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Z.I. Centr'Alp
170, Rue de Chatagnon
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GENERAL INFORMATION

FCCID: **2AKUFSSTR-V2**

1.1. Product description

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.

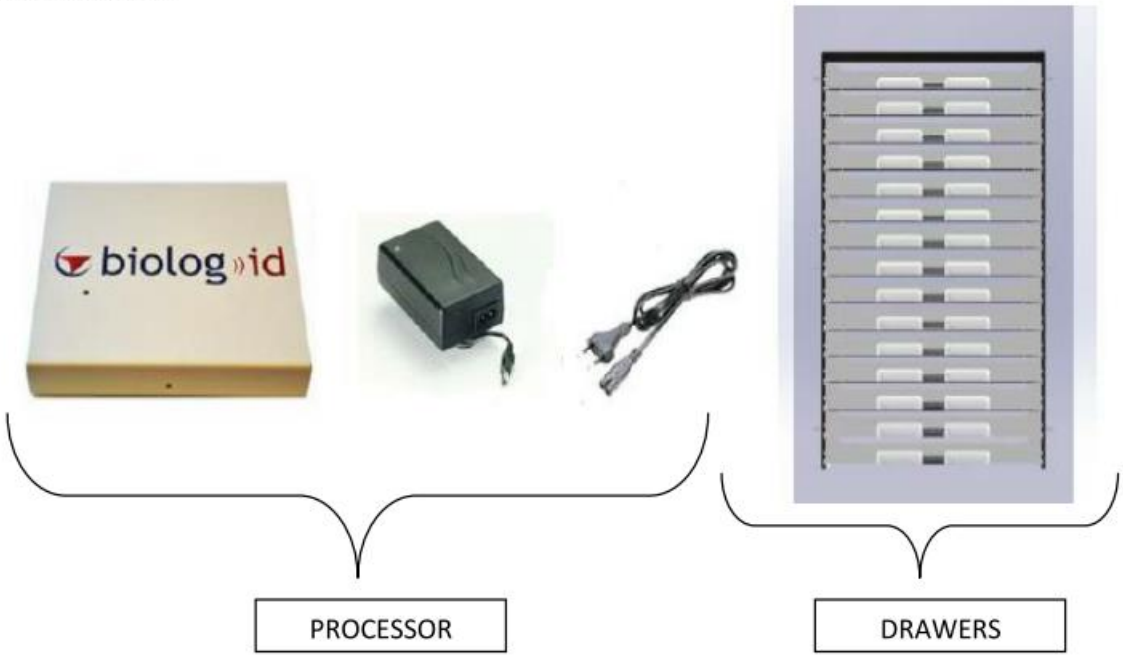

Fig. Example of an SST-R Kit

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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

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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

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

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2.3 Description of the SST-R.

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

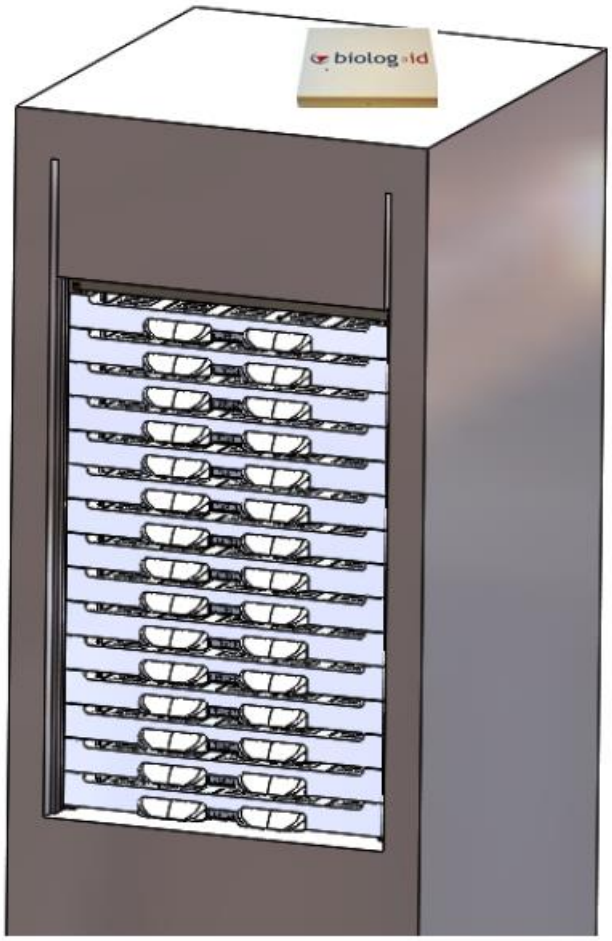

Fig. SST-R kit

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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.

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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.

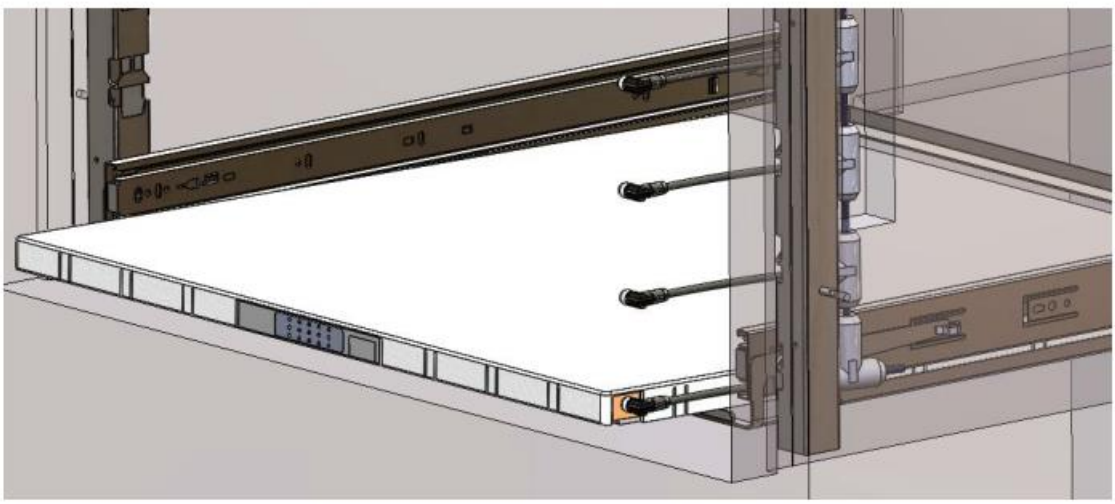

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Fig. satellite box

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.

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1.1. Tested System Details

Equipment Under Test

Inputs/outputs - Cable:

Access	Type	Length used (m)	Declared <3m	Shielded	Under test	Comments
Main power supply	Input	L1-N	1.8	Yes	☐	
Data	Output	RJ45	5	No	☐	Ethernet signals
Data	Output	Others	2.5	Yes	☐	CAN cables
Data	Output	Others	2.5	Yes	☐	Temperature sensor cable

Auxiliary equipment used during test:

Type	Reference	Sn	Comments
Laptop			Use to set the EUT

Equipment information:

Type:	☑ **RFID**			
Frequency band:	[13.553 to 13.567] MHz			
Number of Channel:	1			
Antenna Type:	☑ Integral	☐ External	☐ Dedicated	
Transmit chains:	1			
Receiver chains	1			
Type of equipment:	☐ Stand-alone	☑ Plug-in	☐ Combined	
Equipment type:	☐ Production model	☑ Pre-production model		
Operating temperature range:	Tmin:	☑ -30°C IC ☐ -20°C FCC	☐ 0°C	☐ X°C
	Tnom:	20°C		
	Tmax:	☐ 35°C	☑ 50°C	☐ X°C
Type of power source:	☑ AC power supply	☐ DC power supply	☐ Battery	
Operating voltage range:	Vmin:	☑ 102V/60Hz	☐ XVdc	
	Vnom:	☑ 120V/60Hz	☐ XVdc	
	Vmax:	☑ 138V/60Hz	☐ XVdc	

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1.2. Test Methodology

Both conducted and radiated testing were performed according to the procedures in ANSI C63.4 or ANSI C63.10, FCC Part 15 Subpart C.
Radiated testing was performed at an antenna to EUT distance of 10 meters. During testing, all equipment's and cables were moved relative to each other in order to identify the worst case set-up.

1.3. Test facility

Tests have been performed: **November 21, 2018 to November 27, 2018**

This test facility has been fully described in a report and accepted by FCC as compliant with the radiated and AC line conducted test site criteria in ANSI C63.4 and ANSI C63.10.
This test facility has also been accredited by COFRAC (French accreditation authority for European Union test lab accreditation organization) according to NF EN ISO/IEC 17025, as compliant with test site criteria and competence in 47 CFR Part 15/ANSI C63.4 and EN55022/CISPR22 norms for 89/336/EEC European EMC Directive application. All pertinent data for this test facility remains unchanged.