**SMART STORAGE HIGH DENSITY** 

# SST-HD

# **USER MANUAL**

# 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-HD and how to maintain it properly and safely.

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

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

Throughout this document:

- The term "bag" refers to a bag of packed red blood cells.
- The term " LBP" refers to the Labile Blood Product

#### 1.2 Intended audience.

This manual is intended for all users likely to carry out operations on the SST-HD 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-HD.

Please read the chapter dedicated to general safety instructions carefully.

#### User advice.

If you cannot find answers to questions linked to the operation or use of the SST-HD in this manual, do not hesitate to contact us at the following email address <u>customercare@biolog.com</u>

In the event of a serious incident relating to the SST-HD, this must be reported to the manufacturer and the competent authority for the member state in which you are established.

#### **1.5 Documents supplementing this manual**

The following is provided along with this user manual:



- Installation and maintenance manual. Note that the SST-HD 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 High Density (SST-HD).

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

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

The SST-HD is a Radio-Frequency Identification (RFID) product used to track packed red blood cell (RBC) bags. It improves blood bag storage safety.

The SST-HD is in permanent communication with the RFID tags affixed to the bags. This ensures that the history of each bag is recorded and accessible to users.

The SST-HD tracks all bag movements into and out of the storage unit and displays a stock status.





The SST-HD 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-HD operation.

The SST-HD is designed to be used in a hospital environment by laboratory technicians who have been specifically trained to handle blood products.

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





Fig. Installing the tray modules in a refrigerator

Figure 2 – SST-HD shelf assembly

SST-HD compatible storage units manage the climate-related aspects (temperature and moisture) of the storage of the blood products they contain. The SST-HD in no way alters the performance of the unit in which it is installed.

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



Operating temperature       0°C to 40°C         (GlobTek external supply: 0°C to +50)         SST-HD kit: -10°C to 40°C
(GlobTek external supply: 0°C to +50) SST-HD kit: -10°C to 40°C
(GlobTek external supply: 0°C to +50) SST-HD kit: -10°C to 40°C
SST-HD 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% KH to 95% KH
10% RH to 95% RH
Maximum storage humidity
(CR2032 button cell Recommendation: 40% RH
to 95% RH)
Atmospheric pressure
700hPa
Min/max
1060nPa





#### **2.3 Description of the SST-HD.**

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



#### Figure 4 - SST-HD elementary satellite kit composed of 4 trays and a satellite

The system is designed to have a between 1 and 6 elementary satellites. The device must not be overloaded.



#### 2.3.1 Processor and power supply



The processor in the SST-HD 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 6 - SST-HD wiring harness

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



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#### 2.3.3 Tray



Figure 6 - SST-HD tray

The tray is the module used to store the LBP bags.

The tray must not be overloaded.

There are two ranges of tray:

- Those which can contain up to 14 bags (the HD45);
- Those which can contain up to **18 bags (the HD6o).**

#### 2.3.4 Satellite



Figure 7 - SST-HD satellite

A "satellite" is fitted below each row of trays enabling the bags to be located. The satellite consists of a sub-assembly of RFID antennas which communicate with the RFID tag affixed to the 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 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.





#### 2.4 Hardware and software compatibility

This chapter details the third-party hardware and software compatible with the SST-HD.

#### **2.4.1** Freezer and refrigerator.

The SST-HD is compatible with the refrigerators on the market, provided that they are referenced by Biolog-id.

Before any installation of an SST-HD in a refrigerator, Biolog-id conducts thermal compatibility tests.

For further details, please contact the Biolog-id quality department at: **Qualite@biolog-id.com** 

#### **2.4.2** Cold room.

The SST-HD is compatible with all bag storage cold rooms. When used in this way, the SST-HD is installed using its specific cold room storage unit.

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

#### **2.4.3 RFID tag.**



Figure 8 – Blood bag and RFID tag

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

For further details, please contact the quality department at: Qualite@biolog-id.com

For optimal RFID reading, the side of the bags on which the RFID tag is affixed must all be facing the same way in the tray (all towards the front of the tray)



# Original area

#### Recommendation: For optimal location, the tag should be positioned on the bag as follows:

Figure 9 – Position of the tag on the bag for optimal RFID reading

#### 2.4.4 Third-party software

The SST-HD can link to third-party software and communicate via their web service to share/exchange tracking data relating to bags equipped with RFID tags. The third-party software can then ask the SST-HD 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 from the SST-HD.



# **3** Using the Smart Storage High Density (SST-HD).

The purpose of this chapter is to describe how the SST-HD works.

3.1 Placing bags in the SST-HD and satellite indicator lights

#### **3.1.1** Placing bags in the SST-HD





2 - Place the bag in a vertical position in the trayN.B. Be particularly careful with the tube when handing the bag





3 - Close the tray

# **3.1.2** Satellite light indicators

LED status	Meaning	Action(s) required
Green biolog∍id	The tray is functional and empty	No action required
Flashing green	The satellite is in maintenance mode	Wait for the end of the maintenance currently in progress before handling the trays in question and/or their contents
Blue biolog »id	The tray in question is functional and contains at least one bag	No action required
Flashing blue biolog #id	Tray in which the desired bag is located	Open the tray and remove the bag(s) you are looking for. If no action is taken within five minutes, the flashing stops and the normal cycle is resumed
Orange (Yellow)	RFID read/write error	Please refer to Chapter 6 - 1 <sup>st</sup> level maintenance in this manual
Flashing orange	Firmware update in progress	Wait for the end of the update currently in progress before handling the trays in question and/or their contents
Green-Orange- Red cycle	Satellite rebooting following: • 1 <sup>st</sup> installation • Update • Firmware reboot	Wait until the satellite is functional (blue or green indicator) before handling the trays in question and/or their content
Off biolog.vid	Power supply fault	Please refer to Chapter 6 - 1 <sup>st</sup> level maintenance in this manual



#### 3.2 Processor light indicators

The processor is located outside the refrigerated storage unit. There are three LEDs on the front of the processor, the meanings of which are explained in this chapter.



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

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

Please read these instructions carefully

#### 4.1 General safety instructions.

• The SST-HD 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-HD.

• The safety instructions affixed to or beside the SST-HD 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-HD, please inform Biolog-id customer support (customercare@biolog-id.com).

• The SST-HD must be installed in a blood bank refrigerator, freezer or cold room which is stable and equipped with an anti-tipping system (this generally requires attachment to the wall).



- Never push the SST-HD.
- Never sit on a tray or satellite.
- Never climb onto or walk on a tray or satellite.



RISK	SAFETY INSTRUCTIONS			
Contamination	Follow the cleaning instructions.			
Handling error	<ul> <li>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.</li> <li>Trays must be handled with no sudden movements.</li> </ul>			
Electrical	<ul> <li>Install power supply connecting cables in accordance with applicable national regulations.</li> <li>Take into account the machine-specific electrical voltages and compare them to the voltages available at the installation location on the data plates before the installation is connected.</li> <li>Machine wiring diagrams must be complied with.</li> <li>The device must be connected to a socket with a Circuit Protective Conductor*</li> <li>To prevent the system from breaking down due to problems with other electrical devices, it must be connected to a separate electrical circuit.</li> <li>Under no circumstances should it be connected to a multi-socket along with other electrical devices.</li> <li>Before connecting and commissioning the machine, check that the power supply is connected correctly.</li> <li>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.</li> <li>The power plug serves as a network disconnection device.</li> </ul>			
Mechanical	Regularly check the fixings. Make sure that only trained operators who are familiar with the safety measures use the SST-HD Only pull out the trays using the handles provided. After handling and <b>before releasing the tray, always check that it is in a stable state.</b>			



	Never hang from the satellites.	
Mechanical		
The SST-RHD processor can reach temperatures higher than touch the processor while it is in these conditions.		

# 4.2 RF radiation hazards.

The SST-HD electronic system antennas each emit a frequency of 13.56 MHz with a maximum power output : 6.9 dBµA/m at 3 m for PRD_7170100A. 6.9 dBµA/m at 3 m for PRD_7170200A. (less than the 42 dBµA/m limit threshold).
HD 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 with 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-HD 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 commissioning of the SST-HD in terms of electromagnetic compatibility.

The different cords of the SST-HD must be placed far apart.

Certain types of mobile telecommunication devices such as mobile phones are likely to interfere with the SST-HD. The separation distances recommended in this chapter must therefore be complied with.

The SST-HD 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-HD.

The SST-HD 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\_7170100A and PRD\_7170200A is 6.9dBµA/m at 3m.

The tables below relate to the SST-HD range (PRD\_7170100A et PRD\_7170200A). 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	Type of test	In accordance with
	length		
		RF emission	CISPR 11, Class B
		Harmonic current emissions	IEC 61000-3-2
Power cable	< 3m	Voltage fluctuation and flicker	IEC 61000-3-3
		Electrostatic discharge immunity	IEC 61000-4-2
CAN cable	< 3m	Radiated immunity – Electromagnetic fields	IEC 61000-4-3
		Immunity to fast transient bursts	IEC 61000-4-4
Ethernet cable	> 3m	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-HD 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-HD, including cables specified by the manufacturer. Otherwise the performance of these devices could be adversely affected.

#### Electromagnetic emissions

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



Emission test	Compliance	Electromagnetic environment - comments	
Radiated electromagnetic	Group 1	The PRD_7170100A et PRD_7170200A medical	
disturbance		devices uses RF energy for internal operation.	
(Radiated emissions)			
(CISPR 11)			
Power terminal disturbance voltage	Class B	NA	
(Conducted emissions)			
(CISPR 11)			
Harmonic current emissions	Compliant		
(IEC61000-3-2)			
Voltage variations, voltage	Compliant		
fluctuations and flicker			
(IEC61000-3-3)			

#### Magnetic and electromagnetic immunity

The SST-HD 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	Compliance level	Electromagnetic
	IEC60601		environment/comments
Electrostatic discharge (ESD)	± 8 kV contact discharge	± 8 kV contact discharge	Professional healthcare
(IEC61000-4-2)	± 2 kV; ± 4 kV; ± 8 kV; ± 15 kV air discharge	± 15 kV air discharge	
Fast transient bursts	$\pm$ 2 kV for power supply	± 2 kV for power supply	Professional healthcare
(IEC61000-4-4)	lines	lines ± 1 kV for signal ports	facility environment.
Surges	±1 kV in Differential mode	± 1 kV in Differential mode	Professional healthcare
(IEC61000-4-5)			facility environment.
	± 2 kV in common mode	± 2 kV in common mode	
Power-frequency magnetic field	30 A/m	30 A/m	Professional healthcare facility environment.
(IEC61000-4-8)			,
Voltage dips, short	o% UT for 0.5 cycles	o% UT for 0.5 cycles	Professional healthcare
variations	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	facility environment.
(IEC61000-4-11)			



	o% UT for 1 cycle	o% UT for 1 cycle	
	70% UT	70% UT	
	for 25 cycles at 50 Hz	for 25 cycles at 50 Hz	
	For 30 cycles at 60 Hz	For 30 cycles at 60 Hz	
	Single-phase: at o°	Single-phase: at o°	
Voltage interruptions	o% <i>U</i> T;	o% <i>U</i> T;	Professional healthcare
			facility environment.
(IEC61000-4-11)	for 250 cycles at 50 Hz	for 250 cycles at 50 Hz	
	for 300 cycles at 60 Hz	for 300 cycles at 60 Hz	

#### Electromagnetic immunity, radio frequencies:

The SST-HD 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 PE communication devices (including peripherals such as antenna cables i						
external antennas) sho	Id not be used within 20	cm (12 inches) of any na	int of the PRD 7170100A			
and PRD 7170200A, inc	luding cables specified by	the manufacturer. Other	wise the performance of			
these devices could be a	dversely affected.		I			
Radiated RF	3 V/m	3 V/m	Professional healthcare			
electromagnetic fields			facility environment.			
(JEC61000-4-2)	80 MHZ to 2.7 GHZ	80 MHZ to 2.7 GHZ				
(12001000 4 5)	80% MA at 1 kHz	80% MA at 1 kHz				
Proximity fields emitted by	9 V/m	9 V/m	Professional healthcare			
devices (IEC 61000-6-2	710 MHz, 745 MHz,	710 MHz, 745 MHz,	racincy environment.			
interim method)						
	780 MHz, 5240 MHz,	780 MHz, 5240 MHz,				
	5550 MHz, 5785 MHz	5550 MHz, 5785 MHz				
	27 V/m	27 V/m				
	, .	, .				
	385 MHz	385 MHz				
	28 V/m	28 V/m				
	4.50 MHz 810 MHz	450 MHz 810 MHz				



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	870 MHz, 930 MHz,	870 MHz, 930 MHz,	
	1720 MHz, 1845 MHz,	1720 MHz, 1845 MHz,	
	1970 MHz, 2450 MHz	1970 MHz, 2450 MHz	
Conducted disturbances,	3 V	3 V	Professional healthcare
induced by RF	150 kHz to 80 MHz	150 kHz to 80 MHz	facility environment.
fields (IEC610004-6)		5	
	6 V within ISM band and	6 V within ISM band and	
	band ranging from	band ranging from	$\langle \langle \rangle$
	0.15 MHz to 80 MHz,	0.15 MHz to 80 MHz,	
	80% MA at 1 kHz	80% MA at 1 kHz	-

#### 4.4 Contraindications

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

#### 4.5 Warning for United States 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.



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- Consult the dealer or an experienced radio/TV technician for help.

This PRD 7170100A and PRD 7170200A complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

#### 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.

#### e CANADA / Attention pour les utilisateurs 4.6 Warning t user au (

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.

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 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.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) il ne doit pas produire de brouillage, et (2) l'utilisateur du dispositif doit être prêt a accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada.

Dans le but de réduire les risques de brouillage radioélectrique à l'intention d'autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Le présent appareil est conforme aux niveaux limites d'exigences d'exposition RF aux personnes définies par Industrie Canada. Cet appareil doit être installé afin d'offrir une distance de séparation d'au moins 20cm avec l'utilisateur, et ne doit pas être installé à proximité ou être utilisé en conjonction avec une autre antenne ou un autre émetteur.

# 5 Cleaning instructions

This chapter sets out the SST-HD cleaning procedure to follow.

The device must be cleaned or disinfected before use.

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

The cleaning procedure is as follows:

- Switch the SST-HD to maintenance mode
- Transfer the bags to another storage unit which is in operation



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





• Verify the condition of the trays during reassembly. They must not be cracked, worn or dirty!

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





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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 describes the actions you may be required to perform if a first-level fault occurs during use of the SST-HD.

Symptoms or Faults	Illustration	Actions required
Flashing red indicator on the front of a satellite Potentially no tray may be detected in the position under which the red indicator is displayed		<ul> <li>If there is a tray:</li> <li>Check that the tray is correctly positioned</li> <li>If the problem persists, transfer the tray's contents to an operational tray and inform the member of staff in charge of maintenance so that corrective maintenance can be carried out</li> </ul>
Red indicator on the front of a satellite There may be a communication fault (>4 minutes) or an electrical fault on the antennas and satellite		Transfer its contents to an operational tray and inform the member of staff in charge of maintenance so that corrective maintenance can be carried out. (See Table 2 – Symptoms or faults: Red indicator on the satellite)
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.

#### Table 1 – Symptoms or faults: Overview



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.

#### Table 2 – Symptoms or faults: Red indicator on the satellite

Red indicator on satellite			
Possible causes	Actions		
Data cannot be written	Move the bag to a different space and try again		
The tray has been open for more than 4 minutes	Close the tray		
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-HD, 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.



Version

- 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**

The SST-HD must be disposed of and recycled in accordance with applicable national requirements. The different components of the SST-HD must be sorted and processed in the appropriate waste processing channels.

As the different components of the SST-HD are electrical and electronic, they must be processed by a specialised collection, removal and recycling or destruction channel.

The batteries in the SST-HD components must be removed from the components before being disposed of. They must be processed by a specialised collection, removal and recycling or destruction channel.





# **12 Product identification**

#### PRD717\_0100A label:

biolog»id C	E 🔊 🕫 🕲 E			
1 rue du commandant Robert Malr ZA des Granges 27 300 BERNAY - FRANCE	ait Medical Device Class I Smart Storage Refrigerator High Density			
FCC ID : 2AKUFSSTHD45 IC : 23919-SSTHD45	REF PRD_7170100A			
This device complies with Part 15 of the For conditions: (1) this device may not cause h any interference received, including interfer	CC Rules. Operation is subject to the following two armful interference, and (2) this device must accept rence that may cause undesired operation.			

#### PRD717\_0200A label:

biolog»id C	E 🔊 🕼 FC 🧐
1 rue du commandant Robert Malrai ZA des Granges 27 300 BERNAY - FRANCE	it Medical Device Class I Smart Storage Refrigerator High Density
FCC ID : 2AKUFSSTHD60 IC : 23919-SSTHD60	REF PRD_7170200A SN XXBIAASSNNNNNN
This device complies with Part 15 of the FC conditions: (1) this device may not cause ha any interference received, including interfere	C Rules. Operation is subject to the following two rmful interference, and (2) this device must accept ence that may cause undesired operation.

Detailed view of serial number xxBIAASSNNNNNN

#### Product version: 2 characters

**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



# **13 Description of the logos**



: Read the user manual.



FCC : This product is FCC compliant



CE: This product is CE-compliant.



e This product is NRTL-compliant.



: This product emits an electromagnetic field.



1 rue du commandant Robert Malrait ZA des Granges 27 300 BERNAY FRANCE : This product is manufactured at the address shown

