



SIRscan[®] Lynx

User Manual



Software version: V101.5.11
or higher.

Ref.: MU-2049

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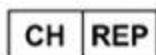
All the documents cited as references are available online on the i2a company website accessible at the address: www.i2a-diagnostics.fr.

MU-1475: Prerequisites for installing a SIRxpert® server workstation

MU-2035: SIRxpert® - Routine

MU-2410: SIRscan® Calibration

MU-710678: SIRxpert® Master - Routine



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Change Tables

Current version:

Updated screens according to version 201.2.2.0 as well as the STAR system.

Version of 24/09/2024:

Updated screenshots following software update 201.1.0.0 and higher.

Version of 18/06/2024:

Change of address for the agent and the Swiss importer.
Modification of the "Computer skills prerequisites" section.

Version of 23/02/2024:

Correction of postal address and website.
Amendment to paragraph 7.3.

Version of 14/04/2023:

Addition of the Swiss agent and the Swiss importer.
Amendment to paragraph 1.
Addition of paragraph 9.4 "Replacement of petri dish support (semi-annual)"

Version of 24/08/2022:

Correction of an error in the table of contents.
Amendment to paragraph 7.3.

1 Foreword

The purpose of this manual is to provide clear and concise support for routine use of the SIRscan® LYNX. The proposed organization can be freely adapted according to the specific needs of the laboratory. However, it has the advantage of streamlining the use of the device in order to get the most out of it.

Reading this manual requires prior knowledge of the use of the SIRxpert® software and the SIRscan® LYNX controller.



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).

VIGILANCE

Any serious incident occurring in connection with the device must be reported to the manufacturer and the competent authority of the country in which the user is established.

2 Warnings

User manuals must be read in their entirety and staff must be trained by i2a or one of its legal representatives before operating the application/instrument.

Always refer to i2a's labeling and instructions to avoid compromising the integrity of the application/instrument.

The user must always operate the application/instrument with full knowledge and the ability to interpret warnings, comments, and alarms.

Personnel using the product must be trained in the use of chemicals and bacteriological risks

The SIRxpert® Master application and i2a instruments comply with the Standards and regulations mentioned in the EU declarations of conformity available on www.i2a-diagnostics.fr.

i2a reagents, consumables and accessories are validated in accordance with European regulations as stated in the EC Declarations of Conformity available at www.i2a-diagnostics.fr. For any other legislation, please contact i2a for more information.

The use of reagents, consumables or accessories other than those supplied by i2a may compromise the performance of the instruments.

In this case, i2a cannot be held responsible for the results generated on a configuration of this type.

Appropriate laboratory protective equipment such as gloves, goggles, and a lab coat must be worn by the user.

Local or national regulations must be applied in all operations.

All peripherals must comply with relevant standards.

2.1 Warranty limitations

The warranty period is stipulated in the general terms and conditions of sale associated with the purchase of this application/instrument.

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

1. The SIRxpert® application must be installed on computers provided or approved by i2a.
2. The application/instrument is used according to the instructions in this document and the relevant manuals.
3. Only the software or hardware specified by i2a should be installed on the system. This software must be the original, copyrighted version.
4. Services and repairs are provided by an i2a-authorized technician, using only i2a-approved spare parts.
5. The laboratory's power supply must comply with national regulations. The mains power cord to be used must be certified in accordance with the regulations in force in the country.
6. The samples are collected and stored under normal conditions.
7. The reagents, consumables and accessories used are those specified in this document as well as in the associated manuals and user guides.
8. Appropriate tools are used during maintenance or troubleshooting operations.



If this device was supplied to you by someone other than i2a or an i2a authorized representative, i2a cannot guarantee this product in terms of specifications, latest revision and latest documentation.

Further information can be obtained from your i2a representative.

2.2 Safety precautions

The SIRxpert® application is a middleware application that works within the framework of diagnostic medical devices that contain electronic/electrical components and moving parts.

The following parts must not be handled or controlled by the user:

- Power supply
- Electronic components

Otherwise, the operator may suffer injuries from an electric shock. Electronic components can shock and injure the user.

Do not alter the device or remove its components (covers, doors, panels, etc.) unless otherwise indicated in this document.

- Moving parts:

It is strictly forbidden to disable the sensors, as this risks causing injury to the operator.

The protective covers must not be opened during operation of the device.

2.3 Biological risks



Consider all samples, specimens and reagents as potentially infectious! Use good laboratory work practices when handling samples.

Wear all protective equipment such as: gloves, lab coat, safety glasses and/or face shields, and comply with all safety practices in effect in your territory as specified in the OSHA recommendations for bloodborne pathogens (29 CFR part 1910.1030) as well as any equivalent biosafety procedures.



All accessible surfaces of the device can potentially be contaminated and represent a biological risk. The operator must wear gloves and a lab coat. Local and national regulations must be applied to all operations.

i2a recommends the use of SURFA'SAFE Premium type disinfectant products from ANIOS for decontaminating the device and strongly recommends their use. Refer to the device's cleaning instructions for cleaning and decontamination.

2.4 Chemical risks



All chemicals must be stored and handled as recommended in their associated safety data sheets.

3 Terms of Use

Failure to comply with the terms of use and safety instructions may compromise user safety. Under no circumstances is the user authorized to dismantle the automated system.

The user must exclusively use consumables that have not exceeded their expiry date according to standard CE1 61010-2-101.

The use of the automated system is reserved for qualified personnel and is subject to training and authorization. The user manual must be read in its entirety and the **referent personnel** must be trained by i2a or one of its legal representatives before operating the application/instrument.

3.1 Environment

The operation of the SIRscan® LYNX and the SIRxpert® application installed on a computer is designed for professional laboratory use .

Contact your local i2a representative for advice on its use in environments that do not meet the recommended specifications.

A barcode printer can be supplied with the machine and uses the open-source software NiceLabel; the terms of use are available at the following address: <https://www.nicelabel.com/legal/open-source-components/#software>

3.2 Location

The application/instrument must be placed on a flat, clean, and level table or workbench.

Avoid direct exposure to sunlight.

Position the device so that it is not exposed to water or steam.

Position the device so that it is free from vibrations or shocks.

Place the device near an independent power supply. Be careful not to position the device in such a way as to make it difficult to operate the disconnecting device. The power cord acts as a disconnecting device.

Good ventilation is necessary. Provide at least 3.5cm of space at the rear of the device to prevent the power supply from overheating.

The ON/OFF switch and the power outlet must always be accessible: the emergency stop is done via this switch.

When positioning the system for operational use, leave the space required for easy access to these elements.

The SIRscan® LYNX should only be moved by authorized and trained personnel.

3.3 Grounding

Proper grounding is required when installing the system.

Check the availability of earth on the wall socket for grounding.

This verification must be carried out by authorized personnel only.

If you are unsure about the equipment's grounding, contact your electrical engineer to verify the grounding.

3.4 Electromagnetic environment control

The application/instrument has been designed to fall below the accepted level of electromagnetic interference in order to function in accordance with its intended use, allowing other devices to also function in accordance with their intended use.

Do not use strong magnetic field emitters (e.g., mobile phones, portable radios, automatic door openers and closing devices, elevators) near the device.

3.5 Environmental protection

3.5.1 Disposal of accessories and consumables

They must be collected by a laboratory specializing in the disposal and recycling of this type of material in compliance with local legislation.

3.5.2 Instruments

They must be disposed of in accordance with local legislation and treated as being contaminated with potentially infectious materials. Appropriate biological precautions must be taken.

Information on the disposal of electrical and electronic equipment and the disposal of batteries and accumulators:



The crossed-out wheeled bin symbol with an underline on the product or accompanying documents indicates that the product requires appropriate treatment, collection and recycling of electrical and electronic equipment (WEEE) under Directive 2012/19/EU, and/or batteries and accumulators/waste under European Union Directive 2006/66/EC.

The symbol can be associated with the chemical symbols below (Cd, Pb, Hg). In this case, it is subject to the requirements of Directive 2006/66/EC for the chemicals in question.

This product must not be disposed of with unsorted household waste.

3.6 Transport and storage conditions

Storage temperature: between 5°C and 50°C (or between 40°F and 122°F)

Before shipping a device by carrier, regardless of the destination, external decontamination of the device must be carried out.

3.7 Symbols

All the labels below are present on the SIRscan® LYNX

	Indicates the manufacturer of the medical device
	Indicates the date on which the medical device was manufactured
	Indicates a medical device intended for use as an in vitro diagnostic medical device
	Indicates to the user that it is necessary to consult the instruction manual.
	Indicates to the user that the instruction manual must be read.
	This designates the manufacturer's serial number so that a specific medical device can be identified.
	Provide the manufacturer's reference number so that the medical device can be identified.
	Indicates that the devices comply with the provisions of the only European regulations applied by the manufacturer
	Do not dispose of electronic products with household waste.

3.8 Interconnection instructions

	Universal Serial Bus or USB is a standard relating to a serial computer bus used to connect computer peripherals to a computer or any type of device designed for this purpose. The USB bus allows for hot-connecting peripherals (when the computer is on) and benefits from Plug and Play, which automatically recognizes the device. 2 USB ports available on the SIRscan® Lynx - 1 USB port for connecting the color camera - 1 USB port for connecting the LED lighting
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4 Unpacking and installation

4.1 Transportation

The transport will be carried out by a service provider.

4.2 Unpacking and installation

Unpacking, installation and any movement of the device must be carried out by a responsible authority.

5 General presentation of the SIRscan® LYNX instrument

The SIRscan® LYNX is an antibiogram reader in agar medium.

The automated system allows control of the steps of the antibiogram, namely reading, expertise, editing and transmission of results.

The SIRscan® LYNX allows standardization of the antibiogram bench with traceability facilitating laboratory accreditation.

The SIRscan® LYNX allows you to read all types of plates:

- Plate 55 mm
- Round 90 mm
- Round 140 mm
- Square 120 mm

The SIRscan® LYNX consists of the following elements:

- A SIRscan® LYNX reader consisting of a drawer
- A 24" screen
- A PC
- The SIRxpert® Antibiogram module
- SIRxpert® Bidirectional

Optional extras:

- A barcode printer (Accessory)
- Barcode scanner
- SIRxpert® Abbreviations (when using i2a disks)
- SIRxpert® batch traceability (when using i2a disks)

5.1 Technical specifications and installation

5.1.1 Technical specifications

- Dimensions (mm): 210 L x 420 H x 540 D
- Net weight: 8 kg
- Installation category: II
- Pollution level: 2
- Mains voltage: 100-240 VAC, 60-50 Hz
- Power consumption: 30 W max
- Heat dissipation: 341 Btu/hr

Operating conditions:

- For indoor use.
- Temperature: from 19°C to 26°C
- Voltage: Fluctuation of the mains voltage up to +/-10% of the nominal voltage.

For the automated system to function correctly, it is necessary to provide a support, taking into account:

- From the PC and the screen.
- The arrangement of Petri dishes to be read and already read.
- Access points for maintenance interventions.

5.1.2 Electric

The SIRscan® LYNX is protected by 2 T 6.3 AL reference input fuses.

The system meets the requirements of European regulations concerning In Vitro Diagnostic Devices.

It is preferable that the SIRscan® LYNX be connected to a dedicated UPS (be careful not to connect the printer or the screen to the UPS).

The power switch for the SIRscan® LYNX is located on the rear right side of the device.

5.1.3 Computer network

The SIRscan® LYNX must be connected to the laboratory network in order to benefit from all functionalities, including remote maintenance.

It is therefore necessary to provide two RJ45 10/100BASE-T network sockets nearby (preferably <10 m) to connect the SIRscan® LYNX and the barcode printer to the network.

5.1.4 Environmental

Place the SIRscan® LYNX in a room at ambient temperature (between 19 and 26°C); its performance decreases in very cold or very hot environments. Do not place the SIRscan® LYNX near a heat source to avoid overheating.

It is necessary to allow a space of 3.5cm around the ventilation openings, and that they are not obstructed.

5.1.4.2 Computer prerequisites

The SIRscan® LYNX operates under a SIRxpert® system which requires a dedicated server that meets the server prerequisites (see MU-1475), running under ADS 12v2 and SIRxpert® V101.5 minimum.

It is **mandatory** that the SIRscan® LYNX be installed on the same VLAN as the server where the SIRxpert® application is installed.



The installation of the antivirus software is the responsibility of the laboratory's IT department in order to guarantee optimal security of the automated system.

The latter must be **obligatorily** configured by excluding the following directories from real-time analysis (and not from scheduled analysis):

C:\ImageBank
C:\Sirweb
C:\Program Files (x86)\Advantage 12.0
C:\SirwebdbADS\
C:\BASESIR
C:\opencv
C:\MinGW
C:\Program Files (x86)\PxeLINK

If a local or domain firewall other than Windows Firewall is in use, it is best to disable the Windows Firewall in the "Control Panel" (note: keep the "Firewall" service active).

For the software or router acting as a firewall, the following ports must be allowed in the following directions: inbound **and** outbound:

- 20, 21: FTP
- 25, 465 or 587: SMTP address depending on the one provided by the client.
- 139, 211, 250-255, 445, 2000-2030: TCP
- 6262: TCP/UDP

6 Use cases – routine use

In order to start using the SIRscan® LYNX, it is imperative that all the settings have been done beforehand (See MU-2035 – SIRxpert® - Settings)

6.1 Automate startup

Turn on the SIRscan® LYNX by pressing the main switch located on the rear right side of the machine near the power cord.

Turn on the PC.

The Windows® operating system is loading (this step may take several minutes).

A Windows® window appears and asks for a username (default "i2a") and a password (default "i2a") for access to Windows®. Pressing "Enter" displays the Windows® desktop.

6.2 Starting SIRxpert®

The SIRscan® LYNX controller requires that the acquisition service be started (see Troubleshooting chapter).

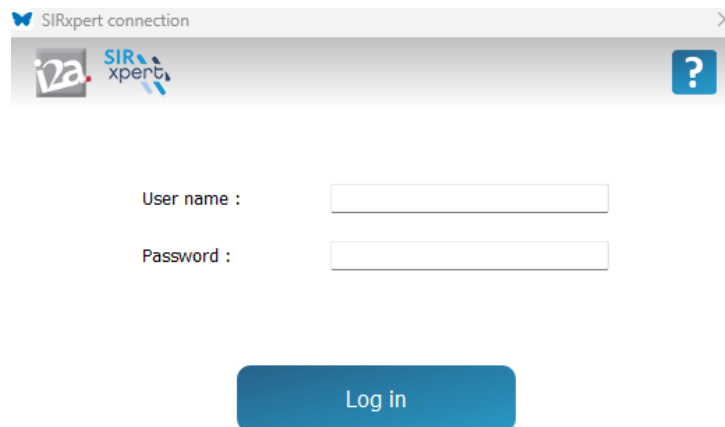
Also, on the server, various services (routine, log and http) must be started as well as the driver.

To check that it has started, you need to look for the presence of the  icon in the Windows® taskbar, at the bottom right.

If this is not the case, start it by double-clicking on its icon.

To start the SIRxpert® application, click on the  icon on the desktop.

Once on the identification window, enter the authentication information (username, password and work session if the laboratory uses it) to arrive at the general menu of SIRxpert®.



SIRxpert connection

i2a SIRxpert ?

User name :

Password :

Log in



The work sessions allow direct access to certain pre-configured modules. Thus, they allow for the personalization of the workstation according to its role and offer the possibility of having an overview of the laboratory's activity.

The configuration of work sessions is detailed in the SIRxpert® configuration manual (Ref MU-2035).

The system then displays the SIRxpert® general menu:



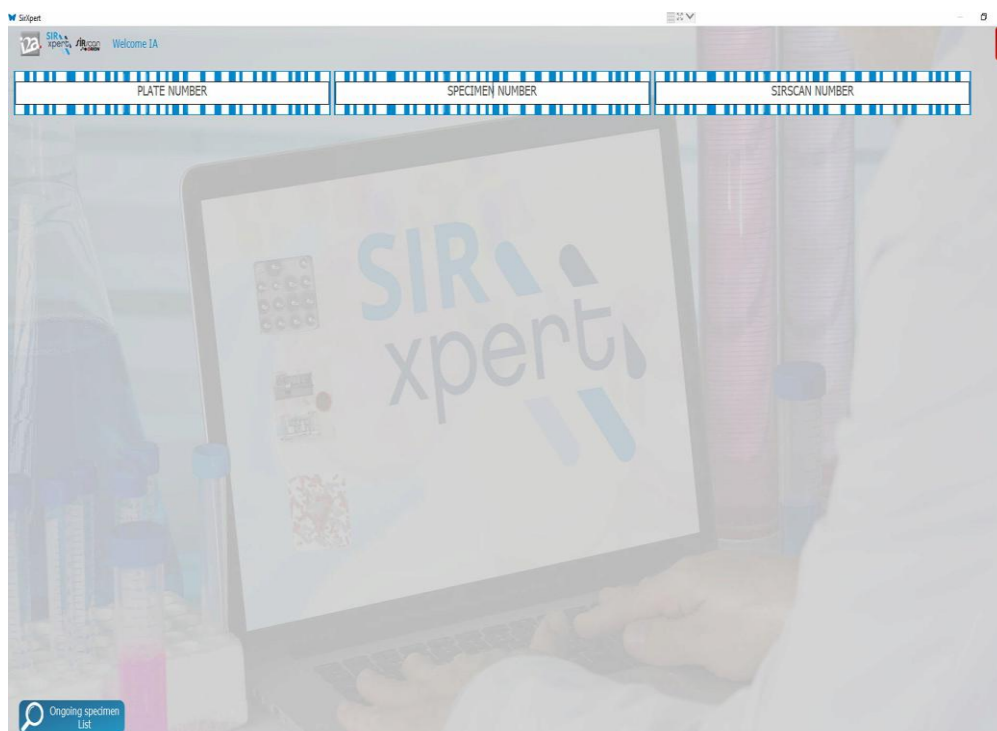
6.3 Case No. 1: No traceability management of antibiotic batches

6.3.1 Manual reading

To access manual reading, from the SIRxpert® general menu, go to the menu **Antibiogram > SIRscan >**

Manual reading .

The following window opens.



Enter the patient file request number.



The system cannot read an unknown request number.

However, if the request is correctly recognized, then SIRxpert® displays the patient's demographics in the "information on the attached request" plate:

Request number	: TEST	Patient number	: TEST	Name	: TEST
First name	: TEST	Gender	: Inconnu	Birthdate	:
Hospitalisation date	:	Stay number	:	Department	: Ward 7C RLH
Laboratory	:	Physician	:	Sampling date	: 14/02/2020
Sample type	: Urethral Swab	Sample origin	:	Body site	:

If IDE (identifications only) or ATG type analyses are attached to the request, then the software displays a window to allow the association of plates being loaded with these IDE and/or ATG analyses.



-  : attached AST (partially or fully loaded)
-  : An ID without AST is attached to the specimen

If the plate being read corresponds to one of the germs (same isolate) presented in the list, simply select the isolate in order to link the plate to that isolate.

To read an antibiogram that does not match pre-existing analyses, click on button  to create a new identification:

Species	
Isolate number	1 
Identification complement	
MS SCORE	

Enter the various identification details and click on the  button to validate.



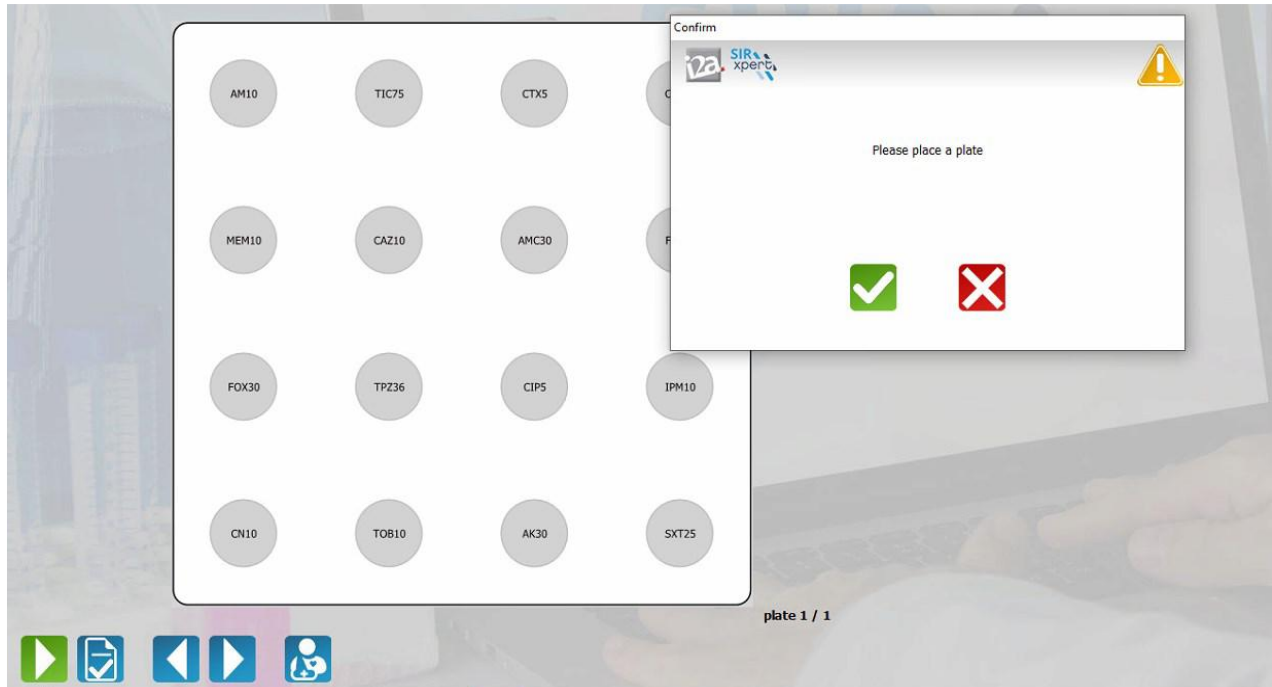
Once the germ is selected, the system displays the compatible antibiograms for that germ.

Then select the antibiogram to read and click on the  button.

If necessary, the  button allows the antibiogram to be read manually, i.e. without reading by camera by the automaton.

Open the drawer so that you can place the plate on top of the drawer. To do this, press on the drawer to unlock it and then open it.

Place the plate according to the orientation indicated by the diagram displayed by the SIRxpert®.



Once the plate is inserted into the felt of the automaton, close the drawer and click on the  button to start reading.

Once the plate has been read, a "Read successfully" message appears. Several actions can then be performed:



- Go to reading validation: allows you to go directly to the reading validation menu.
- Back: allows you to return to reading.
- Switching to the previous plate: allows you to reread the previous plate (when a panel is composed of several plates)
- Moving to the next plate: allows you to read the next plate (when a panel consists of several plates)

Once you have finished reading, go to the "validate readings" menu.

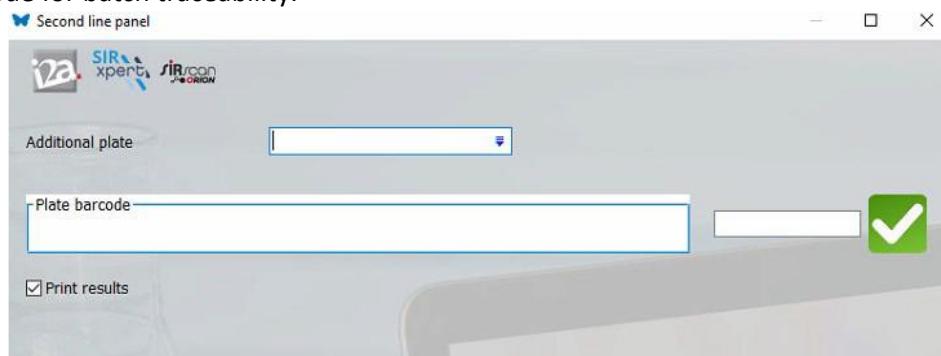
6.3.2 Manual reading of an additional plate

6.3.2.1 From manual reading

After reading an antibiogram manually, it is possible to read an additional plate. To do this, right-click on the antibiogram already read and select "Additional Plate":



The list of additional plates appears, select the desired plate from the drop-down menu and assign the plate's barcode for batch traceability.



It is also possible to directly scan the unique barcode for manual reading as well.

6.3.2.2 From Specimen Management/Reading validation

It is possible to read an additional plate to a given antibiogram by going through the "Specimen Management" or "Reading Validation" menus.

To do this, from the SIRxpert® main menu, go to the menu **AST > Specimen Management**  or **Antibiogram > SIRscan > Reading Validation** .

Select the analysis, then click on the  button and select "Read the second intent".

The list of additional plates appears, select the desired plate from the drop-down menu and assign the plate's barcode for batch traceability.

Second line panel

Additional plate

Plate barcode

☒ Print results

It is also possible to directly scan the unique barcode for manual reading as well. To print the results on the results sheet, please check the "Edit results" plate.

6.3.3 Adding an additional antibiotic

It is possible to add a result from an antibiotic that was not included in the antibiogram settings (e.g., MIC strip).

To do this, from the SIRxpert® main menu, go to the menu **Antibiogram > Specimen Management**  or **Antibiogram > SIRscan > Reading Validation** .

Select the analysis, then click on the  button and select "Add an additional antibiotic".

The following window appears:

Add antibiotics

Additional antibiotic 1 *Please confirm the choice by clicking on enter*

Barcode (Sirscan Disc) 2

Lot number 3

Expiry date 4

Results

☐ Diameter value 5

☐ Operator 6 M.I.C. value 6

☐ Raw result 7

☒ Print result

1. Select the desired antibiotic from the drop-down menu and press the "Enter" key.
2. If necessary, scan the barcode available on the packaging of the i2a antibiotic disc.
3. If necessary, enter the batch number of the i2a antibiotic disc.
4. If necessary, enter the expiry date of the i2a antibiotic disc.
5. If necessary, enter the disk diameter values.

6. If necessary, enter the MIC values from the strip.
7. If necessary, enter the gross result (S, I or R).
8. Just like second-line antibiograms, the result of an additional antibiotic is automatically edited if the "☒ Edit result" plate is checked.
9. Allows for the addition of another antibiotic and the performance of a single assessment.

Once the reading is complete, the SIRxpert® will re-evaluate the antibiogram, taking into account the additional result(s), and will then display an updated results sheet.

6.4 Case No. 2: Managing the traceability of antibiotic batches with i2a discs

6.4.1 In the case of using unique barcodes

6.4.1.1 Label printing

The identification expert allows an antibiogram (or an additional plate) to be assigned directly during the creation of the identification according to various criteria: germ, samples, services, origin of the file, result of a section, etc...

To print barcodes, you need to go to the folder management (the creation of several filters is described in the SIRxpert® user manual - Parameter setting, ref MU-2035).



Select the IDs to print the labels and click on the button.

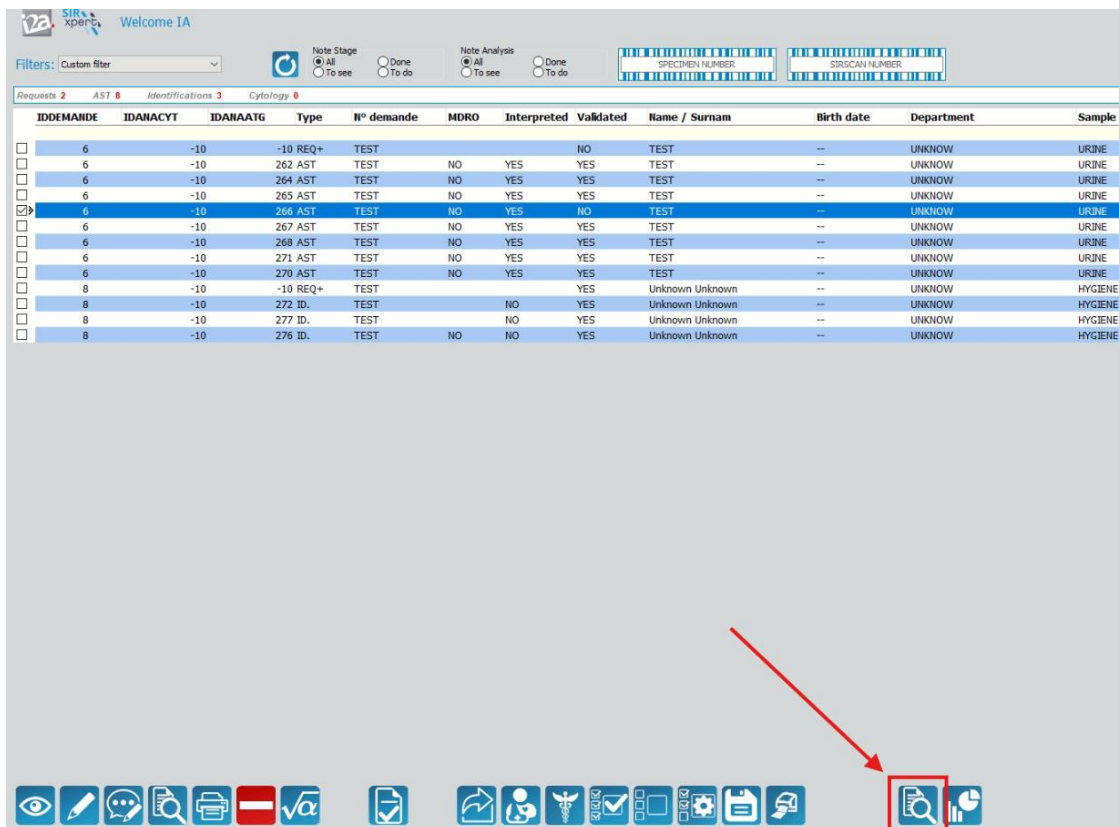
The screenshot shows the SIRxpert software interface. At the top, there's a header with the SIRxpert logo and 'Welcome IA'. Below it, there are tabs for 'Requests 2', 'AST 8', 'Identifications 3', and 'Cytology 0'. A 'Filters: Custom filter' dropdown is visible. Below the tabs, there are two sections: 'Note Stage' and 'Note Analysis', each with radio buttons for 'All To see', 'Done To do', and 'To do'. To the right of these are two barcode displays labeled 'SPECIMEN NUMBER' and 'SIRSCAN NUMBER'. The main part of the interface is a table with columns: IDDEMANDE, IDAHACYT, IDAHAAATG, Type, N° demande, MDRO, Interpreted, Validated, Name / Surnam, Birth date, Department, and Sample. The table contains 15 rows of data. At the bottom, there is a toolbar with various icons. A red arrow points to the icon representing label printing, which is a document with a printer icon.

IDDEMANDE	IDAHACYT	IDAHAAATG	Type	N° demande	MDRO	Interpreted	Validated	Name / Surnam	Birth date	Department	Sample
6	-10	-10 REQ+	TEST				NO	TEST	--	UNKNOW	URINE
6	-10	262 AST	TEST		NO	YES	YES	TEST	--	UNKNOW	URINE
6	-10	264 AST	TEST		NO	YES	YES	TEST	--	UNKNOW	URINE
6	-10	265 AST	TEST		NO	YES	YES	TEST	--	UNKNOW	URINE
6	-10	266 AST	TEST		NO	YES	NO	TEST	--	UNKNOW	URINE
6	-10	267 AST	TEST		NO	YES	YES	TEST	--	UNKNOW	URINE
6	-10	268 AST	TEST		NO	YES	YES	TEST	--	UNKNOW	URINE
6	-10	271 AST	TEST		NO	YES	YES	TEST	--	UNKNOW	URINE
6	-10	270 AST	TEST		NO	YES	YES	TEST	--	UNKNOW	URINE
8	-10	-10 REQ+	TEST				YES	Unknown Unknown	--	UNKNOW	HYGIENE
8	-10	272 ID.	TEST			NO	YES	Unknown Unknown	--	UNKNOW	HYGIENE
8	-10	277 ID.	TEST			NO	YES	Unknown Unknown	--	UNKNOW	HYGIENE
8	-10	276 ID.	TEST		NO	NO	YES	Unknown Unknown	--	UNKNOW	HYGIENE

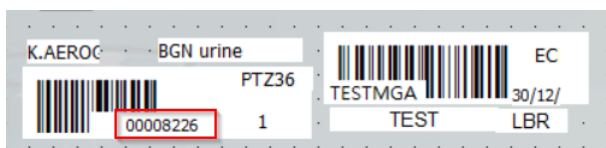
If there is a problem with the labels, it is possible to use the "SIRscan Number" without printing. To do this,



from a SIRxpert® filter, click on the "SIRscan barcode display" button at the bottom right of the filter:



This allows you to view the label that should have been printed and note the number:



6.4.1.2 Performing the antibiogram



Once the barcode label is printed, the antibiogram can then be prepared.
To begin, stick the label on one of the sides of the plate.



Seed the plate.

It is recommended to carry out antibiograms using the SIRscan® kit (ref. 041003) composed of inoclic, SIRscan® Swab and a 0.7mL tube of physiological water in order to have a standard inoculum and to limit the presence of streaks on the agar plates.

Use an i2a dispenser to place the discs onto the agar. The antibiotic indicating the reference position is in position 3 for round plates and in position 8 for the square plate.

i2a dispensers have a label in the correct position, so you just need to align the two labels on the same side (plate and dispenser) and then place the discs in.



No label should be stuck underneath the plate. This action may stop playback.

6.4.2 Link to dispensers

If the laboratory uses i2a antibiotic discs with antibiotic batch traceability activated. If several dispensers are used for the same plate, it is necessary to link the plates to dispensers (very special case).

To do this, from the SIRxpert® main menu, go to the menu **Antibiogram > SIRscan > Linking plates and dispensers** .

Scan all plate barcodes stuck on the plates in the "SIRscan Number" plate (1). Then scan the dispenser's barcode in the "Dispenser Serial No." plate (2):

Specimen number	Complete isolate num	Identification	AST	plate	Plate barcode

In this case, all plates that have been scanned will be assigned with the batch numbers of the antibiotics present in the dispenser.

TESTVANESS	6	42	ETS ORJON	Boîte antibiogramme	00000185
TESTVANESS	7	42	ETS ORJON	Boîte antibiogramme	00000187
TESTVANESS	8	42	ETS ORJON	Boîte antibiogramme	00000189
TESTVANESS	9	42	ETS ORJON	Boîte antibiogramme	00000191

Each time the batch number changes, the dispenser must be modified and then the new plates scanned; the new dispenser will then be assigned.

The  button allows you to delete a plate that was scanned in error. And the  button allows you to clear the entire entered list.

6.4.3 Reading

6.4.3.1 Reading with barcode label

For manual reading, refer to chapter "6.3.1 Manual reading" and select the field "**SIRscan number**" (on the right). This will allow the request to be linked to the antibiogram plate as well as the batch numbers during reading.



6.4.3.2 Label-free barcode reading

In the absence of a label, it is still possible to manage batches of antibiotics with i2a discs. This management method is less precise and should only be used in degraded mode (no printing).

For each selected antibiogram, if the request number is scanned (instead of the unique SIRscan number), the system will display the plates that make up the antibiogram.

Then select the antibiogram to read, and the system will display the plates that make it up.

Dispenser(s) linked to that panel

ETB 1		☒
ETB R		☒

☒ Lot traceability management

- To be able to perform traceability, simply scan the plate barcode on each corresponding frame.
- It is possible to uncheck traceability management; in this case, no batch traceability will be recorded for this reading.

The  button allows the antibiogram to be read manually, i.e. without reading by camera by the automaton.

If traceability information is not provided and the "☒ Lot Traceability Management" plate is checked, the following message appears to allow the use of current batch numbers:

SIRxpert

Do you want to use this dispenser ETB 1 ?
Barcode identified by this sequence: XXX0003XXX

Yes No

No traceability

There are 3 possible choices:

- Yes: uses current batch numbers.
- No: refer to the previous menu to scan plate numbers and have batch traceability.
- No traceability: batch traceability will not be done on this reading.

Once the option is chosen, the reading can be performed.

In the case of additional plates, the list of additional plates appears, select it from the drop-down menu and assign the plate barcode for batch traceability.

Additional plate

Plate barcode

☒ Print results

☒

It is also possible to directly scan the unique barcode for manual reading.

7 Validation of antibiograms

7.1 Validation of readings

The reading validation step allows the diameters read by the SIRscan® LYNX to be validated as well as the predefined tests.

It is possible to create specific filters for validating readings.

The setting of filters/Reading validations is presented in the SIRxpert® setup manual included in the start-up documents (ref. MU-2035).

The interpretation will be done from any client workstation using read validation.

To do this, from the SIRxpert® main menu, go to the menu **Antibiogram > SIRscan > Reading Validation**



Filters are predefined to access the various unvalidated antibiograms.

It is possible to create others to refine these validations (by service, samples, laboratory, etc.).

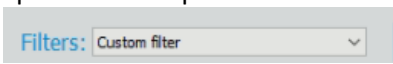
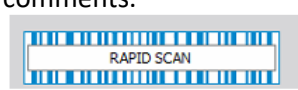
The setting of these filters is described in the SIRxpert® (MU-2035) setting manual.

The screenshot displays the SIRxpert software interface. The top section shows a table of antibiogram results with columns for time, sample ID, date, patient name, sex, age, test name, result, and status. The bottom section shows a grid of images for validation, with a toolbar at the bottom for navigation and editing.

Time	Sample ID	Date	Patient Name	Sex	Age	Test Name	Result	Status				
06:27:00	ATG	100028970940	19/02/2024	Inconnu	COLI 25922	1	ENTEROBACTERIES URINAIRES 201URINES	21	EXT	NON	3843128	
07:03:00	ATG	100028970941	19/02/2024	Inconnu	COLI 25922	1	ENTEROBACTERIES NON URINAIRE:PUS SUP.		EXT	NON	3843128	
07:09:00	ATG	100028971021	19/02/2024	Inconnu	SA 29213	1	STAPHYLOCOQUES 2017 URINES	21	EXT	NON	3843141	
07:07:00	ATG	100028971047	19/02/2024	Inconnu	KPI 700603	1	ENTEROBACTERIES NON URINAIRE:PUS SUP.		EXT	NON	3843148	
05:56:00	ATG	100028972815	19/02/2024	Féminin	E.COLI	1	ENTEROBACTERIES URINAIRES 201URINES	21	EXT	NON	1855914	
06:47:00	ATG	100028972945	19/02/2024	Féminin	K.PNEUMONI	1	9,559	ENTEROBACTERIES URINAIRES 201URINES	21	EXT	NON	5017906
06:04:00	ATG	100028972987	19/02/2024	Féminin	E.COLI	1		ENTEROBACTERIES URINAIRES 201URINES	21	EXT	NON	4914572
06:44:00	ATG	100028973554	19/02/2024	Féminin	E.COLI	1		ENTEROBACTERIES URINAIRES 201URINES	21	EXT	NON	4600802
06:45:00	ATG	100028973704	19/02/2024	Féminin	K.PNEUMONI	1	9,699	ENTEROBACTERIES URINAIRES 201URINES	21	EXT	NON	4222814
05:52:00	ATG	100028973675	19/02/2024	Féminin	E.COLI	1		ENTEROBACTERIES URINAIRES 201URINES	21	EXT	NON	5017968
06:42:00	ATG	100028974553	19/02/2024	Féminin	E.COLI	1		ENTEROBACTERIES URINAIRES 201URINES	21	EXT	NON	5018043
06:38:00	ATG	100028974637	19/02/2024	Féminin	E.COLI	1		ENTEROBACTERIES URINAIRES 201URINES	21	EXT	NON	5018067

When an analysis is selected, the images to be validated appear at the bottom. Simply click on it to enter the validation of readings for this analysis.

Several operations are possible from the top banner of the window:

-  : Selecting another filter
-  : Allows access to the filter settings
-  : Refresh the data
-  : Allows filtering of folders according to the remarks "All / Seen / To see / To do". Note that the "All" checkplate allows you to view the files without comments.
-  : The "Rapid Scan" plate allows access to a file by scanning the request number (note that the search will then be performed on **the entire** database).
-  : The "Plate Number" plate allows access to a file by scanning the expected plate number generated by SIRxpert® for each antibiogram plate.

Several operations are possible from the bottom banner of the window:

-  Allows visualization of batch traceability, identification, and antibiogram images.
-  Make changes to the analysis or the request
-  Display comments related to the analysis or request
-  Show results
-  Print
-  Delete the analysis or request
-  Start the interpretation for the selected file
-  Start the interpretation for the selected folder and move on to the next one.
-  Archive the folder/Cancel archiving the folder or display the global validation (Cyto+ ATG results if both bacteriology and ATG modules are available).
-  Confirm reading and move on to the next one
-  Export the results
-  Display patient history/past/movements
-  Display documents related to the request (prescription, health insurance card, etc.)



Select all rows of the filter



Deselect all rows in the filter



Select the last selection



Print SIRscan labels



Select all rows of the filter



Deselect all rows in the filter



Re-check the last selection



Save the list in CSV, TXT, pdf, HTML, XML format.



Print SIRscan labels



SIRscan barcode visualization

Validating the readings allows us to validate several factors:

- Reading acronyms
- Diameter readings

7.1.1 Disc abbreviation reading (option active only with i2a discs)

The reading of the abbreviations is activated independently on each plate of antibiogram or additional plate.

To do this, from the SIRxpert® general menu, go to the menu for defining antibiograms or additional plates, then once in the plate settings, check the option for reading active ATB abbreviations.

For more information on setting up antibiograms, please refer to the dedicated user manual: MU-2035.

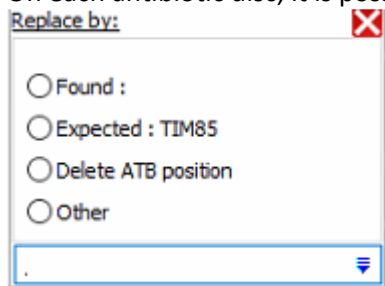
The first step is therefore to check the status of the symbols on the right side of the screen:



There are several colors that correspond to the different states of reading the antibiotic's acronym:

	ATB ok	The antibiotic has been read, it corresponds to the one that was defined in the antibiogram (Acronym read). Or perhaps the reading of the acronym for this antibiotic has been deactivated (acronym not activated).
	Antibiotic not planned	An antibiotic was detected at a location where no antibiotic was expected.
	Disc abbrev. not read	The acronym was not read or the acronym read is not part of the database.
	Different ATB	The symbol read is that of a different antibiotic than the one intended (which was not included in the plate).
	ATB shifted	The antibiotic symbol read is different from the one expected and it was intended to be in a different place in the plate.
	Detection problem	The antibiotic disc was not found: the acronym reading did not take place.
	ATB not referenced	The antibiotic's acronym is unknown or inactive.

On each antibiotic disc, it is possible to display all the options by clicking on the disc:



- Select the found disk
- Select the expected disk
- Remove the antibiotic
- Select another antibiotic: to do this, select the name of the antibiotic from the drop-down menu and then click on "Other".



Switch to theoretical positions

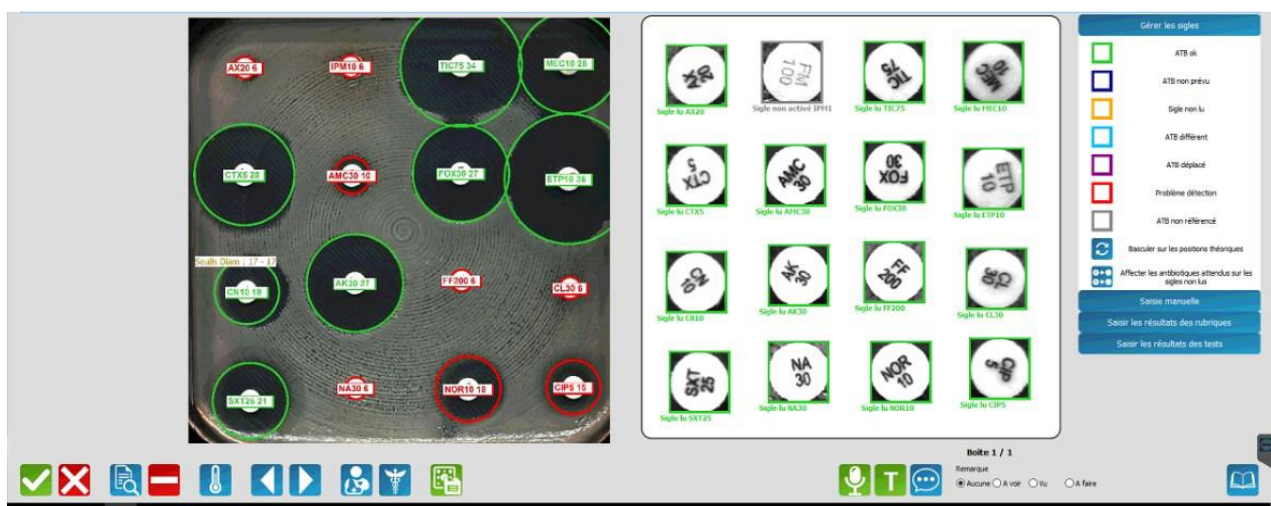
This option allows you to reposition the disks to the theoretical positions. Therefore, if the disks are not found, click here to reposition them correctly.



Affect the expected antibiotics on the disc
abbreviation not read

If several discs are not recognized but are in the correct position, this button allows you to put all unread symbols into expected. Note that if there are multiple plates in the panel, you must do this on all of them.

7.1.2 Diameter validation



It is possible to perform several operations on the image(s) of the plate:

- Change the diameter by clicking on the antibiotic and then using the mouse to adjust the diameter between 6 and 40mm.
- To recenter a diameter, click on the antibiotic (left click on the antibiotic for 1 second to bring up the menu) and then click on recenter.
- Cancel the antibiotic reading.
- Report a mutant colony. Retains the read diameter value but assigns Resistant as the raw result
- Enter a CMI (the SIRscan® ORION is capable of taking images of plates containing CMI strips).
- Assign minimum diameter (6mm) to the antibiotic.
- Allocate the maximum diameter (40mm) to the antibiotic.
- Change the antibiotic.

From version SIRxpert 201.1.3.0, two additional choices have been added to the option to modify an antibiotic: "**Cancel reading** " and "**Delete position ATB** ".

If "**Cancel reading**" is chosen, the system cancels the measured diameter, but the antibiotic may still be visible in the final report if an expert rule applies.

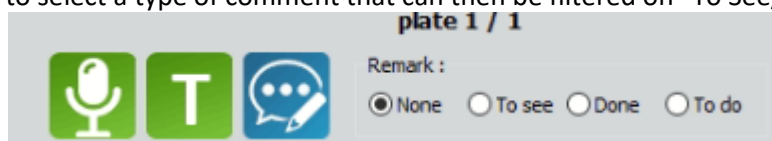
If "**Delete position ATB**" is chosen, the system completely cancels the antibiotic and it will not be present in the final report (if an expert rule concerns this molecule, it will not apply).

From the bottom banner, several operations are possible on the analysis:

-  Save the changes (without launching the analysis)
-  Cancel changes
-  Allows you to validate the changes and launch the analysis.
-  This allows you to validate the changes, launch the expert review, and proceed to the next analysis.
-  Delete the image and the antibiogram analysis.
-  View the results of the antibiogram
-  View bacteriology results
-  Visualize the temperature curve
-  For antibiograms with multiple plates, it allows navigation through the different plates. It is also possible to click on the plate on the left side of the screen. Switching between plates automatically saves the changes made.
-  Display the patient's history/previous history or movements.
-  Display attached prescriptions/documents

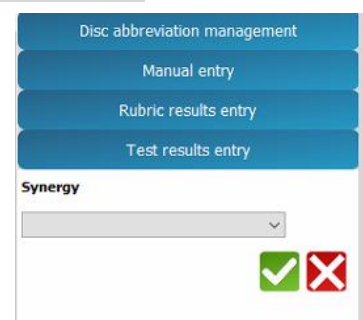
There is also the option to leave an audio message  or text message  and also to leave a memo .

Finally, it is possible to select a type of comment that can then be filtered on "To See/Seen or To Do":



It is also possible to configure **tests** to be completed during reading validation.

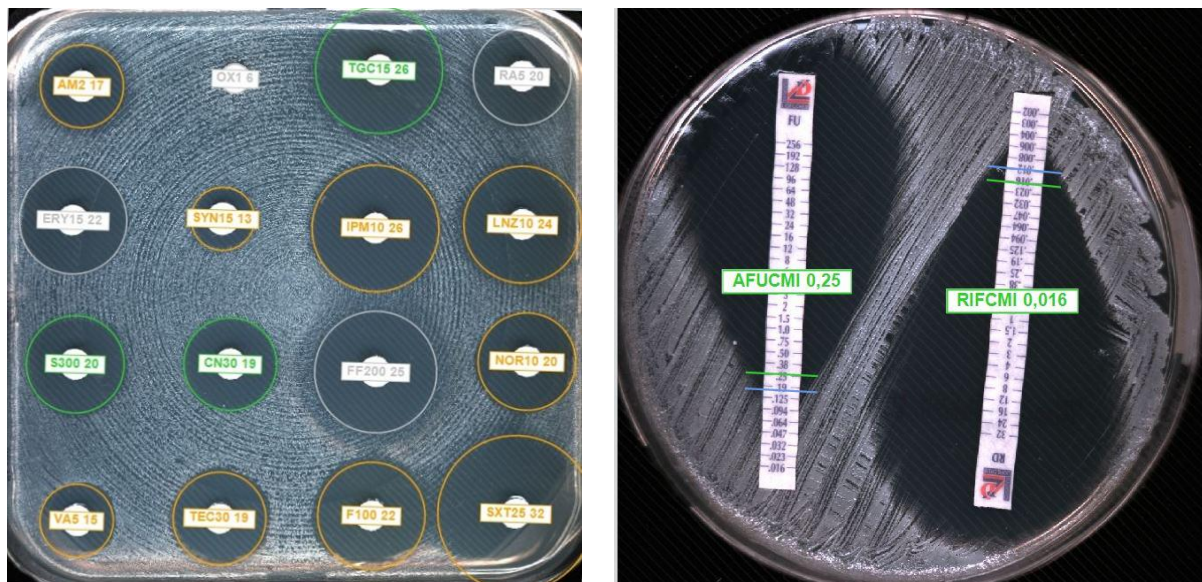
These will be available in the tabs on the right; simply click on "Enter test results" to display the different tests to be completed.



7.1.3 STAR System

From version **201.2.2.0** of SIRxpert®, the SIRscan® Lynx can be equipped with the new reading system: **the STAR system**.

This new module significantly improves the detection of the diameters of i2a antibiotic discs and also allows the detection of the values of i2a MIC strips.



The blue line corresponds to the value read by the automaton, the green line corresponds to the value returned.



Attention, this module is only available to users who have acquired the "STAR" module in addition to the SIRscan® Lynx analyzer for users using i2a reagents (CMI discs and strips).

7.2 Expertise in the antibiogram and visualization of the results

Once the readings have been validated, it is possible to launch the analysis with the  button or to

save the changes without analysis with the  button.

During the assessment, the expert system may request diameter checks; it is possible to review the images taken by the SIRscan® Orion by clicking on button .

When the analysis is complete, the SIRxpert® displays the results.



Information regarding the use of this function is available in the user manual dedicated to the SIRxpert® Master -Routine (Ref. MU-710678)

8 Traceability

8.1 SIRxpert alerts

The various alerts from SIRxpert® are located in the top banner; they are available on all workstations where SIRxpert® is installed:



By clicking on it, you can see the nature of the alerts:



The only way to acquit them is to solve the problem indicated.

8.2 Traceability of operations

Each modification made to the gearplate is tracked by the SIRxpert®. It is possible to have traceability of modifications by analysis, by plate or by antibiotic.

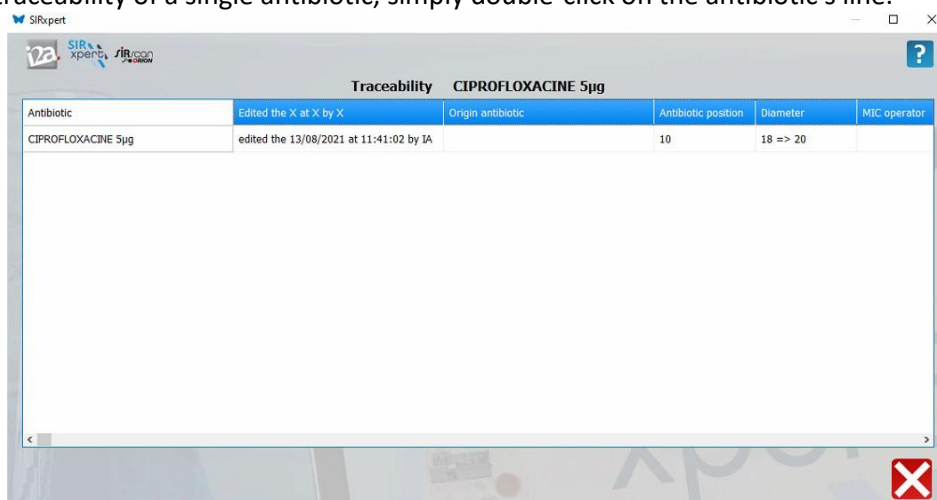
Traceability can be displayed globally by clicking on "analysis change list".



In this window, it is possible to display all the changes made to the analysis. But it is also possible to select a specific plate.

All					
ETB 1					
Antibiotic	Edited the X at X by X	Origin antibiotic	Antibiotic position	Diameter	MIC operator
CEFOXITINE 30µg	edited the 13/08/2021 at 11:41:02 by IA		8	20 => 21	
CIPROFLOXACINE 5µg	edited the 13/08/2021 at 11:41:02 by IA		10	18 => 20	

To view the traceability of a single antibiotic, simply double-click on the antibiotic's line.



8.3 Traces of the SIRxpert

It is possible to access the traces of the SIRxpert® in order to determine all routine operations. To do this, from the SIRxpert® general menu, go to the menu **AST > Utilities > SIRxpert Traces** .

There are several tabs:

- Connection logs: allows you to trace connections to the server
- History Table Spy: allows tracking of user actions
- Settings history: allows you to see the operations performed in the settings menu
- Routine traces: allows you to see the operations performed in the routine menus.

Connection history								
History of the "Mouchard" table								
Settings history								
Routine history								
☒ Today ☐ Other								
Start date : End date :								
Refresh ☐ After Sales Serv Print								
Request N°	User	Software name	Action type	Action	Connection date	Connection time	Fonction #	
TESTKPNEMAT	IA	Reading validation	Edit	Interpretation (AST) Specimen # 57326	13/08/2021	11:41:20	Antibiogramme-Expertise	
TESTKPNEMAT	IA	Reading validation	Edit	Specimen # 57326(IdBoitLue : 59197)Drug: CIP13/08/2021	13/08/2021	11:41:02	Validation par lots	
TESTKPNEMAT	IA	Reading validation	Edit	Specimen # 57326(IdBoitLue : 59197)Drug: FOX13/08/2021	13/08/2021	11:41:02	Validation par lots	
TESTKPNEMAT	IA	Reading validation	Edit	Reading validation on the AST analysis #57326	13/08/2021	11:41:02	Validation par lots	
TESTKPNEMAT	IA	Reading validation	Edit	Unvalidation of the reading on the AST analysis #57313/08/2021	13/08/2021	11:41:02	Validation par lots	
TESTKPNEMAT	IA	Reading validation	Edit	Reading validation on the AST analysis #57325	13/08/2021	11:40:44	Validation par lots	
TESTKPNEMAT	IA	Reading validation	Edit	Interpretation (AST) Specimen # 57325	13/08/2021	11:40:34	Antibiogramme-Expertise	
TEST-12A	IA	Analysis validation	Edit	Unvalidation of susceptibility test # 16195 Specimen 13/08/2021	13/08/2021	10:48:17	Validation biologiste des analyses	

9 Maintenance

The duration of maintenance operations is noted for guidance purposes only.

OPERATION	REF. I2A CONSUMABLES	FREQUENCY	APPROX. DURATION
Electrical shutdown	N / A	Weekly	1 min
SIRscan Measurement Checks® (SIRscan® Calibration)	N / A	Quarterly	2 min
SIRscan® Replacement Calibration	ZN152	Every 4 years	N / A
Drawer decontamination	N / A	Monthly	5 min
Petri dish support replacement	310861 / 310865	Semi-annual	1 min
Replacement of a strip light	100885	Exceptional	5 min



It is strongly recommended to carry out maintenance operations requiring part replacement when the AUTOMATE is switched off (switches in OFF position) to avoid any risk of injury. These operations must be carried out by authorized personnel only.

9.1 Weekly power outage

It is recommended to restart the SIRscan® LYNX at least once a week.

To do this, close the SIRxpert® program, turn off the computer and then the AUTOMATE. Conversely, turn on the AUTOMATE, then turn on the computer, then the SIRxpert® software.

9.2 SIRscan® LYNX measurement checks (quarterly)

The verification of the measurements of the SIRscan® LYNX is a maintenance operation to be carried out **quarterly**.

Each SIRscan® comes with a standard: the SIRscan® Calibration (Article reference i2a: ZN152) which is linked to national standards (certificate available on request).

Between uses, the SIRscan® Calibration must be kept in its original packaging, in the protective foam cover and in the plastic bag, then in the case provided with the analyzer. This will allow it to remain protected from light and avoid any friction that could scratch it and degrade the image capture.

Under these conditions, the lifespan of the SIRscan® Calibration is set at 4 years and its expiry date is identified by the symbol:

Beyond the date mentioned, its effectiveness is no longer guaranteed. It will need to be replaced or calibrated.

The SIRscan® quality control menu is accessible from the SIRxpert® LYNX main menu under **Antibiogram >**

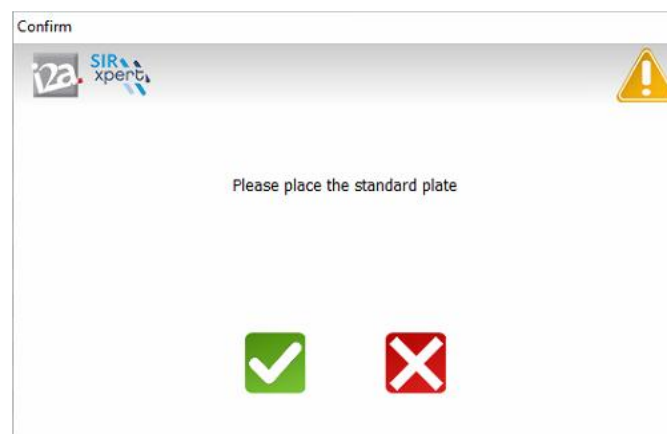
SIRscan > Quality Control

The screen that appears gives a summary of all checks carried out to date and the associated results.

SIRscan standard check

Identifier	User	Date	Result	Calibrate number
116	IA	13/11/2023	CORRECT	02/25
117	IA	15/02/2024	CORRECT	02/25
118	IA	15/02/2024	CORRECT	02/25
119	IA	15/02/2024	CORRECT	02/25
120	IA	15/02/2024	CORRECT	02/25
121	IA	15/02/2024	CORRECT	02/25
122	IA	15/02/2024	CORRECT	02/25
123	IA	15/02/2024	CORRECT	02/25
124	IA	15/02/2024	NOT CORRECT	02/25
125	IA	15/02/2024	CORRECT	02/25
126	IA	07/03/2024	CONFORME	01/20
127	IA	12/03/2024	CONFORME	01/20
128	IA	16/04/2024	CORRECT	01/20
129	IA	13/08/2025	CORRECT	01/20
130	IA	13/08/2025	NOT CORRECT	01/20
131	IA	13/08/2025	NOT CORRECT	01/20
132	IA	19/08/2025	CORRECT	01/20
133	IA	27/01/2026	CORRECT	01/20
134	IA	28/01/2026	CORRECT	01/20

Click on  to perform a new check. The following screen appears:

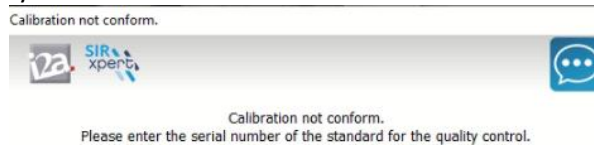


Open the drawer and place the SIRscan® Calibration with the diameters to be measured on top (facing the camera), then click on the  button.

Once the reading is complete, two possibilities can occur:

- Result as expected: enter the serial number of the SIRscan® Calibration in the corresponding plate.
- Non-compliant result: enter the serial number of the SIRscan® Calibration in the corresponding plate.

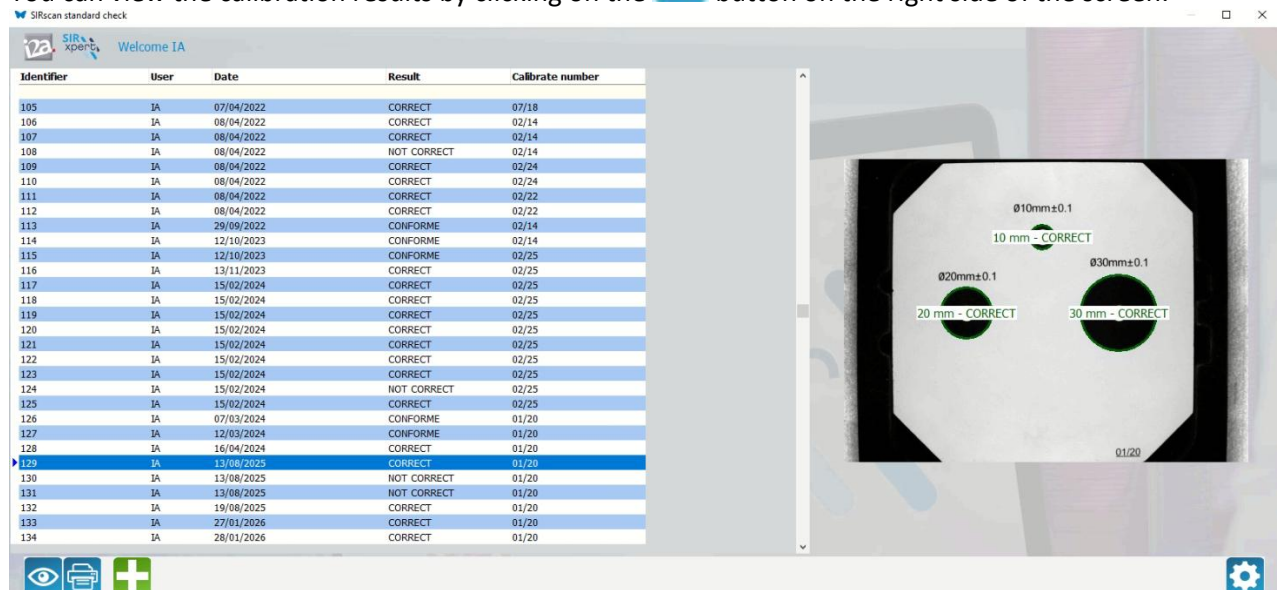
In this case, it is necessary to call i2a's customer service to understand the cause of the problem.



Once the information has been entered, click on  to validate, otherwise click on  to cancel.

Open the drawer and remove the SIRscan® Calibration.

You can view the calibration results by clicking on the  button on the right side of the screen:



The screenshot shows the SIRscan software interface. On the left, there is a table with calibration results. On the right, there is a preview of the calibration target.

Identifier	User	Date	Result	Calibrate number
105	JA	07/04/2022	CORRECT	07/10
106	JA	08/04/2022	CORRECT	02/14
107	JA	08/04/2022	CORRECT	02/14
108	JA	08/04/2022	NOT CORRECT	02/14
109	JA	08/04/2022	CORRECT	02/24
110	JA	08/04/2022	CORRECT	02/24
111	JA	08/04/2022	CORRECT	02/22
112	JA	08/04/2022	CORRECT	02/22
113	JA	29/09/2022	CONFORME	02/14
114	JA	12/10/2023	CONFORME	02/14
115	JA	12/10/2023	CONFORME	02/25
116	JA	13/11/2023	CORRECT	02/25
117	JA	15/02/2024	CORRECT	02/25
118	JA	15/02/2024	CORRECT	02/25
119	JA	15/02/2024	CORRECT	02/25
120	JA	15/02/2024	CORRECT	02/25
121	JA	15/02/2024	CORRECT	02/25
122	JA	15/02/2024	CORRECT	02/25
123	JA	15/02/2024	CORRECT	02/25
124	JA	15/02/2024	NOT CORRECT	02/25
125	JA	15/02/2024	CORRECT	02/25
126	JA	07/03/2024	CONFORME	01/20
127	JA	12/03/2024	CONFORME	01/20
128	JA	16/04/2024	CORRECT	01/20
129	JA	13/06/2025	CORRECT	01/20
130	JA	13/08/2025	NOT CORRECT	01/20
131	JA	13/08/2025	NOT CORRECT	01/20
132	JA	19/08/2025	CORRECT	01/20
133	JA	27/01/2026	CORRECT	01/20
134	JA	28/01/2026	CORRECT	01/20

The calibration target image on the right shows a circular target with various dimensions and labels: $\varnothing 10\text{mm} \pm 0.1$, 10 mm - CORRECT, $\varnothing 20\text{mm} \pm 0.1$, 20 mm - CORRECT, $\varnothing 30\text{mm} \pm 0.1$, 30 mm - CORRECT, and 01/20.

To print a calibration result, click on the  button.



In the case of a non-compliant **result**, check the orientation of the SIRscan® Calibration and perform a new acquisition. If it remains non-compliant, contact i2a's customer service.

9.3 Drawer decontamination (Monthly)

The drawer is cleaned using a disinfectant solution such as Anios®.

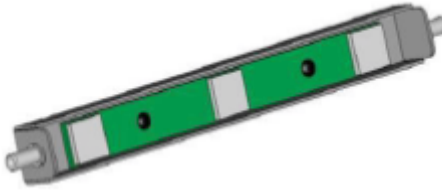
9.4 Petri dish support replacement (semi-annual)

The petri dish support deteriorates over time. In order to maintain good image quality during readings, it is necessary to renew the petri dish support every six months.

To do this, open the drawer and then unscrew the 2 screws holding the petri dish support to the drawer. Once the screws are removed, remove the petri dish support by pulling it slightly towards you. Install the new petri dish support and tighten the retaining screws. Finally, close the reading drawer.

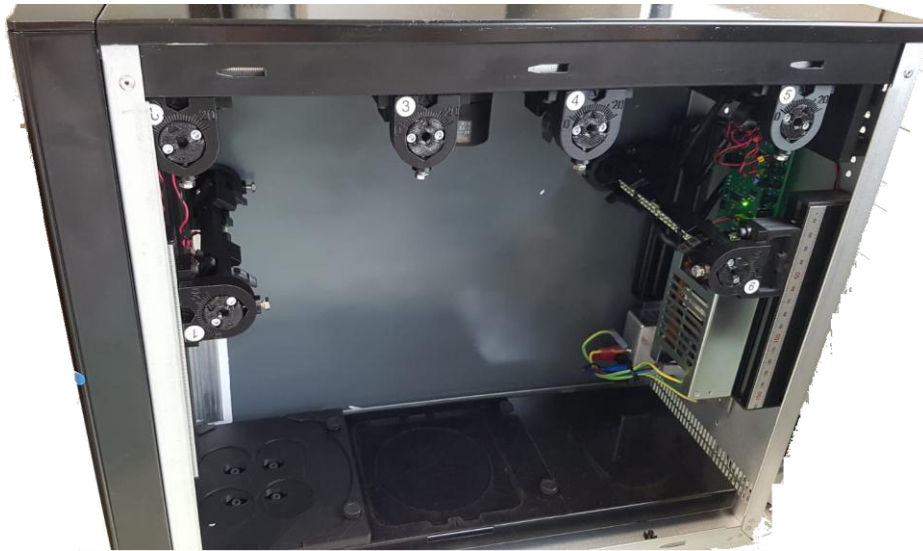
9.5 LED replacement (exceptional)

The lighting ramp is the following sub-assembly:



IMPORTANT NOTE: *If several ramps need to be changed, proceed one after the other: mount/dismount the 1st, then repeat the operation as many times as necessary, so as not to mix up the connectors.*

Turn off the SIRscan® LYNX then unscrew the closing screws of the side covers and remove the 2 side covers.



Locate the orientation of the light bar to be changed, then rotate the light bar to disconnect the connector. Then install the new lighting strip following the same orientation as the initial strip. Replace the side covers and close them using the 4 screws on the back.

10 Troubleshooting

10.1 The reading is not taking place

Verify that the acquisition service is running in the menu "Antibiogram > Sirscan > Connection to acquisition service".

10.2 Start of the Acquisition Service

The acquisition service starts automatically when the PC starts up. However, it may be necessary to turn it on if it is closed.

To turn on the acquisition service, from the SIRxpert® general menu, click on "Connection to acquisition service" located in **Antibiogram > Sirscan > Connection to acquisition service** .

If the service is not running, the button is red like this:



Start it by clicking the button and wait for it to turn green like this:



10.3 Barcodes not found on several plates

Check the connection with the LIS on the SIRxpert® server.

10.4 SIRscan® Calibration not compliant

If the image is too dark or too bright.



In the SIRscan® Calibration menu, click on the  button to access the light settings.



Increase the exposure time and/or gain if the image is not sufficiently illuminated.
Reduce the exposure time and/or gain if the image is too bright.

11 Decontamination procedure – disposal



All biological samples should be considered potentially hazardous.

Before shipping the equipment, it must have been cleaned and decontaminated according to the procedure described below.

The EN-1331 decontamination declaration must be completed and attached to the equipment.

Without this document, duly completed and signed, the device will not be accepted by our After-Sales Service.

11.1 Materials needed

- Disposable nitrile gloves
- Disposable blouse or cotton blouse
- Protective glasses

11.2 Prevention measures

Protective gloves must be worn whenever a laboratory instrument that has been potentially contaminated by blood or other laboratory samples is used. Wearing a lab coat is mandatory in medical biology laboratories.

Hands must be washed immediately after removing gloves and before leaving the laboratory. In case of contamination with blood, the skin surface must be washed thoroughly immediately. Personnel with skin conditions such as exudative lesions or weeping eczema should refrain from handling contaminated equipment.

11.3 Instrument decontamination

The instrument must be decontaminated before removing the machine or any part of the machine from the laboratory; potentially contaminated parts must be decontaminated.

Decontamination procedure:

- Put on nitrile gloves and a lab coat, then:

	Anios-type surface cleaner	Soaking	Destruction	Instructions
Outer shell	X			Decontamination is carried out using a disinfectant solution such as Anios®.
Drawer	X			See Chapter Decontamination Drawer 9.3

11.4 Precautions

All contaminated disposable materials must be disposed of in the container for biohazardous waste available at the laboratory.

Parts of the instrument can be contaminated by bacteria present on contaminated gloves. Therefore, only certain parts of the instrument should be touched and gloves should always be removed or decontaminated before touching uncontaminated parts of the device.

END OF DOCUMENT