Procedure name

IT-1679 Sepax 2 Work Instructions

Select the type of device

	article N°	Denomination	Serial Number
☐	14000	Sepax S-100 (2)	
☐	14100	Sepax RM (2)	

Tools

SecuTest SN: _____
2ml syringe with luer lock / Pressure test chamber / Empty test chamber / Torque wrench / Water kit test

Test Procedure GMAP software

1. *User function tests*

Test the **Stop Button** (Hardware) OK: ☐
Check that the Touch screen displays well, touch-screen function works, **backlight** OK: ☐
Check the accuracy of the touchscreen display (calibrate it if needed) OK: ☐
Check that the **blue LEDs** are switched on OK: ☐

2. *Customer parameters*

Check the **Service Menu** Parameters
GMAP version _____
GMAP build version _____
Windows version _____
Serial number _____
Printer driver _____
Piston position offset _____
Debug => Send Logfile ☐
Patfile Unicode ☐
Page format _____
SepaxNet host (If applicable) _____

Toggle flag activation
Fan monitoring ☐
Cover temp. sensor ☐
Show menu button ☐

Check the **Settings Menu** Parameters
Auto print data ☐
Date and time are correct ☐
Language: _____
Sound volume: _____
Filename donation ID ☐

Check the **Traceability Setup** (if activated and in case of software update): N/A ☐
Enable trace ID ☐
Force Input ID ☐
ISBT128 only ☐

In case of update/reinstallation of protocol, note the **protocol's parameters** below

Parameters: _____

Traceability ID: _____

Test Procedure GMAN software or Automated *Device Inspection Protocol*

Automated Device Inspection Protocol V140

If Automated Device Inspection Protocol is used, skip chapters 3 to 8. Printout report must be then attached to this working procedure.

3. *Electrical power adjust*

Check the following output voltages in the **Manual software** Sepax 2

+ 48.00V	Fuse 1 (4A)	_____	(47.4 < value < 48.6)	DC1 OK: ☐
+ 24.20V	Fuse 2 (2,5A)	_____	(23.7 < value < 24.7)	DC2 OK: ☐
- 12.05V	Fuse 3 (1A)	_____	(-11.55 > value > -12.55)	DC3 OK: ☐
+ 12.05V	Fuse 4 (250mA)	_____	(11.55 < value < 12.55)	DC4 OK: ☐
+ 5.05V	Fuse 5 (4A)	_____	(4.8 < value < 5.3)	DC5 OK: ☐

"If the values is showing a short peak as "minus" (digit over flow), then it can be ignored"

4. *Air tests*

Attach the test **2ml syringe with luer lock** to the line pressure detector.

+2ml of air _____ (1200< value < 1500 mbar) Line+ OK: ☐

-2ml of air _____ (-650 < value < -450 mbar) Line- OK: ☐

Install the Empty test chamber in the centrifuge and connect the stopcock to the line pressure sensor.
Run the air pump to create: (When PRS/VAC required values are reached, use the BLK button to block the circuit).

0 mbar _____ chamber _____ line (ΔMax 20 mbar) ΔChr Line OK: ☐

-300 mbar _____ chamber _____ line (ΔMax 20 mbar)ΔChr Line- OK: ☐

+500 mbar _____ chamber _____ line (ΔMax 20 mbar) ΔChr Line+ OK: ☐

Apply a pressure of **~500 mbar**, close the stopcock and monitor the pressure drop for **1 min**.

Starting pressure _____ mbar **Pressure after 1min** _____ line (ΔMax 5mbar) Line drop OK: ☐

Install the Pressure test chamber in the centrifuge.

Apply maximum pressure	**(ELv 4000)**	_____	(1500 < value < 1900 mbar)	Chr max OK: ☐
Apply maximum vacuum	**(ELv 4000)**	_____	(value < -650 mbar)	Chr min OK: ☐
Apply vacuum or pressure	**(ELv 0)**		(50< value < 150 mbar)	Chr 0 OK: ☐

Perform the test below only in case of sealing system exchange. Otherwise choose N/A
Apply a pressure of 500 mbar and block the circuit. Monitor the pressure drop during 1 minute
Starting pressure_____mbar **Pressure after 1 min**_____mbar (ΔMax 35 mbar) Chr drop OK: ☐ N/A : ☐

With the Pressure test chamber inside the centrifuge apply a pressure of **~500 mbar** and run the centrifuge at **4000 rpm**. Wait **2 min** and then monitor the pressure drop during **1 min**.

Pressure at 2nd min _____ mbar **Pressure at 3rd min** _____ mbar (ΔMax 30 mbar) Chr drop OK: ☐

5. *Chamber volume sensor tests*

Check the not Corrected value **(NC)** in the Manual Sepax without chamber

Offset Empty centrifuge : _____ Pixels (≤10) OK: ☐

Install the **Pressure Test Chamber** in the centrifuge.

Position 1:	_____ Pixels	(62 < value < 74)			OK: ☐
Position 2:	_____ Pixels	Δ of position 1-2	_____	(390<value<410)	Pos 1-2 OK: ☐
Position 3:	_____ Pixels	Δ of position 2-3	_____	(390<value<410)	Pos 2-3 OK: ☐

6. *Optical line sensor tests*

Switch ON the SEPAX 2 and **wait 10 min**. before measuring
Attention: Calibration has to be done with the **lid closed** on the optical sensor.

Without filter

Red LED – Transmission	_____V	(5.5 < value < 6,5V)	Red WF OK: ☐
Blue LED – Transmission	_____V	(6.1 < value < 7,1V)	Blue WF OK: ☐

Black filter

Red LED – Transmission	_____V	(0.0 < value < 0,2V)	Red BF OK: ☐
Blue LED – Transmission	_____V	(0.0 < value < 0,2V)	Blue BF OK: ☐

7. Security tests

Check the **splash detector (Attention: check the reactivity of the spill) approximately 2 sec** OK: ☐

Check the three chamber **cover sensors** OK: ☐

	uC (20≤ T ≤40)	Internal (20≤ T ≤40)	Cover (15≤ T ≤35)	
Check the three **temperature sensors**	_____	_____	_____	OK: ☐

For the cover temperature sensor, pass the finger on the reading window. The value must change OK: ☐

Main fan turns OK: ☐

There must be **three beeps** at start-up + **red light** OK: ☐

8. Centrifuge tower tests

Centrifuge **tower alignment**. The centrifuge should be perfectly centred OK: ☐

Centrifuge **feet stability** OK: ☐

Centrifuge **upper deck** (spill proof ring) is not touching the housing.
The **gap** must be minimum 0.7mm OK: ☐

Check if the centrifuge **covers** are neither broken nor bent, and do not create any vibrations OK: ☐

Run the centrifuge at **8000rpm** with the **pressure test chamber** inside the cabinet, and check for vibrations. OK: ☐

9. Stepper motor tests

Stopcock configuration: Standard ☐ Reduced (CS-570) ☐

Run the protocol "**test stpck pos**" with stop cock ramp and choose time 60s
Go to MAN mode: OK: ☐

With the **torque wrench**, control the two stopcocks in both directions (0,3 < value < 0,5 Nm) OK: ☐

Electrical test according to IEC 62353

Connect the Sepax2 to the Secutest using the power cable, which **belongs to the machine**. Hook up the Secutest to the sector (230VAC/110VAC).

10. Electrical earth test

In RCP mode

With the Secutest check the earth connection at 200mA. **Measuring points have to be < 0.3 Ω**
Test the following points:

The screw on the left hand side of the power connection OK: ☐

The rear fan grill OK: ☐

The top bag holder support (with bag holder inserted) OK: ☐

One central screw on the upper part of the head display OK: ☐

One screw underneath the Sepax (chassis) OK: ☐

11. Insulation test

In R-ISO mode

Set the Secutest to 500V. **Measuring points have to be above 70MΩ**
Test the following points:

The covers central knob OK: ☐

The luer connection OK: ☐

One of the four USB ports OK: ☐

One of the two Ethernet port OK: ☐

The handles fixing bolt on the left side of the device: Rear OK: ☐

The handles fixing bolt on the left side of the device: Front OK: ☐

12. Earth leakage test

In ICD mode

Current Normal Condition / Differential _____ Max value < 0.5mA OK: ☐

Single Fault Current / Alternatif _____ Max value < 1 mA OK: ☐

13. Current and voltage tests

In function mode

Current Consumption _____ Max value <0.65A @230Vac
Max value <1A @110Vac OK: ☐

Other tests

14. Protocol tests

Put the value of position 1 in Section 5 at GMAP/Service menu/ Position piston offset. OK: ☐
Run a complete procedure (e.g. UCB-HES) using a **water kit test.** OK: ☐

15. Visual control

Check the **exterior appearance** of the SEPAX 2 OK: ☐

16. AS-610 Traceability

Installed YES: ☐ NO: ☐
Test the functionality of the barcode reader by scanning a barcode sample below OK: ☐ N/A: ☐
Check the printer power supply and power cable exterior appearance OK: ☐ N/A: ☐
Test the SEPAX 2 printing OK: ☐ N/A: ☐

WWW.BIOSAFE.CH

0123BIOSAFE

1234567890

CTBT-DIR bcB

E0001 03004341 [A]

17. Comments

_____

_____

_____

_____

18. Parts exchanged

Article Number	Designation	Old SN	New SN
In case of battery exchange		Reference	Manufacturing date

Tests conclusion

Tests with Automated Device Inspection Protocol passed

PASS: ☐
NOT PASS: ☐
N/A: ☐

Tests passed for the SEPAX 2

PASS: ☐
NOT PASS: ☐

Approval

Date: _____ Signed: _____