* is marked (flagged).

CONFIGURATION OF MPS EVO WITH ETHERNET NETWORK

To let the machines work on ETHERNET network, **it is necessary to connect all units by an Ethernet cable cod. 9MPSLAN_CAB (to be purchased separately) to a Hub/switch cod. 9MPSHUB_PC (to be purchased separately)** and then the Hub itself to the Ethernet card of computer.

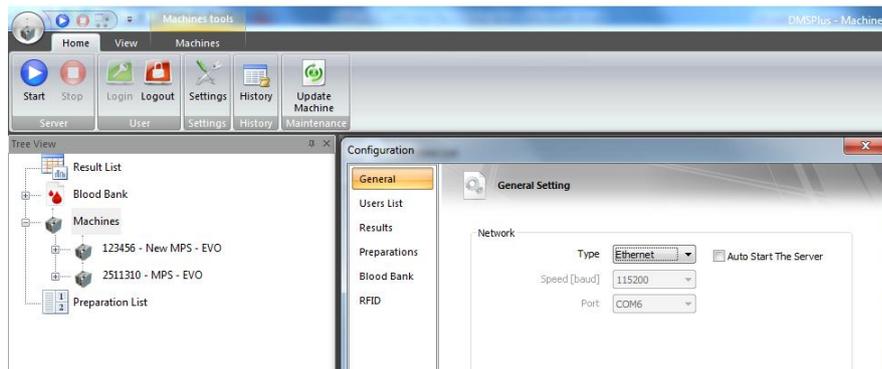
NOTE: if the computer need to be connected also to the blood bank network, it will be necessary to have installed a second Ethernet card too.

ETHERNET CONNECTION DRAWING

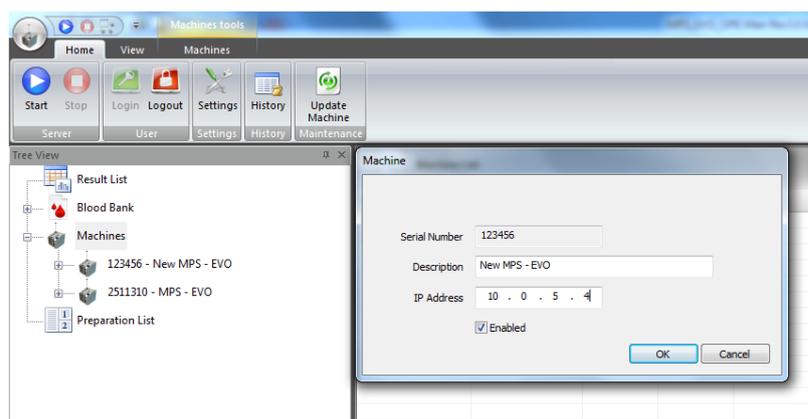


- a. Now we have to create a list of free IP addresses to be used for both Ethernet cards of machines and computer. **NOTE: the IP addresses 10.0.5.0, 10.0.5.1, 10.0.5.2, 10.0.5.3, 10.0.5.4 are reserved and CANNOT BE USED.** For example. If we need to configure ten machines, we might use the following addresses:
1. 10.0.5.100 (IP address of the computer card)
 2. 10.0.5.5 (For first machine), 10.0.5.6 (for second one)... 10.0.5.15 (for tenths machine).
- b. Once you have properly connected the machines to the computer, first of all we should configure the Ethernet card of computer with following settings:

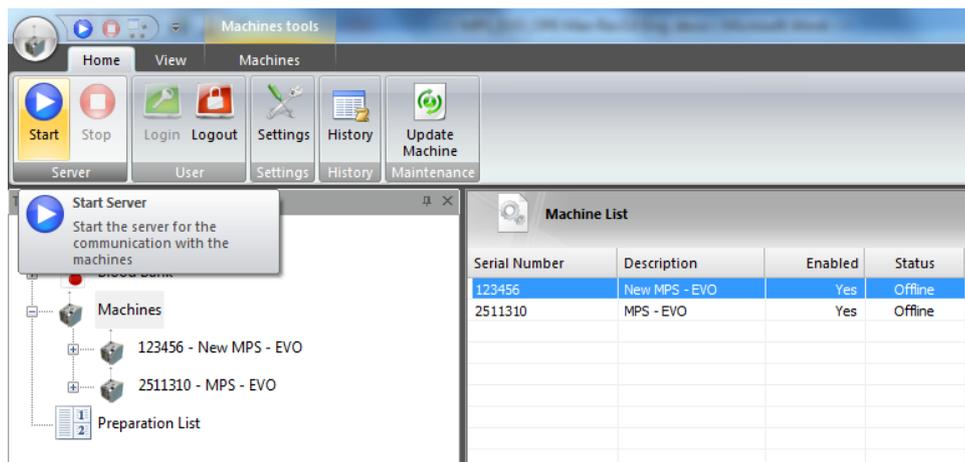
- i. IP: 10.0.5.100
 - ii. Subnet mask : 255.255.255.0
 - iii. Gateway : none value
 - iv. DNS : none value
- c. At this stage all machines must be OFF line, except the one you are currently configuring. This is necessary to avoid IP conflicts due to the initial same IP they have.
- d. Install the DMS Plus software on your computer .
- e. Launch the DMS Plus and then login (default user and password is “service”)
- f. From the menu *Home* → *Settings* → *General*, set the *Network Type* as ETHERNET.



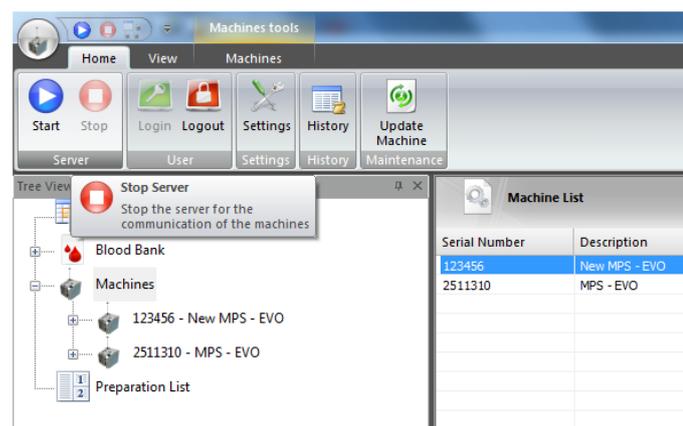
- g. From the left tree select *Machines* and then from the top Ribbon button select *Machines*. Click on *New* and then enter the serial number of the machine (can be found on back data label of the machine) and a description if necessary. In case of new machine the factory set IP address is 10.0.5.4 and set it. If the machine has previously been configured, you can verify its IP address directly from the machine by entering the Menu: *Tech Service* → *Diagnostic*, (default pwd is 000000) *Show Label Data*. Once done, return back to main menu.



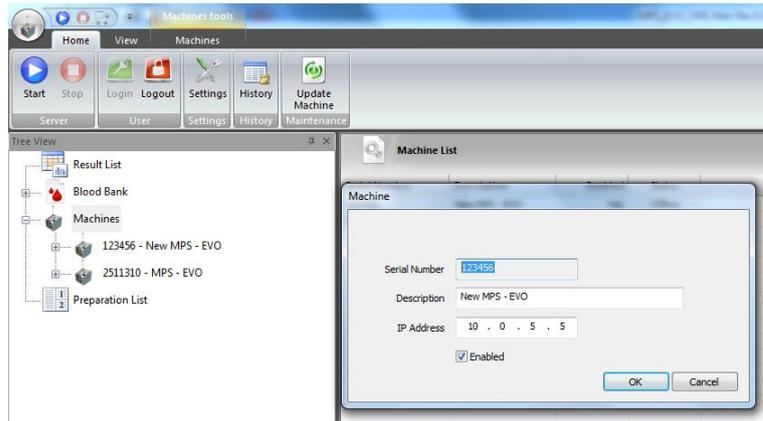
- h. Switch ON only the machine you have to configure: at the end of start-up will appear the Main menu.
- i. From DMS Plus starts the communication server as follow: *Home* → *Start*. All lines of the area *Machines List* of various machines that are ON, should switch from *Status Offline* to *Online* in green colour. If it does not happen, verify that all machines are ON, properly connected and that the IP addresses are compatible and correctly entered: serial numbers can be also found from the machine menu *Tech Service* → *diagnostic*, (default pwd is 000000) *Show label data* menu.



- j. Now it's possible to communicate with the machine and hence, from the left tree click on the serial number of the machine under configuration and then click on top button *Read Machine Head*. (See User Manual of DMS Plus for more details about the use of the software).
- k. Select the window *Specialist* to modify the IP address from the original 10.0.5.4 to the new value of 10.0.5.5 (if first machine), 10.0.5.6 (if second machine)... 10.0.5.15 (if tenth machine).
- l. **Gateway IP Address: you should NEVER modify this value from the original default of 10.0.5.1.** The Gateway value might be modified ONLY by a Network Specialist that knows well your network configuration. That's might be necessary only in case the machines need to be connected to an *Ethernet Subnet* different than the one of computer where DMS Plus has been installed.
- m. Once done, save the new *Machine Head* by clicking on the Ribbon button "SAVE". At this point, the new value has been saved on computer but not yet transferred to the machine.
- n. To transfer the new value and settings to the machine click on "Write Machine Head".
- o. Switch off the Server by clicking on "STOP".



- p. From left tree select *Machines* and hence click on the serial number of the machine to configure. The window of machine appears hence enter the new IP address from the original to new one as 10.0.5.5 (if first machine), 10.0.5.6 (if second machine), ..., 10.0.5.15 (if tenth machine): OK to confirm.



- q. Switch OFF the unit and then ON again by holding the key ENTER pressed until the clamps start-up procedure end: now you can release the ENTER key and hence switch off the unit again. With this procedure we transfer the new IP address to the Ethernet module of the machine.
- r. Switch ON the machine normally and wait for Main Menu on the display.
- s. Start the server of DMS Plus : on *Machine List*, the machine just configured with the new IP address should become *Online*.
- t. Switch off the machine and the server of DMS Plus again.
- u. Repeat all operations from point “g” to “t” for all machines you need to configure and connect to the DMS Plus network.

NOTE: at any new start of DMS Plus software, it will be necessary to manually start its server to permit the communication with the machines, unless the function available at *Home* → *Settings* → *General* → *Auto Start the Server* is marked (flagged).

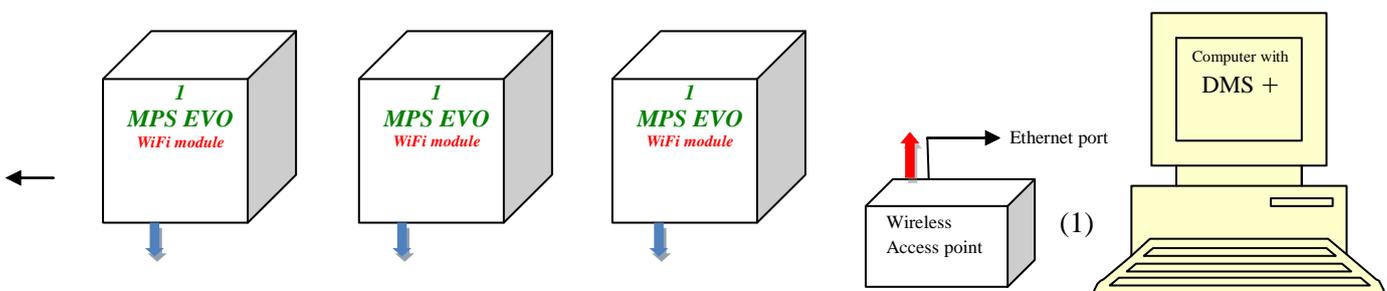
CONFIGURATION OF MPS EVO WITH WIFI NETWORK

To let the machines working on Wi-Fi network, it is necessary to use an **Access Point cod. 9MPSWIFI_AP (sold separately)** that is already configured and ready to be connected to the Ethernet card of computer.

NOTE: if the computer need to be connected also to the blood bank network, it will be necessary to have installed a second Ethernet card too.

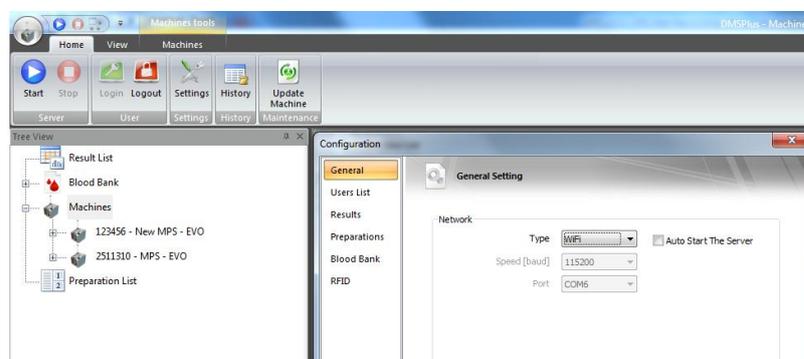
NOTE: The distance between equipment and access point must be equal or below to 50 metres.

Wi-Fi CONNECTION DRAWING

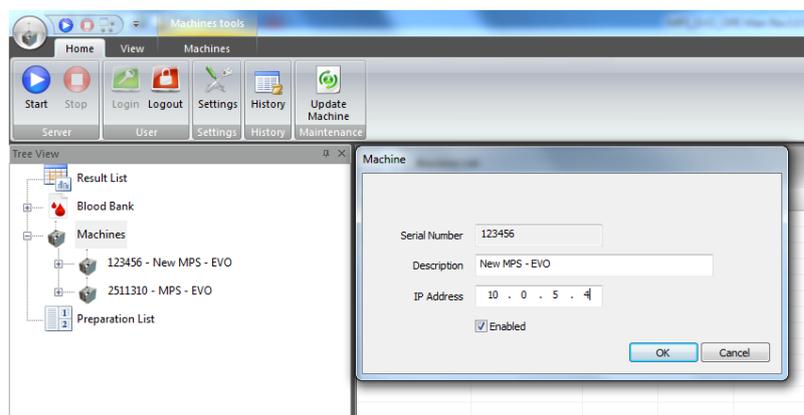


- a. Now we have to create a list of free IP addresses to be used for both Wi-Fi and Ethernet cards of machines and computer. **NOTE: the IP addresses 10.0.5.0, 10.0.5.1, 10.0.5.2, 10.0.5.3, 10.0.5.4 are reserved and CANNOT BE USED.** For example. If we need to configure ten machines, we might use the following addresses:

1. 10.0.5.100 (IP address of the computer card)
 2. 10.0.5.5 (For first machine), 10.0.5.6 (for second one)... 10.0.5.15 (for tenths machine).
- b. Once you have properly connected the Access Point to the computer, first of all we should configure the Ethernet card of computer with the following settings:
- i. IP: 10.0.5.100
 - ii. Subnet mask : 255.255.255.0
 - iii. Gateway : none value
 - iv. DNS : none value
- c. At this stage all machines must be OFF line, except the one you are currently configuring. This is necessary to avoid IP conflicts due to the initial same IP they have.
- d. Install the DMS Plus software on your computer.
- e. Launch the DMS Plus and then login (default user and password is “service”)
- f. From the menu *Home* → *Settings* → *General*, set the *Network Type* as Wi-Fi.

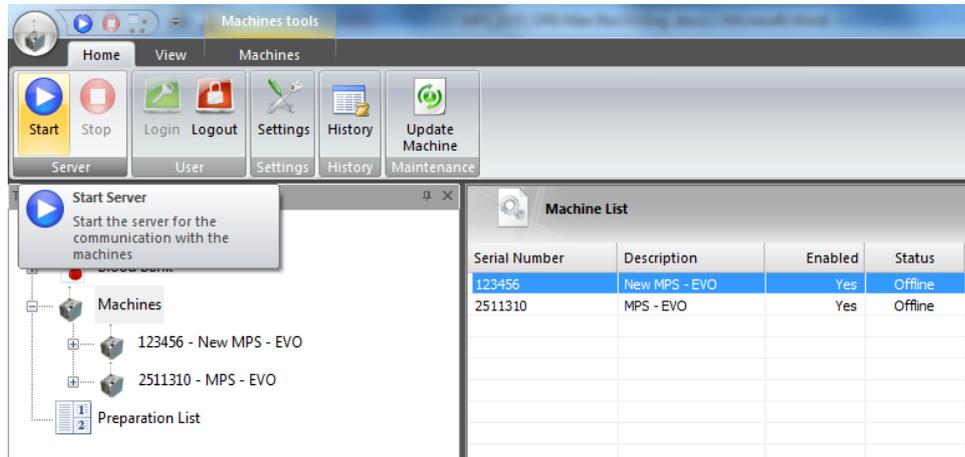


- g. From the left tree select *Machines* and then from the top Ribbon button select *Machines*. Click on *New* and then just enter the serial number of the machine (can be found on back data label of the machine) and a description if necessary. In case of new machine the factory set IP address is 10.0.5.4 and set it.. If the machine has previously been configured, you can verify its IP address directly from the machine by entering the Menu: *Tech Service* → *Diagnostic*, (default pwd is 000000) *Show label data*. Once done, return back to main menu.

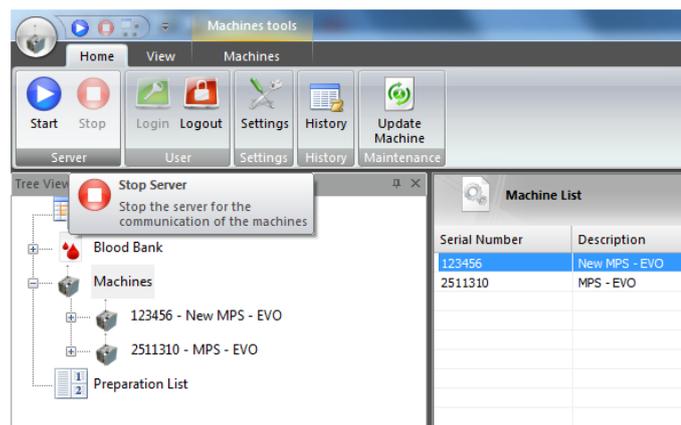


- h. Switch ON only the machine you have to configure: at the end of start-up will appear the Main menu.
- i. From DMS Plus start the communication server as follow: *Home* → *Start*. All lines of the area *Machines List* of various machines that are ON, should switch from *Status Offline* to *Online* in green colour. If it does not happen, verify that all machines are ON, properly connected and that the IP

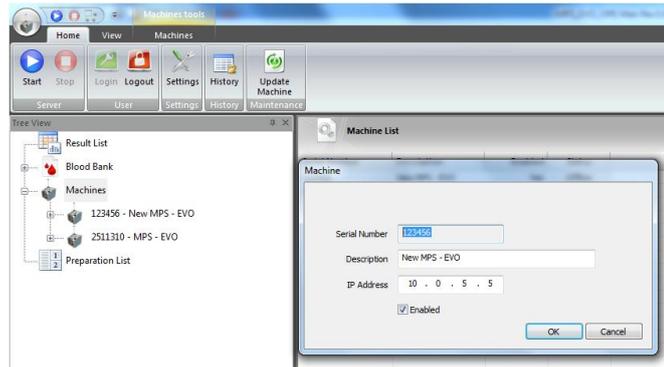
addresses are compatible and correctly entered: serial number can be also found from the machine menu *Tech Service* → *diagnostic*, (default pwd is 000000) *Show label data menu*.



- j. Now it's possible to communicate with the machine and hence, from the left tree click on the serial number of the machine under configuration and then click on top button *Read Machine Head*. (See User Manual of DMS Plus for more details about the use of the software).
- k. Select the window *Specialist* to modify the IP address from the original 10.0.5.4 or what else to the new value of 10.0.5.5 (if first machine), 10.0.5.6 (if second machine)... 10.0.5.15 (if tenth machine).
- l. **Gateway IP Address: this value CANNOT be modified and must remain as set at the factory at 10.0.5.1.**
- m. Once done, save the new *Machine Head* by clicking on the Ribbon button "SAVE". At this point, the new value has been saved on the computer but not yet transferred to the machine.
- n. To transfer the new value and settings to the machine click on "*Write Machine Head*".
- o. Switch off the Server by clicking on "*STOP*".



- p. From the left tree select *Machines* and hence click on the serial number of the machine to configure. The window of machine appears hence enter the new IP address from the original to new one as 10.0.5.5 (if first machine), 10.0.5.6 (if second machine)... 10.0.5.15 (if tenth machine).



- q. Switch OFF the unit and then ON again by holding the key ENTER pressed until the clamps start-up procedure start: now you can release the ENTER key and hence switch off the unit again. With this procedure we transfer the new IP address to the Wi-Fi module of the machine.
- r. Switch ON the machine normally and wait for Main Menu on the display.
- s. Start the server of DMS Plus : on *Machine List*, the machine just configured with the new IP address should become *Online*.
- t. Switch off the machine and the server of DMS Plus again.
- u. Repeat all operations from point “g” to “t” for all machines you need to configure and connect to DMS Plus network

NOTE: at any new start of DMS Plus software it will be necessary to manually start its server to permit the communication with the machines, unless the function available on *Home* → *Settings* → *General* → *Auto Start the Server* is marked (flagged).

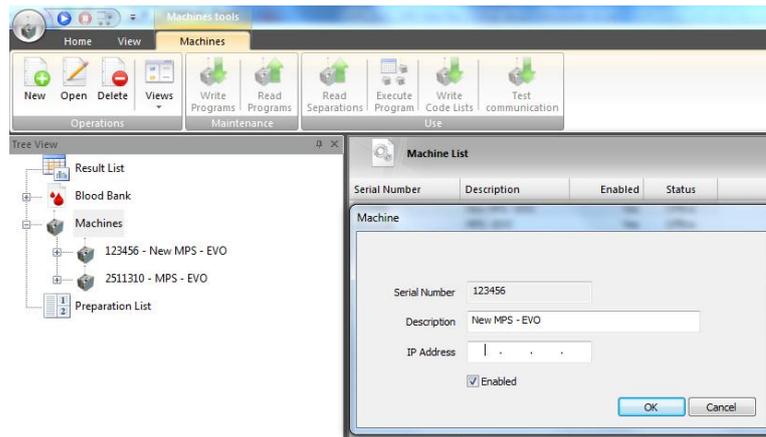
CONVERSION FROM WIFI or ETHERNET NETWORK to RS485

If a machine is configured to communicate on ETHERNET or Wi-Fi network, it is possible to convert it temporary (until it remains ON) or permanently (until new re-configuration occur) to RS485 net.

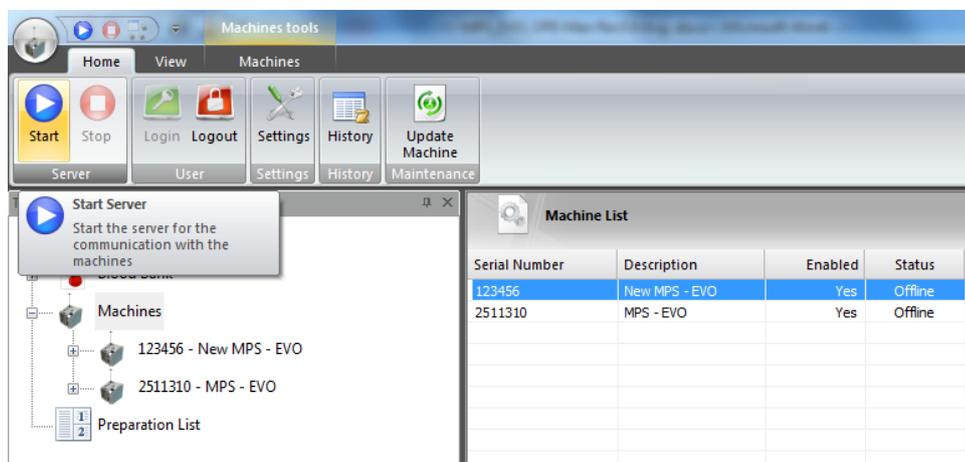
Take care that the DMS Plus software has to be already set for RS485 connection.

Temporary Conversion

- a. Switch ON the machine and wait for the end of start-up to see the main menu,
- b. By the display Menu *Tech.Serv.* → *Diagnostic*, (factory pwd is 000000) select the sub menu “*Set temporarily the RS485 network*”, press ENTER and then back to the Main Menu. Now the machine communicates via serial RS485. The ETHERNET or Wi-Fi is temporary disabled.
- c. Connect the machine via proper serial cable (9MPS070) and Net Adapter (9MPS311) to the computer where the DMS Plus software has been installed.
- d. If necessary, add the machine to the *Machine List*. From left tree select *Machine* and from the Ribbon button click on *New* to enter the serial number of new machine (can be found on the back label of the machine) and a description (if necessary).



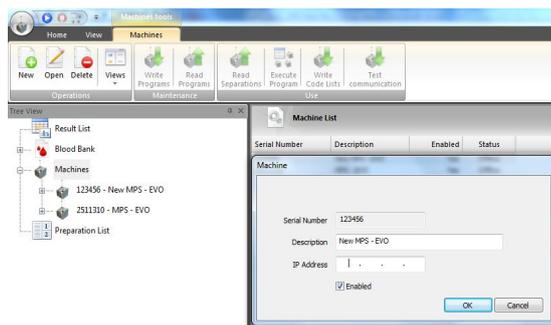
- e. Only now from the DMS Plus start the communication server by clicking on *Home* ->*Start*.



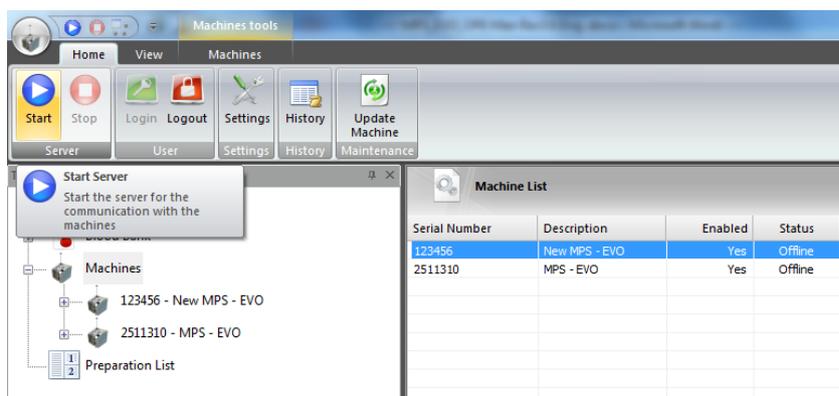
- f. Once you switch OFF and then ON again the machine, it will return back to communicate as before and hence as ETHERNET or Wi-Fi depending by the version.

Permanent Conversion

- Switch ON the machine and wait for the end of start-up to see the main menu,
- By the display Menu *Tech.Serv.* → *Diagnostic*, (*factory pwd is 000000*) select the sub menu “*Set temporarily the RS485 network*”, press ENTER and then back to the Main Menu. Now the machine communicates via serial RS485. The ETHERNET or Wi-Fi is temporary disabled.
- Connect the machine by proper serial cable (9MPS070) and Net Adapter (9MPS311) to the computer where the DMS Plus software has been installed.
- If necessary, add the machine to the *Machine List*. From left tree select *Machine* and from the Ribbon button click on *New* to enter the serial number of new machine (can be found on the back label of the machine) and a description (if necessary).



- e. From the DMS Plus start the communication server by clicking on *Home* → *Start*.



- f. From left tree select *Machine* and click on the serial number of the machine to configure. Click again on top “*Read Machine Head*”. (See User Manual of DMS Plus for more details about the software).
- g. On the right window select *Specialist* and modify the *Network Type* from Ethernet or Wi-Fi to RS485.
- h. Save the new value inside the DMS Plus software by clicking on the top Ribbon button “*SAVE*”.
- i. To transfer the new setting from DMS Plus to the machine, click on the top Ribbon button “*Write Machine Head*”.
- j. Now this machine is permanently configured to communicate via RS485. At any time, by re-configuring the Machine Head is possible to enable back either the Wi-Fi or ETHERNET network.

NOTES:

- I. To activate the communication among the software DMS Plus and the machine/s, all must have same network type and same IP addresses (if applicable): for the machine it must be entered from *Machine* → *Head* → *Specialist* while for the DMS Plus software, it can be set from *Home* → *Settings* → *General* → *Network Type*.
- II. The IP addresses written inside the *Machine Head* of DMS Plus must be transferred to the ETHERNET or Wi-Fi modules of the machine. To do that, switch ON the machine holding the key ENTER pressed until the clamp start-up end and hence, switch OFF the machine and then ON again until the Main menu appears. In this way the new IP settings inside the Machine Head are transferred to the net module that becomes active to communicate. Until this operation is not executed, the net module still continues to communicate using the old IP address.

OPTIONAL ACCESSORIES

Cod. 9MPS040

External tray scale. It is connected directly to the MPS EVO via cable. It can be used to read the weight of any bag, before, during or after the separation.



Cod. 9MPS050

Additional handy sealer. Supplied with 2 m cable is connected to the auxiliary RF port of MPS EVO. It permits manual sealing of any blood bag's tubing.

It can be purchased and added at any time.



Cod. 9MPS060

CCD barcode reader. It can be purchased and added at any time.

OR

Cod. 9MPS060L

LASER barcode reader. It can be purchased and added at any time.



Cod. 9MPS080

CCD COMBO reader for barcode and writers/readers for Tags RFID fulfilling the ISO15693 and 18000-3 Standards.

It can be purchased and added at any time.

OR

Cod. 9MPS080L

LASER COMBO reader for barcode and writers/readers for Tags RFID fulfilling the ISO15693 and 18000-3 Standards.

It can be purchased and added at any time.



Cod. STR.DB.00

Manual tube stripper with s.s. wheels with adjustable distance.



Cod. 9MPS090

Thermal printer for adhesive labels. It permits the preparation of labels to stick on the bags with some reference data such as i.e.: weight of the blood product, ID Donation, Product's type and much more.

The printer must be connected to same computer where the DMS Plus software is installed.



WiFi NET ACCESSORIES

Cod. 9MPSWIFI_AP

WiFi access point. Access point already configured and ready to be connected to the Ethernet card of a computer. It is necessary to let the machines working on WiFi Network. It can be purchased and added at any time.

LAN NET ACCESSORIES

Cod. 9MPSHUB_PC

PC HUB16 in. This Hub/Switch is used to connect MPS EVO to the Ethernet card of a computer. It is necessary to let the machines working on Ethernet Network.

Cod. 9MPSLAN_CAB

Ethernet cable. Cable to connect MPS EVO to the PC HUB.

It can be purchased and added at any time.

RS485 ACCESSORIES

Cod. 9MPS311

Net adapter. This device is used to connect MPS EVO to the computer to let the machines working on RS485 network.

It can be purchased and added at any time.



Cod. 9MPS070

RS485 cable. Cable to connect MPS EVO to MPS EVO and MPSEVO to NET ADAPTER.

It can be purchased and added at any time

Accessories images are shown for illustration purposes only. The Company reserves the right to change accessories at any time without notice.