SMART STORAGE FREEZER

SST-F

USER MANUAL

biolog »id

Connecting healthcare to empower people

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Contents

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-F and how to maintain it properly and safely.

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

Please keep all documentation on the SST-F for its entire service life.

1.2 Intended audience.

This manual is intended for all users likely to carry out operations on the SST-F 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-F.
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-F, do not hesitate to contact us at the following email address 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-F 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 and PDF format.

2 Presentation of the Smart Storage Freezer (SST-F).

2.1 Claimed use of the SST-F.

The SST-F is a class I medical device used as a blood bank freezer/cold room accessory. It is a fixed device which can only be used inside this type of equipment.
The SST-F is a Radio-Frequency Identification (RFID) product used to track Fresh Frozen Plasma (FFP) bags. It improves the storage of Fresh Frozen Plasma.
The SST-F is in permanent communication with the RFID tags affixed to the FFP bags. This ensures that the history of each FFP bag is recorded and accessible to users.
The SST-F tracks all bag movements into and out of a freezer or cold room and displays a stock status.

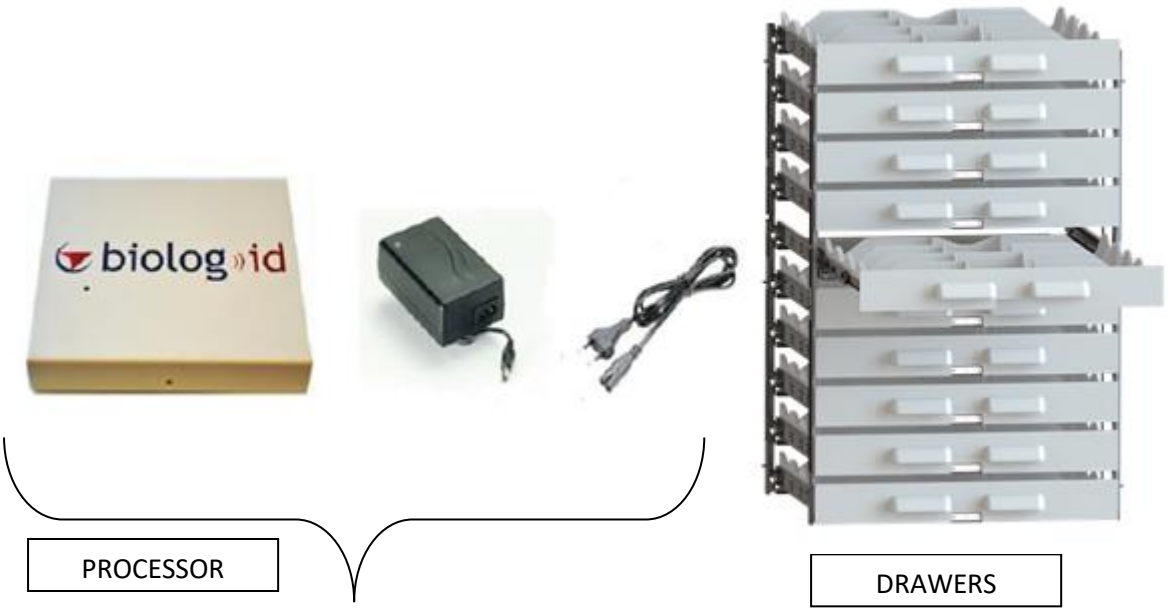


Figure 1 Example of an SST-F Kit

The SST-F 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-F operation.

The SST-F is designed to be used in a hospital environment by laboratory technicians who have been specifically trained to handle FFP bags.

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

Fig. Installing the drawer modules in a freezer

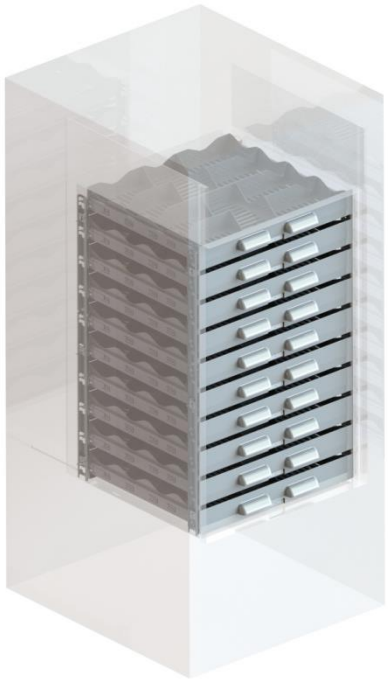


Figure 2 SST-F drawer assembly

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

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

Operating temperature	-40°C to 40°C *(Power supply: -25°C to +40°C)*
Storage temperature	SST-F 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 *(do not exceed 30°C)*
Operating humidity	10% RH to 95% RH
Maximum storage humidity	10% 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-F.

This chapter describes the component parts of the SST-F kit and their function.

Figure 3 SST-F kit

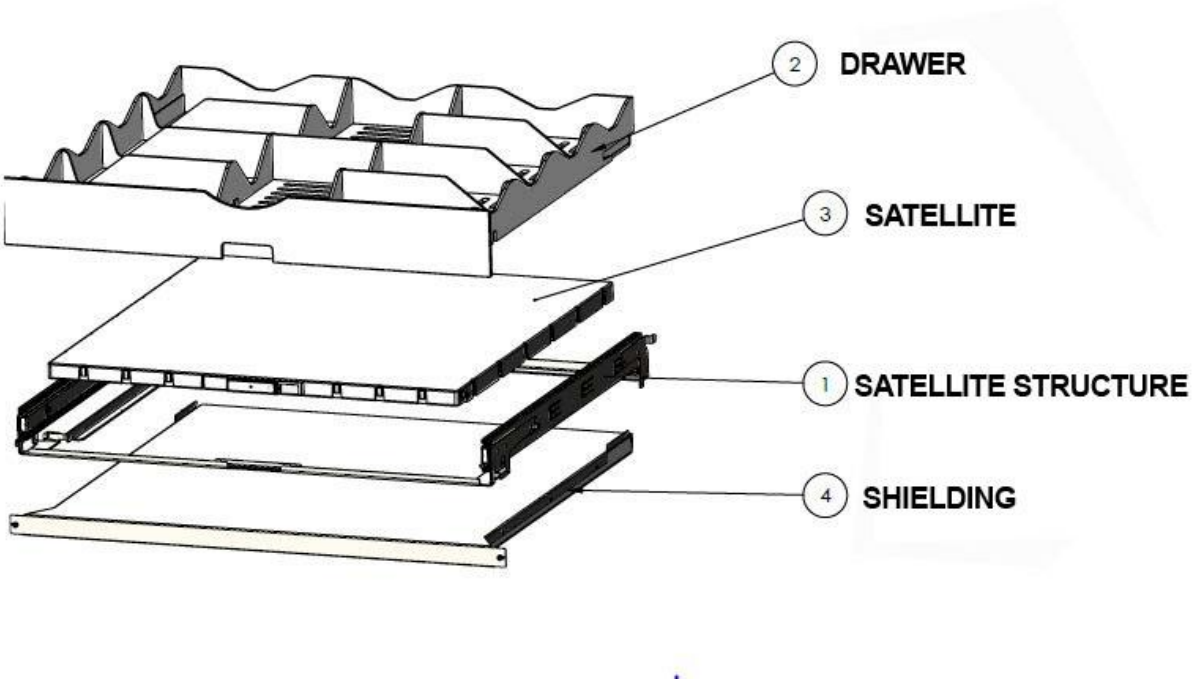


Figure 4 SST-F satellite drawer assembly

Recommendation: For optimal location, the tag must be centred on the bag.

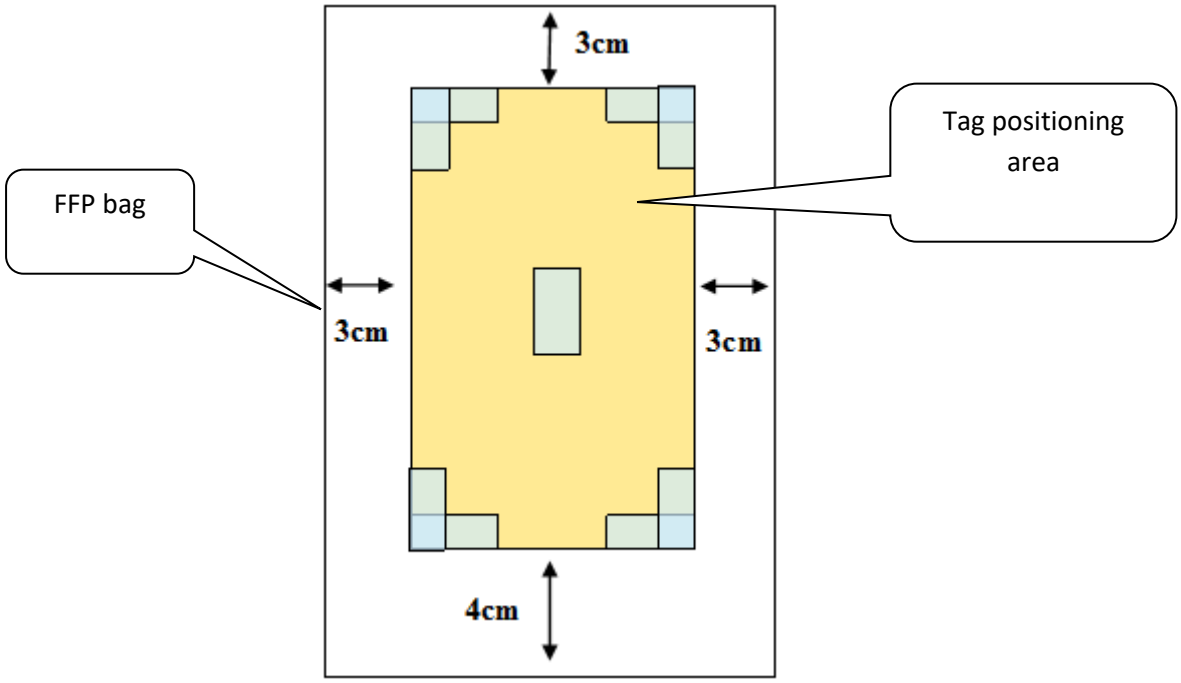


Figure 5 Tag positioning

2.3.1 Processor and power supply.

Figure 6 Processor and power supply

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

Power supply inlet voltage ranges from 100 to 240 VAC.

2.3.2 Wiring harness.

Figure 7 wiring harness

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

2.3.3 Drawer.

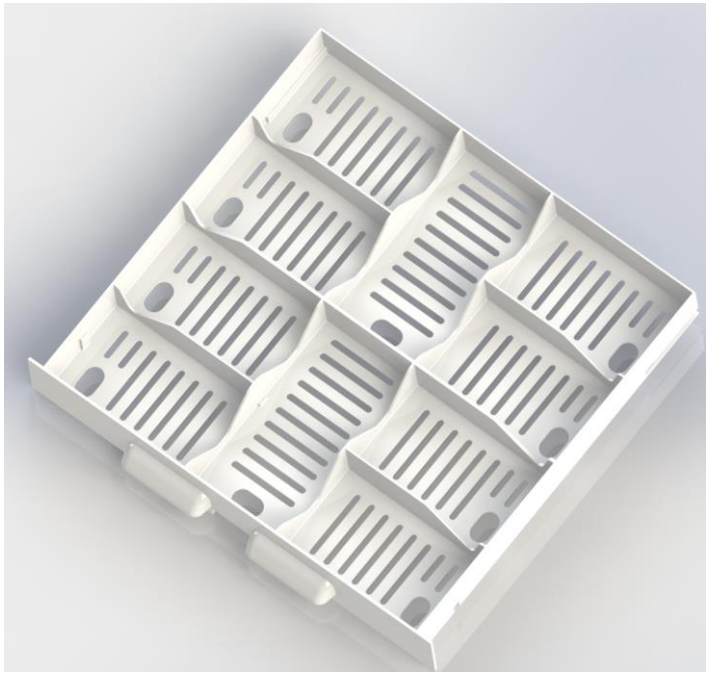


Figure 8 drawer unit

The drawer is a module used to store FFP (fresh frozen plasma) bags.

There is only one range of drawers and it provides **10 spaces:**

- 2 rows of 4 small spaces
- 1 row of 2 large spaces

Up to 3 standard FFP bags from a "contact shock freezer" or 2 bags from a normal freezer can be stacked on top of each other in small spaces.

Up to 3 standard FFP bags from a "contact shock freezer" or 2 apheresis bags from a "contact shock freezer" or 2 bags from a normal freezer can be stacked on top of each other or staggered in large spaces.

Recommendation: Any bag entering the SST-F must be frozen to ensure the effective functioning of the equipment.

2.3.4 Satellite

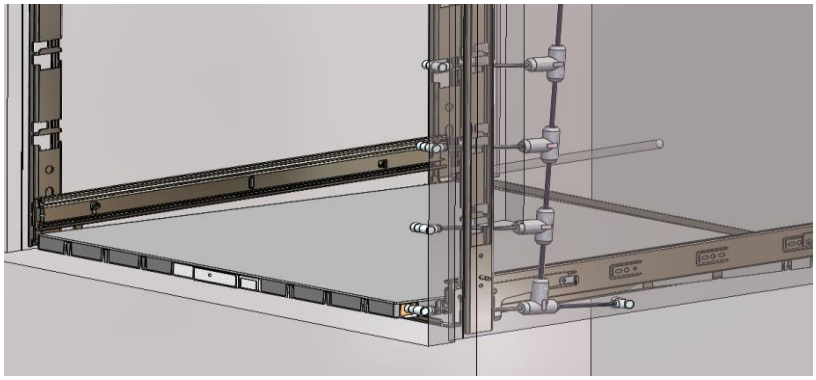


Figure 9 satellite box

The satellite associated with a drawer helps locate the FFP 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 FFP bag.
The operating principle of the RFID system is based on a transponder (RFID tags) and an interrogator (coupler). The interrogator is an active radio-frequency emitter; these radio frequencies activate the RFID tags affixed onto the FFP 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 number of donations corresponding to a unique identifier.

2.3.5 Temperature probe.

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

Figure 10 temperature probe

The only reference temperature is that provided by the controlled climate chamber. The SST-F makes no claims as to temperature-related performance.
The SST-F temperature reading is for information only. This function is unrelated to cold chain maintenance security.

2.4 Hardware and software compatibility

This chapter describes the third-party hardware and software compatible with the SST-F.

2.4.1 Freezer.

The SST-F is compatible with commercially-available freezers referenced by Biolog-id.
For further details, please contact the Biolog-id quality department at: **Qualite@biolog-id.com**

The system is designed to provide 1 to 10 drawers.

The device must not be overloaded.

2.4.2 Cold room.

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

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

2.4.3 RFID tag.

Figure 11 RFID tag and Fresh Frozen Plasma bag

The RFID tag stores product and patient data as well as FFP bag tracking data.

Only passive RFID tags referenced by Biolog-id are compatible with the SST-F.
For further details, please contact the quality department at: **Qualite@biolog-id.com**

2.4.4 Third-party software.

The SST-F can link to third-party programs and communicate via their web service to share/exchange tracking data relating to FFP bags equipped with RFID tags. The third-party programme can therefore ask the SST-F 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-F.

3 Using the Smart Storage Freezer (SST-F).

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

3.1 Placing FFP bags in the SST-F and satellite indicator lights

3.1.1 Installation of FFP bags

1 - Open a drawer

2 - Place the FFP bag in a free space or one with enough room to stack another FFP bag.
Pay special attention to the tube if the FFP bag is unboxed*

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

3.1.2 Light indicators of the satellite

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

Red indicator on the drawer fronts:

Figure 12 Red LED on SST-F

A technical failure has been identified on the RFID. FFP bag tracking may no longer be possible in the drawer showing a red indicator.

Actions required:

- Move the bag to a drawer that works,
- Inform the member of staff in charge of maintenance so that corrective maintenance can be carried out.

Orange indicator on the drawer fronts:

Figure 13 Orange LED on SST-F

A writing failure has been identified on a tag placed in one of the spaces of the drawer showing the orange indicator.

Actions required:

- Put the bag back in the space
- Move the bag to a different space
- Replace the tag as it may be defective

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, the meanings of which 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 either in non-functional mode (faulty) or it is disconnected from the network.
Please refer to Chapter 6 - 1st level maintenance in this manual

Steady green and red LED: Network disconnected.
Please refer to Chapter 6 - 1st 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 - 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 at least 2 hours.

4 Safety instructions.

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

Please read these instructions carefully

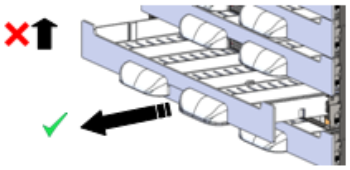
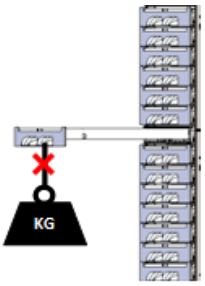
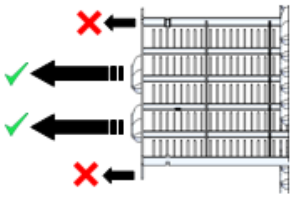
4.1 General safety instructions.

	• The SST-F 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 • Always follow the instructions shown on the safety labels affixed to the SST-F. • The safety instructions affixed to or beside the SST-F 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-F, please inform Biolog-id customer support (support@biolog-id.com).

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

• Never push the SST-F.
• 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, more specifically, are aware of the safety instructions.
Electrical	Power supply connecting cables must be installed in accordance with applicable national regulations. 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. Machine wiring diagrams must be complied with. The device must be connected to a socket with a Circuit Protective Conductor*

Electrical	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. 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-F
Mechanical	Only pull out the drawers using the handles provided Never vertically move the drawer handle when opening and closing the drawer. 
Mechanical	Never hang from the handles or drawers.  Open the drawers using the handles. They must be handled with no sudden movements. 

4.2 RF radiation hazards.

	The SST-F electronic system antennas each emit a frequency of 13.56 MHz with a maximum power output of -2.38dBµA/m at 3m (less than the 42dBµA/m limit threshold).
	MEDICAL ELECTRICAL DEVICES require special EMC precautions. The SST-F 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 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.

4.3 Electromagnetic compatibility:

While the SST-F complies with current electromagnetic compatibility standards, users must ensure that any electromagnetic interference does not create additional risk, such as RF transmitters or other electronic devices.
In this chapter you will find the information you need to ensure the best possible installation and use of the SST-F in terms of electromagnetic compatibility.
The different cords of the SST-F must be placed far apart.
Certain types of mobile telecommunication devices such as mobile phones are likely to interfere with the SST-F. The separation distances recommended in this chapter must therefore be complied with.
The SST-F should not be used in the vicinity or placed on top of another device. If this cannot be avoided, its effective operation must be checked under operational conditions before use.
Using accessories other than those specified or sold by Biolog-id as replacement parts can increase emissions or reduce the immunity of the SST-F.

The SST-F uses 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.
The maximum power output of the PRD-7140100A and PRD_7140300A is -2.38dBµA/m at 3m.

The tables below relate to the SST-F (PRD-7140100A).

All information featured below comes from normative requirements which apply to the manufacturers of medical electrical devices, under standard IEC60601-1-2 Ed3.

Directives and manufacturer declaration - electromagnetic emissions		
The PRD-7140100A is designed to be used in the electromagnetic environment specified below. PRD-7140100A 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-7140100A only uses 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-7140100A is 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-7140100A is designed to be used in the electromagnetic environment specified below. PRD-7140100A 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	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	± 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 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 ± 2kV phase-to-earth	The quality of the power supply network must be equivalent to that of a standard retail or hospital environment.

Directives and manufacturer declaration - electromagnetic immunity			
The PRD-7140100A is designed to be used in the electromagnetic environment specified below. PRD-7140100A 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**
Voltage dips, short outages and voltage fluctuations on 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 power supply network must be equivalent to that of a standard retail or hospital environment. If a PRD-7140100A user requires continuous operation during electrical power supply network outages, we recommend connecting the PRD-7140100A 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.			
Conducted RF emissions CEI 61000-4-6 Radiated RF emissions CEI 61000-4-3	3 Veff 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable or mobile RF communication devices must not be used any closer than the recommended separation distance from any part of the PRD-7140100A, 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 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: 

Directives and manufacturer declaration - electromagnetic immunity			
The PRD-7140100A is designed to be used in the electromagnetic environment specified below. PRD-7140100A 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**
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.			
[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-7140100A is used exceeds the applicable RF compliance level set out above, the PRD-7140100A must be monitored to check that it is operating normally. If the PRD-7140100A is observed to be performing abnormally, additional measures may be needed such as re-orientating or repositioning it. [b] The field strength over the 150 kHz to 80 MHz range must be lower than 3 V/m.			

Recommended separation distances between portable and mobile RF communication devices and the PRD-7140100A			
The PRD-7140100A is designed to be used in electromagnetic environments in which radiated RF emissions are controlled. PRD-7140100A customers and users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (emitters) and the PRD-7140100A, 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 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.			

Directives and manufacturer declaration - electromagnetic immunity			
The PRD-7140100A is designed to be used in the electromagnetic environment specified below. PRD-7140100A 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	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	± 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 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 ± 2kV 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% *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 power supply network must be equivalent to that of a standard retail or hospital environment. If a PRD-7140100A user requires continuous operation during electrical power supply network outages, we recommend connecting the PRD-7140100A to an uninterruptible power supply or battery.

Directives and manufacturer declaration - electromagnetic immunity			
The PRD-7140100A is designed to be used in the electromagnetic environment specified below. PRD-7140100A 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**
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.			

The tables below relate to the SST-F (PRD_7140300A).
All information featured below comes from normative requirements which apply to the manufacturers of medical electrical devices, under standard IEC60601-1-2 Ed4.

Length of cables:

Cables and accessories	Maximum length	Type of test	In accordance with:
Power cable CAN cable Temperature probe cable Ethernet cable	< 3m < 3m < 3m > 3m	RF emission	CISPR 11, Class B
		Harmonic current emissions	IEC 61000-3-2
		Voltage fluctuation and flicker	IEC 61000-3-3
		Electrostatic discharge immunity	IEC 61000-4-2
		Radiated immunity – Electromagnetic fields	IEC 61000-4-3
		Immunity to fast transient bursts	IEC 61000-4-4
		Surge immunity	IEC 61000-4-5
		Conducted immunity – Conducted radio frequency interference	IEC 61000-4-6
		Radiated immunity - Magnetic fields	IEC 61000-4-8
		Voltage dips, short interruptions and voltage variations immunity	IEC 61000-4-11

Recommended separation distances

The SST-F is intended to be used in an electromagnetic environment in which radiated RF disturbances are controlled.

The user or installer of the medical device can help prevent any electromagnetic interference by maintaining a minimum distance, as a function of the maximum power output of the radio frequency transmission equipment. Portable RF communication devices (including peripherals such as antenna cables and external antennas) should not be used within 30 cm (12 inches) of any part of the SST-F, including cables specified by the manufacturer. Otherwise the performance of these devices could be adversely affected.

Electromagnetic emissions

The SST-F is intended to be used in the electromagnetic environment described in the table below. The user and installer must therefore ensure that the SST-F is used in the environment described below.

Emission test	**Compliance**	**Electromagnetic environment - comments**
Radiated electromagnetic disturbance (Radiated emissions) (CISPR 11)	Group 1	The PRD_7140300A medical device uses RF energy for internal operation.
Power terminal disturbance voltage (Conducted emissions) (CISPR 11)	Class B	NA
Harmonic current emissions (IEC61000-3-2)	Compliant	
Voltage variations, voltage fluctuations and flicker (IEC61000-3-3)	Compliant	

Magnetic and electromagnetic immunity

The SST-F is intended to be used in the magnetic and electromagnetic environment described in the table below. The user and the installer must guarantee the compliance of the electromagnetic environment.

Immunity test	Test level according to IEC60601	Compliance level	Electromagnetic environment/comments
Electrostatic discharge (ESD) (IEC61000-4-2)	± 8 kV contact discharge ± 2 kV; ± 4 kV; ± 8 kV; ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Professional healthcare facility environment.
Fast transient bursts (IEC61000-4-4)	± 2 kV for power supply lines	± 2 kV for power supply lines ± 1 kV for signal ports	Professional healthcare facility environment.
Surges (IEC61000-4-5)	± 1 kV in Differential mode ± 2 kV in common mode	± 1 kV in Differential mode ± 2 kV in common mode	Professional healthcare facility environment.
Power-frequency magnetic field (IEC61000-4-8)	30 A/m	30 A/m	Professional healthcare facility environment.
Voltage dips, short interruptions and voltage variations (IEC61000-4-11)	0% UT for 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT for 25 cycles at 50 Hz For 30 cycles at 60 Hz Single-phase: at 0°	0% UT for 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT for 25 cycles at 50 Hz For 30 cycles at 60 Hz Single-phase: at 0°	Professional healthcare facility environment.
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	Professional healthcare facility environment.

Electromagnetic immunity, radio frequencies:

The SST-F is intended to be used in the magnetic and electromagnetic environment described in the table below. The user and the installer must guarantee the compliance of the electromagnetic environment.

Immunity test	Test level	Compliance level	Electromagnetic environment/comments
WARNING: Portable RF communication devices (including peripherals such as antenna cables and external antennas) should not be used within 30 cm (12 inches) of any part of the PRD_7140300A, including cables specified by the manufacturer. Otherwise the performance of these devices could be adversely affected.			
Radiated RF electromagnetic fields (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	Professional healthcare facility environment.
Proximity fields emitted by wireless RF communication devices (IEC 61000-4-3 interim method)	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	Professional healthcare facility environment.
Conducted disturbances, induced by RF fields (IEC610004-6)	3 V 150 KHz to 80 MHz 6 V within ISM band and band ranging from 0.15 MHZ to 80 MHZ, 80% MA at 1 KHz	3 V 150 KHz to 80 MHz 6 V within ISM band and band ranging from 0.15 MHZ to 80 MHZ, 80% MA at 1 KHz	Professional healthcare facility environment.

4.4 Contraindications

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

4.5 Warning for US users

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 sets out the SST-F cleaning procedure to follow.

The device must be cleaned or disinfected before use.

The SST-F 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-F. Staff members who are responsible for cleaning the SST-F must be familiar with how it works, its documentation and the safety instructions in particular.

The cleaning procedure is as follows:

- Switch the SST-F to maintenance mode
- Move the bags into a different freezer
- Verify the condition of the drawer during reassembly
- Do not assemble cracked, worn or dirty drawers.

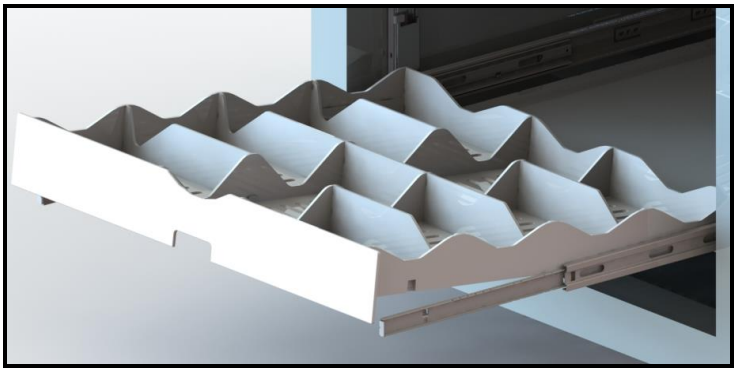


Figure 14 SST-F drawer

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

Figure 15 . Spray the detergent disinfectant onto the area to be cleaned or onto a non-woven wipe.

Figure 16 Spread the product evenly

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

	Before cleaning the SST-F, 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.
	Do not use cleaning products containing: -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
	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-F.

		Actions required
Red indicator on the drawer fronts FFP bag tracking may no longer be possible in the drawer showing a red indicator		1 Move the bag to a drawer 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.

** In the event of a failure, RFID traceability may be interrupted. This interruption is referred to in the product's event log.*

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

Red LED on drawers	
Possible causes	**Actions**
Data cannot be written	Move the bag to a different 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-F, 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

As the medical device is a piece of electrical and electronic equipment, it must be disposed of using a company that specialises in waste collection, removal, recycling or destruction.

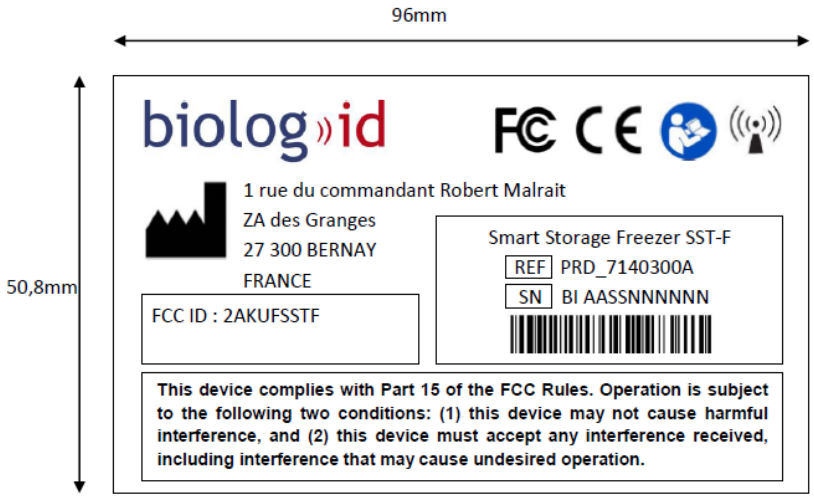
The machine must be recycled in accordance with applicable national requirements.

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 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



Detailed view of serial number BI 17360000XX
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 in accordance with Biolog-Id's instructions

Figure 17 The product label below is affixed to each processor box.