Diagnostics for the Real World

SAMBA III Assay Module

USER GUIDE

C19-0122-EN, Ver 5.0

REF I19-0007-AM

DRW
Diagnostics for the Real World

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1. SAFETY

Read these operating instructions carefully and fully before use. The following symbols are used in this document, the associated equipment and packaging:

Caution: Surfaces may become hot during operation

Caution: potential biohazard

In Vitro Diagnostic medical device

Catalogue number

Serial number

Caution

Consult instructions for use

Manufacturer

Authorised representative in the European Community

Do not dispose of this instrument with regular waste

Direct Current

Keep Dry

Symbols continued:

Fragile, handle with care

This way up

Device for near-patient testing

2. INTENDED PURPOSE

The SAMBA III Instrument system (SAMBA III Assay Module and SAMBA III Tablet Module) is an automated sample extraction, nucleic acid amplification (isothermal or polymerase chain reaction) and real-time fluorescence nucleic acid detection system. The SAMBA III Instrument is used solely in combination with SAMBA III Reagent kits for qualitative, quantitative, or semi-quantitative reporting of test results. The SAMBA III Instrument is intended for use by trained laboratory staff within either centralised hospital laboratories or near- patient environments.

Product description and principle of operation

The SAMBA III Instrument system consists of the SAMBA III Assay Module and the SAMBA III Tablet Module. Each SAMBA III Assay Module (AM) is a small automated robotic machine that processes a set of single-use SAMBA III cartridges which hold all the reagents and materials required to process the input sample. The SAMBA III cartridges are designed to be fully disposable and single use and thus contain all components needed, e.g. reagents and pipette tips. The AM consists of various motor-driven axes of movement, a syringe pump and a number of temperature-controlled zones including thermo-cycling zones for the PCR process. A positive PCR product is detected by an optical module using fluorescence emitted by fluorescent tags linked to specific target probes.

The SAMBA III Tablet Module is the user interface for running of the SAMBA test in the Assay Module and can control up to eight (8) Assay Module units. The Tablet Module has the capability to connect to a Bluetooth printer and an option for connectivity to the institution's Laboratory Information Management System (LIMS) as well as data management system.

3. UNPACKING & SETUP

Unpack the unit carefully and retain the packaging for future use. The Power Supply Adaptor and Mains Lead are located in the bottom of the box. Open the instrument lid and remove the tape on the turret. This tape locks the turret during shipping to protect it from damage.

Place the unit on a flat and level surface away from direct sunlight and drafts, ensuring that both the power button and mains plug are easily accessible.

CONNECTING TO THE POWER SUPPLY

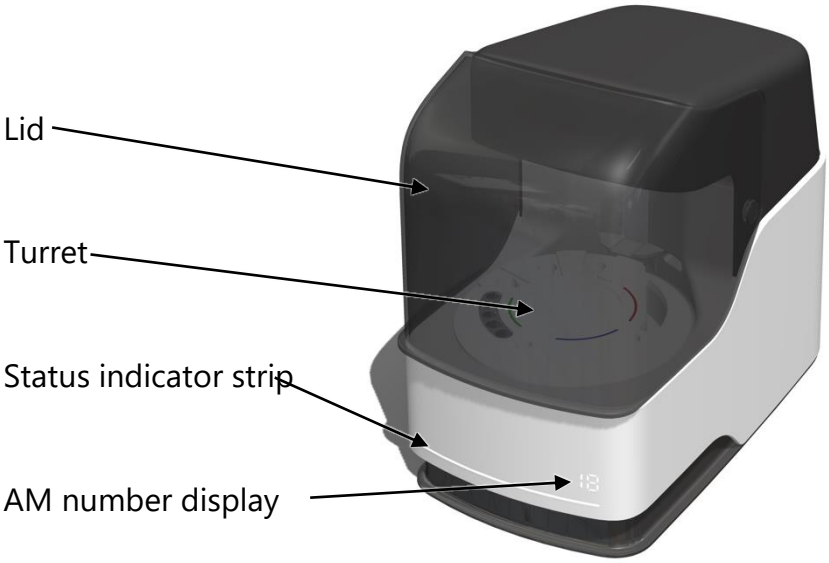
NOTE: The unit is designed to operate at 100-240V AC, 50/60 Hz.
Connect the mains lead to the power supply.
Connect the power supply to the power socket at the back of the unit. Do NOT connect the power supply to the back of the unit when the power supply is turned on. Ensure that the power supply is switched off prior to connecting to the unit.

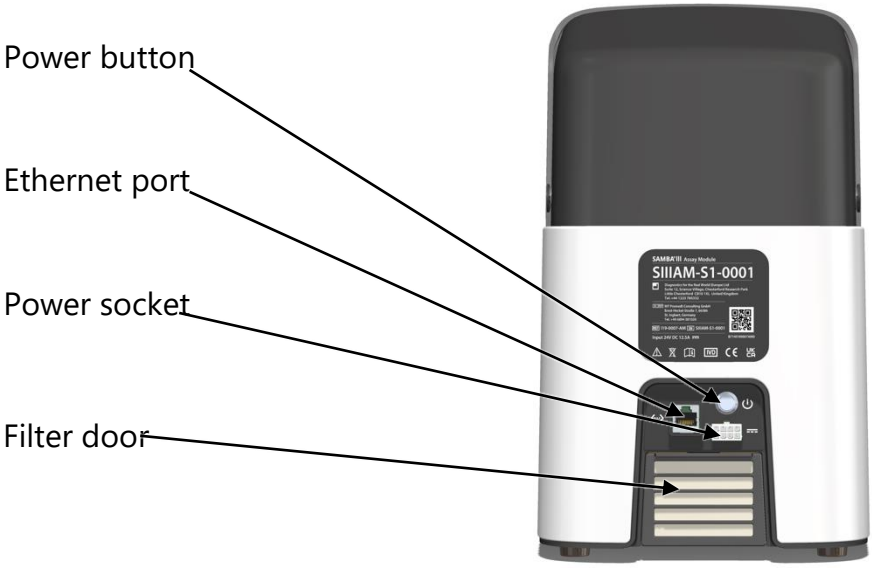
Disconnect from the mains supply when not in service. The use of an Un-Interruptible power supply (UPS) Is recommended to prevent power loss during an assay.

If power interruption is expected to occur, it is highly recommended to connect the unit to an Un-interruptible power supply (UPS).

INSTRUMENT CHECKLIST

1 SAMBA III Assay Module
2 Mains lead
3 Power supply


Lid
Turret
Status indicator strip
AM number display


Power button
Ethernet port
Power socket
Filter door
SAMBA III Assay Module
SIIIAM-S1-0001

STORAGE AND TRANSPORT

Switch off when not in use. For long term storage use the original packaging.

If shipping or transporting the instrument is required, use the original packaging. If this is not available, contact DRW Technical Support. Suitable for shipping via air, sea or lorry and between
-10°C and 60°C.

COMMISSIONING

After shipping or moving the AM, check for transit damage. The SAMBA III instrument system is a designed for plug-and-use but if needed, a DRW Engineer will commission the system prior to use. If the Assay Module is moved after initial commissioning, please contact DRW Technical Support for assistance prior to use.

4. WARNINGS & PRECAUTIONS

- DO NOT operate any SAMBA III AM or conduct any tests unless you have been trained to do so.
- Ensure that there is a reliable electricity supply before starting a test.
- Always wear powder free gloves when using the SAMBA III AM and TM. Eye protection and a lab coat should also be considered.
- Blood and plasma specimens should be handled as biohazardous material as though capable of transmitting infectious diseases.
- Ensure that a clinical/biohazard waste bin is located near the SAMBA AM to ensure the safe disposal of used cartridges and samples.
- DO NOT expose the SAMBA III AM to direct heat, sunlight, water or chemicals. A cleaning solution may be used as described in Section 7, Cleaning.
- DO NOT touch the metal tube pockets immediately after use or when aborting a run. Tube pockets become hot during use.
- Ensure that the power is turned off and disconnect from the mains before moving.
- Use only SAMBA III cartridges manufactured by DRW in this instrument. Failure to do so may damage the instrument and will provide incorrect results.

- Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
- DO NOT interrupt a test (e.g. by interrupting the electricity supply or raising the lid) unless it is intentional to abort the test. To abort a test properly, follow the procedure described in the SAMBA III Tablet Module User Guide (Doc No. C19-0123-EN.
- If a TM loses connection during an assay run, DO NOT turn off an AM when the Indicator strip is green. To obtain test result at the end of a run, wait until indicator strip is white, then turn the AM OFF and then ON. The TM will re-connect and test result will automatically be sent to the TM.
- DO NOT reuse cartridges once they have been loaded and any of the foil seals have been broken.
- DO NOT reuse a sample if the Sample Tube cap has been pierced.
- DO NOT attempt to disassemble any of the cartridges or their constituent parts after use. Doing so risks cross contamination and may invalidate future results. The sample tube and its contents are a biohazard and should be treated accordingly.
- DO NOT attempt to disassemble the SAMBA III AM or TM. There are no user serviceable parts except the AM has an air filter (Section 6.4). Opening the outer cases will void any warranty.
- Do not use this instrument in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.

- If the instrument is not used in a manner specified within this user guide the protection provided by the equipment may be impaired.

NOTE	In the event of any serious incident that occurs in relation to the AM, please report to Diagnostics for the Real World (Europe) Ltd, Authorised Representative and the Competent Authority of the Member State in which the user and/or the patient is established.

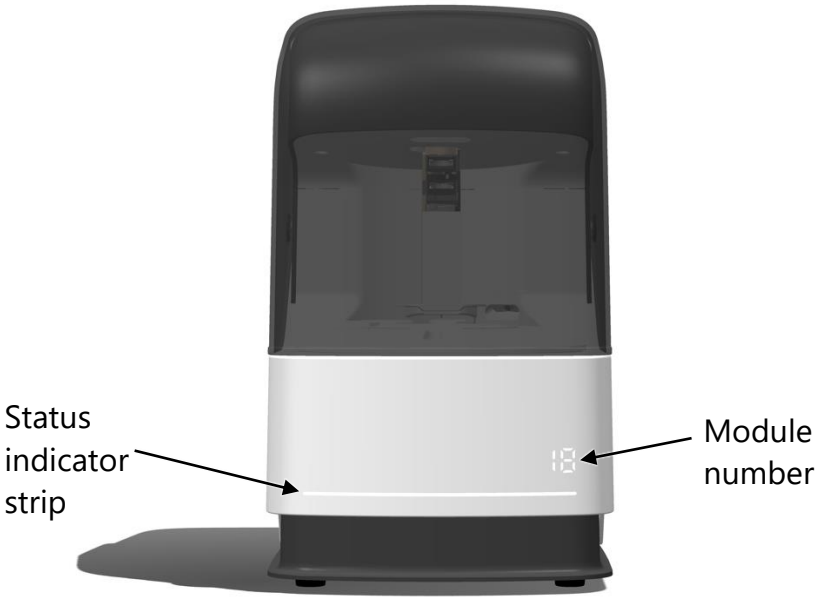
5. OPERATING INSTRUCTIONS

The SAMBA III AM is designed to operate with the SAMBA III TM. The SAMBA III AM and TM are provided ready for use. The SAMBA III TM controls and reports the outcome of tests performed on the SAMBA III AM.

When running assays, you should also read the SAMBA III Assays Instructions for Use (e.g. Doc No. C19-0121 IFU for SAMBA III SCoV-2/Flu/RSV Test).

RUNNING A TEST

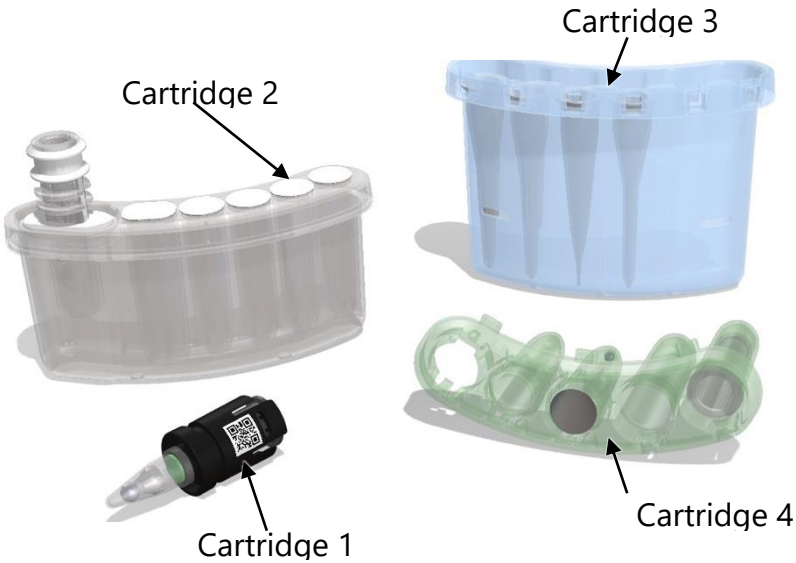
5.1 Switch on the SAMBA III AM. The internal light will illuminate and the status indicator strip on the front of the module will show white and the module number will appear. The AM is now ready for use.



5.2 When you switch on the TM you will need to log in. Log in options can be changed using the TM and configured to use user accounts stored on the TM or on the HM, and will vary depending on your organisation.

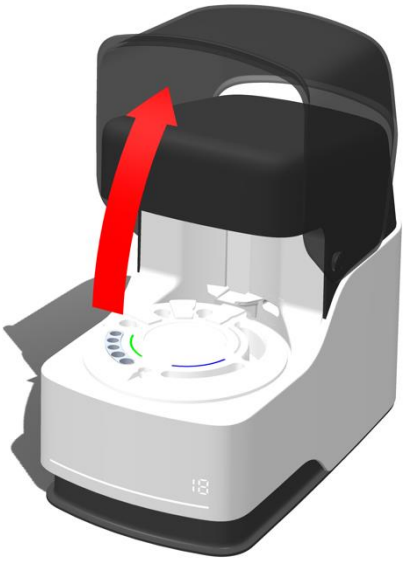
5.3 On the TM select the TM number that you wish to use to run the assay (the Module Number from the front of the AM will be displayed on the TM).

5.4 Cartridges are supplied in a Kit Box which contains enough cartridges to run 12 tests. A set of four to six (4 - 6) cartridges are required to run a test (depending on the assay) and these are supplied in protective bags. Cartridges 1 and 3 and cartridges 2 and 4 are bagged together. There may be more than one cartridge 1 depending on the assay (up to 3).

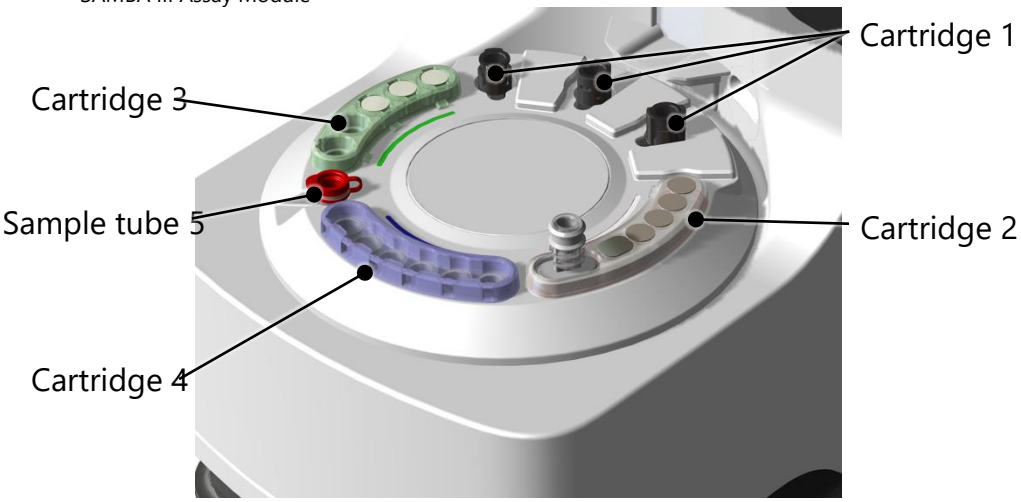


5.5 Using the TM scan the 2D barcode on the Cartridge 2 and 4 bag to identify the assay type. Carefully remove the cartridges from the bags. Visually inspect each cartridge to ensure foil seals are not perforated and cartridges and tubes are securely clipped.

5.6 Open the AM lid to its full extent, (it will stay open unaided) and load the cartridges.

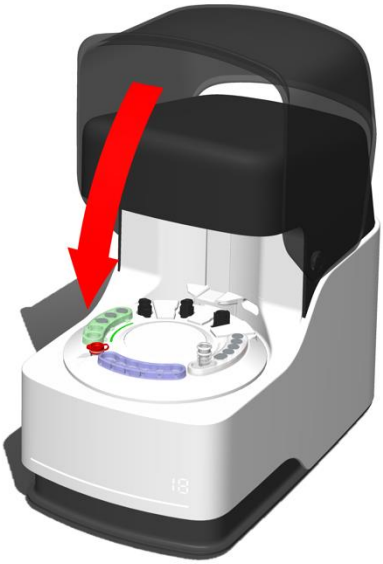


5.7 Each Test set comprises 4 - 6 cartridges. Load all cartridges into the AM following the diagram below. Ensure that all cartridges are fully inserted before proceeding. The turret can be rotated if needed to make it easier to load the cartridges.



⚠ Check that the Sample Tube has the right sample type and the required minimum volume. Refer to the test Instructions for Use for details.

5.8 Close the lid of the AM.



5.9 The AM is now ready to begin testing.

DO NOT OPEN THE LID at any time during a test. This will stop the test and any results will be invalid.

Please refer to the SAMBA III Tablet Module User Guide (C19-0123-EN) for information on how to run a test.

5.10 Once the assay is completed, the AM will come to a stop and the status indicator strip on the front of the machine will appear white. The TM will also indicate that the test has finished.

5.11 The Test Cartridges may now be removed.

5.12 Once all the Cartridges and sample tube have been removed, the SAMBA III AM may either be switched off or prepared for another test.

The used Cartridges and Sample are a biohazard and should be disposed of according to the established procedures for such materials.

If there is a machine issue during the assay (e.g. jam), then the assay is automatically aborted and the status indicator will appear red (error state). The TM reports the issue to the User and prompts removal of all cartridges. Dispose of the cartridges and any obstructions (e.g. pipette tips held in the adaptor head) according to the established procedures for biohazards. Once the cover is closed, the instrument will automatically initialize and the status indicator will appear white (read for use). A User can manually abort an assay via TM. This will stop the assay and prompt the user to remove cartridges. Also, see Section 10, Troubleshooting.

6. MAINTENANCE

6.1 The instrument is designed to require minimal maintenance.

6.2 There are no user serviceable parts inside the machine. The air filter can be removed and cleaned or replaced.

SELF CHECKING

6.3 The SAMBA III AM performs a number of self-tests before beginning each assay. If the self-test identifies any errors, the status indicator strip will appear red. The error will be

reported to the SAMBA III TM.

FILTER

6.4 The air filter built into the rear of the unit will need to be cleaned or replaced from time to time. In excessively dusty environments, filters may need to be cleaned at least once a week. Check the air filter each month to determine if it needs to be cleaned or replaced. Contact DRW Customer Service if a replacement filter is needed. A blocked filter may prevent the instrument from reaching the required working temperatures.

FILTER CLEANING and REPLACEMENT

6.5 Switch off the instrument and disconnect the power adaptor.

The filter should NOT be cleaned or replaced while the instrument is running. First switch off the instrument and disconnect from the power adaptor.

6.6 The filter is located at the back the instrument below the power lead and button. To change the filter, first remove the power lead. Turn the instrument so that you can see and access the back. Pull the filter door open.

6.7 With the door open press the tab on the filter holder to unclip it and then remove it.

6.8 The filter can now be lifted out and removed for cleaning.

6.9 The filter material used is washable. Use running water to wash the filter. Make sure the filter is thoroughly DRY before putting it back into the instrument.

6.10 Putting the washed or replacement filter back into the instrument is a reverse of the steps described above. If the door does not close properly, check that the filter holder is clipped in properly and the filter material is not trapped

between the filter holder and the filter door.

The filters used in the SAMBA III AM are washable filters specifically designed for the unit. Only filters recommended by DRW should be used. See Section 9. Accessories for details.

6.11 Return the instrument to its normal position and reconnect the power cable.

SAFETY GUARD

6.12 The hinged lid is a safety feature and the lid must be closed in normal operation, as the machine will not operate with the lid open. Opening the lid during a Test will interrupt the Test.

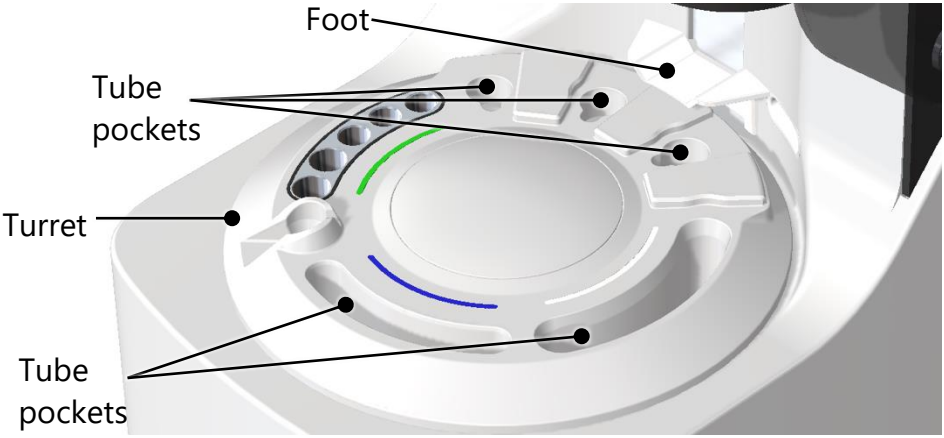
7. CLEANING

Switch off the AM and disconnect from the power adaptor before cleaning. Always wear powder-free gloves.

7.1 At the end of each working day it is recommended that the external surfaces of the machine should be cleaned.

7.2 Use a clean wipe that has been soaked in a Cleaning Solution of 1-part household bleach to 9 parts water (this deals with the contamination). Wring out the wipe so it is damp and not wet. Wipe down the external surfaces. Clean off the bleach solution with a wipe that has been soaked in clean water. Repeat this step if necessary to ensure that no residual bleach solution is left on the machine. Wipe dry using a lint-free cloth.

7.3 The Foot of the instrument will benefit from routine cleaning:



> ⚠ Use only diluted bleach or water as described above. Do not use any other cleaning agents - if in doubt contact DRW Technical Support for further advice.

7.4 The Foot can be cleaned by squeezing the wipe through the space beneath it. It is not recommended to remove the foot.

7.5 The amplification chambers (covered by powered lids) cannot be accessed by the user for cleaning. In case of serious spillages contact DRW Technical Support.

7.6 To clean the Turret: Wipe the surface and clean inside the tube pockets using a solution of 1-part household bleach to 9 parts water. Use swabs or other absorbent material soaked in clean water to remove residual bleach. Finally, use dry swabs or other absorbent material to dry out the tube pockets after cleaning.

SPILLAGES

7.7 If samples are spilled into or onto the instrument, clean the instrument as described in the CLEANING section above.

Spillages of samples are a biohazard, or a potential contamination risk. Users should make sure the instrument is appropriately decontaminated as described in Section 7.

8. SPECIFICATIONS

OPERATING ENVIRONMENT

8.1 The instrument is designed to run under the following environmental conditions:

- indoor use only
- altitude up to 2,000 m
- ambient temperature of 10°C to 30° C.
- relative humidity of up to 80%, relative humidity at 31°C decreasing linearly to 50% relative humidity at 38°C
- mains supply voltage fluctuations up to +10% of the nominal voltage
- transient over-voltages up to the levels of over-voltage category II (devices intended to be plugged into a mains wall outlet).
- to be used in dry environment, of pollution degree 2 (according to IEC664-1) - only non-conductive pollution occurs except that occasionally a temporary conductivity caused by condensation is expected

PHYSICAL

8.2 Approximate dimensions:

Weight:	9.9 kg
Dimensions:	20 x 39 x 34 cm (W x D x H)
Instrument power inlet:	24V DC, 12.5 Amp
Power Adaptor supplied:	Input: 100-240V AC 50/60Hz (4.5 Amp) Output: 24V DC 12.5 Amp

Compliance with 2014/53/EC Radio Equipment Directive (RED)

In accordance with Article 10.8(a) and 10.8(b) of the RED, the following table provides information on the frequency bands used and the maximum RF transmit power of the product:

Frequency Range	Max Transmit power
2.4-2.48 GHz	4 dBm

9. ACCESSORIES

SAMBA spares and accessories available from DRW Technical Support as follows:

Printer paper **C16-0031**
The paper used in the Bluetooth printer is a custom thermal paper guaranteed to last for 10 years.

Replacement filter **C19-0055**
The filter used is washable, but replacements are available.

Bluetooth printer **C16-0032**
The printer that the SAMBA III App has been designed for.

Additional Tablet Module **I19-0007-TM**
An additional Tablet or a replacement can be ordered if needed.

Hub Module (optional) **I19-0007-HM**
A Hub Module or a replacement can be ordered if needed.

SPARES
Turret Hub Cap **C20-0008**
Foot..... **C19-0057**

10. TROUBLESHOOTING

10.1 **The unit does not switch on:**

- Check that the unit is connected to a power supply and the power outlet is switched on
- Check that all power connections, including UPS, are connected and working properly.

10.2 **A red light appears on the status indicator strip at startup:**

- A red light appearing on start-up may be caused by an internal electrical fault detected during the initial self-test or by a movement not being carried out as required, or a heater or cooler block in the instrument not getting to the required temperature. If this happens during startup, turn the machine off and on again (cycle the power).
- A red light may be the result of previously used cartridge parts left in the turret. This will prevent the lids homing and the instrument will fail to move to ready state. Clear all previously used cartridge parts and restart the test using new cartridges.

10.3 **A red light appears on the status indicator strip during a test:**

- Check that the test has not been aborted using the TM. If it has then the red light will disappear.
- A red light may be the result of not following the correct loading sequence. Make sure that you are loading and starting the test as described in the relevant user guide.
- If the test has not been aborted then a red light may be caused by a communication error, a movement not being carried out as required, the lid was opened, or a heater or cooler block in the instrument not getting to the required temperature. Check for any visible signs of mechanical

obstruction (e.g. pipette tips, adaptor head, cartridges).
- Check that the foot is fitted properly (Section 7.3).
- If an obstruction is found that can be cleared, first remove the obstruction and then remove all cartridge parts and restart the test using new cartridges. If the sample tube has been pierced it cannot be reused and a new sample will be required.
- If no obstruction is found, abort the test, recycle power and restart the test. If the sample tube has been pierced it cannot be reused and a new sample will be required.
- A red light may be the result of a faulty adaptor or cartridge. Abort the run, remove all cartridge parts, recycle power using the power button at the back and try running a test using a new set of cartridges.

10.4 The machine stops during an assay but there is no red light on the status indicator strip:
- Check that the power connector is properly connected and that there is power to the instrument.
- Remove all cartridge parts, recycle power using the power button at the back and restart the test using new cartridges. If the sample tube has been pierced it cannot be reused and so a new sample will be required.

10.5 If the above actions do not solve the problem contact DRW Technical Support.

11. TECHNICAL SUPPORT

RETURNING AN ASSAY MODULE

11.1 If it is necessary to return the machine for any reason, contact DRW Technical Support and follow the steps below:

11.2 Remove all used cartridges.

11.3 Clean the instrument as described in **Section 7. Cleaning**.

11.4 Use the original packaging to re-pack the unit. Put the power adaptor into the small box. If the original packaging is not used, the unit may be damaged in transit. Contact DRW Technical Support for packaging instructions.

11.5 Only the last test result is stored on the AM and this only uses a tracking number and so there is no issue of confidentiality.

For technical support/feedback on the SAMBA III Instrument System or for Spares and Accessories contact Diagnostics for the Real World Ltd Technical Support:

UK: Tel +44 1223 785330	Email: service@drw-ltd.com
Contact: Megan Williams	Email: mwilliams@drw-ltd.com
Contact: Sonny M. Assennato	Email: smassennato@drw-ltd.com
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Revision history:

Version no.	Brief description of changes	Date approved
1.0	Initial release	06 November 24
2.0	Updated User Guide throughout to correct minor typos, grammatical errors and formatting. Removed references to HUB and LIMs as it not currently applicable. Added CE and UKCA marks. Updates made for clarity and completeness, thus, risk is low.	10 April 2025
3.0	Updated the Intended Use to align consistently in technical documentation. Updates made for completeness, thus risk is low.	11 June 2025
4.0	Updated the symbols section to include symbol for near-patient testing. Updated intended purpose to include near-patient environments. Updated EU rep symbol. Updates made for clarity and completeness, thus, risk is low.	23 August 2025
5.0	Updated to include the following statement to section 3 for clarity: Do NOT connect the power supply to the back of the unit when the power supply is turned on. Ensure that the power supply is switched off prior to connecting to the unit. Updated image of cartridges on page 14 to current. Updates made for clarity and completeness, thus, risk is low.	29 October 2025

Authorised representative:

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