i-SEP

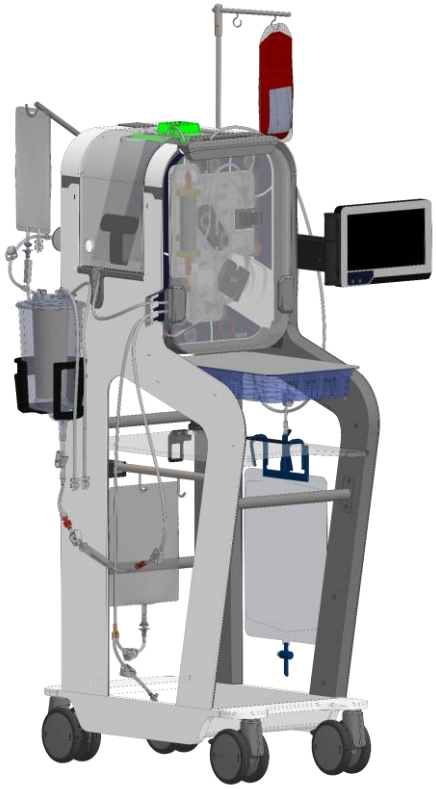
Innovative solutions
& efficiency for the patient

INSTRUCTIONS FOR USE

D-PRO-021

same™ Autotransfusion System by i-SEP

Reference: DS1000



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Smart autotransfusion
for me

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1. GENERAL INFORMATION

i- SEP Autotransfusion System – EN – English

Reference: DS1000

2. IMPORTANT INFORMATION

2.1. INFORMATION FOR THE CUSTOMER

The contents of the Instructions For Use leaflet are copyrighted and owned by i-SEP. Any information or description contained in these instructions may not be reproduced and disseminated to the general public or stored in a database or used in conjunction with professional education without the written consent of i-SEP.

2.2. SAFETY INFORMATION

This Instructions For Use leaflet is intended to be used as a guide for the correct use of the i-SEP Autotransfusion System (ATS) provided by i-SEP. The i-SEP ATS is comprised of reusable equipment also called an Autotransfusion machine (or Device), and Device accessories. This leaflet must be read carefully before using the i-SEP ATS for the first time. This notice is part of the accompanying documents and is therefore an integral part of the ATS. It provides the user with all the information necessary to safely perform the procedures associated with the use of the ATS. The accessories are accompanied by their Instructions For Use. The Instructions For Use leaflet for the Autotransfusion System contains the procedures associated with the accessories that are needed to operate the reusable equipment on the ATS. To read about the specific properties of the accessories (technical descriptions, etc.), please refer to the Instructions For Use for the accessories.

i-SEP guarantees its products when they are used correctly by a properly informed user. Failure to follow the procedures described could result in impaired equipment function, as well as injury to the user and/or patient. When properly assembled, maintained and correctly operated, the i-SEP Autotransfusion System can safely and adequately perform blood loss salvage and treatment functions.

i-SEP accepts no responsibility for problems resulting from failure to follow the instructions and requirements described by the company. Any modifications deemed necessary by the customer must be evaluated by i-SEP.

The safe use of all i-SEP devices requires the user to correctly handle and dispose of blood-contaminated parts. All users of the i-SEP device must fully understand and implement the local policies and procedures for blood-contaminated devices and blood products in each facility where i-SEP products are used.

It is the sole responsibility of the customer to evaluate and ensure the safety of all products obtained from i-SEP's prescription procedures prior to any further application or use. i-SEP accepts no responsibility for the choices made by the user regarding the use of these products and by-products.

Please contact i-SEP for more information and/or complaints see Chapter 2.8). Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the competent authorities of the Member State in which the user and/or the patient are established.

2.3. BRIEF DESCRIPTION

2.3.1. Overview

The i-SEP AutoTransfusion System (ATS) has been designed for intraoperative autotransfusion. The i-SEP ATS is comparable to autologous transfusion systems widely used in operating rooms for decades. i-SEP integrates the blood cell separation technology based on the filtration technique in its autotransfusion system.

The i-SEP ATS is an intraoperative autotransfusion system for salvaging and treating blood loss occurring during surgery or trauma. The i-SEP ATS is a system comprised of a reusable Autotransfusion Device controlled by a computer software, and either sterile or non-sterile reusable or single-use accessories. The system is used to collect autologous blood intraoperatively in a sterile Blood Collection Reservoir (BCR) with an appropriate amount of anticoagulant. This autologous blood is then treated to concentrate and wash out the formed elements of the blood. Contaminants present in the plasma are removed by introducing Washing Solution. The resulting concentrated cells, suspended in physiological saline solution, are transferred into a Reinfusion Bag and can be reinfused into the patient.

2.3.2. Advantages of autotransfusion over allogeneic transfusions

The term ‘autologous transfusion’ is used to describe a procedure in which the same donor or patient is reinfused with blood that has been previously collected or salvaged. Autologous blood can be obtained by the following methods:

- General blood donation;
- Blood salvage during and/or after the procedure;
- Perioperative normovolemic haemodilution (blood sample immediately before surgery and volume replacement with washing solutions) and subsequent reinfusion of the blood sample.

The term allogeneic blood defines blood or blood products for which the donor and recipient are not the same person.

Given the concern over blood-related diseases, an increasing number of doctors and patients are focusing on the risks of allogeneic transfusion, which has resulted in greater interest in autotransfusion. The advantages of autotransfusion are widely described in the literature and can be considered as commonly accepted.
The main advantages include:

- No risk of disease transmission;
- No transfusion reactions;
- No immunosuppression or immunisation phenomena;
- No blood typing or matching required;
- Possible acceptance by patients who refuse allogeneic blood transfusions for religious reasons (Jehovah's Witnesses);
- Reduces demand at blood bank inventories.

The intraoperative autotransfusion method has the following advantages:

- Immediate available at the time of blood loss and in an emergency;
- Excellent quality of the blood cell concentrates.

2.3.3. Historical overview

Allogeneic transfusion was introduced in the early 1800s by Blundell, under the hypothesis that he could have saved a woman's life had he been able to transfuse her blood during a post-partum haemorrhage. In the years that followed, the first cases of successful autologous transfusions were reported in obstetrics, hip surgery or general surgery (systemic intoxication, gangrene due to frostbite, etc.). The treatment of blood was described in 1883 as removing one half litre of blood, removing fibrin from the blood, applying power, and then reinfusing the patient with approximately one quarter litre of their own blood. In the early 1900s, this practice ranged from rare case reports to larger cohorts. Cases have been reported during surgery for ectopic pregnancies, splenectomies, liver lacerations, haemothorax and intracranial operations in Europe, the United States and Australia. Blood was treated prior to reinfusion by adding citrate and filtering through gauze.

Major progress was made in blood donations and storage in the late 1930s and 1940s and blood banks were more widespread, relegating autotransfusion to a secondary level behind allogeneic transfusion. Dyer, Klebanoff and Pathak made significant progress in the development of techniques and devices to facilitate the transfusion of unwashed salvaged blood. These researchers provided a lot of data on clinical outcomes, contaminant filtration and reduced haemolysis. The first device widely used for intraoperative autotransfusion was the Bentley ATS-100 (Bentley Laboratories, Santa Ana, California, USA). It was basically a modified Bentley cardiotomy reservoir and consisted of an aspiration unit activated by a peristaltic pump, a reservoir with a filter and a dispensing end connected directly to the patient or to a storage bag. The technology was further developed in the 1970s with several practical devices becoming available on the market during this decade, when the risk of viral hepatitis via allogeneic transfusion reached 10%.

Simultaneously, apheresis and dialysis technologies were developed using blood filtration devices to preserve cellular elements in particular and to remove contaminants in cases of renal failure, for example. The tangential blood filtration technology has been used for many years.

Blood management has been cited as one of the ten major advances in transfusion medicine over the past 50 years. It has been defined as ‘the appropriate use of blood and blood components with the aim of minimising their use’. Patient blood management has been recognised by the World Health Organization as a way to ‘promote the availability of alternatives to transfusions.’ By minimising blood loss, blood salvaging using autotransfusion systems is one alternative to allogeneic blood and one of the pillars of patient blood management during the peri-surgical period.
i-SEP has registered its ATS as one method for managing patients' blood.

2.3.4. Schematic principle of operation

Intraoperative autotransfusion with the i-SEP Autotransfusion System basically takes place under normal conditions as per the following diagram.

- Blood collection

Salvaged blood is aspirated and mixed with an anticoagulant from the operative field via an i-SEP Aspiration and Anticoagulation Line and transferred to an i-SEP Blood Collection Reservoir (BCR) connected to a Vacuum Generation system (integrated within the Autotransfusion Device). In this BCR containing a filter with a filtration threshold of 40 microns, a first filtration is performed via mechanical retention of the coarse surgical debris.

- Blood treatment

The blood is then treated by the Autotransfusion Device combined with an i-SEP Autotransfusion Treatment Set. i-SEP offers two Autotransfusion Treatment Sets, suitable for the blood volumes to be treated per cycle. With each treatment cycle, the volume of anticoagulated blood salvaged is transferred from the BCR into the Set's treatment circuit. The salvaged blood is washed with a sterile washing solution and concentrated until the blood has a sufficient haematocrit level and until the contaminants in the blood are effectively removed by the washing step. At the same time as the cells are concentrated, and contaminants found in the plasma solution diluted with the washing solution are disposed of in the Waste Bag. When the concentration specifications are reached with the associated specified washing levels, circulation within the treatment circuit stops. The cell concentrate is transferred into the Reinfusion Bag for the Autotransfusion Treatment Set.
These main actions make up one cycle, which itself is made up of various sub-steps.

- Reinfusion

Once the reinfusion product is available, as soon as the user decides and within 6 hours of starting blood collection, the Reinfusion Bag must be disconnected from the Autotransfusion Treatment Set, hung from an independent infusion pole (reinfusion bag bracket) on the Autotransfusion ATS, and the cell concentrate can be reinfused into the same patient using a reinfusion set containing a filtration unit (set not provided by i-SEP).

- Multiple cycles

Collection, processing and reinfusion may be repeated several times depending on the volumes of blood lost by the patient during surgery.

The following figure provides a diagram that shows the principle of the i-SEP Autotransfusion System (ATS).

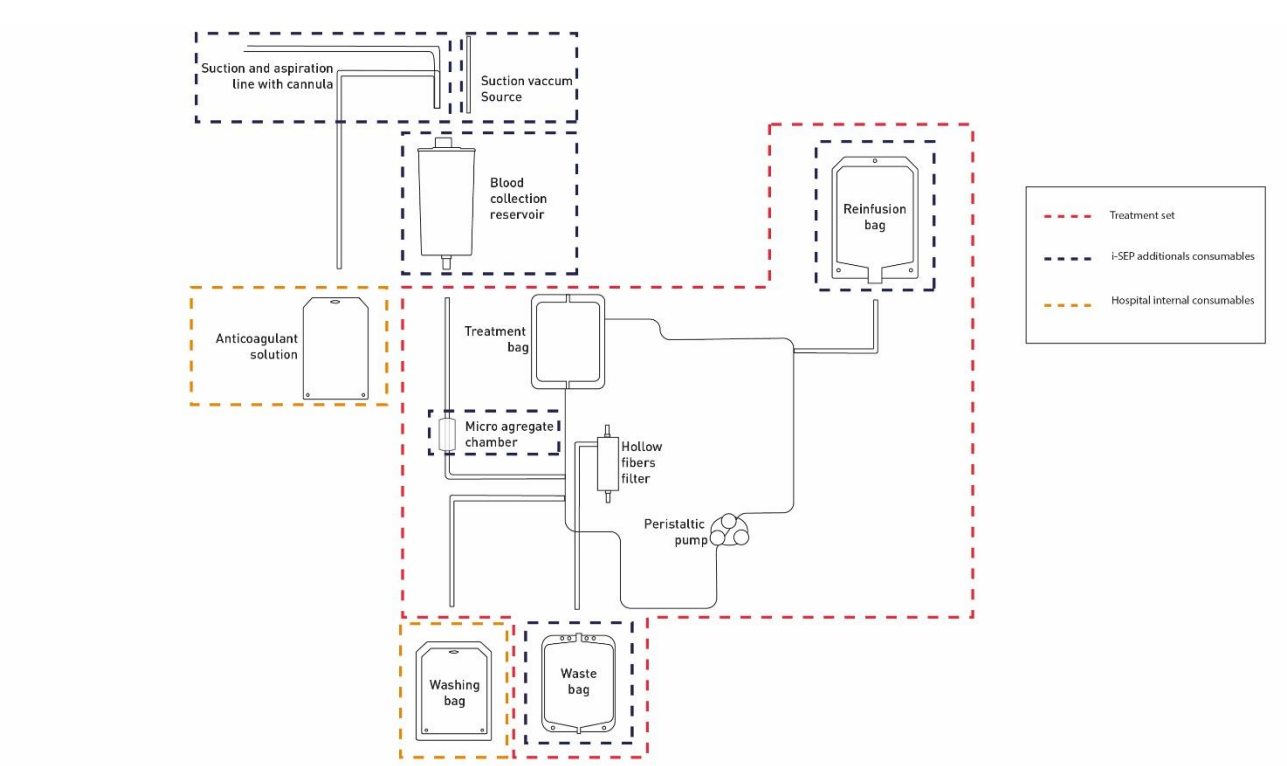

Figure 1: Schematic principle of the i-SEP Autotransfusion System

2.3.5. Tangential flow filtration

Concentration via a filtration membrane is a simple process that involves removing liquid from a solution while retaining non-permeable particles. The porosity of the filtration system of the i-SEP Autotransfusion Treatment Set results in

microfiltration of the blood. The tangential flow filtration (TFF) process is carried out through a hollow fibre cartridge. The incoming flow passes parallel to the front side of the membrane, one part passes through the membrane (permeate) while the rest (concentrate or retentate) is recirculated in the Treatment Bag.

In practice, the Treatment Set containing a hollow fibre filter cartridge is installed and the system is initialised by priming the fibres with the incoming physiological saline solution. A tangential flow is established by putting an incoming fluid flow parallel to the filtration membrane. The concentrate circulates through the treatment loop and the permeate is disposed of via the Waste Line. When the desired red blood cell concentration is reached, the process is stopped, ensuring appropriate anticoagulant and free haemoglobin washing rates. As a result, blood cells are concentrated while contaminants are removed by a succession of washing and concentrating steps. The following figure schematically represents the principle of tangential filtration during autologous blood filtration.
All Autotransfusion Treatment Set references are based on the same technical features of microfiltration.

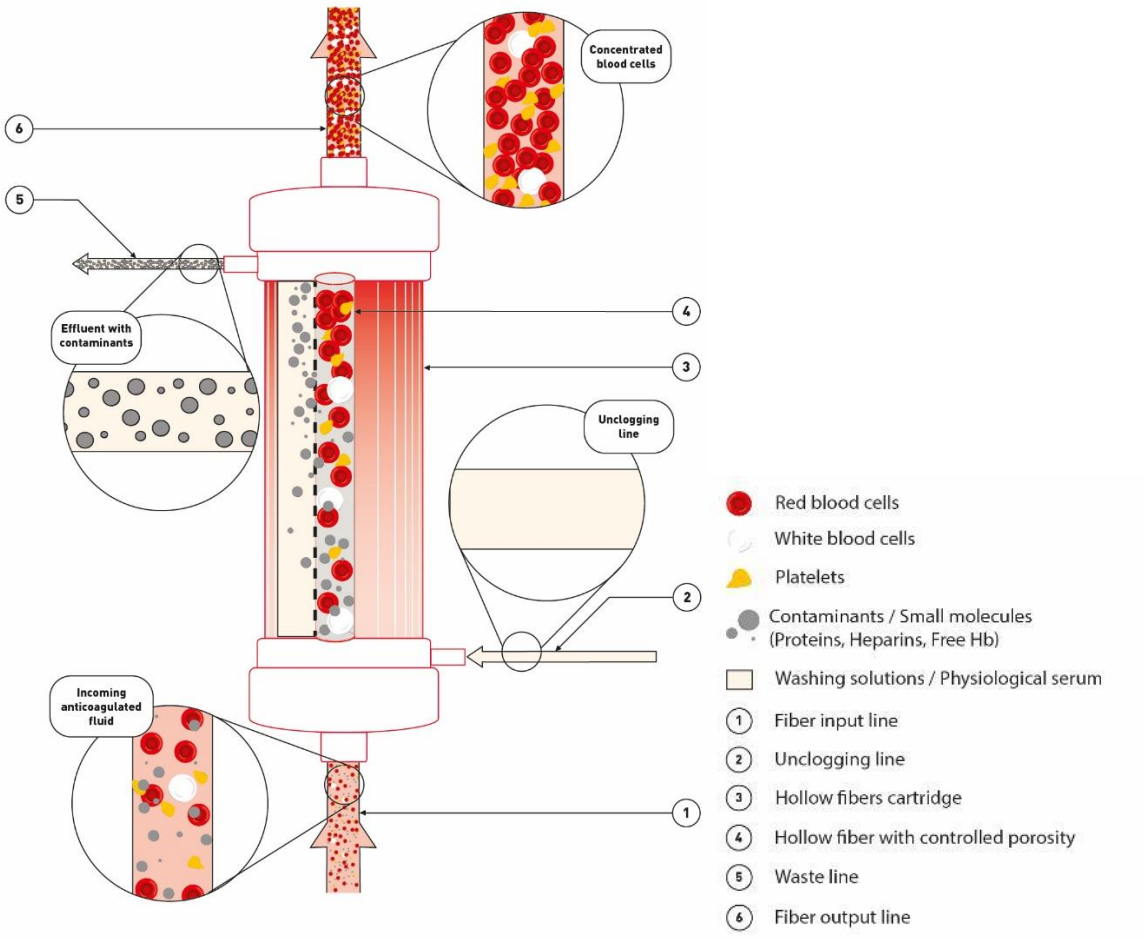

Figure 2: Principle of tangential filtration in the I-SEP ATS

2.4. USE OF THE I-SEP AUTOTRANSFUSION SYSTEM

2.4.1. Intended use

The i-SEP ATS is intended for use in the intraoperative phase to collect and treat blood loss. The concentrated and washed autologous blood product can be reinfused into the same patient.

The i-SEP ATS is designed to operate for 10 years based on 2 uses lasting 6 hours each per day, 350 days per year. Between 2 uses, it is necessary to clean the machine as well as exchange the treatment set.

The machine is designed to be positioned outside the sterile area. Only the XJ-13-05 aspiration line enters into the sterile field (See Figure 3).

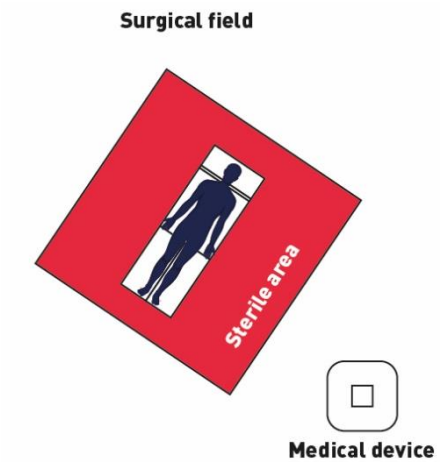

Figure 3: Positioning of the machine (medical device) in the operating room

2.4.2. Fields of application/indications for use

Use of the autotransfusion process is recommended in the following fields of application:

- Cardiac/thoracic surgery;
- Vascular surgery;
- Orthopaedic surgery;
- Obstetric surgery;
- Gynaecology;
- Liver transplant;
- Urology;
- Selected neurosurgical procedures.

The use of the i-SEP ATS should be assessed during each surgical procedure to allow for intraoperative blood salvage from a clean wound, at a salvage rate that allows for aspiration without excessive haemolysis.
At least one of the following criteria may indicate that it would be appropriate to use the i-SEP ATS:

- The expected blood loss is 15% or more of the patient's estimated blood volume;
- Rare blood groups;
- The average transfusion rate for the type of procedure exceeds one unit of blood;
- More than 10% of the patients operated for the procedure require transfusion (intraoperative and postoperative losses).

The Autotransfusion Treatment Set being designed for low volume batches is adapted for every type of low volume blood loss situation. Use of this Autotransfusion Treatment Set would allow blood to be available after small blood losses for an earlier reinfusion to the patient.

2.4.3. Clinical benefits

The anticipated clinical benefits following the use of ATS i-SEP device are related to those associated with autotransfusion:
- the reduction of exposure to allogeneic transfusions. Although the transfusion of allogeneic Red Blood Cells represents one of the most frequently performed medical procedures in hospitalized patients, it is still associated with various side effects such as immune modification, infection or transfusion-associated lung injury (TRALI) and some co-morbidities such as increase of intubation and length of stay in ICU in cardiac surgery. The reduction of exposure to allogeneic transfusion (or allogenic) will thus decrease the apparition of the side effects.
- the fact that the blood to be reinfused is immediately available. The immediate availability of the blood makes surgery simpler and can lead to a reduction in anesthesia time since the logistical constraints of allogeneic blood products are eliminated. The patient therefore benefits from an anesthesia time reduced to what is strictly necessary and therefore from optimal postoperative recovery.

2.4.4. Possible contraindications to Autotransfusion

The risk/benefit ratio of intraoperative blood salvage must be determined on an individual basis by the anaesthetists, surgeons, and transfusion medicine specialists involved in the patient's care.

For example, the use of blood cell concentrate from Autotransfusion Systems must be contraindicated in cases of sepsis or treatment of malignant tumours.

Autotransfusion is contraindicated if the blood is contaminated with Betadine®, benzalkonium chloride, hydrogen peroxide, distilled water, water, alcohol, topical antibiotics, fibrin adhesives, haemostatic agents (Avitene, Gelfoam, other collagen derivatives), thrombin for intravenous administration, methyl methacrylate.

Autotransfusion is contraindicated in cases of suspected sepsis and in cases of contamination with meconium, urine, prostatic fluid, faeces, and the contents of gastric, hepatic, biliary, or amniotic intestinal fluid.

2.4.5. Adverse effects

Complications, i.e. morbidity and mortality in autotransfusion, as in allogeneic transfusions, are associated with the reinfusion of large volumes of blood, i.e. significant administration of anticoagulants and haemolysis. These complications include excessive free haemoglobin, haemoglobinuria, haematuria, gas embolism, sepsis, and pulmonary complications.

2.4.6. Warnings and precautions

Warnings and precautions are provided for various potential risks.

2.4.6.1. General warnings and precautions

- It is forbidden to modify the Autotransfusion System
- The user must read the i-SEP Autotransfusion System's Instructions For Use It is important that the user understands the Instructions For Use and understands the principles of operation for the i-SEP Autotransfusion System before initiating the clinical procedure. Although information is displayed on the screen, it is still mandatory for users to read the Instructions For Use leaflet. The user must read the Instructions For Use leaflets for the i-SEP Autotransfusion System accessories and use the devices in compliance with these instructions.
- This device is intended for use by qualified and informed personnel, namely anesthesiologists/anesthetists or nurses. A qualified and informed anesthesiologist/anesthetist or nurse is an anesthesiologist/anesthetist or nurse who is able to use the device in compliance with the Instructions For Use given in this document.
- Devices must be thoroughly checked after installation. After installation, transport and handling may cause structural and functional damage to the products.
- Before using the i-SEP ATS for the first time, electrical and operational checks must be carried out as per the hospital's protocols and the manufacturer's recommendations.
- Disconnect the i-SEP ATS from the power source before proceeding with cleaning and maintenance.
- Do not use the i-SEP ATS in the presence of flammable agents as this may result in an explosion or fire.
- Even though the machine has alarms, it is still mandatory for users to carefully monitor the system while in operation. If a treatment is unmonitored, this may lead to problems with the operation of the system and/or may have an impact on the quality of the final product.
- Do not touch any moving part such as the pump or the electroclamps. Injuries may occur.
- The physician must consider the information provided by the i-SEP ATS device as indicative. This information must not be used as the sole basis for medical treatment. Specifically, the i-SEP ATS comes with a detector that measures the blood concentration in the liquid entering into the device and that leaving the Treatment Set. This system is primarily indicated to provide users with the blood concentration trend, it is recommended that alternative ways to take blood concentration (haematocrit) measurements be used when it is necessary to evaluate the final haematocrit concentration in the Reinfusion Bag. Similarly, the volumes displayed on the screen are given as an indication.
- Numerous software features integrated in the i-SEP ATS monitor the treatment, particularly blood concentration readings. As for any measurement system, errors may occur and the results obtained may be questioned. In the event that the user of this equipment questions the accuracy of the blood concentration reading, it is recommended to use another method to measure the blood concentration (haematocrit). The same applies to the Waste Line volume and colour control functions.
- If the patient's volume, blood concentration and colour values in the Waste Line are high, it will be necessary to use other standard hospital measuring instruments.
- i-SEP cannot be held responsible for problems arising from inexperienced or inappropriate use.
- For a complete description of how to use the Treatment Sets, refer to the i-SEP Treatment Set user manual (i-SEP document: D-PRO-022).
- Only the single-use i-SEP devices and accessories sterilised by i-SEP are approved for use with the i-SEP Autotransfusion System. The use of single-use and disposable devices from other manufacturers instead of devices and accessories recommended by i-SEP may put the patient at risk.
- The user must follow the labelling information on the packaging and products.
- Due to the presence of phthalates (DEHP), use of this device on children and pregnant or breastfeeding women is restricted. In addition, due to the presence of heparin, it is recommended not to use this product on children under three years of age, although children are not part of the target population.
- The safe operation of all intraoperative blood salvage equipment requires the presence of a dedicated user. Never leave the machine unattended during operation as irreparable damage to the blood may occur. It is the

responsibility of the hospital to ensure that the persons assigned to this task have received appropriate information in the operation of the i-SEP Autotransfusion System and its accessories and are alerted to potential problems.

- The collection of salvaged blood must not be carried out if the blood is contaminated by locally applied drugs or solutions (such as Betadine®, benzalkonium chloride, hydrogen peroxide, distilled water, water, alcohol, topical antibiotics) or by haemostatic agents (such as Avitene, Gelfoam, other collagen derivatives, other haemostatic products such as Horsley's wax), or when using biological (thrombin or fibrin-based) or chemical adhesives, thrombin for intravenous administration, or resin or cement (such as methyl methacrylate).
- A second aspiration line without blood collection must be used to remove any items incompatible with IOS (Intraoperative Blood Salvage) (listed above), debris that could clog the i-SEP ATS, washing fluids, or fumes.
- If the integrated vacuum pump malfunctions, it is possible to use an alternative vacuum source such as, for example, the vacuum source present in the operating room, connected to a vacuum regulator if possible.
- Immediately report any of the following to the personnel in the responsible department: Do not use the i-SEP ATS until corrective measures have been taken:
    a. Damaged or worn out power cord, plug or socket;
    b. Loosened power switches or which do not work with positive action;
    c. A machine that has sustained substantial physical damage;
    d. A machine that has given anyone an electric shock while in use;
    e. A machine that appears to be overheating.
- If any change has been made to the audio signal output, it may take longer for users to realise that the equipment has sounded an alarm.
- Do not use the dedicated autotransfusion blood collection Aspiration Line in order to remove bone fragments, bone marrow, tissue fragments, etc. Use this line to collect as much blood as possible.
- It is the responsibility of the user to deactivate the 'Reinfusion Bag Full' and/or 'Waste Bag Full' alarms, who must also directly check the filling level of these bags.
- If the Reinfusion Bag, Micro-aggregates Chamber and/or Waste Bag are changed, check that the new bags are connected correctly and that the manual clamps are opened again before restarting the treatment so that the Treatment Set does not leak or break (i.e. resulting in blood loss).
- Do not put anything on the machine or on moving parts when the equipment is turned on. Sensitive parts containing load cells needed for the proper functioning of the device may be affected and the treatment could be less effective or even stopped.
- Do not aspirate surgical smoke with the ATS. This decreases the aspiration flow rate.
- Follow the maximum load indications shown on the ATS.
- Do not look directly at the beam of the bar code reader.
- In the event of a machine error, blood not present in the Reinfusion Bag cannot be reinfused without treatment.

2.4.6.2. Infection, risk of disease transmission

- Processed blood may be contaminated with transmissible infectious agents and must always be considered potentially contaminated. Treat all blood and liquids using universal precautions against blood-borne pathogens.
- i-SEP ATS devices and accessories in direct contact with blood must be used within 6 hours of starting blood collection (recommendations of the health authorities including HAS). The blood, which was salvaged intraoperatively then treated, expires 4 hours after the end of the treatment when stored at room temperature (recommendation of the AABB, the American Association of Blood Banks). Bacterial contamination by germs in the air is always possible.
- After use, dispose of the Treatment Set and accessories as per the applicable regulations of the country where the device is being used.
- The sterile single-use devices for the ATS have been designed for single use only and are intended for one patient only. Do not treat the device further. **Do not reuse, reprocess, or resterilise these products.** Reuse, reprocessing, or resterilisation may compromise the structural integrity of the devices and/or create a risk of contamination, which could result in injury, illness, or death to the patient.
- If a single-use device contaminated with blood is to be returned to the company for examination, consult the medical device vigilance contact person and, *at a minimum,* carefully wrap the device in a sealed plastic bag surrounded by absorbent material.
- It is the responsibility of the healthcare facility to prepare and properly identify the product for return. Do not return products that have been exposed to blood-borne infectious diseases.
- Change the Vacuum Line and Antibacterial Filter on the vacuum regulator each time you use the ATS.
- Autotransfusion is contraindicated in cases of suspected sepsis and in cases of contamination with meconium, urine, prostatic fluid, faeces, and the contents of gastric, hepatic, biliary, or amniotic intestinal fluid.
- The system must be carefully observed for leaks before and during use. Leakage can lead to a loss of sterility or blood loss. If a leak is observed before or during use, replace or tighten the connection at the leak if possible. If this is not possible, change the consumable.
- Install the consumable aseptically.
- Wear PPE for the handling of the treatment set and accessories

2.4.6.3. Coagulation disorders

- Collagen-based haemostatic agents must not be used in combination with an autotransfusion system in general. If they are present, temporarily stop intraoperative blood salvage during the use of the agent. After allowing time for the agent to initiate haemostasis in the wound, irrigate the area thoroughly with saline solution and aspirate into non-autotransfusion collection containers before continuing to collect autologous blood for autotransfusion. If the area is not rinsed thoroughly, the haemostatic agent may be drawn into the salvaged blood. This could lead to clotting of the salvaged blood and possible complications of disseminated intravascular coagulopathy in the patient.
- The patient's blood must be anticoagulated, either systemically or regionally, before it is introduced into the i-SEP ATS. Non-anticoagulated or insufficiently anticoagulated blood can cause clots to form in the collection system and in the Autotransfusion Treatment Set. Clots in the salvaged blood can block the system. Such coagulation makes the final blood product unsuitable for reinfusion. Check the Blood Collection Reservoir (outside the filter) for clots and, if necessary, homogenise the BCR and/or add a dose of anticoagulant.
- The recommended anticoagulant solution is 25,000 to 30,000 units of heparin in 1 litre of sterile isotonic saline (NaCl 0.9%). The drip rate must be adjusted during the procedure at a rate of 2 drops per second depending on the blood flow being processed.
- Heparin is a prescription drug. The responsibility for the use of this medication when using the i-SEP Autotransfusion System lies solely with the responsible physician.
- Citrate (ACD-A or CPD 3% to 4% sodium citrate) can also be used as an anticoagulant solution, particularly in cases of known or suspected heparin-induced thrombocytopenia (HIT). The citrate solution to blood volume must be between 1: 5 and 1:10, or approximately 70 ml of citrate per 500 ml of salvaged blood. However, incompatible fluids for IV injection such as heparin or Ringer's solution must not be used in association with citrate, as they may cause coagulation in the system.
- The anticoagulant solution must be added to a physiological saline solution suitable for intravenous use. Sterile water or another irrigation solution must not be used.
- It is possible that insufficient washing of the salvaged blood may result in insufficient removal of the anticoagulant and/or the development of coagulopathies on return of the blood product to the patient. As a result, it is important to carefully monitor the patient's coagulation status to prevent complications.
- Washed and concentrated blood no longer contains coagulation factors. Patients must be monitored for coagulation abnormalities associated with reinfusion of large volumes of processed blood. Practitioners must be prepared to implement appropriate treatments.

2.4.6.4. Creation of haemolysis on collection and during processing

- The quality of the washed blood concentrate is directly related to the quality of the blood salvaged from the patient. The quality of the blood collected depends on the type of procedure and is mainly dependent on the aspiration technique and the vacuum used. The vacuum must be kept as low as possible and must not exceed typical values of -150 mbar (-112 mmHg). The user must be aware that a vacuum force greater than -200 mbar (-150 mmHg) can cause haemolysis.
- Avoid aspiration of blood from the operating field and widely removed blood that may be subject to haemolysis. Use an aspiration cannula of appropriate diameter to limit haemolysis during aspiration.
- The use of vacuum source connection and control systems by other manufacturers may increase haemolysis.
- Only use NaCl 0.9% as a washing solution. Do not use hyper- or hypotonic washing solutions, because they can cause haemolysis.
- Carefully inspect all the tubing to ensure that it is not twisted or bent. Circulating blood in the presence of severe flow restriction is likely to result in high levels of haemolysis with high levels of free plasma haemoglobin. Severe flow restriction on the washing lines could lead to reduced washing efficiency. If in doubt, change the Treatment Set.
- If, during a procedure, it is discovered that any equipment in the vicinity of the blood has overheated, the processed blood cell concentrates must be considered unsuitable for reinfusion.
- Do not use a warm solution as high heat can destroy the blood cells.
- To avoid overheating the system, which could result in haemolysis, do not use the i-SEP Autotransfusion System at temperatures above the recommended operational temperatures (see 7.6.10).
- Avoid any situation that may cause the blood temperature to rise above 37°C.

2.4.6.5. Reinfusion: gas embolism, poor blood quality

- Check that each of the Luer connections is fully tightened all throughout the installation process in order to ensure that there is no loss of sterility
- Do not reinfuse the blood cell concentrate while the processed blood is being transferred into the Reinfusion Bag. The Reinfusion Bag must be disconnected from the i-SEP Autotransfusion Treatment Set prior to reinfusion. The i-SEP Autotransfusion System is not equipped with a system for preventing dosing errors or air infusion. According to the applicable medical device classification, the Autotransfusion System is not intended to be used while directly connected to the patient.

- The Reinfusion Bag has ports for punchers that can be used to connect a transfusion set with an integrated filter (not supplied by i-SEP).
- i-SEP recommends the use of a blood transfusion filter between the Reinfusion Bag and the patient in accordance with current standards (“Perioperative blood components intended for reinfusion shall be reinfused through a filter designed to retain particles that are potentially harmful to the patient - AABB”).
- Prior to reinfusion, connect a transfusion set with an integrated filter (not supplied by i-SEP) to the Reinfusion Bag. Always check that the transfusion set and its integrated filter are filled with blood and are free of air to limit the risk of gas embolism.
- Remove any air from the Reinfusion Bag before administering the contents.
- DO NOT USE A PRESSURE CUFF OR OTHER MECHANICAL DEVICE WITH THE i-SEP AUTOTRANSFUSION SYSTEM. PRESSURE REINFUSION MAY LEAD TO FATAL PERFUSION OF AIR INTO THE PATIENT and the creation of free haemoglobin.
- The blood product is reinfused by gravity.
- If the tubing of the transfusion set contains air, it must be changed before continuing the reinfusion process.
- The blood product containing washed concentrated blood cells contains only a small amount of coagulation factors. The amount of blood product reinfused must be monitored by the physician, and if necessary, the reinfusion procedure may be supplemented with a fresh plasma transfusion.
- Prior to reinfusion of concentrated blood products, the user must ensure that the concentrate is suitable for reinfusion. Diluted concentrates are the result of a system malfunction and may be accompanied by poor washing quality. If in doubt, check the quality of the concentrated blood products PRIOR TO reinfusion.
- The haematocrit monitoring function of the i-SEP Autotransfusion System device is only used to monitor the treatment for programme implementation purposes and is not intended for diagnostic or quality control purposes. The haematocrit values given by the ATS are not a substitute for checking the haematocrit level in the product before reinfusion into the patient. The sensors are not measuring instruments.
- Never reinfuse blood cell concentrate for which high haemolysis is suspected.

2.4.6.6. Electrical safety

- Given that the device is being used in a medical location, the recommendations for the installation of electrical equipment (IEC 60364-7-710) must be followed. All electrical installations must comply with local electrical standards and i-SEP specifications.
- The ATS must be used with the recommended voltage. This information can be found on the data plate for the ATS. Connection to other mains voltages can destroy the ATS or may result in a fire hazard.
- To operate correctly, only the i-SEP ATS alone must be connected to a mains socket protected by the correct fuse (16 A).
- Before turning on the ATS, allow the i-SEP ATS to stabilise at room temperature if it has been previously stored in an area at a temperature other than room temperature.
- Before connecting the equipment, make sure that the main socket is equipped with a ground connection. The equipment must be connected to the main socket which must be the same size as the socket on the equipment. Do not use an adapter.
- To rule out any potential risk of electric shock, the i-SEP ATS must be disconnected from all power sources prior to carrying out any repair or cleaning.
- When the i-SEP ATS is put into use for the first time, it must remain plugged in for 24 hours so that the battery charges correctly.
- Users must avoid touching the i-SEP Autotransfusion System with wet hands and must always work with clean, dry hands. Electrolyte solutions are highly conductive. If liquid is spilled on the i-SEP ATS during operation, immediately turn off the equipment and unplug it before drying the outside parts.
- Always unplug the power cord from the socket with your hands. Never pull on the cord to unplug the machine.
- Make sure that the tamper-proof device on the cable is engaged to ensure that the cable cannot be accidentally unplugged by mistake.
- The use of accessories and cables other than those supplied by i-SEP may increase emissions or decrease the resistance of the i-SEP ATS to emissions from other devices. In addition, the accessories and cables supplied by i-SEP must only be used with the i-SEP ATS. Use with other equipment or systems may increase emissions or decrease the resistance of these pieces of equipment or systems to emissions from other devices.
- The only way to simultaneously disconnect all the poles of the equipment from the mains power supply is to unplug the power cord from the socket. Position the i-SEP ATS so that it is possible to easily disconnect the power cord at the back of the ATS.
- Safety precautions must be taken to ensure that users or other persons do not come into contact with the rotating parts of the ATS. To prevent all risk of contact, a protection lid is installed and it is recommended to leave it closed throughout the treatment.
- THE SECURITY MECHANISMS ON THE ATS MUST NOT BE REMOVED, STOPPED OR DELETED.
- For technical safety reasons, the housings and covers on the ATS must not be removed so as to avoid electric shocks, except for maintenance purposes.
- Batterie replacement by untraining personnel can lead to hazard (excessive temperature, fire, explosion)

- Maintenance must only be carried out by qualified and authorised technical service personnel chosen by i-SEP.
- The housings and covers on the ATS should not be removed without first turning off the power and disconnecting the ATS from the power source.
- Never use the ATS after complete filling of the pressure gauge safety reservoir without completely emptying and cleaning this reservoir.

2.4.6.7. Environmental factors

- The i-SEP Autotransfusion System is intended to be used for autotransfusion in facilities providing patient care, such as operating rooms. This device is NOT intended for use in blood banks or apheresis centres or for use by the blood bank to handle, label, store, hold, or process blood for subsequent reinfusion into the same patient.
- The i-SEP ATS is not intended to be placed in the operating room in the sterile field surrounding the patient.
- Fire hazard! The i-SEP Autotransfusion System should never be used in the presence of flammable agents.
- The i-SEP ATS is not suitable for use in the presence of a flammable anaesthetic mixed with air or with nitrous oxide.
- The plastic materials used in the manufacture of the i-SEP Autotransfusion Treatment Set may be sensitive to chemicals (solvents and some detergents) and to all halogenated hydrocarbon anaesthetic agents (Isoflurane (Forane), Enflurane (Efrane or Ethrane), Halothane (Fluothane or Rhodialothan)). Direct contact must be avoided as these agents attack plastics and can cause them to fail or malfunction. Many plastics are damaged by various solvents, cleaning solutions, or other chemicals. Single-use devices and damaged consumables must not be used.
- The i-SEP Autotransfusion system is an electrical medical device that can be perturbated by electromagnetic interferences. The i-SEP ATS produces electromagnetic interferences. Use the i-SEP ATS in facilities providing patient care, such as operating rooms.

2.4.6.8. Transport-related risks

- To avoid injury to the face, always adjust the reinfusion pole to its lowest position while transporting the i-SEP ATS.
- To avoid potential damage during indoor transport, it is recommended to put the screen in the transport position (turned inwards).
- Do not move the ATS while it is in operation.
- Be sure to store the BCR holder inside the ATS.
- Take care not to move the i-SEP ATS via the support systems (infusion poles, bag stand or BCR stand). These parts are sensitive. Always move the i-SEP ATS using the front or rear handles provided for this purpose and in the direction indicated.
- To avoid potential damage during outdoor transport, use the original shipping packaging for the i-SEP Autotransfusion System.
- Never lay the i-SEP Autotransfusion System on its side as this could damage it.
- I-SEP products must be properly cleaned and packaged prior to their return. The customer must continue to reduce the potential serious health risk associated with the spread of infectious agents by being aware of the risks associated with the shipping, handling and testing of this material.

2.4.6.9. Risks of system failure

Blood spillage or leakage or treatment failure

- In the unlikely event of a power failure, battery power is available and a cycle in progress can be completed, however no new cycles can be started. The manual clamps on the accessories for the i-SEP Autotransfusion System must be closed after the treatment cycle is complete or within five minutes of a power failure if the treatment cycle has not yet started.
- Do not use consumables if they are cracked, dropped or physically damaged.
- Carefully observe the consumable for leaks before and during use. Leakage can lead to a loss of sterility or a loss of blood and/or liquid. If leakage is observed before or during use, replace the consumable device.
- The user must avoid blocking any Autotransfusion Treatment Set tubing carrying fluid to or from the pump. Restricted flow would result in increased pressure in this tube, which could cause major splashes of blood, a leak or disruption to and failure of the treatment process.
- Do not close the Waste Line clamp during a treatment cycle. This could lead to fluid dispersion and haemolysis. The i-SEP ATS does not prohibit changing a Waste Bag during treatment. To replace a full waste bag with another empty bag, use the ‘Change Waste Bag’ function. For detailed instructions, follow the procedures described in the Instructions For Use.
- A vacuum valve is provided to prevent the Blood Collection Reservoir from collapsing if it is exposed to an intense and sudden vacuum:
    - The negative pressure inside the Blood Collection Reservoir must not exceed 250 mmHg (300 mbar).
    - Check that the unused ports are tightly closed by correctly placing the caps in them by pushing down on them completely.

    - Do not block the open control valve on the Blood Collection Reservoir with foreign objects so as to avoid the risk of it collapsing.
- Given the possibility of exposure to blood (potentially contaminated with pathogens) for the user, handling precautions must be observed at all times to avoid such exposure and transmission of these pathogens.
- An adequate amount of processed and concentrated blood cannot always be provided and depends on the blood salvage procedure. Practitioners must be prepared to implement appropriate additional therapies, if necessary.
- The Waste Bag must not be compressed during treatment and must have enough room for it to be filled correctly. If the bag is compressed or cannot be filled correctly (e.g. If it is against a wall or another machine), the treatment may be altered.

Products with deficient or inferior quality compared to the standard mode

- i-SEP recommends that all autologous blood collected be washed prior to reinfusion. The standard mode of the i-SEP Autotransfusion System is designed to provide a safe, high-quality blood product.
- A correct process is not guaranteed if the whole process is not successfully completed.
- Use of the Emergency mode and the Forced Transfer function may result in limited washing of the blood and therefore anticoagulant and free haemoglobin, in particular, may be present in the blood available for reinfusion. It is the sole responsibility of the user to evaluate whether or not it is to the patient's benefit to use the Emergency mode and the Forced Transfer function.
- The Emergency mode places emphasis on a rapid execution rather than the quality of the final product, which is of lesser quality compared with what is guaranteed with the Standard mode. Therefore, its use is reserved for situations in which there is a desperate urgent need for blood compared with the concentration of the blood cells collected and the quality of the washing. It is the sole responsibility of the user to evaluate whether or not it is to the patient's benefit to use the Emergency mode.

Cleaning- and disinfection-related risks

- Use only specific detergents and disinfectants. Users should never use strong bleach directly on the ATS.
- Optical sensors must be clean and clear in order to function correctly. A dirty or obscured lens could interfere with the proper functioning of the sensor. An optical lens should always be thoroughly cleaned after a blood spill. **Never spray the optical sensors.**
- Carefully inspect the inside of the electroclamps before loading the Treatment Set lines and after having cleaned or disinfected the inside of the electroclamps. Material (e.g. gauze, protective material, etc.) must not be left behind inside the electroclamp, as this could inhibit the system's movements.
- The haematocrit reader and other optical sensors must not be scratched during cleaning. In order to ensure this, do not use abrasive materials or solvents which could damage the sensors.
- Do not try to rinse specific areas of the treatment unit directly with the liquid. Leaks could damage the ATS.

Equipment sensitivity

- Touch the screen only with your fingers (with or without gloves). Pointy objects can damage the screen.
- Before use, and especially after connecting the Treatment Set to the BCR, check that the i-SEP Blood Collection Reservoir is fully inserted into its housing on the Autotransfusion System stand. If it is not installed correctly, even the slightest accidental knock to the Collection Reservoir can cause it to detach from the holder.
- Handle the i-SEP Blood Collection Reservoir holder with care when handling the ATS, as the weight sensors are sensitive components.
- Handle the treatment bag holder with care during any handling, especially when installing the i-SEP Autotransfusion Treatment Set, as the weight sensors are sensitive components.
- Follow the positioning of the bags to be hung on the various holders. Specifically, do not hang the Anticoagulant Bag on the Washing Solution holder. Only the Washing Solution Bag should be placed on this stand. The Washing Solution monitoring alarms are monitored using this stand.
- Maintain the i-SEP ATS in good operating condition and calibrate it regularly as per the i-SEP recommendations.
- All manual clamps must be open and the tubing must not be kinked, bent, or flattened, in order to ensure accurate volume measurement and monitoring functions.
- Ensure the correct positioning of the tubing in the various sensors. Incorrect positioning could lead to an incorrect calibration of the system and therefore the production of blood with a lower quality.
- The i-SEP ATS must be immobilised with its brakes on level ground, free of any obstructive material prior to its use. The weight sensors are sensitive to the levelness of the operating surface.
- If the screen indicates incorrect or incomprehensible messages or messages other than those indicated in this manual, immediately stop using the equipment and contact i-SEP's technical department.
- If there is a problem opening the lid due to the opening lock being blocked do not try to force the lid to open. It may be possible to solve the problem by switching the equipment off and on again. If the problem persists, contact the authorised technical department.

2.4.6.10. Equipment installation

- The i-SEP ATS is electromedical equipment and precautions must be taken with regards to its electromagnetic compatibility (EMC).
- Prior to delivery, all of the components and equipment for the i-SEP ATS have successfully passed the quality control tests. Before each ATS is considered as an operational system, it must be checked by the user as per the following instructions: check upon delivery that the container has not been damaged. If there are signs of damage, immediately file a formal claim with the transport agents. Check the equipment carefully and make sure there are no missing parts, or visible signs of damage. If any problems are found, immediately report them be sending a detailed report listing all the problems either to the local representative or directly to i-SEP at the following address:

  i-SEP
  21 rue de la Noue Bras de Fer
  44200 NANTES, France
  maintenance@i-sep.com

2.5. CONSUMABLES

The i-SEP Autotransfusion System Device operates with the following consumables (See Table 1):

Reference	Description	Reference of the associated documentation	Description of the documentation
XJ-13-05	i-SEP Aspiration and Anticoagulation Line	D-PRO-023	Instructions For Use for the i-SEP Aspiration and Anticoagulation Line and the Blood Collection Reservoir
XJ-28-18	i-SEP Blood Collection Reservoir	D-PRO-023	Instructions For Use for the i-SEP Aspiration and Anticoagulation Line and the Blood Collection Reservoir
ST0501	i-SEP Treatment Set	D-PRO-022	i-SEP Treatment Set Instructions For Use
ST0301	i-SEP Treatment Set	D-PRO-022	i-SEP Treatment Set Instructions For Use
BE1000	Additional Reinfusion Bag	D-PRO-025	Reinfusion Bag for Autotransfusion Treatment Set Instructions For Use
BW5000	Additional Waste Bag	D-PRO-026	i-SEP Waste Bag Instructions For Use
BW1000	Additional Waste Bag	D-PRO-026	i-SEP Waste Bag Instructions For Use
LF0000	Additional Micro-aggregates Chamber	D-PRO-027	Instructions For Use for the Micro-aggregates Chamber for Autotransfusion Treatment Set
LE0000	Vacuum Line	D-PRO-023	Plastic accessory, clean, single-use
11813	Antibacterial filter for the vacuum line	N/A	Filtration accessory, sterile, single-use

Table 1: Consumables to operate the i-SEP autotransfusion system device

The following spare parts are also available (See Table 2):

Description	Details
Shelf	Shelf for consumable storage
Storage bin	Storage bin for consumable storage
Optical sensor cover	Cover to protect the optical sensors
Haematocrit reader cover	Cover to protect the haematocrit reader
Mains cable	ATS power cable

Table 2: Spare parts to the i-SEP autotransfusion system device

2.6. COMMISSIONING

Before operating for the first time, the section 7.4 must be carefully studied.

2.7. MAINTENANCE AND REPAIR

Routine maintenance operations described in this Instructions For Use leaflet can be performed by the user. Refer to the maintenance procedures indicated in section 6 in this Instructions For Use leaflet.
Only the manufacturer, or a qualified technician authorised by the manufacturer, can assemble, adjust, modify or repair this Device.

2.8. ADDRESSES

Please contact us if you require any clarifications:

Manufacturer and return address for i-SEP Autotransfusion System devices:
i-SEP
21, rue La Noue Bras de Fer
44200 Nantes
FRANCE

Sales department :
Tel. + 33 (0)2 28 29 02 62 from Monday to Friday, 8:30AM to 17:30PM GMT+1
email: contact@i-sep.com or commercial@i-sep.com

Maintenance/servicing:
Tel. +33 (0)2 28 29 02 62 from Monday to Friday, 8:30AM to 17:30PM GMT+1
email: maintenance@i-sep.com

Clinical support
Tel. +33 (0)2 28 29 02 62 from Monday to Friday, 8:30AM to 17:30PM GMT+1
email: clinique@i-sep.com

3. I-SEP AUTOTRANSFUSION SYSTEM – ATS DESCRIPTION

3.1. ILLUSTRATION OF THE AUTOTRANSFUSION SYSTEM

3.1.1. I-SEP autotransfusion device: front side

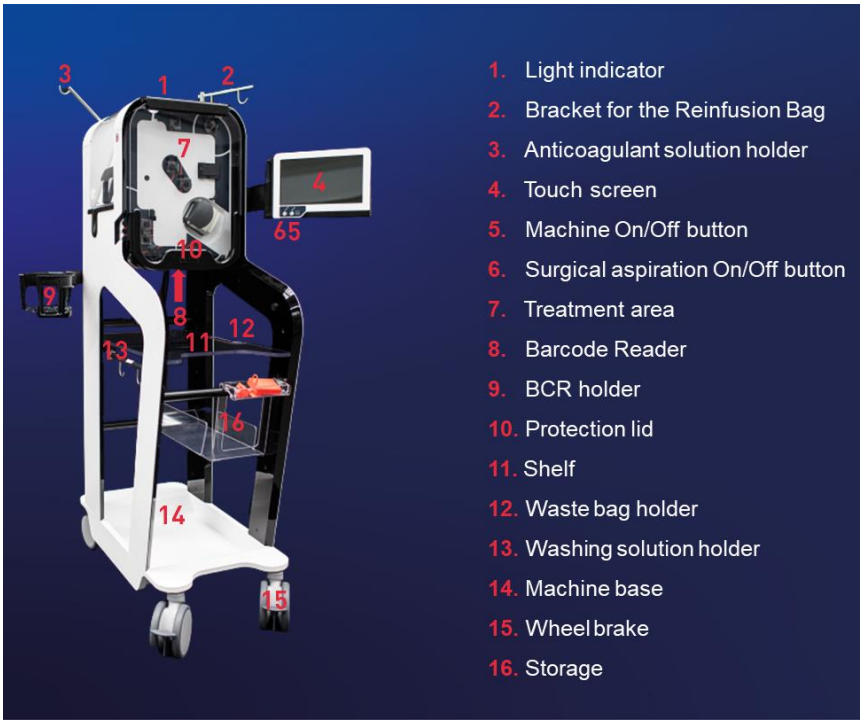

Figure 4: ATS front view

3.1.2. I-SEP Autotransfusion device: rear side

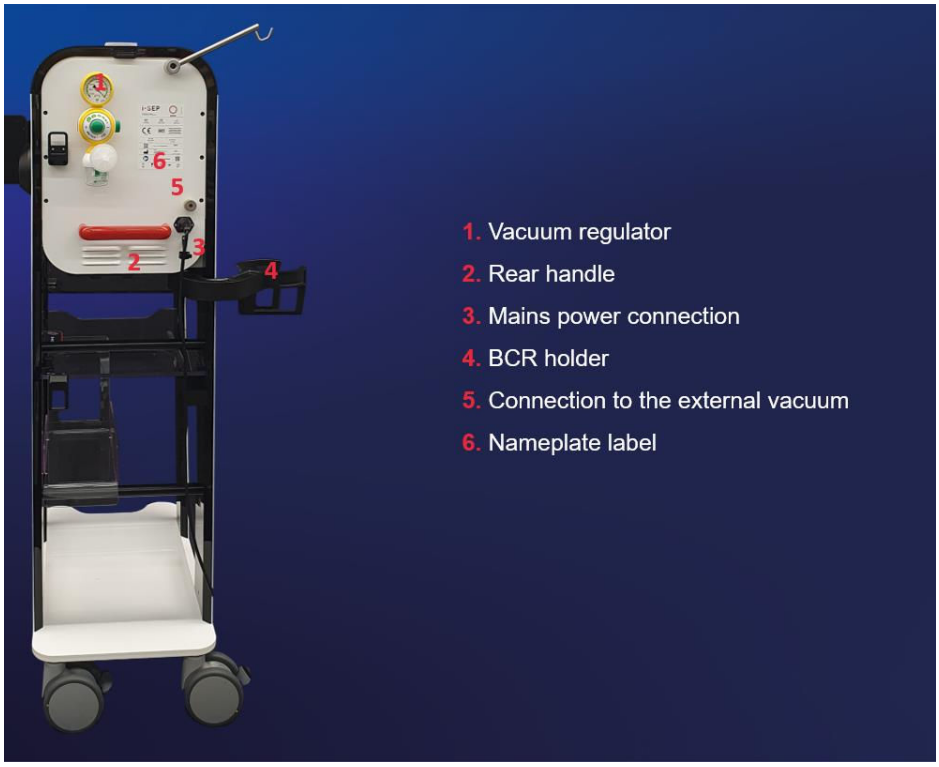

Figure 5: ATS rear view

3.2. HANDLES

The i-SEP ATS has 2 handles, designed to allow manoeuvring and to make it easier to transport the equipment (See Figure 6 and Figure 7).

Figure 6: Rear handle

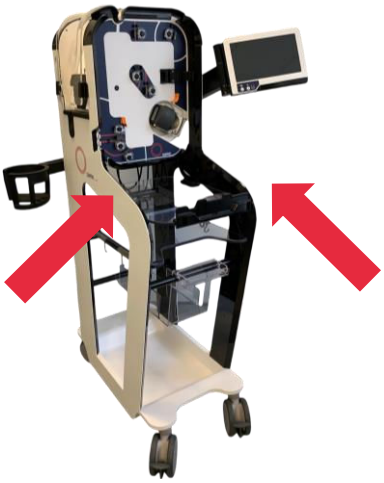

Figure 7: Front handle

3.3. HUMAN MACHINE INTERFACE: TOUCH SCREEN AND DISPLAY, LIGHT INDICATOR

The human-machine interface (HMI) consists of a light indicator and a touch screen on a swivel arm (See Figure 8).

Figure 8: ATS right-side view

3.3.1. Light indicator

The light indicator lets you know the status of the machine without having to look at the screen (See Table 3).

Colour		Meaning
Red		Error
Yellow		Alarm
Blue		Alert
Green		In operation

Table 3: Status of the machine thanks to the light indicator

3.3.2. Touch screen

The control touch screen is located on the right side of the equipment on a stand that allows it to rotate and move from right to left and up and down.

Two types of movement are possible:

1) Modification of the height from 0 to + 30 cm (see Figure 9).

2) Rotation of the HMI (-180° to 0°) (see Figure 10), this makes it possible to adjust the HMI so that it is at an ideal viewing angle for the user as well as to place the screen in the so-called ‘parking’ position when moving the machine so as to avoid collisions.

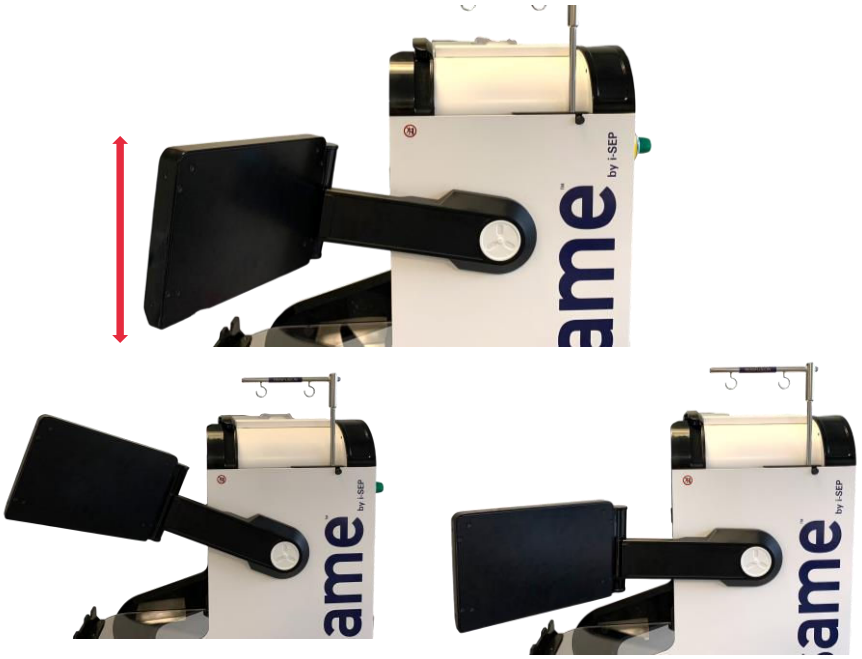

Figure 9: Vertical screen movement

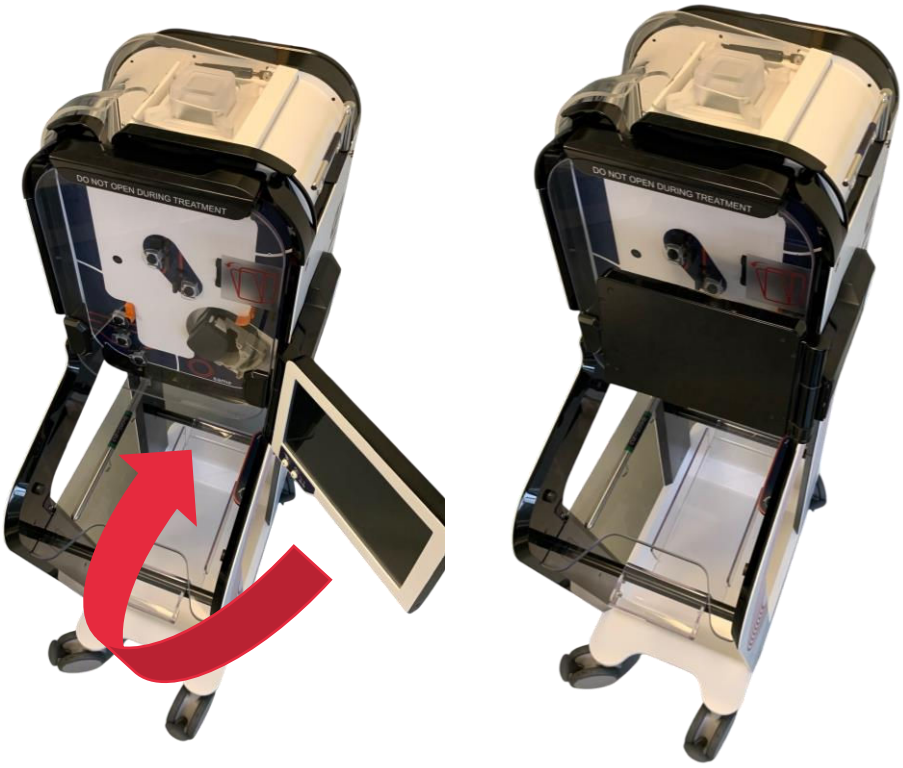

Figure 10: Screen rotation

The screen has 2 major components: the touch screen and the physical buttons on the bottom of the screen (See Figure 11).

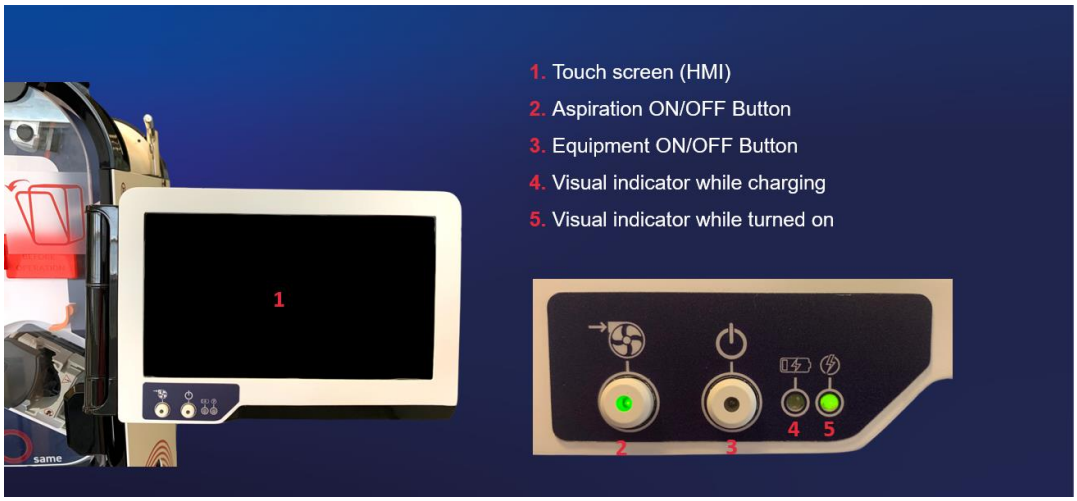

Figure 11: Touch screen

The touch screen measures 10.1 inches in size, it displays different sections. The ATS and the programs are entirely controlled via the screen. The user interacts with the equipment through the touch screen by clicking on the buttons available on the screen. Instructions for operating the device via the screen are provided in the following sections.

3.4. BCR HOLDER

The i-SEP ATS is equipped with a BCR holder (see Figure 12) allowing to:

- Uniquely position the i-SEP Blood Collection Reservoir
- Move the position of the BCR from the front to the back of the ATS.
- Shake the BCR if a clot forms.

Figure 12: BCR arm in open position

The BCR arm has a storage position that allows it to be stored in the support structure (see 2, Figure 12).
The holder allows to constantly monitor the weight of the liquid contained in the Blood Collection Reservoir.

WARNING:

- when taking the BCR arm out or storing it, pay attention to the positioning of the power cable as it can get caught between the structure and the arm, and thus prevent the arm's movements.
- **WARNING:** The Maximum Allowable Load on the Blood Collection Reservoir holder is 5 kg.

3.5. TREATMENT AREA

The treatment area is comprised of several sensors and actuators that are used to carry out and monitor the blood treatment.
The various actuators are:

- 7 x Electroclamps
- 1 x Peristaltic pump

The various sensors are:

- 3 x Optical Sensors
- 1 x Haematocrit Reader
- 1 x Treatment Bag weighing system
- 1 x Treatment Set presence sensor
- 1 x Reinfusion Line presence sensor
- 1 x Pressure sensor

3.5.1. Peristaltic pump

The fluids are circulated via a peristaltic pump. With this pump,

- the collected anticoagulated blood is transferred from the Blood Collection Reservoir to the i-SEP Autotransfusion Treatment Set;
- The sterile washing solution is transferred from the Washing Solution Bag to the Treatment Set;
- The blood to be washed and to be concentrated is circulated within the Treatment Set parts (hollow fibre filter cartridge and Treatment Bag);
- The contaminants are transferred from the hollow fibre filter cartridge to the Waste Bag.
- The blood cell concentrate is transferred from the Treatment Bag to the Reinfusion Bag.

The peristaltic pump is a roller pump fitted with a flap valve that allows the tubing to be inserted and removed (see Figure 13).

Figure 13: Peristaltic pump

The treatment speeds depend on the i-SEP Autotransfusion Treatment Set programmes and models being used.
The pump does not work if the flap valve is not locked. There is a sensor present on the pump to indicate whether the pump is open or closed.
The user cannot directly choose the pump flow rates, these rates are predefined based on the mode; however, users can choose between the various modes (e.g. standard, live, or emergency mode, etc.). The software controls all of the flow rate parameters.

Warning:

- **DO NOT TOUCH THE ADJUSTMENT WHEELS used to OPEN the space housing the tubing for the Treatment Set found on the peristaltic pump. If improperly adjusted, this may result in an error and the treatment may stop. In addition, if the tubing gets narrower, this could cause too much of a reduction in the flow and could create very significant haemolysis at this point of the circuit. If this happens, the quality of the blood to be transfused can no longer be certified.**
- **DO NOT OPEN the pump after the set has been correctly installed until the treatment procedure is stopped at the desired stopping point. Doing so will put the ATS in error mode and the blood will be lost.**
- **Do not put your fingers in the pump while the rollers are rotating.**

3.5.2. Electroclamps

The i-SEP ATS treatment area is equipped with seven electroclamps, each electroclamp is in front of one tubing for the Autotransfusion Treatment Set (see Chapter 3.16.2), as indicated by their nomenclature (see Figure 14).

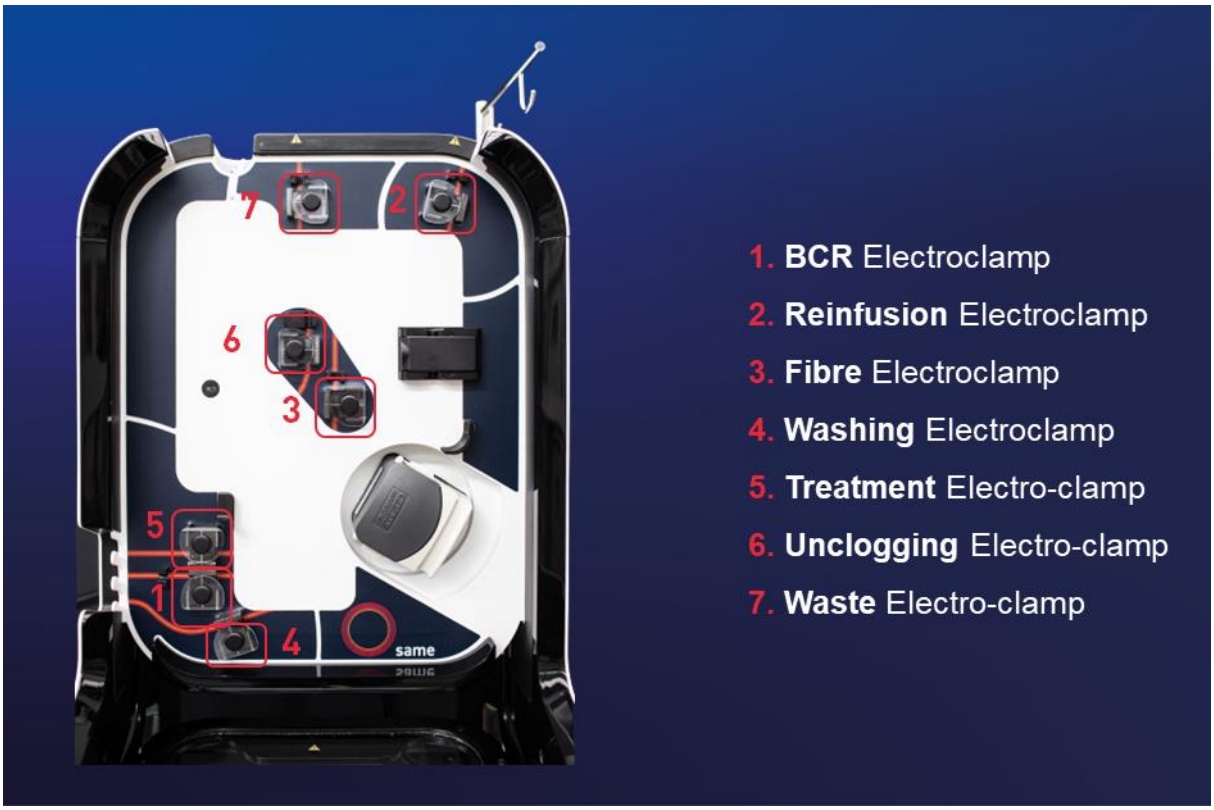

Figure 14: Treatment area

The electroclamps are either in 'open' status, allowing fluids to pass, or in 'closed' status, preventing fluids from passing.
Each electroclamp is controlled independently of the others.
The user cannot control the status of the electroclamps. All actions related to the electroclamps are controlled by the process software for the i-SEP ATS and act according to the steps in progress.

WARNING:

- **DO NOT WORK ON THE ELECTROCLAMPS ONCE THE TREATMENT HAS BEEN LAUNCHED (fluid in the Treatment Set); THIS WILL PUT THE ATS IN FAILURE MODE.**

3.5.3. Optical sensors

The ATS is equipped with three optical sensors that can be used to monitor the treatment (see Figure 15).

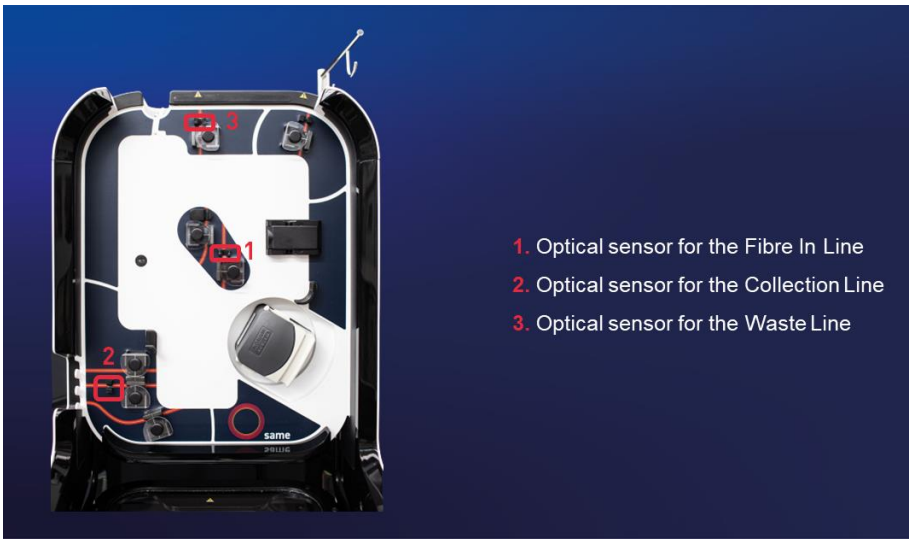

Figure 15: Optical sensor positions

These sensors make it possible to define the presence of tubing as well as the type of liquid contained in the tubing (Washing Solution, blood or air).

3.5.4. Haematocrit reader

The i-SEP ATS incorporates an integrated, non-invasive Haematocrit Reader which provides a haematocrit index for the circulating blood fluid (see Figure 16).

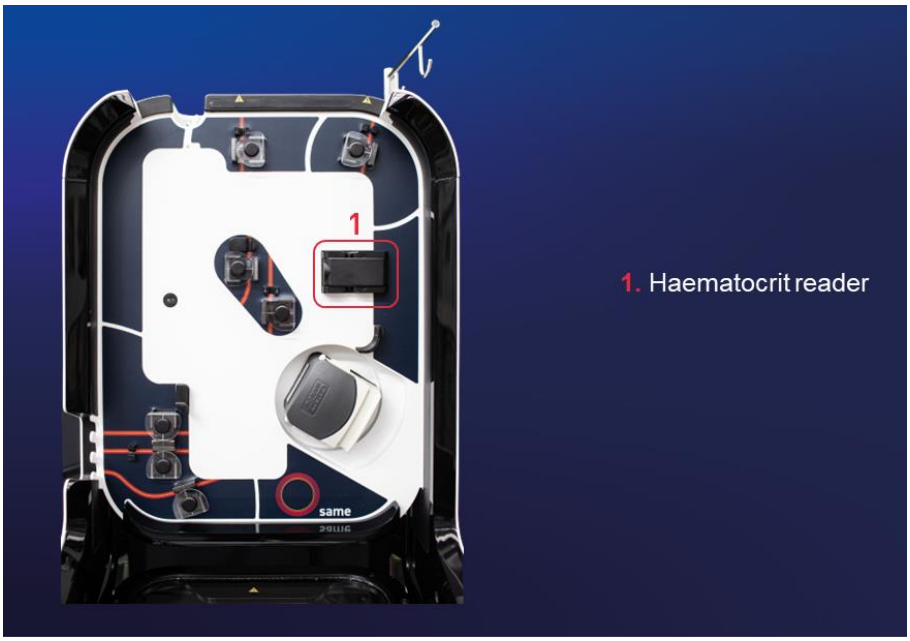

Figure 16: Position of the haematocrit reader

The Haematocrit Reader is placed above the peristaltic pump. The sensor components are placed on the outside of the PVC tube, such that a non-invasive measurement can be taken. Based on the optical properties of the circulating blood, the sensor measures the haemoglobin concentration, without taking the oxygenation status of the cells and plasma protein concentrations into account. The haemoglobin concentrations are converted to percentages of haematocrit.

At the end of treatment, the user is given an estimate of the haematocrit level present in the Reinfusion Bag.
It is also possible to find the values of previous treatments at any time in the history which can be accessed from the HMI. **These values are given for information purposes only and are in no way considered a diagnosis. If the user would like to know the haematocrit level in the blood to be reinfused, a duly authorised laboratory must perform the analysis.**

Note: The haematocrit monitoring function of the i-SEP Autotransfusion Device is only used to monitor the washing concentration and processes for information purposes and is not intended for diagnostic or quality control purposes. The haematocrit values given by the ATS are not a substitute for checking the haematocrit level in the product before reinfusion into the patient. The Haematocrit Reader is not a measuring instrument.

3.5.5. Pressure sensor

The i-SEP ATS is equipped with a pressure sensor to detect overpressure inside the i-SEP Autotransfusion Treatment Set (See Figure 17).

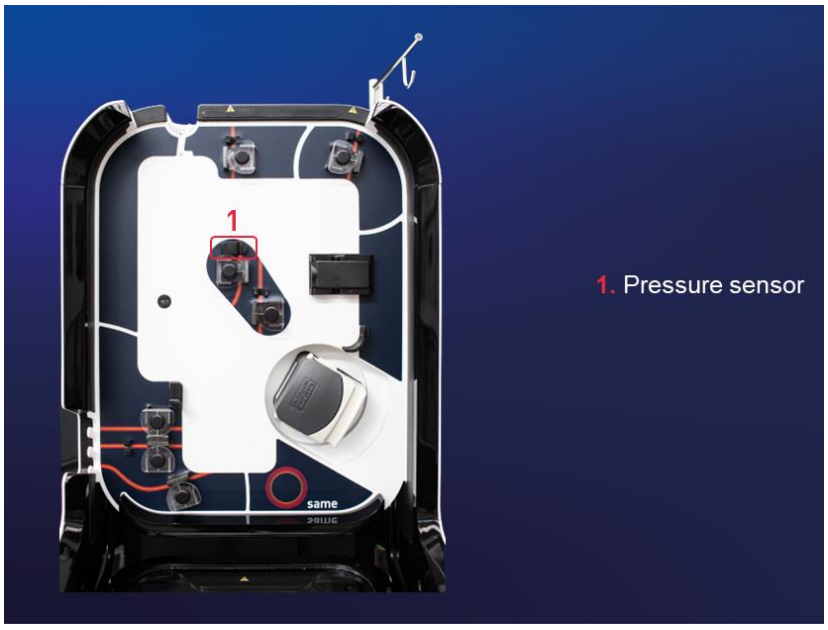

Figure 17: Pressure sensor position

The pressure sensor is a protection measure that detects when the filter or a manual clamp is clogged of if a clamp has remained closed. In addition, the pressure increase would result in the formation of haemolysis in the circulating blood. Protective measures such as unclogging to try to avoid overpressure or stopping the pump are in place in the event of danger. These security settings also help protect the user and nearby people from an accidental exposure to blood (AEB).

3.6. TREATMENT BAG HOLDER AND PROTECTION LID

The Treatment Bag holder is used to hang the Treatment Bag for the i-SEP Autotransfusion Treatment Set and the treatment is monitored via the integrated weighing sensor (See Figure 18).

Figure 18: Treatment bag holder

WARNING:

- In order to ensure that the blood is treated in a correct and reproducible manner, it is imperative to hang the bag from the 4 rods by the corresponding eyelets and to **not pinch the tubing between the protection lid and the structure of the ATS** (See Figure 19**).**
- The Maximum Allowable Load on the Treatment Bag holder is 5 kg.
- Be very careful and make sure to pass the tubing between apart from the Bag in the spaces provided for this purpose.

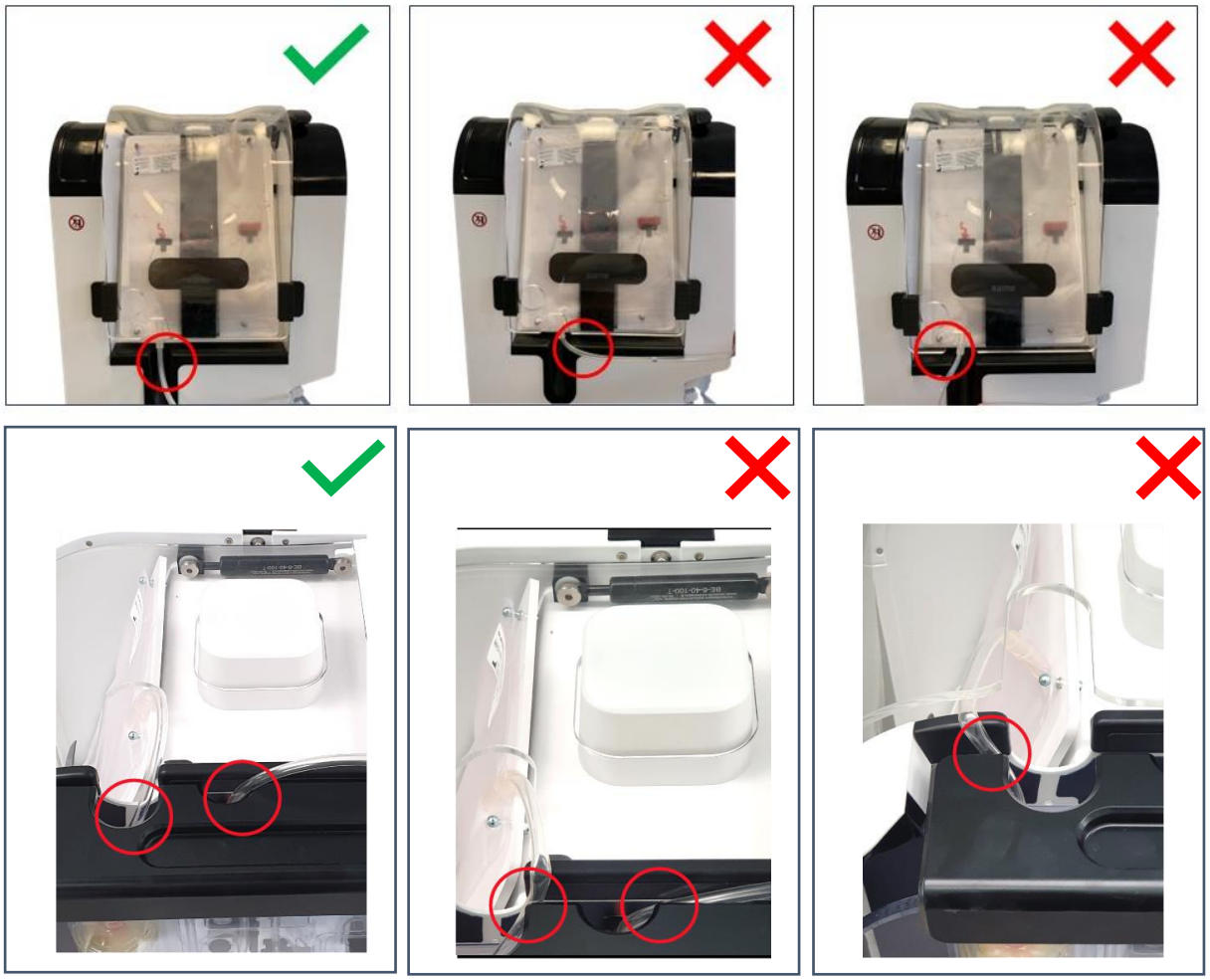

Figure 19: Correct and incorrect positions of the treatment bag

The following figure shows a picture of the protection lid for the Treatment Bag (open and closed) (See Figure 20).

Figure 20: Treatment Bag protection lid

3.7. PROTECTION LID

The protection lid is there to prevent access to moving parts during the treatment as well as to protect against possible blood splashes. The lid is transparent in order to view what is happening under the protection lid and allows the user to view the locations described in the various messages that the user might receive.

The structure features a locking tab allowing to secure the lid once it is closed (see Figure 21).

Figure 21: Locking tab to secure the lid

When the protection lid is open (see Figure 22 - A), it can be used as a sort of table upon which the Treatment Set can be placed during installation.
The treatment can start only if the lid is closed (see Figure 22 – C).

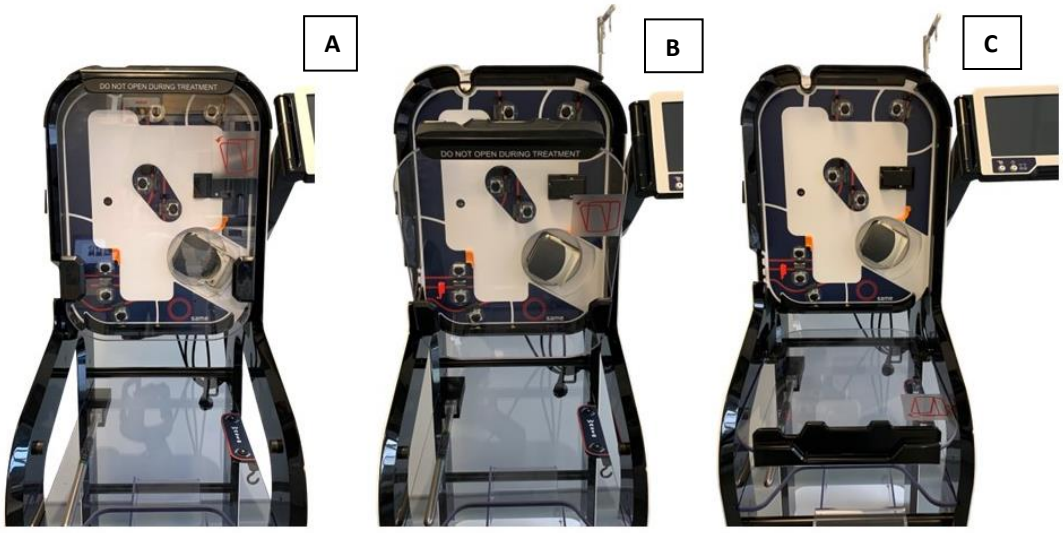

Figure 22: Protection lid A: closed B: intermediate position C: open

The closing of the protection lid is detected by a sensor. If incorrectly closed, an informative message appears on the screen.

The lid must remain closed during all the electroclamp auto-test phases and from the automatic launch until the treatment set unistallation step.
Opening the lid will cause the cancellation of the auto-tests or pausing of the treatment in progress.

WARNING: The Maximum Allowable Load on the protection lid is 20 kg.

3.8. PROTECTION LID UNLOCKING

It is possible to unlock the protection lid if required. It may be useful to uninstall the treatment set in case of an error for example, or to reposition tubing in a sensor.

However, do not manoeuvre the clamps manually, otherwise the machine will trigger an error. Uninstalling of the treatment set in normal operation must necessarily be initiated by an end-of-surgery phase followed by shutting down of the machine (see 4.12 and 4.13).

The locking tab must be disengaged to release the lid (see Figure 21).
The lid can then be lowered.
The machine detects the opening and starts the system safety sequence mode. Do not touch the electroclamps which may already be moving a few seconds after the opening.

Warning:
- **If the protection lid is unlocked and opened, it is no longer possible to be protected against AEB. In this case, use the necessary protections to avoid any risk of AEB.**

3.9. BASE OF THE MACHINE

The i-SEP ATS is mounted on four wheels, enabling good manoeuvrability and mobility.
The 4 wheels can turn freely so that it is easier to move the device. All 4 wheels are equipped with brakes. To engage and disengage the brakes, see Chapter 7.3.

The shape of the foot allows for the parts needed for the treatment mentioned in Chapter 3.16.2 to be stored

The ATS has a shelf (See Figure 23) that can be used as a kind of table for placing consumables and for hanging up the waste bag provided with Autotransfusion Treatment Set references ST0501 and ST0301.

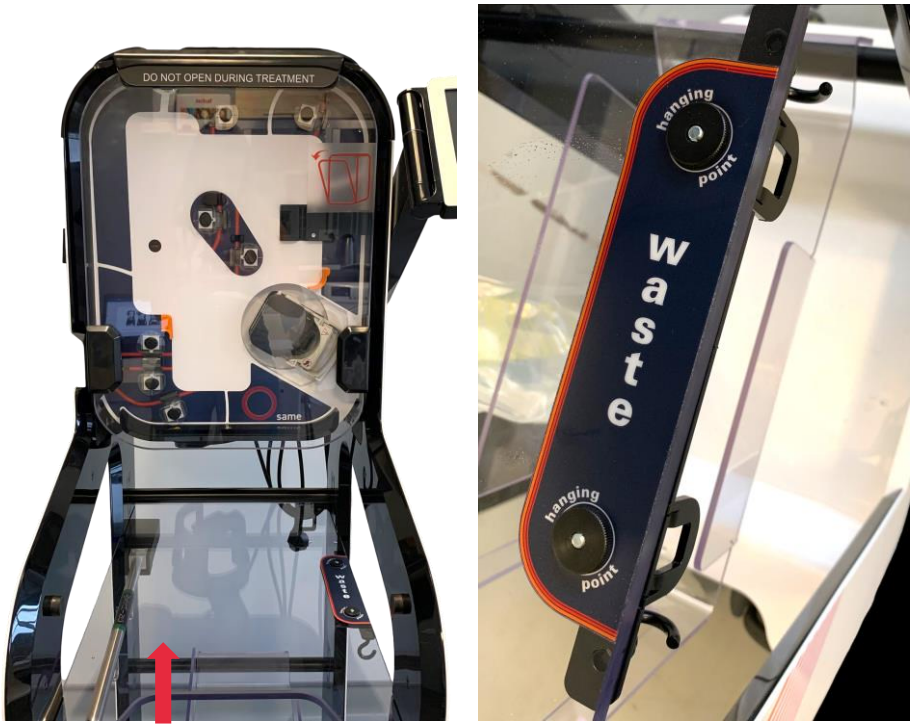

Figure 23: Shelf

A storage bin is also present to store consumables (See Figure 24).

Figure 24: Storage bin

Warning:

- **Do not disassemble the ATS.**
- **To move the ATS, use the rear frame or handle to move the ATS.**
- **Remember to bring in anything that protrudes from the machine when moving it so as to avoid any part of the machine from snagging or breaking. The machine has been designed for this purpose; the HMI, Reservoir arm and pole all fold inside the machine so that it can be moved easily.**
- **The Maximum Allowable Load on the storage shelf is 20 kg.**

3.10. POLES AND HOLDERS

It is possible hang various bags on the ATS (See Figure 25).
There is a pole located on the right side of the ATS that is there to hold the Reinfusion Bag for the Treatment Set.
There is a holder found towards the bottom left side of the ATS that is there to hold the Washing Solution Bags.
There is one final last pole found on the rear of the machine that is there to hold the Anticoagulant Solution Bag.

WARNING:

- **The Maximum Allowable Load on the Reinfusion pole is 5 kg.**
- **The Maximum Allowable Load on the Washing Solution holder is 10 kg.**
- **The Maximum Allowable Load on the Anticoagulation pole is 5 kg.**

Figure 25: Poles and holders

3.11. BATTERY

The ATS is equipped with a battery that will allow the machine to finish the cycle in progress, to continue until the blood is transferred into the Reinfusion Bag and to place the ATS in safety mode while waiting for the power to come back on.
The vacuum flow for the surgeon will be reduced when in battery mode in order to optimise the energy consumption.

Note:

- *The ATS will not start if there is no mains power.*

- *If a treatment has not already been started at the time of the power failure, it is impossible to start a new treatment while in battery mode. Users cannot assemble or disassemble the battery. Only a person who is qualified to open the machine can carry out these operations.*

The following screen will be displayed when there is a power failure (See Figure 26).

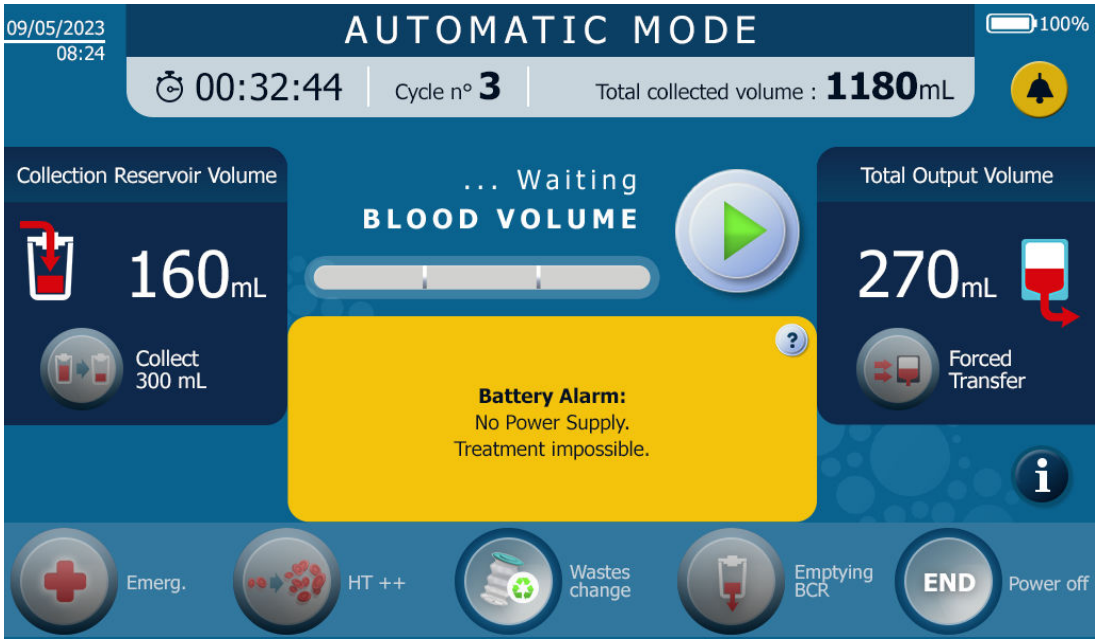

Figure 26: Screen displayed when there is a power fail

3.12. BARCODE READER

The i-SEP ATS is equipped with a laser reader for the data-matrix code, a.k.a. a barcode reader; this barcode reader is located below the treatment area (see Figure 27).
The barcode reader is used to scan the QR code of the i-SEP Autotransfusion Treatment Set used.
Reading the QR code allows to:

- Adjust the parameters of the ATS to the Autotransfusion Treatment Set model chosen by the user;
- Ensure that the i-SEP Autotransfusion Treatment Set is not used past its expiry date;
- Associate the patient's history with the model and batch number of the i-SEP Autotransfusion Treatment Set used.

Figure 27: Position of the barcode reader and Data-Matrix

Warning: Laser beam. Avoid looking directly at the beam. Class 2 laser device. The use of commands or adjustments, or the performance of procedures other than those specified in this document may lead to exposure to visible laser light. The laser scanner uses a low power laser diode. Even though momentarily looking directly at the laser beam does not cause any known biological damage, avoid looking at it just as you would avoid looking at a very powerful light source, such as the sun. Make sure that the eyes of anyone observing this procedure are protected from the laser beam, including via reflective surfaces such as mirrors, etc.
For safety reasons, the laser scanner is turned off once the scan is performed. It is not possible to revert to other parameters after the scan has been performed. If the user has used the wrong set, it is possible to disassemble the Treatment Set and scan a new Treatment Set.

3.13. VACUUM REGULATOR

A vacuum regulator (See Figure 28) is provided as a reusable device with the i-SEP Autotransfusion System. The accessory is used to control the amount of vacuum applied when collecting blood.
The vacuum regulator is connected:

- Through a vacuum tube to the i-SEP ATS's internal vacuum pump. Users cannot access it.
- Through a vacuum line via the antibacterial filter attached to the vacuum regulator going to the i-SEP Blood Collection Reservoir.

The vacuum regulator is a type RVTM3 regulator (Medical Technology). It is turned on by pressing on the green side switch and it is turned off by pressing on the red side switch.

Figure 28: Vacuum regulator

3.14. CLEATS USED TO STORE THE POWER CABLE

Two cleats are found on the back of the ATS; the power cable is wrapped around them for storage purposes (See Figure 29).

Figure 29: Cleats used to store the power cable

3.15. OPTICAL SENSOR COVERS

The ATS comes with 4 orange covers for protecting the optical sensors during storage: 3 sensors are for the fluid optical sensors and 1 is for the Haematocrit Reader (see Figure 30).

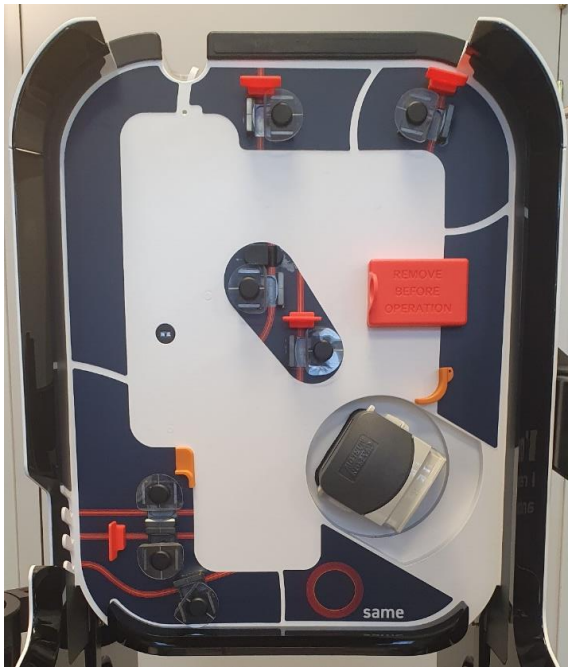

Figure 30: Covers protecting the optical sensors

Remember to remove them when starting the ATS.

3.16. DESCRIPTION OF THE ACCESSORIES - SINGLE-USE STERILE DEVICES, REUSABLE DEVICES - AND SEPARATE CONSUMABLES NEEDED TO OPERATE THE ATS

3.16.1. General considerations

For a complete description of the single-use sterile devices associated with the ATS, refer to the specific Instructions For Use.
Specifically, the warnings and precautions relating to sterility, maintaining sterility and compliance with expiry dates are described and must be followed.

3.16.2. Single-use sterile devices

3.16.2.1. i-SEP Autotransfusion Treatment Set

- **General description**

The complete Instructions For Use for the device are available (i-SEP document: D-PRO-022).
The i-SEP Autotransfusion Treatment Set (see Figure 31), irrespective of the model, consists of a set of lines connected by connectors and distributors that are used to link together the containers, bags or filtration systems.
The figure below shows the components of a Treatment Set.

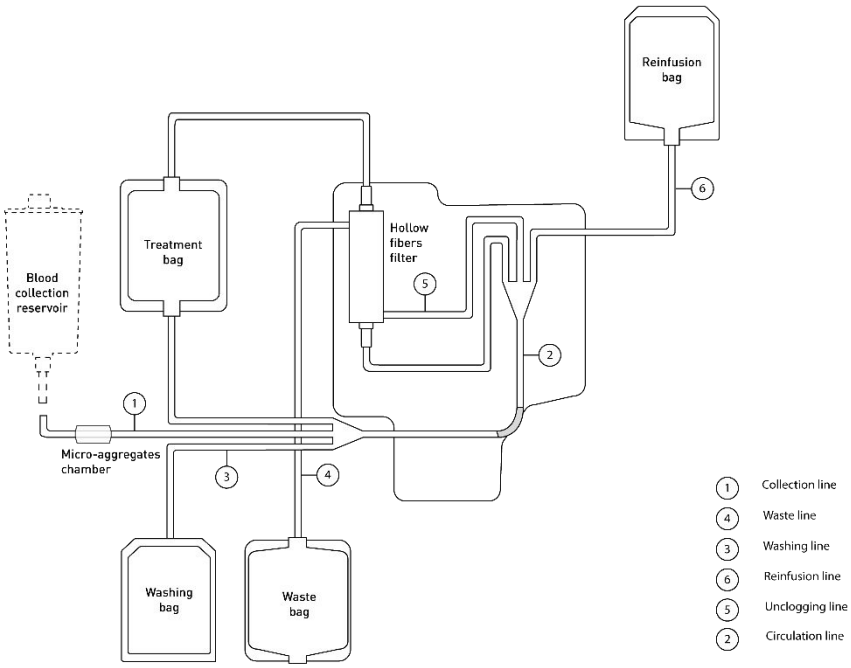

Figure 31: Structure of the i-SEP Autotransfusion Treatment Set

- **Description of the i-SEP Autotransfusion Treatment Set models**

Four i-SEP Autotransfusion Treatment Set references are available (i-SEP document: D-PRO-022), for heavy or lighter bleeding. The technical specifications associated with the sets are given in the table below (See Table 4):

	i-SEP Autotransfusion Treatment Set	
Specifications	**ST0301**	**ST0501**
Volume treated in the first cycle	500 ml	700 ml
Volume treated starting from the 2nd cycle	300 ml	500 ml
Maximum usage characteristics	15 cycles, lasting 6 hours	15 cycles, lasting 6 hours
Treatment capacity in blood volume	4.5 litres	7.5 litres
Waste Bag volume	5 litres	5 litres

Table 4: Description of the i-SEP Autotransfusion Treatment Set models

Each Treatment Set is packaged in an individual, single-use blister pack with a white hermetically sealed inner seal sterilised by gamma rays. This blister pack comes with a QR code to be scanned by the ATS in order to adjust the treatment parameters according to the types of sets.

3.16.2.2. i-SEP Aspiration and Anticoagulation Line

The complete Instructions For Use for the device are available (i-SEP document: D-PRO-023).
The i-SEP Aspiration and Anticoagulation Line consists of double tubing for aspirating blood on the surgical field and for simultaneous anticoagulation. These two parallel tubes come together in the adapter for the aspiration cannula (large lumen: aspiration, small lumen: anticoagulation). This line has been sterilised beforehand since part of it is in direct contact with the patient.

The three available connections are:

- The end joining the Aspiration Line and the Anticoagulation Line is fitted with an adapter in order to connect a surgical aspiration cannula that is to be given to the surgeon in sterile conditions.
- A 1/4” connector is found at the end of the Aspiration Line, for connection to a 1/4" port on an i-SEP Blood Collection Reservoir;
- A puncher is found at the end of the Anticoagulation Line, for connection to a sterile isotonic saline bag containing a suitable anticoagulant for the indication.

Packaging: individual, 2 packages, 1 of which is sterile (2 layers of surgical paper).
Sterilisation: ethylene oxide

3.16.2.3. i-SEP Blood Collection Reservoir

The complete Instructions For Use for the device are available (i-SEP document: D-PRO-023).
The i-SEP Blood Collection Reservoir has an upper part with a watertight cover that has six inlet ports, and its bottom part has an outlet that is extended by extension tubing.
Inside the i-SEP ATS, the BCR is connected by:

- A 1/4” port with a blue cap (small diameter) on the upper side of the BCR, that connects to the i-SEP Aspiration and Anticoagulation Line;
- One port with a yellow protection cap for connecting an i-SEP vacuum line for creating a vacuum;
- A female Luer outlet port with a removable transparent protective cap, that connects to the male Luer connection on an i-SEP Autotransfusion Treatment Set.

Capacity: 2.5 litres.
Packaging: individual.
Sterilisation: ethylene oxide

3.16.2.4. Waste Bag

Additional Waste Bags are available via i-SEP for use with the i-SEP Autotransfusion Treatment Set.
Adhesive tape, without gel, is used to fold them. There is an anti-return valve present so as to prevent any unintentional fluid flow.

Capacity: 5 litres (BW5000) or 10 litres (BW1000).
Packaging: individual.

3.16.2.5. Reinfusion bag

Additional i-SEP Reinfusion Bags are available for use with the i-SEP Autotransfusion Treatment Set.

Capacity: 1000 ml.
Packaging: individual.
Sterilisation: gamma radiation.

3.16.2.6. Vacuum line (connection of the BCR vacuum regulator)

A vacuum line provided by i-SEP is used to connect the antibacterial filter that is attached to the vacuum regulator to the 1/4” port (with its yellow cap off) located on the cover of the i-SEP Blood Collection Reservoir.
The Vacuum Line must be changed each time the ATS is used.

3.16.2.7. Antibacterial filter for the vacuum line

A plastic antibacterial filter is provided by i-SEP and is found on the vacuum regulator outlet.
The filter must be changed with each use of the ATS and during surgery if the quality of the aspiration is reduced. During certain types of surgery, even though this is not recommended, surgical smoke can be drawn in by the Aspiration and Anticoagulation Line. This may cause partial clogging of the antibacterial filter and would have an impact on the quality of the aspiration; it is then necessary to change the antibacterial filter. In this case, the colour of the filter will have changed.

3.16.2.8. Other accessories not provided by i-SEP, and needed to operate the ATS

- **Transfusion set with filter**

A transfusion set with a filter should be used if the user decides to reinfuse the patient with the blood product.
The Transfusion Set must be changed for each patient when using the ATS.
The transfusion set is not provided by I-SEP.

- **Aspiration cannula**

A surgical aspiration cannula (Yankauer type) is positioned at the end of the Aspiration and Anticoagulation Line.
The cannula is a sterile, single-use device.
The surgical aspiration cannula is not provided by i-SEP.

3.16.3. Consumables

Consumables not provided by i-SEP are required for the ATS to work.

3.16.3.1. Washing solution

The washing solution used with the i-SEP ATS is a sterile isotonic sodium chloride solution (NaCl 0.9%). It is recommended to use 1, 2 or 3 litre bags with the ATS depending on the type of set used.

3.16.3.2. Anticoagulant

The patient's blood may be anticoagulated upstream depending on the type of surgical intervention and is simultaneously anticoagulated when the blood is introduced into the i-SEP ATS via the Aspiration Line.

4. USE OF THE I-SEP AUTOTRANSFUSION SYSTEM

4.1. GENERAL FUNCTIONING OF THE I-SEP AUTOTRANSFUSION SYSTEM

During a surgical procedure indicated for the use of the i-SEP ATS, when bleeding occurs, the salvaged blood is simultaneously drawn up and anticoagulated by the i-SEP Aspiration and Anticoagulation Line. The diluted anticoagulated blood is collected in the i-SEP Blood Collection Reservoir. A first filtration via mechanical retention of the coarse surgical debris is performed in the BCR through the internal filtration mesh that has a filtration threshold of 40 microns.
Depending on the characteristics of the installed i-SEP Autotransfusion Treatment Set, when the volume of diluted anticoagulated blood is reached, the ATS launches the standard treatment program: the collected blood circulates in a loop in the Treatment Set, and especially in the hollow fibre filter cartridge, until the treated blood product has a sufficient haematocrit index level. The treatment phase includes washing steps with a sterile washing solution (NaCl 0.9%). Simultaneously, the waste fluids are disposed of in the Waste Bag. When the machine detects that the target haematocrit index has been reached and the associated washing steps have been performed, the circulation within the Treatment Set is stopped and the treated blood product is transferred to the Reinfusion Bag. The treated blood product can be reinfused into the patient. Single-use accessories and other consumables are disposed of as per the healthcare establishment's standard procedures.

4.2. APPLIED PARTS

The applied parts are:
- The entire interior of the Treatment Set
- The Blood Collection Reservoir
- The Vacuum Line
- The Aspiration Line
- The Pressure Gauge Safety Reservoir.

Applied parts are type CF.

4.3. ACCESSIBLE PARTS

The accessible parts are:
- During installation: the entire exterior of the ATS.
- During the calibration of the clamps, only the external parts not found under the protection lid except for the Reinfusion electroclamp, Waste electroclamp, Washing electroclamp, TTT electroclamp and BCR electroclamp.
- During the treatment: only the external parts not found under the protection lid.

WARNING: do not put your fingers in the electroclamps when calibrating the clamps. This symbol means to be careful.

4.4. ESSENTIAL PERFORMANCES

In line with the test conditions set out in IEC 60601-1-2, the i-SEP ATS ensures essential performances for the safe use of the machine.

As per the i-SEP specifications, the following essential performances are not degraded:
- Treatment Bag weighing
- Haematocrit reading
- Warning display if an error is observed.

4.5. TECHNICAL PREREQUISITES

Before using the i-SEP ATS for its intended use:
- The user must have read this Instructions For Use leaflet and specifically the warnings and precautions (see Chapter 2.4.6);
- The ATS is first put into use by i-SEP or an approved technical service provider (see Chapter 7.4);
- The maintenance procedures are up to date (see Chapter 6);
- The storage conditions were and still are appropriate (see Chapter 7.1);
- The battery works (see Chapter 3.11);
- The ATS has been correctly transported (see Chapter 7.3);
- The ATS has been cleaned and disinfected (see Chapter 6);

- The ATS has been placed in its dedicated place of use, the brakes have been activated (see Chapter 7.3.1)
- The required equipment is available: single-use devices, reusable devices and consumables (see Chapter 3.16).

4.6. CONNECTING AND STARTING THE ATS

4.6.1. Electrical connections

A power cable for the Autotransfusion System is supplied with the i-SEP ATS. It can be seen in Chapter 3.1.2 on the rear view of the ATS.
At the interface with the ATS, the cable is plugged into the IEC socket found on the back of the i-SEP ATS (see Figure 32).

Figure 32: Mains connection

The cable is equipped with a system that prevents the plug from being pulled out accidentally once the plug is plugged in. Pull the red button in order to remove the plug safely (See Figure 33).

Figure 33: Red button to remove the plug

The cable connects the ATS to the electrical current of a wall socket or an electrical column in the operating room (the configuration depends on the country of purchase).
The cable must be plugged into the wall outlet or column as per the technical characteristics described in Chapter 7.6.

The ATS does not have a general On/Off switch so that the battery can be charged as soon as it is connected to the mains. As soon as the power cable is plugged in, this turns on the ATS.

→ Connect the end of the electric cable provided to the IEC socket located on the back of the ATS (See Figure 34).
→ Plug the ATS into the mains socket.

Figure 34: Electrical connection

The green light comes on (See Figure 35).

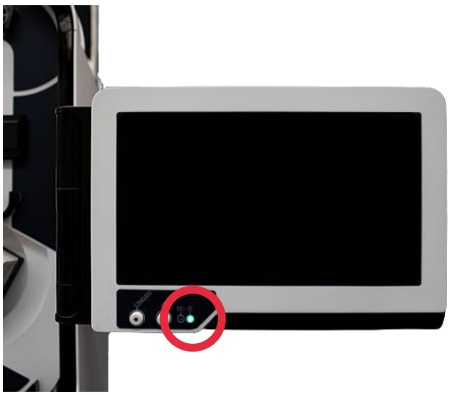

Figure 35: Mains light

4.7. ON/OFF FOR THE ATS AND VACUUM PUMP

4.7.1. ATS On/Off switch

The machine's power switch, a push-button type switch, is located on the left side of the touch screen holder.

The machine is turned on by pressing the ' ' push-button labelled ' '.
A green light indicator in the centre of the button indicates that the HMI has been switched on (See Figure 36).

To shut down the machine, press the push button ' ' for at least 2 seconds and clear the information message on the touch screen.

Note: When the machine is stopped, the light indicator is off.

It is impossible to start the machine using the battery if there is no mains power.

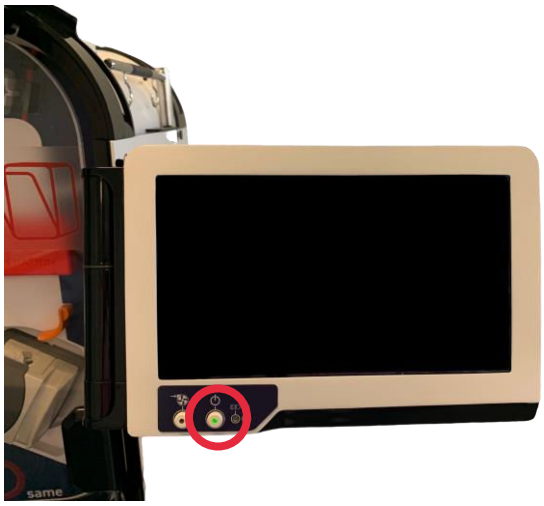

Figure 36: Machine start button

4.7.2. Aspiration On/Off switch

The Aspiration power switch, a push-button type switch, is located on the left side of the touch screen holder (see Figure 37). The integrated vacuum pump is turned on by pressing the push-button for at least 1 seconds, labelled ' '. A green light indicator indicates that the Aspiration has been turned on.

The pump is stopped by pressing on the ' ' push-button for at least 1 seconds.

Note: The light indicator turns off when the aspiration has stopped.

Figure 37: Pump On/Off button enabling aspiration

4.8. INITIALISATION OF THE ATS

- A 'Welcome' screen is displayed (See Figure 38), and the system is automatically initialised if the protection lid is in the closed position (self-tests).

Figure 38: Welcome screen

Warning: The ATS screen must be turned on without a Treatment Set being installed; if a set has been installed, the ATS will prompt the user to remove it.

A screen indicates that the ATS is being calibrated (See Figure 39).

Figure 39: Calibration screen

Access to the electronic instructions for use is display on screen

4.9. INSTALLATION OF THE I-SEP AUTOTRANSFUSION TREATMENT SET

The Set installation screen displays a representation of the i-SEP Autotransfusion ATS, the various parts of the machine can be distinguished (See Figure 40). The HMI will prompt you to install the various parts of the set. A red arrow ion the left visual indicates where the part is located on the machine. The visual on the right-hand side of the screen, like a zoom, shows details about the operation to be performed.

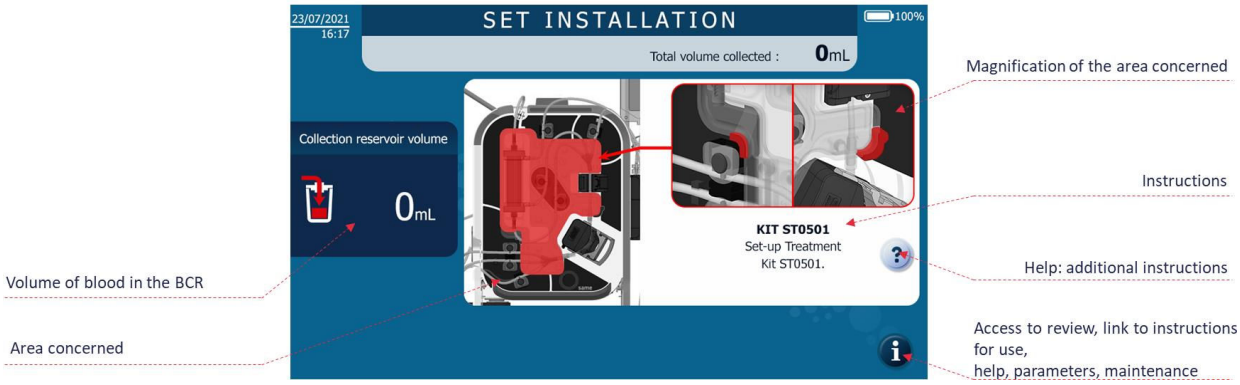

Figure 40: Installation screen

When a part is installed, the screen will disappear indicating that the part has been positioned correctly. Then another screen will appear and will prompt the user to perform the next operation. These screens will appear one after the other until the entire set has been installed on the machine.
If the parts are not installed in logical order, the machine automatically takes the completion of each step into account and does not display the corresponding screens.

If a part is uninstalled after it was already installed, the screen will reappear to inform the user that the part is not correctly installed.

If needed, a help screen for each part is available by pressing the symbol (?) on the HMI. This screen details the operations to be performed while offering a different visual.

At the end of the installation, a message prompts the user to check the parts that could not be detected automatically, and a calibration is performed.

4.9.1. Opening the treatment bag protection lid

The following screen appears next (See Figure 41).

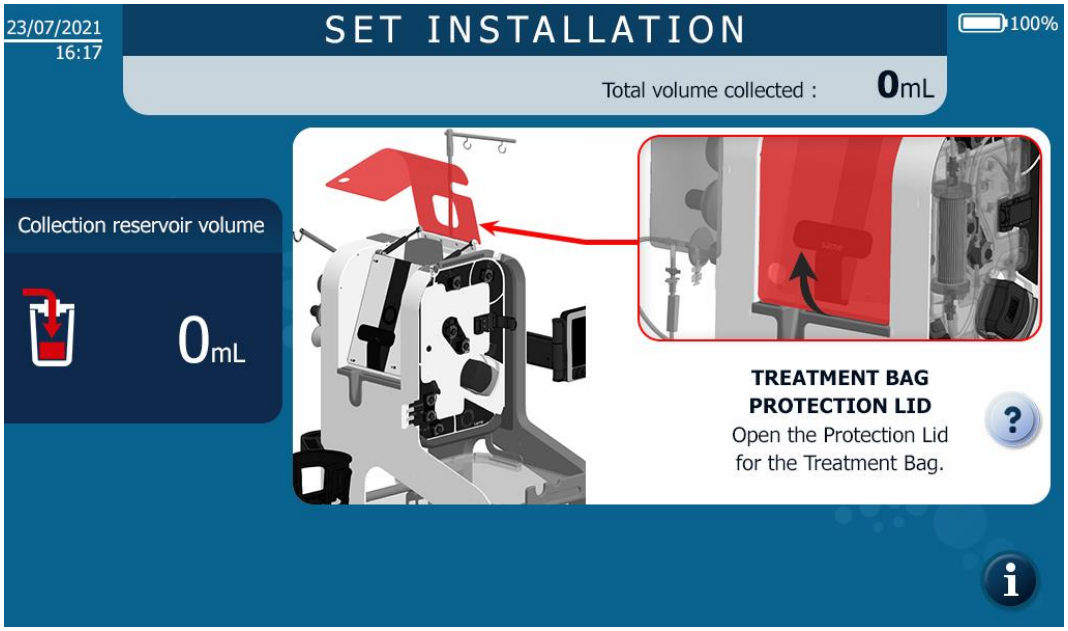

Figure 41: Installation opening treatment bag protection lid screen

Open the treatment bag protection lid to go to the next step.

4.9.2. Opening the roller pump lid

The following screen appears next (See Figure 42).

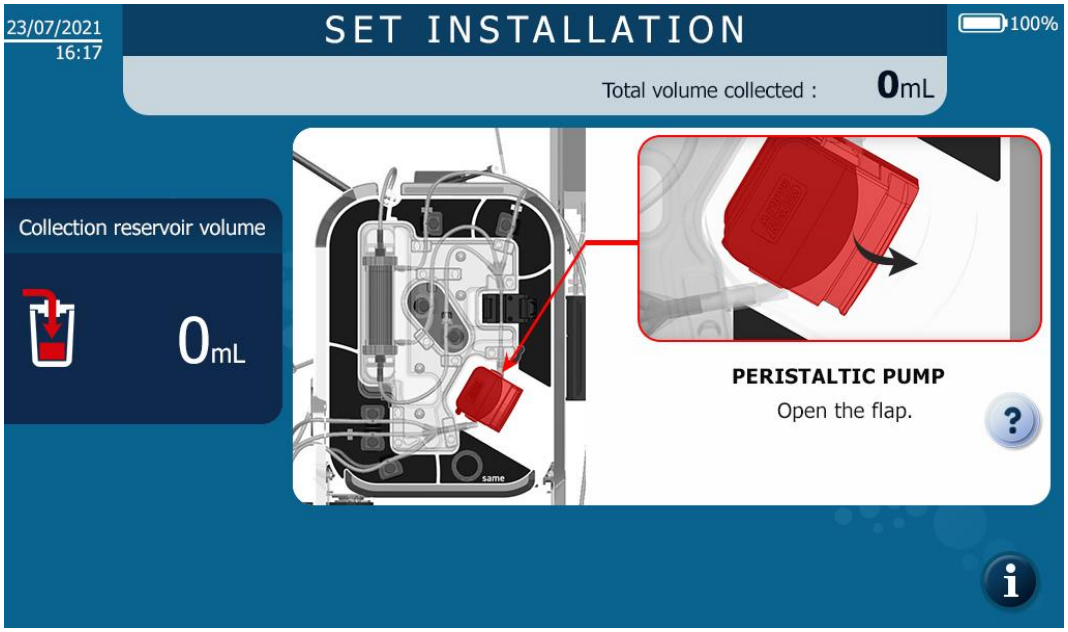

Figure 42: Opening roller pump lid screen

4.9.3. Opening of the haematocrit reader

The following screen appears next (See Figure 43).

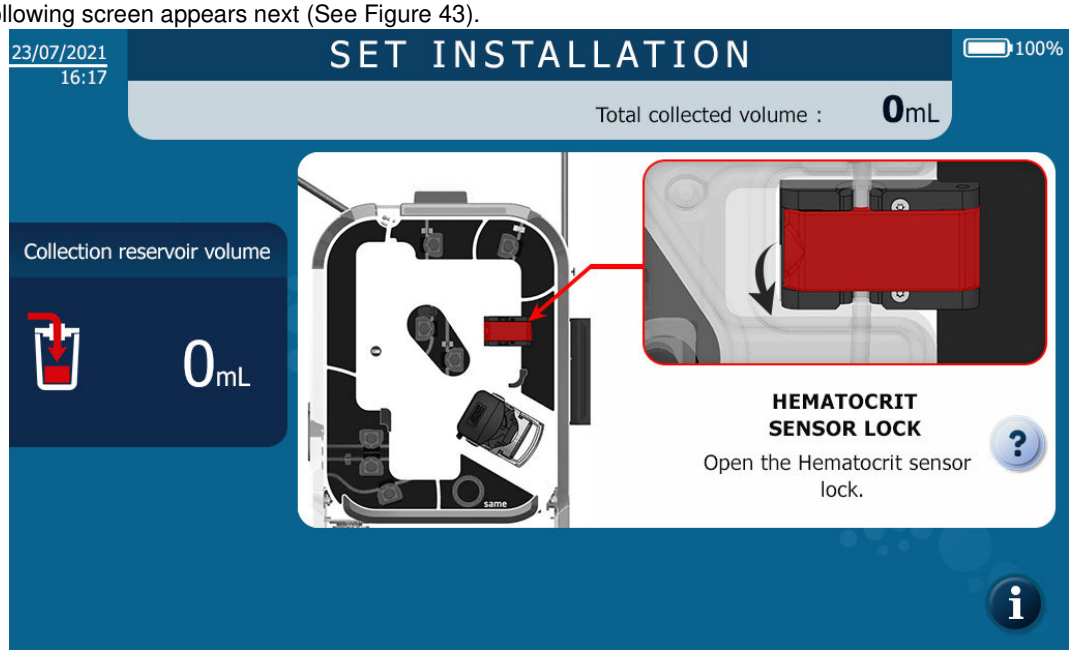

Figure 43: Opening haematocrit reader

4.9.4. Scanning the QR code for the Treatment Set

In order to make it possible to recognise the type of set that will be installed, the bar code located on the blister pack label must be scanned by the machine (See Figure 44).

- → Select the desired Treatment Set model depending on the clinical context of use encountered, and in particular according to the expected volumes of blood loss.
- → With the help of the barcode reader and as indicated on the HMI screen (see Figure 44), scan the code of the label on the white inner seal on the packaging in order to enable the ATS Autotransfusion to identify the i-SEP Autotransfusion Treatment Set model. If difficult to read or if there is a reading error, move the blister pack from left to right (see Figure 45).

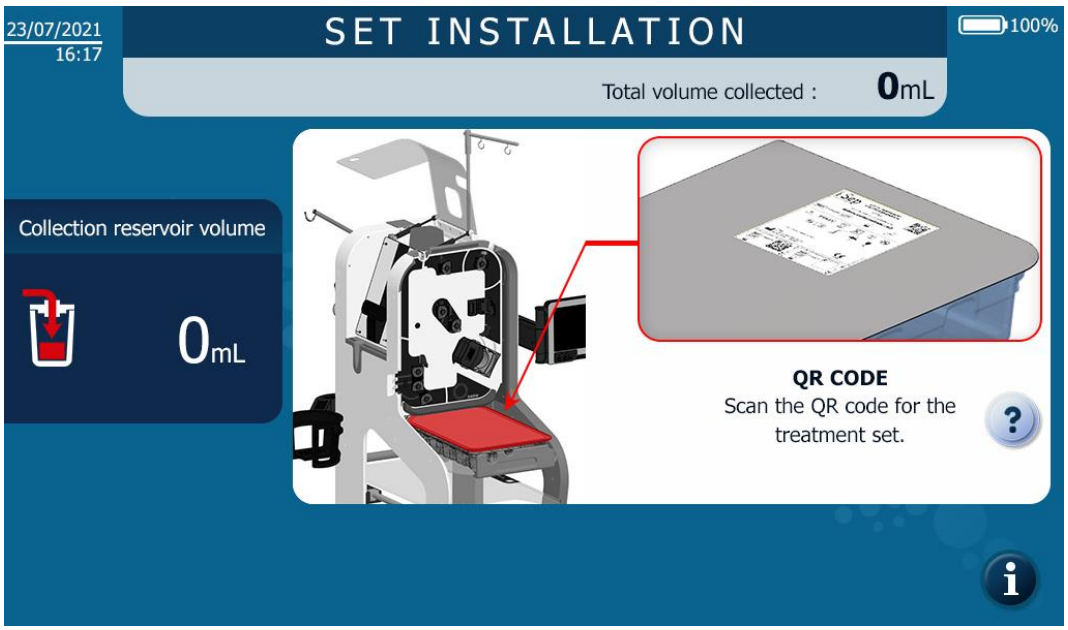

Figure 44: QR code scan installation screen

Figure 45: Scanning the QR code

4.9.5. Installation of the Treatment Set

The following screen appears after scanning the Treatment Set (See Figure 46).

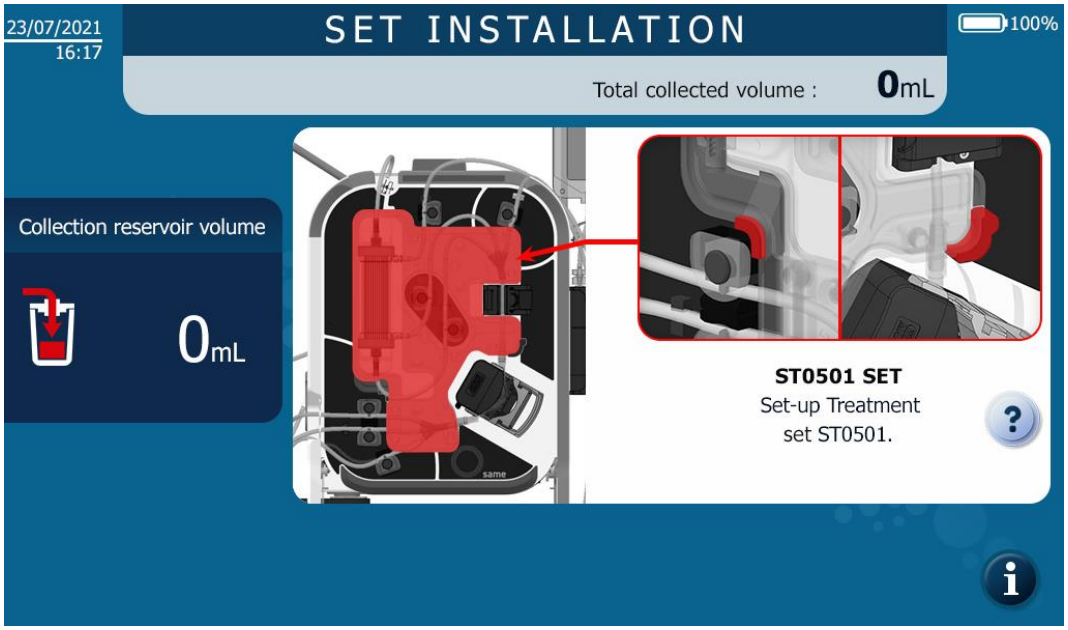

Figure 46: Treatment Set installation screen

→ Open the sterile i-SEP Autotransfusion Treatment Set package by pulling the opening tab on the white inner seal towards you (See Figure 47).

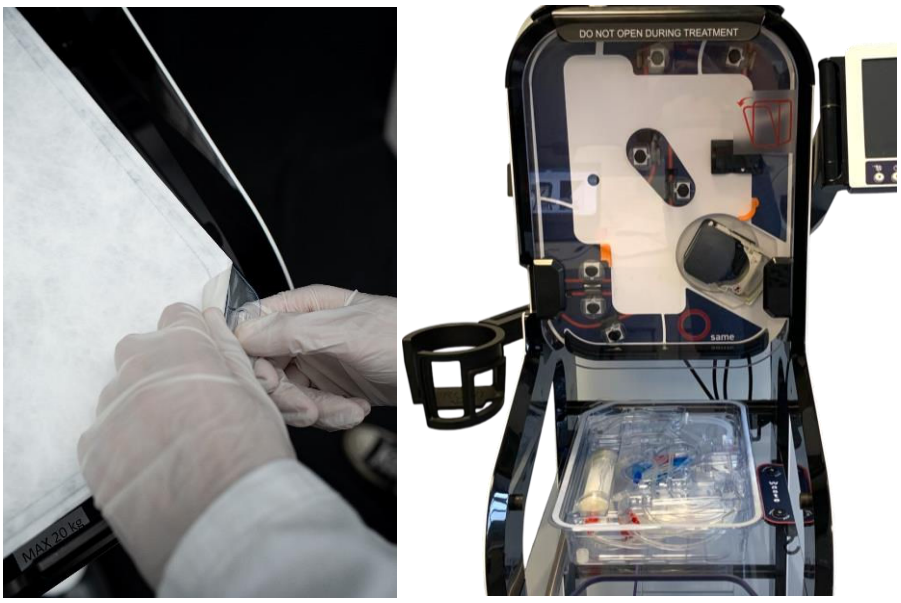

Figure 47: Opening the Set

→ Position the template, in vertical position, by pressing it against the ATS treatment area, using 2 centring supports (1 and 2) as shown on the figure below (See Figure 48).

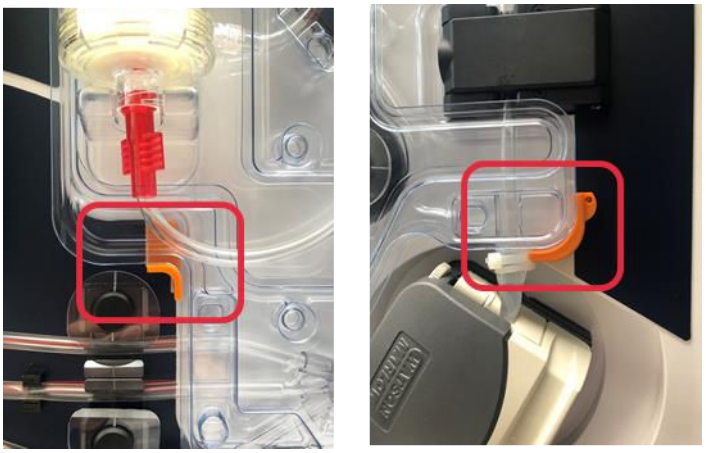

Figure 48: Clipping in the Set

Warning: Push the kit template strongly at the supports to the bottom. The kit template must pass through several grooves.

4.9.6. Inserting the Treatment Bag

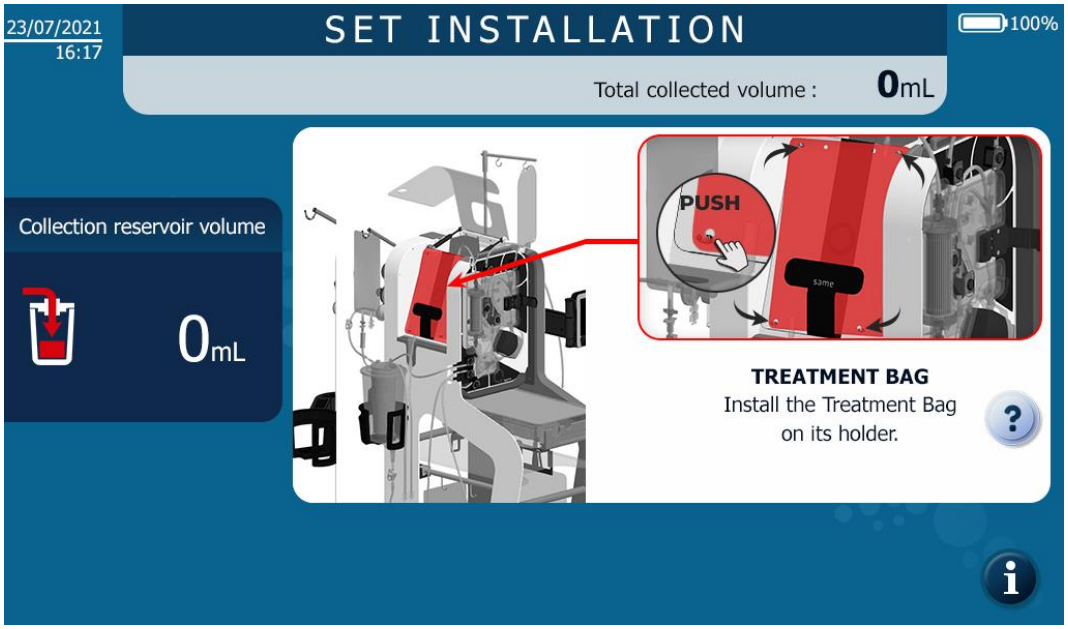

Figure 49: Treatment Bag installation screen

- **Inserting the Treatment Bag:**

  → Position the Treatment Bag in the dedicated holder for this purpose on the left side of the ATS, where the four rods are found on the holder (See Figure 50).

Figure 50: Treatment Bag installation

Warning: it is imperative that the bag is attached to the four rods in order to minimise the risk of disruptions while the blood is in circulation as disruptions could result in haemolysis.

→ Make sure to correctly position the tubing at the top and the bottom of the Treatment Bag in the groove provided for this purpose (See Figure 51).

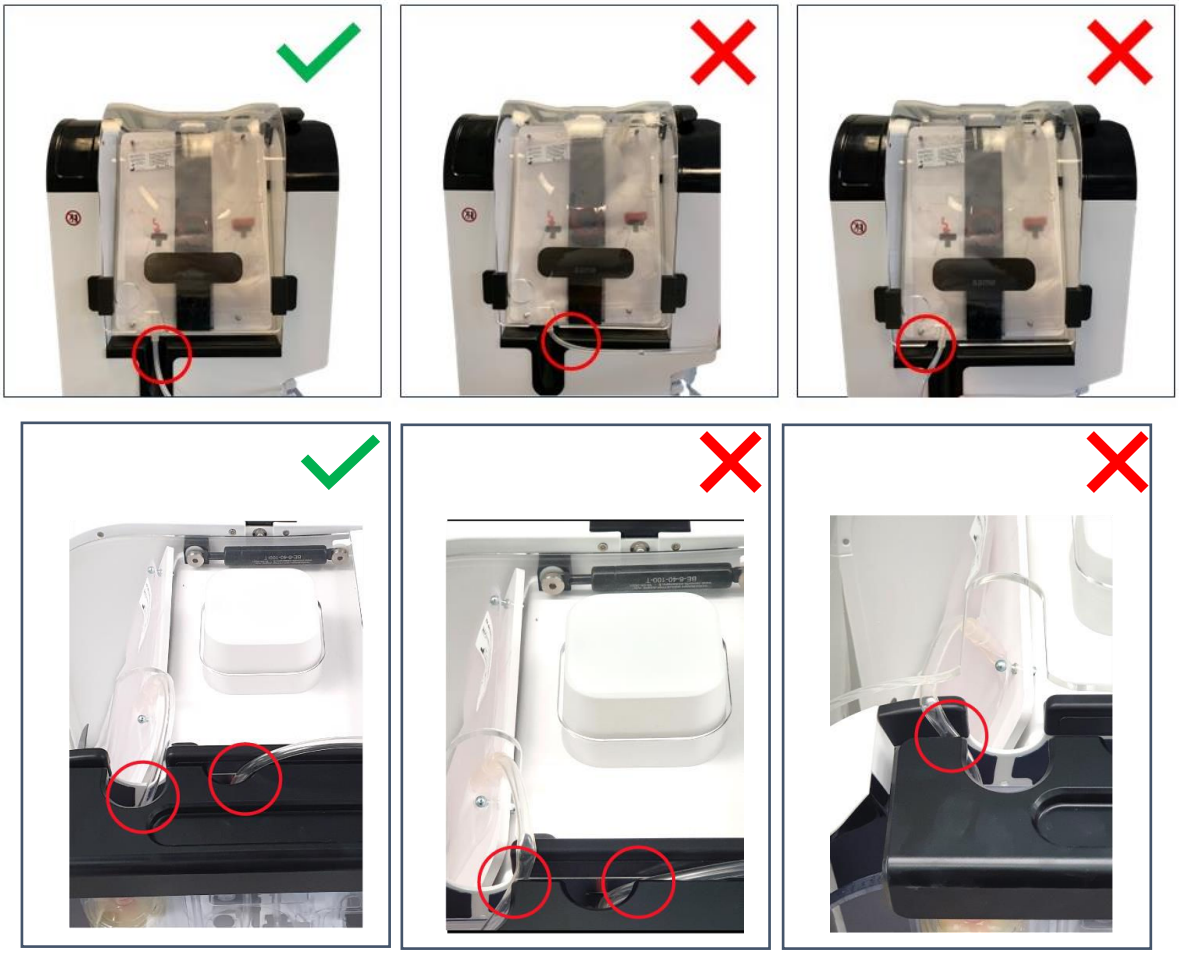

Figure 51: Correct of incorrect positioning of the treatment bag

4.9.7. Closing the Treatment Bag lid

The following screen appears next (See Figure 52).

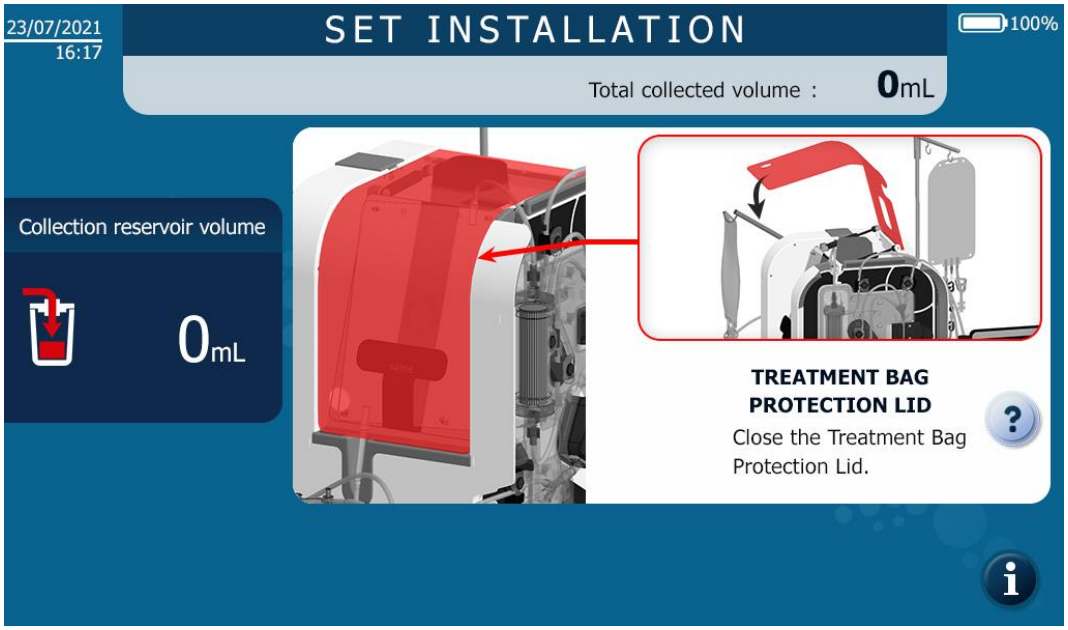

Figure 52: Closure of the treatment bag protection lid

Close the Treatment Bag lid while ensuring that the tubing is positioned in the lid opening (See Figure 53).

Figure 53: Closed and open Treatment Bag protection lid

Warning:

- **If the tubing is trapped by the Treatment Bag lid, the bag will be weighed incorrectly, and it will not be possible to perform the treatment correctly.**

4.9.8. Inserting the tubing in the Fibre IN sensor

The following screen appears next (See Figure 54).

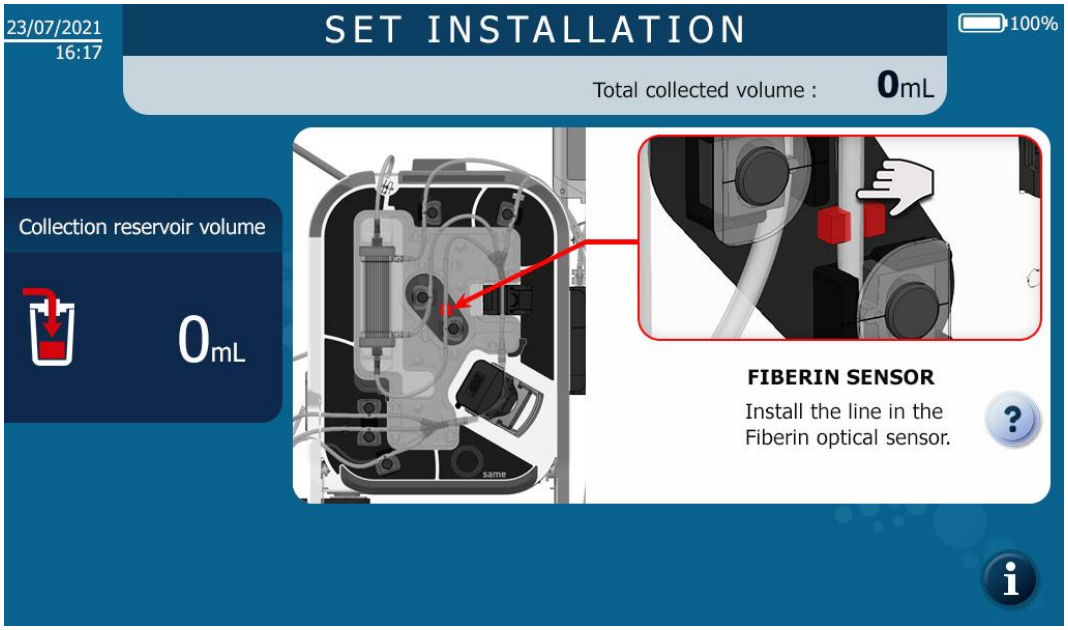

Figure 54: Fibre IN sensor installation screen

→ Position the tubing in the Fibre IN sensor and use your finger to press on it so as to fully push it in the sensor (See Figure 55).

Figure 55: Fibre IN sensor tubing installation

4.9.9. Inserting the tubing in the Pressure sensor

The following screen appears next (See Figure 56).

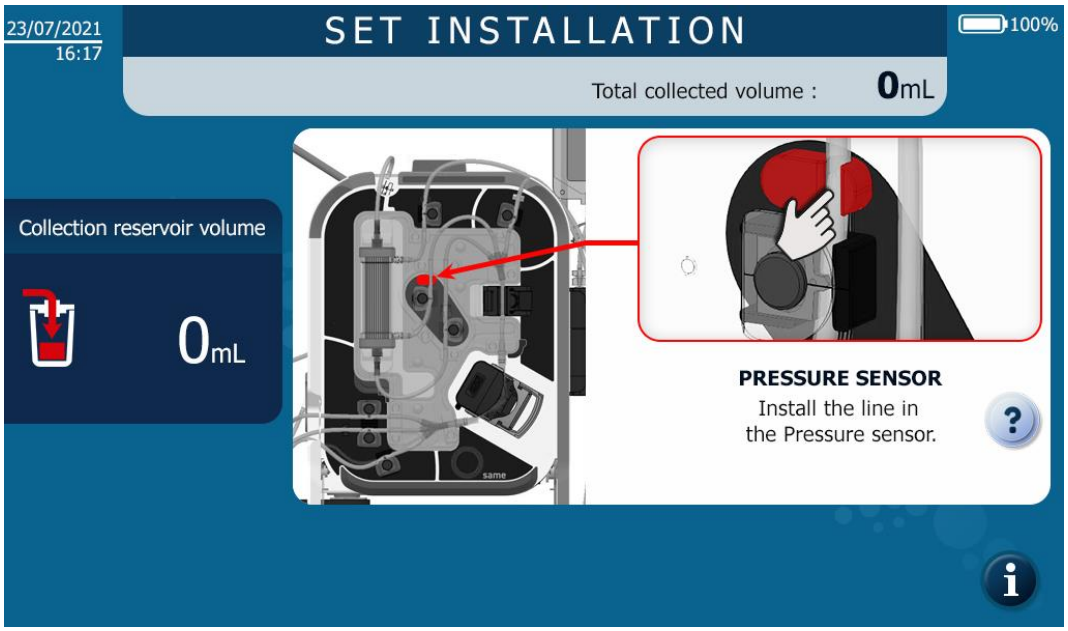

Figure 56: Pressure sensor installation screen

→ Position the tubing in the Pressure sensor and use your finger to press on it so as to fully push it in place (see Figure 57).

Figure 57: Pressure sensor installation

4.9.10. Inserting the tubing in the peristaltic pump

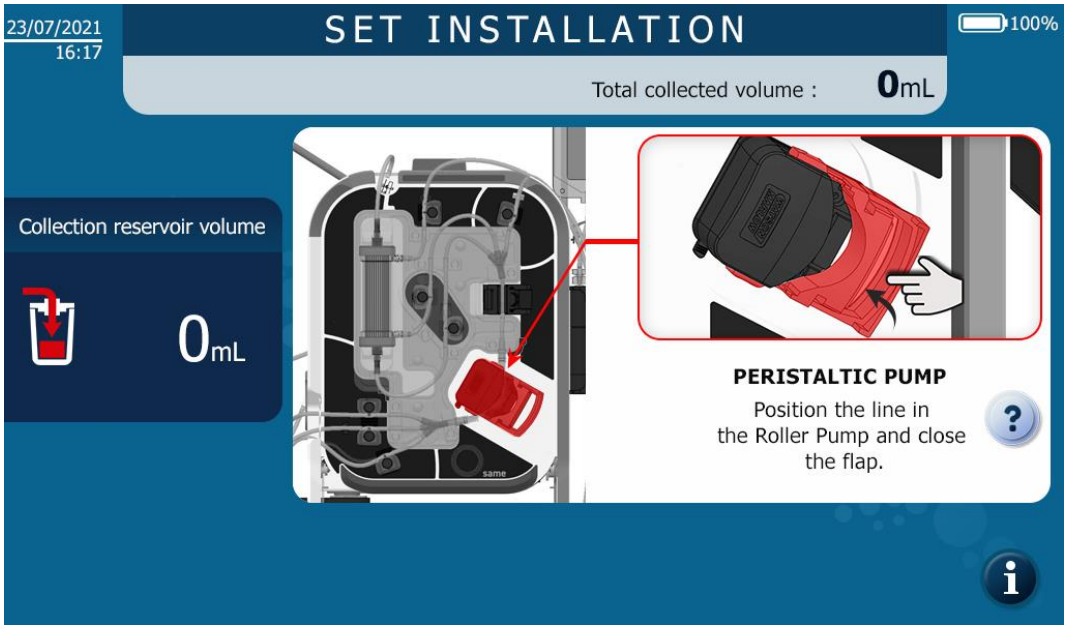

Figure 58: Peristaltic pump installation screen

→ Position the silicone tubing in the peristaltic pump, while ensuring that the tubing is centred on the rollers and close the pump's flap valve (See Figure 59).

→ Verify that:

- All tubing going into and leaving the pump is not bent or under strain.

- Tubing holders are not cutting into the tubing.

If so, check the integrity of the tubing and reposition the tubing in the pump if the tubing has not been damaged. **If there is a breach of integrity of the tubing or if in doubt, replace the set.**

Figure 59: Tube installation in the peristaltic pump

4.9.11. Installation of the Reinfusion Line in the Reinfusion sensor

The following screen appears next (See Figure 60).

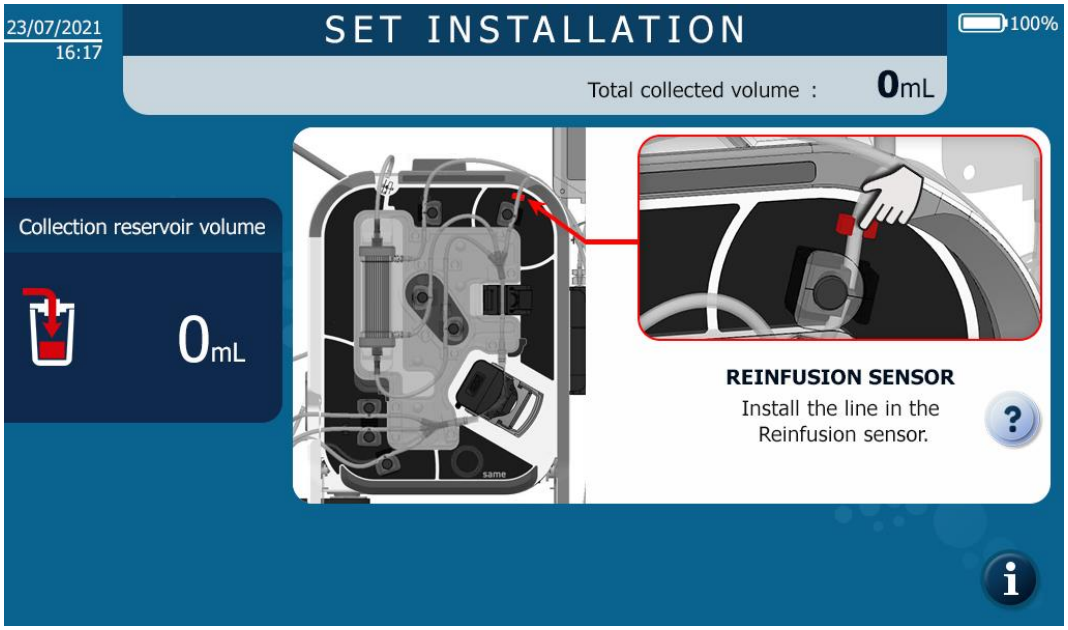

Figure 60: Installation of the reinfusion line in the reinfusion sensor

→ Put the Reinfusion Line in the line presence sensor (see Figure 61).

Figure 61: Sensor for the Reinfusion Line

4.9.12. Inserting the tubing in the Haematocrit Reader

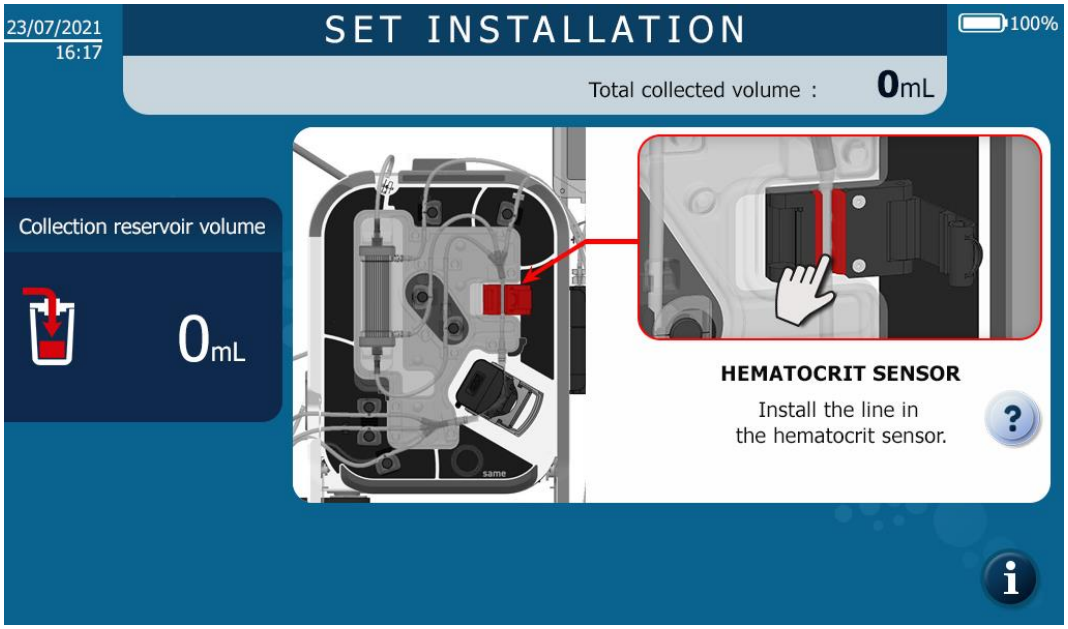

Figure 62: Haematocrit Reader installation screen

→ Position the tubing in the Haematocrit Reader and use your finger to press on it so as to fully push it in place (See Figure 62).

4.9.13. Closing the Haematocrit Reader lock

The following screen appears next (See Figure 63).

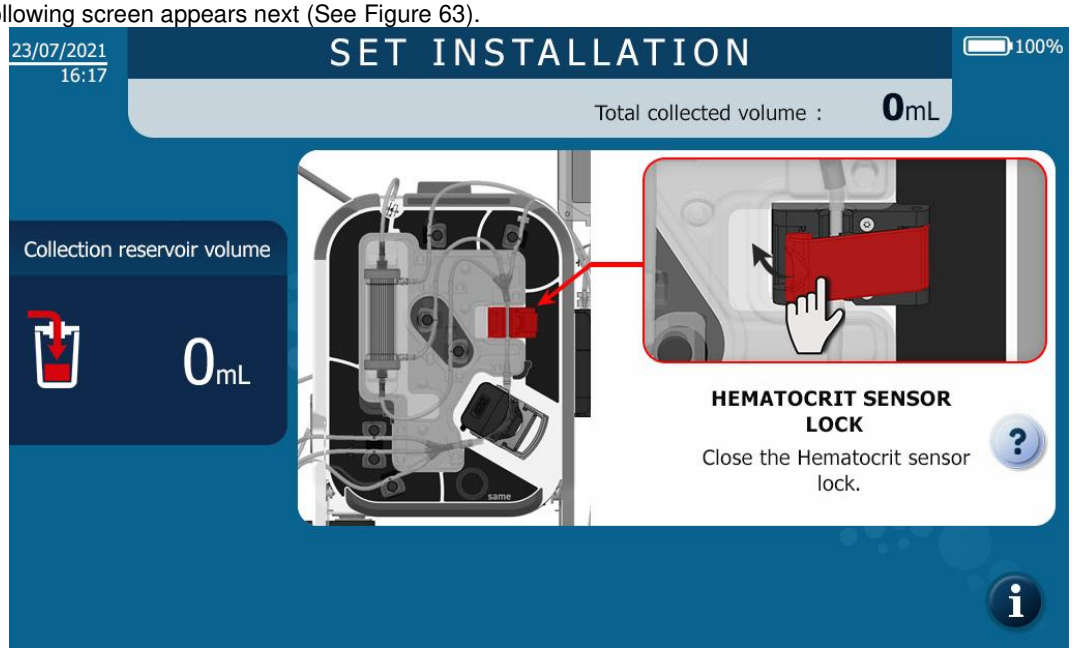

Figure 63: Close of the Haematocrit Reader lock

→ Close the flap valve on the Haematocrit Reader (See Figure 64).

Figure 64: Closing the flap valve of the Haematocrit Reader

4.9.14. Installing an i-SEP Blood Collection Reservoir

The following screen appears next (See Figure 65).

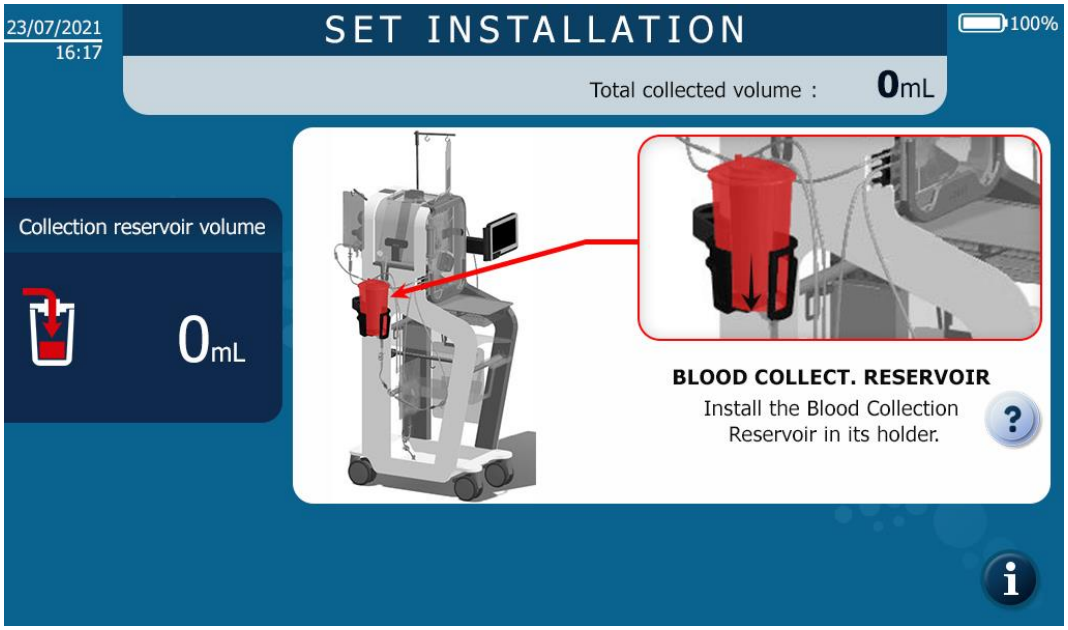

Figure 65: Blood Collection Reservoir installation screen

Unfold the Reservoir arm from the ATS (See Figure 66).

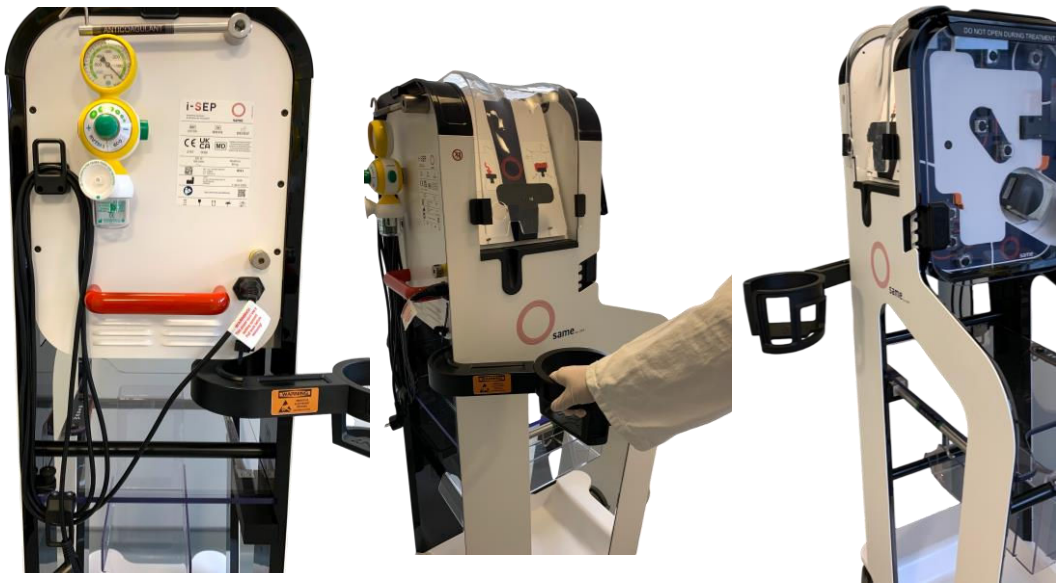

Figure 66: Unfolding the Reservoir arm

→ Open the transparent outer package containing the i-SEP Blood Collection Reservoir.
→ Slide the Blood Collection Reservoir into the Reservoir holder (See Figure 67).
→ Close the manual clamps on the jar outlet extension line tubing.

Figure 67: Reservoir installation

→ Close the clamps on the Collection Line and then connect the Collection Line for the i-SEP Autotransfusion Treatment Set to the i-SEP BCR by screwing on 2 Luer connectors (See Figure 68).

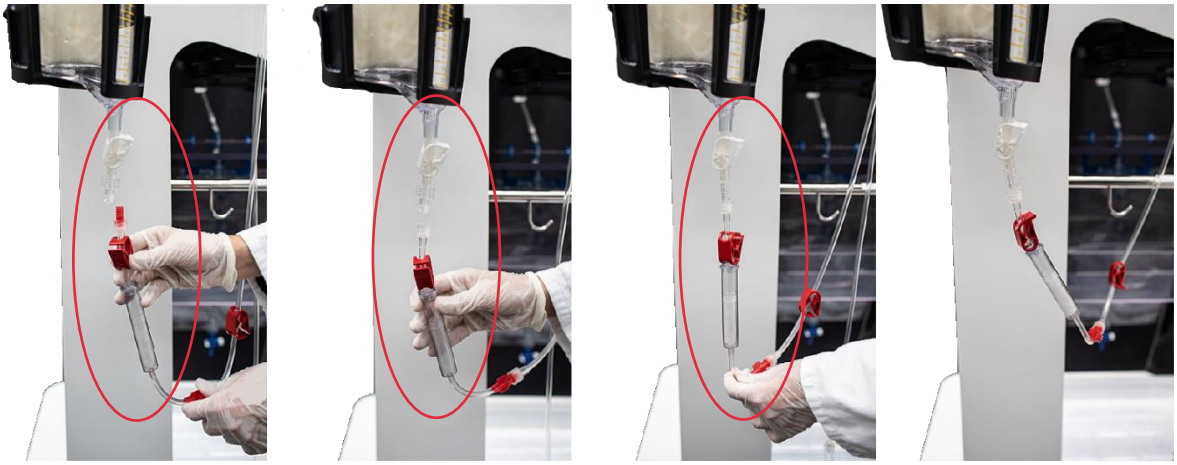

Figure 68: Connection with the Treatment Set

4.9.15. Inserting the tubing in the Collection Line optical sensor

The following screen appears next (See Figure 69).

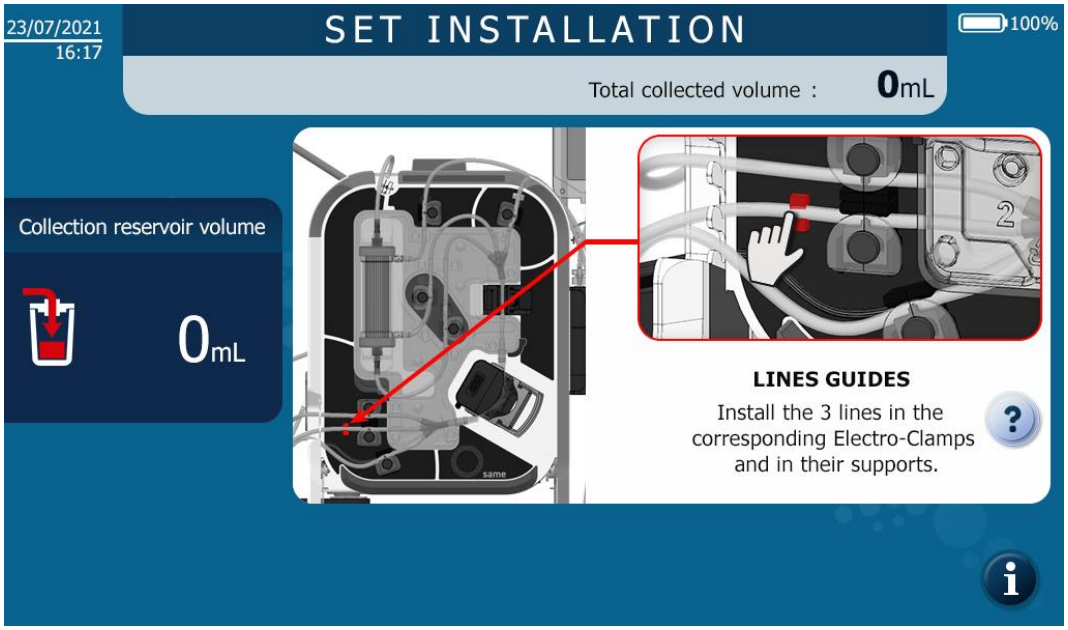

Figure 69: Collection Line optical sensor installation screen

→ Position the tubing in the Collection Line optical sensor and use your finger to press on it so as to fully push it in the sensor (See Figure 70).

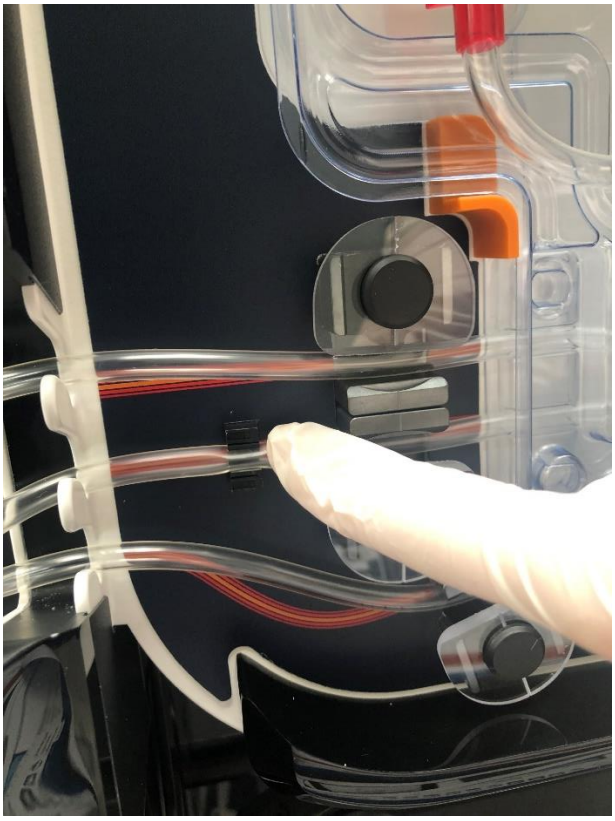

Figure 70: Collection Line optical sensor tubing installation

4.9.16. Inserting the Washing Solution Bag

The following screen appears next (see Figure 71):

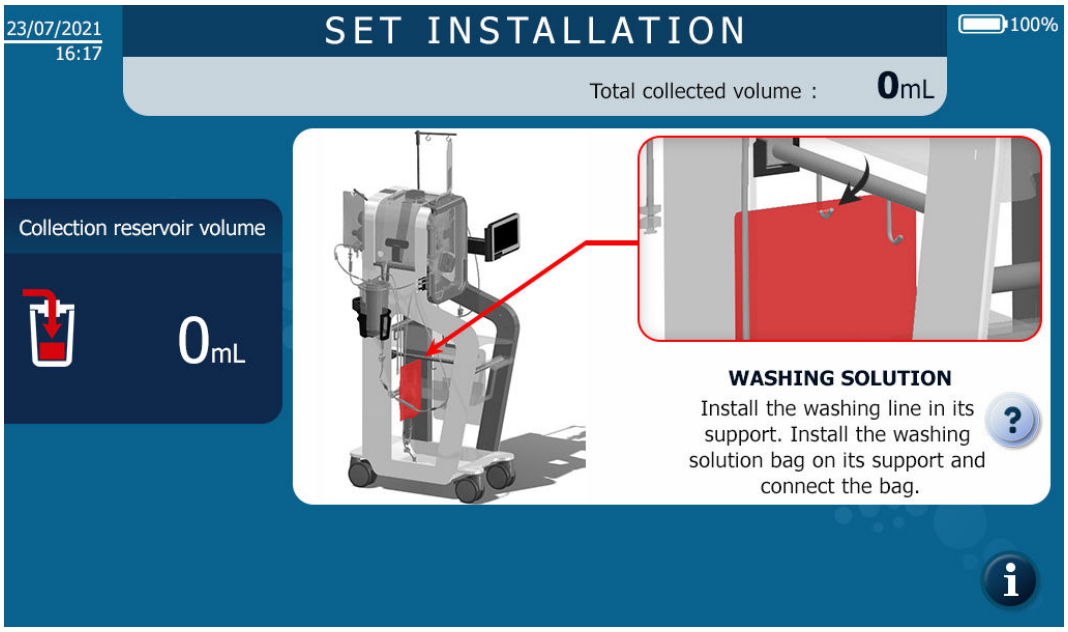

Figure 71: Washing Solution installation screen

The Washing Solution Bag is set up as follows (see Figure 72):

- → Close the manual clamps on the Washing Line.
- → Connect one or two bags of sterile isotonic saline solution to the Washing Line via one or two Washing Line punchers.
- → If the second bag of isotonic saline solution is not connected, then leave the second manual clamp closed.
- → Hang the bag(s) of Washing Solution from the pole provided for this purpose on the ATS; If 2 bags are hung from the pole, it is then recommended to connect the 2 bags to the punchers. The volume of the remaining Washing Solution is monitored by weighing, and if a 2nd bag is not connected this will interfere with the bag exchange alerts.

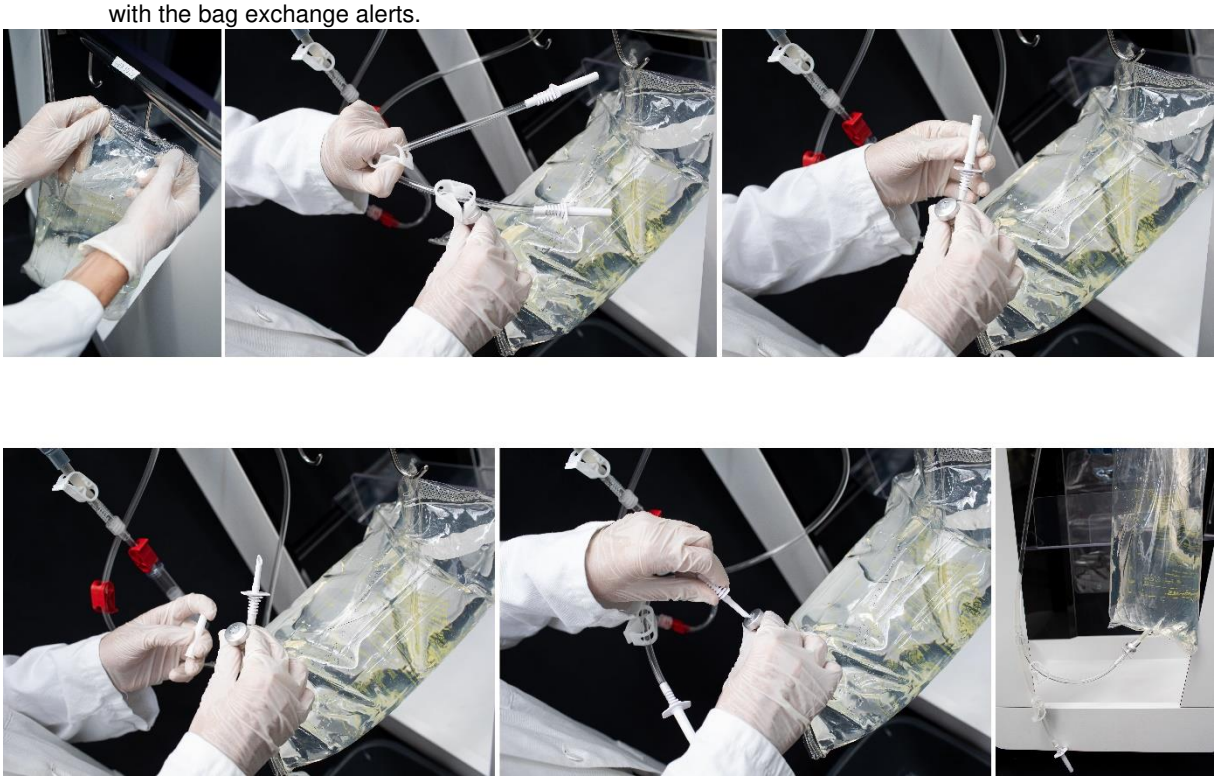

Figure 72: Washing Solution Bag installation

4.9.17. Inserting the tubing in the Waste sensor

The following screen appears next (See Figure 73).

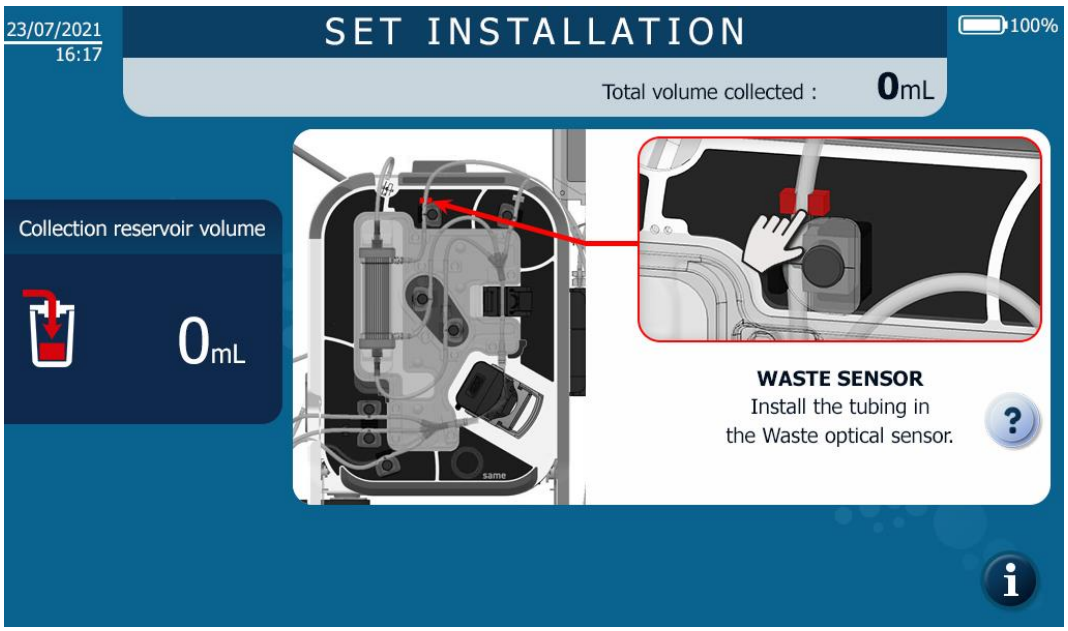

Figure 73: Waste sensor installation screen

→ Position the tubing in the Waste sensor and use your finger to press on it so as to fully push it in the sensor (See Figure 74).

Figure 74: Waste sensor tubing installation

4.9.18. Inserting the non-detectable parts and verifications

The following screen appears next (See Figure 75).

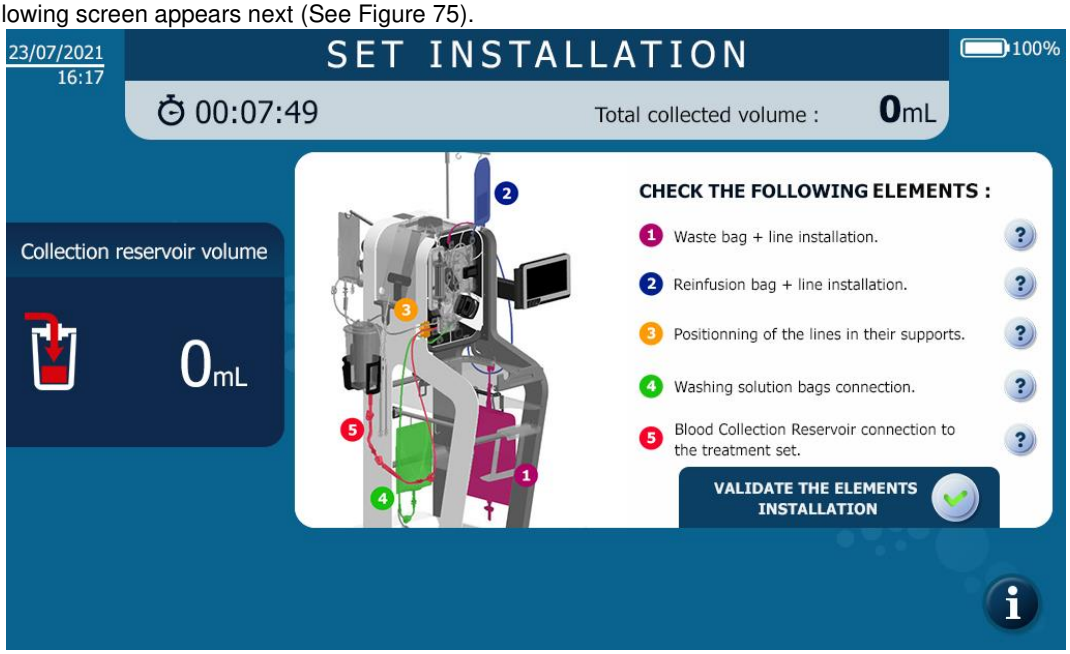

Figure 75: Installation of non-detectable parts screen

4.9.18.1. Inserting the Waste Bag

The Waste Bag is set up as follows (5-litre or 10-liter Waste Bag) (See Figure 76):

- Take the i-SEP Waste Bag from the i-SEP Autotransfusion Treatment Set and unfold it completely.

Warning: If the walls of the Waste Bag stick together, change the i-SEP Waste Bag.

- Hang the Waste Bag on the i-SEP Autotransfusion System shelf using the 2 hooks on the bag.

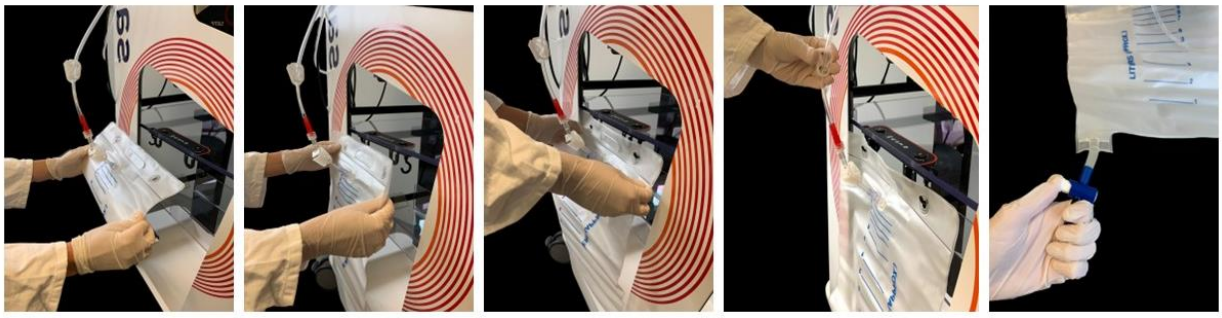

Figure 76: Installation of the Waste Bag

- Check that the Luer connection is correctly tightened.
- Check that the drain valve is closed.

4.9.18.2. Inserting the Reinfusion Bag.

→ Remove the pole for the Reinfusion Bag by pulling upwards, install the bracket at the desired height (See Figure 77).

Figure 77: Pole for the Reinfusion Bag

→ Hang the Reinfusion Bag on one of the hooks on the ATS Reinfusion Bag pole (on the back) using the central eyelet on the bag; the pole can be rotated even if the height is fixed. To lower the pole, operate the lever (See Figure 78).

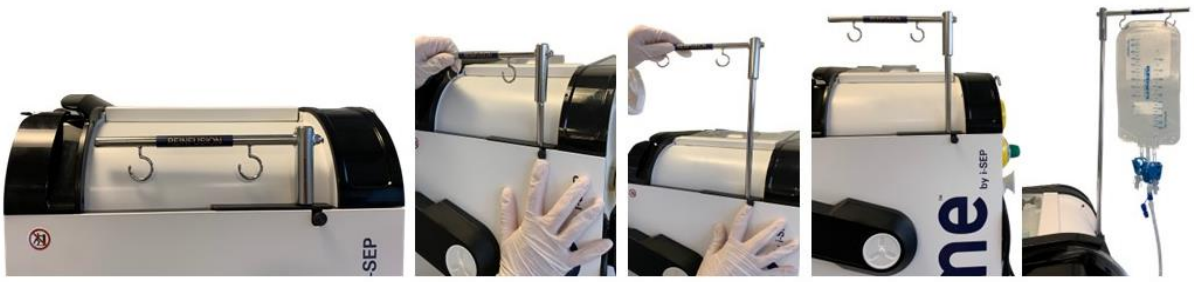

Figure 78: Reinfusion Bag installation

→ Put the Reinfusion Line in the appropriate line guide (See Figure 79).

Figure 79: Insertion of the Reinfusion Line in the line guide

4.9.18.3. Inserting the tubing in the electroclamps

→ Put the tubing at the bottom of the grooves on all of the electroclamps (See Figure 80).

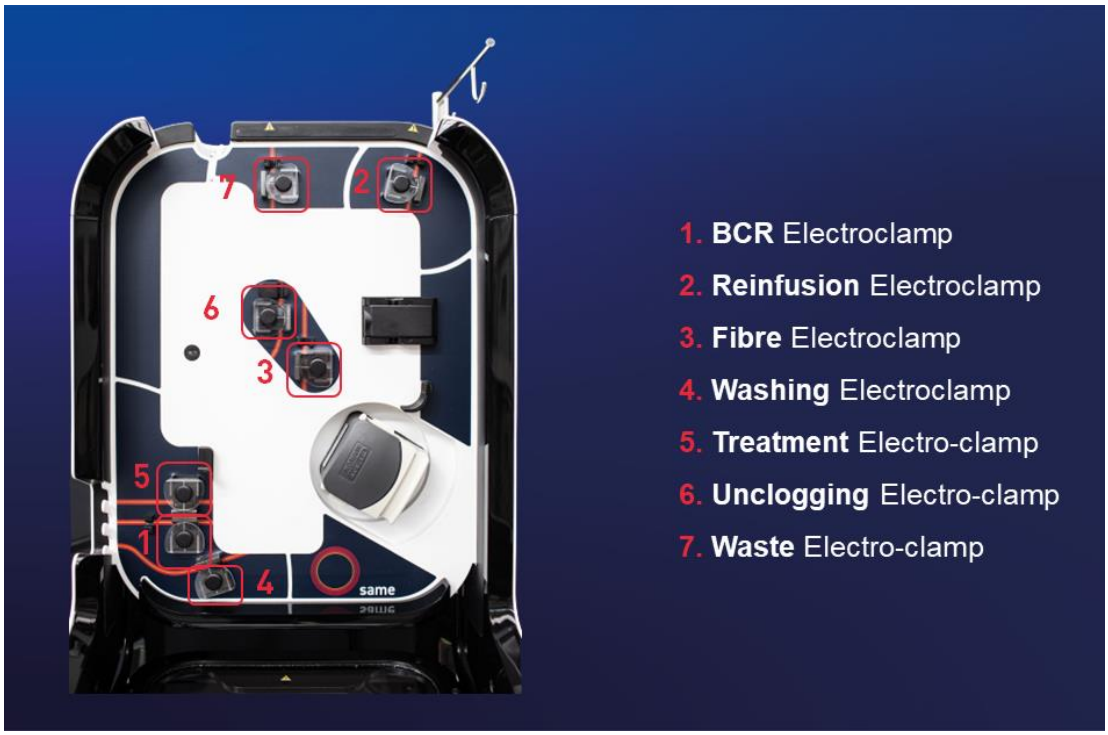

Figure 80: Installation of the electroclamps

4.9.18.4. Inserting the tubing in the tubing bracket

→ Put the tubing at the bottom of the tubing bracket grooves (See Figure 81).

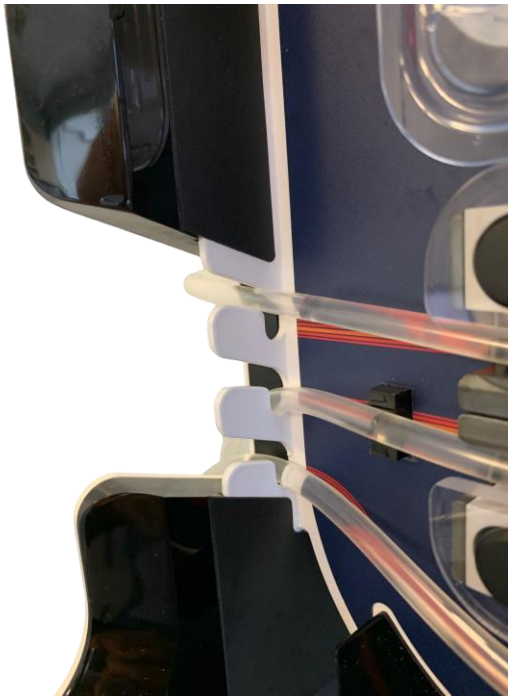

Figure 81: Tubing installation in the tubing bracket

4.9.18.5. Checks and validations

→ Before validating the installation, check the following:
- Connection of the i-SEP Treatment Set to the Washing Solution Bag
- Connection of the i-SEP Treatment Set to the Blood Collection Reservoir
- The position of the tubing in the electroclamps

→ Validate the installation by pressing on the button (See Figure 82).

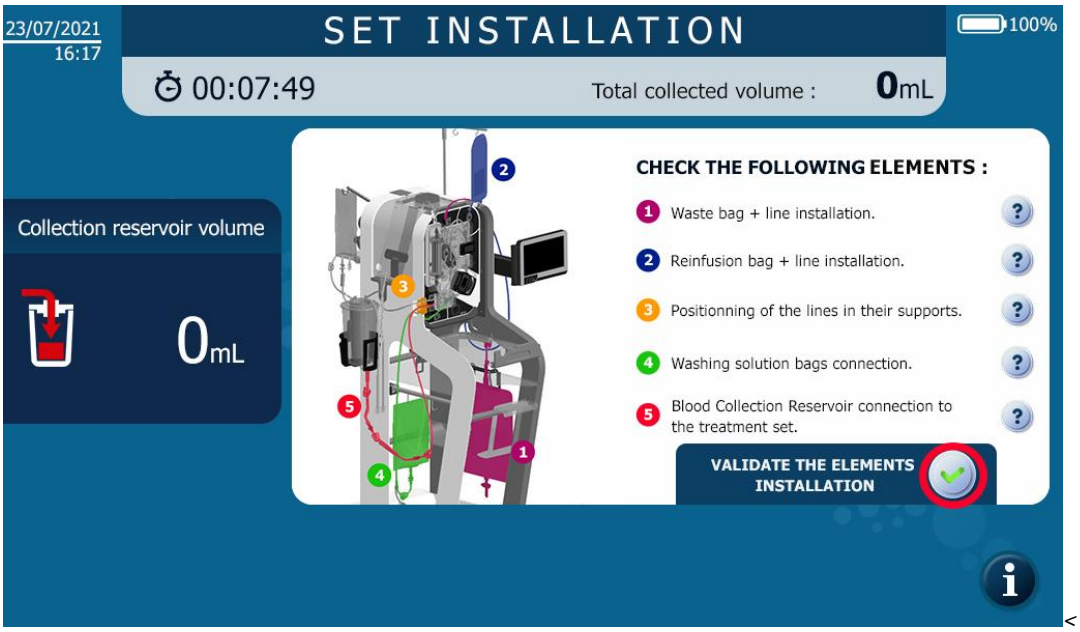

Figure 82: Validating the verification of the non-detectable parts

4.9.19. Closing the protection lid

The following screen appears (See Figure 83).

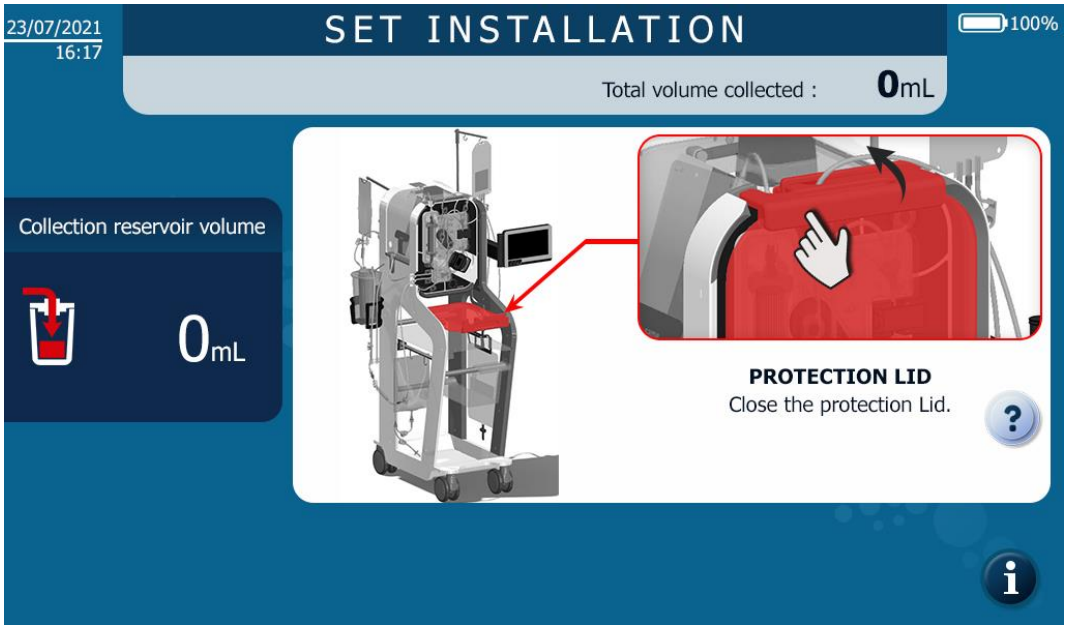

Figure 83: Closed protection lid installation screen

→ Close the protection lid (See Figure 84).

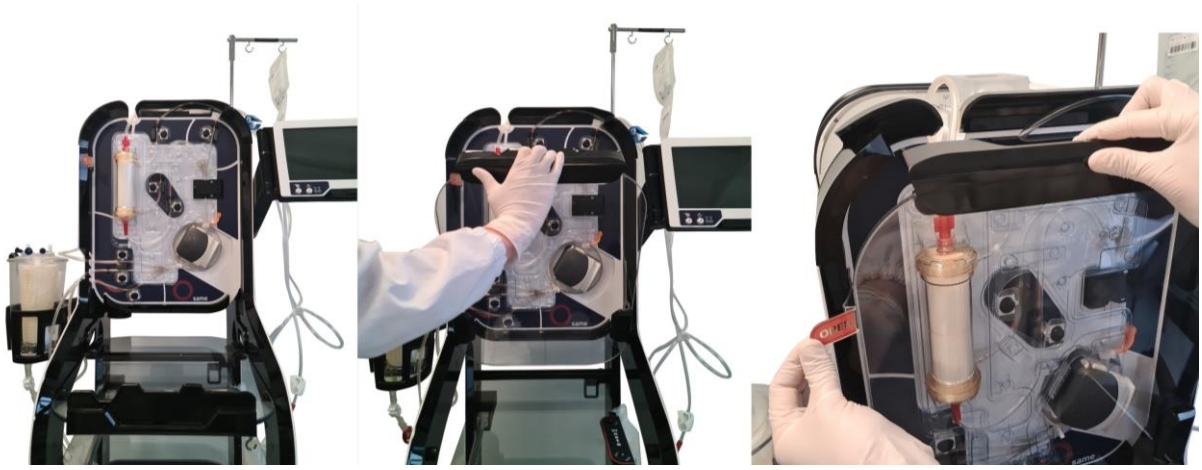

Figure 84: Closure of the protection lid

When the protection lid is closed, the machine will automatically launch an auto-test step. The electroclamps rotate and the sensors are calibrated (See Figure 85).

If the cover is opened during the auto-test phase, it will cancel the test.

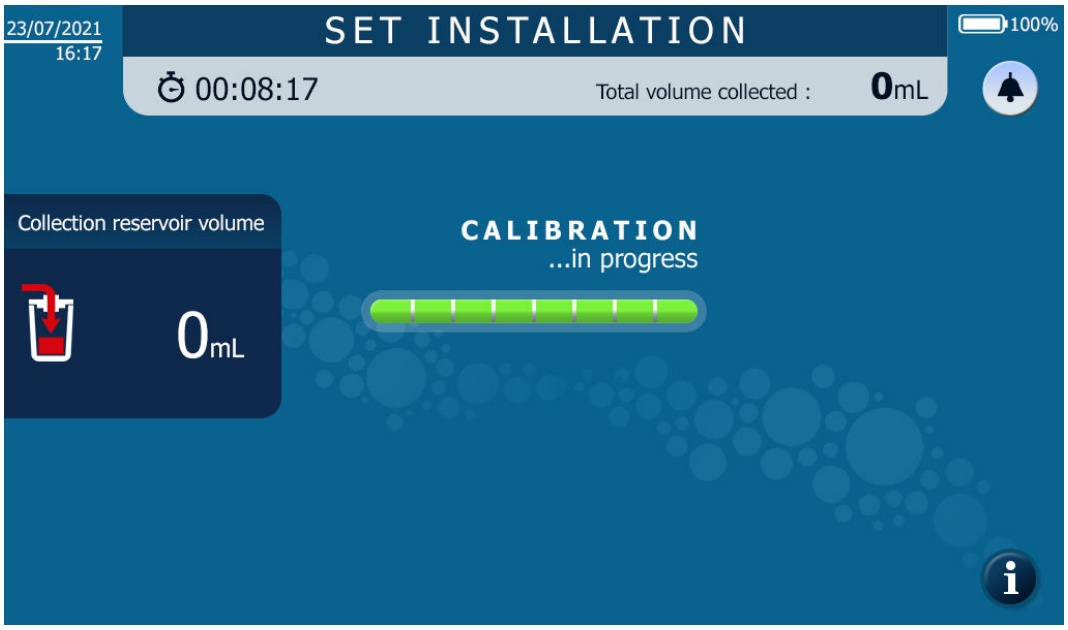

Figure 85: Calibration screen post Set installation

4.9.20. Setting up the aspiration and preparing the Blood Collection Reservoir.

The blood salvaged from the patient during the intraoperative phase is collected in the Collection Reservoir which is connected to an Aspiration and Anticoagulation Line and to a vacuum generation system.

4.9.20.1. Turning on the surgical vacuum

→ Turn on the i-SEP ATS surgical vacuum pump as described in section 4.7.2.

4.9.20.2. Installing the vacuum regulator system

The i-SEP ATS has an internal vacuum pump inside the system and does not need to be connected to the wall outlets in order to have access to the vacuum. The vacuum regulator is mounted and connected to the i-SEP ATS (See Figure 86).

→ Install an antibacterial filter (Legend 5) on the appropriate vacuum regulator outlet.
→ Connect one end of the i-SEP Vacuum Line (Legend 6) to the outlet for the antibacterial filter.
→ Turn on the vacuum regulator by pressing the green button (Legend 3) on the vacuum regulator.
→ While clamping or sealing the i-SEP Vacuum Line, adjust the vacuum to a level between 0 and -200 mbar, ideally -150 mbar, by turning the green adjustment wheel (Legend 4) on the vacuum regulator. The vacuum level is indicated on the dial (Legend 1) with an indicator gauge needle (Legend 2).
If the Aspiration and Anticoagulation Line is not immediately connected to the Reservoir, turn the vacuum pump off and restart it when installing the Aspiration and Anticoagulation Line.

Note: If necessary, it is possible to connect the machine to the wall vacuum by using the standardised vacuum plug (Legend 7) on the back of the i-SEP ATS and repeating the operations described above.

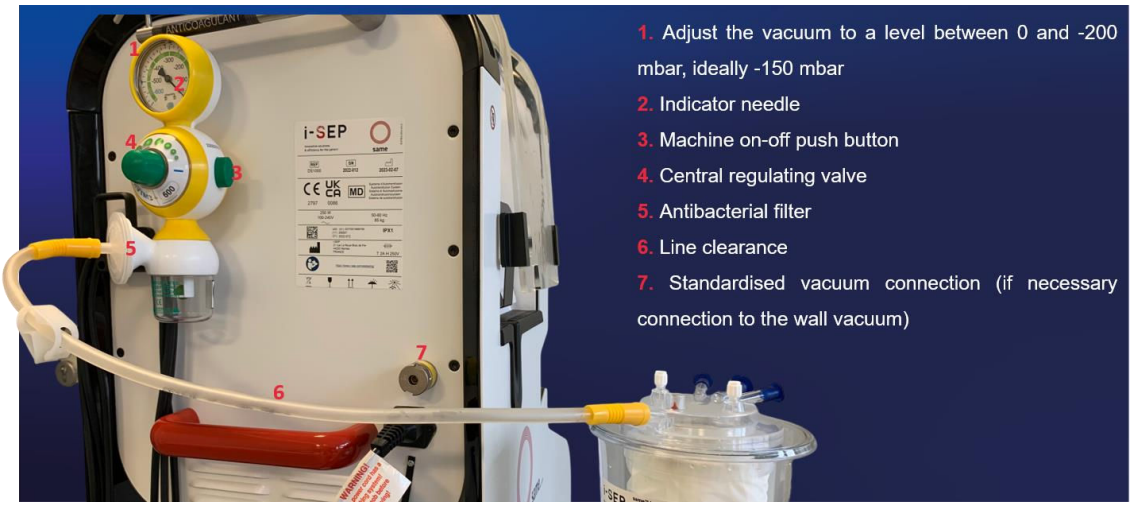

Figure 86: Vacuum installation

Warning:

- **Change the Vacuum Line and antibacterial filter on the vacuum regulator each time you use the i-SEP ATS. The devices are single-use devices, intended to be used with one single patient.**

4.9.20.3. Installing the i-SEP Vacuum Line on the BCR

→ Attach one end of the vacuum line to the antibacterial filter previously installed on the flow regulator supplied with the ATS.

→ Attach the other end to the vacuum inlet port (yellow cap) on the lid of the i-SEP Collection Reservoir (See Figure 87).

Figure 87: Aspiration vacuum installation

4.9.20.4. Installing the anticoagulant solution

→ Lift the hook on the anticoagulant solution holder on the top (at the back) of the i-SEP ATS (See Figure 88).

→ Prepare a bag or a vial of anticoagulant solution containing heparin as described in the Warnings and precautions chapter (Chapter 2.4.6).

→ Hang the anticoagulant solution container on the hook for the anticoagulant solution holder found on the back of the i-SEP ATS.

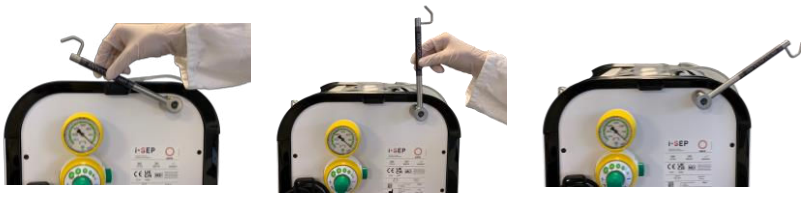

Figure 88: Anticoagulant solution holder

4.9.20.5. Installing the i-SEP Aspiration and Anticoagulation Line

→ Open the outer packaging of the i-SEP Aspiration and Anticoagulation Line using the easy-open systems above the seal (See Figure 89).

Figure 89: Easy-open system for the outer packaging

→ Using aseptic techniques, present the inner packaging to an operator working in sterile conditions.
→ Transfer the inner sterile packaged device to the sterile field.

In the sterile field,

- Open the first paper package using aseptic techniques, making sure never to touch the 2nd package. To do this, first pull on the label that says “PULL TO OPEN”, then unfold each piece using the ends (See Figure 90).

Figure 90: Opening the first paper package of the i-SEP aspiration and anticoagulation line

- Use the tab that says “PULL TO OPEN” on the 2nd piece (indicated by a red arrow in Figure 91) to access the 2nd package.

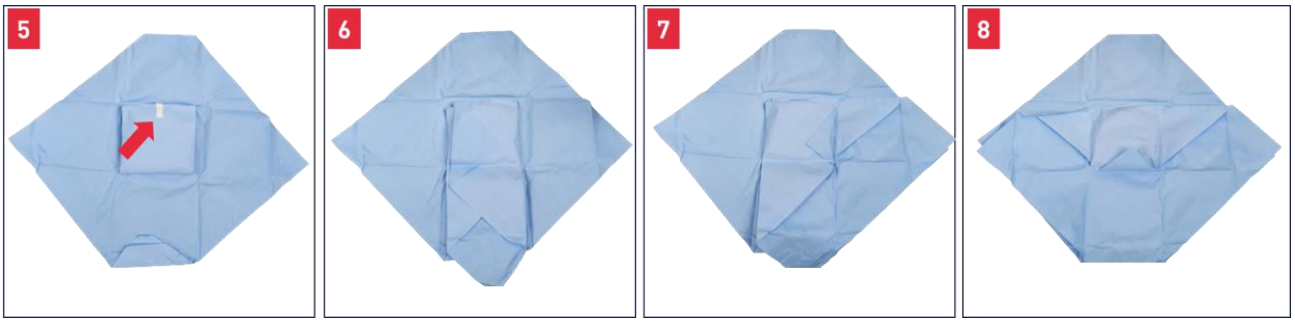

Figure 91: 2nd sterile package after opening the first package of the i-SEP aspiration and anticoagulation line

- Give the line, still in its sterilised paper (See Figure 92), to the sterile operating room nurse.

Figure 92: Aspiration and Anticoagulation Line in its sterile field.

The suction line then looks like this (See Figure 93).

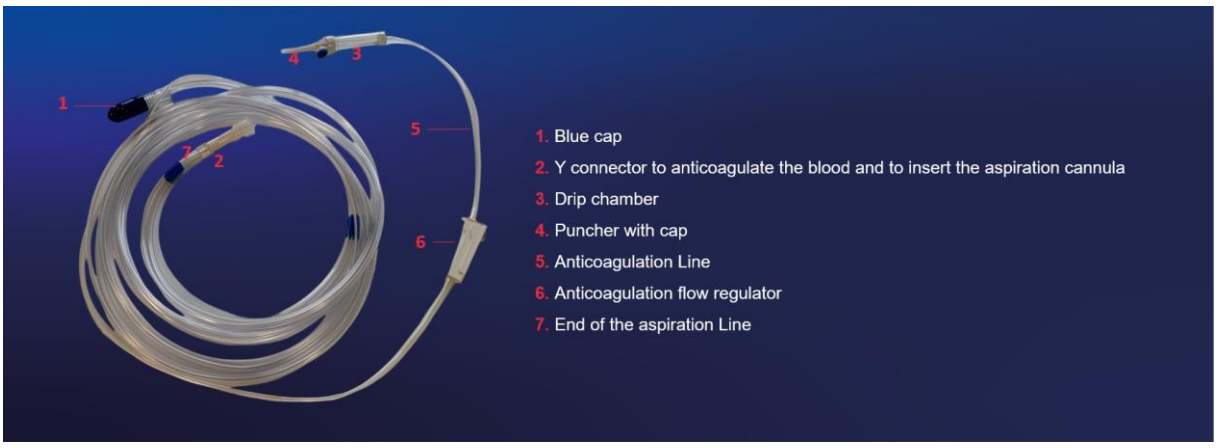

Figure 93: i-SEP aspiration and anticoagulation line

4.9.20.6. Connecting the i-SEP Aspiration and Anticoagulation Line and the i-SEP Blood Collection Reservoir

→ Remove the blue protective cap (Figure 93, Legend 1) on the large-diameter tube from the Aspiration Line.
→ Remove a blue plug attached to one of the two 1/4” blood inlet ports on the lid of the Blood Collection Reservoir (one of the two connectors in Figure 94, Legend 1 below).

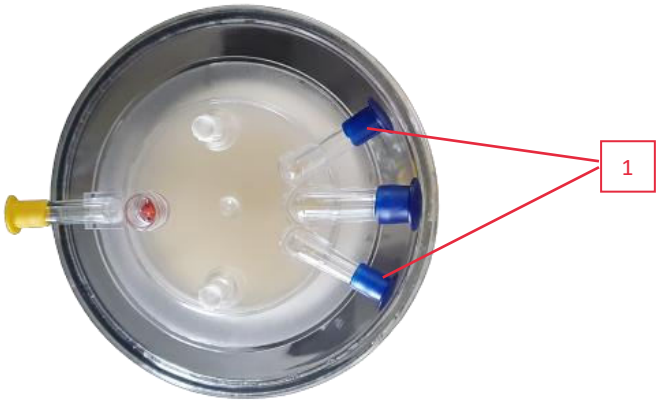

Figure 94: Top view of the Collection Reservoir

→ Connect the Aspiration Line (Figure 93, Legend 1) to the inlet on the Reservoir lid.

4.9.20.7. Connecting the i-SEP Aspiration and Anticoagulation Line to the anticoagulation solution

Remove the protective cap from the white inner seal positioned at the end of the Anticoagulation Line (Figure 93, Legend 4).

→ Using an aseptic technique, puncture the infusion seal on the previously prepared anticoagulant solution container.
→ Check that the vacuum pump is operating and that the manual clamp on the Vacuum Line is open.

4.9.20.8. Priming the i-SEP Blood Collection System

→ With the vacuum system running, open the flow regulator on the Anticoagulant Line and allow approximately 150 to 200 ml of anticoagulant solution to be extracted into the Reservoir before starting to salvage the blood (see Figure 95). This volume should ensure adequate moistening of surfaces in contact with the blood.
→ Close the flow regulator if waiting for blood before launching the treatment, otherwise adjust to the flow rate to 120 drops/minute.

Note: It can be helpful to monitor the volume in the BCR in the HMI.

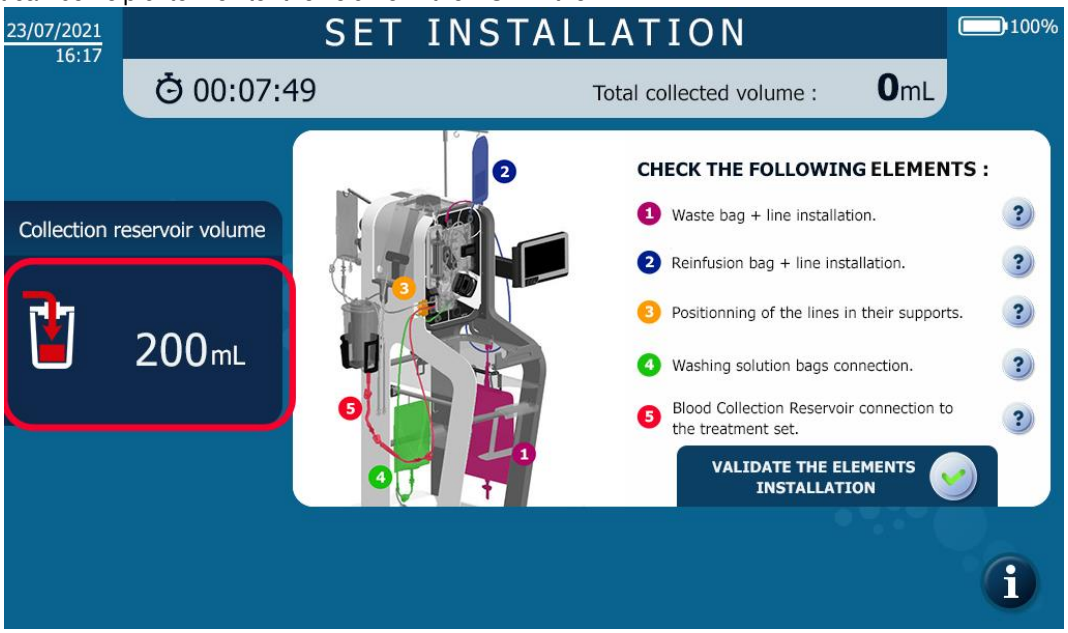

Figure 95: Monitoring the Reservoir priming

4.9.21. Opening the manual clamps

The following final installation screen appears (See Figure 96).

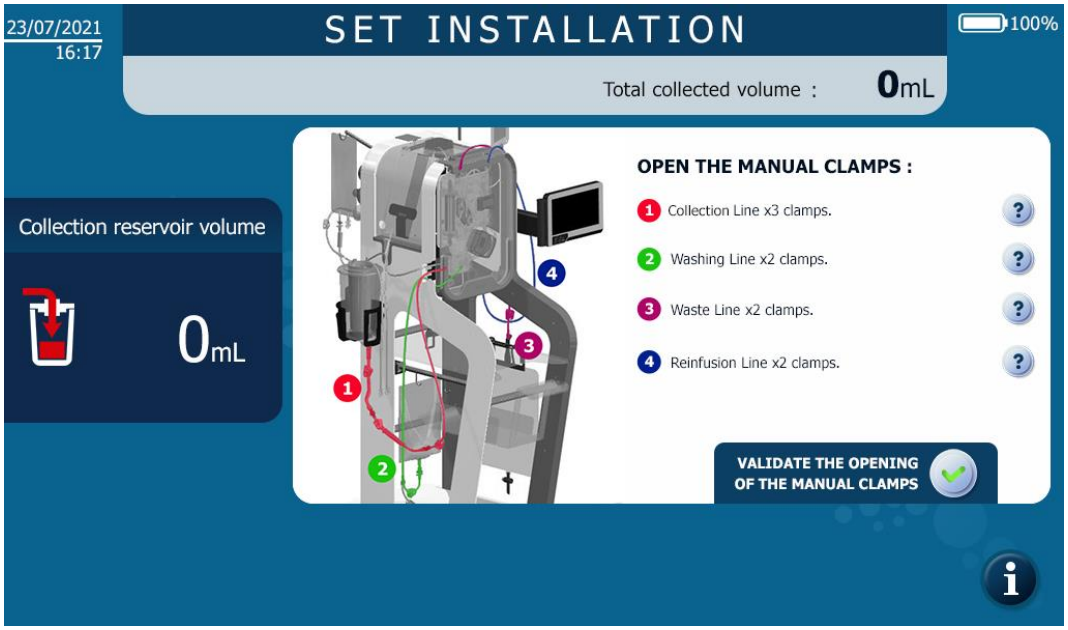

Figure 96: Open manual clamps installation screen

→ Open the manual clamps on all the lines and validate to finalise the installation of the Treatment Set.

4.9.22. Starting the treatment

Once the Treatment Set is installed, a screen is displayed prompting the user to start the treatment in automatic mode (See Figure 97).

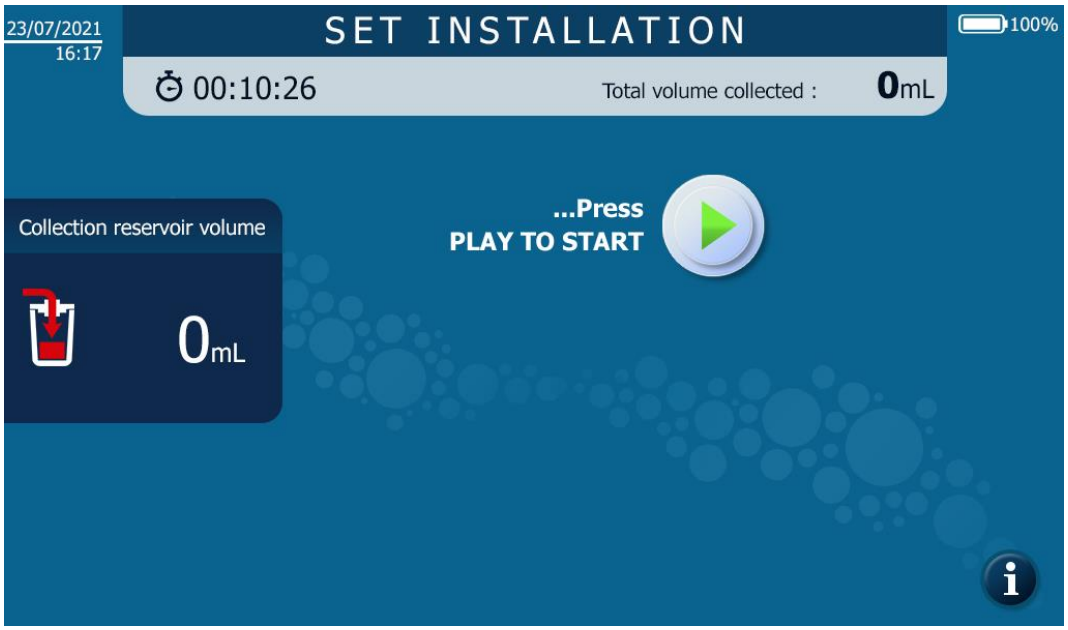

Figure 97: End of Treatment Set installation screen

→ Press Play to launch the treatment in automatic mode

4.10. TREATMENT

During the treatment, to make reading easier, the screen has been divided into different display windows in which the same type of information is displayed (See Figure 98).

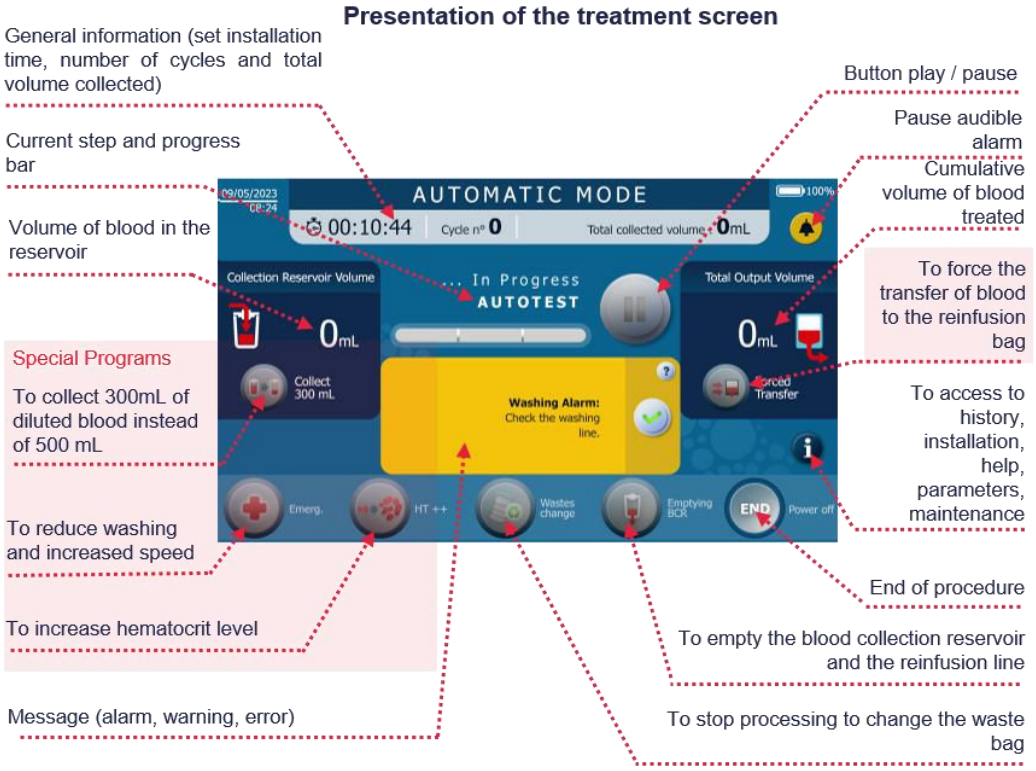

Figure 98: Treatment screen

Treatment with the i-SEP ATS is defined by the succession of programme phases. These phases are represented by the progress bar moving forward and the updating of the phase name in full. The following sequence of steps is displayed:

Waiting for blood volume	
Set transfer	
Treatment 1/3	
Treatment 2/3	
Treatment 3/3	
Reinfusion transfer	
Preparing for the next cycle	

Figure 99: Progress bar

Warning: do not touch the machine (besides the screen) during the auto-test and treatment phases.

4.10.1. Auto-tests

- Once the user has pressed Play, the i-SEP Autotransfusion System carries out the preliminary phase of the treatment (see Figure 100). Thus, the Treatment Set is primed by the circulation of the washing solution (priming). This step enables self-tests to be carried out to check the various sensors as well as to expel the air contained in the Treatment Set.
- If no anomalies in the program sequence are reported, the system automatically moves on to the next phase. In the event of an anomaly, refer to Chapter 5.

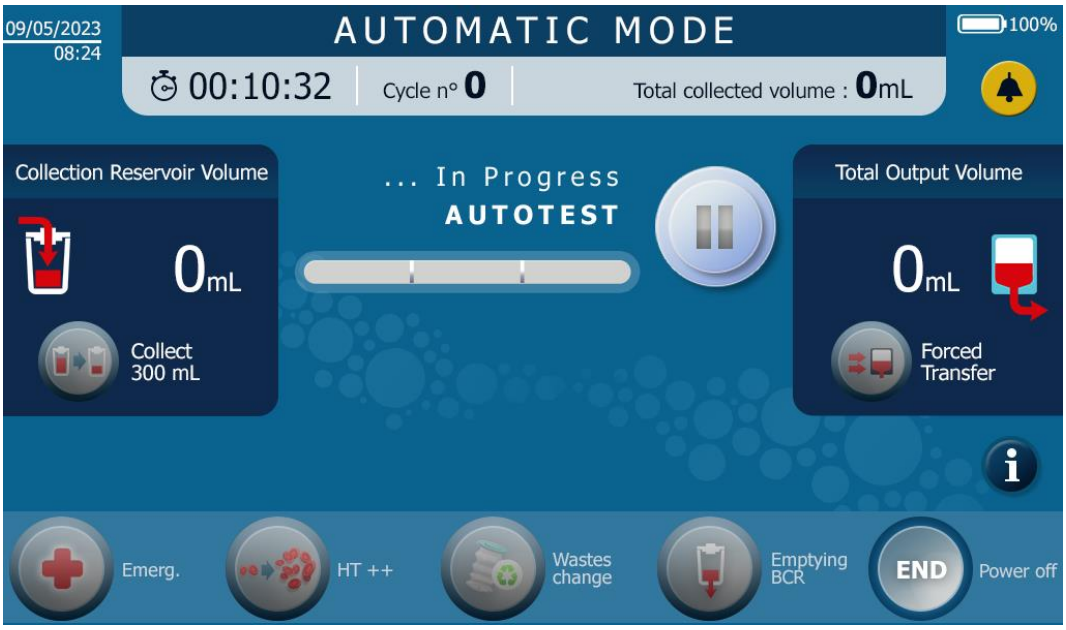

Figure 100: Auto-test screen

4.10.2. Waiting for blood volume

- The system waits for the blood to collect in the Blood Collection Reservoir until it reaches the threshold volume required to launch a treatment.

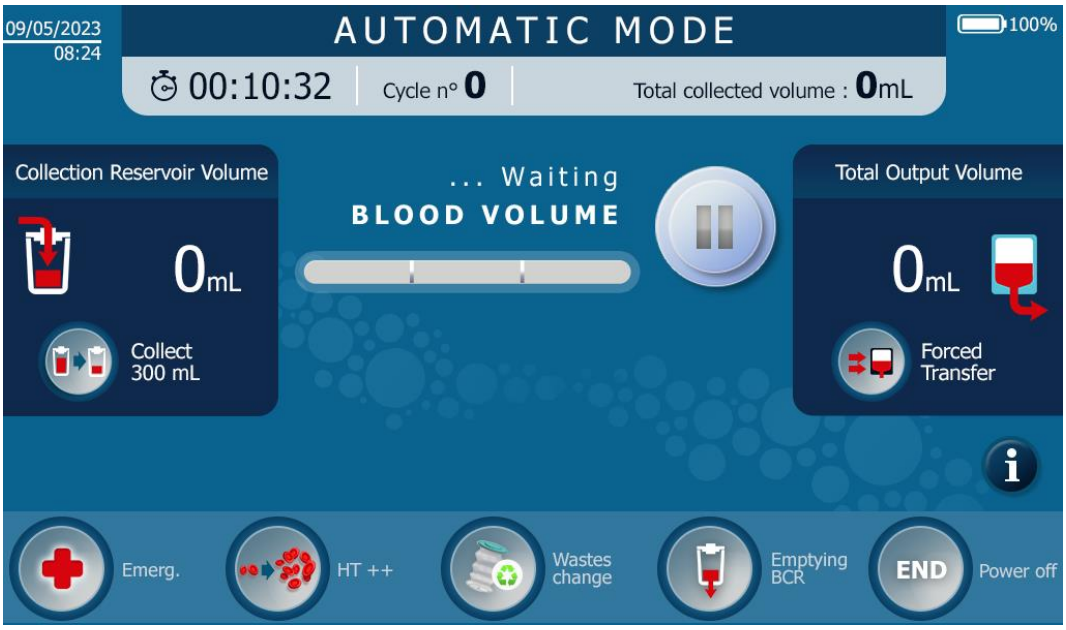

Figure 101: Example of the Waiting for Blood screen

4.10.3. Treatment

- Anticoagulated blood is transferred from the Collection Reservoir to the Treatment Set.
- The anticoagulated blood is washed and concentrated.
    - The washing solution is automatically pumped into the Treatment Set at defined wash rates;
    - The blood fluid circulates in the set between the Treatment Bag and the fibre (concentration);
    - The fluid to be removed is evacuated from the treatment circuit to the Waste Bag via the Waste Line;
    - The system is then washed (dilution);

- The concentration and dilution step repeats three times. The step name incorporates a notion of progress among these three repetitions.

An example of a screen is shown below (See Figure 102).

Figure 102: Example of a treatment screen

- If no anomalies in the program sequence are reported, the system automatically moves on to the next phase. In the event of an anomaly, refer to Chapter 5.

4.10.4. Reinfusion transfer

- The washed and concentrated blood product is transferred from the Treatment Set circuit to the Reinfusion Bag.
- If no anomalies in the program sequence are reported, the system automatically moves on to the next phase. In the event of an anomaly, refer to Chapter 5.

4.10.5. Preparing for the next cycle

At the end of the blood transfer in the reinfusion bag, the machine initiates a step to prepare the next cycle, during which the entire set is purged and cleaned.

After this step, a summary of the output data from the treatment that was just completed is presented on the screen, as shown in the fictitious example below (see Figure 103).

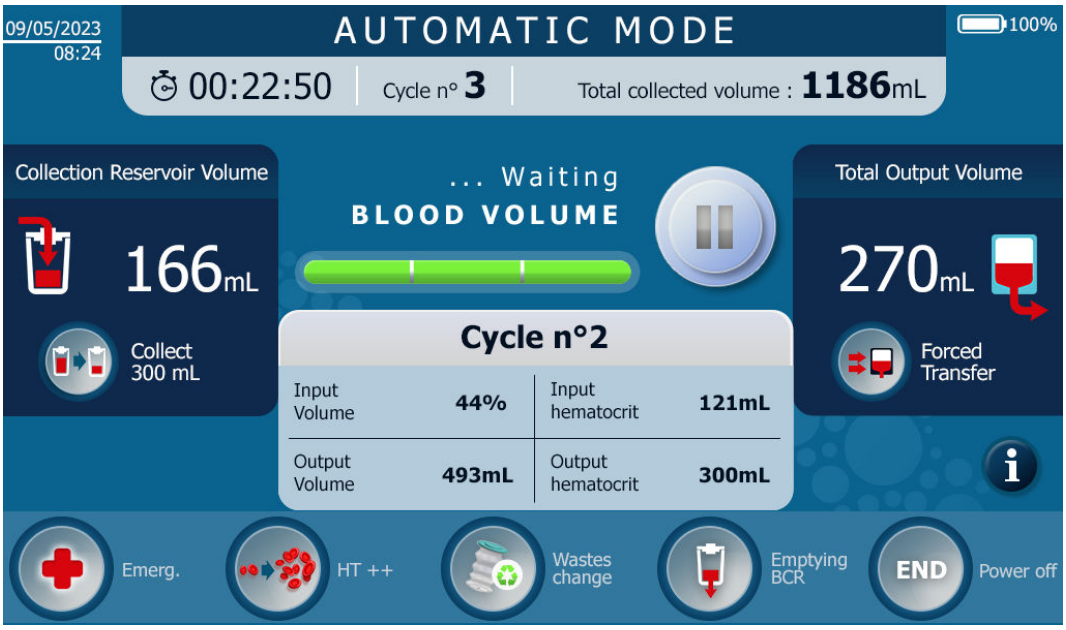

Figure 103: End of treatment summary

4.10.6. Cycle repetition

- Once the blood product has been treated, the programme goes back to the Waiting for Blood phase.
- If enough anticoagulated blood is collected in the BCR, then a new treatment cycle starts: the program returns to the phase described in 4.10.2.
- The cycle number increases by one.
- If the volume of anticoagulated blood collected is less than the threshold for automatically launching a new cycle, the user has two options:
    - Treat the volume of blood collected: see Chapter 4.11.7;
    - Do not treat the volume of blood collected until there is enough blood to launch a new cycle.

4.11. TREATMENT OPTIONS

4.11.1. General view – choosing a programme

The standard mode is automatically launched when the ATS is started. The user can switch from standard mode to emergency mode or implement specific functions that match the context of use.
The contexts of use that guide the selection of a mode or a function are described in the following table:

Type of programme	Programme name	Context of use
Modes	Standard mode	Standard conditions of use: it is not an emergency situation, an high-quality autologous blood product is requested within a standard period of time.
	Emergency mode	An autologous blood product is required as soon as possible due to an emergency situation occurring during surgery, e.g. haemorrhaging. There may be residues of heparin and free haemoglobin above the specified thresholds.
Functions	Haematocrit ++	The user is accustomed to working with a blood product with a high haematocrit index, higher than 55% (fifty-five percent). It is not an emergency situation.
	Collect 300 ml	Volumes lower than the threshold volumes defined in automatic mode can be treated, for periodically closer reinfusions. As an example, a surgery displays two operating sequences: a first sequence that generates small blood losses and a second that generates significant blood losses. The 300 ml treatment function can be selected during the first surgical sequence, so as to have a empty Collection Reservoir available prior to the start of the second surgical sequence. Attention: This function is only available for the ST0501GB model.
	Forced transfer	During a treatment in automatic mode, the user needs the treated blood product to be available more quickly. The length of the treatment is shorter than in standard mode. There may be residues of heparin and free haemoglobin above the specified thresholds. The blood product concentration is > 40% (forty percent).

Type of programme	Programme name	Context of use
	Last treatment	At the end of the intended use of the ATS, the user can treat the volume of blood remaining in the Blood Collection Reservoir so that the remaining blood is not wasted. The characteristics of the concentrated blood product are presented for information purposes (concentrated blood volume, estimated final haematocrit level).The user will be informed if the characteristics of the treated product do not correspond to those defined for the standard mode (haematocrit level greater than forty percent). The user can decide if the output product is treated for reinfusion or if it should be thrown away.
	Changing the Waste Bag	This function enables the user to safely change the waste bag because it is faulty or it is almost full. The machine will record the request and stop the treatment at the best time to change it.
Pausing the programme	Pause	This function enables the user to take a break, or immediately stop the peristaltic pump if there is a problem. The treatment is stopped and can be restarted later.

4.11.2. Pausing

The  button is used to pause the system for various reasons, the machine stops immediately.

If a request to pause the machine is made during a step where the filter is in blood, a time-out is launched so as not to let the blood clog (plug) the filter. Once this time-out has elapsed, the system will automatically unclog the filter in order to keep the Treatment Set working and to ensure correct filtration when the treatment is restarted.

It is possible to stop the treatment during the filter cleaning phase by pressing the STOP  button.

The STOP button is replaced by the PLAY button. 
To restart the unclogging step, press the PLAY button.
Warning: the longer the filter remains in blood during a STOP, the higher the risk of increased deterioration of the hollow fibres and/or an increase in the treatment duration.

Once the machine is paused, simply press the central button again to restart the treatment  It will automatically pick up where it left off during the current cycle.

4.11.3. Emergency mode

Depending on the context of the surgery, the user may want to switch into the Emergency mode (see 4.11.1).

- Press the  button to activate the Emergency mode.
- The following message appears on the screen:
  'Activation of this mode entails a risk of heparin and free haemoglobin being present in the blood'
- Validate by pressing on the  button or refuse by pressing on the  button.
- If no choice has been made by the user, the message disappears without initiating the function after a given time (several seconds).
- When the Emergency mode is activated, an active Emergency mode button  appears and this mode is indicated in the top banner (see Figure 104).

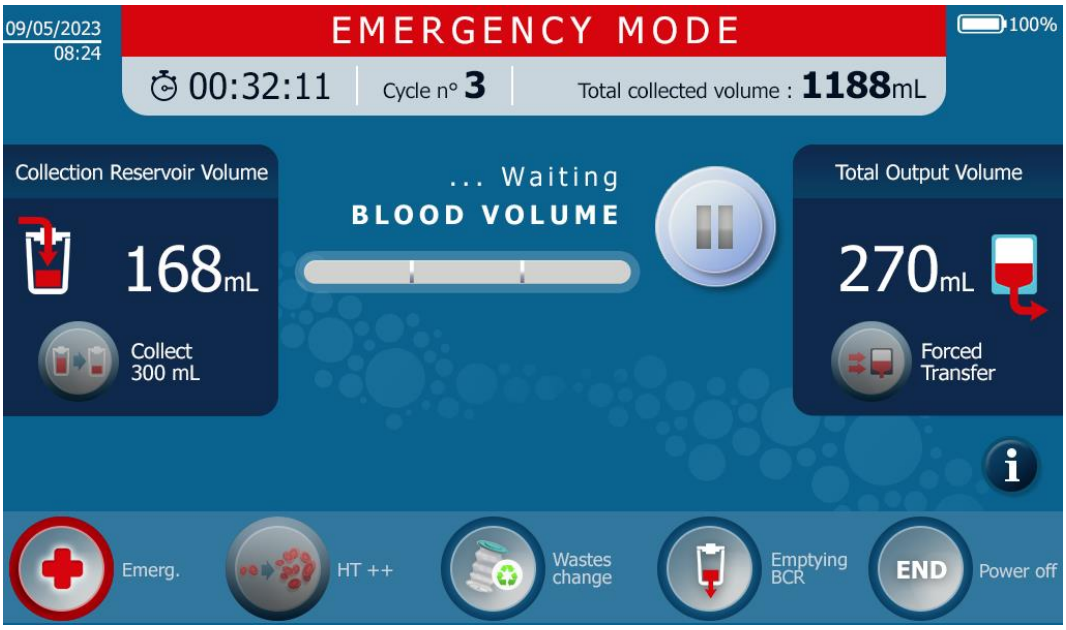

Figure 104: Emergency mode

- The Emergency mode may reduce the number of concentrations and/or the wash volume in the treatment.
- The Emergency mode ends with the transfer of the treated blood product as per the emergency mode.
- The Emergency mode remains activated.
- Press the Emergency button again to deactivate the mode.

Note:

- In Emergency mode, the HT++ haematocrit function is not available.
- In Emergency mode, the Forced transfer function is not available.

4.11.4. Forced transfer

Depending on the context of use, the user may want to switch into the 'Forced transfer' function (see paragraph 4.11.1).

- This function allows the blood to be quickly returned to the Reinfusion Bag.
- Press on  button to activate the 'Forced transfer' function (See Figure 105).

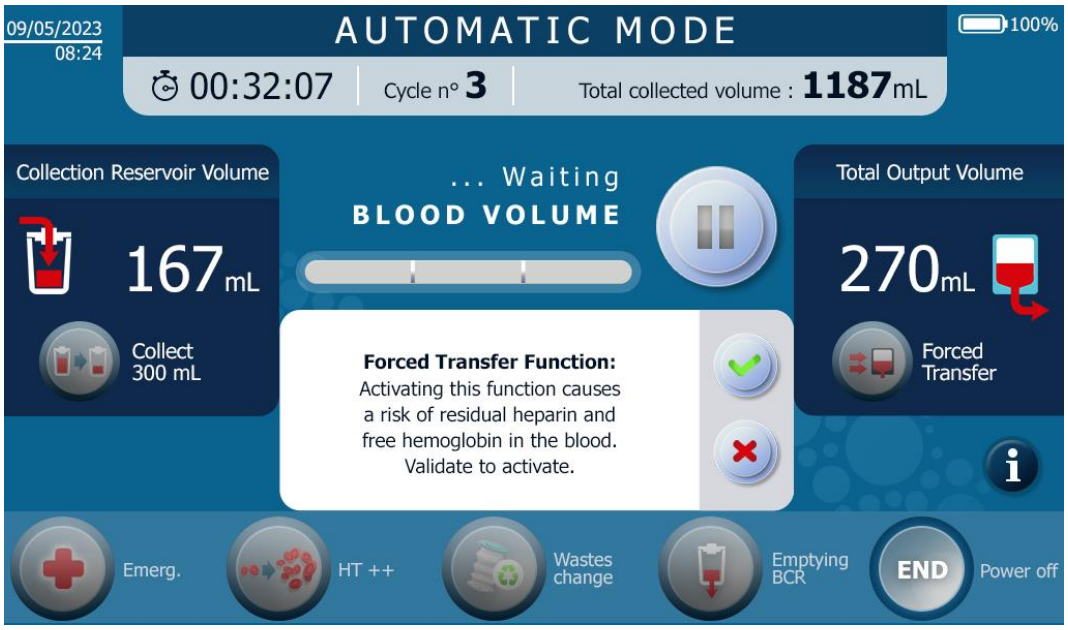

Figure 105: Forced Transfer Function Screen

- Validate by pressing the  button or refuse by pressing the  button.

- When the 'Forced transfer' function is activated, an activated Forced transfer function button  is displayed and the top banner turns purple (see Figure 106).
- The 'Forced transfer' function ends with the transfer of the treated blood product, as per the Standard mode, to the concentration in which it is found.
- The 'Forced transfer' function is automatically deactivated for the next cycle.

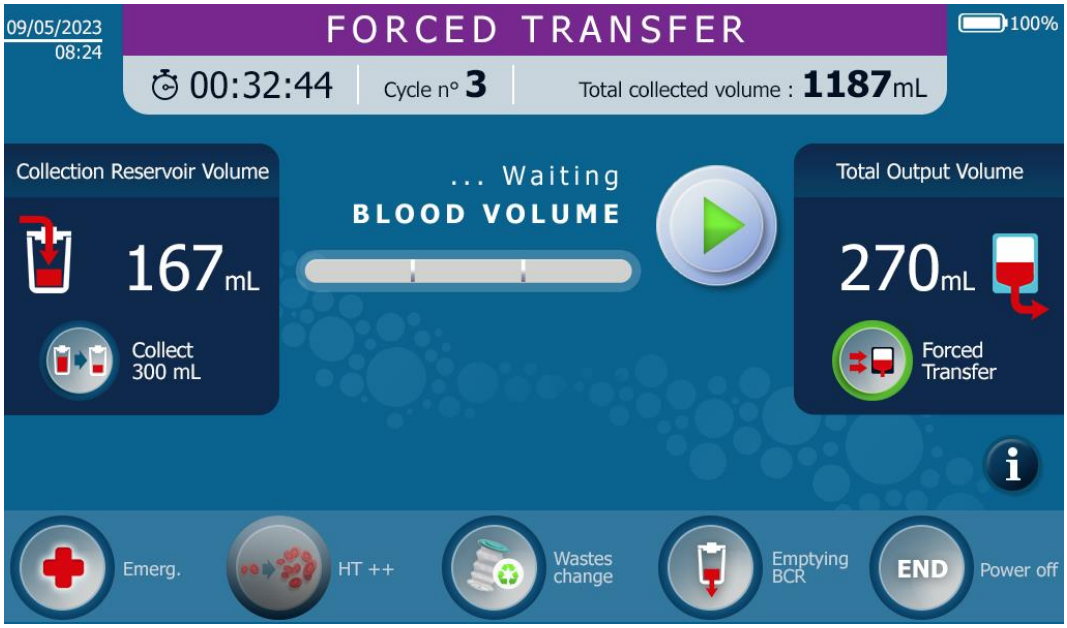

Figure 106: Forced transfer screen with function activated

Note:

- **Once the 'Forced transfer' function has been activated, only the Emergency mode can be activated.**

4.11.5. 300 ml treatment

Depending on the context of use, the user may want to switch into the '300 ml treatment' function. This function cannot be activated if a ST0301 set is used.

- This function makes it possible to treat a smaller volume.
  Note: this function can only be activated if a ST0501 Treatment Set is used

- Press the  button to activate the 300 ml treatment function.
- The following message appears on the screen (See Figure 107):

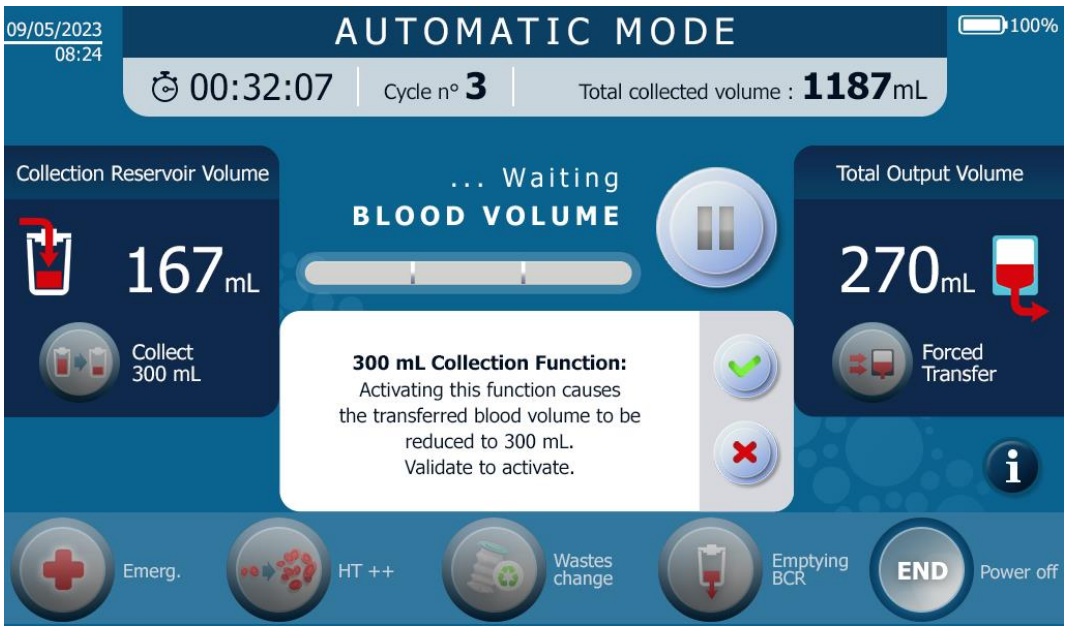

Figure 107: 300mL treatment screen

- Validate by pressing the  button or refuse by pressing the  button.

- The activated '300 ml treatment' function is displayed by a Treatment function button  (See Figure 108).
- The '300 ml treatment' function remains activated for the next cycle.
- Press the 300 ml treatment button again to deactivate the function.

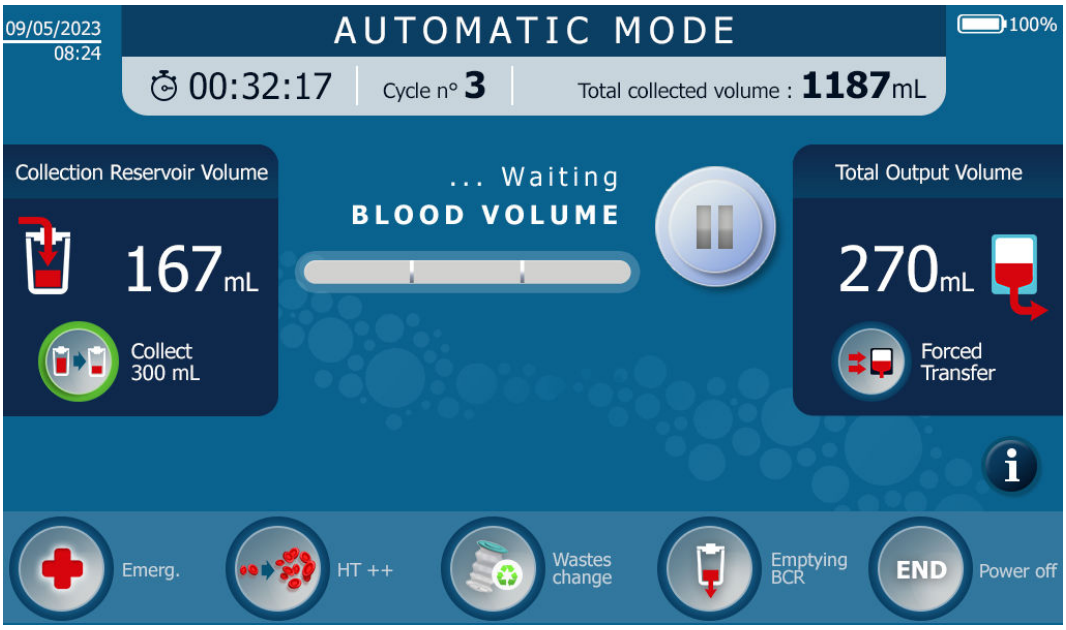

Figure 108: 300mL treatment screen with the function activated

4.11.6. High haematocrit concentrations

Depending on the context of use, the user may want to switch into the 'HT++' function (See Figure 109).

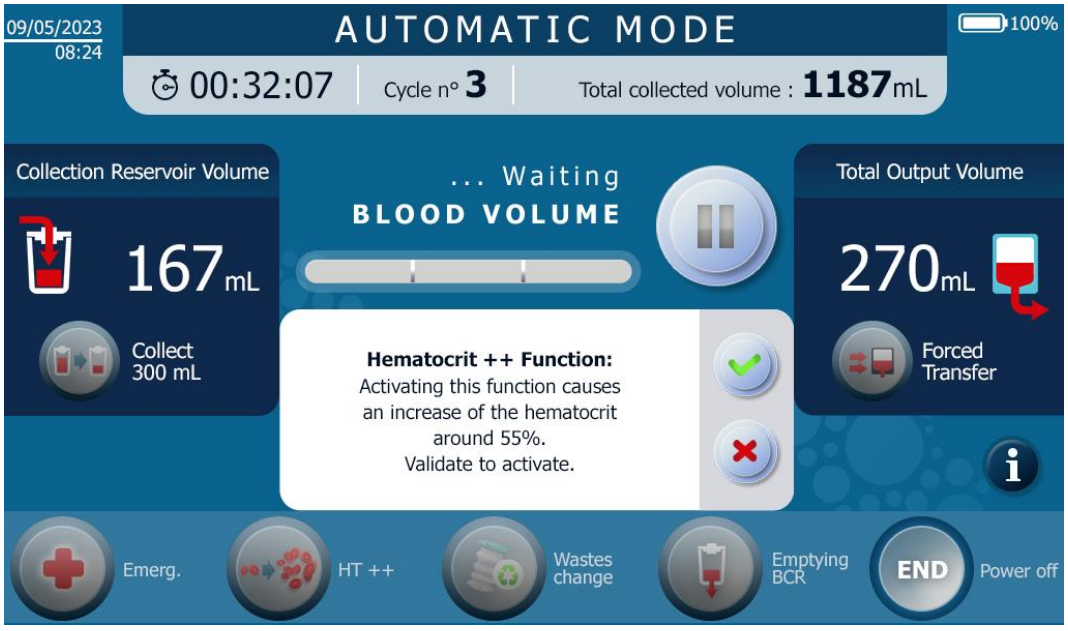

Figure 109: High haematocrit screen

- This function makes it possible to obtain blood in the Reinfusion Bag with a haematocrit concentration higher than 55%.
- Press the  button to activate the HT++ function.
- The following message appears on the screen:
- 'The activation of this mode results in an increase in the haematocrit index to 55%, a longer treatment and a loss of platelets. Validate the launch'

- Validate by pressing on the  button or refuse by pressing on the  button.
- The activated 'HT++' function is displayed by an active HT++ function button  . (See Figure 110)
- The 'HT++' function is automatically deactivated after the blood is transferred into the Reinfusion Bag.

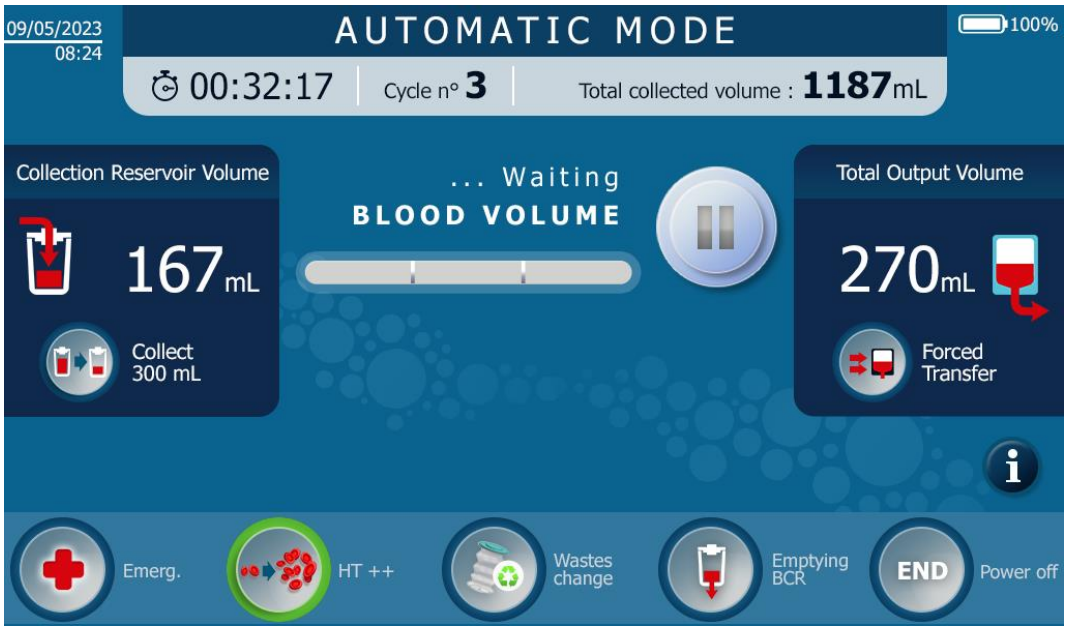

Figure 110: High haematocrit screen with the function activated

Note:

- **Once the HT++ function has been activated, all the other modes or functions can be launched.**

4.11.7. Last treatment

- The 'Last Treatment' function makes it possible to empty the BCR (See Figure 111).
- Press the  button to activate the Last Treatment function.
- The following message appears on the screen:
  'Last Treatment Function: Activating this function causes the emptying of the blood collection reservoir. Validate to activate.'

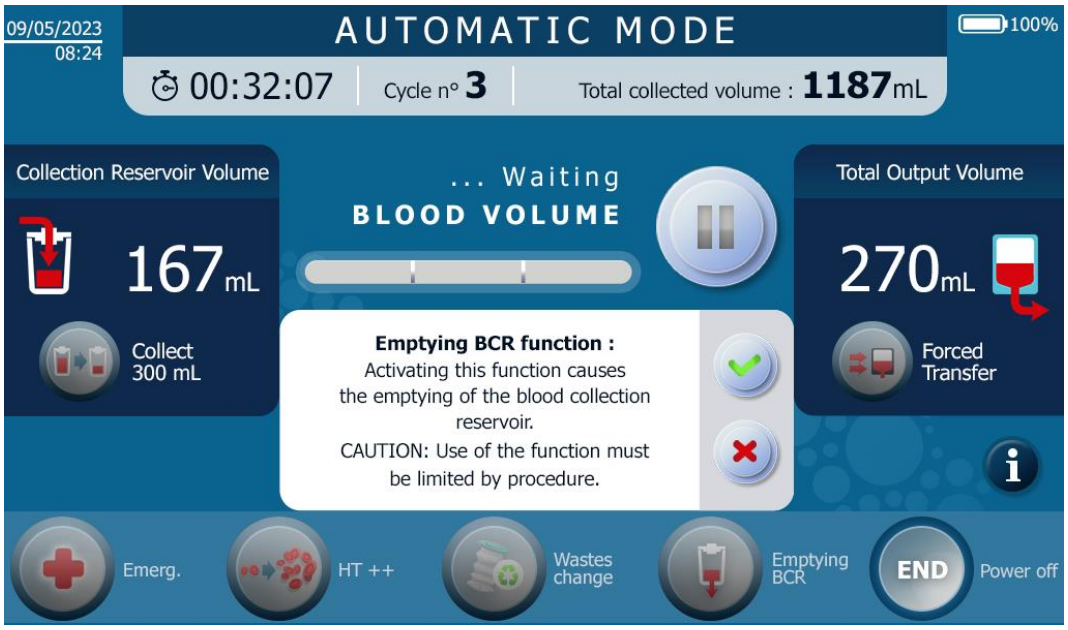

Figure 111: Last Treatment launch

- Validate by pressing the  button or refuse by pressing the  button.
- The activated 'Last Treatment' function is displayed by an active Last Treatment function button  .
- The haematocrit concentration in the treated blood product is calculated. The user receives an alarm message if it is not possible to meet the treatment specifications, i.e. if there is not enough blood to treat (the system's dead volumes are reached).
- The use of Last Treatment Function can lead to an air inlet in the treatment set.
- Once the blood has been treated and transferred to the Reinfusion Bag, the Reinfusion Line is emptied to fully salvage the treated blood product.

Notes:

- **In the event of an unexpected occurrence of blood loss, it is always possible for the operator to launch a treatment. The treated blood will be diluted with the Washing Solution (NaCl 0.9%) present in the Reinfusion Line.**
- **The Last Treatment Function can be used to treat a highly diluted blood.**

4.11.8. Changing the Waste Bag

- The function makes it possible to stop the system at the right moment in order to replace the Waste Bag that is full of the system's washing effluents with an additional Waste Bag supplied by i-SEP.
- The function can be called up by the user or by the System at any time.

To activate the Change Waste Bag function, the user:

- Press the  button to activate the Change Waste Bag function.
  The programme takes the request into account and pauses the system at a time when there is no clogging risk for the fibre. The programme then prompts the user to change the Waste Bag
- Exchange the full Waste Bag for an empty Waste Bag (see Chapter 0).

- Validate by pressing the  button to let the machine know that the change has been made and to restart the cycle where it left off.

Note: the monitoring of the volume of the waste bag is reset to zero from as soon as it is validated.

- **The System informs you of the need to change the Waste Bag (See Figure 112):**
  - Depending on how full the Waste Bag is, a message appears in the information inset on the screen to alert you about the filling level in the Waste Bag.
  - If the maximum allowable volume is exceeded without the user activating the Change Waste Bag function, the ATS will wait until the next best time to turn off the system.
  - The programme pauses the system when there is no risk of clogging of the fibre. The programme then prompts the user to change the Waste Bag.
  - Exchange the full Waste Bag for an empty Waste Bag (see Chapter 4.14.1.3).

Figure 112: Change Waste Bag screen after the user request

- Validate by pressing the button 

4.12. END OF SURGERY

- The 'End of surgery' function allows to shut the machine down

Press the 

button to activate the Machine Shutdown function or press at least two seconds on the  push button on the screen holder (red circle below, see Figure 113).

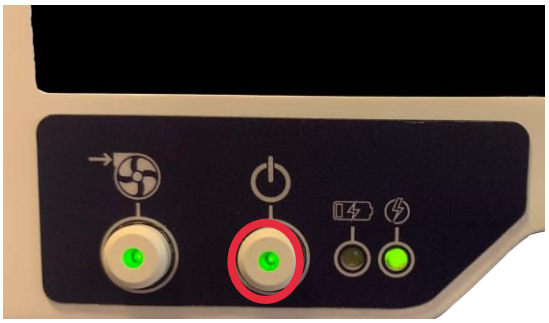

Figure 113: ATS in operation

If the button is pressed during a cycle, the ATS performs the 'End of surgery' function.
If the user presses the button before starting the programme in Automatic mode, the HMI will go to the shutdown screen.
Then, close the manual clamps and validate to turn off the HMI.

If the button is pressed during a treatment cycle, the ATS performs a "End of surgery".

- The following message appears on the screen (see Figure 114):

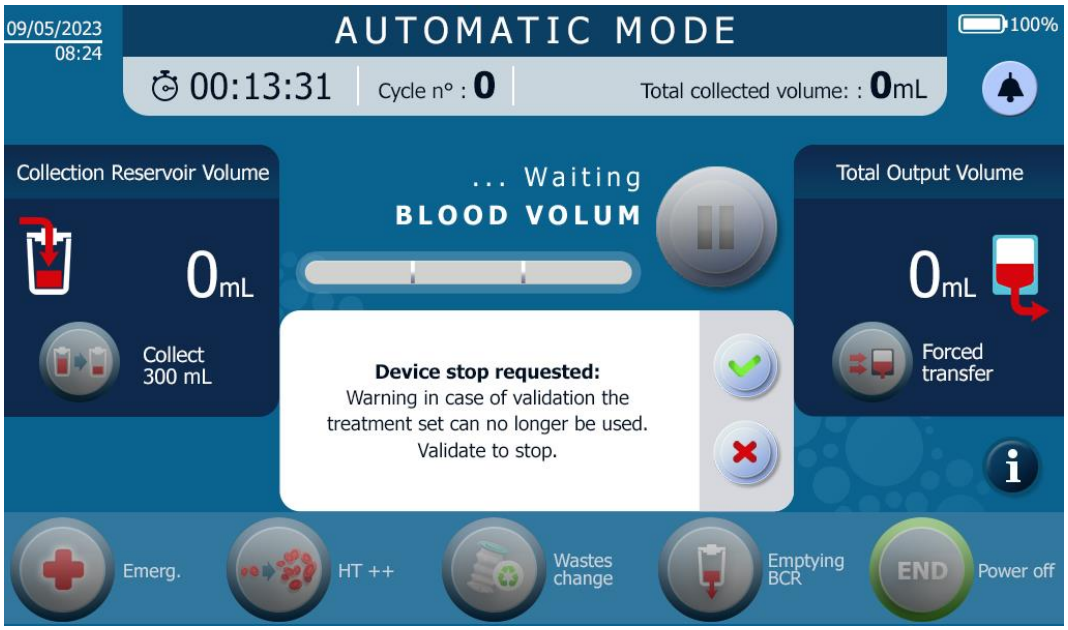

Figure 114: End of surgery activation

- Validate by pressing the button  or refuse by pressing the  button.
- If validated, a new screen with a summary of the surgery appears (see Figure 115).

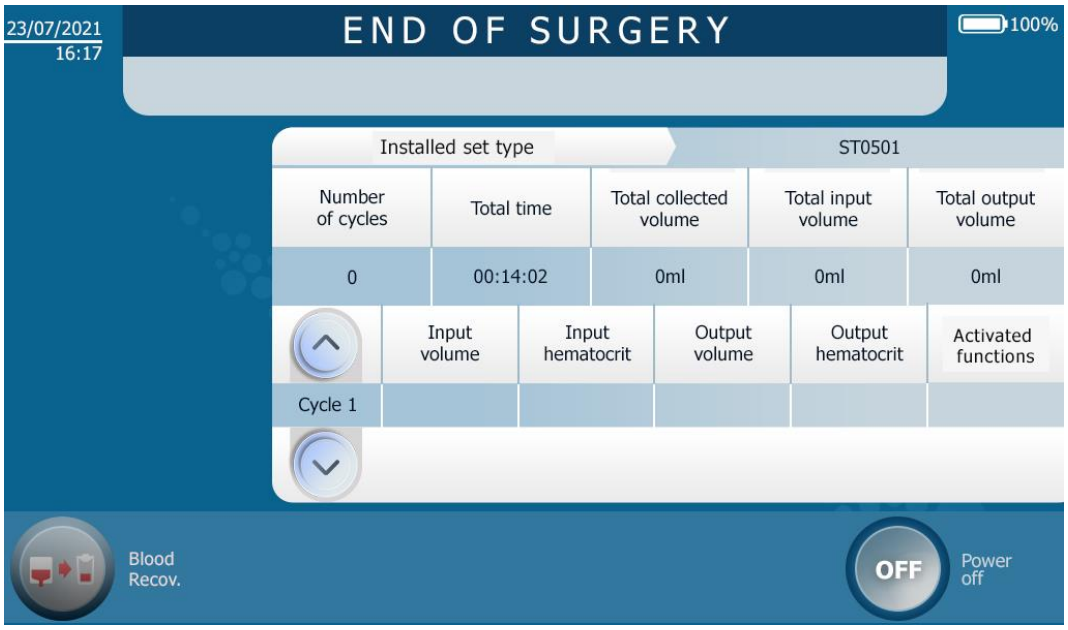

Figure 115: End of surgery screen

- The user is asked to:
  - Turn off the ATS in order to uninstall the Treatment Set by pressing 'OFF' 
  - The residual blood present in the Treatment Bag can be collected in the BCR by pressing the  button. In this case, the Treatment and BCR electroclamps open and the blood is transferred via gravity until the Treatment Bag is empty.

4.13. MACHINE SHUTDOWN

If the OFF button is pressed, the shutdown screen is displayed. Close the manual clamps as requested (See Figure 116).

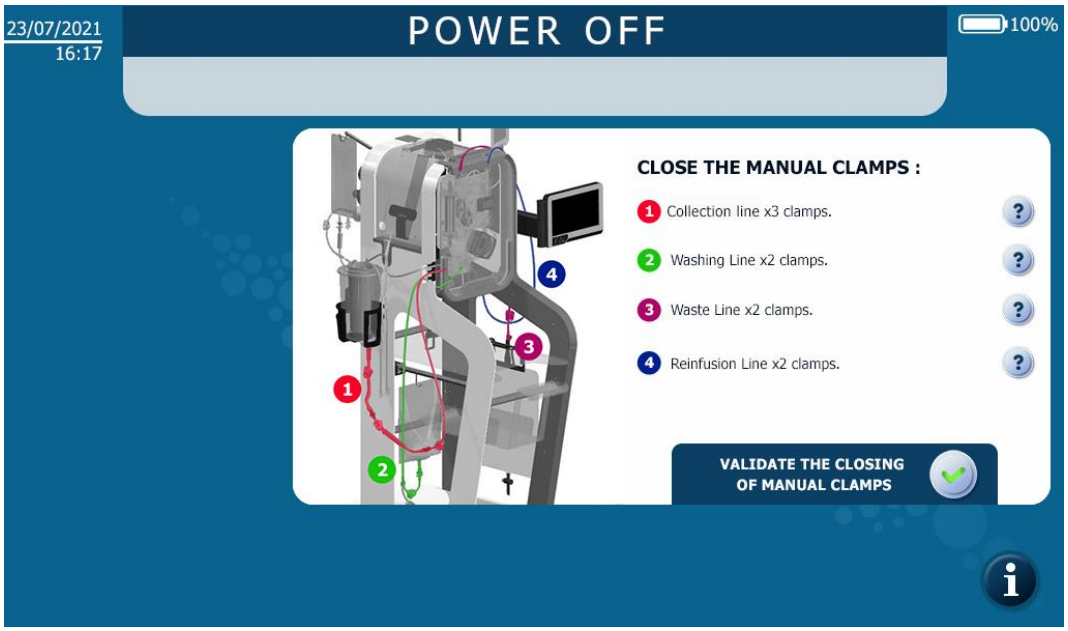

Figure 116: Request for closing the manual clamps for machine shutdown

- Validate the opening of the electroclamps by pressing the  button.

The electroclamps on the machine open; the screen turns off. The procedure is ended.

4.13.1. Stopping the surgical vacuum pump

To turn on the i-SEP ATS surgical vacuum pump please see section 4.7.2.

Note:

- The surgical vacuum pump can be turned off at any time.

4.14. CHANGING, UNINSTALLING AND DISPOSING OF ACCESSORIES

4.14.1. Changing bags

4.14.1.1. Changing the Washing Solution Bag

The washing solution bag can be changed when the user realises that one or the two washing solution bags are empty or when the machine displays the following screen (See Figure 117).

Figure 117: Screen when the machine detects that the washing solution bag should be changed

Three possible scenarios:

- First, the physiological saline bags are used and empty at the same time. To change this bag, wait for the ATS to finish a treatment cycle or pause the treatment when the fibre is in physiological saline (See Figure 118):
  - Close the manual clamps on the Washing Lines.
  - Disconnect the puncher from the empty Washing Solution Bag (sterile NaCl 0.9%).
  - Perforate the seal (having previously removed the protective cap) on the new Washing Solution Bag with the available puncher.
  - Reopen the clamp on the newly supplied Washing Line.
  - Repeat the 2 operations above to replace the second bag.
  - Resume the rest of the procedure.

- Second, if 2 bags are installed and only one bag is empty, the bag can be exchanged during the treatment.
  - Close the manual clamp on the Washing Line corresponding to the empty or missing Washing Solution Bag.

- Open the clamp on the 2nd Washing Line (full bag).
- Disconnect the puncher from the empty Washing Solution Bag (sterile NaCl 0.9%).
- Perforate the seal (having previously removed the protective cap) on the new Washing Solution Bag with the freed puncher.
- Resume the rest of the procedure.

- Third, if only 1 bag is installed and empty. To change this bag, wait for the ATS to finish a treatment cycle or pause the treatment when the fibre is in physiological saline (See Figure 118):
  - Close the manual clamp on the Washing Line.
  - Disconnect the puncher from the empty Washing Solution Bag (sterile NaCl 0.9%).
  - Perforate the seal (having previously removed the protective cap) on the new Washing Solution Bag with the freed puncher.
  - Reopen the clamp on the newly supplied Washing Line.
  - Resume the rest of the procedure.

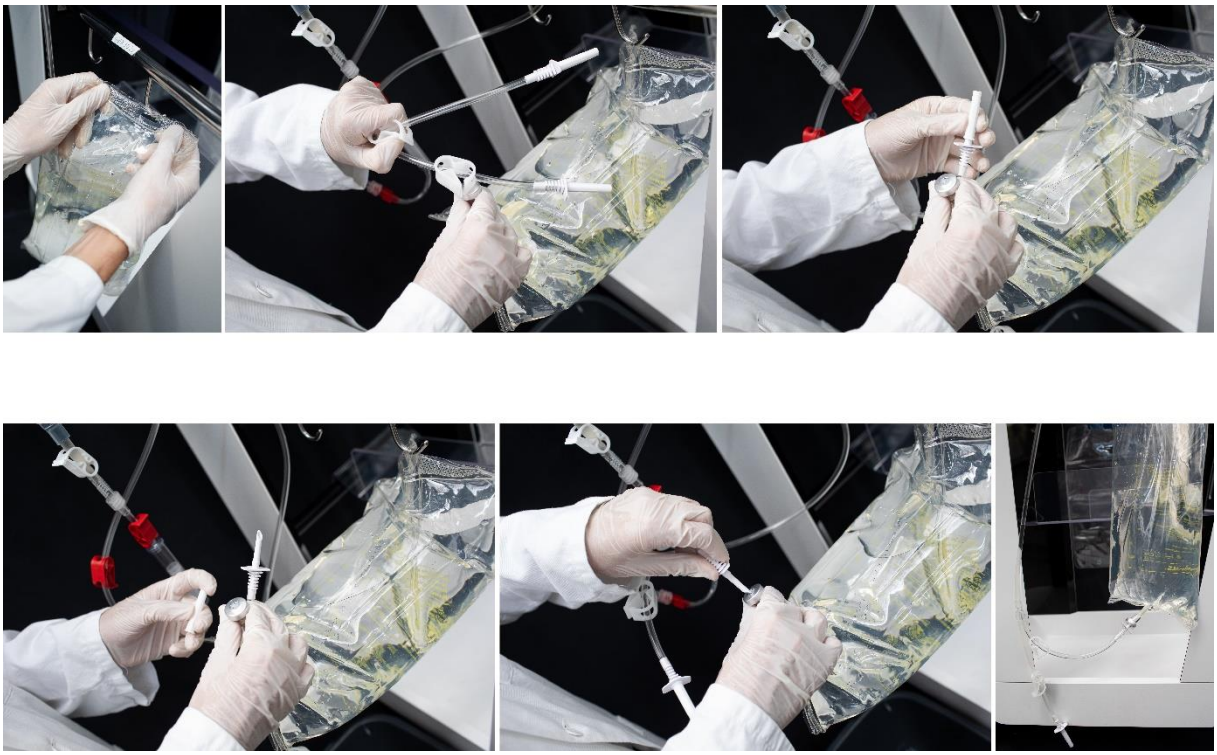

Figure 118: Changing the Washing Solution Bag

4.14.1.2. Changing the Reinfusion Bag

The Reinfusion Bag can be changed (See Figure 119) at various moments:

- When the treatment is in progress: pause the treatment (see Chapter 4.11.2) and follow instructions 1 to 8 below.
- When prompted by the ATS: Follow the steps below and press the  button to resume the treatment.

Figure 119: Reinfusion Bag

The operations to be carried out are as follows (see Figure 120 and Figure 121):

1. Close the manual clamp for the Reinfusion Line under the Reinfusion Bag.
2. Close the manual clamp for the Reinfusion Line located between the flow distribution line and the Luer connection for the Set's Reinfusion Line.
3. Disconnect the Reinfusion Bag containing the concentrate by unscrewing the Luer connector.
4. Close the Luer cap for the Reinfusion Bag, with the cap attached to the Luer connector. Remember to remove the cap from the Reinfusion Line beforehand and to store it in the detachable storage provided for this purpose for possible future use.
5. Unwrap a new Reinfusion Bag.
6. Connect the empty Reinfusion Bag.
7. Check that the manual clamp for the Reinfusion Line under the new Reinfusion Bag is open.
8. Open the manual clamp for the Reinfusion Line located between the flow distribution line and the Luer connection for the Set's Reinfusion Line.

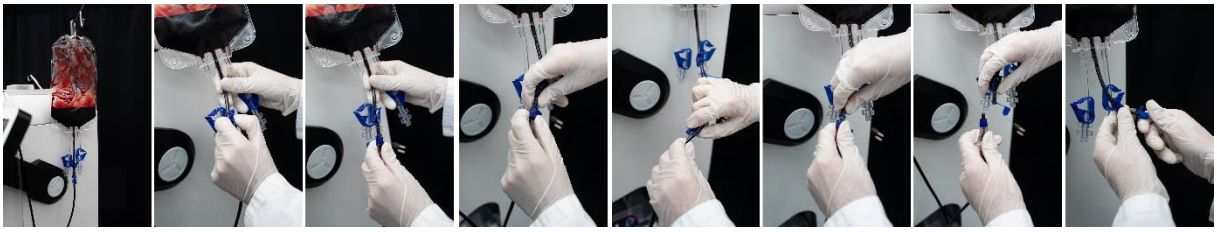

Figure 120: Changing the Reinfusion Bag 1/2

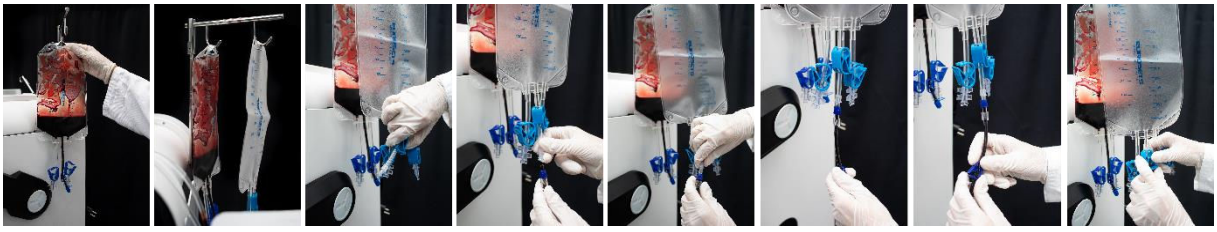

Figure 121: Changing the Reinfusion Bag 2/2

Warning:

- **Properly reconnect a new Reinfusion Bag in order to avoid blood loss or the risk of AEB**
- **Open the clamp on the new Reinfusion Bag to avoid blood splashes.**
- **Remember to wear PPE for this handling**

4.14.1.3. Changing the Waste Bag

The Reinfusion Bag can be changed (See Figure 122) at 2 different times:

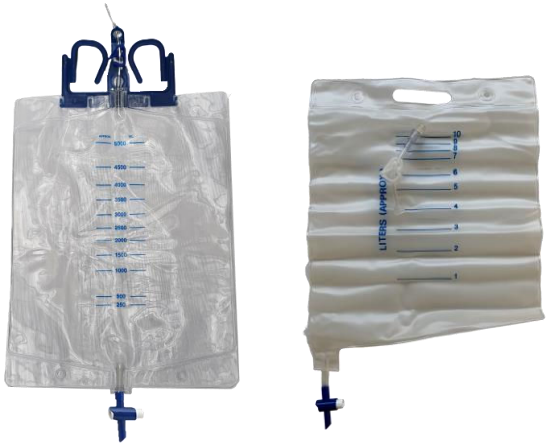

Figure 122: Waste Bag (BW5000: left and BW1000: right)

- If the Waste Bag is too full according to the user and they decide to activate the bag change on the HMI 
    - Wait for the Autotransfusion System to prompt you to change the Waste Bag or wait for the Autotransfusion System to finish a treatment cycle
    - A message will appear to indicate that the Waste Bag can be changed.
- If the Waste Bag is too full and the machine detects too much waste, the ATS will prompt the user to change the Waste Bag:
    - A message will appear to indicate that the Waste Bag can be changed.

In both situations, carry out the following steps (See Figure 123).

1. Close the manual clamp on the waste line of the i-SEP Treatment Set.
2. Unpack a new empty i-SEP Waste Bag.
3. Unscrew the Luer connection on the waste line.
4. Screw the empty bag onto the Luer connector connection on the waste line.
5. Close the full Waste Bag with the cap provided for this purpose on the Waste Bag.
6. Dispose of the Waste Bag according to the healthcare facility's standard procedures.
7. Insert the Waste Bag as described in the instructions provided in Section 4.9.18.1 (Inserting the Waste Bag).

Figure 123: Replacement of the waste bag (BW1000)

Warning:

- **Reopen the clamp on the waste line so that the following concentrations run correctly.**
- **Remember to wear PPE for this handling.**

4.14.1.4. Changing the Micro-aggregates Chamber

The Micro-aggregates Chamber (See Figure 124) located at the inlet on the Treatment Set can be changed during treatment. The Micro-aggregates Chamber is changed if it is blocked by clots in particular.

Figure 124: Micro-aggregates Chamber

The steps to carry out this exchange are as follows (See Figure 125 and Figure 126):

- To exchange the Micro-aggregates Chamber, pause the treatment.
- Close the clamp on the outlet tubing of the i-SEP Blood Collection Reservoir and the clamp on the Micro-aggregates Chamber in place.
- Close the clamp on the transfer line of the i-SEP Autotransfusion Treatment Set in place.
- Open the outer packaging of the additional i-SEP Micro-aggregates Chamber using aseptic technique.
- Close the clamp on the new i-SEP Micro-aggregates Chamber.
- Unscrew the Luer connection of the Micro-aggregates Chamber in place just after the Collection Reservoir.
- Remove the cap from the red top luer of the new i-SEP Micro-aggregates Chamber.
- Connect the new i-SEP Micro-aggregates Chamber at the bottom of the outlet tubing of the i-SEP Blood Collection Reservoir. The connection is made with the dialysis Luer.
- Screw the previously removed red Luer cap onto the used Micro-aggregates Chamber to avoid any risk of blood spillage.
- Remove the transparent Luer cap from the bottom tube of the new i-SEP Micro-aggregates Chamber.
- Disconnect the Luer connector at the bottom of the Micro-aggregates Chamber in place, screw the previously transparent removed Luer cap and put the latter in the appropriate waste bin.
- Connect the salvage line from the i-SEP Autotransfusion Treatment Set to the bottom tube of the new i-SEP Micro-aggregates Chamber. The connection is made with the dialysis Luer.
- Open the clamp on the outlet tubing of the i-SEP Blood Collection Reservoir.
- Open the clamp on the i-SEP Micro-aggregates Chamber.
- Open the clamp on the salvage line of the i-SEP Autotransfusion Treatment Set.
- Remove as much air as possible from the i-SEP Micro-aggregates Chamber by pressing on it 3 or 4 times.
- Resume the rest of the procedure.

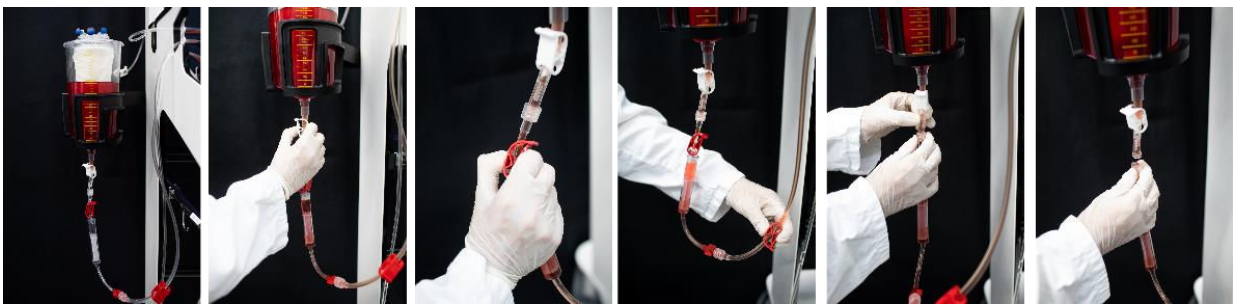

Figure 125: Changing the Micro-aggregates Chamber 1/2

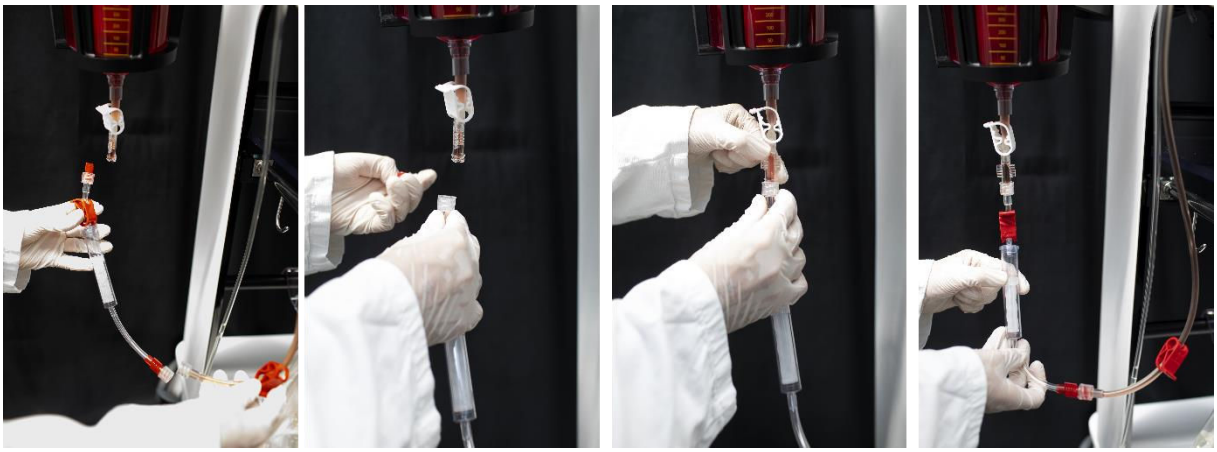

Figure 126: Changing the Micro-aggregates Chamber 2/2

Warning:

- **It is highly recommended to use PPE for this handling.**

4.14.2. Final and complete uninstallation

The final and complete uninstallation of the accessories is done while the ATS is turned off. All consumable parts can be thrown away according to the healthcare facility's standard procedures, given that they contain blood potentially contaminated with pathogenic substances.

Note:

- Accessories cannot be uninstalled if the ATS is not turned off.
- One by one, remove the used consumable accessories from the treatment area, poles, specific holders for the ATS.

Warning:

- **It is highly recommended to use PPE for this handling.**

4.14.3. Disposal

All Aspiration and Anticoagulation Line, Blood Collection Reservoir, Treatment Set, Reinfusion Bag, Washing Solution Bag and Waste Bag consumables still connected at the end of use are disposed of by throwing them in the appropriate operating theatre waste bin.

4.15. REINFUSION

4.15.1. Disconnection of the Reinfusion Bag for the Set

At the end of the transfer phase, when the ATS is paused or in the Waiting for Blood phase, disconnect the Reinfusion Bag in the same manner as if changing the bag (see Chapter 4.14.1.2.).
The treated blood product contained in the bag is available for reinfusion into the same patient.

Attention: refer to the Warnings and precautions (see Chapter 2.4.6.).

4.15.2. Connecting a new i-SEP Reinfusion Bag

If it is planned to run a new cycle, connect a new Reinfusion Bag in the same manner as if changing the bag (see Chapter 4.14.1.2).

4.16. OTHER AVAILABLE SCREENS

4.16.1. Help

If information, an alarm, an alert or an error is displayed, the user can request more details by pressing the help button inserted in the messages (See Figure 127).

Figure 127: Help button

The help screen provides more information to order to guide the user.
The screen is broken down as follows (See Figure 128):

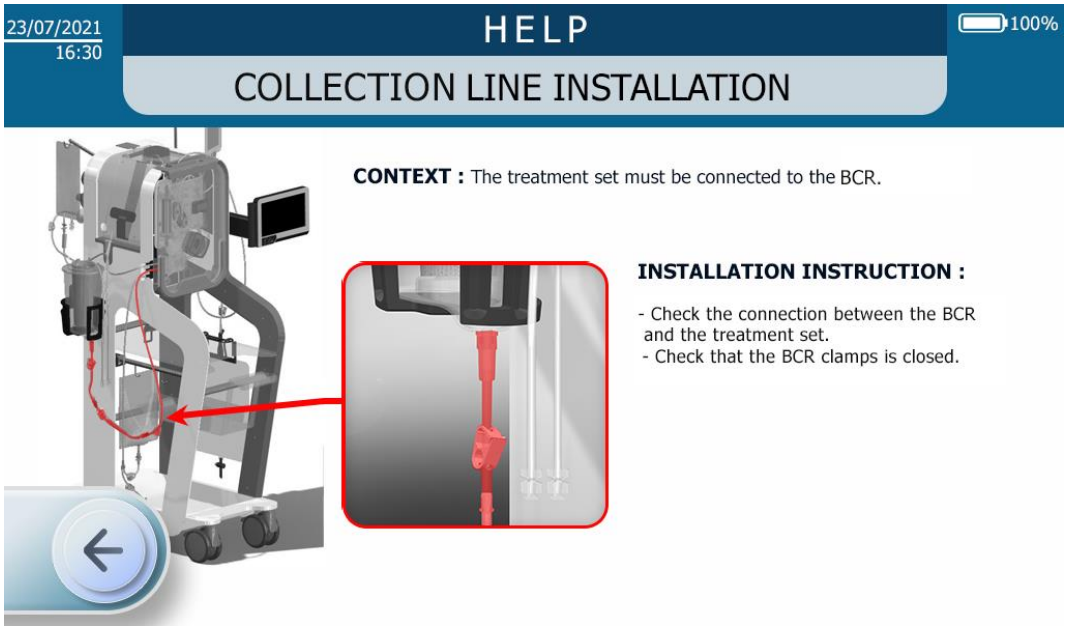

Figure 128: Example of a help screen

The user can exit the help screen in three different ways:

- By pressing on the arrow pointing to the left;
- By allowing a certain amount of time to elapse after which the help screen automatically disappears and goes back to the previous screen.
- If a new alarm goes off, the help session is closed automatically.

4.16.2. Information

The user can have access to information regarding the use of the Autotransfusion System by pressing the information button (See Figure 129).

Figure 129: Information button

The information button can be accessed in the following phases:

- Set installation,
- Treatment.

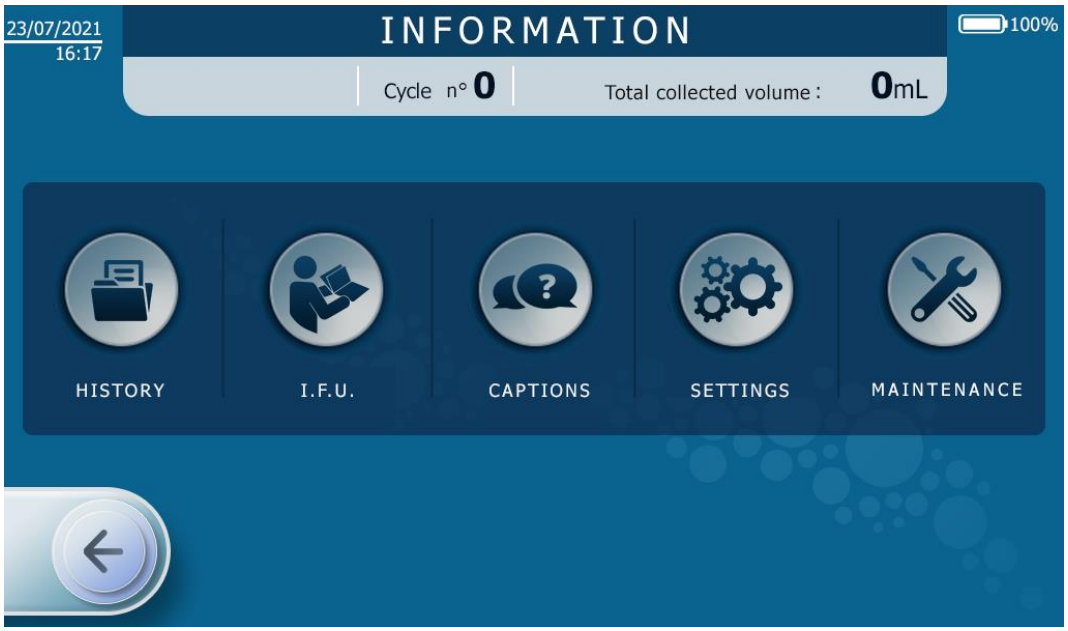

Figure 130: Information screen

Once the information screen is displayed, the user can choose between five menus:

- History: presentation of the information about the equipment and the treatment used for the last treatments - see Chapter 4.16.2.1
- Manual: Address and QR code to access the electronic manual
- Help: presentation of the i-SEP ATS modes and functions – see Chapter 4.16.2.2
- Parameters: ATS parameter settings – see Chapter 4.16.2.3
- Maintenance: see 4.16.2.4

The user can go into one of the five menus offered by pressing the corresponding button.
A password is needed to unlock the maintenance menu.

The user can exit the help screen in three different ways:

- By pressing on the arrow pointing to the left;
- By allowing a certain amount of time to elapse after which the Information screen automatically disappears and goes back to the previous screen.
- If a new alarm goes off, the Information screen is closed automatically.

4.16.2.1. History

At the end of the procedure, the History screen appears by either a direct stop or by using the Information button (See Figure 131).

The History screen includes the output data report for the last ten autotransfusion treatments performed.

On the left-hand side of the screen, the user selects the treatment (listed by the day and time of the procedure) for which they would like to see the information appear.
The right-hand side of the screen displays the data for the selected treatment, either in summary form (cumulative data) for a patient who underwent several treatments on the same day at successive times, or in detail, per cycle.

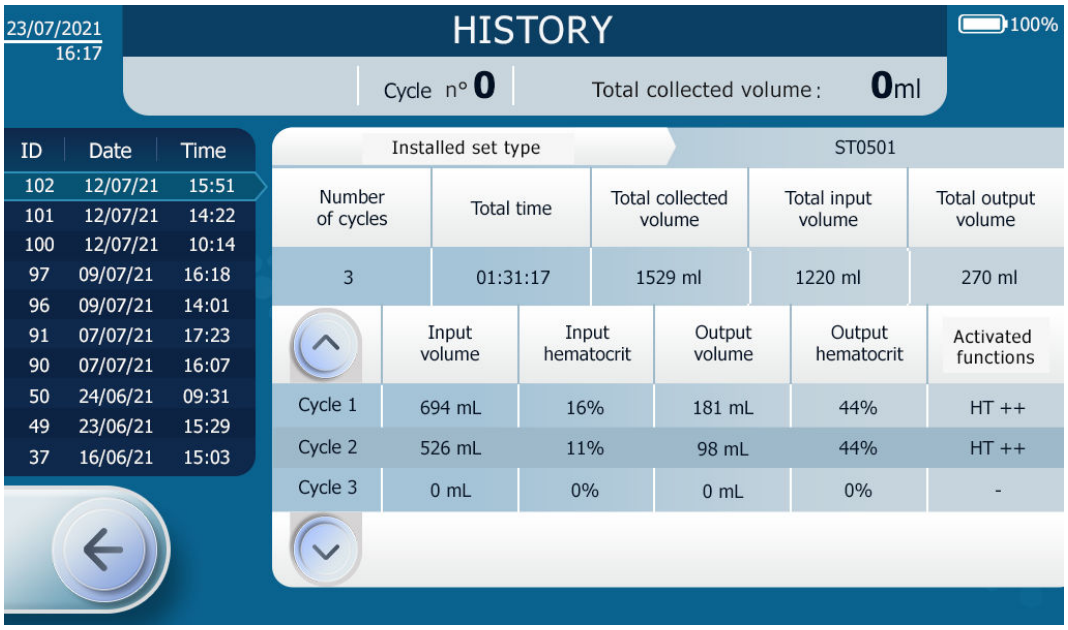

Figure 131: History screen

The user can exit the history screen in two different ways:

- By pressing on the arrow pointing to the left;
- By allowing a certain amount of time to elapse after which the history screen automatically disappears and goes back to the previous screen.
- If a new alarm goes off, the history screen is closed automatically.

4.16.2.2. Help - Legend

The Legend/Help screen is a screen that explains the modes and functions available in the i-SEP Autotransfusion System (See Figure 132).
The legends are listed, the user cannot activate any of the buttons from this screen.

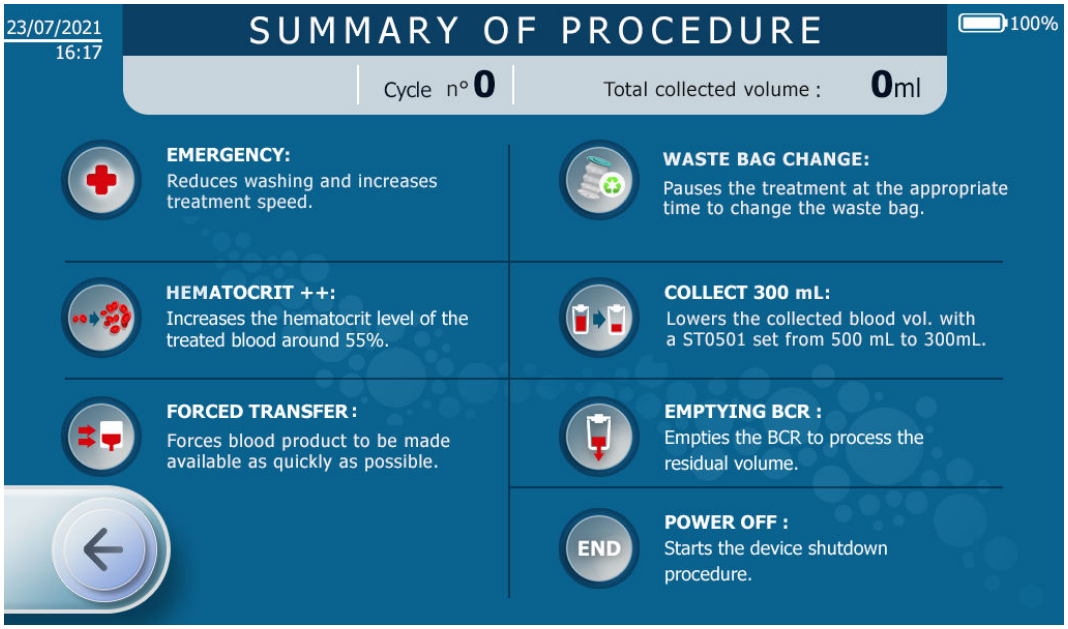

Figure 132: Legend screen

The user can exit the legend screen in two different ways:

- By pressing on the arrow pointing to the left;
- By allowing a certain amount of time to elapse after which the legend screen disappears and goes back to the previous screen.

- If a new alarm goes off, the legend screen is closed automatically.

4.16.2.3. Parameters

The parameters screen allows to adjust the following parameters (See Figure 133):

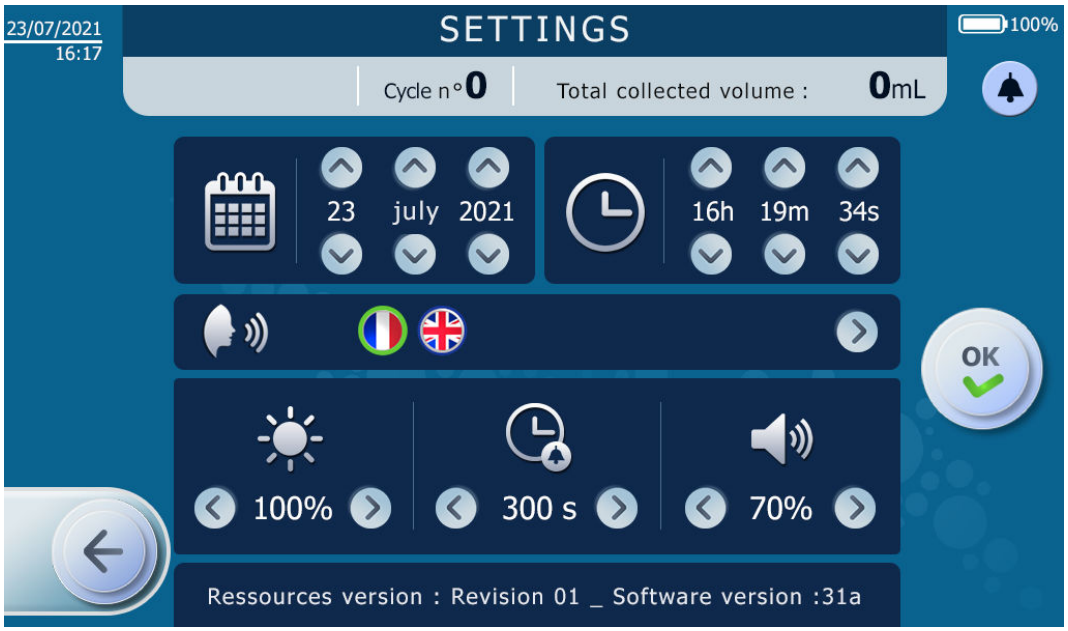

Figure 133: Parameters screen

- **Date (calendar)**
  - According to the format DD MMM YYYY
  - To do this, the user presses the up and down arrows for each date entity.
- **Time (clock)**
  - According to the format hours minutes seconds
  - To do this, the user presses the up and down arrows for each time entity.
- **Language (face and sound waves coming out of the mouth)**
  - To do this, the user presses on the flag of the language wanted.
- **Screen brightness (sun)**
  - The screen brightness can be adjusted by pressing on the arrows pointing to the left (less brightness) or to the right (more brightness).
- **Alarm mute duration**
  - The length of time an alarm is silent before the audio signal turns back on can be defined by the user. This time cannot be less than a defined time of several seconds.
  - To select the duration, the user presses the arrows pointing to the left (decrease in duration) or to the right (increase in duration).
- **Sound volume**
  - The sound volume of the sound messages can be adjusted, on an internal scale from 10 to 100% within the ATS.
  - To adjust the sound level, the user presses the arrows pointing to the left (decrease in volume) or to the right (increase in volume).

4.16.2.4. Maintenance

- Only the maintenance personnel authorised by i-SEP can access this section with a specific access code (See Figure 134 and Figure 135).

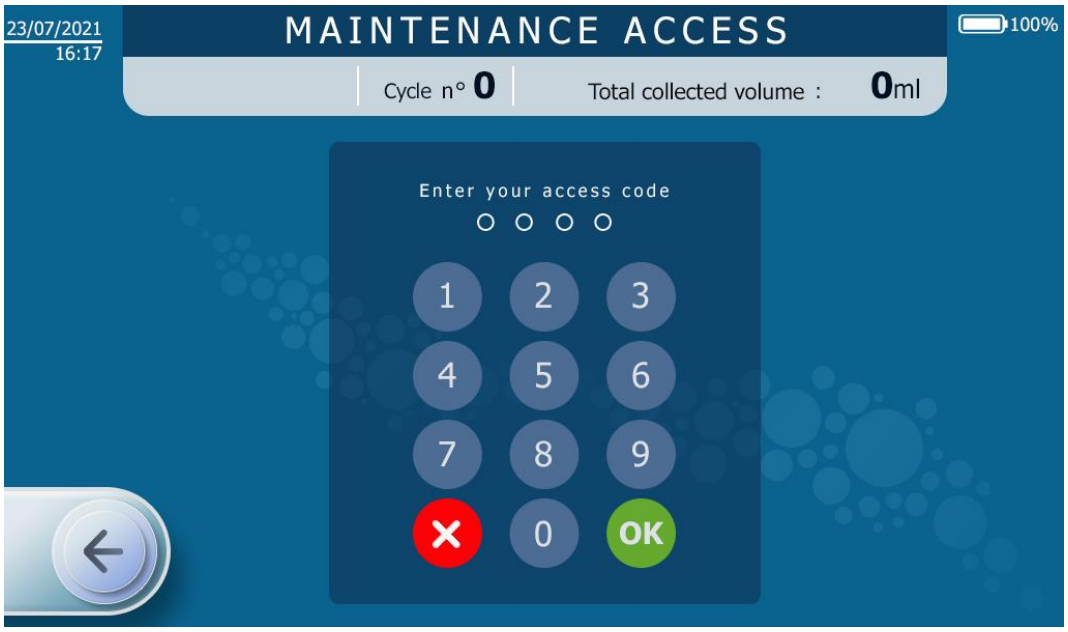

Figure 134: Access code required to access the maintenance mode

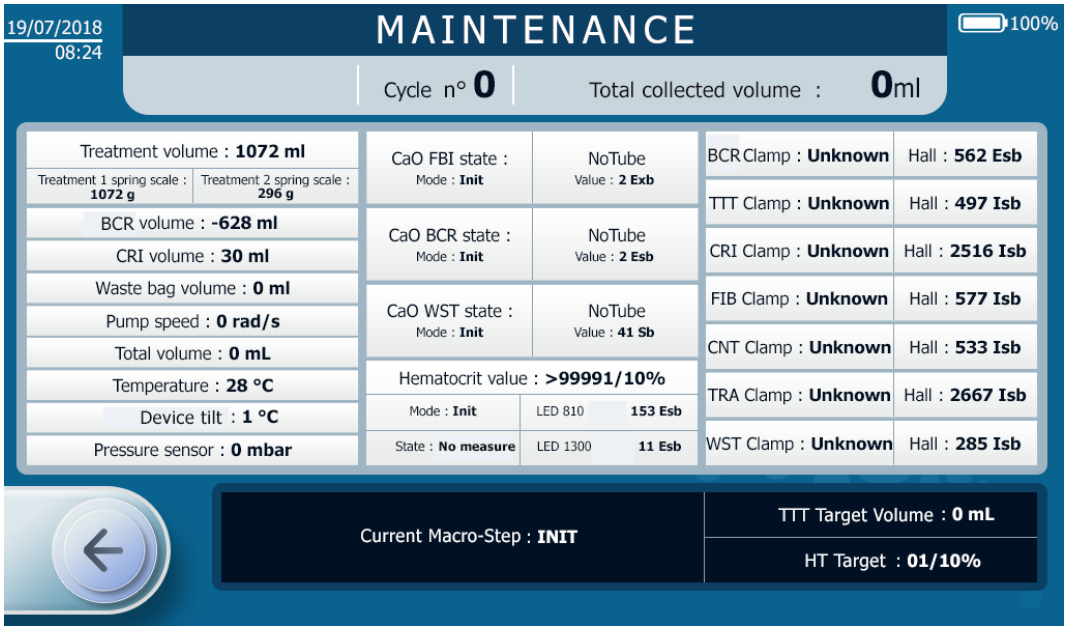

Figure 135: Example of maintenance screen

4.17. GENERAL PRECAUTIONS

To avoid critical situations, it is important that all alarms, precautions and warnings for safe use are followed.

When using the ATS, the user must always check the devices meticulously.

Refer to section 2.4.6 for more information about the Warnings and precautions for use.

4.18. MONITORING AND VERIFICATIONS

While the equipment is in use, the system carries out multiple tests in order to verify the safety and performance of the device. If functional anomalies are detected, appropriate safety measures are taken immediately.

Only one error, alarm or alert can be active at the same time. If more than one abnormal situation is detected at the same time, the equipment will respond to the situation with the highest priority.

Depending on the error, alarm or alert detected, the device will go into a safe mode in order to first and foremost protect the blood undergoing treatment.

4.19. FORCED SHUTDOWN OF THE ATS

If a standard shutdown of the ATS (see 4.7) can not be done, forced shutdown procedures are available.

4.19.1. Case 1: System error

If the ATS is in system error (red and steady light indicator and continuous sound signal), unplug the main power supply and press the physical ON/OFF button on the HMI for 10 seconds.

The machine automatically powers off after this procedure.

4.19.2. Case 2: Technical error

If the ATS is in technical error (see 4.20: red and blinking light indicator), unplug the main power supply and press the physical ON/OFF button on the HMI for 15 seconds.

The machine automatically powers off after this procedure.

4.19.3. Case 3: 'Final resort'

In order to be able to shutdown the ATS in the following cases:
- The touch screen is unavailable but no technical error is detected,
- The physical ON/OFF button is unavailable,
- The full HMI is not functioning.

Follow the procedure below:
- Unplug the main power supply,
- Open the protection lid of the treatment bag,
- Maintain the washing bag support to a value of at least -1 000g for 10 seconds.

The machine automatically powers off after this procedure.

This procedure is always activated, regardless the functioning mode and does not need any prerequisites to be activated.

4.19.4. Treatment set deinstallation following forced shutdown

When applying one of the forced shut-off procedures described above, there is a possibility that the machine will be locked (electroclamps closed).
In order to release the treatment set present on the ATS, it is necessary to restart the machine: during the auto-tests on restart, the machine will indicate that a treatment set is present on the ATS and will prompt the user to uninstall it.

Note: if the ATS is no longer functional despite the restart, switch off the ATS (possibility to use the forced shutdown procedures), unlock the protection lid (see **Erreur ! Source du renvoi introuvable.**) and operate manually the electroclamps to release the treatment set and proceed with the deinstallation.

4.20. DEFINITIONS

If the i-SEP ATS detects an anomaly during a programme, the user will receive an informative message. The anomaly can be categorised in one of three groups:

- **Alert:**
  - The ATS does not pause the system. The ATS warns that the user must take precautions.

- The message is displayed against a blue background 
- The pause button is always available regardless of which type of anomaly is detected.

- **Alarm:**
  - The ATS pauses the programme; the alarm is considered to be 'blocking'. The ATS provides the user with instructions on how to resolve the problem.
  - If, after the alarm has appeared five times in a row, and after five attempts to resolve the problem, the anomaly returns again, the ATS changes the status from alarm to error.
  - The message is displayed on a yellow background 

- **Error:**
  - The ATS is out of order, the user cannot do anything. The treated blood product can be salvaged, in most cases, in the BCR. The user must call the Technical Department for the maintenance of the ATS.
  - The message is displayed on a red background 
  - For errors during the treatment phase, a blood salvage function is available in most cases by pressing the salvage button  (See Figure 136).

Note: The blood salvage function is not available if the quality of the blood to be reinfused can no longer be certified due to the failure or if a technical problem hinders the proper functioning.
The electroclamps will open in order to collect the blood via gravity in the Blood Collection Reservoir and will close at the end of the operation.
The BCR will then be transferred to another piece of equipment.

Figure 136: Screen when the salvage button is activated

5. TROUBLESHOOTINGS

5.1. ERRORS

The following table lists the error titles and the text describing the displayed message. Each error and the associated information for understanding and resolving the error is then described individually in the following sections.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
FiberIN Sensor Error: Failure detected.	0x000F0100	RED	Failure	The FiberIN optical sensor is defective.	- Switch off the device to remove the treatment set. - If the problem persists, contact the technical support.	Treatment continuation impossible.
FiberIN Sensor Error: Failure detected.	0x00240020	RED	Failure	The FiberIN optical sensor is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
FiberIN Sensor Error: Failure detected.	0x00110004	RED	Failure	The FiberIN optical sensor is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
FiberIN Sensor Error: Failure detected.	0x000F0040	RED	Failure	The arrival of blood was not detected in the treatment set depsite 10 attempts.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - If the problem persists, contact the technical support.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Hemato. Sensor Error: Failure detected.	0x000F0004	RED	Failure	The Hematocrit sensor is non-functional.	- Switch off the device to remove the treatment set. - If the problem persists, contact the technical support.	Treatment continuation impossible.
Waste Sensor Error: Failure detected.	0x00110002	RED	Failure	The Waste optical sensor is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Waste Sensor Error: Failure detected.	0x00240040	RED	Failure	The Wastes optical sensor is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
BCR Sensor Error: Failure detected.	0x000F0010	RED	Failure	The BCR optical sensor is defective.	- Switch off the device to remove the treatment set. - If the problem persists, contact the technical support.	Treatment continuation impossible.
Overpressure Error: Failure detected.	0x00238000	RED	Failure	Excessive pressure was detected 10 times while transferring blood to the reinfusion bag.	- Switch off the device to remove the treatment set. - Change the treatment set. - If the problem persists, contact the technical support.	Treatment continuation impossible.
BCR E-Clamp Error: Failure detected.	0x00230004	RED	Failure	The BCR Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
BCR E-Clamp Error: Failure detected.	0x00030002	RED	Failure	The BCR Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
BCR E-Clamp Error: Failure detected.	0x00140001 0x00140002 0x00140004 0x00140008 0x00140010	RED	Failure	The BCR Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Unclogg. E-Clamp Error: Failure detected.	0x00230040	RED	Failure	The Unclogging Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Unclogg. E-Clamp Error: Failure detected.	0x00030020	RED	Failure	The Unclogging Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Unclogg. E-Clamp Error: Failure detected.	0x00180001 0x00180002 0x00180004 0x00180008 0x00180010	RED	Failure	The Unclogging Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Waste E-Clamp Error: Failure detected.	0x00230100	RED	Failure	The Wastes Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Waste E-Clamp Error: Failure detected.	0x00030080	RED	Failure	The Waste Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Waste E-Clamp Error: Failure detected.	0x001A0001 0x001A0002 0x001A0004 0x001A0008 0x001A0010	RED	Failure	The Waste Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Fiber E-Clamp Error: Failure detected.	0x00230020	RED	Failure	The Fiber Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Fiber E-Clamp Error: Failure detected.	0x00030010	RED	Failure	The Fiber Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Fiber E-Clamp Error: Failure detected.	0x00170001 0x00170002 0x00170004 0x00170008 0x00170010	RED	Failure	The Fiber Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
TTT E-Clamp Error: Failure detected.	0x00230008	RED	Failure	The Treatment Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
TTT E-Clamp Error: Failure detected.	0x00030004	RED	Failure	The Treatment Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
TTT E-Clamp Error: Failure detected.	0x00150001 0x00150002 0x00150004 0x00150008 0x00150010	RED	Failure	The Treatment Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Washing E-Clamp Error: Failure detected.	0x00230010	RED	Failure	The Washing Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Washing E-Clamp Error: Failure detected.	0x00030008	RED	Failure	The Washing Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Washing E-Clamp Error: Failure detected.	0x00160001 0x00160002 0x00160004 0x00160008 0x00160010	RED	Failure	The Washing Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Reinf. E-Clamp Error: Failure detected.	0x00230080	RED	Failure	The Reinfusion Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Reinf. E-Clamp Error: Failure detected.	0x00030040	RED	Failure	The Reinfusion Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Reinf. E-Clamp Error: Failure detected.	0x00190001 0x00190002 0x00190004 0x00190008 0x00190010	RED	Failure	The Reinfusion Electro-Clamp is non-functional.	- If desired, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Treatment Error: Failure detected.	0x00234000	RED	Failure	No waste disposal detected despite 10 attempts.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Waste Sensor Error: Failure detected.	0x000F0200	RED	Failure	The Waste optical sensor is defective.	- Switch off the device to remove the treatment set. - If the problem persists, contact the technical support.	Treatment continuation impossible.
Waste Sensor Error: Failure Detected.	0x000F2000	RED	Failure	The washing solution is not detected in the wastes despite 10 attempts.	- Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
BCR Sensor Alarm: Failure detected.	0x00240080	RED	Failure	The BCR optical sensor is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
BCR Sensor Alarm: Failure detected.	0x00110001	RED	Failure	The BCR optical sensor is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Overpressure Error: Failure detected.	0x00240002	RED	Failure	Overpressure was detected. The treatment set is out of services.	- Switch off the device to remove the treatment set. - Change the treatment set. - Check the anticoagulation before starting the treatment. - If the problem persists, contact the technical support.	Possible to continue the treatment with a new treatment set.
Overpressure Error: Failure detected.	0x00240001	RED	Failure	Overpressure detected in the treatment set despite 9 unclogging attempts.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Restart the device and install a new treatment set.	Treatment continuation impossible.
Treatment Error: Failure detected.	0x00232000	RED	Failure	No waste disposal detected despite 10 attempts.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Treatment Error: Failure detected.	0x000F4000	RED	Failure	No waste elimination detected despite 10 attempts.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - If the problem persists, contact the technical support.	Treatment continuation impossible.
Treatment Bag Error: Failure detected.	0x000F0002	RED	Failure	The washing solution is not detected in the treatment bag despite 10 attempts.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - If the problem persists, contact the technical support.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Treatment Bag Error: Failure detected.	0x00108000	RED	Failure	The treatment bag load cells are defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Treatment Bag Error: Failure detected.	0x00100200	RED	Failure	The treatment bag load cells are defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Treatment Bag Error: Failure detected.	0x00100100	RED	Failure	The treatment bag load cells are defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Treatment Bag Error: Failure detected.	0x00100001 0x00100010	RED	Failure	The treatment bag load cells are defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Treatment Bag Error: Failure detected.	0x00100002 0x00100020	RED	Failure	The treatment bag load cells are defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Treatment Bag Error: Failure detected.	0x000F1000	RED	Failure	The treatment bag load cells are defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Maintenance Error: Maintenance date exceeded.	0x00230001	RED	Failure	The mandatory maintenance date has passed.	- Contact the technical support to solve the problem.	Treatment continuation impossible.
Treatment Error: Maximum number of cycles reached.	0x000F0400	RED	Failure	The maximum number of cycles that can be achieved with a treatment set has been reached.	- The performance of the treatment set is no longer sufficient. - Switch off the device to remove the set treatment. - Restart the device and install a new treatment set.	Install a new treatment set.
Collection Reservoir Error: Failure detected.	0x00100800	RED	Failure	The BCR load cell is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Collection Reservoir Error: Failure detected.	0x00100400	RED	Failure	The BCR load cell is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Collection Reservoir Error: Failure detected.	0x00100004 0x00100040	RED	Failure	The BCR load cell is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Washing Error: Failure detected.	0x00100008 0x00100080	RED	Failure	The washing load cell is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Washing Error: Failure detected.	0x00101000	RED	Failure	The washing load cell is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Washing Error: Failure detected.	0x00102000	RED	Failure	The washing load cell is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Set Sensor Error: Failure detected.	0x000F0001	RED	Failure	The treatment set detection sensor is defective.	- Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Battery Level Error: Imminent shutdown.	0x00240008	RED	Failure	Minimum battery level reached.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Leave the device connected to the main power supply for the next use. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Washing Error: Failure Detected.	0x000F0008	RED	Failure	The washing solution is not detected in the treatment set despite 10 attempts.	- Switch of the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Pressure sensor Error: Failure detected.	0x000F0020	RED	Failure	The pressure sensor is defective.	- Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Peristaltic Pump Error: Pump flap opened.	0x000F8000	RED	Failure	Peristaltic pump flap opened.	- Warning: Risk for the user. - If desired and possible, proceed with the recovery of blood the BCR. - Switch off the device to remove the treatment set. - Restart the device and install a new treatment set.	Treatment continuation impossible.
Temperature Error: Device overheating.	0x001C0001	RED	Failure	An excessive temperature has been detected in the device. The blood being processed is altered.	- Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Peristaltic Pump Error: Failure detected.	0x001D0001	RED	Failure	The peristaltic pump speed is incorrect.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Peristaltic Pump Error: Failure detected.	0x001D0002	RED	Failure	The peristaltic pump speed is incorrect.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Peristaltic Pump Error: Failure detected.	0x001D0004	RED	Failure	The peristaltic pump speed is incorrect.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000C0001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000C0002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Electronic Error: Failure detected.	0x00070001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00070002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00070004	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00070008	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00070010	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Electronic Error: Failure detected.	0x00080001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00080002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00080004	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00090001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00090002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Electronic Error: Failure detected.	0x00090004	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00090008	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000A0100 0x000A0200 0x000A0400 0x000A0800 0x000A1000 0x000A2000 0x000A4000 0x000A8000	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000E0001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Electronic Error: Failure detected.	0x000E0010	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x001E0001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x001E0002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00020001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00060001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Electronic Error: Failure detected.	0x00040001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00050001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00050002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00050004	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00220001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Electronic Error: Failure detected.	0x00220002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00104000	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000D0001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000D0002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000D0004	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Electronic Error: Failure detected.	0x000D0008	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000D0010	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000D0020	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000D0040	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000D0080	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Electronic Error: Failure detected.	0x000D0100	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000D0200	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000B0001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000B0002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000B0004	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Electronic Error: Failure detected.	0x000B0008	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00250001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00250002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x001F0001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x001F0002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Electronic Error: Failure detected.	0x000E0004	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x000E0002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00230002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00260001	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Electronic Error: Failure detected.	0x00260002	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Hemato. Sensor error: Failure detected.	0x00240010	RED	Failure	The Hematocrit sensor is non-functional.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Battery Error: Battery Failure.	0x00200001	RED	Failure	A battery fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Battery Error: Battery Failure.	0x00200002	RED	Failure	A battery fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Battery Error: Battery Failure.	0x00200004	RED	Failure	A battery fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
FiberIN Sensor Error: Failure detected.	0x00230200	RED	Failure	The FiberIN optical sensor is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Waste Sensor Error: Failure detected.	0x00230400	RED	Failure	The Waste optical sensor is defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.
Treatment Set Error: Failure detected.	0x00230800	RED	Failure	A leak has been detected in the treatment set.	- Switch off the device to remove the treatment set. - Restart the device and install a new treatment set. - If the problem persists, contact the technical support.	Treatment continuation impossible.
Electronic Error: Failure detected.	Others	RED	Failure	An electronic fault has been detected.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	Treatment continuation impossible.

5.2. ALARMS

The following table lists the alarm titles and the text describing the displayed message. Each alarm and the associated information for understanding and resolving the alarm is then described individually.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Collection Reservoir Alarm: Check the presence of blood in the collection reservoir. Validate to confirm OR wait.	0x00000000. 00400000	YELLOW	General	The arrival of blood in the treatment set is not detected. Blood that is too diluted can be interpreted as no blood.	- Check the opening of the manual clamps on the collection line. - Verify the presence of blood in the BCR and shake it if needed. - Validate to confirm the presence of blood and restart the transfer OR wait for blood aspiration in the BCR before restarting.	The program is stopped until the notification is validated.
Waste Sensor Alarm: Autotest failure.	0x00000000. 00020000	YELLOW	General	A problem has been detected during the Waste optical sensor autotest.	- Check that there are no elements in the BCR optical sensor. - Clean the optical sensor with a dry cotton swab or a dry compress. - Validate to restart.	The program is stopped until the notification is validated.
FiberIN Sensor Alarm: Autotest failure.	0x00000000. 00010000	YELLOW	General	A problem has been detected during the FiberIN optical sensor autotest.	- Check that there are no elements in the BCR optical sensor. - Clean the optical sensor with a dry cotton swab or a dry compress. - Validate to restart.	The program is stopped until the notification is validated.
BCR Sensor Alarm: Autotest failure.	0x00000000. 00008000	YELLOW	General	A problem has been detected during the BCR optical sensor autotest.	- Check that there are no elements in the BCR optical sensor. - Clean the optical sensor with a dry cotton swab or a dry compress. - Validate to restart.	The program is stopped until the notification is validated.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
BCR E-Clamp Alarm: Check the position of the line.	0x00000000. 20000000	YELLOW	General	The BCR Electro-Clamp could not perform its autotest.	- Check that no element is preventing the electro-clamp from performing its autotest. - Reposition the line if necessary. - Validate to restart the autotest.	The program is stopped until the notification is validated.
Unclogg. E-Clamp Alarm: Check the position of the line.	0x00000002. 00000000	YELLOW	General	The Unclogging Electro-Clamp could not perform its autotest.	- Check that no element is preventing the electro-clamp from performing its autotest. - Reposition the line if necessary. - Validate to restart the autotest.	The program is stopped until the notification is validated.
Waste E-Clamp Alarm: Check the position of the line.	0x00000008. 00000000	YELLOW	General	The Waste Electro-Clamp could not perform its autotest.	- Check that no element is preventing the electro-clamp from performing its autotest. - Reposition the line if necessary.	The program is stopped until the notification is validated.
Fiber E-Clamp Alarm: Check the position of the line.	0x00000001. 00000000	YELLOW	General	The Fiber Electro-Clamp could not perform its autotest.	- Check that no element is preventing the electro-clamp from performing its autotest. - Reposition the line if necessary. - Validate to restart the autotest.	The program is stopped until the notification is validated.
Washing E-Clamp Alarm: Check the position of the line.	0x00000000. 80000000	YELLOW	General	The Washing Electro-Clamp could not perform its autotest.	- Check that no element is preventing the electro-clamp from performing its autotest. - Reposition the line if necessary. - Validate to restart the autotest.	The program is stopped until the notification is validated.
TTT E-Clamp Alarm: Check the position of the line.	0x00000000. 40000000	YELLOW	General	The Treatment Electro-Clamp could not perform its autotest.	- Check that no element is preventing the electro-clamp from performing its autotest. - Reposition the line if necessary. - Validate to restart the autotest.	The program is stopped until the notification is validated.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Reinf. E-Clamp Alarm: Check the position of the line.	0x00000004. 00000000	YELLOW	General	The Reinfusion Electro-Clamp could not perform its autotest.	- Check that no element is preventing the electro-clamp from performing its autotest. - Reposition the line if necessary. - Validate to restart the autotest.	The program is stopped until the notification is validated.
Waste Line Alarm: Check the waste line.	0x00000000. 00000040	YELLOW	General	The elimination of the treatment bag volume could not be done.	- Check the manual clamp on the waste line. - Verify that nothing is blocking the support of the treatment bag - Validate to restart.	The program is stopped until the notification is validated.
Fiber in blood Alarm: Fiber cleaning in progress.	0x00000000. 00000800	YELLOW	General	The contact time between the blood and the fiber is too long.	- Wait for the end of the fiber cleaning. - Validate the notification or press play to resume the treatment.	The program starts a fiber unclogging step before starting again normally.
Overpressure Alarm: Fiber unclogging in progress.	0x00000000. 00200000	YELLOW	General	Overpressure detected in the blood pathway.	- Fiber unclogging in progress. - Treatment will automatically restart after unclogging. - Check the anticoagulation dose.	The program continues without the need for further action.
Clogged Fiber Alarm: Check waste line and fiber.	0x00000080. 00000000	YELLOW	General	No progress in treatment. Clogged fiber.	- Check the waste line. - Check the remaining capacity of the waste bag. - Check that there is no stress on the treatment bag support. - If the problem persists, switch off the device to remove the treatment set. - Restart the device and install a new treatment set.	The program is stopped until the notification is validated.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Clogged Fiber Alarm: Check waste line and fiber.	0x00000100. 00000000	YELLOW	General	No progress in treatment. Clogged fiber.	- Check the waste line. - Check the remaining capacity of the waste bag. - Check that there is no stress on the treatment bag support. - If the problem persists, switch off the device to remove the treatment set. - Restart the device and install a new treatment set.	The program is stopped until the notification is validated. After a defined period of time, the fiber is unclogged automatically.
QR-code Alarm: Wrong scanned QRcode, try again.	0x00000000. 00000001	YELLOW	General	The scanned QR code is not recognized.	- Validate the notification and scan another QR-Code or another treatment set.	The program is stopped until the notification is validated.
Hemato. Sensor Alarm: Autotest failure.	0x00000000. 00040000	YELLOW	General	A problem has been detected during the hematocrit sensor autotest.	- Check that there are no elements in the hematocrit sensor. - Clean the hematocrit sensor lenses with a dry coton swab or a dry compress. - Validate to restart.	The program is stopped until the notification is validated.
Hemato. Sensor Alarm: Check the circulation line.	0x00000000. 00000200	YELLOW	General	No blood detected in the Hematocrite sensor.	- Check the circulation line. - Validate to restart the treatment.	The program is stopped until the notification is validated.
Battery alarm: Insufficient level if mains failure.	0x00020000. 00000000	YELLOW	General	The battery level is not sufficient to ensure treatment in case of a power failure.	- Validate the notification to keep using the device with the risk of losing the blood in case of power failure. - Leave the device connected to the mains power supply for the next use.	The program is stopped until the notification is validated.
Levelness Alarm: Check the levelness under the device.	0x00001000. 00000000	YELLOW	General	The levelness sensor has detected a horizontality problem.	- Place the machine on level ground. - Validate to restart.	The program is stopped until the notification is validated.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Waste bag Alarm: Change the waste bag.	0x00000000. 00001000	YELLOW	General	The waste bag is full and must be changed.	- Clamp the waste line, disconnect and remove the full waste bag. - Unfold the new waste bag. - Place the unfolded bag on its support. - Reconnect the bag. - Open the manual clamp on the waste line. - Validate to restart the treatment.	The program is stopped until the notification is validated.
Clogged Fiber Alarm: Check waste line and fiber.	0x00000020. 00000000	YELLOW	General	No progress in treatment. Clogged fiber.	- Check the waste line. - Check the remaining capacity of the waste bag. - Check that there is no stress on the treatment bag support. - If the problem persists, switch off the device to remove the treatment set. - Restart the device and install a new treatment set.	The program is stopped until the notification is validated.
Clogged Fiber Alarm: Check waste line and fiber.	0x00000040. 00000000	YELLOW	General	No progress in treatment. Clogged fiber.	- Check the waste line. - Check the remaining capacity of the waste bag. - Check that there is no stress on the treatment bag support. - If the problem persists, switch off the device to remove the treatment set. - Restart the device and install a new treatment set.	The program is stopped until the notification is validated. After a defined period of time, the fiber is unclogged automatically.
Washing Alarm: Washing solution bag volume insufficient.	0x00000000. 00002000	YELLOW	General	The washing solution bag is empty.	- Quickly change the washing solution bag.	The program is stopped until the notification is validated.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Set Usage Time Alarm: Usage of blood not recommended (>6h).	0x00000000. 00004000	YELLOW	General	The blood collection started over 6hours ago. As per the circular DGS/DH/AFS 97-57, the blood can no longer be used.	- Switch off the device to remove the treatment set. - Change the BCR. - Restart the device and install a new treatment set. - The use of the blood present in the reinfusion bag is under the responsability of the practitioner. - The conformity of blood is not longer ensured by i-SEP.	Validate the alarm to continue treatment with the blood quality under the user's responsibility. Relpace the set to continue using the device with the blood quality ensured by i-sep.
Washing Alarm: Check the washing line.	0x00000000. 00000004	YELLOW	General	The washing solution is not detected in the treatment set.	- Check the manual clamp on the washing line - Check the volume of the washing solution bag and the correct insertion of the spike. - Add a second washing solution bag. - Verify that nothing is blocking the support of the treatment bag - Validate to restart the treatment.	The program is stopped until the notification is validated.
Waste Line Alarm: Check the waste line.	0x00000000. 00000020	YELLOW	General	The washing solution is not detected in the wastes.	- Open the manuel clamp on the waste line and check the waste bag. - Check the washing solution bag. - Validate to restart.	The program is stopped until the notification is validated.
Pressure sensor alarm: Check that there is no line.	0x00000000. 00080000	YELLOW	General	A problem has been detected during the pressure sensor autotest.	- Check that there is no line in the pressure sensor and validate.	The program is stopped until the notification is validated.
Overpressure Alarm: Check the reinfusion line.	0x00000200. 00000000	YELLOW	General	Overpressure detected while transferring blood to the reinfusion bag.	- Open the manual clamps on the reinfusion line. - If the reinfusion bag is full, change it. - Validate to restart the treatment.	The program is stopped until the notification is validated.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Reinfusion Line Alarm: Chech the reinfusion line.	0x00000800. 00000000	YELLOW	General	The blood is not transferred to the reinfusion bag.	- Verify that nothing is constraining the treatment bag support. - Open the manual clamp on the reinfusion line. - Change the reinfusion bag if full. - Validate to restart the treatment.	The program is stopped until the notification is validated.
Collected Volume Alarm: Collected vol. >32L ignored.	0x00008000. 00000000	YELLOW	General	The total collected volume is greater than 32L. Any new collected volume will not be displayed in the total.	- The treatment is continuing. - Further collected volume will not be counted in the total collected volume.	The program is stopped until the notification is validated.
Reinfusion Bag Alarm: Change Reinfusion bag.	0x00000400. 00000000	YELLOW	General	The reinfusion bag is full.	- Change the reinfusion bag. - Validate to restart the treatment.	The program is stopped until the notification is validated.
Overpressure Alarm: Fiber unclogging in progress.	0x00000000. 00100000	YELLOW	General	Overpressure detected in the blood pathway.	- Fiber unclogging in progress. - Treatment will automatically restart after unclogging. - Check the anticoagulation dose. - Check that there are no clots in the blood collection reservoir. - Check the anticoagulation and increase it as needed.	The program continues without the need for further action.
QRcode Alarm: Scanned set expired.	0x00000000. 00000002	YELLOW	General	The scanned treatment set is expired.	- Take a treatment set that is not expired. - Validate the notification and scan the new treatment set.	The program is stopped until the notification is validated.
Stop activated Alarm: The downtime reduces the possibility of restarting.	0x00000000. 00800000	YELLOW	General	The button STOP has been pressed.	- Press the PLAY button to resume the treatment.	The program is stopped until the PLAY button is pushed.
Battery Alarm: No Power Supply. Treatment impossible.	0x00010000. 00000000	YELLOW	Main power failure	Mains power loss.	- Treatment start impossible. - Connect the device to the main power supply.	The program will restart normally once the power is back on

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Battery Alarm: Very low battery level. Treatment impossible.	0x00040000. 00000000	YELLOW	General	The device is no longer plugged into the mains power and the battery level is very low.	- Treatment start impossible. - Quickly connect the device to the mains power supply or switch off the device before automatic shutdown.	The program will restart normally once the power is back on
Microaggregate Chamber Alarm: Change the micro-aggregates chamber.	0x00000000. 01000000	YELLOW	General	The treatment bag could not be emptied. The micro-aggregate chamber may be clogged.	- Check the manual clamps on the recovery line. - To replace the micro-aggregate chamber, close the 3 clamps on the recovery line. - Change micro-aggregate chamber. - Open the 3 clamps on the recovery line. - Prime chamber by pressing on body. - Validate to restart treatment.	The program is stopped until the notification is validated.
Washing Alarm: Washing solution bag volume insufficient.	0x00000000. 00000008	YELLOW	General	The washing solution is not detected in the treatment set.	- Check the manual clamp on the washing line - Check the volume of the washing solution bag and the correct insertion of the spike. - Verify that nothing is blocking the support of the treatment bag - Validate to restart the treatment.	The program is stopped until the notification is validated.
Washing Alarm: Washing solution bag volume insufficient.	0x00000000. 00000010	YELLOW	General	The washing solution is not detected in the treatment set.	- Check the manual clamp on the washing line - Check the volume of the washing solution bag and the correct insertion of the spike. - Verify that nothing is blocking the support of the treatment bag - Validate to restart the treatment.	The program is stopped until the notification is validated. After a defined period of time, the fiber is unclogged automatically.
Treatment Alarm: Shock detected. Immobilize the device.	0x00000000. 00000080	YELLOW	General	A sudden variation in the weighing of the treatment bag has been detected.	- Check the stability of the device. - Check that there are no disruptions on the device. - Check that there are no disruptions on the lectern. - Validate to restart the treatment.	The program is stopped until the notification is validated.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Treatment Alarm: Shock detected. Immobilize the device.	0x00000000. 00000100	YELLOW	General	A sudden variation in the weighing of the treatment bag has been detected.	- Check the stability of the device. - Check that there are no disruptions on the device. - Check that there are no disruptions on the lectern. - Validate to restart the treatment.	The program is stopped until the notification is validated. After a defined period of time, the fiber is unclogged automatically.
Hemato. Sensor Alarm: Check the positionning of the line.	0x00000000. 02000000	YELLOW	General	A problem was detected during the Hematocrit sensor autotest.	- Check that the line is correctly inserted in the Hematocrit Reader. - Validate to proceed to a sensor cleaning.	The program is stopped until the notification is validated.
FiberIN Sensor Alarm: Check the positionning of the line.	0x00000000. 04000000	YELLOW	General	A problem was detected during the FiberIN optical sensor autotest.	- Check that the line is correctly inserted in the FiberIN optical sensor. - Validate to proceed with a sensor cleaning.	The program is stopped until the notification is validated.
Waste Sensor Alarm: Check the positionning of the line.	0x00000000. 08000000	YELLOW	General	A problem was detected during the Waste optical sensor autotest.	- Check that the line is correctly inserted in the Waste optical sensor. - Validate to proceed with a sensor cleaning.	The program is stopped until the notification is validated.
BCR Sensor Alarm: Check the positionning of the line.	0x00000000. 10000000	YELLOW	General	A problem was detected during the BCR optical sensor autotest.	- Check that the line is correctly inserted in the BCR optical sensor.	The program is stopped until the notification is validated.
Washing Alarm: Check the washing line.	0x00080000. 00000000	YELLOW	General	The washing solution is not detected by the FiberIN optical sensor.	- Check the manual clamp on the washing line. - Check the correct insertion of the spike into the washing solution bag. - Validate to restart.	The program is stopped until the notification is validated.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Waste Line Alarm: Check the waste line.	0x00100000. 00000000	YELLOW	General	The washing solution is not detected by the waste optical sensor.	- Check that the manual clamp on the waste line is opened. - Check the remaining capacity of the waste bag. - Check the manual clamp on the washing line. - Check the correct insertion of the spike in the washing bag. - Validate to restart.	The program is stopped until the notification is validated.
Set installation Alarm: Wrong washing line installation detected.	0x00000010. 00000000	YELLOW	General	A wrong washing line installation in its support has been detected.	- Open the protection cover. - Reposition the washing line in the Washing Electro-Clamp and in its support (see image opposite). - Close the protection cover. - Validate to restart. - In case of a leak on one of the lines, switch off the device to remove the set. Then restart the device and install a new treatment set.	The program is stopped until the notification is validated.
Fiber in blood Alarm: Fiber cleaning in XXs.	0x00000000. 00000400	YELLOW	General	The pause mode is activated. Prolonged contact between the blood and the fiber can cause clogging of the latter.	- Quickly resume the treatment by pressing the play button. - Fiber will be cleaned if the contact time with blood is too long.	The program is stopped until the PLAY button is pushed.
Filtration Failure Alarm: Change of kit recommended. Press VALIDATE to start cycle.	0x00002000. 00000000	YELLOW	General	A filter module fault has been detected. Loss of blood in the waste.	- It is not recommended to continue with the faulty kit. - Switch off the machine to remove the kit. - Restart the machine and install a new treatment kit.	The program is stopped until the PLAY button is pushed.
Protection Lid Alarm: Treatment interrupted. Risk of injury. Close the lid before resuming.	0x00200000. 00000000	YELLOW	General	The protection lid is open. Risk of treatment failure, injury and blood exposure.	- The treatment is stopped. - Close the protection lid to continue. - Downtime reduces the likelihood of recovery.	The program can be restarted normally once the protective cover has been closed.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Protection Lid Alarm: Risk of injury. Close the lid before resuming.	0x00200000. 00000000	YELLOW	General	The protection lid is open. Risk of treatment failure, injury and blood exposure.	- The treatment is stopped. - Close the protection lid to continue. - Downtime reduces the likelihood of recovery.	The program can be restarted normally once the protective cover has been closed.
Protection Lid Alarm: Validate to restart.	0x00400000. 00000000	YELLOW	General	The protection lid is open. Risk of treatment failure, injury and blood exposure.	- The treatment is stopped. - Validate to restart.	The program is stopped until the notification is validated.
Test Mode Activated: Do not use in clinical conditions.	0x00800000. 00000000	YELLOW	General	DO NOT USE IN CLINICAL CONDITIONS. Machine performance and safety cannot be guaranteed	- Contact technical support to to solve the problem.	The program is stopped until the notification is validated.

5.3. ALERTS

The following table lists the alert titles and the text describing the displayed message. Each warning and the associated information for understanding and resolving the error is then described individually in the following sections.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Waste Bag Alert: Waste bag volume > 75%.	0x00000000.00004000	BLUE	Information	The waste bag is filled up to 75%.	- The treatment is continuing. - Prepare a new waste bag. - Press the change waste bag button and/or wait for the device to invite you to make the change.	The program continues without the need for further action.
Collection Reservoir Alert: Check the reservoir or start the treatment if full.	0x00000000.00000400	BLUE	Information	The treatment bag load cells are defective.	- If desired and possible, proceed with the recovery of blood in the BCR. - Switch off the device to remove the treatment set. - Contact the technical support to solve the problem.	The program continues without the need for further action.
Washing Alert: Critical washing solution volume.	0x00000000.00002000	BLUE	Information	The washing solution bag is nearly empty.	- The treatment is continuing. - Prepare a washing solution bag	The program continues without the need for further action.
Treatment Bag Alert: Max. Volume reached.	0x00000000.04000000	BLUE	Information	Maximum volume of the treatment bag reached.	- The treatment is continuing. - Check that the manual clamp on the waste line is opened. - Check the remaining capacity of the waste bag. - Check that nothing is constraining the treatment bag support.	The program continues without the need for further action.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Set detected Alert: Remove the set for the autotest.	0x00000000.00000001	BLUE	Information	A treatment set has been detected on the device which prevents the correct processing of the autotests.	- Remove the treatment set from the device. - If no treatment set is installed, clean the optical sensor with a dry cotton swab or a dry compress and leave the protection lid opened. - Validate to restart the autotest.	The program is stopped until the notification is validated.
Protection Lid Alert: Please close the protection lid.	0x00000000.00008000	BLUE	Information	The protection lid is open.	- Close the protection lid to continue.	The program continues without the need for further action.
Set Usage Time Alert: 30 minutes before blood expiration.	0x00000000.00010000	BLUE	Information	The blood collection started over 5,5hours ago. As per the circular DGS/DH/AFS 97-57, the blood can no longer be used after 6hours.	- Switch off the device to remove the treatment set. - Change the BCR. - Restart the device and install a new treatment set. - The use of the blood present in the reinfusion bag is under the reponsability of the practitioner. - The conformity of blood will not be ensured by i-SEP after 6 hours.	The program continues without the need for further action.
Pressure sensor Alert: Pressure not detected.	0x00000000.00040000	BLUE	Information	The pressure detection test failed. An overpressure might not be detected.	- The treatment is continuing. - Check the integrity of the treatment set.	The program continues without the need for further action. If in doubt, exchange the treatment set.
Transfer Start Alert: Homogenize the reservoir. Validate to start.	0x00000000.00400000	BLUE	Information	A validation of the automatic mode start is mandatory.	- Homgeneize the blood in the BCR. - Validate the start of the treatment of the blood that is in the BCR.	The program is stopped until the notification is validated.
Waste Bag Alert: Request registered. Wait for stop.	0x00000000.00020000	BLUE	Information	A request to change the waste bag has been initiated. The treatment will automatically stop for the change.	- The treatment is continuing. - Wait to be invited to change the waste bag.	The program continues without the need for further action.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Treatment Bag Alert: Check the positioning of the treatment bag.	0x00000000.00001000	BLUE	Information	Fault detected on the Treatment Bag holder.	- The treatment is continuing. - Verify that no element is pressing or lifting the treatment bag support.	The program continues without the need for further action.
Alert Empty reservoir: Concentration started.	0x00000000.00200000	BLUE	Information	An absence of blood has been detected in the pathway indicating an empty BCR or an obstructing clot.	- The treatment is continuing. - Check the anticoagulation for the next treatment.	The program continues without the need for further action.
Sampling Alert: Collect the samples. Validate to start.	0x00000000.00000008	BLUE	Information	As part of the clinical studies, it is mandatory to take samples.	- Close the clamps on the collection line. - Connect the blood sampling system. - Open the clamp under the BCR. - Perform the sampling. - Close the clamp under the BCR. - Remove the blood sampling system. - Put the cap back on the Luer lock. - Open the clamps on the collection line.	The program is stopped until the notification is validated.
Levelness Alert: Sensor failure.	0x00000000.80000000	BLUE	Information	The levelness sensor is defective: the levelness of the device cannot be verified. This may impact the quality of the treatment.	- The treatment is continuing. - Place the machine on level ground. - Notify technical support	The program continues without the need for further action.
Overpressure Alert: Check the waste line.	0x00000000.02000000	BLUE	Information	Overpressure detected in the blood pathway.	- The treatment is continuing. - Check the anticoagulation dose. - Check that the manual clamp of the waste line is opened. - Remember to shake the BCR before transfer.	The program continues without the need for further action.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Overpressure Alert: Check the anticoagulation.	0x00000000.01000000	BLUE	Information	Overpressure detected while transferring blood to the treatment bag.	- The treatment is continuing. - Check the anticoagulation and increase it as needed. - If the problem persists, switch off the device to remove the set. Then restart the device and install a new treatment set.	The program continues without the need for further action.
Speaker Alert: Speaker failure detected.	0x00000000.00000002	BLUE	Information	The speaker test has failed.	- The treatment is continuing. without necessary intervention.	The program continues without the need for further action.
Set Usage Time Alert: Usage of blood not recommended (>6h).	0x00000000.40000000	BLUE	Information	The blood collection started over 6hours ago. As per the circular DGS/DH/AFS 97-57, the blood can no longer be used.	- Switch off the device to remove the treatment set. - Change the BCR. - Restart the device and install a new treatment set. - The use of the blood present in the reinfusion bag is under the responsability of the practitioner. - The conformity of blood is not longer ensured by i-SEP.	The treatment continues with the blood quality under the user's responsibility. Relpace the set to continue using the device with the blood quality ensured by i-SEP.
Collected Volume Alert: Collected vol. >32L is no longer counted.	0x00000000.20000000	BLUE	Information	The total collected volume is greater than 32L. Any new collected volume will not be displayed in the total.	- The treatment is continuing. - Further collected volume will not be counted in the total collected volume.	The program continues without the need for further action.
Washing Alert: Check the washing solution bag holder.	0x00000000.00000800	BLUE	Information	Disruption detected on the washing solution bag support.	- The treatment is continuing. - Verify that nothing is pressing or lifting the washing solution bag support.	The program continues without the need for further action.

Message	Notification code	Warning		Cause	Instruction	Continuation of the programme
		Light indicator	Audio signal			
Battery Alert: Battery function unavailable.	0x00000004.00000000	BLUE	Information	Battery fault detected, battery-powered operation impossible.	- The treatment is continuing. - Treatment continues but there is a risk of losing the blood in case of power failure. - Contact the technical support to solve the problem.	The program continues without the need for further action.
Hematocrit sensor Alert: Hematocrit inconsistency.	0x00000008.00000000	BLUE	Information	Inconsistency between the blood volume and hematocrit reader.	- The treatment is continuing. - CAREFULLY verify that nothing is constraining the treatment bag support.	The program continues without the need for further action.
Maintenance Alert: Mandatory maitenance date is approaching.	0x00000040.00000000	BLUE	Information	The mandatory maintenance date approaches.	- The treatment is continuing. - Contact the technical support to schedule the maintenance.	The program continues without the need for further action.
TTT bag lid Alert: Close the treatment bag protection lid.	0x00000100.00000000	BLUE	Information	The treatment bag protection lid is opened. Warning: risk of blood exposure.	- The treatment is continuing. - Do not touch the treatment bag. - Close the treatment bag protection lid.	The program continues without the need for further action.
Reinfusion Bag Alert: Reinfusion bag full. Wait for the stop before replacement.	0x00000000.00800000	BLUE	Information	The reinfusion bag is full.	- The treatment is continuing. - Treatment will stop automatically to change the bag. - Wait the reinfusion bag alarm to change the reinfusion bag.	The program continues without the need for further action.
Diluted blood or Air bubble Alert: Possible diluted blood or treatment kit leak.	0x00000000.10000000	BLUE	Information	Highly diluted blood or air bubbles have been detected in the blood pathway.	- The treatment is continuing. - Verify that the blood in the lines is highly diluted. - Verify without opening the protective cover that the treatment kit and its connections have got sealing and integrity.	The program continues without the need for further action.

6. MAINTENANCE

6.1. DEFINITIONS

There are 2 types of maintenance:

- **Routine maintenance: defined by all maintenance actions that must be performed regularly by i-SEP ATS** users.
- **Preventive maintenance**: defined by all maintenance actions performed by technicians authorised by i-SEP at intervals defined by the manufacturer.

6.2. ROUTINE MAINTENANCE

Regular care maintenance is important for the operation of the i-SEP ATS. By doing so, this:

- Increases the operational safety and reliability
- Reduces the risk of breakdowns
- Increases the lifespan of all components.

The routine maintenance instructions that are given in the following sections are part of the operating conditions for the ATS. This applies to both the routine maintenance performed by ATS users and the preventive maintenance performed by the authorised service technicians and other testing bodies.

6.2.1. General maintenance instructions

6.2.1.1. Safety instructions for routine maintenance

- Prior to performing routine maintenance operations, completely disconnect the ATS from the power supply. Make sure the equipment is turned off.
- Make sure to follow the regulations for routine maintenance as well as the specified maintenance intervals stated in the instruction manual.
- Follow the separate instructions for each accessory.
- Use the recommended cleaning agents.
- Wear protective gloves when handling blood-contaminated consumables.

6.2.1.2. Disposal of consumables

The environmental regulations require appropriate means to dispose of wastes separated by their chemical compounds. The technical personnel at the hospital involved in the disposal of the consumables must have been properly informed.

6.2.2. Routine visual inspection

The ATS must be inspected periodically for any problems such as bent or broken push buttons, collisions, cracks, frayed or twisted power cords, and loose or missing hardware. Use of the ATS should be stopped if one or more of these anomalies is detected until the problem is corrected and it has been verified that the device is working correctly again.

In particular, check the power cable: check that the power supply insulation and shield are not damaged over the entire length of the cable (clearly visible cracks, cuts or kinks). Replace the power cable if it is damaged. Ensure that the technical department checks the defective accessories in all cases.

If the ATS is not used for more than six months, the ATS battery must be recharged prior to use. To do so, connect the ATS to the mains using the power cable and check that the battery charge indicator is on (see. Figure 137).

Figure 137: Connecting the ATS to power

6.2.3. Cleaning and disinfection

Only disinfect the ATS in the event of contamination with blood.

Before cleaning the ATS, disconnect it from the power source and make sure the equipment is turned off.

Once the ATS has been cleaned, remember to put the 4 covers back on the optical sensors (see. Figure 138).

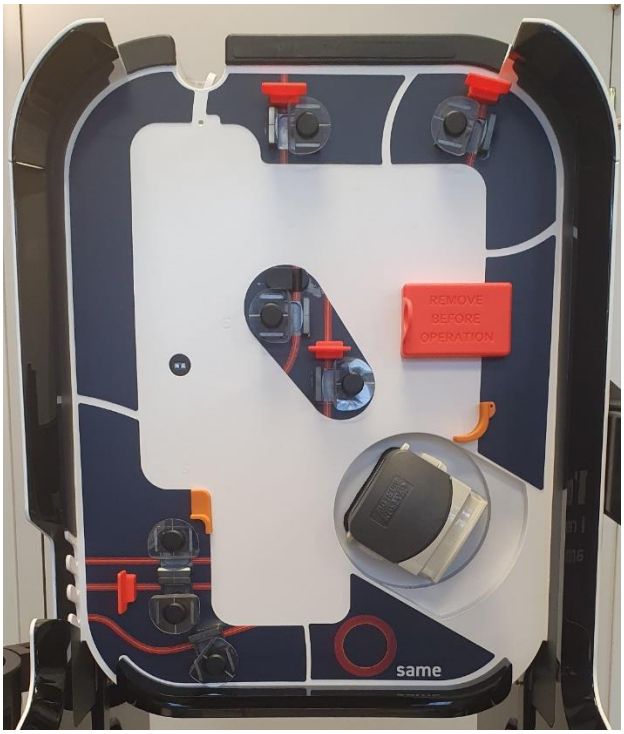

Figure 138: Covers on optical sensors

6.2.3.1. External surfaces

Clean all the surfaces of the equipment, including the base.

- **Cleaning**: use water-based solutions (preferably soapy)

Warning: refer to the required dilutions and the instructions provided by the manufacturer for the cleaning product (carefully read the product instructions and labels).

- **Disinfection**: use products specifically intended for rubber/plastic medical tools and devices. Rinse with water and dispose of the disinfectant to prevent possible damage. Refer to the required dilutions and the instructions provided by the manufacturer for the cleaning product (carefully read the product instructions and labels).

Warning: do not use disinfectants containing sodium hypochlorite, aldehydes and solvents.

- The underside of the trunk should also be cleaned.

6.2.3.2. Screen

To clean the screen:

- Use a soft, lint-free cloth.
- The cloth can be used dry or slightly damp with a mild cleanser or ethanol.

Warning: never apply a cleaning agent directly on the surface of the touch screen; if a cleaning agent is spilled on the touch screen, wipe it off immediately with an absorbent cloth.

The cleaning agent must have a neutral pH (i.e. neither acidic nor basic). Carefully wipe the surface dry.

Warning: never use acidic or basic cleaners or organic chemicals such as paint thinner, acetone, toluene, xylene, propyl alcohol, isopropyl alcohol or kerosene.

The use of improper cleaning agents may alter the optical properties of the screen and/or damage its features.

6.2.3.3. Clamps

- **Cleaning:** use quick-drying contact cleaner.
- Use a dry cotton swab to clean the corners.
- Use compressed air to remove any residue.

As each clamp is individually calibrated, DO NOT REMOVE THE CLAMPS when cleaning them.

6.2.3.4. Optical sensors

- **Cleaning**: use quick-drying contact cleaner.
- Do not use abrasive cleaning solutions.
- Use a dry cotton swab to clean between the sensors.
- Use compressed air to remove any residue.
- Install the protection lid.

6.2.3.5. Haematocrit reader

- **Cleaning**: use quick-drying contact cleaner.
- Do not use abrasive cleaning solutions.
- Use a dry cotton swab to clean between the reader slot.
- Use compressed air to remove any residue.
- Close the Haematocrit Reader cover.
- Install the protection lid.

6.2.3.6. Peristaltic pump

- Remove the pump head by pressing on the tab at the base and turn the pump head by ¼ of a turn.
- Soak in a detergent solution diluted to 0.25% in cold water for at least 1 hour, wipe dry then disinfect with a wipe soaked in 70% isopropyl alcohol.
- When reassembling the pump, align the rotation axis.
- Do not use solvent.

6.2.3.7. Pressure gauge

If there is liquid in the Safety Reservoir located under the pressure gauge:

- Unscrew the Reservoir under the pressure gauge (See Figure 139).
- Clean using water (soapy or non-soapy) and then disinfect using a 70% isopropyl alcohol wipe.

Figure 139: Reservoir under the pressure gauge

- Screw the Safety Reservoir back on.

6.2.3.8. Pressure sensor

- **Cleaning**: use quick-drying contact cleaner.
- **Disinfection**: use products specifically intended for rubber/plastic medical tools and devices. Rinse with water and dispose of the disinfectant to prevent possible damage. Refer to the required dilutions and the instructions provided by the manufacturer for the cleaning product (carefully read the product instructions and labels).
- Use a dry cotton swab to clean the corners.
- Use compressed air to remove any residue.

6.2.4. List of parts that can be replaced by the user

Some of the parts for the i-SEP ATS can be directly replaced by the user and do not need to be installed by a technical department.
While not expected, a user may need to replace the following parts.

6.2.4.1. Shelf

Disassembling the shelf:

- Lift the shelf stop upwards (See Figure 140)

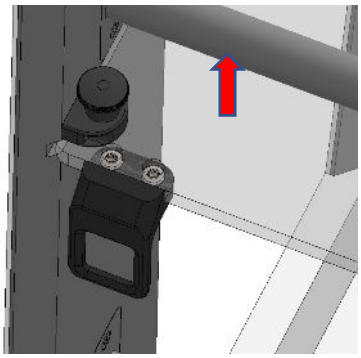

Figure 140: Disassembling the shelf (1/3)

- While holding the stop up, slide the shelf forward (See Figure 141)

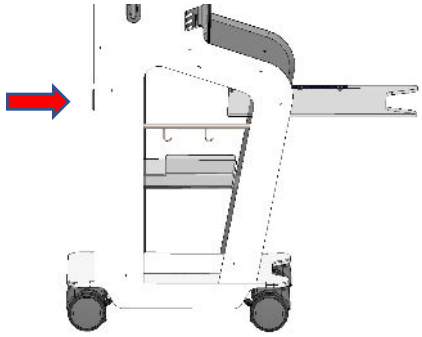

Figure 141: Disassembling the shelf (2/3)

- Disassemble the cleat by unscrewing the 2 screws (See Figure 142)

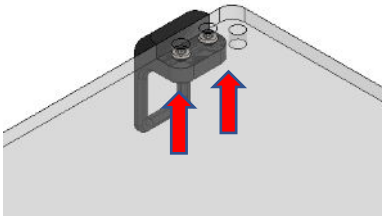

Figure 142: Disassembling the shelf (3/3)

Assembling the shelf (See Figure 143):

- Screw the cleat onto the new shelf
- Introduce the shelf in the grooves intended for this purpose while holding the stop up.

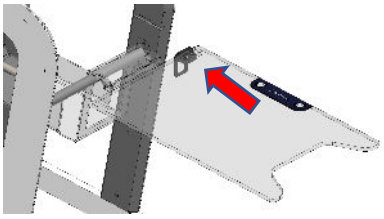

Figure 143: Assembling the shelf

6.2.4.2. Storage bin

The storage bin can be changed by removing the previous one and replacing it with a new one (See Figure 144).

Figure 144: Storage bin

6.3. PREVENTIVE MAINTENANCE

Preventive maintenance should be performed on the i-SEP ATS by an authorised technical department at regular intervals as per the maintenance contract (if there is one). Irrespective of whether a maintenance contract exists or not, the i-SEP ATS must undergo regular maintenance by an authorised technical department. The ATS must be serviced by an authorised technical department every 12 months.

6.4. EQUIPMENT REPAIR

Hospital personnel are authorised to perform the routine checks described in this section. Preventive maintenance as well as corrective maintenance on the ATS must be carried out by the technical departments authorised by i-SEP.

i-SEP will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of ATS
that are designated as repairable by service personnel.

7. TECHNICAL INFORMATION

7.1. MAXIMUM RECOMMENDED LOADS

The following table lists the maximum recommended loads per holder to ensure machine stability during normal use.

	Treatment bag (litres)	Blood Collection Reservoir (litres)	Reinfusion pole (litres)	Anticoagulation pole (litres)	Washing solution pole (litres)
Static configuration	1.2	2.6	2.0	1.0	6.0
Movement configuration	1.2	2.6	2.0	1.0	6.0

7.2. STORAGE

The i-SEP ATS should be put away and stored in a well-ventilated place with only slight temperature variations.
The storage temperature limits are the ambient temperatures (10°C → 40°C) and with a humidity from 20% →85%HR.

7.3. TRANSPORT

Before moving the machine and in order to reduce the risk of damage to the components, it is recommended to

- Remove the consumable from the ATS machine
- Only use the handles in the front and in the rear (See chapter 3.2).

It is recommended to put the ATS in the following configuration:

- Screen folded inwards (see Figure 145).

Figure 145: Folded screen

- Reservoir arm folded inwards (see Figure 146).

Figure 146: Folded down bocal arm

- Reinfusion brackets lowered and stored away (see Figure 147).

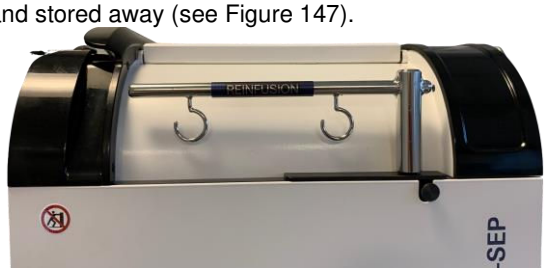

Figure 147: Stem lowered and stowed

- Anticoagulant bracket folded down at the rear of the ATS (see Figure 148).

Figure 148: Folded stem

7.3.1. Inside a building

The ATS's four wheels are equipped with brakes fitted with a mechanical locking system (cf. Figure 149).

Figure 149: ATS wheels

- Release the brake: Lift up the lever on each brake.
- Move the ATS: To move the ATS, use the front and rear handles (see paragraph 3.2).
- Push or pull ATS by handles in the direction of axis (See Figure 150).

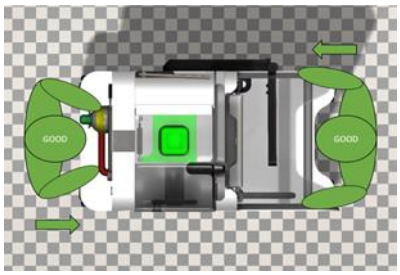

Figure 150: Good handling

- Apply the 4 locking brakes: lower the lever on each brake.

WARNING:

- DO NOT MOVE THE MACHINE BY THE SIDE AS THERE IS A RISK OF THE ATS TIPPING OVER. (See Figure 151).

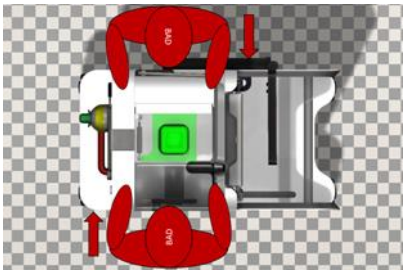

Figure 151: Wrong handling

7.3.2. Getting around small obstacles

- To avoid damaging the i-SEP ATS, always move the ATS slowly and with the rear wheels first (pull the ATS rather than push it).

7.3.3. Outside a building

- When transporting the i-SEP ATS outside a building, the machine must be transported in the original packaging provided for this purpose (see Figure 152).

Figure 152: Original packaging

7.4. First use/Commissioning

- Before using the ATS for the first time, make sure that delivery is complete.
- Only i-SEP or teams approved by i-SEP or biomedical engineers at authorised healthcare establishments can turn the machine on for the first time and carry out the associated functional tests.
- The addresses for the maintenance and service providers are given in Chapter 2.8.
- The power cord is supply by fitter.
- The maintenance label is glue by fitter to indicate the next due maintenance date (See Figure 153).

Figure 153: Maintenance label

- Before installation, the device is in maintenance mode (See Figure 154) indicating that no treatment should be performed.

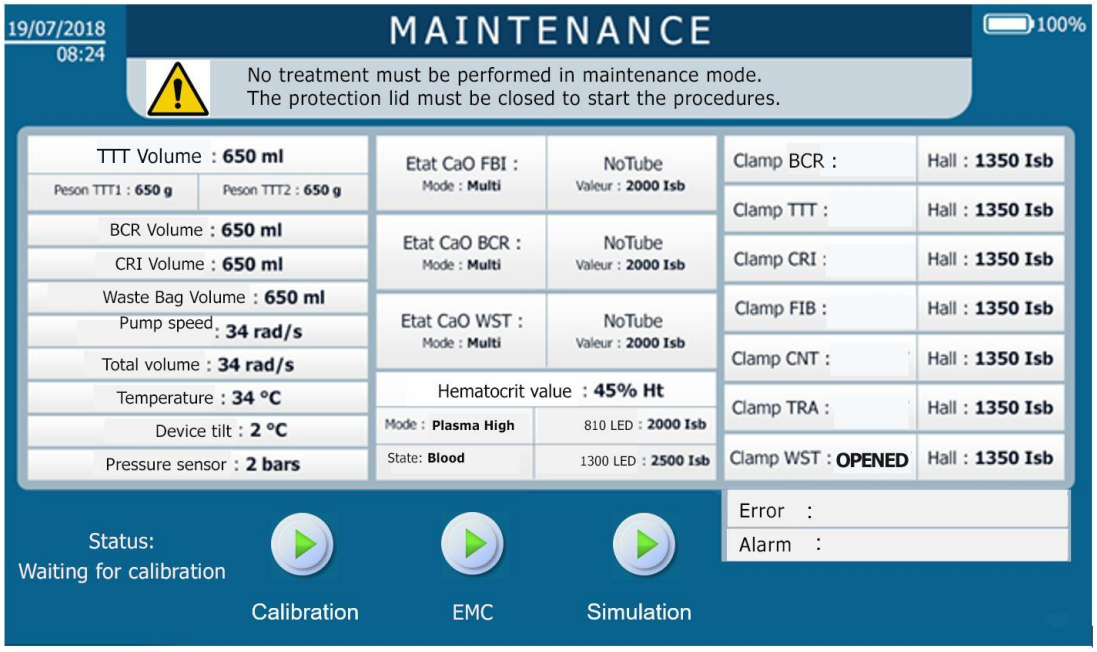

Figure 154: Maintenance screen

- When the installation is correctly done, the device is turn on to the user mode.

7.5. COMPLAINTS / SERIOUS INCIDENTS REPORTING

In the event of a complaint, a form must be completed and sent to the address indicated on the form.

In the event of failure of the i-SEP Autotransfusion Treatment Set, the defective set must in every case be kept in its packaging and sent to i-SEP upon request.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer (See section 2.8) and the competent authority of the Member State in which the user and/or patient is established.

7.6. TECHNICAL CHARACTERISTICS

7.6.1. Dimensions and weight

Dimensions:

Characteristics	Depth (cm)	Height (cm)	Open reservoir arm and open screen widths (cm)
Retracted poles	90	155	85
Elongated poles	90	183	85

Weight:
ATS weight: 85 kg

7.6.2. Materials used

Plastic, metal and electronic components.

7.6.3. User products

Disposal of user products as per to the applicable regulations in force.
Machine discarded is done by i-SEP.

7.6.4. Electrical safety

• Level of protection against electric shocks	Type: class I
	Symbol:
• Leakage currents	According to IEC 60601-1
• Protection against ingress of liquids and solid objects	IPX1

7.6.5. Power supply

•	Mains voltage	100-240 V AC
		50 Hz 60Hz
		Symbol: ~
	Power	250W

7.6.6. Electromagnetic compatibility

The electromagnetic safety of the Autotransfusion System is ensured by compliance with IEC/EN 60601-1-2.

7.6.7. Laser level certificate

The laser scanner is in compliance with the applicable requirements set forth in standard EN 60825-1 (and CDRH 21 CFR 1040) on the date of manufacture. Laser light is visible to the human eye and emitted from the window on the front of the scanner.

7.6.8. Symbols

Explanation of the symbols used for the i-SEP Autotransfusion System labels:
The table below (See Table 5) describes and explains the symbols on all the labels associated with the i-SEP Autotransfusion System, except symbols for single-use sterile devices (for these, refer to the specific labels).

SYMBOL	TITLE	SYMBOL	TITLE
Manufacturing			
	Manufacturer	IPX1	Type of protection
 YYYY-MM-DD	Production date		Series number
	Catalogue number, commercial reference		
Bar code or 2D-Matrix with (01) … (11)… (21)…	Unique device identification: (01) Medical Device Identifier (11) Date of manufacture (YYYY-MM) (21) Series number		
Electrical connection			
	Alternative current		Earth fault protection
	“ON/OFF” (push-push)	 T 2A H 250V	Fuses
	TYPE CF APPLIED PART		
Transport, Storage			
	Can be broken or damaged if not handled with care		Top
	Protect from moisture		Keep away from all sources of light
Safe use			
	Refer to the Instructions For Use		Refer to the Instructions For Use for all important safety-related information such as warnings and precautions, which for various reasons cannot be included on the medical device itself
	Refer to the Instructions leaflet/booklet		Do not push
	Danger laser radiation		Danger
Disposal			
	General recovery/recycling symbol (only applicable to the cardboard packaging, not applicable to the device itself)		Waste from electrical and electronic equipment that need to be collected separately

Table 5: Symbols

7.6.9. Fuses

Warning: Fuses may only be replaced by qualified personnel authorised by the manufacturer.

7.6.10. Environmental conditions

7.6.10.1. Use

• Operational temperature	19 - 25°C
• Humidity	45 -65% RH
• Stability	+/- 5% compared with level ground
• Altitude	Less than 2000 m
• Atmospheric pressure	80->105 kPa

Table 6: Conditions of use

7.6.10.2. Storage and transport

Warning: Before storing or transporting the machine, refer to the general precautions for use as well as to the transport recommendations (See chapters 7.2 and 7.3)

- When the machine is in the original packaging, its transport and storage is compatible with the atmospheric conditions of all usual means of transport (air, sea, rail and road):
  - Temperature: -10°C -> 60°C
  - Humidity: 5%->80% HR; RH non-condensing
- When the machine is not in the packaging, the indoor transport and storage of the machine must take place under ambient conditions (see section 7.2).

7.6.11. External connections

No external connection to the i-SEP Autotransfusion System is possible, except for reasons of putting the machine into service/back into service and for maintenance purposes, carried out by i-SEP or approved technical service providers.

7.6.12. Acoustic level

Acoustic level: 60 dB(A)

7.7. BIBLIOGRAPHY

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5. FDA. GUIDANCE FOR INDUSTRY - ALTERNATIVE TO CERTAIN PRESCRIPTION DEVICE LABELING REQUIREMENTS. DOCUMENT ISSUED ON: 1/21/2000.

8. LIMITED WARRANTY

This Limited Warranty is in addition to the purchaser's statutory rights under the applicable regulations.
i-SEP guarantees that all necessary care has been taken in the manufacture of this medical device as required by the nature and intended use of the device. i-SEP guarantees that the medical device can function as described in the Instructions For Use provided it is used in accordance with the Instructions For Use by a qualified user and before the expiry date indicated on the packaging However, i-SEP cannot guarantee that the user will use the device correctly, nor can it guarantee that incorrect treatment or diagnosis and/or the particular physical and biological characteristics of a patient will not affect the performance and effectiveness of the device with detrimental consequences for the patient, even if the specified Instructions For Use have been followed. i-SEP, while stressing the need to strictly comply with the Instructions For Use and to adopt all necessary precautions for the proper use of the device, shall not be liable for any loss, damage, costs, incidents, or consequences arising directly or indirectly from the misuse of this device. i-SEP undertakes to replace a defective medical device at the time of its release or during its shipment by i-SEP until the time of delivery to the end user, unless such defect is due to improper handling by the purchaser. The above Warranty is in lieu of all other warranties, express or implied, written or oral, including, but not limited to, warranties of merchantability and fitness for a particular purpose. No person, including a representative, agent, reseller, distributor, or intermediary of i-SEP or any other industry or trade organisation is authorised to make any representation or warranty with respect to this medical device, except as expressly set forth herein. i-SEP disclaims any warranty of merchantability and any warranty of fitness for a particular purpose with respect to this product other than as expressly set forth herein. The purchaser agrees to abide by the terms of this Limited Warranty and agrees in particular, in the event of any dispute or litigation with i-SEP, not to bring any claims based on alleged or proven modifications or alterations to this Limited Warranty by any representative, agent, reseller, distributor, or other intermediary. The existing relationship between the contracting parties (also in the event that this is not in writing) to which this Warranty is given, as well as all disputes connected with it or in connection with it, as well as anything connected with it or any dispute concerning this Warranty, its interpretation and its execution, without exception or reservation, shall be governed exclusively by French law and jurisdiction. The court selected is the court in Nantes (France).

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