

**SMART STORAGE**  
**REFRIGERATOR USER MANUAL**  
**SST-R**



**biolog** » **id**

Connecting healthcare to empower people

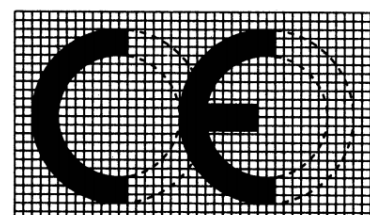
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## 1 General user information.



### 1.1 Purpose of the manual.

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

This manual clearly and extensively gives you information on how to use the SST-R and how to maintain it properly 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 documentation on the SST-R for its entire service life.

### 1.2 Intended audience.

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

### 1.3 Structure of the manual.

The structure of the chapters follows the chronological order of the various usage phases of the SST-R.

One chapter is dedicated to general safety instructions. Please read this chapter carefully.

### 1.4 User advice.

If you cannot find answers to questions linked to the operation or use of the SST-R, do not hesitate to contact us at the following email address [support@biolog-id.com](mailto:support@biolog-id.com)

## 1.5 Documents supplementing this manual

The following is provided along with this user manual:

- Installation and maintenance manual. **Note that the SST-R must be installed by a trained individual authorised by Biolog-id.**
- Manual for using the HMI (Human Machine Interface)

All these manuals are available in paper format only.

## 2 Presentation of the Smart Storage Refrigerator (SST-R).

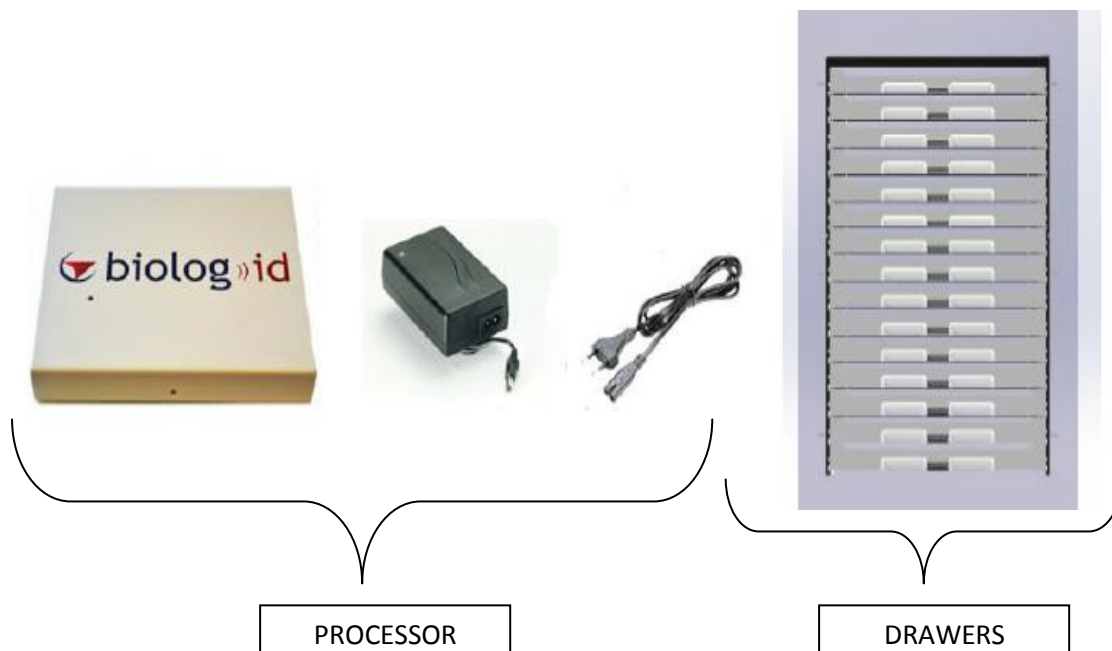
### 2.1 Claimed use of the SST-R.

The SST-R is a class I medical device used as a blood bank refrigerator/cold room accessory. It is a fixed device which can only be used inside this type of equipment.

The SST-R is a Radio-Frequency Identification (RFID) product used to track packed red blood cell (RBC) bags. It improves the storage of red blood cells.

The SST-R continuously communicates with the RFID tags affixed onto the RBC bags so that the history of every RBC bag is saved and accessible to users.

The SST-R tracks all bag movements into and out of a refrigerator or cold room and displays a stock status.



***Fig. Example of an SST-R Kit***

The SST-R can also exchange and write data by communicating with third-party software. This software can then display data relating to a bag (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 specifically 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. (See Chapter 2.4, Hardware and software compatibility).



***Fig. example of SST-R kit integration into a refrigerator***

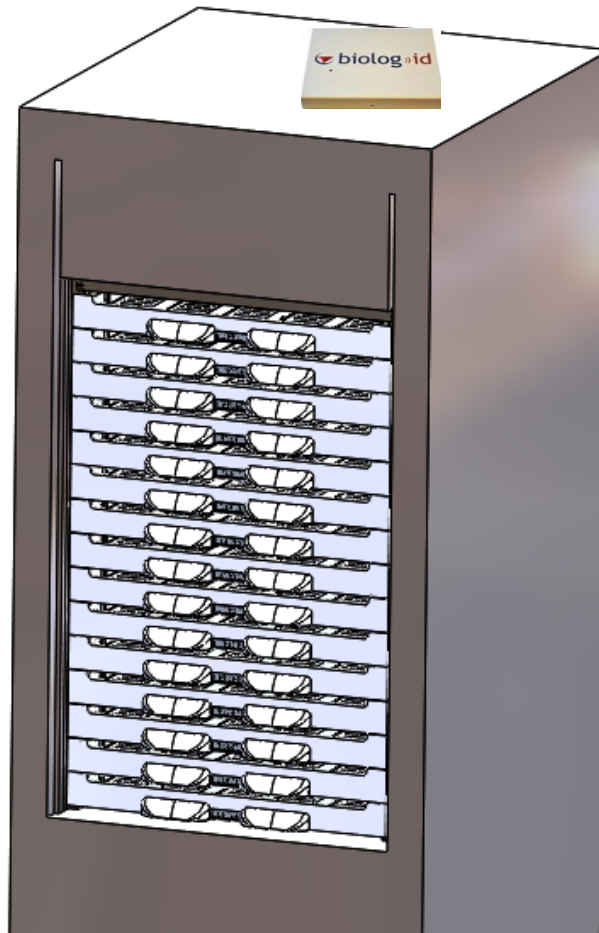
The SST-R-compatible blood bank refrigerator/cold room controls the climate-related aspects (temperature and moisture) of RBC product storage. The SST-R does not affect the performance of the refrigerator/cold room.

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

<b>Operating temperature</b>	0 to 40°C <i>(Power supply: -25°C to +40°C)</i>
<b>Storage temperature</b>	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  Recommended: +10°C to +25°C <i>(do not exceed 30°C)</i>
<b>Operating humidity</b>	40% RH to 95% RH
<b>Maximum storage humidity</b>	40% RH to 95% RH  (CR2032 button cell Recommendation: 40% RH to 95% RH)
<b>Atmospheric pressure</b>  <b>Min/max</b>	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*



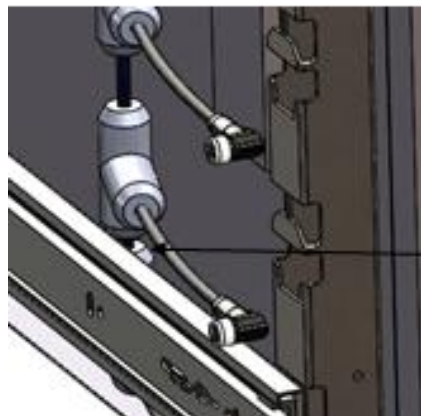
### 2.3.1 Processor and power supply.



*Fig. Processor and its power supply*

The processor in the SST-R system manages the data and queries and transfers information to higher-level applications such as third-party software.

### 2.3.2 Wiring harness.



*Fig. wiring harness*

A wiring harness supplies power to every drawer and carries data between the processor and the RFID antennas.

### 2.3.3 Drawer.



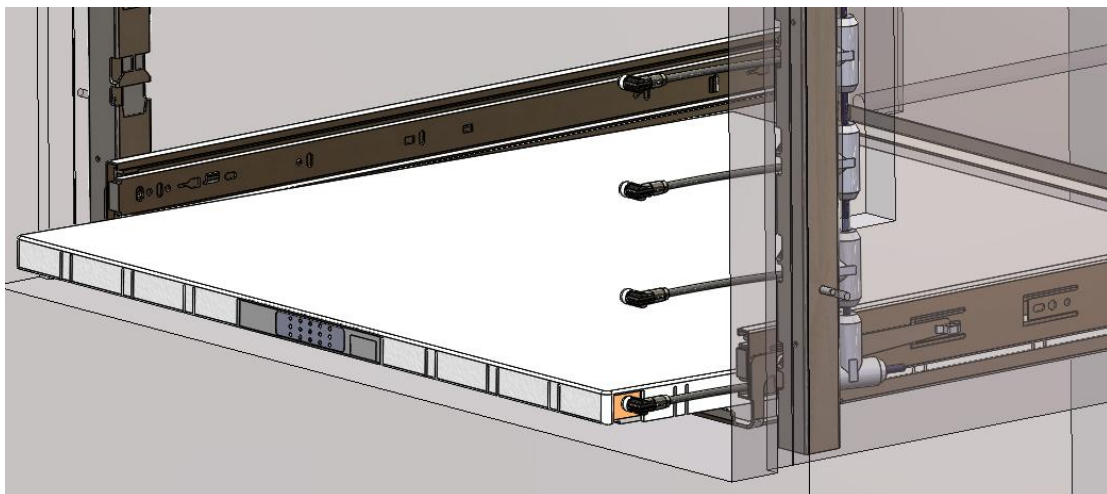
*Fig. drawer unit*

The drawer is a module used to store RBC bags.

There are 3 ranges of drawers with different storage arrangements:

- **6 spaces** i.e. 2 rows of 3 spaces.
- **8 spaces** i.e. 2 rows of 4 spaces.
- **12 spaces** i.e. 3 rows of 4 spaces.
- **15 spaces** i.e. 3 rows of 5 spaces.

### 2.3.4 Satellite.



*Fig. satellite box*

The satellite associated with a drawer helps locate the RBC bags.

A “satellite” is installed underneath every drawer. The satellite consists of a sub-assembly of RFID antennas which communicate with the RFID tag affixed to the RBC bag.

The operating principle of the RFID system is based on a transponder (RFID tags) and an interrogator (coupler). The interrogator is an active radiofrequency emitter; these radio frequencies activate the RFID tags affixed onto the RBC bags 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 RFID tag responds. A simple command might involve returning the donation number corresponding with a unique identifier.

### 2.3.5 Temperature probe.

The temperature probe integrated into the SST-R is waterproof. It measures the temperature of an area.



*Fig. temperature probe*

Only the temperature of the temperature-controlled chamber is representative. 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 compatible with the SST-R.

### 2.4.1 Refrigerator.

The SST-R is compatible with some refrigerators listed by Biolog-id.

For more information, please contact the quality service of Biolog-id at this address : **quality@biolog-id.com**

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

- ✓ 2 rows of 3 spaces (6 spaces / 3x2)
- ✓ 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.

Before installing an SST-R in a cold room, Biolog-id conducts compatibility tests on the SST-R and the Cold room.

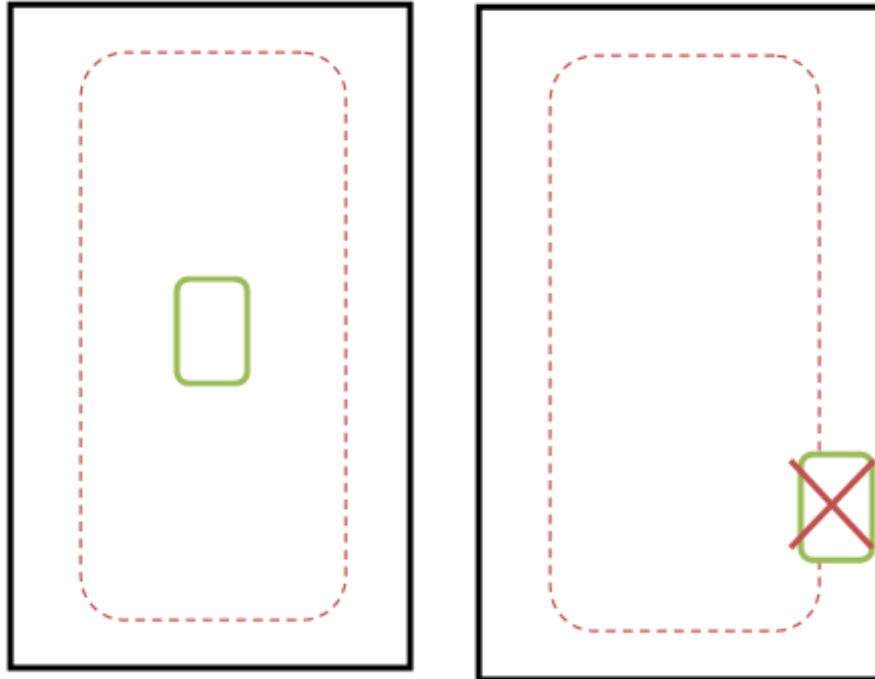
### 2.4.3 RFID tag.



*Fig. RFID tag and blood bag*

The RFID tag stores product and patient data as well as RBC bag tracking data.  
The passive RFID tags compatible with the SST-R are listed by Biolog-id.

The RFID chips have to stick on the label of the RBC bag. For each location, the tag must be positioned in a delimited central area as in the diagram below.



*Delimitation of the reading area (proportional to a location)*

RFID tags positioned between two zones or outside the red zone are not identified by the SST-R.

For more information, please contact the quality service of Biolog-id at this address : [quality@biolog-id.com](mailto:quality@biolog-id.com)

#### **2.4.4 Third-party software.**

The SST-R can link to third-party programmes and communicate via their web service to share/exchange tracking data relating to RBC bags equipped with RFID tags. The third-party programme can therefore ask the SST-R to write data to the RFID tag memory.

If third-party software is used, its compatibility must be validated. In this case, please contact Biolog-id.

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

### 3 Using the Smart Storage Refrigerator (SST-R).

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

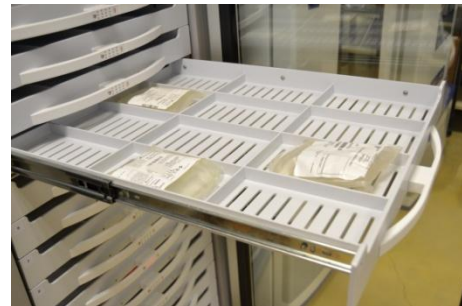
#### 3.1 Installation of the RBC bags in the SST-R and drawers' indicator lights



1 - Open a drawer

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

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



3 - LEDs lighting up 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 diagnosis mode (RFID and LED operation verification), the front of the drawer flashes



4 - LED lighting up red on a space: Loss of RBC traceability in the space with a red LED.  
Please refer to Chapter 6 - First-level maintenance in this manual

### 3.2 Light indicators of 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.



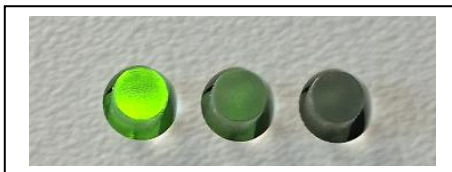
**Red LED on (green LED off):** The processor is in non-functional mode (faulty).

Please refer to Chapter 6 - First-level maintenance in this manual



**Green and red LEDs on:** Network disconnected.

Please refer to Chapter 6 - First-level maintenance in this manual



**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 - First-level maintenance in this manual



A battery integrated to the calculator keeps the monitoring functions of the RFID electronics functioning in case of power outage for at least 2 hours.

## 4 Safety instructions.

This chapter provides a detailed description of the safety instructions applicable when using the SST-R.

Please read these instructions carefully

### 4.1 General safety instructions.

	<ul style="list-style-type: none"> <li>• Ensure that the installation and settings work is carried out by qualified personnel. Operations carried out by personnel lacking the requisite skills may affect the performance of the device and cause personal injury or equipment damage.</li> <li>• Only qualified customer service technicians are authorised to carry out maintenance operations and repairs.</li> <li>• Ensure the connecting cable is not trapped or kinked during installation or when moving the device.</li> <li>• The SST-R must be positioned in such a way that the disconnection mechanism is difficult to use.</li> <li>• Never dismantle or modify any of the system components after the installation has been validated</li> <li>• Never place any objects other than blood bags in a drawer</li> <li>• Never lean on a drawer</li> <li>• The SST-R must not be stored or used outside the temperature and atmospheric pressure ranges specified in this manual (Chapter 2.2)</li> <li>• Never cover the SST-R drawers and/or obstruct the air vents.</li> <li>• The SST-R must be fixed in such a way as to prevent it from being dismantled without tools (for maintenance purposes).</li> <li>• To prevent short-circuiting or oxidation of the metal parts, never allow water or any other liquid to penetrate into the device</li> <li>• Use of the SST-R is restricted to trained personnel qualified to work in a medical environment.</li> <li>• Unless carrying out maintenance (see installation and maintenance manual), never unplug the power supply (220V AC/12V DC), never disconnect the connecting cables between the drawers and never disconnect the Ethernet network cable.</li> </ul>
	<ul style="list-style-type: none"> <li>• The SST-R must only be used with original accessories and spare parts as these are the only accessories/spare parts whose reliability, safety and compatibility with our medical device have been controlled</li> <li>• Always follow the instructions shown on the safety labels affixed to the SST-R.</li> <li>• 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 damaged during the service life of the SST-R, please inform Biolog-id customer support (support@biolog-id.com).</li> </ul>



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



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

- For the effective storage of products and optimal, safe use, the tubes must be folded beneath the bag.

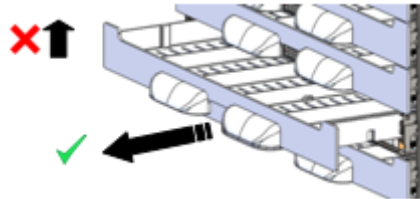


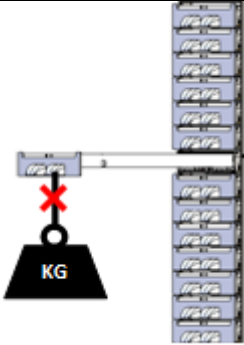
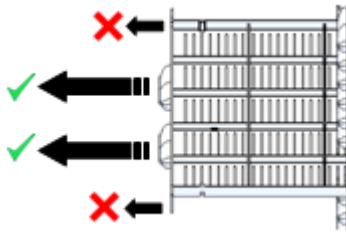
*Example of storage with folded tubes*

- It is forbidden to store products on the top cover.




RISK	SAFETY INSTRUCTIONS
<b>Contamination</b>	Follow the cleaning instructions.
<b>Handling</b>	Operators must undergo authorised Biolog-id training so that they know how the product works, are familiar with the documentation and, more specifically, are aware of the safety instructions.
<b>Electrical</b>	Power supply connecting cables must be installed in accordance with applicable national regulations.
<b>Electrical</b>	Machine-specific electrical voltages must be taken into account and compared with the voltages available at the installation location on the data plates before the installation is connected.
<b>Electrical</b>	Machine wiring diagrams must be complied with.
<b>Electrical</b>	The device must be connected to a socket with a circuit protection conductor
<b>Electrical</b>	To prevent the system from breaking down 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
<b>Electrical</b>	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.
<b>Mechanical</b>	Regularly check the fastenings. Ensure that only trained operators familiar with safety measures use the SST-R
<b>Mechanical</b>	Only pull out the drawers using the handles provided  Never vertically move the drawer handle when opening and closing the drawer.    Never hang from the handles or drawers.

<b>Mechanical</b>	 <p>Open the drawers using the handles.</p> <p>They must be handled with no sudden movements.</p> 
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#### 4.2 RF radiation hazards.

	<p>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 exceeding 2W).</p>
	<p>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.</p>
	<p>Portable or mobile RF communication devices can affect MEDICAL ELECTRICAL DEVICES</p>
	<p>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 EM SYSTEM and used as spare parts to replace internal components.</p>
	<p>The DEVICE or EM SYSTEM must not be used beside other devices or stacked on top of them.</p>
	<p>The DEVICE or EM SYSTEMS can be affected by interference caused by other devices even if they comply with CISPR EMISSION requirements.</p>

### 4.3 Electromagnetic compatibility:

The SST-R complies with applicable electromagnetic compatibility standards, however, the user will ensure that any electromagnetic interference does not create an additional hazard, such as radiofrequency transmitters or other electronic devices. In this chapter you will find necessary information to ensure an installation and a commissioning of the SST-R in best conditions in terms of electromagnetic compatibility. The different cords of the SST-R must be distant from each other. Some types of mobile telecommunication devices such as mobile phones are likely to interfere with the SST-R. The separation distances recommended in this chapter must therefore be strictly observed.

The SST-R must not be used near or on another device. If this cannot be avoided, it must be checked for proper operation under the conditions of use before use. Use of accessories other than those specified or sold by Biolog-id as replacement parts may result in increased emission or decreased immunity of the SST-R.

The SST-R uses the frequency 13.56 MHz. The frequency band is 13.553 - 13.567Mhz compliant with ISO 15693. The modulation type is ASK, the RF mode is TX / RX. The apparent power is 100mW.

The tables below are for the SST-R type:

- 4x2 (PRD\_7130100D),
- 4x3 (PRD\_7130200C),
- 5x3 (PRD\_7130300A).

All the information below is based on the normative requirements to which the manufacturers of electromedical devices are subject, in the sense of the standard IEC60601-1-2 Ed3.

<b>Directives and manufacturer declaration - electromagnetic emissions</b>		
The PRD-7130100D, PRD-7130200C, and PRD-7130300A models are designed to be used in the electromagnetic environment specified below. PRD-7130100D, PRD-7130200C, and PRD-7130300A customers or users must ensure that their devices are used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - directives</b>
RF emissions CISPR11	Group 1	The PRD 7130100D, PRD-7130200C, and PRD-7130300A models only use RF energy for internal functions. As a result, RF emissions are extremely low and unlikely to cause interference in nearby electronic devices.
RF emissions CISPR11	Class B	The PRD-7130100D, PRD-7130200C, and PRD-7130300A 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-7130100D, PRD-7130200C, and PRD-7130300A models are designed to be used in the electromagnetic environment specified below. PRD-7130100D, PRD-7130200C, and PRD-7130300A 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	± 6kV on contact ± 8kV into the air	± 6kV on contact ± 8 kV into the air	Floors must be made of wood, concrete or ceramic tiles. If floors are covered in synthetic materials, relative humidity should be at least 30%.
Fast transient bursts CEI 61000-4-4	± 2kV for electrical supply lines ± 1kV for input/output lines	± 2kV for electrical supply lines ± 1 kV for input/output lines	The quality of the power supply network must be equivalent to that of a standard retail or hospital environment.
Transient overvoltage CEI 61000-4-5	± 1 kV phase-to-phase ± 2kV phase-to-earth	± 1 kV phase-to-phase ± 2 kV phase-to-earth	The quality of the power supply network must be equivalent to that of a standard retail or hospital environment.
Voltage dips, short outages and voltage fluctuations on power supply input lines CEI 61000-4-11	<5% <i>UV</i> (>95% <i>UV</i> dip) for 0.5 cycles 40 % <i>UV</i> (60% <i>UV</i> dip) for 5 cycles 70% <i>UV</i> (30% <i>UV</i> dip) for 25 cycles <5% <i>UV</i> (>95% <i>UV</i> dip) for 5 seconds	<5% <i>UV</i> (>95% <i>UV</i> dip) for 0.5 cycles 40% <i>UV</i> (60% <i>UV</i> dip) for 5 cycles 70% <i>UV</i> (30% <i>UV</i> dip) for 25 cycles <5% <i>UV</i> (>95% <i>UV</i> dip) for 5 seconds	The quality of the power supply network must be equivalent to that of a standard retail or hospital environment. If a PRD-7130100D, PRD-7130200C, and PRD-7130300A user requires continuous operation during electrical power supply network outages, we recommend connecting the PRD-7130100D, PRD-7130200C, and PRD-7130300A to an uninterruptible power supply or battery.
Power-frequency magnetic field (50/60 Hz) CEI 61000-4-8	3 A/m	3 A/m	Power-frequency magnetic fields must remain at levels characteristic of a representative location in a typical retail 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-7130100D, PRD-7130200C, and PRD-7130300A models are designed to be used in the electromagnetic environment specified below. PRD-7130100D, PRD-7130200C, and PRD-7130300A 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
Conducted RF emissions CEI 61000-4-6	3 V <sub>eff</sub> 150kHz to 80MHz	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-7130100D, PRD-7130200C, and PRD-7130300A, including the cables, as calculated using the applicable equation for the emitter frequency.  <b>Recommended separation distance</b>  $d = 1.17 \sqrt{P}$  $d = 1.17 \sqrt{P}$ 80MHz to 800MHz
Radiated RF emissions CEI 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 2.34 \sqrt{P}$ 800MHz to 2.5GHz  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 <sup>a</sup> , must be below the compliance level in each of the range of frequencies. <sup>b</sup>  Interference can be caused by proximity to devices marked with the following symbols:  

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

<sup>a</sup> 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-7130100D, PRD-7130200C, and PRD-7130300A is used exceeds the applicable RF compliance level set out above, the PRD-7130100D, PRD-7130200C, and PRD-7130300A must be monitored to check that it is operating normally. If the PRD-7130100D, PRD-7130200C, and PRD-7130300A is observed to be performing abnormally, additional measures may be needed such as re-orientating or repositioning it. <sup>b</sup> 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-7130100D, PRD-7130200C, and PRD-7130300A**

The PRD-7130100D, PRD-7130200C, and PRD-7130300A models are designed to be used in electromagnetic environments in which radiated RF emissions are controlled. PRD-7130100D, PRD-7130200C, and PRD-7130300A customers and users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (emitters) and the PRD-7130100D, PRD-7130200C, and PRD-7130300A, 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 the transmitter's frequency		
	150kHz to 80MHz $d = 1.17 \sqrt{P}$	80MHz to 800MHz $d = 1.17 \sqrt{P}$	800MHz to 2.5GHz $d = 2.34 \sqrt{P}$
0.01			
0.1	0.37m	0.37m	0.74m
1			
10			
100			

In the case of a transmitter whose assigned maximum output power is not indicated above, the recommended separation distance  $d$  in metres (m) can be estimated using the applicable equation for the transmitter frequency, where  $P$  is the maximum characteristic power output of the transmitter 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 may not be applicable to all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and persons.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

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

The tables below are for SST-R 3x2 (PRD\_7130400B).

All the information below is derived from the normative requirements to which the manufacturers of electromedical devices are subject, in the sense of the standard IEC60601-1-2 Ed4.

Cable length:

Cables and accessories	Maximum length	Type of test	Compliant with
Power cable	< 3m	RF emission	CISPR 11, Classe B
		Harmonic current emission	IEC 61000-3-2
		Fluctuation of Voltage and Flicker of Voltage	IEC 61000-3-3
CAN cable	< 3m	Electrostatic discharge immunity	IEC 61000-4-2
Temperature probe cable	< 3m	Radiated Immunity - Electromagnetic Fields	IEC 61000-4-3
Ethernet cable	> 3m	Immunity to fast electrical transients in salvo	IEC 61000-4-4
		Immunity to shock waves	IEC 61000-4-5
		Driving immunity - Radiofrequency driving disturbance	IEC 61000-4-6
		Radiated Immunity - Magnetic Fields	IEC 61000-4-8
		Immunity to voltage dips, short interruptions and voltage variations	IEC 61000-4-11

Recommended separation distances :

The SST-R 3x2 is intended for use in an electromagnetic environment in which the disturbance due to RF radiation are controlled.

The user or installer of the medical device can help to avoid electromagnetic interference by maintaining a minimum distance, depending on the maximum power of the radio frequency transmission equipment. RF portable communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the SST-R 3x2, including cables specified by the manufacturer. Otherwise, the performance of these devices may be altered.



### Electromagnetic emissions

The SST-R 3x2 is intended for use in the electromagnetic environment described in the table below. The user and the installer must therefore ensure that the SST-R 3x2 is used in the environment described below.

Emission test	Compliance	Electromagnetic environment - remarks
Electromagnetic radiation disturbance (Radiated emissions) (CISPR 11)	Group 1	The PRD_7130400B medical device uses RF energy for its internal function.
Interference voltage at the power terminals (Emissions conducted) (CISPR 11)	Class B	NA
Harmonic current emission (IEC61000-3-2)	Compliant	
Voltage variations, voltage fluctuations and flicker (IEC61000-3-3)	Compliant	

### Magnetic and electromagnetic immunity

The SST-R 3x2 is intended for use in the magnetic and electromagnetic environment described in the table below. The user and the installer must ensure that the electromagnetic environment is compliant.

Immunity test	Test level according to IEC60601	Level of compliance	Electromagnetic environment / remarks
Electrostatic discharge (ESD) (IEC61000-4-2)	± 8 kV in contact ± 2 kV; ± 4 kV; ± 8 kV; ± 15 kV in the air	± 8 kV in contact ± 15 kV in the air	Environment of a professional health care facility.
Fast electrical transients in bursts (IEC61000-4-4)	± 2 kV for power lines	± 2 kV for power lines ± 1 kV for signal ports	Environment of a professional health care facility.
Shockwaves (IEC61000-4-5)	± 1 kV in Differential mode ± 2 kV in common mode	± 1 kV in Differential mode ± 2 kV in common mode	Environment of a professional health care facility.
Magnetic field at assigned industrial frequency (IEC61000-4-8)	30 A/m	30 A/m	Environment of a professional health care facility.
Voltage dips, brief interruptions and voltage variations (IEC61000-4-11)	0% UT pour 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315°	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Environment of a professional health care facility.

	0% UT pour 1 cycle 70% UT for 25 cycles at 50 Hz for 30 cycles at 60 Hz Single phase: at 0°	0% UT for 1 cycle 70% UT for 25 cycles at 50 Hz for 30 cycles at 60 Hz Single phase: at 0°	
Voltage interruptions (IEC61000-4-11)	0 % UT; For 250 cycles at 50 Hz For 300 cycles at 60 Hz	0 % UT; for 250 cycles at 50 Hz for 300 cycles at 60 Hz	Environment of a professional health care facility.

**Electromagnetic immunity, radiofrequency:**

The SST-R 3x2 is intended for use in the magnetic and electromagnetic environment described in the table below. The user and the installer must ensure that the electromagnetic environment is compliant.

Immunity test	Test level	Level of compliance	Electromagnetic environment / remarks
<p>WARNING: RF portable communication devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the PRD_7130400B, including cables specified by the manufacturer. Otherwise, the performance of these devices may be altered.</p>			
Radiofrequency electromagnetic fields radiated  (IEC61000-4-3)	3 V/m  80 MHz to 2.7 GHz  80 % MA at 1 kHz	3 V/m  80 MHz to 2.7 GHz  80 % MA at 1 kHz	Environment of a professional health care facility.
Proximity Fields Transmitted by RF Wireless Communication Devices (IEC 61000-4-3 Method provisional)	9 V/m  710 MHz, 745 MHz,  780 MHz, 5240 MHz,  5550 MHz, 5785 MHz  27 V/m  385 MHz  28 V/m  450 MHz, 810 MHz,  870 MHz, 930 MHz,  1720 MHz, 1845 MHz,  1970 MHz, 2450 MHz	9 V/m  710 MHz, 745 MHz,  780 MHz, 5240 MHz,  5550 MHz, 5785 MHz  27 V/m  385 MHz  28 V/m  450 MHz, 810 MHz,  870 MHz, 930 MHz,  1720 MHz, 1845 MHz,  1970 MHz, 2450 MHz	Environment of a professional health care facility.
Conducted disturbances, induced by fields  RF (IEC610004-6)	3 V  150KHz to 80MHz  6 V in ISM band and  band between  0.15 MHz and 80 MHz,  80% MA at 1 KHz	3 V  150KHz to 80MHz  6 V in ISM band and  band between  0.15 MHz and 80 MHz,  80% MA at 1 KHz	Environment of a professional health care facility.

#### 4.4 Contraindications

As a preventive measure, it is recommended that people fitted with pacemakers do not use the SST-R.

#### 4.5 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 outlines the process which must be followed when cleaning the SST-R.

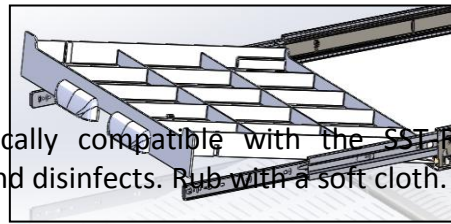
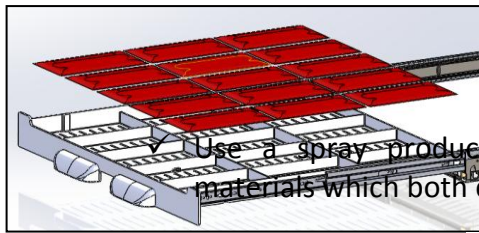
The device must be cleaned or disinfected before use.

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 trained by the company are authorised to clean the SST-R. Staff members responsible for cleaning the SST-R must be familiar with how it works, its documentation and more specifically safety instructions.

The cleaning procedure is as follows:

- ✓ Switch the SST-R to maintenance mode
- ✓ Remove the bags before dismantling a drawer (move the bags into a different refrigerator)
- ✓ Verify the condition of the drawer during reassembly
- ✓ Do not assemble cracked, worn or dirty drawers.



Use a spray product chemically compatible with the SST-R component materials which both cleans and disinfects. Rub with a soft cloth.




*Fig. 1. Spray the detergent disinfectant onto the area to be cleaned or onto a non-woven wipe.*



*Fig. 2. Spread the product evenly*

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




	Before cleaning the SST-R, always switch it to maintenance mode (see HMI manual).
	Risk of damage caused by unsuitable cleaning tools such as high-pressure washers, pressurised water or water jets.
	<b>Do not use cleaning products containing:</b>
	<ul style="list-style-type: none"> <li>-Acids or halogen compounds (chlorides, bromides, halides)</li> <li>-Strongly acidic salts such as formic acid or sulphonic amino acid descalers</li> <li>- Drain unblockers, hydrochloric acid, silver cleaners</li> <li>- Chlorine</li> </ul>

	- Abrasive compounds or scourers (scouring powder, steel wool)
	- Polishing products, waxes, bleaching agents
	Always follow the cleaning product manufacturers' instructions regarding temperature, dosage, acting time, etc.

After completing all cleaning operations, check that the device is operational.

## 6 First-level maintenance.

This chapter outlines the first-level faults\* you may encounter when using the SST-R.

		Actions required
<p><b>Red indicator on the drawer fronts</b></p> <p>RBC bag tracking may no longer be possible in the space showing a red indicator</p>		<ol style="list-style-type: none"> <li>1 Move the bag to a functional space,</li> <li>2 Inform the member of staff in charge of maintenance so that corrective maintenance can be carried out.</li> </ol>
<p><b>Red indicator on the front of the processor</b></p>		<p>Inform the member of staff in charge of maintenance so that corrective maintenance can be carried out.</p>
<p><b>Red and green indicators on the front of the processor</b></p>		<p>Inform the member of staff in charge of maintenance so that corrective maintenance can be carried out.</p>

\* In case of fault, the RFID traceability can be interrupted. This interruption is referenced in the product event log.

When a red LED appears, try to detect the cause of the fault and eliminate it as quickly as possible.

<b>Red drawer space LED</b>	
<b>Possible causes</b>	<b>Action</b>
Data cannot be written	Move the bag to another space and try again
The drawer has been open for more than 4 minutes	Close the drawer
Communication with processor lost	Inform the member of staff in charge of maintenance so that corrective maintenance can be carried out.



## 7 Warranty

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

## 8 Transport

When receiving the SST-R, verify that it has not been damaged during transport.

If you notice any transport-related anomalies, immediately contact your carrier or retailer and show them the delivery note or purchase order.

The required transport conditions are determined by Biolog-id. They must be respected to preserve the physical integrity of the device.

## 9 Manufacturer liability

The manufacturer shall not be held liable in the following cases:

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

## 10 Service life

The service life of the device under recommended usage and maintenance conditions is 10 years.

## 11 Disposal and recycling

Because the medical device is an item of electric and electronic equipment, it must be disposed of via a specific waste collection, removal, recycling or destruction process.



The machine must be recycled in accordance with applicable national requirements.

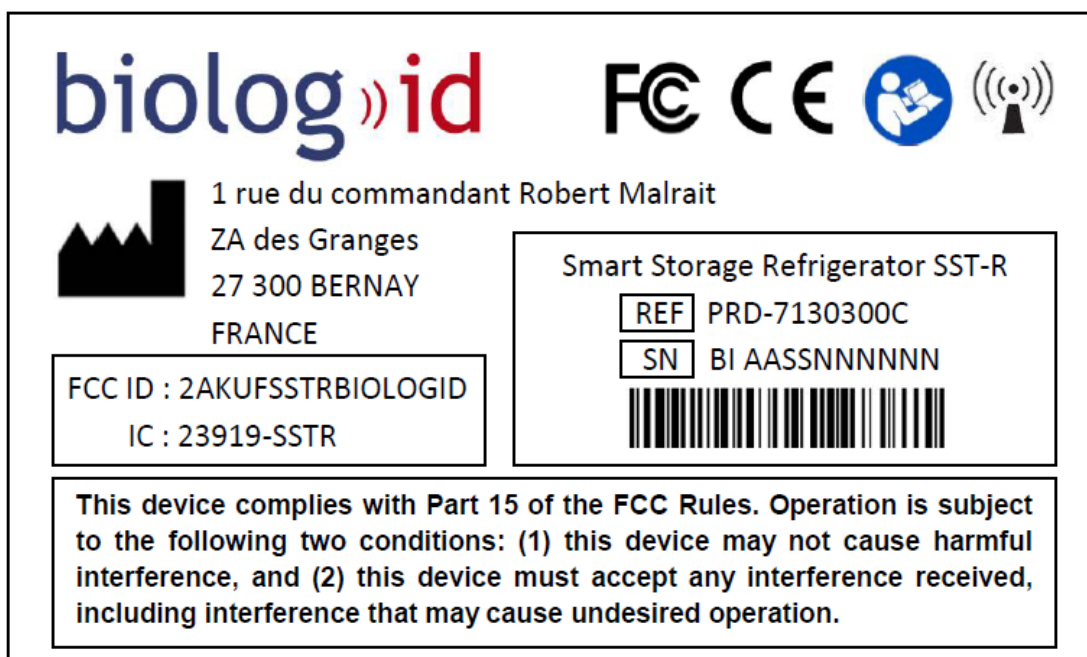
European Union legislation requires that member states collect and dispose of electrical and electronic equipment separately from other unsorted municipal waste.

The product, including accessories, cells and batteries, must not be disposed of as recyclable waste.

Cells and batteries must be removed before the machine is disposed of or scrapped, and must be deposited in specially provided local collection boxes.

## 12 Product identification

The product label below is affixed to each processor box.



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 52: 45 represents week 45
- **Serial number:** 6 characters: 000001 to 999999

Only reset to 1 when the maximum value is reached or in accordance with Biolog-Id's instructions