

User Manual

SIRscan® Discs Dispenser



Reference: MU-0210

Version 09

Validé : 06/08/26

i2a ■ 401, rue du Walhalla, Parc Eurêka ■ 34000 Montpellier, France ■

Phone. +33 4 67 50 48 00 ■ Fax. +33 4 67 17 09 06 ■ i2a@i2a.info ■ <https://i2a-diagnostics.fr/>

Template: TEM-711687 (Version 03)





PRODUCT NAME(S)	Square Antibiotic Disc Dispenser Round Antibiotic Disc Dispenser
COMMERCIAL REFERENCE(S)	800256 800226
DEVICE VERSION	Version 6.7 Version 3.3

Revision history

Version	Amended section	Description of modification
9	10	Correction of references in the malfunction table.
8	5.3 10.2.1	Addition of ambient temperature before dispenser use Addition of information related to dispenser with captive fasteners
7	All	Bringing the manual into compliance with the requirements of Annex I, Chapter III of Regulation (EC) 2017/746. Compliance with new template and new cover page.
6	N / A	Integration of the reference to SIRxpert (MU-1897 manual in addition to SIRweb MU-1555). Deletion of BD positions. A photo has been added for a better understanding of the purpose of the metal rod.
5	N / A	Amendment to the regulatory section. Addition of warranty limits.
4	N / A	Modifications following image error; compatible positions.
3	N / A	Amendment to the paragraph concerning compatible positions.
2	N / A	Update to the Cleaning/Decontamination procedure. Warning about the risk of contamination if a piston height spacer is not used. Modification of the number of compatible replacement cartridge positions.
1	N / A	Creation.

Table of references

All the documents cited as references are available online on the i2a company website accessible at the address: www.i2a-diagnostics.fr.

Reference	Title
MU-1155	Management of dispenser and traceability of antibiotic batches



CMC Medical Devices GmbH
Rigistrasse 3
CH - 6300 ZUG



Axon Lab AG
Täfernstrasse 15
CH – BADEN-DÄTTWIL



i2a - Parc Eurêka 401, avenue du Walhalla 34000 Montpellier - France
 Such. +33 4 67 50 48 00 - Fax. +33 4 67 17 09 06
 email: i2a@i2a.info - www.i2a-diagnostics.fr



FR: TABLEAU DES SYMBOLES / EN: TABLE OF SYMBOLS / ES: TABLA DE LOS SÍMBOLOS / IT: ABELLA DEI SIMBOLI / TABELLE DER SYMBOLE

	Fr: Fabricant / En: Manufacturer / Es: Fabricante / It: Fabbricante / De: Hersteller
	Fr: Date de fabrication / En: Manufacturing date / Es: Fecha de fabricación / It: Data di produzione / De: Herstellungsdatum
	Fr: Attention voir notice d'instructions / En: Caution, consult accompanying documents / Es: Atención, ver instrucciones de uso / It: Attenzione, vedere le istruzioni per l'uso / De: Vorsicht, Begleitdokumente beachten
	Fr: Référence du catalogue / En: Catalog number / Es: Número de catálogo / It: Numero di catalogo / De: Bestellnummer
	Fr: Numéro de série / En: Serial number / Es: Número de serie / It: Numero di serie / De: Seriennummer
	Fr: IUD / En: UDI / Es: UDI / It: UDI / De: UDI
	Fr: Dispositif médical de diagnostic in vitro / En: In Vitro Diagnostic Medical Device / Es: Producto sanitario para diagnóstico in vitro / It: Dispositivo medico-diagnostico in vitro / De: Für In Vitro Diagnostik
	Fr: Distributeur / En: Distributor / Es: Distribuidor / It: Distributore / De: Verteiler
	Fr: Importateur / En: Importer / Es: Importador / It: Importatore / De: Importeur
	Fr: Risques biologiques / En: Biological hazards / Es: Riesgos biológicos / It: Rischi biologici / De: Biologische Risiken



SUMMARY

Modifications history.....	2
Table of references.....	2
1 Foreword	5
2 Warranty limitations	5
3 Device presentation	6
4 Clinical benefits / performance / mechanism of action	7
5 Prerequisites before use and instructions for use	7
5.1 List of materials provided	7
5.2 Requirements regarding installation, user training and qualification	8
5.3 Prerequisites before use	8
5.4 SIRscan® discs	8
6 Storage/handling/disposal conditions	9
6.1 Storage conditions	9
6.2 Disposal of the dispenser	9
7 Warnings, precautions, required measures and restrictions on use	10
7.1 Biological risks	10
7.2 Chemical risks.....	10
8 Vigilance	10
9 Operating instructions.....	11
9.1 Inserting the cartridges.....	11
9.2 Agar protection in case of cartridge absence	12
9.3 Discs distribution.....	13
9.4 Removal of antibiotic cartridges	14
9.5 User maintenance	15
9.5.1 Cleaning the dispenser	15
9.5.2 Dispenser decontamination	15
9.5.3 Decontamination of the storage box.....	15
10 Malfunctions	16
10.1 Simple malfunctions.....	16
10.2 Unblocking the dispenser	17
10.2.1 Square dispenser	17
10.2.2 Round dispenser.....	19



1 Foreword

The purpose of this manual is to present all possible operations for optimal use of the two antibiotic disc dispensers designed and manufactured by the company i2a.



If you have any questions that are not answered in this manual, please contact i2a customer service by phone at +33 (0)4 67 50 48 10 or by email at i2asav@i2a.info.

Customer service is available Monday to Friday from 8:00 AM to 6:30 PM and Saturday from 8:00 AM to 3:30 PM (UTC+1 time).



This information sheet is available online on the i2a company website, accessible at: www.i2a-diagnostics.fr

2 Warranty limitations

The warranty period is stipulated in the general terms and conditions of sale associated with the purchase of the device.

In order to maintain the validity of the guarantee, the following conditions must be fully met:

- The device must be used according to the instructions in this document and the relevant manuals.
- Samples must be collected and stored in accordance with good laboratory working practices
- Only services and repairs provided by a technician authorized by i2a are permitted
- Only appropriate tools and spare parts used by i2a must be used during maintenance or troubleshooting operations.



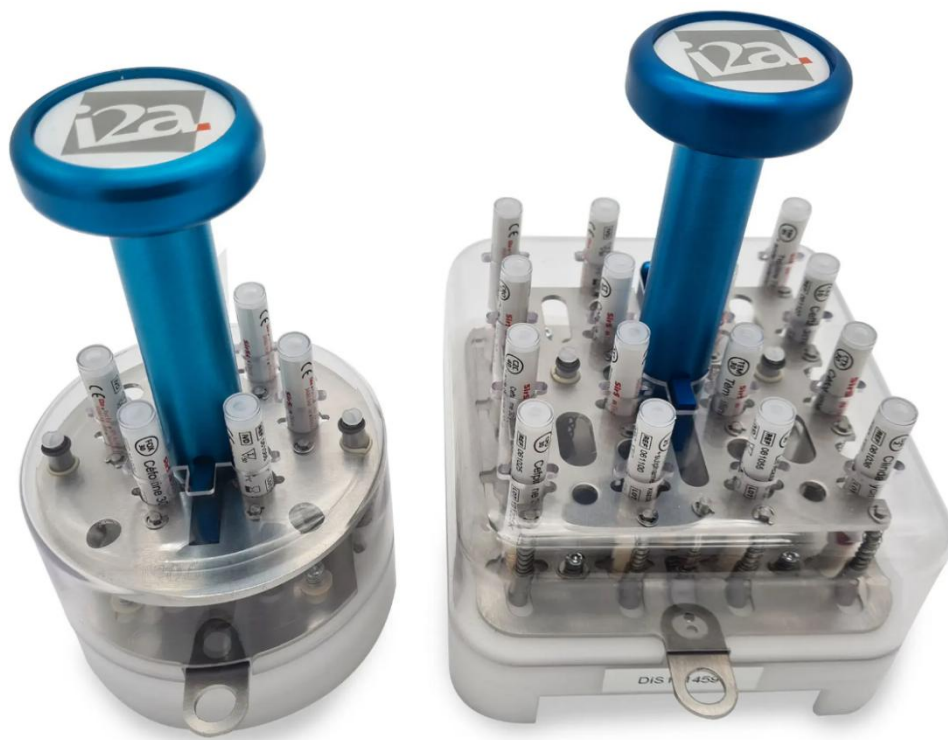
If this device was not provided to you directly by i2a or an authorized representative, i2a cannot guarantee its specifications, its latest version, or the associated documentation.
For more information, contact your i2a representative.

3 Device presentation

SIRscan® discs manual dispensers are designed to allow laboratory professionals to deposit antibiotic discs onto agar media, in order to perform antibiograms in accordance with standardized methods.

I2A designs two types of antibiotic disc dispensers:

- A round dispenser that can hold up to 6 antibiotic cartridges, suitable for culture dishes with a diameter of 90 mm
- A square dispenser that can hold up to 16 antibiotic cartridges, suitable for 120 mm square culture dishes



The target population corresponds to the non-specific population of all ages suspected of having a bacterial infection.

The SIRscan® Discs dispenser is intended for use in medical biology laboratories by trained and qualified personnel in the clinical field. This includes microbiologists, laboratory technicians, and other healthcare professionals who work in a clinical laboratory environment. It is not intended for direct use by patients or the general public.

It is used in hospital or private medical bacteriology analysis laboratories.

4 Clinical benefits / performance / mechanism of action

The SIRscan® Discs dispenser allows for rapid placement of antibiotic discs on the culture medium. Although the dispenser has no direct clinical performance, it allows the user to apply multiple discs in a single operation, depending on the device configuration.

The purpose of using the dispenser is to:

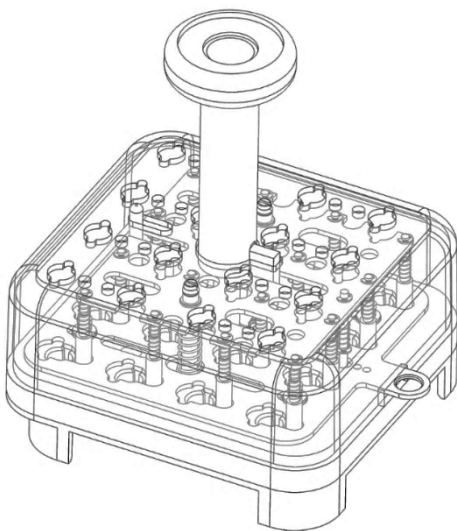
- Simplify the positioning of the discs on the agar.
- Helps maintain consistent spacing, depending on the device design.
- Reducing individual handling of disks can help limit some sources of error related to manual handling.

5 Prerequisites before use and instructions for use

5.1 List of materials provided

The SIRscan® Discs dispenser comes with the following components:

- A round or square dispenser (depending on the dispenser model)
- A storage box with a lid
- A screwdriver
- A desiccant
- 6 or 12 piston height shims (depending on the dispenser model)



x1



x1



x1



x1



x6 or x12



5.2 Requirements regarding installation, user training and qualification

It is important to fully read this manual. No specific training is required to use disc dispensers, however, some precautions should be taken:

- Place the dispenser on a clean table or worktop
- Avoid shocks and vibrations
- Respect the storage conditions between uses of the dispenser (see paragraph 6.1 of this manual)

5.3 Prerequisites before use

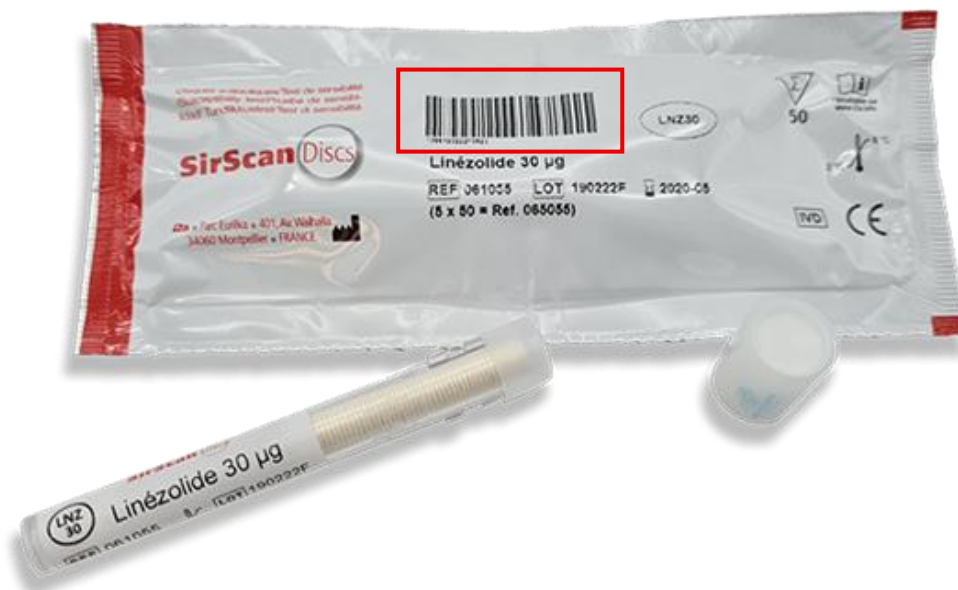
Check the visual condition of the dispenser (absence of marks, scratches, etc.), then clean all its parts with 70° denatured alcohol (see section "8.5 – User Maintenance").

If you store the dispenser in the fridge, keep it for 25 minutes at room temperature before use.

5.4 SIRscan® discs



Only i2a SIRscan® discs must be used with the dispenser. Unsupplied i2a reagents, consumables or accessories may compromise the performance of the dispenser. i2a accepts no responsibility for results obtained with a non-compliant configuration.



Before using the device, perform the following checks:

1. Check the condition of the individual packaging of the antibiotic cartridge before opening (no tears, etc.) to ensure no exposure to UV rays.
2. Remove the antibiotic cartridge from its individual packaging (keep it).
3. Check for the presence of desiccant in the packaging and the cap on the cartridge, to ensure the absence of moisture.
4. In case of apparent defect, contact the appropriate customer service (see section '1 – Foreword'), specifying the number corresponding to the barcode indicated on the cartridge packaging (see red box).



6 Storage/handling/disposal conditions

6.1 Storage conditions

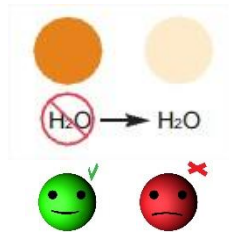
After use, store the dispenser with the desiccant in its storage box to protect it from shocks and moisture. Observe the storage temperatures of the antibiotic cartridges.

For first use of the desiccant:

- Remove the aluminum seal.
- Place the capsule flat on the support, cardboard side up.

The desiccant in the storage box must be changed routinely, at least once a week. It must be replaced immediately if a color change indicates moisture saturation (from orange to pale yellow).

It is recommended to use two desiccants alternately to more easily assess color changes indicating moisture saturation.



To regenerate the water-saturated desiccant, simply place it in an oven (temperature < 50°C) until the color goes back to orange.

After one year of use, or if the desiccant does not return to orange after regeneration, it is recommended to replace it with a new one. (ref. **310353**).

In case of damage to the box, dispenser, or desiccant, contact i2a customer service (see 'Foreword') and specify the reference of the item to be replaced:

- Round dispenser box: ref. **300363**
- Square dispenser box: ref. **300376**
- Desiccant: ref. **310353**

6.2 Disposal of the dispenser

If the dispenser has been purchased, discard it in accordance with the laboratory's applicable standards.

If the dispenser is loaned by i2a, remove the cartridges, decontaminate the dispenser (see section '8.5 – User maintenance'), and contact i2a to obtain the return procedure (see section '1 – Foreword').



7 Warnings, precautions, required measures and restrictions on use



In case of infectious danger, malfunction or degradation, refer to section "8.5 - User Maintenance".

7.1 Biological risks

Consider all samples, specimens and reagents as potentially infectious.

Consider all accessible surfaces of the device as potentially contaminated and presenting a biological risk.

Apply good laboratory work practices when handling samples.

Wear personal protective equipment that complies with current regulations (examples: gloves, lab coat).

Adhere to local safety practices, including OSHA recommendations for bloodborne pathogens (29 CFR part 1910.1030) or any equivalent biosafety procedure.

Use disinfectant products recommended by i2a or equivalent for decontaminating the device.

Refer to section "8.5 - User Maintenance" for cleaning and decontamination instructions.

7.2 Chemical risks

Store and handle all chemicals in accordance with the recommendations on their safety data sheets.

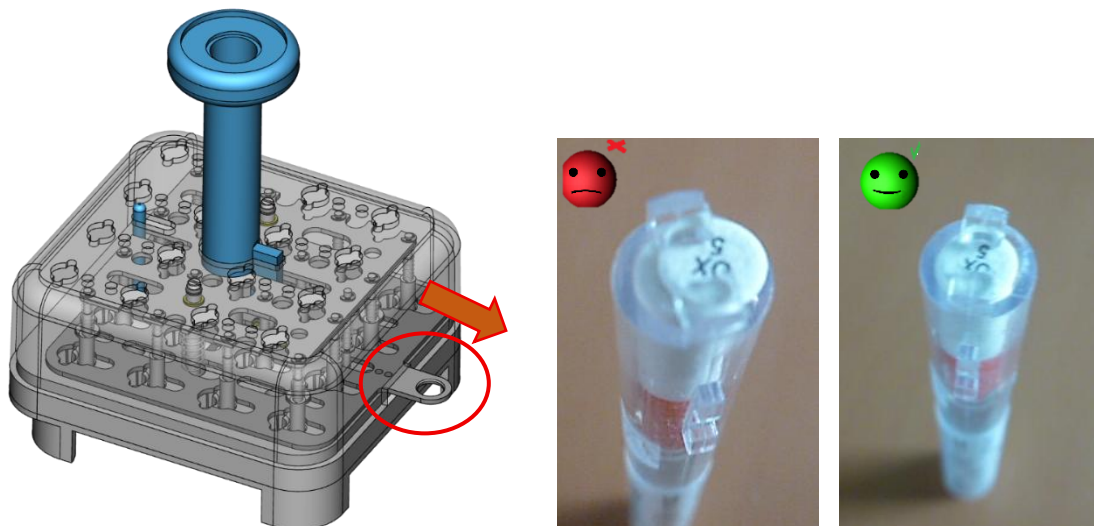
8 Vigilance

Any serious incident occurring in connection with the device must be reported to the manufacturer via the email address reactovigilance@i2a.info and to the competent authority of the country in which the user is established.

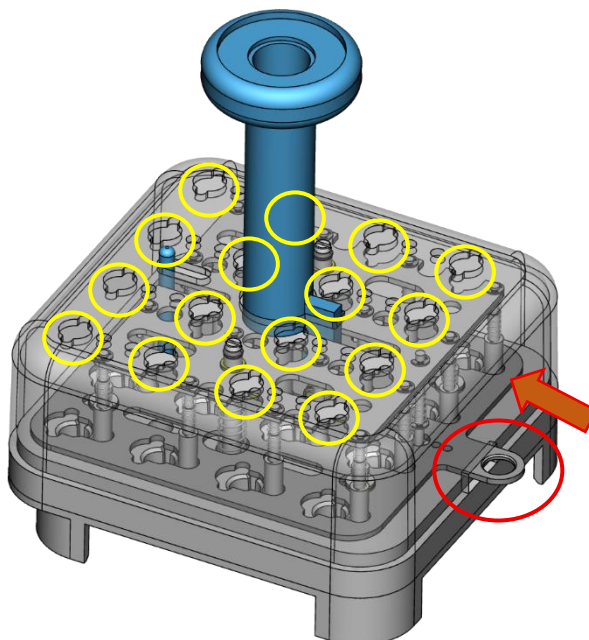
9 Operating instructions

9.1 Inserting the cartridges

Before using the dispenser, it is necessary to install the cartridges of the SIRscan® discs. To do this, simply follow the procedure below:



1. Unlock the dispenser by pulling the metal tab as shown (red circle).
2. Remove the cap from the antibiotic cartridge.
3. Use pliers to recenter the first disc of the cartridge if it is not aligned.

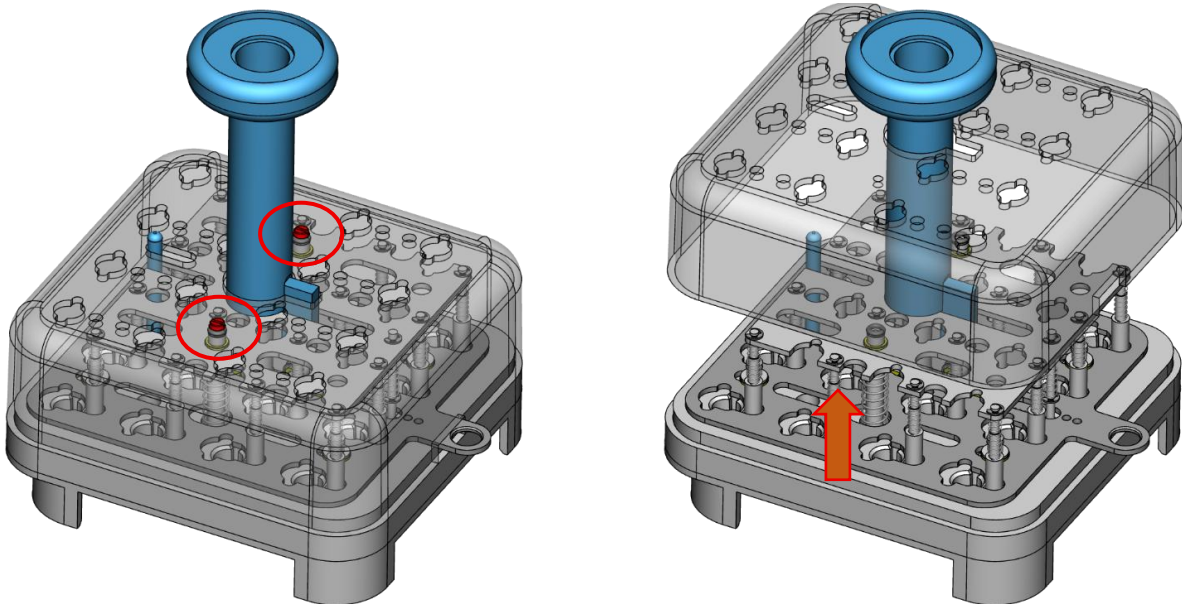


4. Position the desired number of antibiotic cartridges in the dispenser, with the disc facing downwards, until fully inserted (yellow circles).
5. If dispenser locations do not contain antibiotic cartridges, refer to section “8.2 – Agar protection in the absence of a cartridge”.
6. Scan the barcode on the packaging of each inserted cartridge using the handheld scanner (see MU-1897).
7. Lock the dispenser by pushing the metal tab as shown (red circle).

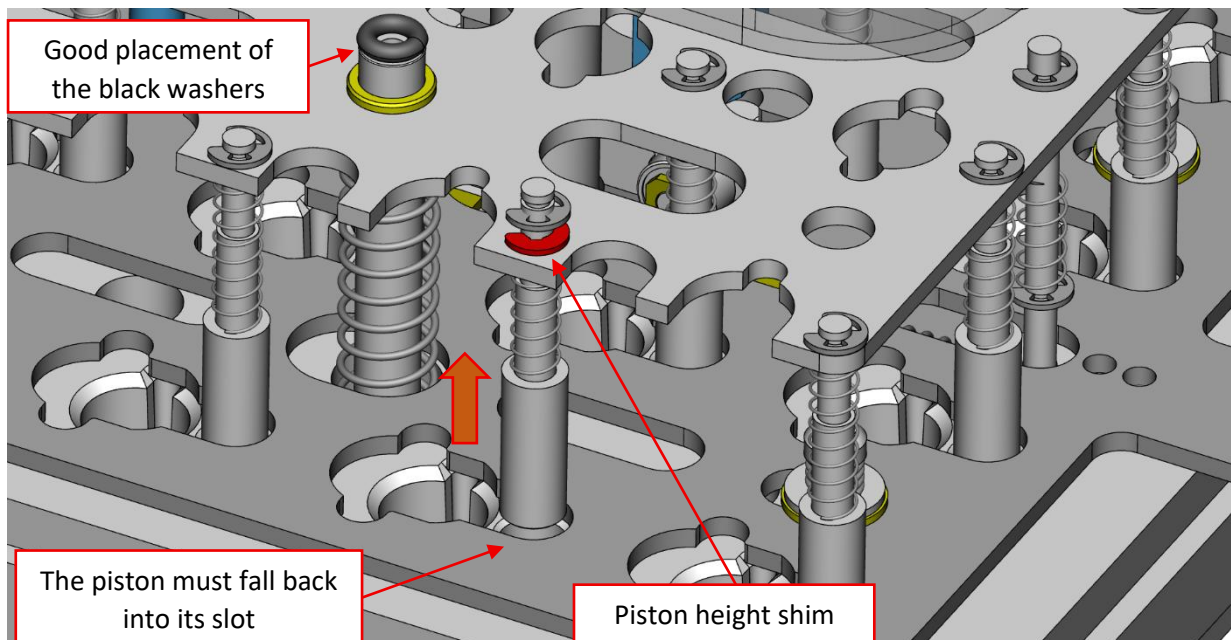
8. Check that the cartridges are correctly inserted by turning the dispenser upside down. The cartridges should not fall out.

9.2 Agar protection in case of cartridge absence

If a slot is not in use, it must be blocked to prevent contamination of the agar. To do this, simply follow the procedure below:



1. Unscrew the 2 plastic screws on the hood and the black washers with the screwdriver provided.
2. Lift the hood (be careful not to lose the two black washers under the plastic screws and the hood).



3. Lift the piston to be protected.
4. Place the piston height shim under the piston retaining circlip.
5. Release the piston.
Place the piston height shim against the metal plate. If it is not properly positioned, check that the piston is correctly seated in its slot.
6. Reposition the hood, ensuring that the two black washers underneath are correctly positioned.



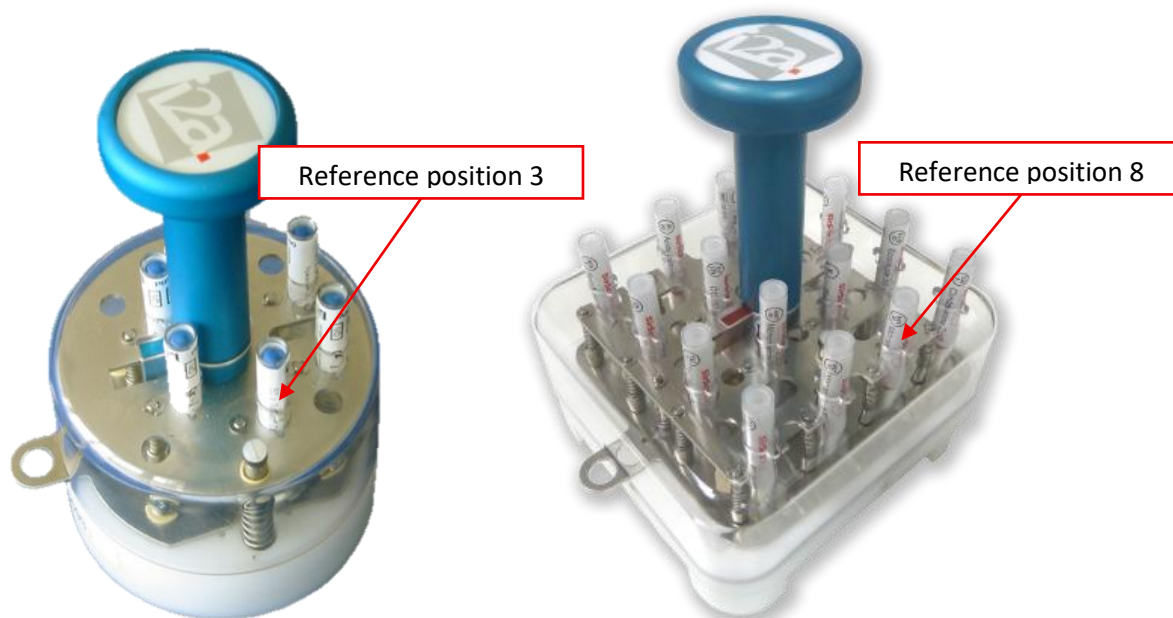
7. Screw the 2 plastic screws onto the cover (and the two black washers) with the screwdriver supplied.
8. Test the dispenser: the piston must not go out from the white base when you push the handle.

9.3 Discs distribution

Once the SIRscan® Discs cartridges are in place, the dispenser is ready for use. To do this, simply follow the procedure below:

The dispenser adapts to the height of the agar thanks to the four height positions of the stem. To place the discs according to the height of the agar, simply follow the following procedure:

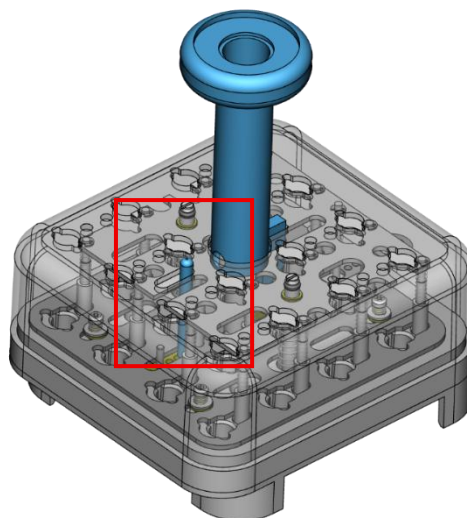
1. Position the agar plate under the dispenser, with the procedure that follows:
 - If the Sirscan label on the agar plate: the barcode must be aligned with the barcode on the dispenser.
 - If there is no Sirscan label on the agar plate: put the agar plate under the dispenser first (no specified position is necessary) then attach the label to the agar plate (refer to cartridge position 3 for round boxes and cartridge position 8 for square boxes).



2. *[during first use]* Put the rod in position 1.
 3. Fully push the dispenser handle.
- Note: In case of a problem, see section "9 - Malfunctions"

When the cartridge discs are on the agar, the following steps are necessary:

4. Release the dispenser handle.
5. Put the lid back on the agar plat
6. Turn the agar plate over: the discs must bond perfectly to the agar.
7. *[During first use]* If the discs does not bond the agar, position the control rod in position 2, 3 or 4 until optimal adhesion is achieved.



9.4 Removal of antibiotic cartridges

Once emptied, the antibiotic cartridges can be removed from the dispenser. To do this, simply follow the procedure below:

1. Unlock the dispenser by pulling the metal tab.
2. Remove the antibiotic cartridges from the dispenser.
3. Remove the piston height shim if necessary.

Finally, clean all parts of the dispenser with 70% denatured alcohol (see section "8.5 - User Maintenance").



9.5 User maintenance

9.5.1 Cleaning the dispenser

Each time antibiotic cartridges are changed, it is recommended to perform a cleaning procedure on the dispenser. To do this, simply follow the procedure below:

1. Remove the cartridge from the dispenser
2. Clean all parts of the dispenser with a lint-free cloth dampened with 70% denatured alcohol:
 - Before first use
 - Before replacing the antibiotic cartridges
 - Every week
 - Before sending the dispenser by postal mail (inter-laboratory transfer; return for repair, etc.)
3. Allow the dispenser to dry.

9.5.2 Dispenser decontamination



No decontamination by autoclave (or any other heat treatment), bleach or acetone.



Do not fully immerse the dispenser in the disinfectant detergent.



Follow the precautions for use and the specific action of the product used.

It is necessary to decontaminate only the lower part of the dispenser (white base under the transparent hood) and the entire exterior of the dispenser with a lint-free cloth soaked in disinfectant detergent at the following frequencies:

- Every week after alcohol cleaning
- If a contamination of the piston occurs because there is no piston height shim (see section "8.2 - Protection of the agar in case of absence of a cartridge")
- After handling that could cause possible contamination of the dispenser (or a part of it)
- Before sending the dispenser by postal mail (inter-laboratory transfer; return for repair, etc.)

If necessary, fully decontaminate the holes in the lower part of the dispenser with a cotton swab soaked in disinfectant detergent. Fully decontaminate the pistons with a cloth soaked in disinfectant detergent (press the central handle to extend the pistons).

9.5.3 Decontamination of the storage box



No decontamination by autoclave (or any other heat treatment).

If the dispenser storage box touches a contaminated dispenser or another contaminated material, fully decontaminate it with a disinfectant detergent.



10 Malfunctions

10.1 Simple malfunctions

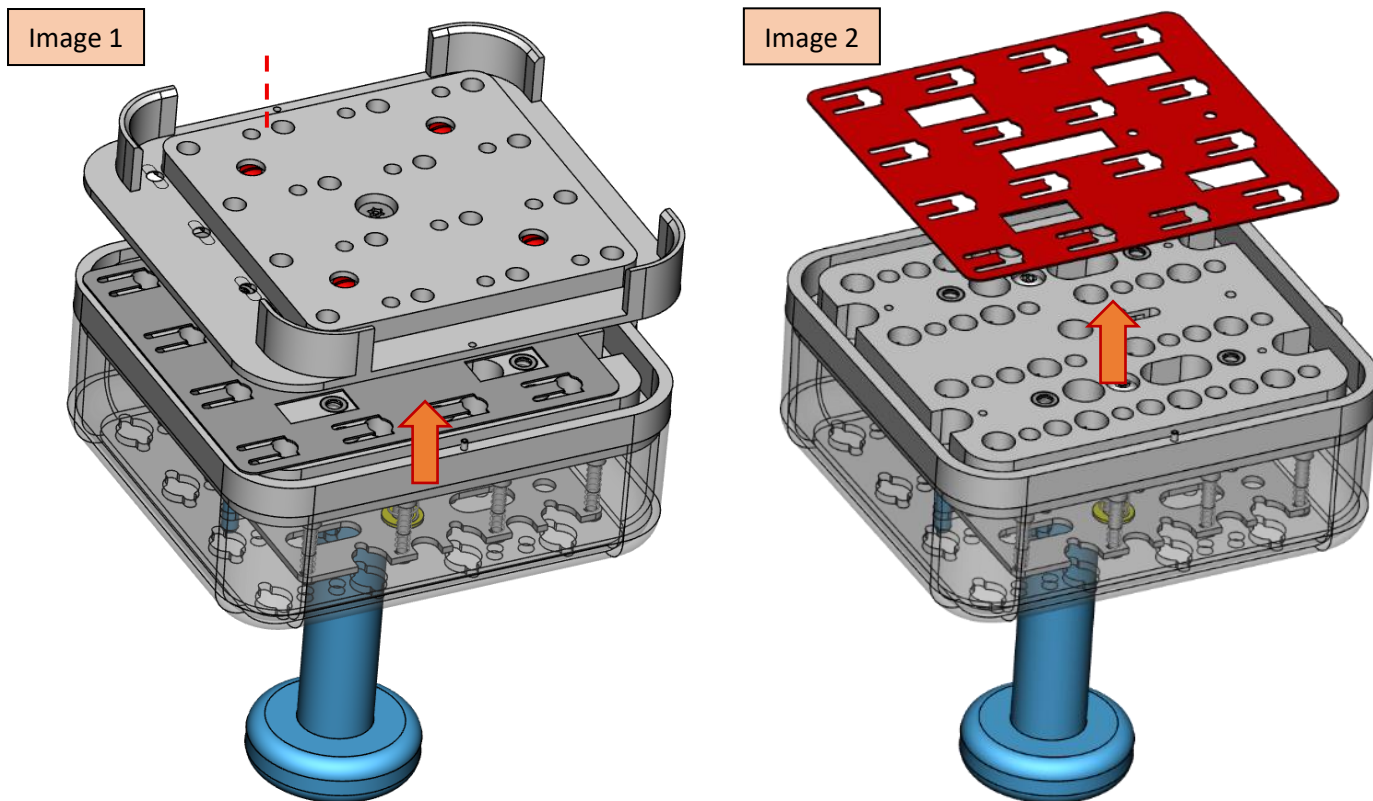
In the event of a dispenser malfunction, the simplest causes are grouped in the table below:

Problem encountered	Probable cause(s)	Recommended solution(s)
No locking or difficult locking	Disc poorly centered in cartridge	Check the position of the disc on the cartridge cf. "9.1- Inserting the cartridges"
	Non-compliant cartridge	Replace the cartridge if both disc retaining tabs are defective.
Discs not enough/too deeply pressed down in the agar	Incorrect adjustment of the dispenser piston height	Adjust the height of the dispenser cf. « 8.3 - Distribution of disks »
	A height adjustment clip and a cartridge are positioned in the same location	Remove the height adjustment clip cf. "8.2 - Agar protection in the absence of a cartridge"
No dispense of the SIRscan® discs	One cartridge is empty	Replace the empty cartridge with a full one cf. "8.4 – Removal of antibiotic cartridges" and "8.1 – Insertion of cartridges"
No dispense of the SIRscan® discs despite being present in the cartridge.	The cartridge is incorrectly positioned.	Place the cartridge correctly in its slot cf. "9.1- Inserting the cartridges"
	The dispenser is not in the locked position.	Lock the dispenser cf. "9.1- Inserting the cartridges"

10.2 Unblocking the dispenser

The dispenser must be unblocked if there is a blockage during locking, unlocking, or if there is a blockage of the cartridges or the cartridge discs. To do this, simply follow the procedure below:

10.2.1 Square dispenser



Prepare a clean work surface to prevent discs expulsion. Turn the dispenser over and disassemble the white base of the dispenser (**Image 1**):

1. Unscrew a quarter turn the 4 screws with the screwdriver provided.

Note: for dispensers with captive fasteners, fully unscrew the 4 captive fasteners.

2. Carefully remove the white base using the screwdriver as a lever.

Next, remove the metal guide plate (**Image 2**), to releasing the cartridges.

Image 3

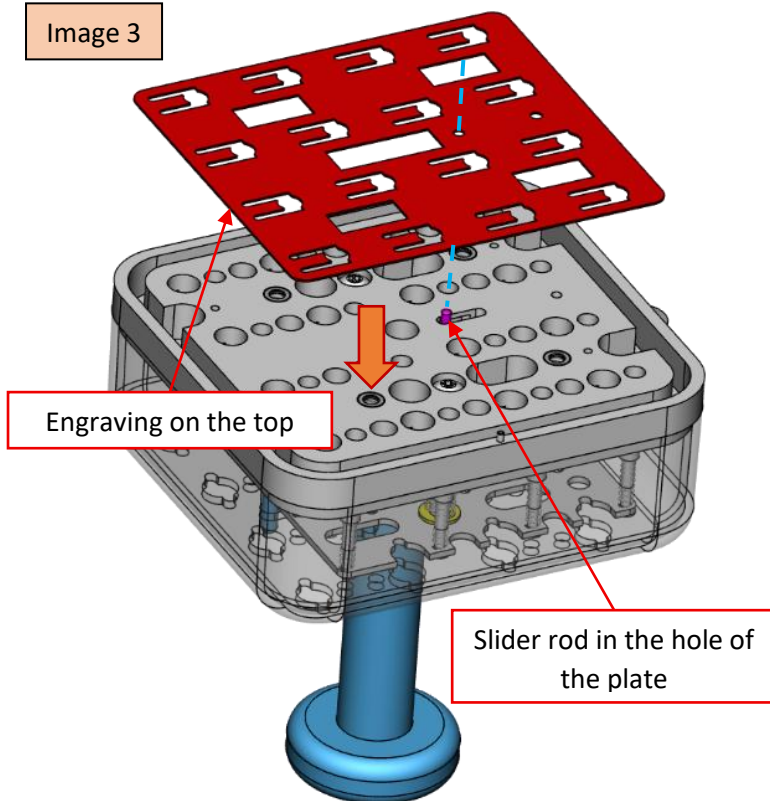
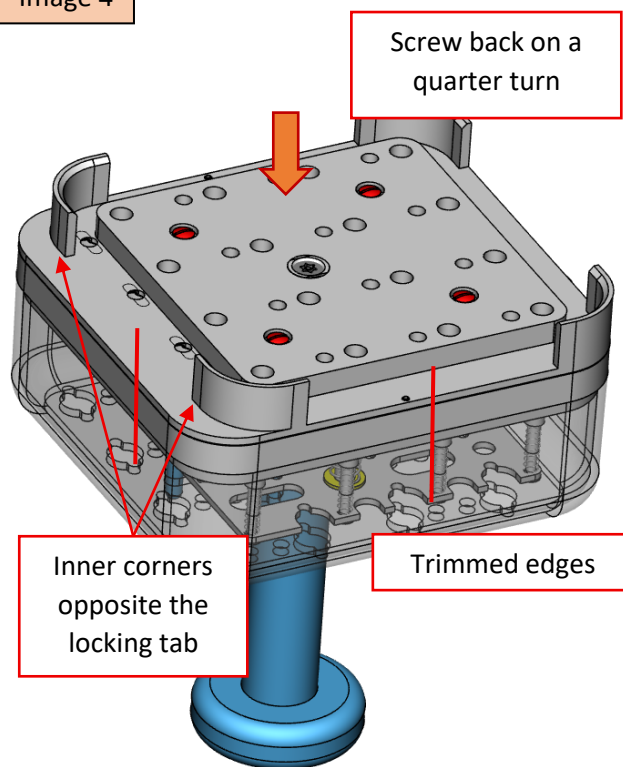


Image 4



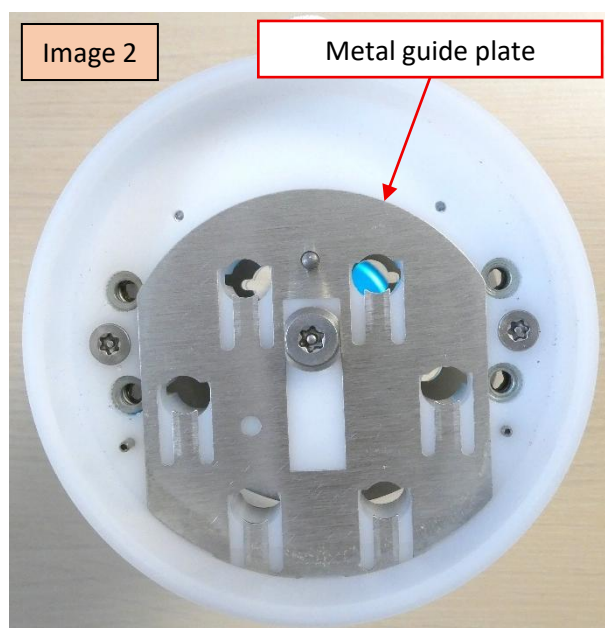
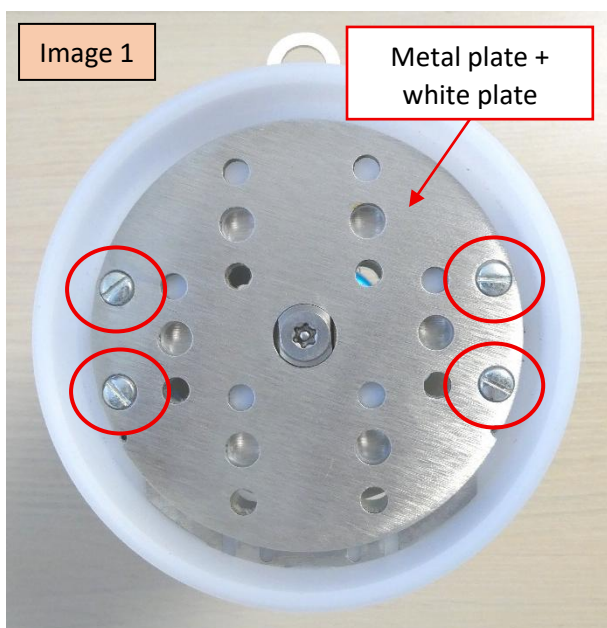
Put back the metal guide plate on the dispenser as shown (**Image 3**), then the white base of the dispenser (**Image 4**) and tighten the 4 screws a quarter turn on the white base with the screwdriver.

Note: for dispensers with captive fasteners, screw the 4 captive fasteners back on completely.

Test the dispenser.

If the problem continues, contact i2a support (see section "1 - Foreword").

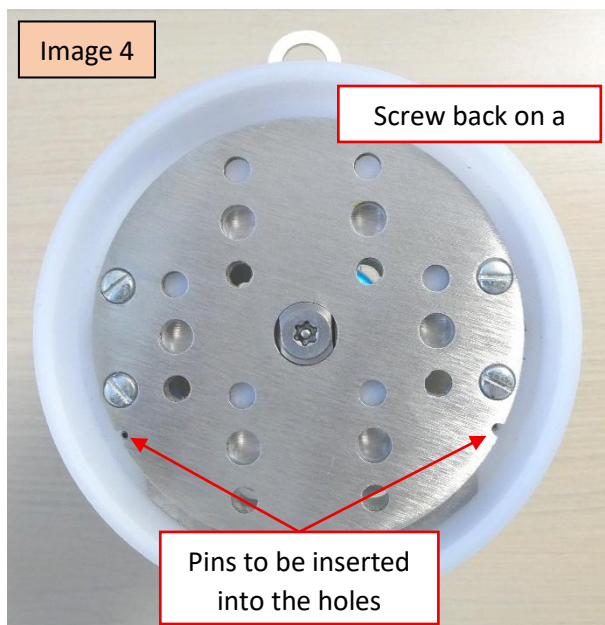
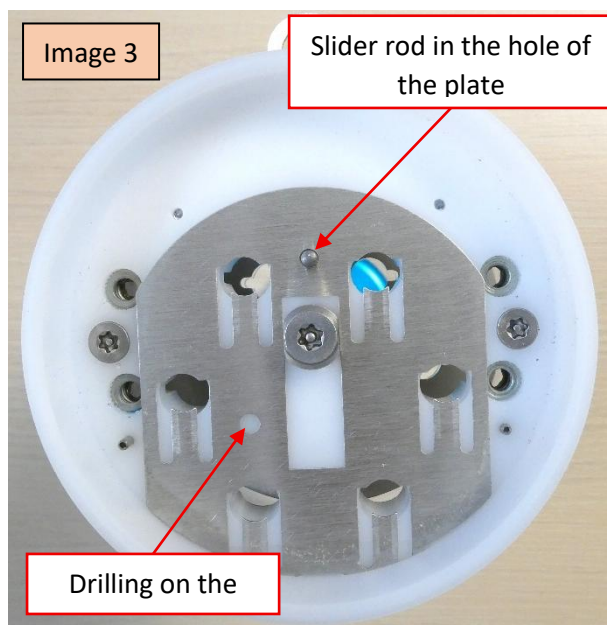
10.2.2 Round dispenser



Prepare a clean work surface to prevent discs expulsion. Turn the dispenser over and disassemble the white base of the dispenser (**Image 1**):

1. Unscrew the 4 screws (red circles) with the screwdriver provided.
2. Carefully remove the white base using the screwdriver as a lever.

Next, remove the metal guide plate (**Image 2**), to releasing the cartridges.



Put back the metal guide plate on the dispenser as shown (**Image 3**), then the white base of the dispenser (**Image 4**) and and tighten the 4 screws a quarter turn on the white base with the screwdriver.

Test the dispenser.

If the problem continues, contact i2a support (see section "1 - Foreword").

END OF DOCUMENT