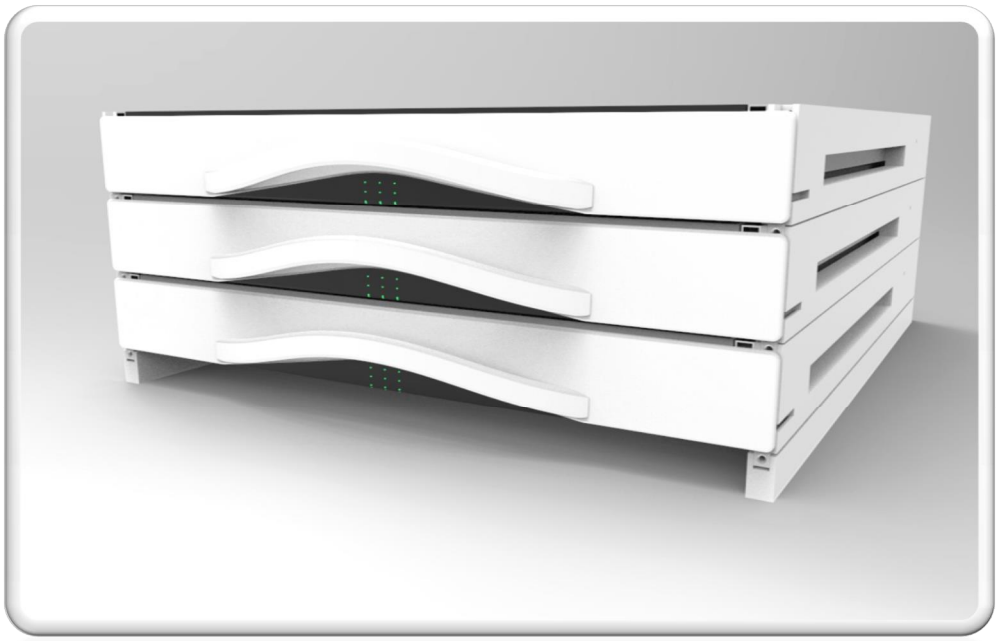
USER MANUAL

SMART STORAGE FOR FRIDGE

SST-R



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1 General user information.

1.1 Purpose.

Please read this user manual meticulously and in its entirety before using the equipment.

This manual clearly and extensively sets out how to use the SST-R and service it correctly and safely.

The illustrations and images contained in this manual represent all the SST-R models.
This also applies to all the actions, comments and explanations contained in this manual.

Please keep all the SST-R documentation for the service life of your equipment.

1.2 Intended audience.

This manual is intended for all users likely to carry out operations on the SST-R during its usage cycle. It covers all the main fields and topics for the various user groups.

1.3 Structure.

The chapters are arranged chronologically in SST-R usage phase order, making it quick and easy to find answers to specific questions by selectively reading the contents of the relevant topics.
One of the chapters is devoted to the general safety instructions. Please read it meticulously.

1.4 Advice.

If you cannot find answers to questions arising from SST-R operation or general questions concerning the work done by the SST-R in this manual, please do not hesitate to contact us at **support@biolog-id.com**

1.5 Accompanying documents

The following are provided in addition to this user manual:

- General installation and maintenance instructions
- A manual on using the HMI (Human Machine Interface)
- Information on spare parts
- Certificates

All manuals are available in hard copy only.

The SST-R must be installed by Biolog-id trained and authorised personnel.

2 Overview of the Smart Storage Fridge (SST-R).

2.1 SST-R intended use.

The SST-R is a class I medical device used as a blood bank refrigerator/cold room accessory. It is a fixed device that can only be used inside buildings.

The SST-R is a Radio-Frequency Identification (RFID) product used to track packed red blood cell (RBC) bags. It improves blood bag storage safety by recording the history of each bag and making it available to the user. This system tracks all bag movements into and out of the refrigerator or cold room.

The SST-R is in permanent communication with the RFID tags affixed to the RBC bags so that it can display the stock status.

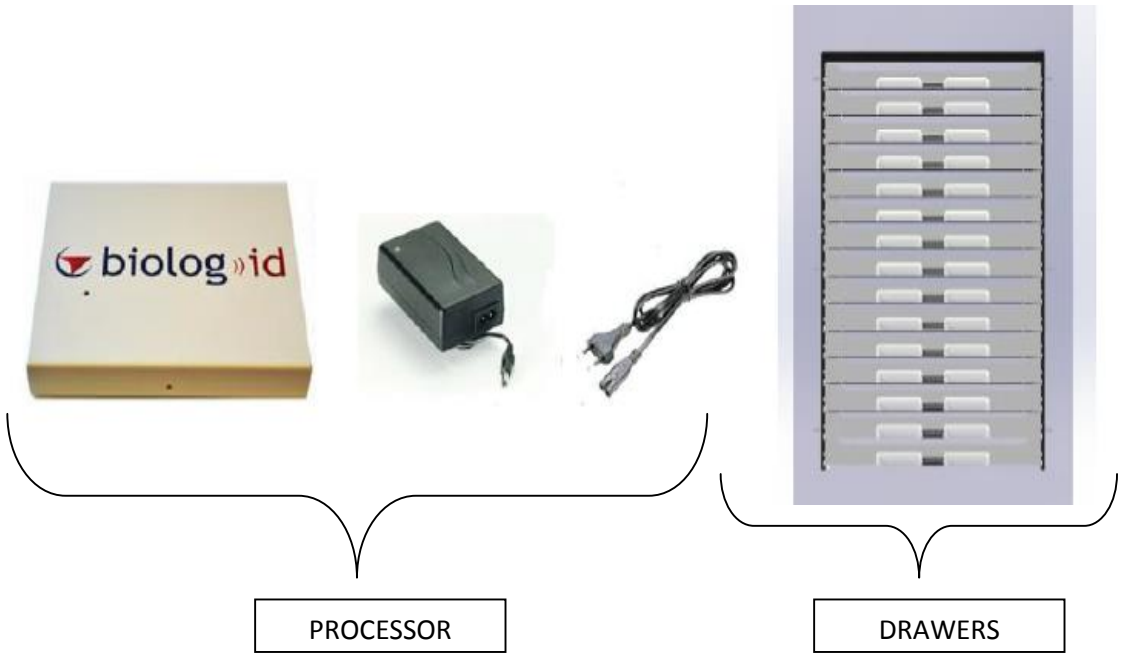


Fig. Example of an SST-R Kit

The SST-R can also exchange and write data by communicating with a third party program linked to the SST-R that displays bag data (expiry date, movements, etc.).

2.2 Required environmental characteristics for SST-R operation.

The SST-R is designed to be used in a hospital environment by laboratory technicians who have been specially trained to handle RBC bags.

The SST-R is used inside a blood bank refrigerator/cold room that has been specifically qualified to work with this medical device. (cf Chapter 2.4, Hardware and software compatibility).

Fig. Installing the drawer modules in a refrigerator

Fig. SST-R drawer assembly

The SST-R-compatible blood bank refrigerator/cold room controls the climate-related aspects (temperature and hygrometry) of labile blood product storage. The SST-R does not impact the performance of the refrigerator/cold room.

The required environmental characteristics for SST-R operation are specified in the table below. It is important that these are followed in order for the SST-R to operate correctly

Operating temperature	0 to 40°C *(Power supply: -25°C to +40°C)*
Storage temperature	SST-R Kit: -10°C to 40°C Special recommendations must be followed when storing the following two components: Battery: 1 year: -20°C to 25°C 3 months: -20°C to 45°C 1 month: -20°C to 60°C Button cell: CR2032 Recommendation: +10°C to +25°C *(do not exceed 30°C)*
Operating humidity	40% RH to 95% RH
Maximum storage humidity	40% RH to 95% RH (CR2032 button cell Recommendation: 40% RH to 95% RH)
Atmospheric pressure **Min / Max**	700hPa 1060hPa

2.3 Description of the SST-R.

This chapter details the component parts of the SST-R kit and their functions.

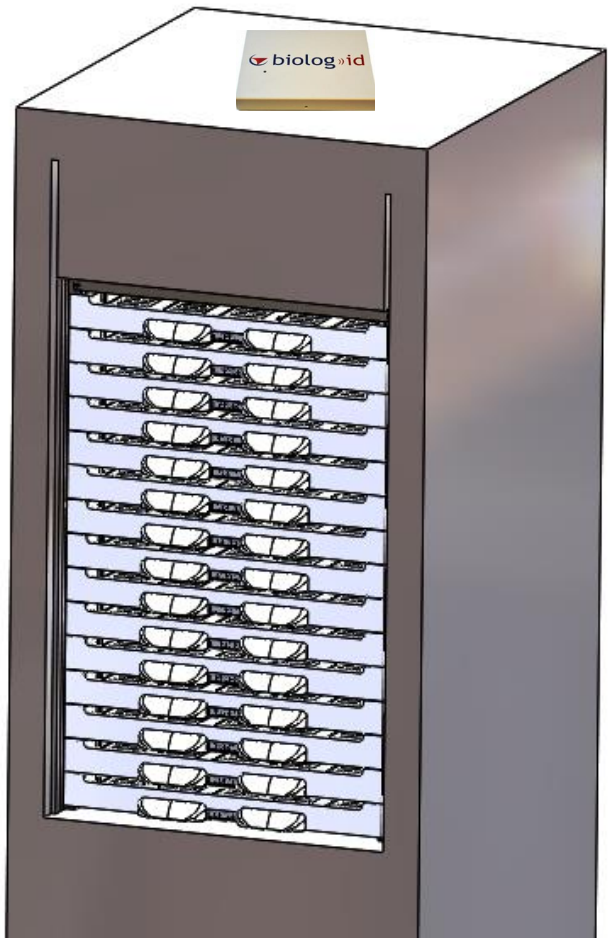


Fig. SST-R kit

2.3.1 Processor and power supply.

Fig. Processor and power supply

The middleware referred to as the processor in the SST-R system manages the data, queries and transfers to higher level applications such as third party programs.

2.3.2 Wiring harness.

Fig. wiring harness

The wiring harness supplies power to the individual drawers and carries the data between the processor and the RFID antennas.

2.3.3 Drawer.

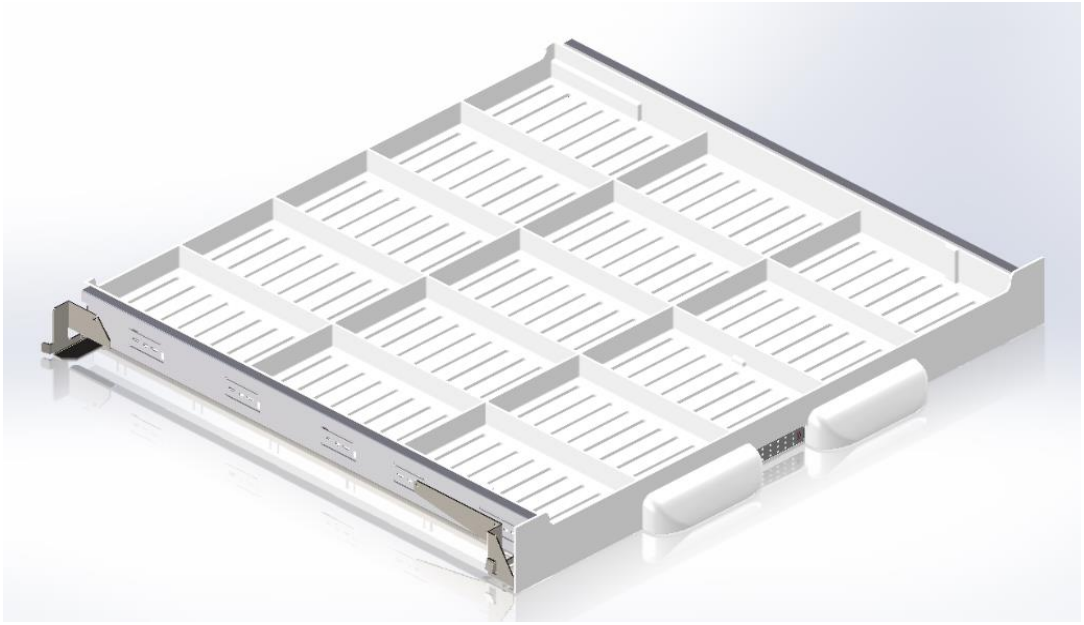


Fig. drawer unit

The drawer is the module used to store the RBC bags.

There are 3 ranges of drawers with different storage arrangements:

- **8 spaces** (2 rows of 4 spaces).
- **12 spaces** (3 rows of 4 spaces).
- **15 spaces** (3 rows of 5 spaces).

2.3.4 Satellite.

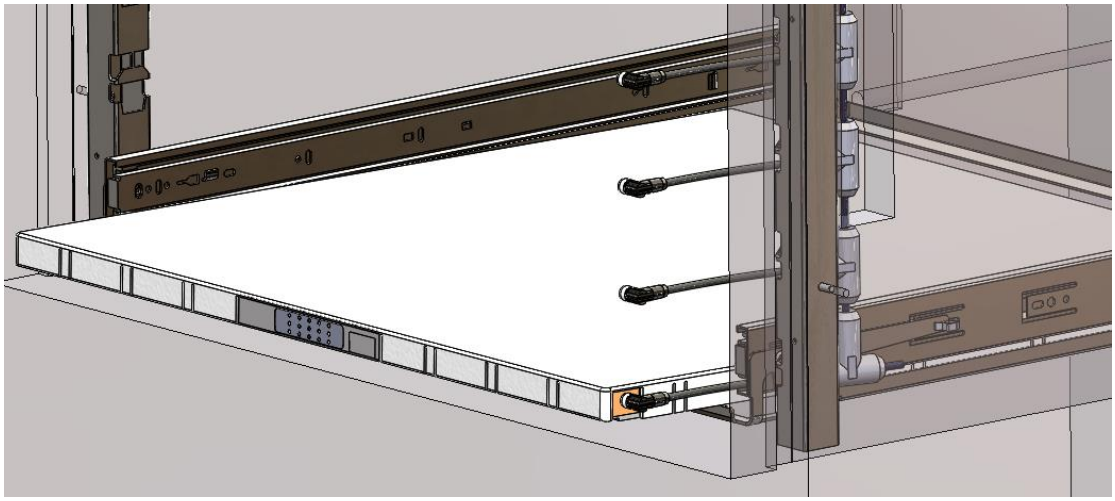


Fig. satellite box

Drawer satellites provide RBC bag location.

A satellite is installed beneath each drawer. Satellites consist of a sub-assembly of RFID antennas that communicate with the RFID (Tag) in the RBC bag label.

The RFID system operates on the principle of a transponder (tags, RFID labels, etc.) and an interrogator (coupler). The interrogator is an active radiofrequency emitter which activates the RFID labels located in the space by supplying them with the energy they need to operate. In addition to supplying the energy, the interrogator also sends specific commands to which the tag responds. A simple command might involve returning the number of donations corresponding to a unique identifier.

2.3.5 Temperature probe.

The temperature probe integrated into the SST-R is a sealed unit. It is used to measure zone temperatures.

Fig. temperature probe

The only reference temperature is that provided by the controlled climate chamber. The SST-R makes no claims as to temperature-related performance.

The SST-R temperature reading is for information only. This function is unrelated to cold chain maintenance security.

2.4 Hardware and software compatibility

This chapter details the third party hardware and software that is compatible with the SST-R.

2.4.1 Refrigerator.

The SST-R is compatible with the refrigerators listed in the table below:

Refrigerator	SST-R range	Number of drawers	Maximum number of bags
Angelantoni BBR 700	4 x 3	15	180
B Medical System BR 750	5 x 3	15	225
B Medical System BR 490	4 x 2	14	112
B Medical System BR 410	4 x 2	11	88
B Medical System BR 250	4 x 2	5	40

Depending on which type of refrigerator is used, three drawer combination ranges may be available:

- ✓ 2 rows of 4 spaces (8 spaces / 4x2)
- ✓ 3 rows of 4 spaces (12 spaces / 4x3)
- ✓ 3 rows of 5 spaces (15 spaces / 5x3)

The system is designed to provide 1 to 15 drawers.

The device must not be overloaded.

2.4.2 Cold room.

The SST-R is compatible with all RBC bag storage cold rooms. When used in this way, the SST-R is installed using the specific cold room fixing kit.

(Demonstrate whether or not cold room testing is required)

2.4.3 RFID label.

Fig. RBC bag and RFID tag

Fig. RFID label and blood bag

The RFID label stores the product and patient data and RBC bag tracking data.

The following passive RFID labels are compatible with the SST-R:

TBC + DIMENSIONS + supplier reference (PARAGON, etc.)

Supplier ref	Dimensions
TAG_HF_100E1PS140_1R_75SLIS45	
TAG_HF_102E1AI102_R5_31SLIS16	
TAG_HF_102E1AI102_R5_50LRI2K50	
TAG_HF_102E1PI102_R5_31SLIS16	
TAG_HF_ETI4"X4"_RW_SLI_S	
TAG_HF_INA47X47_RW_SLI_S	
TAG_HF_INA52X52_RW_LRI2K	
TAG_HF_INA55X55_RW_LRI2K	
TAG_HF_INA55X55_RW_SLI_S	
TAG_HF_INI34X20_RW_SLI_S	
TAG_HF_INI45X20_RW_LRI2K	
TAG_HF_INW34X20_RW_SLI_S	
TAG_HF_PA43X34X20_RW_LRI2K	
TAG_HFIN34X20_RWBS_SLI_S	

2.4.4 Third party software.

The SST-R can link to third party programs and communicate over their web service to share/exchange RBC bag tracking data (using a standard communication protocol). The third party program can therefore ask the SST-R to write data to the RFID label memory.

Before this type of software is used, its compatibility will be validated.

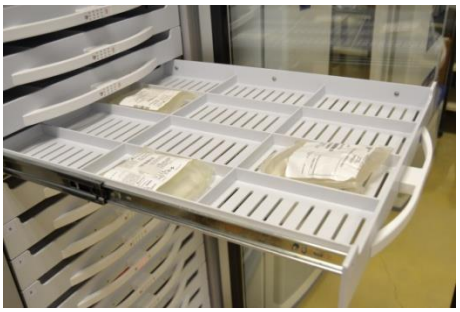
The third party system is responsible for interpreting the data received by the SST-R.

3 Using the Smart Storage Fridge (SST-R).

The purpose of this chapter is to show how the SST-R works.

3.1 How to place the RBC bags in the SST-R:

1 - Open a drawer



2 - Place the RBC bag in the drawer with the tube folded beneath it*

**For better visibility, we recommend putting the bag label on top.*

3 - LEDs showing blue*: indicates which spaces are available in a drawer.

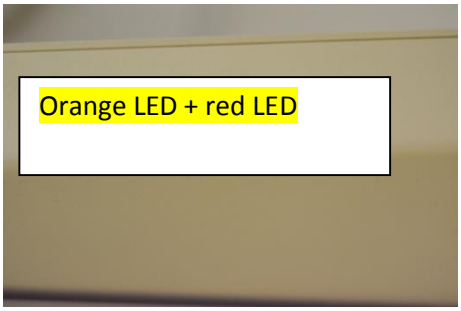
**In this SST-R model, this function is only applicable if a third party system is linked to the web service.*

Please note: In diagnostic mode (RFID and LED operation verification), the front of the drawer flashes

3.2 Using the processor:

The processor is located outside the refrigerated chamber. There are three types of LED on the front of the processor and their meanings are explained in this chapter.

Steady green LED: The processor is in normal operating mode and is functioning normally.
Flashing green LED: The processor is in maintenance operating mode and is functioning normally.
Steady orange LED: The battery is fully charged
Flashing orange LED: The battery is charging.



Orange LED + red LED

Steady red LED: The processor is either in non-functional mode (faulty) or it is disconnected from the network. Please refer to Chapter 6 - 1st level maintenance in this manual

Green LED + red LED

Steady green and red LED: Network disconnected.

Please refer to Chapter 6 - 1st level maintenance in this manual

Green LED only

Green LED only: the battery is no longer charging and may be discharged. Make sure that the mains cable is plugged in.

Please refer to Chapter 6 - 1st level maintenance in this manual

A battery integrated into the processor box provides backup power to keep the RFID electronic surveillance functions working for less than 2 hours.

4 Safety instructions.

This chapter provides a detailed description of the safety instructions to apply when using the SST-R.
Please pay special attention to these instructions

4.1 General safety instructions.

- Ensure that the installation and settings work is carried out by qualified personnel. Operations carried out by personnel lacking the requisite skills could impact the performance of the device and cause personal injury or equipment damage.
- Only qualified customer service technicians are authorised to carry out maintenance operations and repairs.
- Make sure that the connecting cable is not trapped or kinked during installation or when moving the device.
- The SST-R must be positioned in such a way that the disconnection mechanism is difficult to use.
- Never dismantle or modify any of the system components after the installation has been validated
- Never place any objects other than blood bags in a drawer
- Never lean on a drawer
- The SST-R must not be stored or used outside the temperature and atmospheric pressure ranges specified in this manual (Chapter 2.2)
- Never cover the SST-R drawers and/or obstruct the air vents.
- The SST-R must be fixed in such a way as to prevent it from being dismantled without tools (for maintenance purposes).
- To prevent short-circuiting or oxidisation of the metal parts, never allow water or any other liquid to penetrate into the device
- Use of the SST-R is restricted to trained personnel who are qualified to work in a medical environment.
- Unless carrying out maintenance (see the installation and maintenance manual), never unplug the electrical power supply (220V AC/12V DC), never disconnect the connecting cables between the drawers and never disconnect the Ethernet network cable.

	• The SST-R must only be used with original accessories and spare parts because these are the only accessories/spare parts whose reliability, safety and compatibility with our medical device are controlled • Always follow the instructions shown on the safety labels affixed to the SST-R (see Chapter XXXX). • The safety instructions affixed to the SST-R or beside it must remain legible and complete throughout the period the product is in use. If the safety labels become discoloured or are damaged during the service life of the SST-R, please inform Biolog-id customer support (support@biolog-id.com).

• The SST-R must be installed in a refrigerator which is stable and equipped with an anti-tipping system (this generally requires it to be fixed to a wall).

• Never push the SST-R.
• Never sit on a drawer.
• Never climb onto or walk on a drawer.

RISK	SAFETY INSTRUCTIONS
Contamination	Follow the cleaning instructions.
Handling	Operators must undergo authorised Biolog-id training so that they know how the product works, are familiar with the documentation and in particular, are aware of the safety instructions.
Electrical	The electrical supply connecting cables must be installed in accordance with applicable national regulations.
Electrical	The machine-specific electrical voltages must be noted and the voltages on the data plates must be compared with the voltages available at the installation location before the installation is connected.
Electrical	The machine wiring diagrams must be followed.
Electrical	The device must be connected to a socket with a Circuit Protective Conductor*
Electrical	To prevent the system from developing a fault due to problems with other electrical devices, it must be connected to a separate electrical circuit. Under no circumstances should it be connected to a multi-socket along with other electrical devices.

RISK	SAFETY INSTRUCTIONS
Electrical	Before connecting and commissioning the machine, check that the power supply is connected correctly. Ensure that the device connecting plug is readily accessible so that it can be pulled out easily when necessary, without having to push other devices out of the way. The power plug serves as a network disconnection device.
Mechanical	Regularly check the fixings. Make sure that only trained operators who are familiar with the safety measures use the SST-R
Mechanical	Only pull out the drawers using the handles provided

4.2 RF radiation hazards.

	The SST-R electronic system antennas each emit a frequency of 13.56 MHz with a power output of 200 mW (the law applicable to the design of RFID readers prohibits a power output over 2 W).
	MEDICAL ELECTRICAL DEVICES require special EMC precautions. The SST-R must be installed and commissioned in accordance with the EMC data supplied in the ACCOMPANYING DOCUMENTS.
	Portable or mobile RF communication devices can affect MEDICAL ELECTRICAL DEVICES
	Using ACCESSORIES, transducers or cables other than those specified can increase EMISSIONS or reduce the IMMUNITY of the DEVICE or EM SYSTEM. This does not include transducers and cables sold by the MANUFACTURER of the DEVICE or the EM SYSTEM and used as spare parts to replace internal components.
	The DEVICE or EM SYSTEM must not be used beside other devices or stacked on top of them.
	The DEVICE or EM SYSTEMS can be affected by interference caused by other devices even if they comply with CISPR EMISSION requirements.

Directives and manufacturer declaration - electromagnetic emissions		
The PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C models are designed to be used in the electromagnetic environment specified below. PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C customers or users must ensure that their devices are used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - directives**
RF emissions CISPR11	Group 1	The PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C models only use RF energy for internal functions. As a result, RF emissions are extremely low and are unlikely to cause interference in nearby electronic devices.
RF emissions CISPR11	Class B	The PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C models are suitable for use in all buildings, including domestic and those connected directly to the public low-voltage electrical power supply network that supplies power to domestic dwellings.
Harmonic emissions CEI 61000-3-2	Class B	
Voltage fluctuations/ Flicker CEI 61000-3-3	Compliant	

Directives and manufacturer declaration - electromagnetic immunity			
The PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C models are designed to be used in the electromagnetic environment specified below. PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C customers or users must ensure that their devices are used in such an environment.			
Immunity test	**Test level CEI 60601**	**Level of compliance**	**Electromagnetic environment - directives**
Electrostatic discharges (ESD) CEI 61000-4-2	± 6 kV on contact ± 8 kV into the air	± 6 kV on contact ± 8 kV into the air	The floors must be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic material, relative humidity must be at least 30%.
Fast transient bursts CEI 61000-4-4	± 2 kV for electrical supply lines ± 1 kV for input/output lines	± 2 kV for electrical supply lines ± 1 kV for input/output lines	The quality of the electrical power supply network must equate to that in a typical commercial or hospital environment.
Transient overvoltages CEI 61000-4-5	± 1 kV between phases ± 2 kV between phase and earth	± 1 kV between phases ± 2 kV between phase and earth	The quality of the electrical power supply network must equate to that in a typical commercial or hospital environment.
Voltage dips, short outages and voltage fluctuations in the electrical power supply input lines CEI 61000-4-11	<5% *UV* (>95% *UV* dip) for 0.5 cycles <40 % *UV* (60 % *UV* dip) for 5 cycles <70% *UV* (30% *UV* dip) for 25 cycles <5% *UV* (>95% *UV* dip) for 5 seconds	<5% *UV* (>95% *UV* dip) for 0.5 cycles <40 % *UV* (60 % *UV* dip) for 5 cycles <70% *UV* (30% *UV* dip) for 25 cycles <5% *UV* (>95% *UV* dip) for 5 seconds	The quality of the electrical power supply network must equate to that in a typical commercial or hospital environment. If a PRD-7130100C, PRD-7130110C, PRD-7130120C or PRD-7130130C user requires continuous operation during electrical power supply network outages, we recommend connecting the PRD-7130100C, PRD-7130110C, PRD-7130120C or PRD-7130130C to an uninterruptible power supply or battery.
Magnetic field at the electrical network frequency (50/60 Hz) CEI 61000-4-8	3 A/m	3 A/m	Magnetic fields at the electrical network frequency must be at levels that are characteristic of a typical commercial or hospital environment.
NOTE *UV* is the voltage of the AC network before application of the test level.			

Directives and manufacturer declaration - electromagnetic immunity
The PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C models are designed to be used in the

electromagnetic environment specified below. PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C customers or users must ensure that their devices are used in such an environment.

Immunity test	Test level According to CEI 60601	Level of compliance	Electromagnetic environment - directives
Emissions - Conducted RF CEI 61000-4-6	3 Veff 150 kHz to 80 MHz	3 V	Portable or mobile RF communication devices must not be used any closer than the recommended separation distance from any part of the PRD-7130100C, PRD-7130110C, PRD-7130120C or PRD-7130130C, including the cables, as calculated using the applicable equation for the emitter frequency. **Recommended separation distance** $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.34 \sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum characteristic power output of the emitter in Watts (W) as provided by the manufacturer of the emitter, and *d* is the recommended separation distance in metres (m). The strength of the fixed RF emitter fields, determined by carrying out an electromagnetic survey on site [a], must be below the compliance level in each of the range of frequencies. [b] Interference can be caused by proximity to devices marked with the following symbols: 
Emissions - Radiated RF CEI 61000-4-3	3 V 80 MHz to 2.5 GHz	3 V	

NOTE 1 At 80 MHz and at 800 MHz, the highest range of frequencies is applicable.
NOTE 2 These directives might not be applicable to all situations. Electromagnetic propagation is affected by absorption and reflections of structures, objects and persons.

[a] The strength of the fixed emitter fields such as radiotelephone base stations (cellular/cordless), mobile terrestrial radios, amateur radios, AM and FM radio transmitters and TV transmitters cannot be calculated theoretically with any degree of accuracy. To assess the electromagnetic environment due to fixed RF emitters, an on-site electromagnetic survey must be carried out. If the strength of the field measured at the location in which the PRD-7130100C, PRD-7130110C, PRD-7130120C or PRD-7130130C is used exceeds the applicable RF compliance level set out above, the PRD-7130100C, PRD-7130110C, PRD-7130120C or PRD-7130130C must be monitored to check that it is operating normally. If the PRD-7130100C, PRD-7130110C, PRD-7130120C or PRD-7130130C is observed to be performing abnormally, additional measures may be needed such as re-orientating or repositioning it.
[b] The field strength over the range 150 kHz to 80 MHz must be lower than 3 V/m.

Recommended separation distances between portable and mobile RF communication devices and the PRD-7130100C, PRD-7130110C, PRD-7130120C or PRD-7130130C

The PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C models are designed to be used in electromagnetic environments in which radiated RF emissions are controlled. PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C customers and users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (emitters) and the PRD-7130100C, PRD-7130110C, PRD-7130120C or PRD-7130130C, as recommended below and in accordance with the maximum emitted power of the communication devices in question.

Maximum assigned output power of the emitter W	**Separation distance according to emitter frequency**		
	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.34 \sqrt{P}$
0.01			
0.1	0.37m	0.37m	0.74m
1			
10			
100			

In the case of an emitter whose assigned maximum output power is not given above, the recommended separation distance *d* in metres (m) can be estimated using the applicable equation for the emitter frequency, where *P* is the maximum characteristic power output of the emitter in Watts (W) according to its manufacturer.
NOTE 1 At 80 MHz and at 800 MHz, the separation distance for the highest range of frequencies is applicable.
NOTE 2 These directives might not be applicable to all situations. Electromagnetic propagation is affected by absorption and reflections of structures, objects and persons.

Directives and manufacturer declaration - electromagnetic immunity

The PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C models are designed to be used in the electromagnetic environment specified below. PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C customers or users must ensure that their devices are used in such an environment.

Immunity test	**Test level CEI 60601**	**Level of compliance**	**Electromagnetic environment - directives**
Electrostatic discharges (ESD) CEI 61000-4-2	± 6 kV on contact ± 8 kV into the air	± 6 kV on contact ± 8 kV into the air	The floors must be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic material, relative humidity must be at least 30%.
Fast transient bursts CEI 61000-4-4	± 2 kV for electrical supply lines ± 1 kV for input/output lines	± 2 kV for electrical supply lines ± 1 kV for input/output lines	The quality of the electrical power supply network must equate to that in a typical commercial or hospital environment.
Transient overvoltages CEI 61000-4-5	± 1 kV between phases ± 2 kV between phase and earth	± 1 kV between phases ± 2 kV between phase and earth	The quality of the electrical power supply network must equate to that in a typical commercial or hospital environment.
Voltage dips, short outages and voltage fluctuations in the electrical power supply input lines CEI 61000-4-11	<5% *UV* (>95% *UV* dip) for 0.5 cycles <40 % *UV* (60 % *UV* dip) for 5 cycles <70% *UV* (30% *UV* dip) for 25 cycles <5% *UV* (>95% *UV* dip) for 5 seconds	<5% *UV* (>95% *UV* dip) for 0.5 cycles <40 % *UV* (60 % *UV* dip) for 5 cycles <70% *UV* (30% *UV* dip) for 25 cycles <5% *UV* (>95% *UV* dip) for 5 seconds	The quality of the electrical power supply network must equate to that in a typical commercial or hospital environment. If a PRD-7130100C, PRD-7130110C, PRD-7130120C or PRD-7130130C user requires continuous operation during electrical power supply network outages, we recommend connecting the PRD-7130100C, PRD-7130110C, PRD-7130120C or PRD-7130130C to an uninterruptible power supply or battery.
Magnetic field at the electrical network frequency (50/60 Hz) CEI 61000-4-8	3 A/m	3 A/m	Magnetic fields at the electrical network frequency must be at levels that are characteristic of a typical commercial or hospital environment.

NOTE *UV* is the voltage of the AC network before application of the test level.

The PRD-7130100C, PRD-7130110C, PRD-7130120C and PRD-7130130C models use the 13.56 MHz frequency.
The frequency band is 13.553 - 13.567 MHz in accordance with the ISO 15693 standard. The modulation type is ASK and the RF mode is TX/RX.
Apparent power is 100 mW.

4.3 Contraindications

As a preventive measure, it is recommended that people fitted with pacemakers do not use the SST-R. To be corroborated and added to the FMECA

4.4 Warning for users in United States

Federal Communication Commission Interference Statement 47 CFR Section 15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

NO UNAUTHORIZED MODIFICATIONS

47 CFR Section 15.21

CAUTION: This equipment may not be modified, altered, or changed in any way without signed written permission from Biolog-id. Unauthorized modification may void the equipment authorization from the FCC and will void the Biolog-id warranty.

This device complies with FCC RF radiation exposure limits set forth for general population (uncontrolled exposure). This device must be installed to provide a separation distance of at least 20cm from all persons and must not be collocated or operating in conjunction with any other antenna or transmitter.

5 Cleaning instructions

This chapter explains the process to follow when cleaning the SST-R.

The device must be cleaned or disinfected before use.

The SST-R must be cleaned at least once a month and more frequently if necessary in order for it to operate correctly.

Only staff members qualified by the company are authorised to clean the SST-R. Staff members who are responsible for cleaning the SST-R must be familiar with how it works, its documentation and the safety instructions in particular.

The cleaning procedure is as follows:

- ✓ Switch the SST-R to maintenance mode
- ✓ Move the bags into a different refrigerator
- ✓ Use a spray product that is chemically compatible with the SST-R component materials and cleans and disinfects. Rub with a soft cloth (ANIOS XXXX cleaner)

Fig. 1. Apply the detergent disinfectant spray to the area to clean or to a non-woven wipe.

Fig.2. Spread the product evenly

To clean the SST-R and maintain it in good working condition, we advise following the instructions below.

	Before cleaning the SST-R, always switch it to maintenance mode (cf HMI manual). This rule also applies to maintenance operations.
	The SST-R materials may be damaged if unsuitable cleaning tools, high pressure washers, pressurised water or water jets are used.
	Never use cleaning products containing the following: -Acids or halogen compounds (chlorides, bromides, halides) -Strongly acidic salts such as formic acid or sulphonic amino acid descalers - Drain unblockers, hydrochloric acid, silver cleaners - Chlorine - Abrasive compounds or scourers (scouring powder, steel wool) - Polishing products, waxes, bleaching agents
	It is essential that the manufacturers' instructions for the cleaning product regarding temperature, dosage, acting time, etc. used are followed to the letter.

After completing all the cleaning operations, check that the device works.

6 First level maintenance.

This chapter explains the first level faults you might encounter when using the SST-R.

		Actions to carry out
Red indicator on the drawer fronts Blood bag tracking may no longer be possible in the space showing a red indicator		1 Move the bag to a space that works, 2 Inform the member of staff in charge of maintenance so that corrective maintenance can be carried out.
Red indicator on the front of the processor		Inform the member of staff in charge of maintenance so that corrective maintenance can be carried out.
Red and green indicators on the front of the processor		Inform the member of staff in charge of maintenance so that corrective maintenance can be carried out.

Change the image (consistency)

Requires updating

Red drawer space LED	
Possible causes	**Action**
Data cannot be written	Move the bag to a different space and try again
The drawer has been open for longer than 4 minutes	Close the drawer
Communication with processor lost	Switch to maintenance mode, then restart the processor

Red processor LED	
Possible causes	**Action**
CAN bus communication lost	Switch to maintenance mode and restart the processor
The CAN bus power supply has short-circuited	Switch to maintenance mode and restart the processor
The processor probe has become disconnected	Connect the temperature probe
The Ethernet network has become disconnected	Unplug the Ethernet cable and plug it back in again
Insufficient SD card memory	Check that a notification has been sent to the third party system. Contact the administrator.
Power supply fault on at least one drawer	Check that a notification has been sent to the third party system. Contact the administrator.
Battery charger fault	Check that a notification has been sent to the third party system. Contact the administrator.

When a red LED appears, try to detect the cause of the fault and eliminate it as quickly as possible.
Contact the supplier of your device if it malfunctions.
Never carry out repairs or modifications without first obtaining authorisation from Biolog-Id.
Before carrying out any maintenance operations, the SST-R must be switched to maintenance mode (cf HMI Manual).

7 Warranty

Failure to observe any of the recommendations will void the warranty.

8 Transport

Check the device for damage when it is delivered.
If you notice any transport-related anomalies, immediately contact your carrier or retailer and show them the delivery note or purchase order.
Required transport conditions: See the transport crate description (BC)

9 Manufacturer liability

The manufacturers cannot be held responsible in the following cases:

- Failure to observe the manufacturer's installation recommendations.
- Work or repairs carried out by persons who are not authorised by the manufacturer.
- Using the device as part of an electrical installation that does not comply with the applicable regulations.
- Using the device for purposes other than those specified in this manual
- Using accessories (tags, temperature probe, etc.) other than those supplied by Biolog-Id

10 Service life

The service life of the device under recommended maintenance conditions is 10 years. After this period, the device is no longer covered by the CE marking.

11 Disposal and recycling

Because the medical device is an item of electric and electronic equipment, it must be disposed of using a company that specialises in waste collection, removal, recycling or destruction.

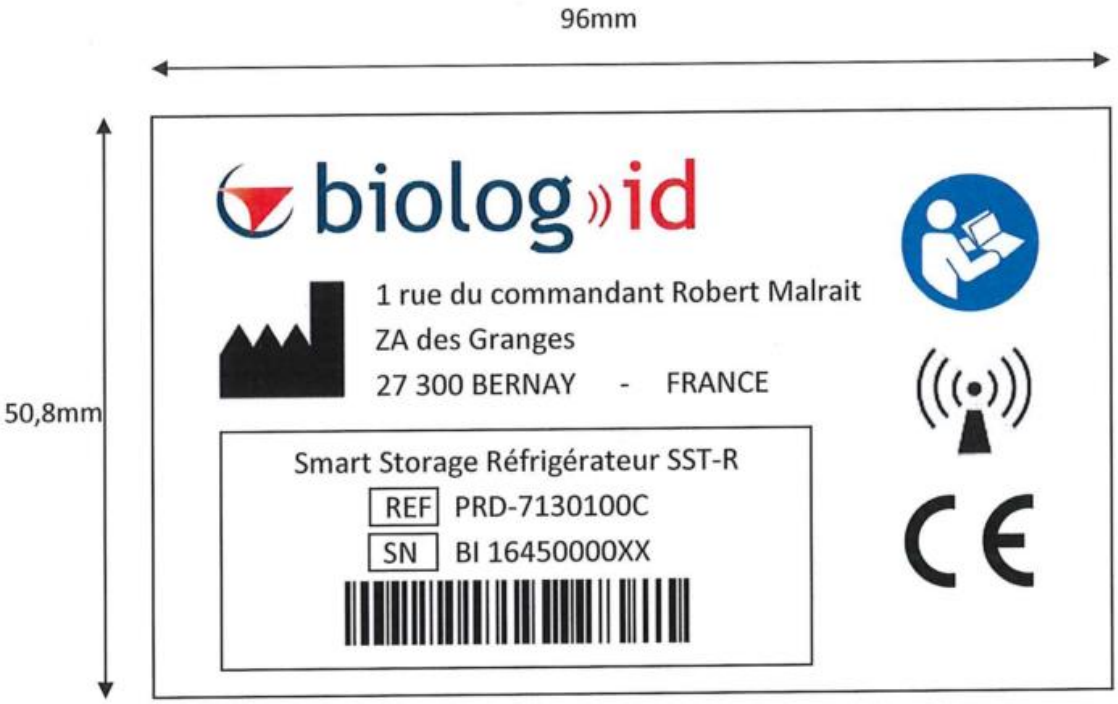
The machine must be recycled in accordance with the applicable national requirements.
European Union legislation requires that member states collect and dispose of electrical and electronic equipment separately from other unsorted communal waste.
Our devices fall into Category X as defined in directives 2002|95|EC (RoHS) and 2002|96|EC (WEEE).
The product including the accessories, cells and batteries must not be disposed of as recyclable waste.
The cells and batteries must be removed before the machine is disposed of or scrapped and must be deposited in the specially provided local collection boxes.

12 Product identification

The product label below is affixed to each processor box.

Etiquette d'identification PRD713 pour la France :

Référence étiquette AVERY : L6012-20
Format: 96 x 50,8mm



Detailed view of serial number BI 16450000XX

- **Supplier index**: 2 letters: BI (index allocated to each supplier and provided by BIOLOG_ID: BI represents Biolog-Id).
- **Year**: 2 characters: 00 to 99: 16 represents 2016
- **Week**: 2 characters: 01 to 53: 45 represents week 45
- **Serial number**: 6 characters: 000001 to 999999

Only reset to 1 when the maximum value is reached or on Biolog-Id's instructions.