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Thermo Scientific™ Sensititre™ ARIS HiQ™ System

INSTRUCTIONS FOR USE

Installation, use, and maintenance

for use with:
Thermo Scientific™ Sensititre™ SWIN™ Software System

REF V4000

Publication Number MAN0017782

Revision L.0

UK CA CE IVD

For Prescription Use Only. For In Vitro Diagnostic Use.

ThermoFisher SCIENTIFIC

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Revision history: Pub. No. MAN0017782

Revision	Date	Description
L.0	28 February 2023	A correction was made to the manufacturing address.
K.0	28 July 2022	IVDR compliance was added to allow continued instrument sales in Europe. The changes include the following: • Illustrations were updated to reflect new warning labels and new label for the back of the instrument. • Regulatory symbols were added to the front cover. • New warnings were added. • Conformity symbols (page 12) was updated with FCC and UKCA marks and Intertek ETL was replaced by the SGS mark. • Medical device symbols (page 13) was updated with all of the new symbols that are present on the label and packaging. • Instrument safety (page 14) was updated with the serious incidents caution. • Electrical safety (page 14) was updated with a new power cord warning. • Safety and electromagnetic compatibility (EMC) standards (page 16) were updated.
J.0	25 January 2022	• New warnings were added. • Illustrations were updated to reflect new warning labels.
H.0	26 January 2021	• The European Medical Directive was corrected to 98/79/EC. • The Plate Section List screen was updated with firmware changes.
G.0	12 October 2020	The acceptable range in the Safety and electromagnetic compatibility (EMC) standards was corrected.
F.0	11 August 2020	• Useful life was changed to 8 years. • Instrument images were updated throughout the document. • Warning notes were added throughout the document.
E.0	7 May 2020	• UPS recommendation was added. • Useful life was changed to 7 years. • Temperature probe installation and removal instructions were added.
D.0	27 December 2019	• Appendix D, “System performance” was added. • Cyber security standards were added.
C.0	9 April 2019	• Instructions were added for interrupting the shuffle feature. • Instructions were added for manually clearing obstructions from the incubation chamber. • Troubleshooting was added for short- and long-term power outages. • The 30-minute alert screen was added.
B.0	26 February 2019	• Clarified use of cleaning solutions. • Added limitations of use statements. • Updated screen shots. • Removed IVD logo from the front cover. • Added useful life to system specifications. • Added tables without values to system performance.

Revision	Date	Description
A.0	19 November 2018	New document was created for the Thermo Scientific™ Sensititre™ ARIS HiQ™ System.

The information in this guide is subject to change without notice.

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Rx only: Caution: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner. (USA only)

Copy Restriction: Thermo Scientific™ Sensititre™ ARIS HiQ™ software installed on the instrument is the proprietary property of Thermo Fisher Scientific, and may not be copied, transmitted, modified or reverse-engineered.

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Contents

1 Safety

WARNING! GENERAL SAFETY. Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, and so on). To obtain SDSs, visit **thermofisher.com/support**.

Safety symbols on the system and in the documentation

Symbols can be found on the system to warn against potential hazards or convey important safety information, including the **Caution** and **Warning** hazard symbol ⚠. When encountering this hazard symbol the user should refer to this user manual for further information in relation to the specific hazard and any actions that must be taken.

In this document, the hazard symbol is used along with one of the following user attention words:

- **CAUTION!** – Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.
- **WARNING!** – Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.

Safety symbols

Table 1 General symbols

Symbol and description
CAUTION! An appropriate safety instruction should be followed, or caution to a potential hazard exists.
WARNING! An appropriate safety instruction should be followed, or caution to a potential hazard exists.
WARNING! Dangerous Voltage. To indicate hazards arising from dangerous voltages.
CAUTION! Biological Hazard. To warn of a biological hazard, and to take care to avoid exposure to a biological hazard or risk.
CAUTION! Crushing of Hands. To warn of a closing motion of mechanical parts of equipment, and to avoid injury to hands when in the vicinity of the closing mechanical parts.

Table 2 Specific alerts for the ARIS HiQ™ system

Alert
WARNING! Only qualified, Sensititre™ system-trained service engineers should install, repair, or service the system.
WARNING! If the ARIS HiQ™ system is used in a manner not specified by the manufacturer, the safety protection provided by the equipment may be impaired.
WARNING! Some parts of the ARIS HiQ™ system operate at a hazardous voltage. Only qualified, Sensititre™ system-trained service engineers should install, repair, or service the system.
WARNING! The ARIS HiQ™ system has a front access door that can be opened. This door is protected by an interlock safeguard that stops movement within the incubation chamber when the door is opened. The interlock safeguard must not be disabled.
WARNING! The ARIS HiQ™ system is used with biohazardous materials, and appropriate precautions must be taken at all times.

Location of safety labels on the system

Figure 1 ARIS HiQ™ front panel

(1) Potential biohazard.

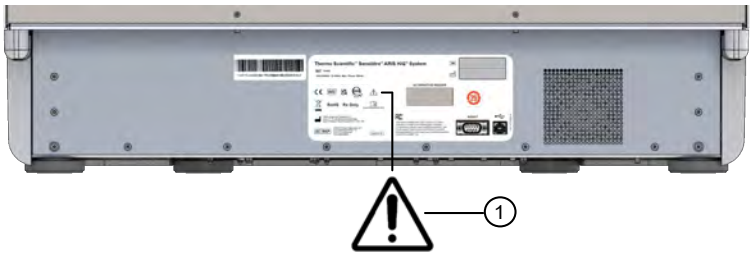


Figure 2 ARIS HiQ™ rear panel

(1) Please refer to this user guide when interacting with the instrument.

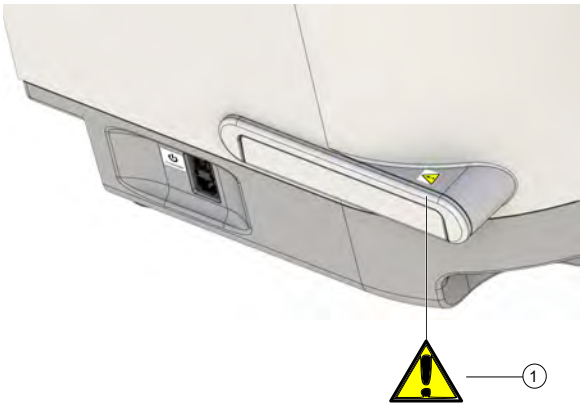


Figure 3 ARIS HiQ™ side panel

① Beware of the extending side arm. Note: This feature is currently inactive.

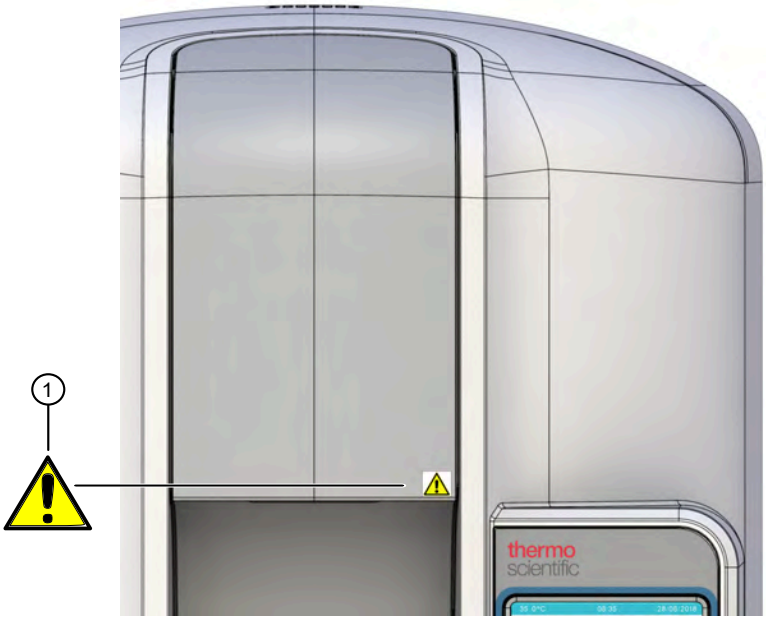


Figure 4 ARIS HiQ™ front panel

① Be cautious when opening or closing the ARIS HiQ access door.

Control and connection symbols

Symbol	Description
	On (Power)
	Off (Power)
	Protective earth (ground) To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.
	Alternating current

Conformity symbols

Conformity mark	Description
	Represents compliance to US and Canadian product safety standards as determined through independent testing and certification by SGS Group.
	Indicates that the product conforms to Regulation (EU) 2017/746 (*in vitro* diagnostic medical devices Regulation).
	Symbol for the marking of electrical and electronic equipment in accordance with Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) indicating that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. For professional users in the European Union: Contact your dealer or supplier for information on disposal of this product. For professional users outside of the European Union: Follow local requirements for disposal of this product. Contact local authorities or dealer and ask for the correct method of disposal.
	Environmental protection symbol of the China RoHS directive. The number in the symbol indicates the "Environment-friendly Use Period" of the product in years. The symbol is used if a substance restricted in China is used in excess of the maximum permitted limit.
	Indicates conformity with United Kingdom requirements.
	Indicates the device compliance with applicable sections of Part 15 of the US Federal Communications Commission (FCC) Rules.

Contact Technical Support for end of life disposal.

WEE/CH0116XU	Within the European Union, end of life disposal is provided by B2B Compliance.

Medical device symbols

Symbol	Description	Symbol	Description
	MANUFACTURER		CONSULT INSTRUCTIONS FOR USE
	DATE OF MANUFACTURE (YYYY-MM-DD)	REF	CATALOG NUMBER
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE	SN	SERIAL NUMBER
Rx Only	PRESCRIPTION DEVICE	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
CE	EUROPEAN CONFORMITY ASSESSMENT	UK CA	INDICATES CONFORMITY WITH UNITED KINGDOM REQUIREMENTS
	FRAGILE, HANDLE WITH CARE		UPPER AND LOWER LIMITS OF HUMIDITY
	UPPER AND LOWER TEMPERATURE LIMIT		THIS WAY UP
	DO NOT USE IF PACKAGE IS DAMAGED. CONSULT INSTRUCTIONS FOR USE		CAUTION
Made in UK	MADE IN THE UNITED KINGDOM		KEEP DRY
	PACKAGING MATERIAL		

Instrument safety

General

CAUTION! Do not remove instrument protective covers. If you remove the protective instrument panels or disable interlock devices, you may be exposed to serious hazards including, but not limited to, severe electrical shock, laser exposure, crushing, or chemical exposure.

Physical injury

CAUTION! Moving Parts. Moving parts can crush, pinch and cut. Keep hands clear of moving parts while operating the instrument. Disconnect power before servicing.

Serious incidents

CAUTION! Serious incidents. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the relevant regulatory authority in which the user and/or the patient is established.

Electrical safety

WARNING! Ensure appropriate electrical supply. For safe operation of the instrument:

- Plug the system into a properly grounded receptacle with adequate current capacity.
- Ensure the electrical supply is of suitable voltage.
- Never operate the instrument with the ground disconnected. Grounding continuity is required for safe operation of the instrument.

WARNING! Power Supply Line Cords. Use properly configured and approved line cords for the power supply in your facility.

WARNING! Disconnecting Power. To fully disconnect power either detach or unplug the power cord, positioning the instrument such that the power cord is accessible.

WARNING! Power cord. Use a power cord that is adequately rated (IEC60320 C13 R-A 10A). We recommend using the power cord supplied with the instrument.

Cleaning and decontamination

CAUTION! Cleaning and Decontamination. Use only the cleaning and decontamination methods specified in the manufacturer's user documentation. It is the responsibility of the operator (or other responsible person) to ensure the following requirements are met:

- No decontamination or cleaning agents are used that could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in the equipment.
- The instrument is properly decontaminated a) if hazardous material is spilled onto or into the equipment, and/or b) prior to having the instrument serviced at your facility or sending the instrument for repair, maintenance, trade-in, disposal, or termination of a loan (decontamination forms may be requested from customer service).
- Before using any cleaning or decontamination methods (except those recommended by the manufacturer), users should confirm with the manufacturer that the proposed method will not damage the equipment.

End of life disposal

CAUTION! End of life disposal must comply with local regulations.

Thermo Fisher Scientific operates a product take-back scheme designed to efficiently remove certain products from a customer's site when they have reached the end of their useful life. Typically that means reclaiming instruments to avoid wasteful disposal or perhaps harvesting or recycling components. We are dedicated to meeting global recycling requirements, and our take-back scheme is designed to divert waste from landfill.

Contact Technical Support for end of life disposal.

b2b compliance WEE/CH0116XU	Within the European Union, end of life disposal is provided by B2B Compliance.

Safety and electromagnetic compatibility (EMC) standards

The equipment complies with the emission and immunity requirements described in GB/T 18268.26.

WARNING! It is the user's responsibility to ensure that a compatible electromagnetic environment can be maintained in order that the equipment will perform as intended.

It is recommended that the electromagnetic environment should be evaluated prior to operation of the equipment.

WARNING! It is forbidden to use this equipment in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF (radio frequency) sources), as these may interfere with the proper operation.

WARNING! This equipment is designed and tested as Class A equipment defined in GB 4824. It may cause radio interference, in which case, you may need to take measures to mitigate the interference.

WARNING! This equipment is designed and tested as Class A equipment defined in CISPR 11. This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

WARNING! This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

WARNING! EMC testing of the ARIS HiQ has been completed successfully to the EMC standards listed in "EMC standards and regulations" on page 17. These EMC standards do not take into consideration the effect on EMC of Sensititre™ plates which may be inside the instrument. Therefore, emissions which exceed the levels required by the EMC standards, cannot be ruled out when the instrument contains plates. NOTE: Sensititre™ plates used with the instrument do not contain electrical or electromagnetic component(s) and are therefore very unlikely to have any effect on EMC.

Basic performance of electromagnetic compatibility: During tests for electromagnetic compatibility, each module of the equipment was found to work normally, and the software had no abnormal error information before, during, or after the test. Testing was completed using a quantifiable standard solution (ASK calibration solution) with a mean fluorescence intensity of 1500±2%.

The instrument design and manufacture complies with the following standards and requirements for safety and electromagnetic compatibility:

Safety standards

Reference	Description
IEC 61010-1	*Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements. Instrument complies with electrical safety standard requirements of* *EN 61010-1:2010+A1:2019* *IEC 61010-1:2010 +A1:2016* *UL 61010-1, 3rd edition, 2019* *CAN/CSA C22.2 No. 61010-1-12 (R2017)*
IEC 61010-2-101 EN 61010-2-101 CSA 61010-2-101	*Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment. Instrument complies with electrical safety standards requirement of IEC 61010-2-101:2018.*

EMC standards and regulations

Reference	Description
IEC 61326-2-6	*Electrical Equipment for Measurement, Control, and Laboratory Use – EMC Requirements – Part 2-6: Particular Requirements - In Vitro Diagnostic (IVD) Medical Equipment* *Instrument complies with the emission and immunity requirements of* *EN IEC 61326-2-6:2021* *IEC 61326-2-6:2020*
FCC Part 15.107 and Part 15.109	*Federal Communications Commission (FCC) US Code of Federal Regulations, Title 47, Part 15 (47 CFR 15) Radio Frequency Devices*
ICES-001	*Canadian Interference-Causing Equipment Standard (ICES): Industrial, Scientific and Medical (ISM) Equipment*
IEC 60601-1-2:2014 Immunity to proximity fields	*Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests* *IEC 60601-1-2:2014* *Table 9*

Environmental design standards

Reference	Description
Directive 2012/19/EU	European Union “WEEE Directive”—Waste electrical and electronic equipment
Directive 2011/65/EU	European Union “RoHS Directive”—Restriction of hazardous substances in electrical and electronic equipment
SJ/T 11364-2014	“China RoHS” Standard—Marking for the Restricted Use of Hazardous Substances in Electronic and Electrical Products For instrument specific certificates, visit www.thermofisher.com/us/en/home/technical-resources/rohs-certificates.html.

Cyber security standards

Reference	Description
ANSI/CAN/UL 2900-1:2017	Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements
UL 2900-2-1	Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems

Chemical safety

WARNING! GENERAL CHEMICAL HANDLING. To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below. Consult the relevant SDS for specific precautions and instructions:

- Read and understand the Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. To obtain SDSs, see the "Documentation and Support" section in this document.
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with adequate ventilation (for example, fume hood).
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer's cleanup procedures as recommended in the SDS.
- Handle chemical wastes in a fume hood.
- Ensure use of primary and secondary waste containers. (A primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage.)
- After emptying a waste container, seal it with the cap provided.
- Characterize (by analysis if necessary) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
- Ensure that the waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.
- **IMPORTANT!** Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.

Biological hazard safety

WARNING! Potential Biohazard. Depending on the samples used on this instrument, the surface may be considered a biohazard. Use appropriate decontamination methods when working with biohazards.

WARNING! BIOHAZARD. Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. Conduct all work in properly equipped facilities with the appropriate safety equipment (for example, physical containment devices). Safety equipment can also include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Individuals should be trained according to applicable regulatory and company/ institution requirements before working with potentially biohazardous materials. Follow all applicable local, state/provincial, and/or national regulations. The following references provide general guidelines when handling biological samples in laboratory environment.

- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020
  https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2020-P.pdf
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs)
  www.who.int/publications/i/item/9789240011311
- UK Health and Safety Executive, Advisory Committee on Dangerous Pathogens, *Biological agents: Managing the risks in laboratories and healthcare premises*; found at **www.hse.gov.uk/biosafety/biologagents.pdf**

2 Product information

IMPORTANT! Before using this product, see Chapter 1, “Safety”.

This document can also be referred to as the User Guide.

Note: Figures and images that are presented in this document are for illustrative purposes only. They are not to be regarded as representations of actual test information, results, or components.

Product description

The Thermo Scientific™ Sensititre™ ARIS HiQ™ System is a benchtop automated read and incubation system (ARIS) for antimicrobial susceptibility testing using Sensititre™ microtitration plates.

The ARIS HiQ™ system is designed for use with the Thermo Scientific™ Sensititre™ SWIN™ Software System (version 3.4). The ARIS HiQ™ system handles plate management and incubation. The ARIS HiQ™ system and the SWIN™ system work together to read and interpret up to 100 Sensititre™ plates, generating minimum inhibitory concentration (MIC) and breakpoint (BP) results.

Note: For detailed instructions about use of Sensititre™ SWIN™ Software System, see *Sensititre™ SWIN™ Software System Instructions For Use* (Pub. No. MAN0017791).

Intended use

The ARIS HiQ™ system, the SWIN™ system, and these instructions for use are for the sole use of trained laboratory personnel for clinical, veterinary, industrial, and research use applications.

Where used in a clinical setting, the intended use is:

The Thermo Scientific™ Sensititre™ ARIS HiQ™ System is part of the Sensititre™ AST system and is an automated plate management device containing an incubator and embedded OptiRead™ module. The Thermo Scientific™ Sensititre™ ARIS HiQ™ System is designed for use with the Thermo Scientific™ Sensititre™ SWIN™ Software System. The ARIS HiQ™ and SWIN™ systems work together to read Sensititre™ (18–24 hr) susceptibility plates, generating minimum inhibitory concentration (MIC) and interpreting breakpoint (BP) results for non-fastidious and fastidious microorganisms.

Limitations of use

- The ARIS HiQ™ system can be used only for plate management of Sensititre™ plates that are specifically produced for automated reading. Do not attempt to read non-Sensititre™ plates or Sensititre™ manual-read-only plates using the ARIS HiQ™ system.
- The Sensititre™ ARIS HiQ™ System can only be used for plate management of Sensititre™ 18–24 hour MIC or Breakpoint plates. Please refer to the Sensititre™ 18–24 hour MIC or Breakpoint Susceptibility System package insert for additional instructions, interpretations, limitations, and references.
- The performance of the antibiotic Augmentin with *Staphylococcus* spp. in combination with the integrated OptiRead™ module has not been evaluated.
- The ability of the integrated OptiRead™ module to detect resistance to the antibiotic Trimethoprim/Sulfamethoxazole (SXT) in *S. aureus* isolates is unknown because a sufficient number of resistant isolates were not available at the time of comparative testing.
- The integrated OptiRead™ module should not be used to read Trimethoprim/Sulfamethoxazole (SXT) with coagulase negative *Staphylococcus* spp. SXT should be read manually.
- The performance of the integrated OptiRead™ module with Sensititre™ MIC or Breakpoint Susceptibility plates inoculated using a manual pipette has not been evaluated.
- *Streptococcus bovis* and beta-hemolytic *Streptococcus* Groups C, F, and G have not been evaluated with the integrated OptiRead™ module in combination with the ARIS HiQ™ system.
- *Burkholderia cepacia*, *Stenotrophomonas maltophilia*, *Pseudomonas* spp. other than *P. aeruginosa*, and *Acinetobacter baumannii*, have not been evaluated with the integrated OptiRead™ module used in combination with the ARIS HiQ™ system.

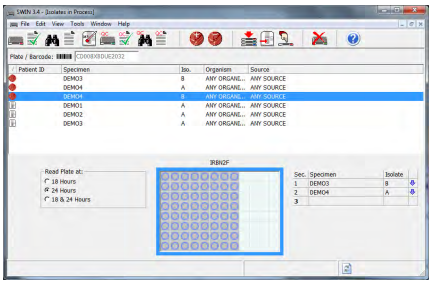
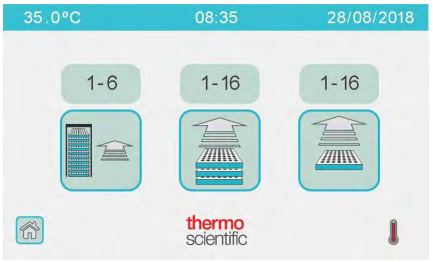
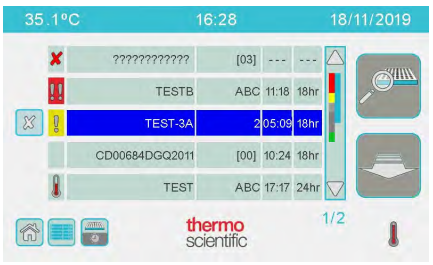
ARIS HiQ™ system features

Feature	Description
Plate capacity	• Total of 100 Sensititre™ plates (10 racks hold 10 plates each).
Racks	• 10 easily cleaned racks are located on the internal walls of the ARIS HiQ™ system. • The 11th utility rack is located on the internal side of the turntable. • Empty racks can be stored inside the incubation chamber. • Racks enable secure movement of plates in the laboratory and rapid loading of the ARIS HiQ™ system.
Turntable and partition	• The turntable rotates to move racks into or out of the incubation chamber. • The turntable partition prevents adverse effects on the temperature inside the incubation chamber by minimizing air exchange during loading or unloading. The partition is removable to allow easy access to the incubation chamber. • An empty utility rack is always positioned behind the turntable partition, ready for the next ARIS HiQ™ system activity.

(continued)

Feature	Description
Robotic plate transfer	• A plate and rack gripper assembly is used to transfer plates or racks in the incubation chamber, minimizing manual handling. • The gripper assembly and utility rack function together to: – Load single plates. – Move plates in the incubation chamber. – Consolidate completed plates into racks for rapid, bulk unloading using the rack unloading function.
Shuffle feature	The shuffle feature automatically: • Moves plates into racks based on the order in which they will be read. • Consolidates completed plates into the minimum number of racks, enabling rapid unloading using the rack unloading function.
Temperature control	• The temperature inside the incubation chamber is controlled at ±1°C of the set temperature. • Multiple fans circulate the air inside the incubation chamber. • The design of the ARIS HiQ™ system ensures that the plates warm up evenly. • The temperature is continuously monitored by sensors that are located within the incubation chamber. If the temperature deviates from the acceptable range, an alert is displayed on the screen. See “Temperature alerts” on page 97.
Plate reads	An integrated OptiRead™ module reads Sensititre™ microtitration plates at the time specified during plate setup in SWIN™ software.
Integrated barcode reader	An integrated barcode reader reads the Sensititre™ plate barcode. The barcode: • Contains plate information, including plate type and possible incubation times. • Acts as a link between the SWIN™ system and the ARIS HiQ™ system.
Integration with SWIN™ system	• Plate information flows automatically from the SWIN™ system to the ARIS HiQ™ system. • Plate read information flows from the ARIS HiQ™ system to the SWIN™ system. • The ARIS HiQ™ system retains read information from plates if the connection to the SWIN™ system is temporarily lost.
User interface	• LCD touchscreen. • Intuitive prompts for all user actions.
Communications interface	Provides communications between the ARIS HiQ™ system and the SWIN™ system.

Workflow and overview of system activities

Workflow		System activity
Set up plates in SWIN™ software (page 47) ▼		The SWIN™ system: • Accepts plate information and incubation time from the plate barcode. • Sends plate information to the ARIS HiQ™ system.
Load plates or racks into the ARIS HiQ™ system (page 49) ▼		**1.** The integrated barcode reader scans the plate barcodes. **2.** Plate locations are recorded in the system inventory.
Plate incubation and reading (page 56) While plates are incubating, the plate status can be viewed on the LCD touchscreen of the ARIS HiQ™ system. ▼		**1.** After the appropriate incubation time, the system robotically moves each plate to the OptiRead™ module. **2.** The plate is read, then returned to a rack. **3.** The information from the plate read is automatically transferred to the SWIN™ system, where processing and report generation are performed.
Unload racks or plates (page 57)		The system robotically moves plates and racks for unloading.

Basic operations

Parts of the system

Front view

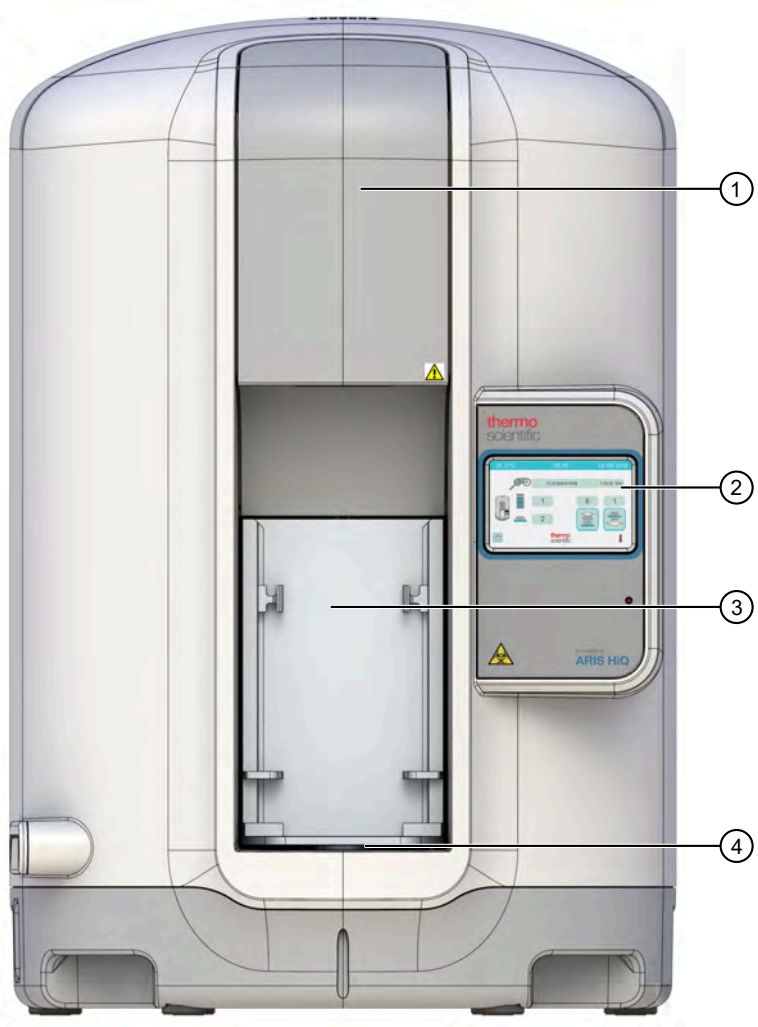


Figure 5 ARIS HiQ™ system front view

1. Access door.
2. Touchscreen.
3. Turntable partition.
4. Turntable.

Rear view

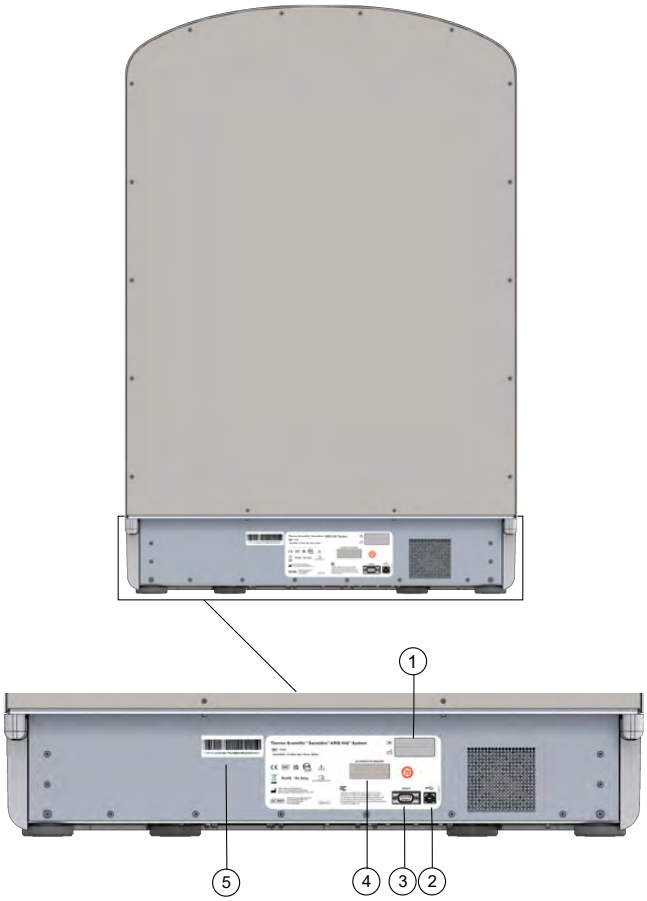


Figure 6 ARIS HiQ™ system rear view

1. Serial number.
2. USB port.
3. Serial RS232 port.
4. Alternative reader port.
5. UDI label.

Table 3 ARIS HiQ™ input and output connections and interconnection with other equipment

Port Name	Port Purpose and Connection[1]
Serial RS232 port	This port is currently disabled. It exists only for potential future product expansion purposes.
USB Port	This port is used for communications with the SWIN™ system PC[2].
Alternative Reader Port	This port is currently disabled. It exists only for potential future product expansion purposes.

[1] Only the USB Port is used for interconnection to the SWIN™ PC.
[2] PCs connected to the ARIS HiQ™ should meet relevant local safety standards.

Side view

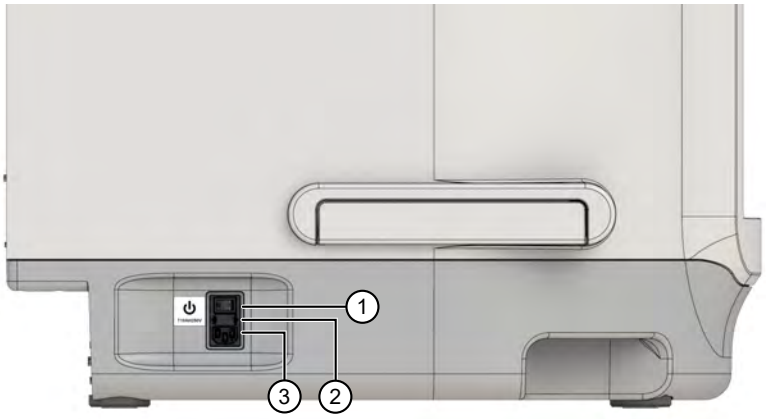


Figure 7 ARIS HiQ™ system side view

1. Main power switch.
2. Power inlet fuse.
3. Main power socket.

Internal components

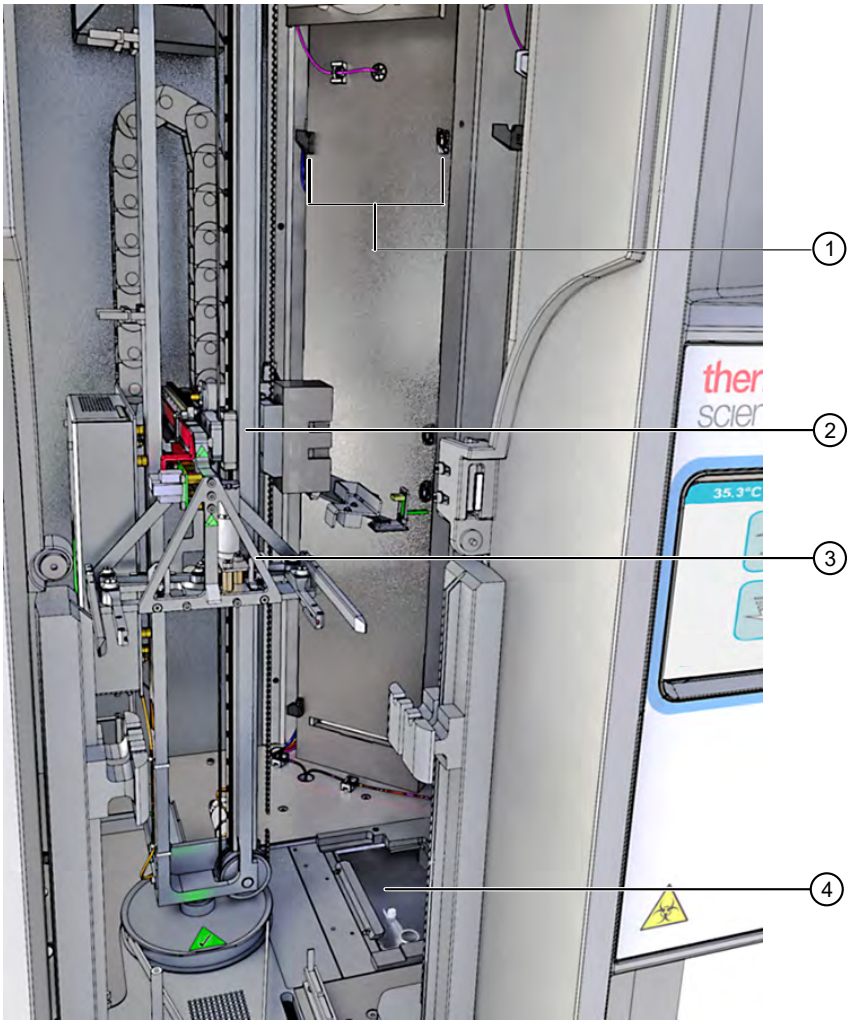


Figure 8 ARIS HiQ™ system—key internal components

① Rack locators.
② Transfer arm assembly.
③ Plate/rack gripper assembly.
④ OptiRead™ module.

Racks and plates

Racks are designed to stand upright on a workbench. An ergonomic handle on the top is designed for easy and safe rack movement throughout the laboratory. The rack design also enables correct and secure mounting into the ARIS HiQ™ system.

Each rack holds up to 10 plates. Up to 10 racks can be mounted inside the walls of the incubation chamber. An 11th empty utility rack is located behind the turntable partition.

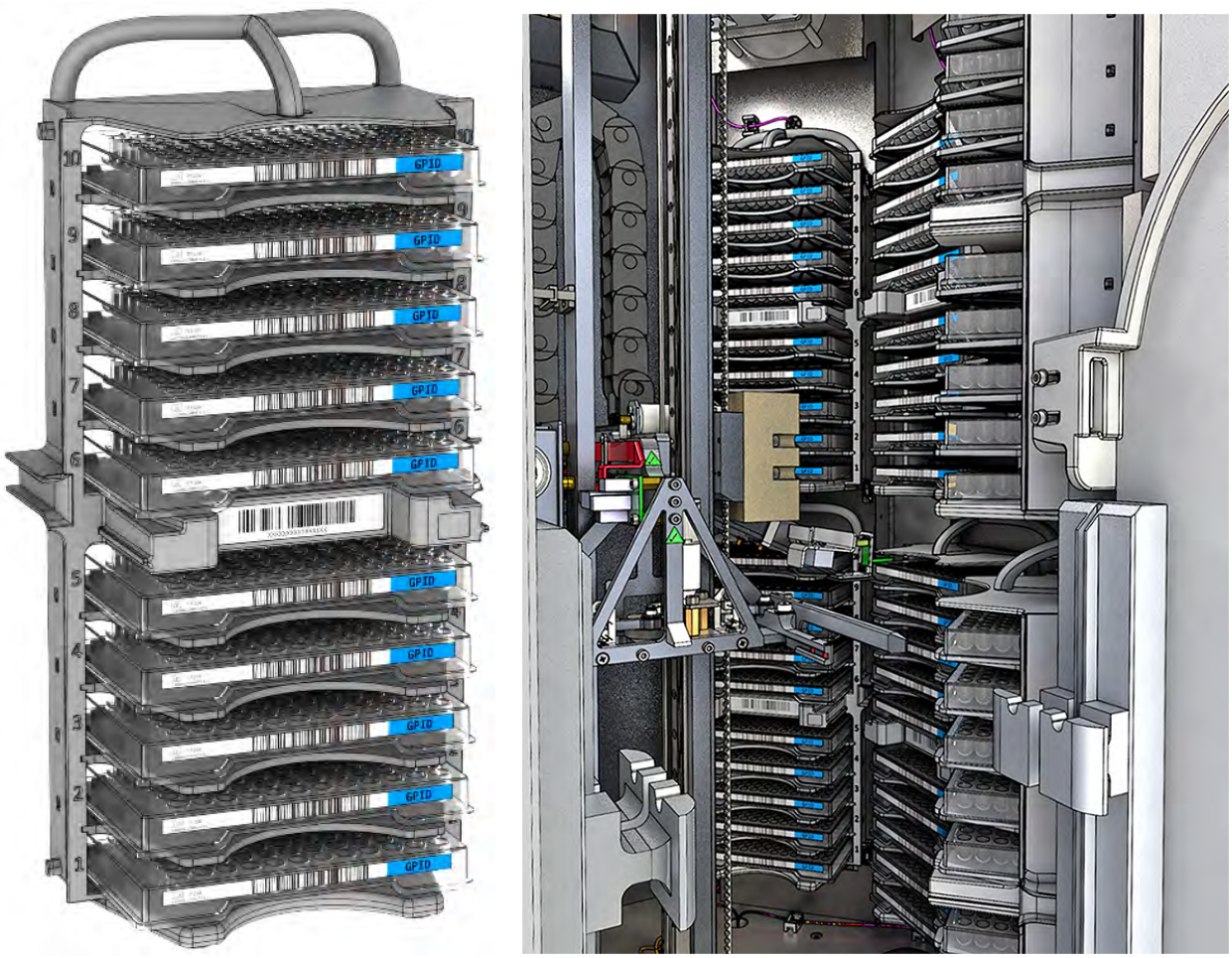
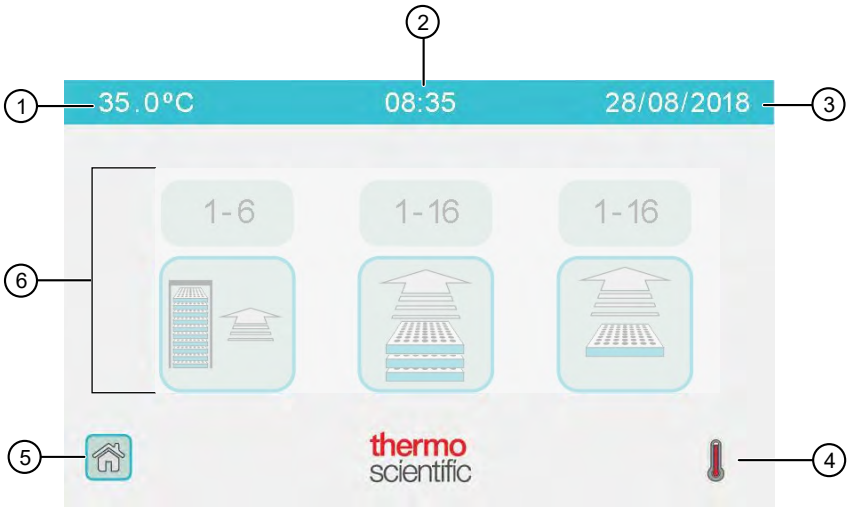


Figure 9 Racks, free-standing (left) and mounted inside the ARIS HiQ™ system (right)

Screen descriptions

Touchscreen overview



1. Current incubator temperature.
2. SWIN™ system time (the ARIS HiQ™ system and the SWIN™ system synchronize when the ARIS HiQ™ is powered on, if connected).
3. SWIN™ system date.
4. Current status icons (see Table 4 on page 32).
5. **Home** screen button: touch to return to **Home** screen from other screens.
6. Screen-specific indicators and buttons.

Table 4 Current status icons

Icon	Description
	Indicates that plate barcodes are being read.
	Indicates that plates or racks are being loaded.
	Indicates that plates or racks are being unloaded.
	Indicates that the robotic arm inside the system is moving.
	Indicates that the incubator is at the correct temperature.
	Indicates that the incubator is below set temperature.
	Indicates that the incubator is above set temperature.
	Indicates that plates are being read.

Table 5 Active vs inactive buttons

Appearance	Status
	Active
	Inactive

Home screen (main menu)

To go to the **Home** screen, while in any screen that has the **Home** button, touch on the bottom left of the screen.

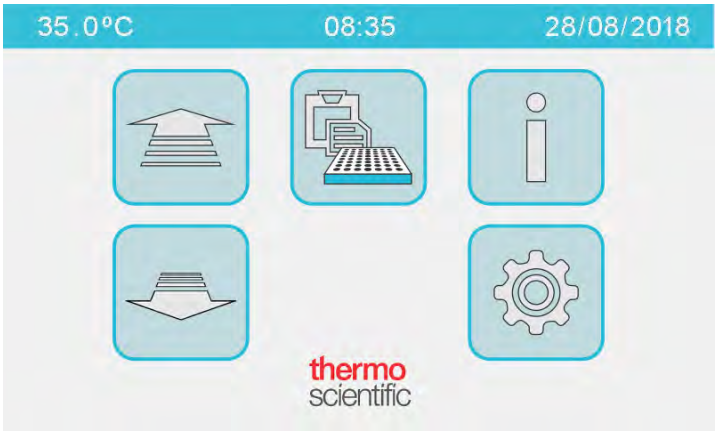


Figure 10 Home screen

Table 6 Buttons in the Home screen

Button	Description
	Touch to go to the **Load** screen.
	Touch to go to the **Unload** screen.
	Touch to go to the **Plate Section List** screen.
	Touch to go to the **System Status** screen.
	Touch to go to the **Configuration** screen.

System Status screen

To go to the **System Status** screen, while in the **Home** screen, touch .

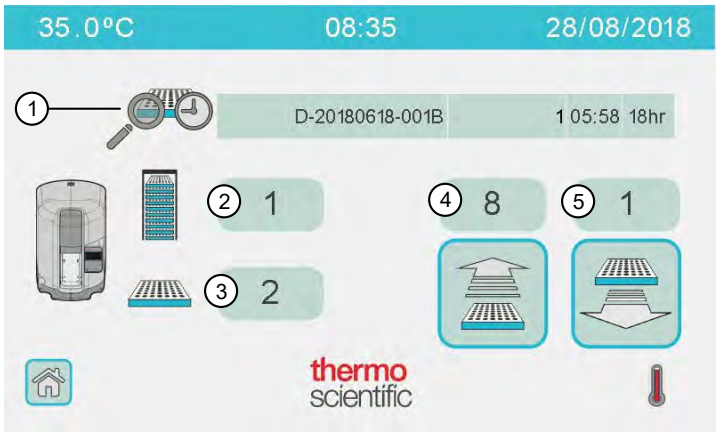


Figure 11 System Status screen

1. Indicates plate information for the next plate to be read (see “Plate Section List screen” on page 36).
2. Indicates the number of racks within the system.
3. Indicates the number of plates within the system.
4. Indicates the number of empty plate shelves within the system.
5. Indicates the number of completed plates or plates with no plate information that are available for unloading.

Table 7 Buttons in the System Status screen

Button	Description
	Touch to load plates. See “Load options” on page 49.
	Touch to unload plates. See “Unload plates” on page 60.

Load screen

To go to the **Load** screen:

- In the **Home** screen, touch .
- In the **System Status** screen, touch .

Note: If the **Load** screen remains idle for more than 3 minutes, the system defaults to the **System Status** screen. See “System Status screen displays unexpectedly” on page 85.

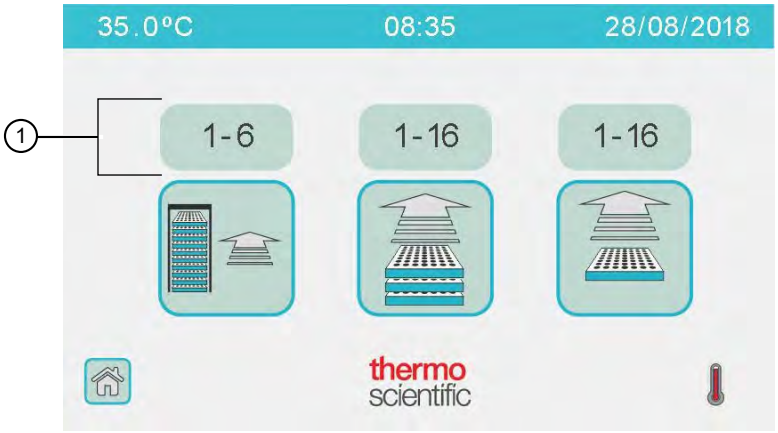


Figure 12 Load screen

① Indicates the number of available plate or rack spaces (see “Load options” on page 49).

Table 8 Buttons in the Load screen

Button	Description
	Touch to load racks. See “Load options” on page 49.
	Touch to load plates using the **Enhanced Load** option. See “Load options” on page 49.
	Touch to load plates using the **Single Plate Load** option. See “Load options” on page 49.

Unload screen

To go to the **Unload** screen:

- In the **Home** screen, touch  .
- In the **System Status** screen, touch  .

Note: If the **Unload** screen remains idle for more than 3 minutes, the system defaults to the **System Status** screen. See “System Status screen displays unexpectedly” on page 85.

Figure 13 Unload screen

① Indicates the number of empty racks that are available for unloading.
② Indicates the number of completed plates, or plates with no plate information, that are available for unloading.

Table 9 Buttons in the Unload screen

Button	Description
	Touch to unload empty racks. See “Unload options” on page 57.
	Touch to unload plates. See “Unload options” on page 57.

Plate Section List screen

To go to the **Plate Section List** screen, while in the **Home** screen, touch  .

The **Plate Section List** screen lists specimen/isolates that are in process. After read times are finished and the plate is unloaded, the specimen/isolate is automatically removed from this screen.

CAUTION! Ensure that you read and understand the information in the Plate Section List screen before operating the ARIS HiQ™ system. Plate status icons can indicate that an action is required within a specific time period. Failure to act in this time period can result in plates missing their scheduled read windows. These plates will need to be remade and retested.

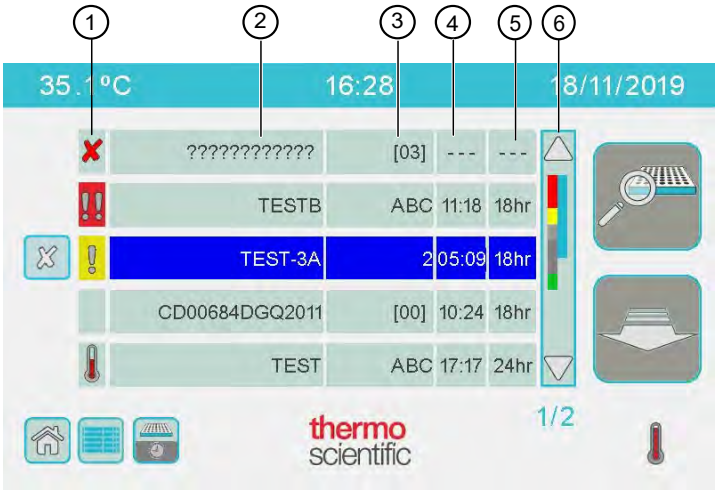


Figure 14 Plate Section List screen

① Plate status (see Table 11 on page 38).
② Specimen name/number.
③ Isolate identifier.
④ Time of the next plate read.
⑤ Total incubation time for the plate, for the next scheduled read.
⑥ Scroll bar to navigate within the **Plate Section List** screen. The colors on the left side of the scroll bar indicate the plate status (see Table 12 on page 38).

Table 10 Buttons in the Plate Section List screen

Button	Description
	Select a row for a specimen/isolate, then touch to delete. Only specimen/isolates in plates that are not in the ARIS HiQ™ system can be deleted in this screen.
	Select a row for a specimen/isolate, then touch to start Instant Read. See “Use Instant Read to read a plate” on page 84.
	Select a row for a specimen/isolate, touch the button, then follow the prompts to unload the plate.
	Touch to deselect all specimen/isolate rows in the Plate Section List screen.
	Touch to toggle the order in which the plates are displayed. **Note:** By default, plates are ordered by plate status, then by the specimen name or the time of the next plate read, depending on the selected toggle view.

Table 11 Plate status icons

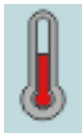
Icon	Plate status description
	The plate is incubating.
	The plate is completed. Plates may now be unloaded, see “Unload plates” on page 60.
	The SWIN™ system has sent plate information to the ARIS HiQ™ system, but the plate is not loaded in the system. Load these plates as soon as possible.
	Read error or unreadable barcode error indicates: • The OptiRead™ module failed to return result information for a plate read. Remove the plate and inspect for growth. Plates with growth may be read using a mirror viewer or the Vizion™ system. Specimens showing no growth must be retested. In Table 20 on page 106, see number 6. *or* • The ARIS HiQ™ system has detected a plate but is unable to read the barcode. In Table 20 on page 106, see number 7.
	The plate is not loaded in the system, and it is overdue for a scheduled read by at least one hour. These plates cannot be read, and the results cannot be used. Specimens on these plates must be retested. Delete the specimen from the Plate Section List, see Table 10 on page 37.

Table 12 Plate status colors in the scroll bar

Color	Description
Red	One of the following: • The plate is not loaded in the ARIS HiQ™ system and is overdue for a scheduled read by ≥1 hour (see Table 11 on page 38). • The ARIS HiQ™ system was unable to read the plate (in Table 20 on page 106, see number 6). • The ARIS HiQ™ system has detected a plate, but is unable to read the barcode (in Table 20 on page 106, see number 7).
Yellow	The SWIN™ system sent plate information to the ARIS HiQ™ system, but the plate is not loaded (see Table 11 on page 38).
Light grey	The plate information is not displayed; the entry shows only a barcode (in Table 20 on page 106, see number 5).

Table 12 Plate status colors in the scroll bar *(continued)*

Color	Description
Dark grey	The plate is incubating (see Table 11 on page 38).
Green	The plate incubation and reading is complete (see Table 11 on page 38).

Configuration screen

To go to the **Configuration** screen, while in the **Home** screen, touch 

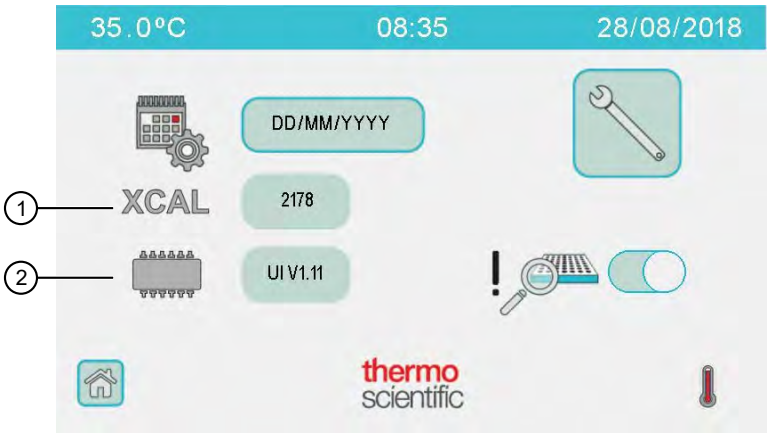
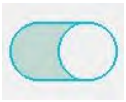


Figure 15 Configuration screen

① Indicates the XCAL value.
② Indicates the firmware version.

Table 13 Buttons in the Configuration screen

Icon or button	Description
	Touch to change the date format.
	Touch to go to the **Engineering** screen (for Sensititre™ system-trained service engineers only).
	Touch to switch on/off the **Close to Readtime** warning.

Wait screen

The **Wait** screen is displayed when the system is performing tasks, preventing other activities from running at the same time.

Note: If **Wait Shuffle** is displayed, the task can be interrupted by touching the screen. The ARIS HiQ™ system completes the current task, then allows user operations.

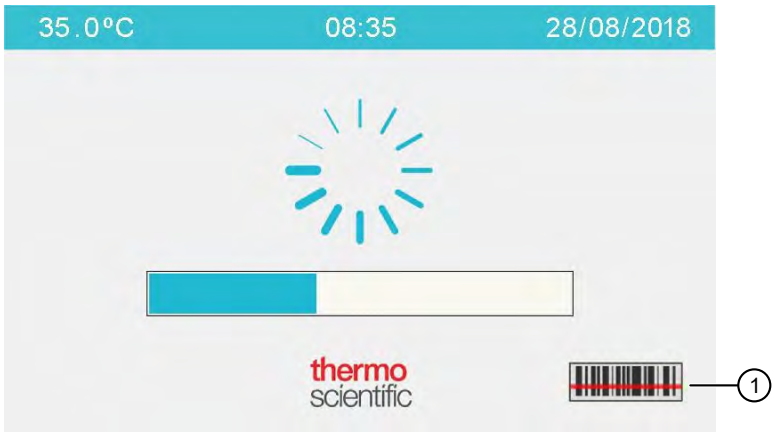


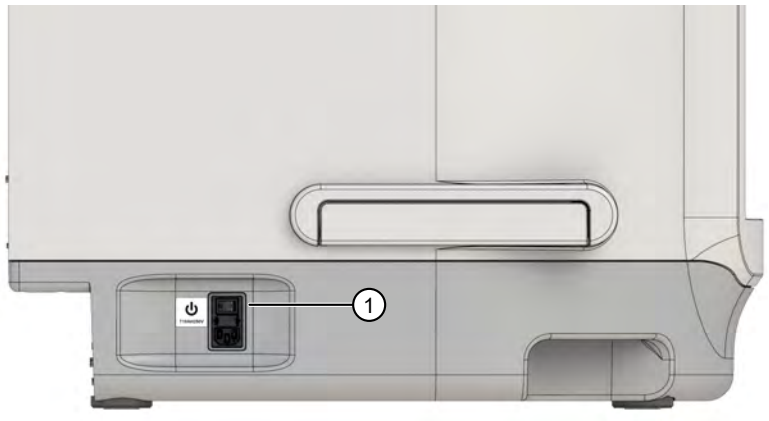
Figure 16 Wait screen

① **Current status** indicator. For a list of indicators, see Table 4 on page 32.

Power on the ARIS HiQ™ system

After storage or shipping, allow the system to reach ambient conditions before it is powered on.

Power on the ARIS HiQ™ system with the main power switch on the side of the system.



① Main power switch.

The **Wait** screen is displayed as the system performs a self-calibration and a full inventory scan. When the inventory is complete, the **Home** screen is displayed.

Place plates in racks

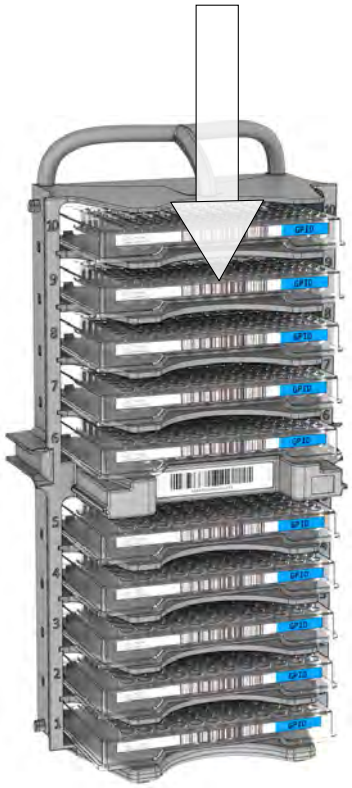
WARNING! The ARIS HiQ™ system is used in the processing of hazardous infectious disease samples for susceptibility and identification testing. These samples can transmit infectious diseases. Wear protective clothing and eyewear when collecting and handling samples and when operating the system. Follow the procedures set up by your institution for meeting Federal/Governmental, State, and Local regulations.

Only personnel who are trained in susceptibility testing techniques should operate the system.

CAUTION! Ensure that plates are correctly placed in each rack shelf.

CAUTION! Ensure that racks are correctly mounted on the turntable (see “Mount a rack on the turntable” on page 42).

1. Hold the plate with the plate barcode facing away from the rack.
2. Place the plate firmly into the shelf of the rack, so that the back of the plate securely engages the pins at the back of the shelf.
3. Test for a secure placement of plates by running a finger over each plate, then down the rack, simultaneously gently pushing each plate to the back of its shelf.



Mount a rack on the turntable

WARNING! The ARIS HiQ™ system is used in the processing of hazardous infectious disease samples for susceptibility and identification testing. These samples can transmit infectious diseases. Wear protective clothing and eyewear when collecting and handling samples and when operating the system. Follow the procedures set up by your institution for meeting Federal/Governmental, State, and Local regulations.

Only personnel who are trained in susceptibility testing techniques should operate the system.

CAUTION! Ensure that plates are correctly placed in each rack shelf (see “Place plates in racks” on page 41).

CAUTION! Ensure that racks are correctly mounted on the turntable.

Lift the rack over the turntable, then lower the rack onto the turntable sockets.

IMPORTANT! Ensure that all 4 rack mount points are placed securely onto all 4 turntable sockets.

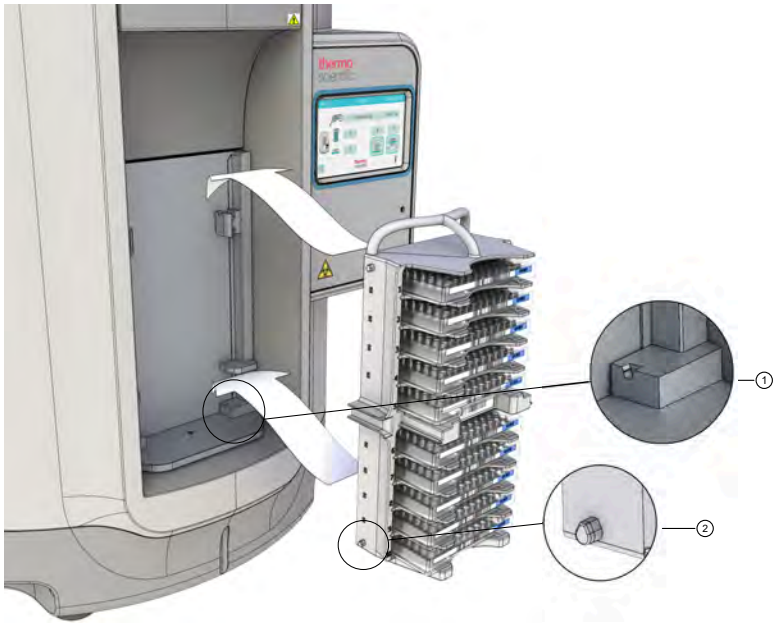


Figure 17 Correct mounting of the rack on the turntable

1. Turntable socket.
2. Rack mount point.

4 Set up and run plates in the ARIS HiQ™ system

Cautions and warnings for error-free operation

WARNING! The ARIS HiQ™ system is used in the processing of hazardous infectious disease samples for susceptibility and identification testing. These samples can transmit infectious diseases. Wear protective clothing and eyewear when collecting and handling samples and when operating the system. Follow the procedures set up by your institution for meeting Federal/Governmental, State, and Local regulations.

Only personnel who are trained in susceptibility testing techniques should operate the system.

WARNING! While the turntable is turning, the  icon flashes red as a warning. Keep away from the turntable.

CAUTION! Ensure that the host computer with SWIN™ software is always connected to the ARIS HiQ™ system.

After plates are read, transfer of information occurs between the ARIS HiQ™ system to the SWIN™ system.
If the connection between the ARIS HiQ™ system and the SWIN™ system is interrupted, see “Connection with SWIN™ system is lost” on page 85.

CAUTION! Monitor the ARIS HiQ™ System user interface periodically to ensure that all alerts and errors are resolved promptly.

CAUTION! Ensure that plates are correctly placed in each rack shelf (see “Place plates in racks” on page 41).

CAUTION! Ensure that racks are correctly mounted on the turntable (see “Mount a rack on the turntable” on page 42).

CAUTION! Do not load more than 50 ID plates that require a 5-hour read within a 1-hour window. The system is then able to schedule 5-hour plates for reading within their 30-minute read window.

CAUTION! Do not attempt to open the ARIS HiQ™ system access door when plates are being read.

CAUTION! Use the ARIS HiQ™ system to read Sensititre™ plates that are produced for automated reading. Do not attempt to read non-Sensititre™ plates or plates that are produced only for manual read.

CAUTION! Prepare, inoculate, and handle plates according to the instructions in the test kit, to ensure that correct results are generated and reported. Personnel using the SWIN™ system and the ARIS HiQ™ system must be appropriately trained and follow all relevant protocols.

CAUTION! Ensure that all Sensititre™ plates are carefully sealed with the seals that are provided with the plates, before loading the plates into the ARIS HiQ™ system.

CAUTION! Do not attempt to use damaged plates in the ARIS HiQ™ system.

CAUTION! Discard any unused Sensititre™ plates that have passed their expiration date. Do not attempt to use these plates in the ARIS HiQ™ system. In addition, do not reuse multi-isolate plates that have unused sections.

CAUTION! Open the ARIS HiQ™ system access door by lifting forward and upward until the end-stop is reached. This is the fully opened position. Do not partially open the access door (see Figure 32 on page 87).

We recommend that you proceed with caution as to not injure yourself on the open door.

Enter plate information in SWIN™ software

CAUTION! Sensititre™ ARIS HiQ™ System can be used only with Sensititre™ SWIN™ Software System (version 3.4).

CAUTION! Plate information must be entered in the SWIN™ software to obtain results.

CAUTION! If plates are loaded into the ARIS HiQ™ system more than 3 hours:

- ***Before*** data are sent from the SWIN™ system, then the scheduled read window for the plate is missed, and the specimens must be retested.
- ***After*** data are sent from the SWIN™ system, then the plates are read too early unless they have been incubated appropriately outside of the ARIS HiQ™. To resolve, use the Instant Read Function to read the plates within their required read window.

If a plate is loaded into the ARIS HiQ™ system without plate information, a message is displayed in the SWIN™ software prompting you to remove the plate, then enter the plate information. The plate can be unloaded from the **Plate Section List** screen of the ARIS HiQ™ system, where it is listed with the plate barcode in the specimen field.

If the error is noticed at the time the plate is loaded, then...	If the error is noticed sometime after the plate is loaded, then...
1. Unload the plate. 2. Enter the plate information in the SWIN™ software. 3. Reload the plate. The read occurs automatically at the correct time.	1. Unload the plate. 2. Enter the plate information in the SWIN™ software. 3. Reload the plate. 4. Using the Instant Read function, read the plate at the correct time.

Set up plates in SWIN™ software

- **If plates have not been loaded in the ARIS HiQ™ system**: plate information can be sent to the ARIS HiQ™ system from the SWIN™ system.
- **If plates have been loaded in the ARIS HiQ™ system**: the SWIN™ system automatically sends the batched plate information to the ARIS HiQ™ system.

For detailed instructions, see *Sensititre™ SWIN™ Software System Instructions For Use* (Pub. No. MAN0017791).

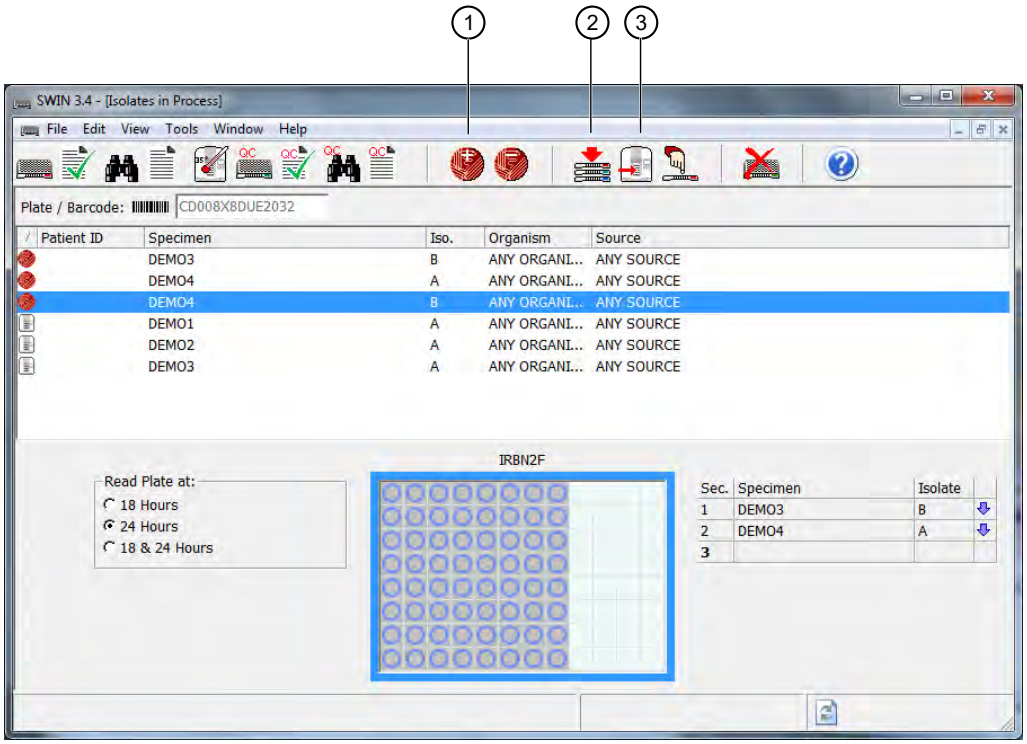


Figure 18 SWIN™ software Isolates in Process screen

① Click to add a specimen/isolate combination.
② Click to batch plate information.
③ Click to send plate information to the ARIS HiQ™ system.

1. In SWIN™ software, in the **Isolates in Process** screen, click .
2. Create one or more specimen/isolate combinations.
3. Scan the plate barcode.
   A plate schematic is displayed near the bottom of the screen.
4. Drag the specimen/isolate combination to the appropriate section of the plate.
5. Send the plate information to the ARIS HiQ™ system or batch the plate information.
   - Click to send plate information to the ARIS HiQ™ system.
   - Click to batch plate information.

6. Repeat step 1 through step 5 until all plates have been entered into SWIN™ software and each specimen/isolate combination is assigned to a section on a plate.

7. If plate information was batched at step 5, click  to send batched plate information to the ARIS HiQ™ system.

Load plates or racks into the ARIS HiQ™ system

Load options

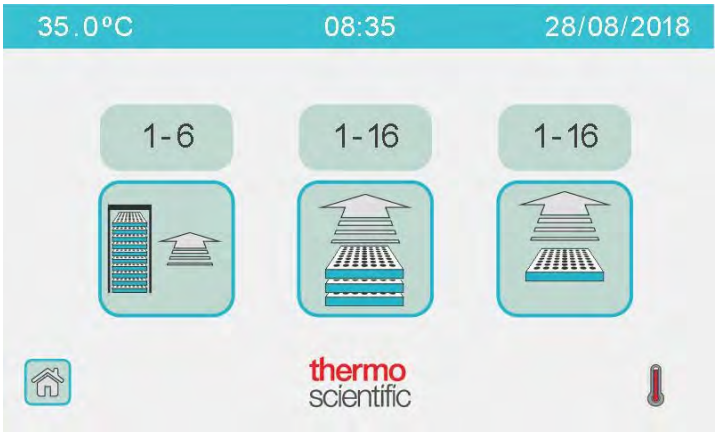


Figure 19 Load screen

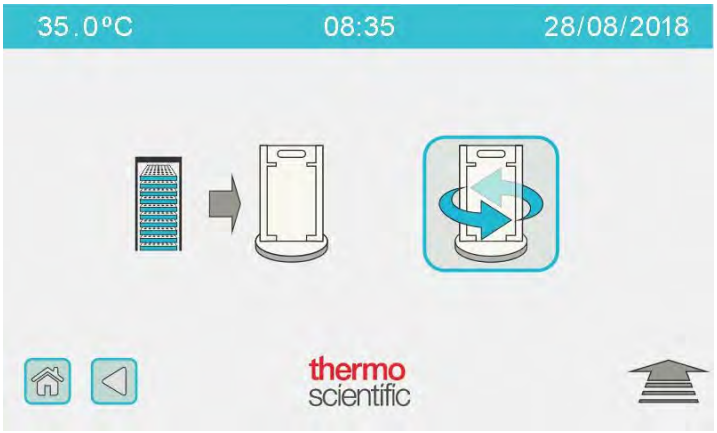
Table 14 Plate and rack load options

Type	Description	Availability indicator[1]	Description
Rack Load 	• Full or empty racks are loaded into the system. • Useful if racks are used to transport plates in the laboratory before loading into the system. • Allows plates to be loaded in bulk for faster loading time.	1-6	Indicates the number of rack positions that are available. The example image indicates 6 available rack positions.
Enhanced Load 	• Plates are loaded into the utility rack, then the rack is positioned within the system. An empty rack takes the utility position for continued plate loading. • Useful if racks are retained in the system.	1-16	Indicates the number of plate shelves that are available in racks that are positioned inside the system. The example image indicates 16 available plate shelves.
Single Plate Load 	• Plates are loaded into the utility rack, then moved to empty rack shelves within the system from the utility rack. • Useful for loading a few plates at a time. • Used when there are no empty racks available within the system.	1-16	Indicates the number of plate shelves that are available in the racks that are positioned inside the system. The example image indicates 16 available plate shelves.

[1] Located above each button

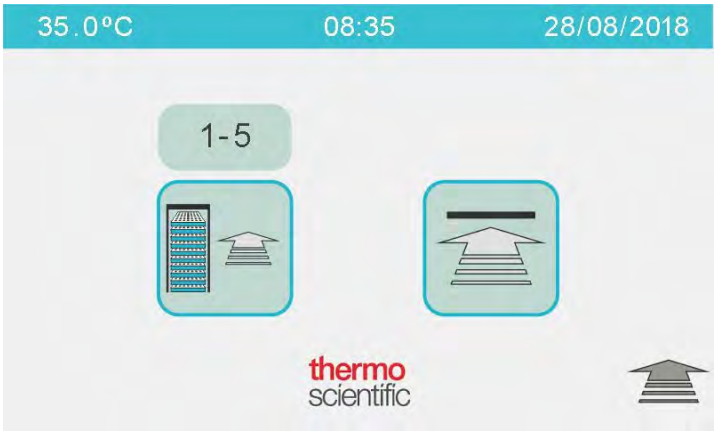
Load racks

1. In the **Load** screen, touch .
2. Load a rack onto the turntable, then touch .

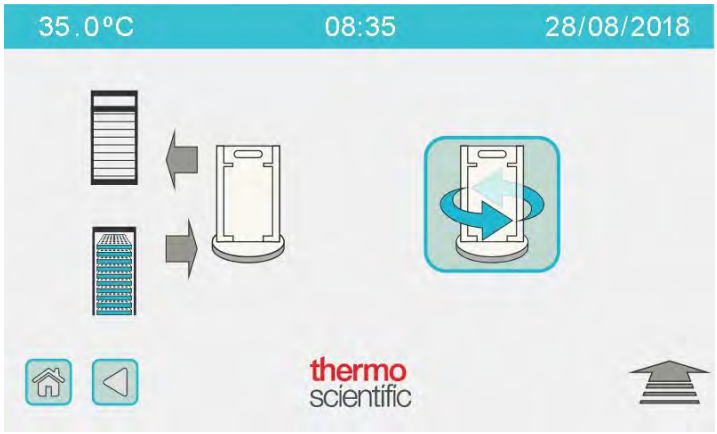


The rack rotates to the inside of the system. The robotic arm moves the rack to the inside wall of the system.

3. To load additional racks, touch .

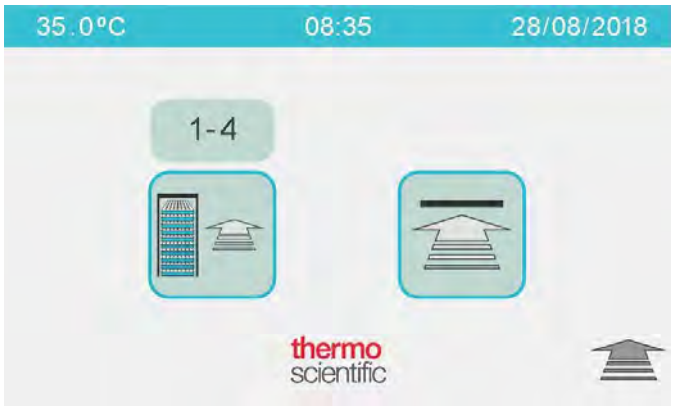


4. Load the next rack onto the turntable, then touch .

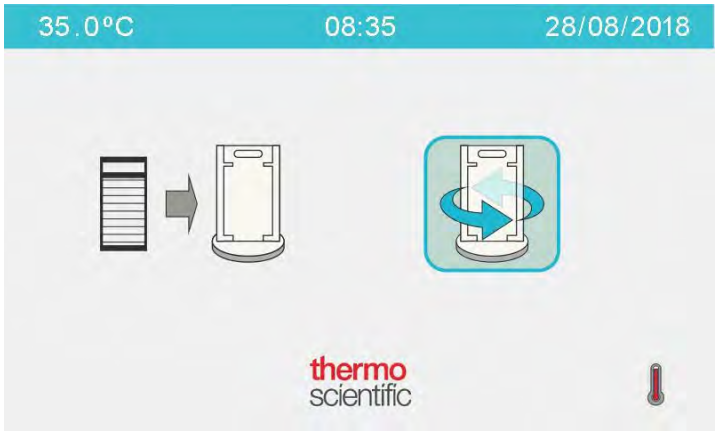


5. Following the system prompts, repeat step 3 and step 4 to load additional racks into the remaining available positions on the inside wall of the system.

6. After all racks are loaded, touch .



7. Load an empty rack on the turntable, then touch .

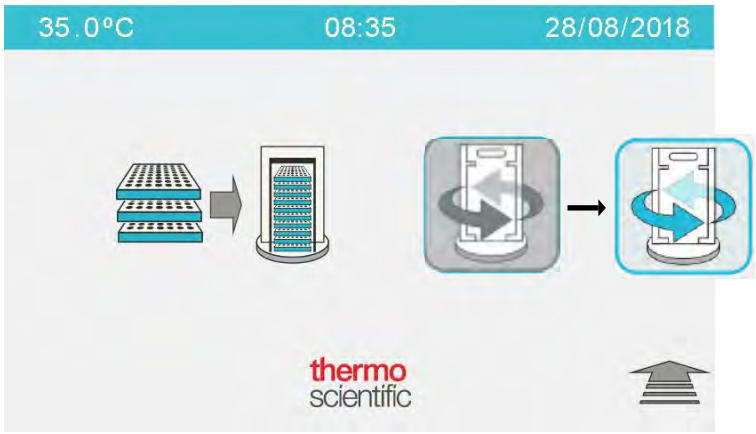


After the empty utility rack is rotated to the inside of the turntable, the system scans the rack for plates, scans plate barcodes, updates the plate inventory, then the **System Status** screen is displayed with updated indicators.

Load plates using the Enhanced Load option

Note: There must be one or more empty racks inside the system.

1. In the **Load** screen, touch .
2. Touch .
   The turntable rotates to present the empty utility rack to the outside of the system.
3. Load plates into the rack, then touch .
   The **Rotate Turntable** button is active after the system has moved the next empty rack onto the back of the turntable.



4. To load additional plates, touch .

5. Repeat step 3 and step 4 to load plates into the remaining available empty racks.
   If there are no more completely empty racks available, but there are shelves within partially filled racks, the display changes to the **Single Plate Load** screen. Touch to continue loading (see “Load single plates” on page 55).

6. After all the plates are loaded using the **Enhanced Load** option, touch .

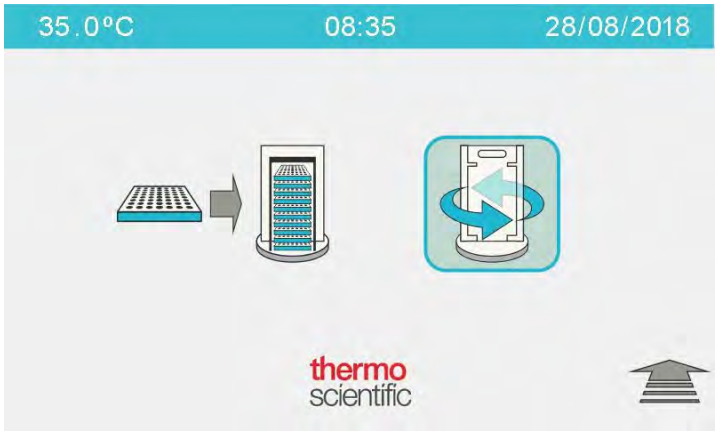
7. Load an empty rack on the turntable, then touch .

The **System Status** screen is displayed with updated indicators.

Load single plates

Note: There must be one or more empty shelves in racks inside the instrument.

1. In the **Load** screen, touch .
2. Touch .
   The turntable rotates to present the empty utility rack to the outside of the system.
3. Load plates into the rack, then touch .



4. To load additional plates, touch .

5. Repeat step 3 and step 4 to load plates into the remaining available shelves.
   The button is active as long as there are available shelves.

6. After all plates are loaded, touch .

The **System Status** screen is displayed with updated indicators.

CAUTION! When unloading plates (either in racks or individually) from the ARIS HiQ™ system, ensure that the appropriate plates have been removed from the system. In particular, if you find any unfinished plates have been incorrectly unloaded, then reload these plates without delay to complete the incubation and read cycles. Plates that are found to be outside of incubation for longer than 15 minutes should be discarded and remade in order to ensure the accuracy of all results.

Plate incubation and reading

The ARIS HiQ™ system manages incubation time and plate reads. Plate status can be monitored in the **Plate Section List** screen (see “Plate Section List screen” on page 36).

After plates are read, the information is automatically transferred to the SWIN™ system for processing and report generation.

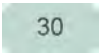
Completed plates are ready for unloading.

Unload racks or plates

Unload options

Figure 20 Unload screen

Table 15 Plate and rack unload options

Type	Description	Availability indicator [1]	Description
Rack Unload 	Used only for unloading empty racks.		The example image indicates that 7 racks are available for unloading.
Plate Unload 	Used for unloading completed (or unidentified) plates. The system combines all completed plates into the smallest number of racks, which enables faster unloading of plates.		Indicates the number of completed (or unidentified) plates that are available for unloading. The example image indicates that 30 plates are available for unloading. 10 completed plates can be unloaded in one rack, or all 30 in 3 racks.

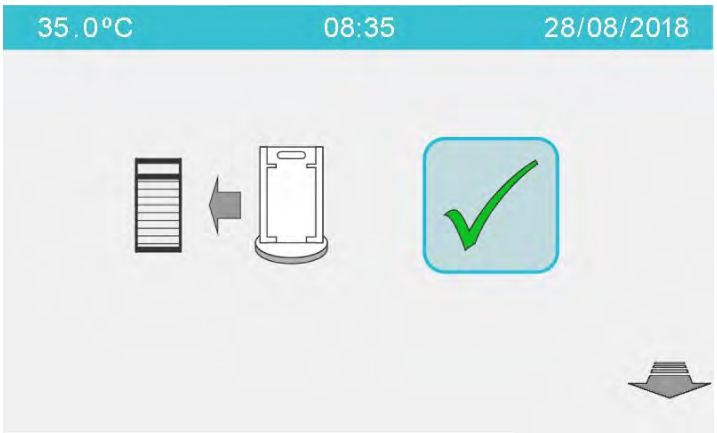
[1] Located above each button

Unload empty racks

1. In the **Unload** screen, touch .

2. Touch .
   The turntable rotates to present the empty utility rack to the outside of the system.

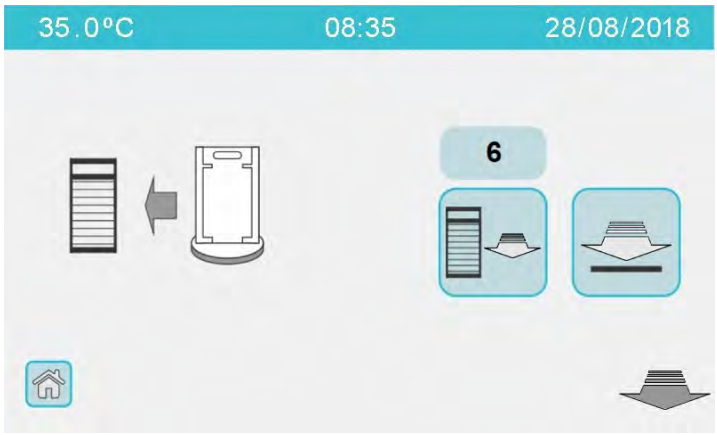
3. Remove the empty rack, then touch .



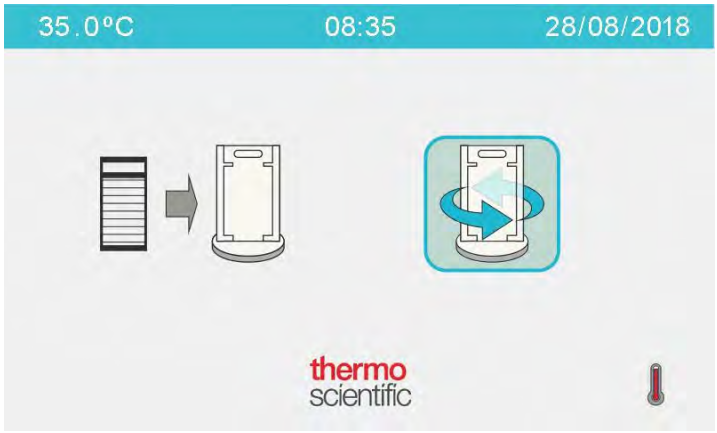
   The robotic arm moves an empty rack from the inner wall of the system to the inside position on the turntable.

4. Touch , then remove the presented rack.

5. To continue unloading additional racks, touch  .



6. Touch  , then remove the presented rack.
7. Repeat step 5 and step 6, to unload the required number of empty racks.
8. After the required number of empty racks are unloaded, touch  .
9. Place an empty rack on the turntable, then touch  .

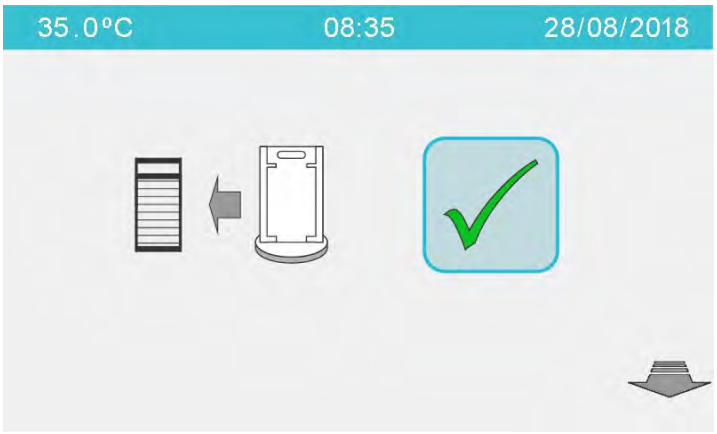


The **System Status** screen is displayed with updated indicators.

Unload plates

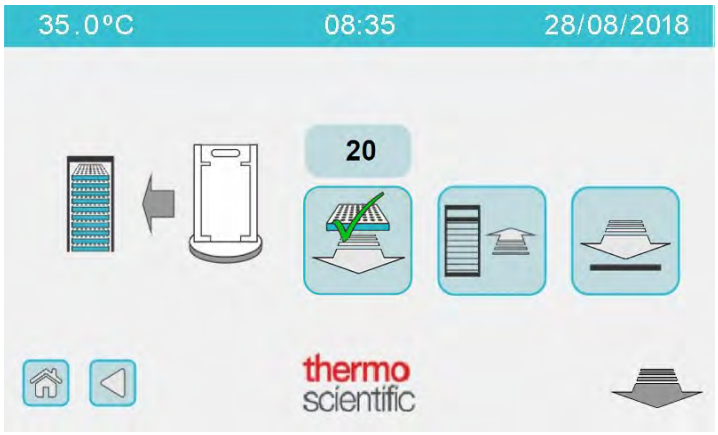
1. In the **Unload** screen, touch .

2. Touch .
   The turntable rotates to present the empty utility rack to the outside of the system.
3. Remove the empty rack, then touch .



   The robotic arm moves a rack containing completed plates to the inside of the turntable.
4. Touch , then remove the presented rack.

5. Select to continue unloading completed plates, load empty racks, or complete unloading.

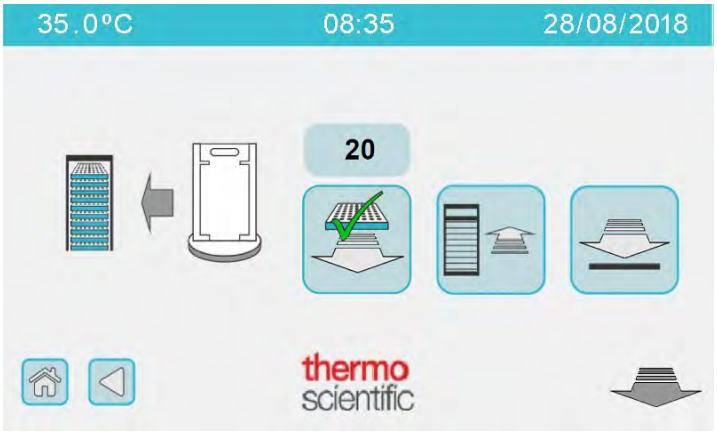


Options to continue	Action
Continue unloading completed plates 	Go to “Unload plates—continue unloading racks with completed plates” on page 62.
Load empty racks 	Touch  . The **Load** screen is displayed. To load empty racks, see “Load racks” on page 50.
Complete unloading 	Go to “Unload plates—complete the plate unload sequence” on page 64.

Unload plates—continue unloading racks with completed plates

This procedure continues the unload sequence from step 5 on page 61.

1. Touch .



The robotic arm moves a rack containing completed plates to the inside of the turntable.

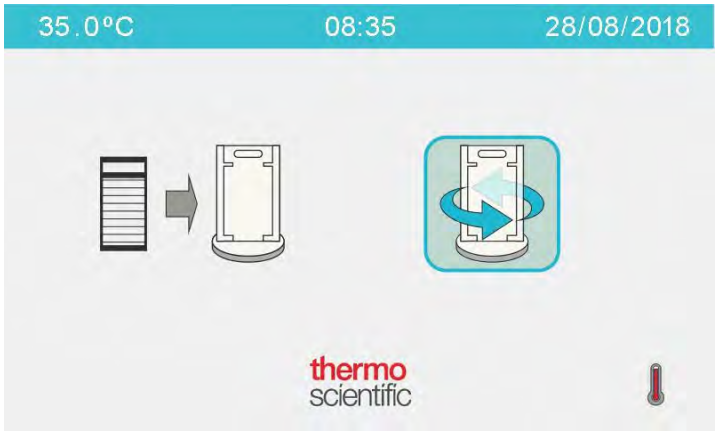
2. Touch .
3. Remove the presented rack, then repeat step 1 and step 2 to continue unloading racks with completed plates.

- If the remaining completed plates are in racks with plates that are not completed, the system begins the process for unloading completed plates using the utility rack. See “Unload plates—continue unloading completed plates using the utility rack” on page 63.
- If there are no completed plates available for unloading, go to “Unload plates—complete the plate unload sequence” on page 64.

Unload plates—continue unloading completed plates using the utility rack

If the remaining completed plates are in racks with plates that are not completed, the system starts the process to move completed plates to the utility rack for unloading.

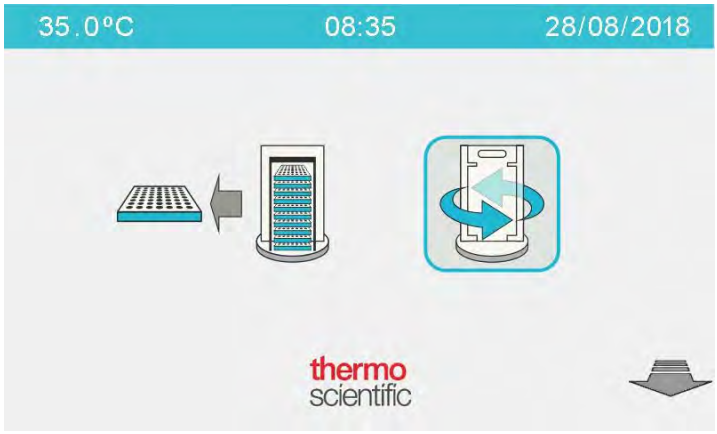
1. When prompted, place an empty rack on the turntable outside the system, then touch .



   The empty rack is moved to the inside of the turntable, then the robotic arm places completed plates in the rack.

2. Touch .

3. Remove the plates from the presented rack, then touch .

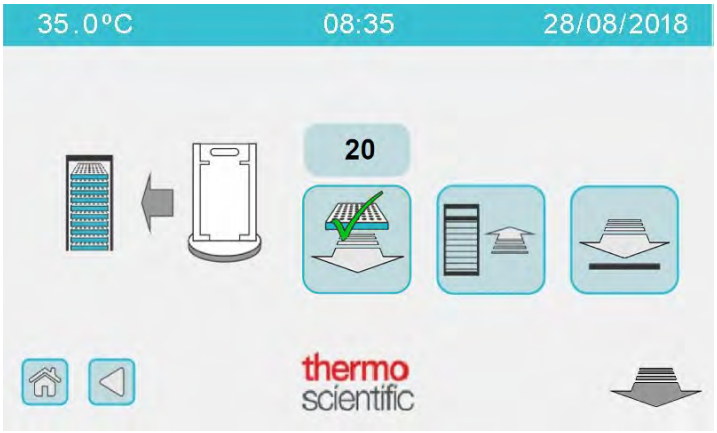


After the emptied rack is rotated to the inside of the turntable, the **Unload** screen is displayed, indicating the remaining number of plates and racks available to unload. See “Unload plates” on page 60.

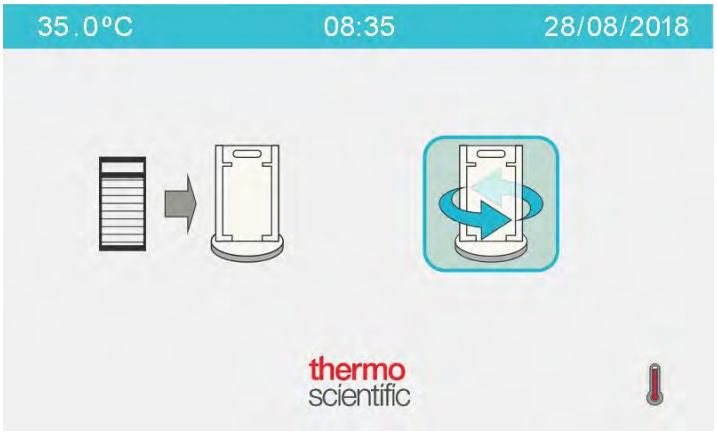
Unload plates—complete the plate unload sequence

This procedure completes the unload sequence from step 5 on page 61 or step 3 on page 62.

1. Touch  .



2. Place an empty rack on the turntable, then touch  .



The **System Status** screen is displayed with updated indicators.

Interrupt the shuffle feature

The shuffle feature runs automatically as a background activity. The feature is activated when there is no user or reading activity for more than 5 minutes.

The shuffle feature works optimally when there is an excess of internal racks loaded relative to the number of plates.

To use the ARIS HiQ™ system while it is shuffling, for example to load or unload plates, touch the screen display. The ARIS HiQ™ system displays a **Wait** screen while it completes handling of the plate being shuffled, then it is available for user interactions.

5 Maintenance

Preventive maintenance

The ARIS HiQ™ system requires annual preventive maintenance to ensure maximal reliability. Thermo Fisher Scientific cannot warrant the performance of any system that is not maintained in accordance with the maintenance schedule. Preventive maintenance reduces the risks of unplanned service visits and associated costs that may impede laboratory workflow and lead to a delay in patient care. Thermo Fisher Scientific and authorized distributors offer Extended Service Agreements, which cover preventive maintenance and, optionally, full coverage for instrument failures. Such agreements provide peace of mind and fixed costs to ensure the ongoing reliability and uptime of the instrument. To learn more, please contact your Account Manager or Technical Support.

CAUTION! Failure to adhere to the preventive maintenance schedule can result in product reliability problems that can lead to a delay in patient care.

Disclaimer: Thermo Fisher Scientific will not warrant the performance of any system that is not maintained in accordance with the Thermo Fisher Scientific preventive maintenance program.

Recommended inspection

CAUTION! Open the ARIS HiQ™ system access door by lifting forward and upward until the end-stop is reached. This is the fully opened position. Do not partially open the access door (see Figure 32 on page 87).

We recommend that you proceed with caution as to not injure yourself on the open door.

Table 16 Recommended inspection

Frequency	Inspection item	Instructions
Weekly	Door interlock safeguard. See Figure 21 on page 67.	Perform a door interlock safeguard test: Inspect and operate the door interlock safeguard to ensure that it works correctly. 1. Fully open the access door. See Figure 32 on page 87. 2. View the touchscreen for error 907. See "Error codes" on page 99. 3. Confirm that fans and motor to the transfer arm are deactivated.
Weekly	Turntable partition interlock safeguard. See Figure 33 on page 88.	Perform a turntable partition interlock safeguard test: Inspect and operate the turntable partition interlock safeguard to ensure that it works correctly. 1. Complete the door interlock safeguard test above. 2. Lift the turntable partition, then remove it from the system. See Figure 33 on page 88. 3. Close the access door, then touch ✓. This clears error 907. See "Error codes" on page 99. The system checks for other open interlock safeguards. 4. View the touchscreen for error 907. See "Error codes" on page 99. 5. Confirm that the fans and motor to the transfer arm are deactivated.
As needed	Inspect the exterior and interior for loose parts.	If loose parts are found, contact Technical Support.

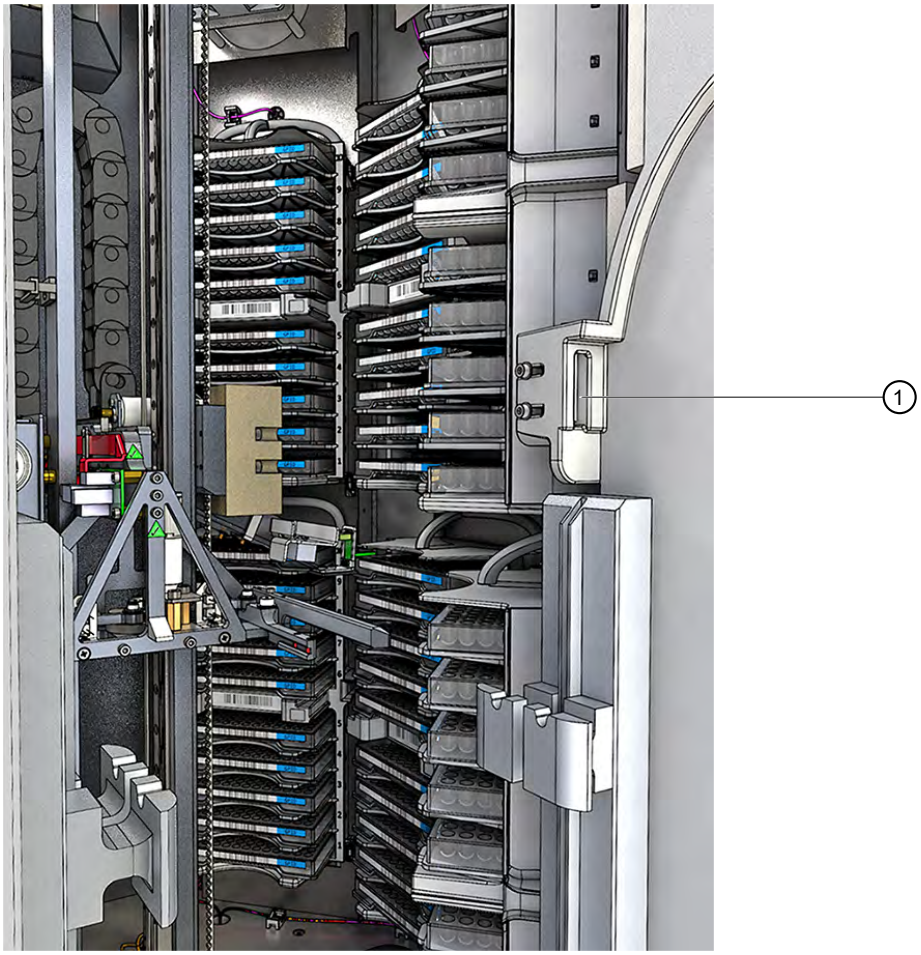


Figure 21 Door interlock safeguard

① The door interlock safeguard is found under the access door.

Replace the power inlet fuse

The fuse in the power inlet can be replaced by the user.

1. Power off the ARIS HiQ™ system, then disconnect the power cord.
2. Remove the used fuse, then replace it. See Figure 22.

   The system is shipped with a spare fuse that is located in the fuse box. If there is no spare fuse, obtain a new fuse.

   - Rating: T10AH250V (5 mm X 20 mm)
3. Push the fuse box back into place.

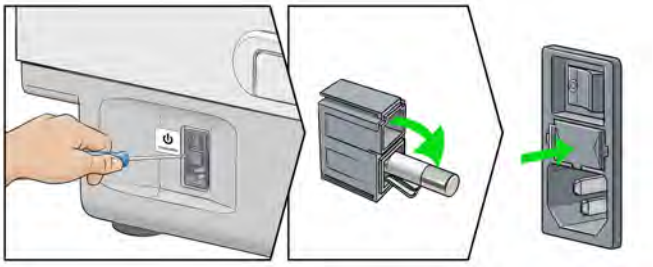


Figure 22 Replacement of the fuse in the power inlet

WARNING! All other fuses internal to the ARIS HiQ™ system should be changed only by a Sensititre™ system-trained service engineer.

Cleaning

WARNING! Disconnect the power cable from the ARIS HiQ™ system before applying disinfectant. Allow the disinfectant to evaporate before reconnecting the power cable.

WARNING! Do not use an aerosol, as it can leave a deposit on the circuit boards, leading to permanent damage.

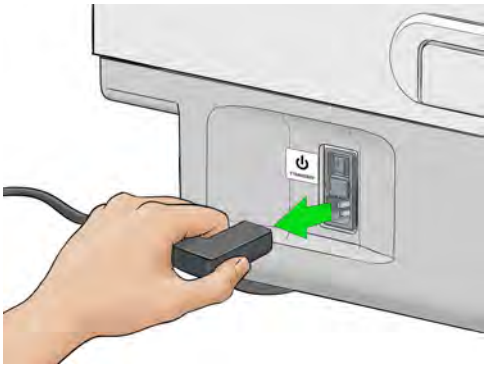
CAUTION! For additional information about cleaning and decontamination, see "Cleaning and decontamination" on page 15.

CAUTION! Open the ARIS HiQ™ system access door by lifting forward and upward until the end-stop is reached. This is the fully opened position. Do not partially open the access door (see Figure 32 on page 87).

We recommend that you proceed with caution as to not injure yourself on the open door.

General cleaning instructions

IMPORTANT! Disconnect the power cable from the ARIS HiQ™ system before cleaning.



Use one of the following cleaning solutions for decontamination and cleaning of the ARIS HiQ™ system:

- 70% isopropanol (IPA)—use as the primary cleaning solution for decontamination and cleaning.
- 0.5% sodium hypochlorite—recommended only for cleaning spills.

IMPORTANT! Spray cleaning solutions onto cleaning cloths. Do not spray cleaning solutions directly on interior or exterior surfaces. See Figure 23 on page 70.

Ensure that all surfaces are dry before powering on the system.

Discard cleaning products according to local regulations.

Figure 23 Recommended method for cleaning with solutions

Spray the cleaning solution on a cloth, then use the cloth to wipe down the surfaces.

Cleaning schedule and recommendations

WARNING! Before cleaning the ARIS HiQ™ system, power off the system and disconnect the cable from the ARIS HiQ™ system.

IMPORTANT! Items that are not listed in the following table are to be cleaned and lubricated only by a Sensititre™ system-trained service engineer.

Use 70% isopropanol (IPA) as the primary cleaning solution for decontamination and cleaning of the ARIS HiQ™ system.

Table 17 Cleaning recommendations and schedule

Frequency	Exterior items	Interior items[1]
Weekly	• Exterior surfaces of the ARIS HiQ™ system and the racks • Turntable and turntable partition • Plate racks • Touchscreen • Main case work	Visually check the glass plate on the internal OptiRead™ module for smears or dirt (see Figure 24 on page 72). Use a low-lint tissue manufactured specifically for cleaning optics. Follow the instructions provided with the tissues. **Note:** Do not use dry tissues, because this could scratch the glass. **1.** Lift the access door of the ARIS HiQ™ system, then lift the turntable partition to completely remove it (see Figure 32 on page 87 and Figure 33 on page 88). **2.** Spray a low-lint tissue with cleaning solution, then wipe the glass plate on the internal OptiRead™ module. **3.** Let the cleaning solution evaporate before using the ARIS HiQ™ system.
As needed	• Exterior surfaces of the ARIS HiQ™ system and the racks • Turntable and turntable partition • Plate racks • Touchscreen • Main case work • Power and communication cables	• Clean the glass plate on the internal OptiRead™ module if smears or dirt are seen when checking. At a minimum, clean every month. • Counterbalance weight and guide. See Figure 25 on page 72. • Narrow and wide arm grippers. See “Gripper assembly” on page 92. • Base plate. Wipe the base plate with a cloth dampened with cleaner. Do not spray on the surface. See Figure 26 on page 73.

[1] To expose the internal chamber, lift the front access door (see “Access the incubation chamber” on page 86), then remove the turntable partition.

Figure 24 Location of glass plate on the internal OptiRead™ module

The glass plate is found on the bottom right of the ARIS HiQ™ system incubation chamber.

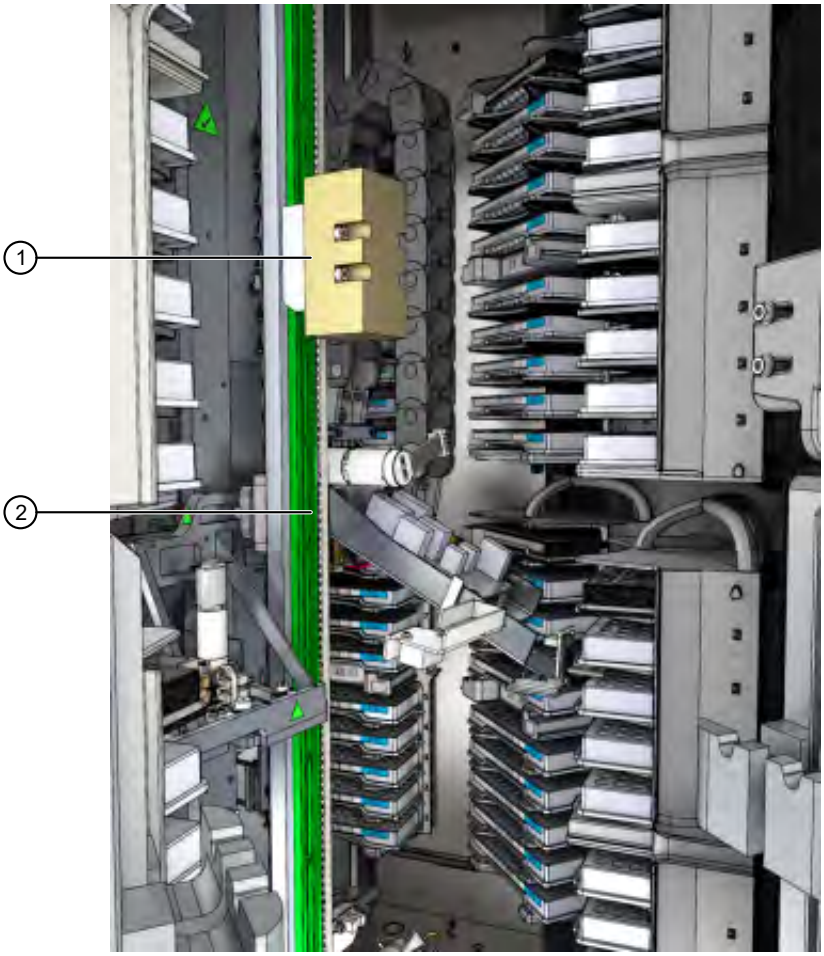


Figure 25 Counterbalance weight and guide

① Counterbalance weight.
② Counterbalance guide.

Figure 26 Base plate

The base plate is the floor of the system, excluding the OptiRead™ module.

6 Install, remove, or service *in situ* a temperature probe

CAUTION! Moving parts can crush, pinch, and cut. Keep hands clear of moving parts while operating the instrument. Disconnect power before installing, removing, or servicing any temperature probe hardware within the ARIS HiQ™ instrument.

WARNING! **Disconnecting Power.** To fully disconnect power either detach or unplug the power cord, positioning the instrument such that the power cord is accessible.

CAUTION! Open the ARIS HiQ™ system access door by lifting forward and upward until the end-stop is reached. This is the fully opened position. Do not partially open the access door (see Figure 32 on page 87).

We recommend that you proceed with caution as to not injure yourself on the open door.

IMPORTANT! The installation, removal, or *in situ* servicing is designed to support temperature probes with the following specifications:

- Probe diameter of 3 mm to 8 mm
- Probe length of 25 mm to 200 mm
- Minimum cable length of 1000 mm
- Cable diameter of 1.5 mm to 5.0 mm

Prepare the Sensititre™ ARIS HiQ™ System for installing or removing a temperature probe

The following instructions are applicable when installing, removing, or *in situ* servicing a temperature probe within the Sensititre™ ARIS HiQ™ System.

1. Use appropriate personal protective equipment (gloves, gowns, eye protection, etc.) to protect against chemical and biological hazards.
2. Fully unload the instrument of all plates and racks using the **Unload** functions on the instrument.

3. Turn off the instrument using the power inlet switch, then disconnect the power cable.

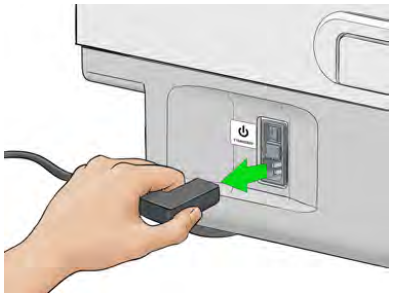


Figure 27 Disconnect the power cable from the instrument

4. Open the instrument access door by raising and pulling the door forward and upward by the recessed handle.

Figure 28 Access door to the incubation chamber

CAUTION! Open the ARIS HiQ™ system access door by lifting forward and upward until the end-stop is reached. This is the fully opened position. Do not partially open the access door.

We recommend that you proceed with caution as to not injure yourself on the open door.

Make sure to open the access door to its full extend to allow for safe and clear access to the inside of the incubation chamber.

5. Lift the turntable partition until it clears the mount on the turntable.

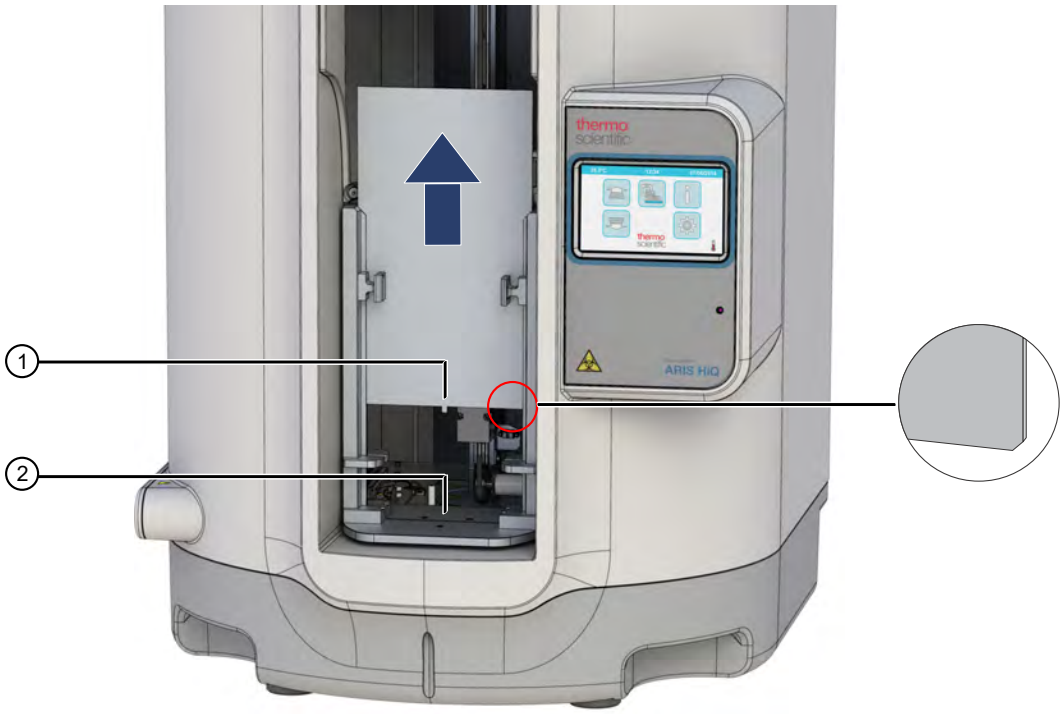


Figure 29 Turntable partition

The bevels at the bottom corners of the partition are designed to facilitate reinsertion of the partition in the mount.

① Turntable partition pin. The pin engages the interlock safeguard when the partition is fully inserted into the mount.

② The interlock safeguard is located in the depression of the turntable.

IMPORTANT! Do not damage the pin at the base of the partition. Avoid contact with the pin to prevent injury.

6. Remove the Utility Rack sitting inside the turntable by lifting the rack upwards by its handle and rotating it sideways to remove it through the opening.

7. Slowly and gently relocate the Gripper Arm to the position shown in Figure 30.
   The Gripper Arm can be moved around during the temperature probe installation if needed.

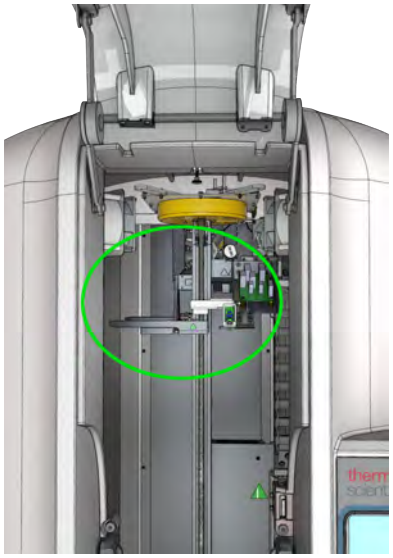


Figure 30 Suggested position of the Gripper Arm

8. Perform any necessary decontamination steps to the inside of the instrument.

Install a temperature probe

Proceed with the instructions listed in "Prepare the Sensititre™ ARIS HiQ™ System for installing or removing a temperature probe" on page 74 before installing a temperature probe.

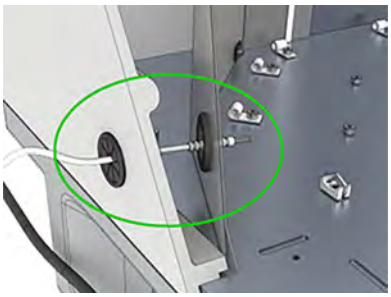
1. Identify the probe entry point located on the left side of the instrument just above the power inlet.

2. Remove the blanking plug from the entry point using a small flat screwdriver.

   Proceed with caution when removing the blanking plug to avoid damage to the instrument casework.

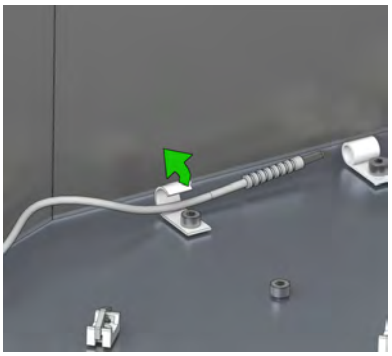
3. Insert the temperature probe through the slitted bung provided with the instrument, then through the entry point.

4. Make sure that the probe passes through the hole in the metal chassis located just past the entry point inside the instrument.



5. Insert the bung into the entry point to close it.

6. Route the temperature probe cable across the chassis plate, then up the back wall of the instrument using the pre-fitted cable clips.



7. Arrange the cable so the probe head and terminating cable are located as shown in the following picture.

Ensure that the probe end is not touching the metal casing and is clear of the clips.

IMPORTANT! Ensure that there is no excess of cable exposed or loose between the clips. It could be a snagging hazard for the gripper arm during its operation.

8. Tighten the adjustable clips by pulling the fastener tab to secure the probe end and cable in place.

IMPORTANT! Ensure that any tools or other objects are removed from the inside of the instrument.

Remove a temperature probe

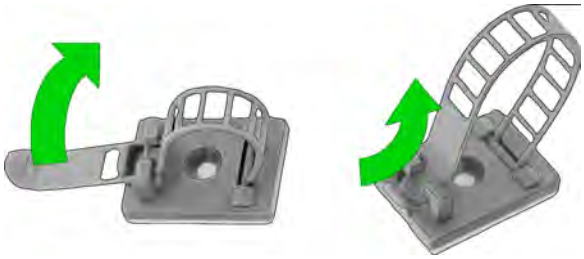
Proceed with the instructions listed in "Prepare the Sensititre™ ARIS HiQ™ System for installing or removing a temperature probe" on page 74 before removing a temperature probe.

1. Release the probe head and cable from the three clips on the back wall of the chassis.

   a. Hold the fastener tab on the clip.

   b. Lift the tab to a 45° angle.

c. Push the tab to feed the fastener strap through the slit.



2. Unclip the probe cable from the 5 clips located on the baseplate and the back wall of the instrument.

3. Carefully extract the temperature probe through the slitted bung.

IMPORTANT! Ensure that any tools or other objects are removed from the inside of the instrument.

Guidelines for servicing *in situ* a temperature probe

- Proceed with the instructions listed in “Prepare the Sensititre™ ARIS HiQ™ System for installing or removing a temperature probe” on page 74 before servicing *in situ* a temperature probe.
- Ensure that there is no excess of cable exposed or jutting out between the clips. It could be a snagging hazard for the gripper arm during its operation.
- Ensure that any tools or other objects are removed from the inside of the instrument.

A Troubleshooting

First steps when encountering a problem

If you encounter an unexpected problem, we recommend:

- **Pause for a moment.** Do not immediately do anything with the instrument or the software.
- **Observe.** Consider the situation with the whole system (including instrumentation, software, related peripherals, and the surroundings).
  - There may be an obvious issue.
  - You may be observing a smaller secondary issue relating to a more obvious wider issue.
  - It is important to try and take in the entire situation and circumstances regarding the problem. This provides the best chances of correctly assessing the situation and considering the right steps to record key information about it, leading to its resolution.

How to work through a problem and record information

Detailed steps and considerations when working through a problem:

1. Is the problem a known issue that is recorded in either this User Guide or the Errata notice?
   - If yes, follow the instructions in these documents to resolve. It is important that you also notify technical support that you have encountered this issue.
2. Is the problem mechanical? Are there/were there any signs of the following types of issues?
   - A loud noise from the instrument when the problem occurred.
   - The instrument robotics/automation froze or appeared to stop working? For example, has the turntable stopped part way through its movement?

This would suggest that a hardware problem has occurred.

- Has a rack/plate dropped?
- Is there any evidence that a collision has taken place?
- Is there an obstruction of some kind that is getting in the way?

3. Are the software and instrument User Interfaces presenting screens and information that look incorrect? Are any errors listed?
   - If an error number is encountered, see “Alerts” on page 97.
   - If a software error or exception has been raised, what information is provided? Consider what is happening with the overall software/instrument.
   - Are any communication problems being reported by the software? If NO, look at the Communications Manager (see “Retrieve the log files” on page 109) directly to see whether a problem has been encountered which is not being reported via a warning message. Please refer to the *Sensititre™ SWIN™ Software System Instructions For Use* (Pub. No. MAN0017791) for instructions to re-enable the instrument
   - If a User Interface screen or information presented in it looks incorrect, does this provide any clues as to the possible cause?

It is important to record all relevant information for the issue encountered; this may include:

- The circumstances that led up to the problem occurring (for example, details of the various plate types and numbers of plates in use).
- Photographs and/or video. You can use a camera phone.

We recommend that you contact Technical Support for any issues that remain unresolved, following an initial investigation that does not resolve the identified problem.

Use Instant Read to read a plate

WARNING! Sensititre™ plates should be read only at the incubation times that are specified by the plate type. The Instant Read function should be used only in exceptional circumstances.

Depending on the Sensititre™ system, plates are read automatically at specified times. It is possible to intervene to read a plate at any time using the Instant Read function. If there is a need to read the plate at a non-specified time, use Instant Read.

In the **Plate Section List** screen, touch  to start Instant Read. See “Plate Section List screen” on page 36 and Table 10.

Note: If Instant Read is selected for a multi-isolate plate, all specimen/isolate combinations associated with the plate are read.

System Status screen displays unexpectedly

The ARIS HiQ™ system user interface is designed with a 3–minute timeout function. The timeout is activated when the Load or Unload screens remain idle for more than 3 minutes.

The timeout defaults to the ARIS HiQ™ **System Status** screen, and allows the ARIS HiQ™ system to read scheduled plates. Touch any button, then follow the prompts to continue.

Connection with SWIN™ system is lost

IMPORTANT! The ARIS HiQ™ system must remain connected to the SWIN™ system, because information is continuously transferred between the two systems. If the connection is lost, a warning message is displayed on the SWIN™ system and the ARIS HiQ™ system.

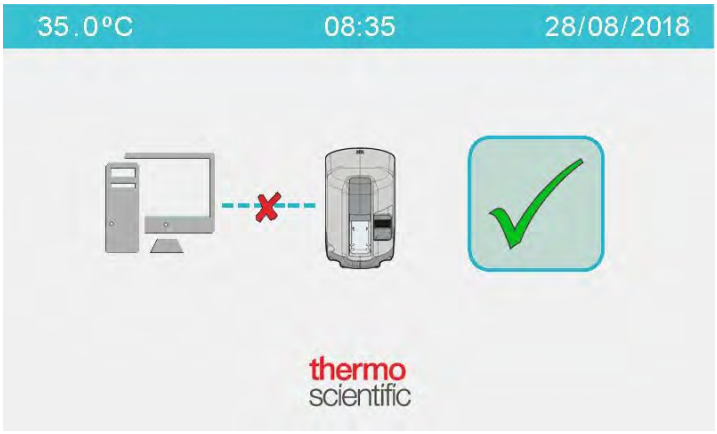


Figure 31 ARIS HiQ™ system message warning that the connection with the SWIN™ system is lost

If the connection is lost, follow these steps:

1. Ensure that the communication cable is plugged in to both systems.
2. Power off the ARIS HiQ™ system and the SWIN™ system, wait 15 seconds, then power on the systems.
3. If communication does not resume between the two systems, contact Technical Support.

Troubleshooting that requires access to the incubation chamber

The ARIS HiQ™ system has been designed and built to ensure trouble-free operation. Rarely is there a need to conduct manual work inside the incubation chamber. However, provision has been made to allow safe, manual access to the incubation chamber so that any problems that arise can be easily resolved.

WARNING! Do not use the methods in this section to bypass normal ARIS HiQ™ system operations. Use these methods only if problems occur and plates or racks cannot be removed using the ARIS HiQ™ system Unload workflow. See “Unload racks or plates” on page 57.

WARNING! Do not attempt to work inside the incubation chamber when ARIS HiQ™ system mechanisms are operating, as serious injury can occur. An interlock safeguard is in place to prevent injury. Do not attempt to override the interlock safeguard.

WARNING! Power off, then disconnect the power from the system before accessing the incubation chamber.

CAUTION! Open the ARIS HiQ™ system access door by lifting forward and upward until the end-stop is reached. This is the fully opened position. Do not partially open the access door (see Figure 32 on page 87).

We recommend that you proceed with caution as to not injure yourself on the open door.

Access the incubation chamber

IMPORTANT! Do not open the access door at a time when a plate read is in progress.

1. Use the recessed handle to raise, then pull the access door forward and upward. See Figure 32 on page 87.
2. Open the access door to its full extent to have safe, clear access to the inside of the incubation chamber.

   To ensure safety, the ARIS HiQ™ system detects that the access door is opened, and power is disabled to the internal moving parts. Although power to the internal moving parts is disabled:

   - The OptiRead™ module pauses operation.
   - If the turntable was in motion when the access door is raised, the turntable stops after a brief delay (less than 2 seconds).

3. Remove the turntable partition: lift the partition up until it clears the mount on the turntable. See Figure 33 on page 88.

   When the partition is removed, the internal chamber mechanisms are exposed, and the transfer arm assembly is visible.

   IMPORTANT! Do not damage the pin at the base of the partition. Avoid contact with the pin to prevent injury.

4. After work inside the incubation chamber is complete, reinsert the partition, ensuring that the beveled corners are at the bottom.

   After the turntable partition is replaced and the front access door is closed, the system performs an inventory scan.

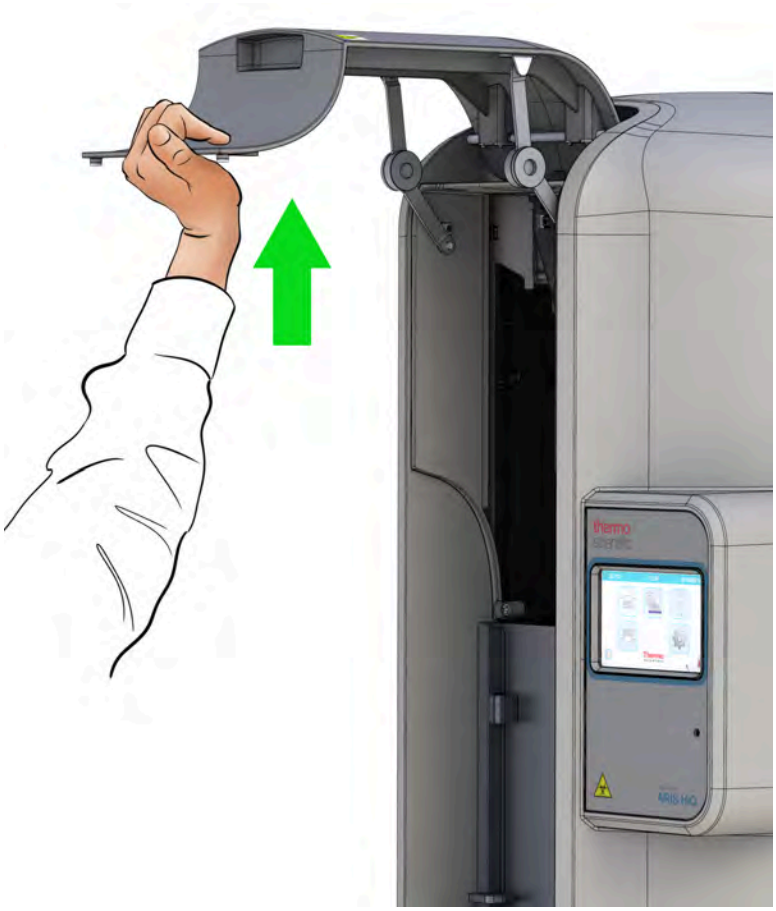


Figure 32 Access door to the incubation chamber

CAUTION! Open the ARIS HiQ™ system access door by lifting forward and upward until the end-stop is reached. This is the fully opened position. Do not partially open the access door.

We recommend that you proceed with caution as to not injure yourself on the open door.

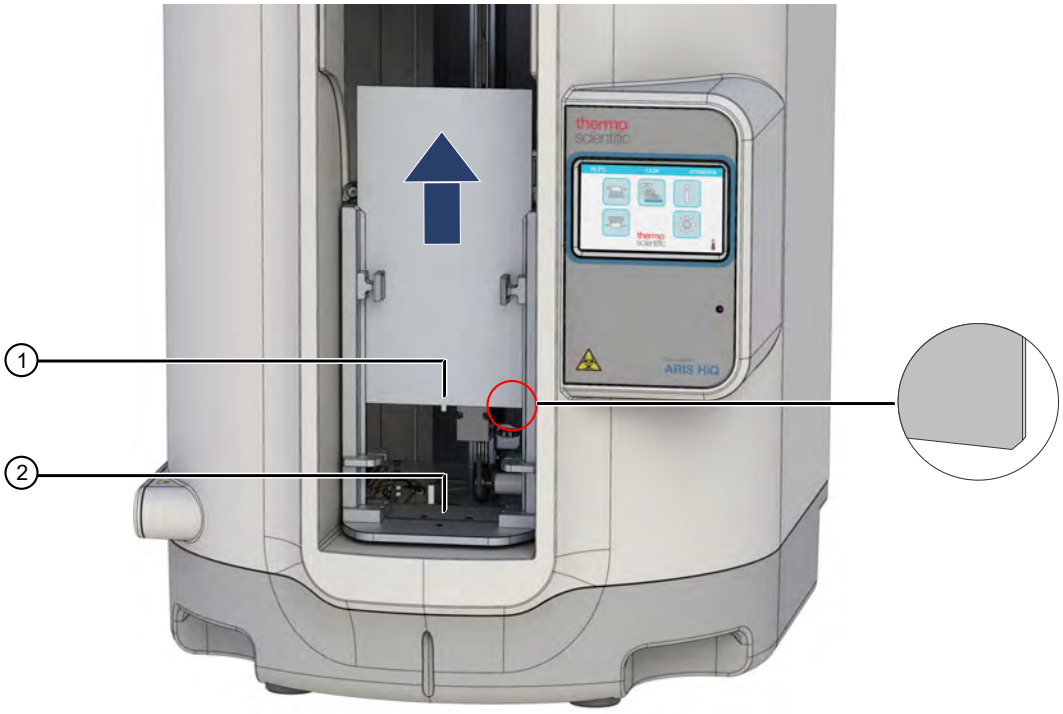


Figure 33 Turntable partition

The two bottom corners of the partition are designed with bevels to ease the reinsertion of the partition into the mount on the turntable.

① Turntable partition pin. The pin engages the interlock safeguard when the partition is fully inserted into the mount.
② The interlock safeguard is located in the depression of the turntable.

Manually remove obstructions from the incubation chamber

If a plate or rack handling error occurs, an obstruction may be present that restricts or blocks the movement of the ARIS HiQ™ robotics. To remove obstructions manually:

1. Access the ARIS HiQ™ system by opening the access door, then removing the turntable partition (see “Access the incubation chamber” on page 86).
2. Remove the obstruction.

Potential obstruction	Action
Plate or rack that is not held correctly in the gripper causing it to protrude outward	Remove the plate or rack.
Dropped plate	See “Remove dropped plates or racks from the incubation chamber” on page 94.
Dropped rack	
Plate that collided with another plate—the ARIS HiQ™ system is attempting to load a plate into a position where a plate is already present	Remove both plates from the ARIS HiQ™ system, then reload using the load function.
Rack that collided with another rack—the ARIS HiQ™ system is attempting to load a rack into a position where a rack is already present	Remove both racks from the ARIS HiQ™ system, then reload using the load rack function.

Touch point labels

Touch point labels indicate surfaces that can be pushed or pulled to move the transfer arm assembly manually. Apply pressure only to surfaces marked with a touch point label.

Figure 34 Touch point label

Move the transfer arm assembly

All the mechanisms are mounted on a central column that are collectively called the transfer arm assembly. Occasionally, the transfer arm assembly must be moved manually; for example, to access a plate in the incubation chamber.

The transfer arm assembly is robust, but it can be damaged with mishandling.

To move the transfer arm assembly, apply pressure only to the surfaces marked with a touch point label. See “Touch point labels” on page 89.

IMPORTANT! Touch only the surfaces that are marked with a touch point label. Do not apply pressure on any other internal component.

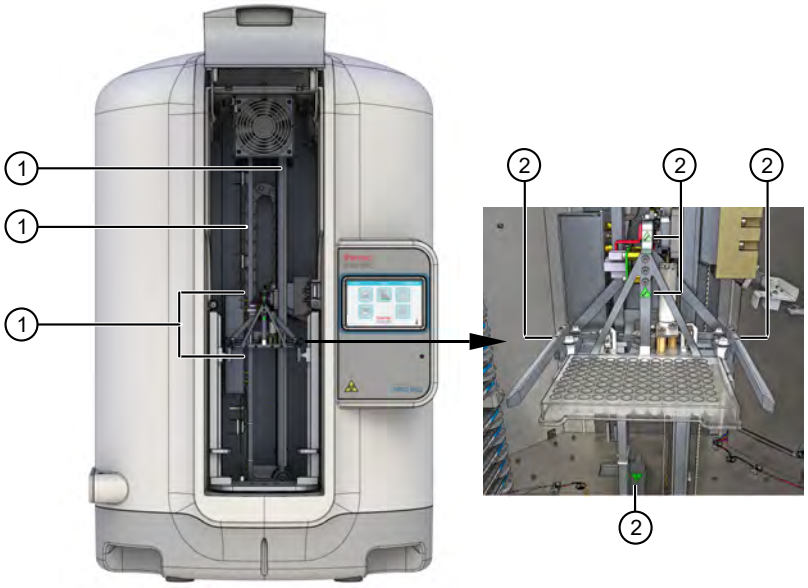


Figure 35 Transfer arm assembly

① The transfer arm assembly includes 2 vertical metal bars and the gripper assembly.
② Location of touch point labels on the gripper assembly.

Manually remove a plate from a rack

1. Access the incubation chamber (see “Access the incubation chamber” on page 86).
2. Carefully lift the plate to release the plate from the pins at the back of the rack shelf, then withdraw the plate completely from the shelf.
3. Carefully maneuver the plate through the front of the ARIS HiQ™ system.

Manually remove a rack from the incubation chamber

1. Access the incubation chamber (see “Access the incubation chamber” on page 86).
2. Carefully lift the rack from its mount, using the handles on the top of the rack.
3. Carefully maneuver the rack through the front of the ARIS HiQ™ system.

Remove a plate from the gripper

1. Access the incubation chamber (see “Access the incubation chamber” on page 86).
2. If needed, remove the utility rack from the turntable.
3. If needed, carefully rotate the transfer arm assembly so that the plate is to the front of the ARIS HiQ™ system.

IMPORTANT! Touch only the areas that are marked with a touch point label. See “Touch point labels” on page 89.

4. Find the narrow pair of grippers on the transfer arm assembly. See Figure 36 on page 92 to help identify the grippers.

5. Carefully move the plate up and down on the transfer arm until it is in a good position for removal.
   a. Steady the gripper. If the gripper is not steadied properly, the assembly moves forward when the plate is removed.

   b. Hold the plate by its two short edges and carefully maneuver it towards you until it is removed from the gripper jaws.

6. Remove the plate through the front opening of the ARIS HiQ™ system.

7. Replace the empty utility rack and the turntable partition.

8. Close the front access door.

9. Use the Load function to load any plates that were removed from the ARIS HiQ™ system before incubation was complete.

Remove a rack from the gripper

1. Access the incubation chamber (see “Access the incubation chamber” on page 86).

2. If needed, remove the utility rack from the turntable.

3. If needed, carefully rotate the transfer arm assembly so that the rack is to the front of the ARIS HiQ™ system. Ensure that the rack does not drag across the base of the instrument.

4. Find the wide pair of grippers on the transfer arm assembly. See Figure 37 on page 93 to help identify the grippers.

5. Carefully move the rack up and down on the transfer arm until it is in a good position for removal.
   a. Hold the rack with one hand on the center of the rack, and steady the gripper. If the gripper is not steadied properly, the assembly moves forward when the rack is removed.

   b. Keeping the rack steadied, grip the rack in the center, and gently maneuver it outward until it is removed from the gripper jaws.

6. Remove the rack through the front opening of the ARIS HiQ™ system.

7. Replace the empty utility rack and the turntable partition.

8. Close the front access door.

9. Use the Load function to load any plates that were removed from the ARIS HiQ™ system before incubation was complete.

Gripper assembly

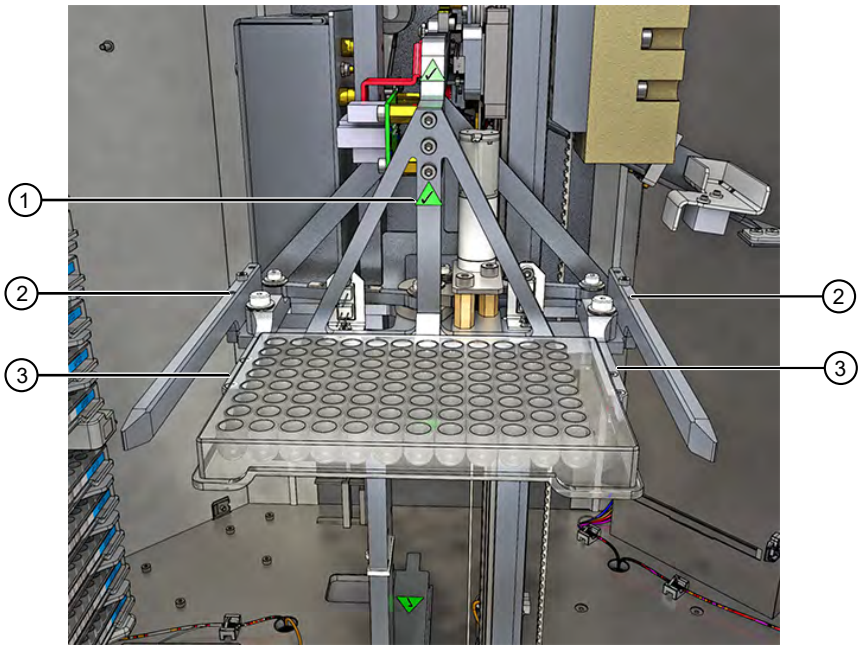


Figure 36 Narrow and wide arm grippers

① Touch point label. Indicates a surface that can safely be held or pushed.
② Wide gripper jaw for holding racks.
③ Narrow gripper jaw, shown holding a plate.

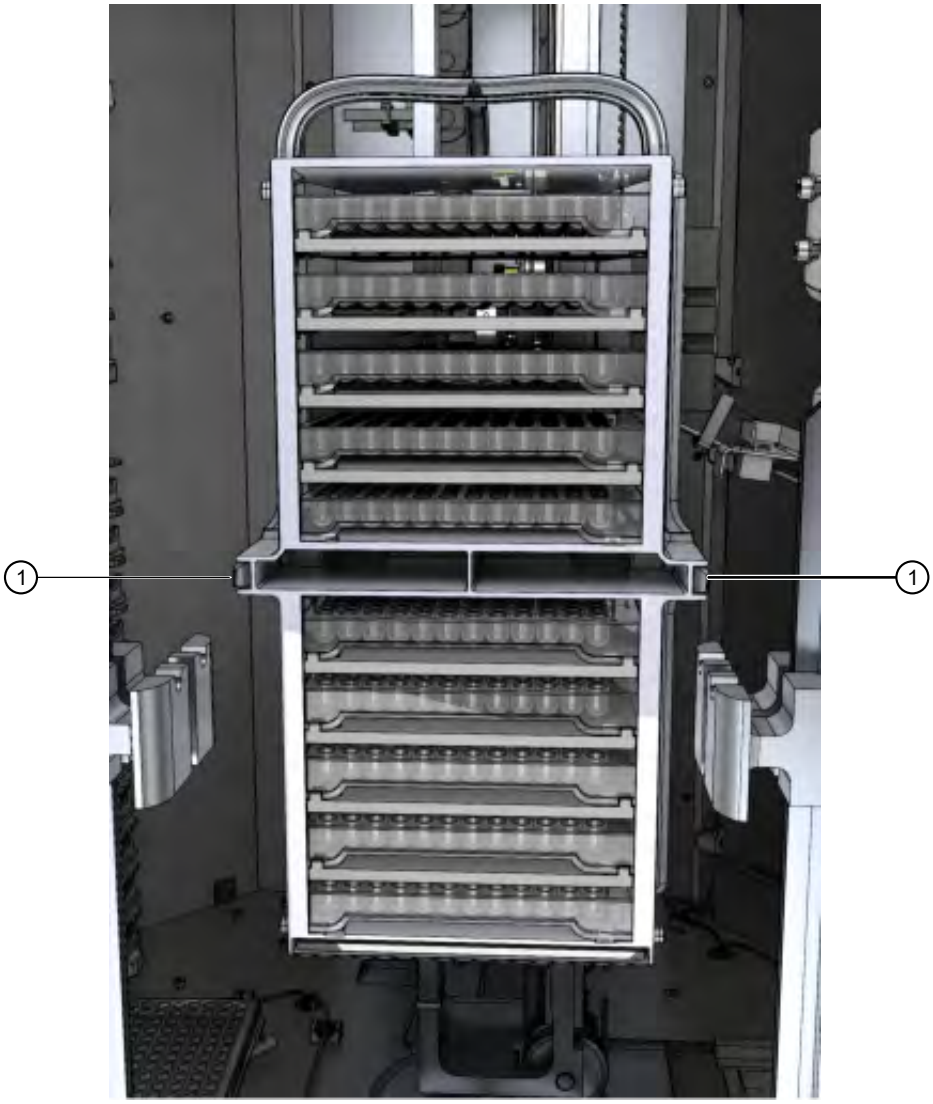


Figure 37 Wide arm gripper holding a rack

① Wide arm gripper jaws.

Remove dropped plates or racks from the incubation chamber

If the ARIS HiQ™ system is correctly maintained, not disturbed during operation, and remains in a stable position, plates and racks are unlikely to drop inside the incubation chamber.

If plates or racks are dropped to the bottom of the chamber, manually remove the dropped plates or racks.

1. Access the incubation chamber (see “Access the incubation chamber” on page 86).
2. If needed, remove the utility rack from the turntable.
3. Gently rotate the transfer arm assembly, then move the gripper up or down until it is in a comfortable position to give easy access to fallen plates.
4. Remove any fallen plates or racks.
5. Perform any necessary decontamination.
6. Replace the utility rack, then the turntable partition.
7. Close the front access door, then touch ✓ to clear error 907 (access door open).

If a plate was being read in the OptiRead™ module when the access door was opened, error code 202 is displayed after the door is closed and error code 907 is cleared. In this case, open the access door, remove the plate from the gripper jaws, then reload the plate. See error code 202 in “Error codes” on page 99.

Troubleshooting short- or long-term power outages

CAUTION! Failure to handle ARIS HiQ™ and SWIN™ system power outage events correctly can result in incorrect plate read scheduling.

Table 18 Power outage events and solutions

Power outage type	Observations	Actions
Long-term or overnight power loss to the laboratory	The power is still turned off.	1. Dispose of the affected plates. 2. Remake the affected plates, then incubate and read.
	The power is turned on, but the SWIN™ software is not running.	
	The temperature in the ARIS HiQ™ system is reduced, and/or the scheduled read windows were missed.	
Short-term power loss to the laboratory	A temperature warning is displayed on the user interface.	Assess whether the plates being incubated were affected by a reduced incubation temperature.

Table 18 Power outage events and solutions *(continued)*

Power outage type	Observations	Actions
Short-term power loss to the laboratory	The plates were not read at their scheduled times.	• If yes, then dispose of the affected plates. Remake the affected plates, then incubate and read. • If no, and the power loss is noted AFTER any scheduled plate reads are due, and the read window has passed, then: – Dispose of the affected plates. – Remake the affected plates, then incubate and read. • If no, and the power loss is noted BEFORE any scheduled plate reads are due, then: – Resend plate data from the SWIN™ system to the ARIS HiQ™ system, allowing the plates to be read within their scheduled read windows.
Power loss to the SWIN™ PC only, includes deliberately turning off the power	The plates were read by the ARIS HiQ™ system against the last scheduled read windows provided by the SWIN™ software.	Read results data are held by the ARIS HiQ™ system until SWIN™ system communication is restored. Once the communication is restored, the data will be transmitted. **1.** Restart the SWIN™ PC and SWIN™ software. **2.** As a precautionary measure, retransmit plate data from the SWIN™ system to the ARIS HiQ™ system.
	A SWIN™ communications loss is displayed on the ARIS HiQ™ system user interface.	
	The SWIN™ notification center indicates the time of power and communication loss.	
Short-term power loss to the ARIS HiQ™ system, includes deliberately turning off the power	The power is off and the ARIS HiQ™ system is inactive. The user interface is blank.	Using information from the notification center, assess whether the plates being incubated were affected by a reduced incubation temperature. • If yes, then dispose of the affected plates. Remake the affected plates, then incubate and read. • If no, then resend the plate data from the SWIN™ system to the ARIS HiQ™ system, allowing the plates to be read within their scheduled plate windows.
	The power is on, and the user interface displays the Home screen.	
	The SWIN™ notification center indicates the time of power and communication loss.	
	The power is on and the ARIS HiQ™ system displays a reduced temperature on the display ribbon.	

Table 18 Power outage events and solutions *(continued)*

Power outage type	Observations	Actions
Long-term power loss to the ARIS HiQ™ system	The power is off and the ARIS HiQ™ system is inactive. The user interface is blank.	Assess if the plates being incubated were affected by a reduced incubation temperature. Dispose of any affected plates. Remake the affected plates, then incubate and read.
	The power is on, and the user interface displays the Home screen.	
	The SWIN™ notification center indicates the time of power and communication loss.	
	The power is on and the ARIS HiQ™ system displays a reduced temperature on the display ribbon.	

Alerts

Temperature alerts

The temperature warning is displayed if the temperature is out of range for approximately 5 minutes. This delay allows the system to account for short-term temperature variations that can occur if large numbers of plates are loaded or removed from the system.

Condition	Error screen
Temperature too low	
Temperature too high	

CAUTION! If plates have been incubating in the ARIS HiQ™ system with the temperature out of range for longer than 15 minutes, the test becomes invalid and the plates must be discarded appropriately.

If the temperature is not corrected within 15 minutes, restart the system. Allow 1 hour for the system to return to normal temperature.

Note: If the temperature remains out of range, remove plates from the ARIS HiQ™ system and incubate off-line in another incubator. At the end of the off-line incubation, the plates can still be read in the ARIS HiQ™ system using the Instant Read function. If the problem continues to occur, contact Technical Support.

Plate error alert

Figure 38 Plate error alert

The **System Status** screen displays a yellow exclamation point that indicates the SWIN™ software has sent plate information to the ARIS HiQ™ system for a plate that is not loaded in the system.

30-minute alert

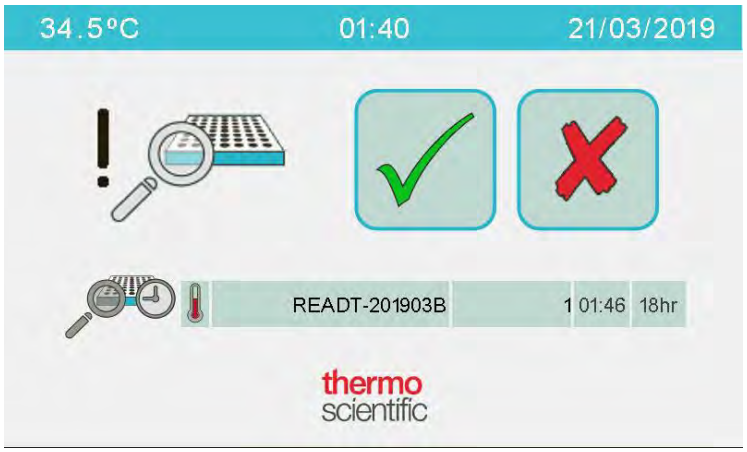


Figure 39 30-minute alert

The **30-minute alert** screen is displayed if an attempt is made to load or unload plates within 30 minutes of a plate read. To ensure that a scheduled plate read can proceed, touch ✓ to continue the load/unload action, or return to the previous screen by touching ✘.

Error codes

If a system error occurs, an error code is displayed on the error screen.

Figure 40 Error screen and error code

Table 19 Error codes and actions

Error code	Action
001 – Checksum failure	Fatal error. Contact Technical Support.
002 – Processor watchdog error	1. Inspect the inside of the system. If there is a plate on the OptiRead™ module, remove it. 2. To clear the error, touch ✓. The system performs an inventory scan. 3. If the error persists, contact Technical Support. 4. Ensure that results have been recorded for the removed plate. 5. If not, reload the plate and use Instant Read.
003 – Sequence state transition did not occur within required time	Note the sequence of actions leading to the error and report this to Technical Support.
004 – Loading error. Unexpected utility rack detected	Raise the access door and inspect the incubation chamber for the presence of a rack on the inside of the turntable. • If a utility rack is present: a. Remove the turntable partition, then remove the rack. b. After replacing the partition, and closing the access door, touch ✓ to clear the error message. • If there is no rack present: the proximity sensor may be faulty, contact Technical Support.
005 – Temperature too low	See “Temperature alerts” on page 97.
006 – Temperature too high	See “Temperature alerts” on page 97.

Table 19 Error codes and actions *(continued)*

Error code	Action
008 – Barcode error The system cannot read the plate barcode	If the error occurs while loading plates using the Rack Load or Enhanced Load option, error code 008 is displayed. 1. In the **Plate Section List** screen, identify which plate barcode was not read. See “Other errors” on page 106 (is displayed in the plate status, and **????????** is displayed in the specimen number field). 2. In the **Plate Section List** screen, highlight the affected plate and touch **Unload**, then follow the prompts to unload the plate. 3. Inspect the plate barcode for damage (for example, poor printing/torn label). 4. If damage is detected, replace the barcode label (a spare label is provided in the package with the plates). 5. Rescan the plate in the SWIN™ system, re–enter the plate information, then reload the plate. See “Load plates or racks into the ARIS HiQ™ system” on page 49. **Note:** All specimen/isolate combinations associated with the plate are reread. If the ARIS HiQ™ system fails to recognize numerous plate barcodes, this suggests a setup problem with the system. Contact Technical Support.
	If the error occurs while loading plates using the Single Plate Load option, the error code is not displayed. The system does not load the plate. Instead, it unloads the plate automatically. 1. Inspect the plate barcode for damage (for example, poor printing/torn label). 2. If damage is detected, replace the barcode label (a spare label is provided in the package with the plates). 3. Rescan the plate in the SWIN™ system, re–enter the plate information, then reload the plate. See “Load plates or racks into the ARIS HiQ™ system” on page 49. If the ARIS HiQ™ system fails to recognize numerous plate barcodes, this suggests a setup problem with the system. Contact Technical Support.
009 - Barcode initialization error	This error code can occur if the barcode scanner failed to initialize at start-up. The error can occur when power is restored after an access door has been opened and closed. 1. Touch to clear the error. The system re-initialization runs after dismissing an error notification. 2. If the re-initialization is successful, the initial error can be disregarded. 3. If the error is not cleared, contact Technical Support.

Table 19 Error codes and actions *(continued)*

Error code	Action
010 – Too many plates	This error is displayed if the user attempts to load more than 100 plates. • If there are completed plates inside the system: remove them before attempting to load additional plates. • If the system is full of incubating plates: **a.** Incubate the additional plates off-line, in another incubator. **b.** At the scheduled read times, load the plates into the ARIS HiQ™ system, then perform Instant Read. See “Use Instant Read to read a plate” on page 84. Plate information that has been entered in SWIN™ software is transmitted to the ARIS HiQ™ system when the plate is loaded.
011 – A request to take the system into run mode while a read is in progress	Contact Technical Support.
012 – More than 50 plates with 5-hour reads	**1.** Touch ✓ to clear the error. **2.** Remove 5-hour-read plates in excess of 50.
101 – OptiRead™ module mechanism timeout	**1.** Power off the ARIS HiQ™ system. **2.** Wait at least 15 seconds, then power on. **3.** If the error is not cleared, contact Technical Support. **Note:** If the OptiRead™ module was reading when the error appeared, perform an Instant Read on the plate. See “Use Instant Read to read a plate” on page 84.
105 – OptiRead™ module mechanism movement error	Contact Technical Support.
106 – OptiRead™ module calibration up error	Contact Technical Support.
107 – OptiRead™ module calibration down error	Contact Technical Support.
108 – OptiRead™ module failed to start reading	Contact Technical Support.
201 – Gripper jaws overclosed	**1.** Open the access door, then inspect the gripper jaws for problems. See “Gripper assembly” on page 92. **2.** Close the access door, then touch ✓ to clear the error. The system performs an inventory scan. **3.** If the error is not cleared, contact Technical Support.

Table 19 Error codes and actions *(continued)*

Error code	Action
202 – Gripper jaws unexpectedly holding a plate	1. Open the access door. 2. Carefully remove the plate from the jaws of the gripper. See "Gripper assembly" on page 92, and "Remove a plate from the gripper" on page 90. 3. Close the access door, then touch ✓ to clear the error. The system performs an inventory scan. 4. If the plate was not completed, reload it using the Load function.
203 – Gripper jaws closed unexpectedly	1. Open the access door, then inspect the gripper jaws. See "Gripper assembly" on page 92. 2. Close the access door, then touch ✓ to clear the error. The system performs an inventory scan. 3. If the error is not cleared, contact Technical Support.
204 – Gripper jaws open unexpectedly	1. Open the access door, then inspect the gripper jaws. See "Gripper assembly" on page 92. 2. Close the access door, then touch ✓ to clear the error. The system performs an inventory scan. 3. If the error is not cleared, contact Technical Support.
205 – Gripper jaws detection faulty	Contact Technical Support.
206 – Gripper status error	Status of gripper is different than expected. See "Gripper assembly" on page 92. 1. Open the access door, then inspect the gripper jaws. 2. Close the access door, then touch ✓ to clear the error. The system performs an inventory scan. 3. If the error is not cleared, contact Technical Support.
304 – Horizontal movement of transfer arm is obstructed	1. Open the access door, then inspect the transfer arm. Carefully remove any obstruction from the chamber, and any plate or rack from the jaws of the gripper. See "Manually remove obstructions from the incubation chamber" on page 89. To access the incubation chamber, see page 86. 2. Close the access door, then touch ✓ to clear the error. The system performs an inventory scan. 3. If the error is not cleared, contact Technical Support.
307 – Horizontal movement timeout	1. Open the access door, then inspect the internal space. Carefully remove any obstructions. See "Manually remove obstructions from the incubation chamber" on page 89. 2. Close the access door, then touch ✓ to clear the error. The system performs an inventory scan. 3. If the error is not cleared, contact Technical Support.

Table 19 Error codes and actions *(continued)*

Error code	Action
308 – Horizontal movement motor not commissioned	Contact Technical Support.
309 – Horizontal movement motor is not responding	Contact Technical Support.
310 – Horizontal movement motor is moving when it should be static	Contact Technical Support.
311 – Horizontal movement motor fault	Contact Technical Support.
312 – Horizontal movement motor is too slow or too fast	Contact Technical Support.
404 – Vertical movement is obstructed	1. Open the access door, then inspect the gripper arm. Carefully remove any obstructions, or plates, or racks in the gripper jaws. See "Manually remove obstructions from the incubation chamber" on page 89. 2. Close the access door, then touch ✓ to clear the error. The system performs an inventory scan. 3. Remove any uncompleted plates, then return them to the system using the **Load** function. 4. If the error is not cleared, contact Technical Support.
407 – Vertical movement timeout	1. Open the access door, then inspect the internal space for obstructions. Carefully remove any obstructions from the chamber or gripper jaws. See "Manually remove obstructions from the incubation chamber" on page 89. To access the incubation chamber, see page 86. 2. Close the access door, then touch ✓ to clear the error. The system performs an inventory scan. 3. If the error is not cleared, contact Technical Support.
408 – Vertical movement motor not commissioned	Contact Technical Support.
409 – Vertical movement motor is not responding	Contact Technical Support.
410 – Vertical movement motor is moving when it should be static	Contact Technical Support.
411 – Vertical movement motor fault	Contact Technical Support.
412 – Vertical movement motor is too slow or too fast	Contact Technical Support.

Table 19 Error codes and actions *(continued)*

Error code	Action
504 – Rotational movement is obstructed	1. Open the access door, then inspect the gripper arm. Carefully remove any obstructions. See “Manually remove obstructions from the incubation chamber” on page 89. 2. Close the access door, then touch ✓ to clear the error. The system performs an inventory scan. 3. If the error is not cleared, contact Technical Support.
507 – Rotational movement timeout	1. Open the access door, then inspect the internal space. Carefully remove any obstructions. See “Manually remove obstructions from the incubation chamber” on page 89. 2. Close the access door, then touch ✓ to clear the error. The system performs an inventory scan. 3. If the error is not cleared, contact Technical Support.
508 – Rotational movement motor not commissioned	Contact Technical Support.
509 – Rotational movement motor is not responding	Contact Technical Support.
510 – Rotational movement motor is moving when it should be static	Contact Technical Support.
511 – Rotational movement motor fault	Contact Technical Support.
512 – Rotational movement motor is too slow or too fast	Contact Technical Support.
601 – Load door timeout	1. Ensure that any racks on the turntable are correctly placed. Manually straighten the turntable. 2. Touch ✓, then touch ⟳. 3. If the error is not cleared, power off the ARIS HiQ™ system, wait at least 15 seconds, then power on the system. 4. If the error is not cleared, contact Technical Support.
602 – Lock pin is up when it is expected to be down	1. Power off the ARIS HiQ™ system. 2. Wait at least 15 seconds, then power on the system. 3. If the error is not cleared, contact Technical Support.
608 – Turntable failed to rotate when requested	1. Power off the ARIS HiQ™ system. 2. Wait at least 15 seconds, then power on the system. 3. If the error is not cleared, contact Technical Support.

Table 19 Error codes and actions *(continued)*

Error code	Action
701 – Door lock pin timeout	**1.** Power off the ARIS HiQ™ system. **2.** Wait at least 15 seconds, then power on the system. **3.** If the error is not cleared, contact Technical Support.
702 – Door lock pin is stuck in the up position	**1.** Power off the ARIS HiQ™ system. **2.** Wait at least 15 seconds, then power on the system. **3.** If the error is not cleared, contact Technical Support.
703 – Door lock pin is stuck in the down position	**1.** Power off the ARIS HiQ™ system. **2.** Wait at least 15 seconds, then power on the system. **3.** If the error is not cleared, contact Technical Support.
704 – Door lock pin is stuck midway between the up and down positions	**1.** Power off the ARIS HiQ™ system. **2.** Wait at least 15 seconds, then power on the system. **3.** If the error is not cleared, contact Technical Support.
907 – Access door is open	**1.** Close the access door. **2.** Ensure that the turntable partition is correctly seated. **3.** Ensure that the partition has been inserted correctly. **4.** Ensure that the pin on the bottom of the turntable partition is in place and not damaged. **5.** Touch ✓. The system performs an inventory scan. **6.** If a plate was being read when the door was opened, error code 202 is displayed at this point. In this case, open the access door, remove the plate from the gripper jaws, then reload the plate, as described in error code 202.

Other errors

Table 20 Other errors and actions

Other errors		Actions
1	System display does not illuminate	• Ensure that the power cable is connected firmly. • Ensure that the system is plugged into a powered socket. • Ensure that the system is powered on at the back of the system. • Check the power inlet fuse and replace if necessary (see “Replace the power inlet fuse” on page 68).
2	System does not move past the splash screen on start-up	1. Power off the ARIS HiQ™ system. 2. Wait at least 15 seconds, then power on. 3. If the error is not cleared, contact Technical Support.
3	ARIS HiQ™ icon does not appear on the SWIN™ system	See “Connection with SWIN™ system is lost” on page 85.
4	A message that the connection with the SWIN™ computer has been lost is displayed on the SWIN™ system and the ARIS HiQ™ system	See “Connection with SWIN™ system is lost” on page 85.
5	In the **Plate Section List** screen, plate information is not displayed —the entry shows only a barcode	The plate did not have a specimen/isolate assigned in the SWIN™ system. 1. In the **Plate Section List** screen, touch the row for the plate, touch  , then follow the prompts to unload the plate. **Note:** All specimen/isolate combinations associated with the plate are unloaded. 2. In SWIN™ software, enter the plate information and assign specimen/isolates to the plate. **Note:** All specimen/isolate combinations must be re-assigned. 3. Send the plate information to the ARIS HiQ™ system. 4. In the ARIS HiQ™ system, reload the plate using the Load function. **Note:** All specimen/isolate combinations are reread.
6	In the **Plate Section List** screen, ✘ is displayed next to the plate details	The ARIS HiQ™ system was unable to read the plate, possibly due to insufficient fluorescence signal. 1. Unload the plate and examine for growth. 2. If visible growth is present, read the plate using a mirror viewer or the Vizion™ system.

Table 20 Other errors and actions *(continued)*

Other errors		Actions
7	In the **Plate Section List** screen,  is displayed in the plate status, and **????????** is displayed in the specimen number field	The ARIS HiQ™ system has detected a plate, but it is unable to read the barcode. **1.** If only one plate is seen with this warning, unload the plate using the Unload function. **2.** Examine the barcode for physical or mineral oil damage. **3.** If damage is seen: **a.** Remove the specimen/isolate from SWIN™ software. **b.** Attach a different barcode label to the plate. **c.** Re-enter the specimen details into SWIN™ software. **d.** Reload the plate using the Load function of the ARIS HiQ™ system. **4.** If several plates are seen with this warning, the plate or barcode sensors might be faulty or incorrectly aligned. Contact Technical Support.
8	The touchscreen display is stuck on the **Rotate Turntable** screen	**1.** Power off the ARIS HiQ™ system. **2.** Wait at least 15 seconds, then power on the system. **3.** If the error is not cleared, contact Technical Support.
9	System does not restart after the turntable partition has been replaced	**1.** Ensure that the turntable partition has been inserted correctly (beveled corners and pin on the bottom). **2.** Inspect the pin at the base of the turntable partition for damage. **3.** If the pin has been damaged, or if no other reason can be found, contact Technical Support.
10a	Plate information cannot be sent from the SWIN™ system to the ARIS HiQ™ system	Plate information was previously sent from the SWIN™ system to the ARIS HiQ™ system, then later removed from only one of the systems. **1.** Ensure that the plate information is removed from each system. • In SWIN™ software, in the **Incubating in ARIS** screen, click the specimen/isolate combination for the plate, then click  . • In the ARIS HiQ™ system: **a.** In the **Plate Section List** screen, touch the row for the plate (the row might not display specimen/isolate information), then touch  . **b.** Follow the prompts to unload the plate. **Note:** All specimen/isolate combinations associated with the plate are unloaded. **2.** Set up the plate in the SWIN™ system, then send the plate information to the ARIS HiQ™ system. **Note:** All specimen/isolate combinations are reread.

Table 20 Other errors and actions *(continued)*

Other errors		Actions
10b	Plate information cannot be sent from the SWIN™ system to the ARIS HiQ™ system	The user is attempting to load more than 100 plates. See Error code 010 (Table 19 on page 99).
11	In the **Plate Section List** screen, plate information cannot be deleted	A plate was unloaded due to an error, and it is not reloaded. 1. Reload the plate using the Load function. 2. The plate details should appear in the **Plate Section List** screen. Select the row for the plate, then touch  .
12	Information was not sent to the ARIS HiQ™ system from the SWIN™ system	If a plate was being read while plate information was sent from the SWIN™ system, the ARIS HiQ™ system might not have stored the plate information. To manually retransmit plate information: In SWIN™ software, in the **Incubating in ARIS** screen, click  .
13	ARIS HiQ™ system is not performing an inventory scan	Contact Technical Support.

Record useful information and obtain Data Logs

To ensure the best possible support and quickest resolution, it is important to record all relevant information for the issue encountered, this may include:

- The circumstances that led up to the problem occurring (for example, details of the various plate types and numbers of plates in use).
- Photographs and/or video. You can use a camera phone.
- Log taken from the computer on which the software is installed or from the instrument (see “Retrieve the log files” on page 109).

Retrieve the log files

Retrieve the log files immediately after an error has been encountered to ensure that no information on the error is lost before sending the files to Technical Support.

Make sure to create a text file named ***Communications Log_[date].txt*** and a text file named ***Error Log_[date].txt*** on your computer before starting the following procedure.

1. Right-click the **SWIN Communications Manager** icon in your computer taskbar, then select **ARIS HQ Status**.

2. In the **Communications Log** tab, click **Copy to Clipboard**, then paste it in ***Communications Log_[date].txt***.
3. Save, then close ***Communications Log_[date].txt***.
4. In the **Error Log** tab, select the ARIS HiQ™ that had the error from the dropdown menu, then click **Error Log**.
5. Copy the displayed error log, then paste in ***Error Log_[date].txt***.
6. Save, then close ***Error Log_[date].txt***.
7. In the **Error Log** tab, click **Firmware Log**.
8. Click **OK** to save the firmware log to the folder of your choice.
9. Close **SWIN Communications Manager**.
10. Share with Technical Support the following set of files:
    - ***Communications Log_[date].txt***
    - ***Error Log_[date].txt***
    - All files with names staring with ***COM...*** created in step 8.
    - All files found in `C:\Program Files (x86)\SWIN\TEMP`.

B

System installation

WARNING! The ARIS HiQ™ system must be installed, set up, and calibrated by a Sensititre™ system-trained service engineer. Software configuration is carried out during installation.

The computer running the SWIN™ software must be supplied by Thermo Fisher Scientific. The computer is set up during installation of the ARIS HiQ™ system by a Sensititre™ system-trained service engineer.

WARNING! The ARIS HiQ™ system should be installed only on a fixed bench without casters, made from non-combustible substrate. The bench should be able to support 103 kg (226.6 lb).

WARNING! Do not move the ARIS HiQ™ system after installation. Only a Sensititre™ system-trained service engineer should move or repackage the system for shipment.

WARNING! In instances where the use of the ARIS HiQ™ system will be discontinued or the ARIS HiQ™ system will need to be relocated/transported to a new location, the ARIS HiQ™ system should first be emptied of racks, Sensititre™ microplates, and biological samples, then disinfected in line with the cleaning instructions. Electrical power should also be disconnected by unplugging the power cord.

Installation site requirements

Parameter	Requirement
Electrical sockets	4 (instrument, monitor, computer, printer)
Main supply voltage	100-240 VAC
	Main voltage shall not exceed ±10%
Bench rating	A fixed bench (without casters) made from a non-combustible substrate. The bench should be able to support 103 kg (226.6 lb). Include space for an accompanying computer.
Clearance height	At least 1,300 mm (51.18 in) above the bench
System clearances	Left: 280 mm (11 in)
	Right: 50 mm (2 in)
	Rear: 10 mm (0.4 in)
	Top: 175 mm (7.9 in)
Operating altitude	Up to 2000 m (6,562 ft)
Environmental operating conditions	Location should be out of direct sunlight and drafts.[1]

[1] Heat and bright light from windows must be shaded and must not cause local high temperatures outside acceptable ambient range. Cold air movement from air conditioning or ventilation must not cause local low temperatures outside acceptable ambient range. See Appendix C, “System specifications”.

IMPORTANT! The Sensititre™ ARIS HiQ™ System requires uninterrupted power to function. If you choose to use an uninterruptible power supply (UPS), we recommend a 1440VA capacity for UPS sizing. This will provide between 28 to 60 minutes of UPS back-up power, dependent upon the usage of the Sensititre™ ARIS HiQ™ System.

Unpack the ARIS HiQ™ system

WARNING! The ARIS HiQ™ system must be unpacked and moved to the point of operation under the instruction of a Sensititre™ system-trained service engineer. The system should be installed on a fixed bench (without casters) made from a non-combustible substrate. The bench should be able to support 103 kg (226.6 lb). Contact Technical Support if the system must be moved.

The ARIS HiQ™ system is delivered to the installation site.

Note: If the packaging or instrument shows signs of damage during transportation, contact Technical Support. Do not use the instrument.

Retain the packing material for later use.

System calibration

All adjustments to and calibration of the ARIS HiQ™ system are performed by Sensititre™ system-trained service engineers during installation and regular servicing. Adjustments or calibrations are not required during day-to-day operations.

C System specifications

Parameter	Specification
Instrument dimensions	Width: 750 mm (29.53 inches)
	Depth: 735 mm (28.94 inches)
	Height: 1,125 mm (44.31 inches)
Weight	System, empty (no racks, no plates): 90 kg (198.5 lb)
	System, full (11 racks - 10 internal racks, 1 utility rack, 100 plates, 100 µL of water per plate well): 103 kg (226.6 lb)
Main supply voltage	100–240 VAC
	Main voltage shall not exceed ±10%
Main input frequency	50–60 Hz
Electrical safety class	Class 1 [the power supply must have a protective earth (ground) connection at all times]
System capacity	100 Thermo Scientific™ Sensititre™ plates
Environmental operating conditions	Indoor use only
	Temperature: 20–30°C, when incubating at 35°C (see “Installation site requirements” on page 111)
	Relative humidity: 5–80% non-condensing
	Environmental pressure: 70–106 kPa
	Operating altitude: up to 2000 meters (6,562 feet)
	Installation category II
	Dissipated heat: 1706.071 BTU/hr
Noise generated	74 dB when reading a plate at maximum noise level. dB reading taken at the touchscreen operating position.
Shipping temperature	–20°C to 50°C
Shipping relative humidity	5–80% non-condensing
Storage temperature	0–40°C
Storage relative humidity	5–80% non-condensing

(continued)

Parameter	Specification
Shipping weight	130.5 kg (287.1 lb)
Shipping dimensions	Width: 950 mm (37.4 inches)
	Depth: 950 mm (37.4 inches)
	Height: 1,600 mm (63 inches)
Pollution degree	Pollution degree: 2
Incubation temperature	Factory pre-set to 35±1°C
Length of operation	Continuous
Power consumption	790 VA (Max)
Main fuse rating	T10AH250V (5 mm X 20 mm)
Communications	RS 232 – C DTE (not currently configured)
	USB 2.0 for communication connection to Sensititre™ SWIN™ Software System
Useful life	8 years[1]

[1] Useful life is applicable for the Chinese market only. The Useful life of Sensititre™ ARIS HiQ™ has been determined by continuous, accelerated, reliability testing, designed to be representative of normal use. Accelerated Reliability testing has been structured to account for planned preventative maintenance events (such as annual servicing), in addition to any repairs and replacement parts found to be required.

D

System performance

ARIS HiQ™ system performance and isolate summary

The performance of the ARIS HiQ™ system was evaluated by means of a method of comparison study conducted at one internal site. The study was designed to evaluate the performance of the ARIS HiQ™ system compared to the legacy ARIS™ 2X system and OptiRead™ instrument using Sensititre™ (18–24 hour) susceptibility plates. Specimens were incubated and read according to Sensititre™ technical insert specifications. Organisms were evaluated based on indications and FDA-recognized Sensitive, Intermediate, Resistant (SIR) ranges.

The following fastidious Gram positive and non-fastidious Gram negative and Gram positive challenge microorganisms were tested:

Table 21 Challenge study for isolates

Non-Fastidious organisms	
Gram-Negative organisms	**Number of isolates**
E. cloacae	4
E. coli	8
K. aerogenes	5
K. oxytoca	4
K. ozaenae	1
K. pneumoniae	10
M. morganni	1
P. mirabilis	3
P. vulgaris	3
P. rettgeri	3
P. stuartii	2
S. marsescens	10
P. agglomerans	1
S. odorifera	1
A. hydrophila	2

Table 21 Challenge study for isolates *(continued)*

Non-Fastidious organisms	
Gram-Negative organisms	**Number of isolates**
Acinetobacter spp.	6
P. aeruginosa	11
Total	75

Non-Fastidious organisms	
Gram-Positive organisms	**Number of isolates**
E. faecalis	15
E. faecium	10
E. durans	2
E. gallinarum	1
E. raffinosus	1
S. aureus	27
S. epidermidis	12
S. haemolyticus	3
S. warneri	2
S. saprophyticus	1
S. capitis	1
Total	75

Fastidious organisms	
Gram-Positive organisms	**Number of isolates**
S. pneumoniae	25
β-hemolytic Group Streptococcus spp.	32
Viridans Group Streptococcus spp.	18
Total	75

Two non-fastidious organisms in this study, one Gram-negative (*P. aeruginosa*) isolate and one Gram-positive (*E. gallinarum*) isolate, did not grow on either the ARIS HiQ™ or the legacy ARIS™ system. Among the fastidious organisms, one isolate each of *S. dysgalactiae* and *S. pneumoniae* failed to grow. Taking these results into account, the growth rate for the non-fastidious Gram-negative and

Gram-positive challenge isolate panels were 98.7% (74/75). The growth rate for the fastidious panel was 97.3% (73/75).

ARIS HiQ™ system performance stratified by drug and organism group

- **EAN:** Essential Agreement Number
- **EA:** Essential Agreement
- **CAN:** Categorical Agreement Number
- **CA%:** Categorical Agreement Percent

Table 22 Non-fastidious Gram-Positive organisms (ARIS HiQ™ system vs. Legacy ARIS™/OptiRead™)

Drug	Organism group	Total	EAN	EA %	Eval total	Eval EAN	Eval EA%	CAN	CA%
Ceftaroline	*S. aureus*	27	27	100	27	27	100	26	96.3
Chloramphenicol	*Enterococcus* spp.	28	28	100	22	22	100	28	100
	S. aureus	27	27	100	22	22	100	26	96.3
	CoNS	19	19	100	17	17	100	19	100
Ciprofloxacin	*Enterococcus* spp.	28	28	100	19	19	100	27	96.4
	S. aureus	27	27	100	18	18	100	27	100
	CoNS	19	19	100	15	15	100	19	100
Clindamycin	*S. aureus*	27	27	100	0	0	0	27	100
	CoNS	19	19	100	1	1	100	19	100
Dalbavancin	*S. aureus*	27	26	96.3	27	26	96.3	27	100
Daptomycin	*E. faecalis*	15	15	100	15	15	100	15	100
	S. aureus	27	26	96.3	25	24	96.0	27	100
	CoNS	19	19	100	17	17	100	19	100
Erythromycin	*Enterococcus* spp.	28	28	100	8	8	100	27	96.4
	S. aureus	27	26	96.3	10	9	90	25	92.6
	CoNS	19	19	100	1	1	100	19	100

Table 22 Non-fastidious Gram-Positive organisms (ARIS HiQ system vs. Legacy ARIS/OptiRead) *(continued)*

Drug	Organism group	Total	EAN	EA %	Eval total	Eval EAN	Eval EA%	CAN	CA%
Gentamicin	*S. aureus*	27	26	96.3	23	22	95.7	27	100
	CoNS	19	19	100	2	2	100	18	94.7
Linezolid	*Enterococcus* spp.	28	28	100	25	25	100	28	100
	S. aureus	27	27	100	27	27	100	27	100
	CoNS	19	19	100	4	4	100	19	100
Oxacillin	*S. aureus*	27	27	100	15	15	100	27	100
	CoNS	19	19	100	8	8	100	19	100
Penicillin	*Enterococcus* spp.	28	28	100	17	17	100	28	100
	S. aureus	27	27	100	4	4	100	27	100
	CoNS	19	19	100	8	8	100	18	94.7[1]
Quinupristin/ Dalfopristin	*Enterococcus* spp.	28	28	100	17	17	100	26	92.9
	S. aureus	27	27	100	0	0	0	27	100
	CoNS	19	19	100	0	0	0	19	100
Tedizolid	*E. faecalis*	15	15	100	15	15	100	15	100
	S. aureus	27	27	100	27	27	100	27	100
Telavancin	*E. faecalis*	15	15	100	12	12	100	15	100
	S. aureus	27	27	100	27	27	100	27	100
Tetracycline	*Enterococcus* spp.	28	28	100	11	11	100	28	100
	S. aureus	27	27	100	7	7	100	27	100
	CoNS	19	19	100	11	11	100	19	100
Vancomycin	*Enterococcus* spp.	28	28	100	14	14	100	28	100

Table 22 Non-fastidious Gram-Positive organisms (ARIS HiQ system vs. Legacy ARIS/OptiRead) *(continued)*

Drug	Organism group	Total	EAN	EA %	Eval total	Eval EAN	Eval EA%	CAN	CA%
Vancomycin	*S. aureus*	27	27	100	26	26	100	27	100
	CoNS	19	19	100	16	16	100	18	94.7
D-Test 1[2]	*Enterococcus* spp.	28	–	–	–	–	–	28	100
	S. aureus	27	–	–	–	–	–	16	96.3[3]
	CoNS	19	–	–	–	–	–	19	100
D-Test 2[4]	*Enterococcus* spp.	28	–	–	–	–	–	28	100
	S. aureus	27	–	–	–	–	–	27	100
	CoNS	19	–	–	–	–	–	19	100
Cefoxitin Screen[5]	*S. aureus*	27	–	–	–	–	–	27	100
HLAR Screen: Gentamycin 500 µg/mL	*Enterococcus* spp.	28	–	–	–	–	–	28	100
	S. aureus	27	–	–	–	–	–	27	100
	CoNS	19	–	–	–	–	–	19	100
HLAR Screen: Streptomycin 1000 µg/mL[6]	*Enterococcus* spp.	28	–	–	–	–	–	28	100

[1] The categorical very major error rate for penicillin when testing coagulase-negative *Staphylococci* CoNS challenge isolates is 6.3% (1/16). Based on the essential agreement and lack of an intermediate breakpoint for penicillin, the overall adjusted very major error rate for coagulase-negative *Staphylococci* (CoNS) was not included because this test is only cleared for use with *Enterococcus* spp.

[2] Erythromycin - 4 µg/mL; Clindamycin - 0.5 µg/mL.

[3] A single major error was observed for D-test 1 with *S. aureus*. This result was considered a random error occurrence and is acceptable.

[4] Erythromycin - 8 µg/mL; Clindamycin - 1.5 µg/mL.

[5] Cefoxitin - 6 µg/mL.

[6] 27 *S. aureus* isolates and 19 coagulase negative *Staphylococci* (CoNS) challenge isolates were also tested but performance was not included because this test is only cleared for use with *Enterococcus* spp.

Table 23 Non-fastidious Gram-Negative organisms (ARIS HiQ™ system vs. Legacy ARIS™/OptiRead™)

Drug	Organism group	Total	EAN	EA %	Eval. total	Eval. EAN	Eval. EA%	CAN	CA%
Ampicillin	*Aeromonas hydrophila*	2	2	100	0	0	0	2	100
	Enterobacteriaceae	56	56	100	7	7	100	53	94.6
Cefazolin	*Aeromonas hydrophila*	2	2	100	0	0	0	2	100
	Enterobacteriaceae	56	56	100	9	9	100	59	100
Cefepime	*Acinetobacter* spp.	6	6	100	2	2	100	6	100
	Aeromonas hydrophila	2	2	100	1	1	100	2	100
	Enterobacteriaceae	56	56	100	18	18	100	51	91.1
Ceftazidime	*Acinetobacter* spp.	6	6	100	1	1	100	6	100
	Aeromonas hydrophila	2	1	50	1	1	100	1	50
	Enterobacteriaceae	56	56	100	11	11	100	56	100
Chloramphenicol	*Acinetobacter* spp.	6	6	100	3	3	100	6	100
	Aeromonas hydrophila	2	2	100	1	1	100	2	100
	Enterobacteriaceae	56	56	100	40	40	100	54	96.4
Ertapenem	*Aeromonas hydrophila*	2	2	100	1	1	100	2	100
	Enterobacteriaceae	56	54	96.4	48	46	95.8	55	98.2
Gentamicin	*Acinetobacter* spp.	6	6	100	2	2	100	6	100
	Aeromonas hydrophila	2	2	100	2	2	100	2	100

Table 23 Non-fastidious Gram-Negative organisms (ARIS HiQ system vs. Legacy ARIS/OptiRead) *(continued)*

Drug	Organism group	Total	EAN	EA %	Eval. total	Eval. EAN	Eval. EA%	CAN	CA%
Gentamicin	*Enterobacteriaceae*	56	55	98.2	40	39	97.5	55	98.2
Levofloxacin	*Acinetobacter* spp.	6	6	100	5	5	100	6	100
	Aeromonas hydrophila	2	2	100	2	2	100	2	100
	Enterobacteriaceae	56	56	100	40	40	100	54	96.4
Piperacillin/ Tazobactam	*Acinetobacter* spp.	6	6	100	2	2	100	6	100
	Aeromonas hydrophila	2	2	100	1	1	100	2	100
	Enterobacteriaceae	56	56	100	30	30	100	54	96.4
	P. aeruginosa	10	10	100	9	9	100	10	100
TMP/SMX	*Acinetobacter* spp.	6	6	100	3	3	100	6	100
	Aeromonas hydrophila	2	2	100	0	0	0	2	100
	Enterobacteriaceae	56	56	100	9	9	100	56	100
Tetracycline	*Acinetobacter* spp.	6	6	100	5	5	100	6	100
	Aeromonas hydrophila	2	2	100	2	2	100	2	100
	Enterobacteriaceae	56	56	100	36	36	100	52	92.9
Ticarcillin	*Acinetobacter* spp.	6	6	100	1	1	100	6	100
	Acinetobacter spp.	2	2	100	0	0	0	2	100
	Enterobacteriaceae	56	56	100	13	13	100	55	98.2
	P. aeruginosa	10	10	100	4	4	100	10	100

Table 24 Fastidious organisms (ARIS HiQ™ system vs. Legacy ARIS™/OptiRead™)

Drug	Organism group	Total	EAN	EA %	Eval total	Eval EAN	Eval EA%	CAN	CA%
Amoxicillin/ clavulanic acid	*S. pneumoniae*	24	24	100	22	22	100	23	95.8
Cefepime	*S. pneumoniae*	24	24	100	24	24	100	23	95.8
	β-hemolytic Group *Streptococcus* spp.	31	31	100	30	30	100	31	100
	Total	55	55	100	54	54	100	54	98.2
Cefotaxime	*S. pneumoniae*	24	24	100	23	23	100	22	91.7
	β-hemolytic Group *Streptococcus* spp.	31	31	100	18	18	100	31	100
	Viridans Group *Streptococcus* spp.	18	18	100	15	15	100	17	94.4
	Total	73	73	100	56	56	100	70	95.9
Ceftaroline	*S. pneumoniae*	24	24	100	24	24	100	23	95.8
	β-hemolytic Group *Streptococcus* spp.	25	25	100	25	25	100	25	100
	Total	49	49	100	49	49	100	48	98.0
Chloramphenicol	*S. pneumoniae*[1]	24	24	100	12	12	100	24	100
	β-hemolytic Group *Streptococcus* spp.	31	31	100	31	31	100	31	100

Table 24 Fastidious organisms (ARIS HiQ system vs. Legacy ARIS/OptiRead) *(continued)*

Drug	Organism group	Total	EAN	EA %	Eval total	Eval EAN	Eval EA%	CAN	CA%
Chloramphenicol	Viridans Group *Streptococcus* spp.	18	18	100	18	18	100	18	100
	Total	73	73	100	61	61	100	73	100
Clindamycin	*S. pneumoniae*	24	24	100	14	14	100	24	100
Daptomycin	*β-hemolytic* Group *Streptococcus* spp.	31	30	96.8	31	30	96.8	31	100
Dalbavancin	*β-hemolytic* Group *Streptococcus* spp.	31	31	100	31	31	100	31	100
	Viridans Group *Streptococcus* spp.	18	18	100	16	16	100	18	100
	Total	49	49	100	47	47	100	49	100
Erythromycin	*S. pneumoniae*	24	24	100	8	8	100	24	100
	β-hemolytic Group *Streptococcus* spp.	31	30	96.8	26	25	96.2	31	100
	Viridans Group *Streptococcus* spp.	18	18	100	7	7	100	18	100
	Total	73	72	98.6	41	40	97.6	73	100
Levofloxacin	*S. pneumoniae*	24	24	100	24	24	100	24	100
	β-hemolytic Group *Streptococcus* spp.	31	31	100	27	27	100	31	100

Table 24 Fastidious organisms (ARIS HiQ system vs. Legacy ARIS/OptiRead) *(continued)*

Drug	Organism group	Total	EAN	EA %	Eval total	Eval EAN	Eval EA%	CAN	CA%
Levofloxacin	Viridans Group *Streptococcus* spp.	18	18	100	18	18	100	18	100
	Total	73	73	100	69	69	100	73	100
Linezolid	*S. pneumoniae*	24	24	100	21	21	100	24	100
	β-hemolytic Group *Streptococcus* spp.	31	31	100	31	31	100	31	100
	Total	55	55	100	52	52	100	55	100
Meropenem	*S. pneumoniae*	24	24	100	17	17	100	24	100
	S. pyogenes	14	14	100	2	2	100	14	100
	Total	38	38	100	19	19	100	38	100
Penicillin	*S. pneumoniae*	24	24	100	19	19	100	24	100
	β-hemolytic Group *Streptococcus* spp.	31	31	100	14	14	100	31	100
	Viridans Group *Streptococcus* spp.	18	18	100	13	13	100	18	100
	Total	73	73	100	46	46	100	73	100
Trimethoprim / sulfamethoxazole	*S. pneumoniae*	24	24	100	4	4	100	23	95.8
Tedizolid	*β-hemolytic* Group *Streptococcus* spp.	31	31	100	31	31	100	31	100

Table 24 Fastidious organisms (ARIS HiQ system vs. Legacy ARIS/OptiRead) *(continued)*

Drug	Organism group	Total	EAN	EA %	Eval total	Eval EAN	Eval EA%	CAN	CA%
Tedizolid	Viridans Group *Streptococcus* spp.	18	18	100	16	16	100	18	100
	Total	49	49	100	47	47	100	49	100
Telavancin	*β-hemolytic* Group *Streptococcus* spp.	31	31	100	31	31	100	31	100
	Viridans Group *Streptococcus* spp.	18	18	100	16	16	100	18	100
	Total	49	49	100	47	47	100	49	100
Tetracycline	*S. pneumoniae*	24	24	100	10	10	100	24	100
	β-hemolytic Group *Streptococcus* spp.	31	30	96.8	18	17	94.4	31	100
	Viridans Group *Streptococcus* spp.	18	18	100	11	11	100	17	94.4
	Total	73	72	98.6	39	38	97.4	72	98.6
Vancomycin	*S. pneumoniae*	24	24	100	21	21	100	24	100
	β-hemolytic Group *Streptococcus* spp.	31	31	100	31	31	100	31	100
	Total	55	55	100	52	52	100	55	100

[1] A single categorical very major error was observed for ceftaroline when testing *S. pneumoniae* (1/24). Based on essential agreement and lack of an intermediate breakpoint for ceftaroline, the overall adjusted very major error rate for *S. pneumoniae* isolates was 0% (0/24).

QC organisms and reproducibility results

The FDA and CLSI recommended QC strains for non-fastidious Gram-negative and Gram-positive organisms (Table 25) were tested at two sites using both the ARIS HiQ™ and legacy ARIS™. Twenty replicates were conducted per site for each QC strain/antimicrobic combination. For each antimicrobic evaluated, at least one QC organism exhibited acceptable results (>95% in-range results), except for Cefepime tested with *E. coli* ATCC® 25922™ and *P. aeruginosa* ATCC® 27853™. This was attributed to not including the full CLSI/FDA recommended dilution range for QC testing with these two organisms.

Table 25 QC organisms: tested and evaluated in line with the CLSI - M07 protocols

Organism	Type number
Gram positive	
S. aureus	29213
S. aureus	BAA-977
E. faecalis	29212
E. faecalis	51299
Gram negative	
E. coli	25922
E. coli	35218
P. aeruginosa	27853
Fastidious	
S. pneumoniae	49619

Reproducibility testing was conducted at one internal site utilizing 3 separate operators on 3 separate instruments on 3 separate days. 25 non-fastidious gram-positive organisms and 25 gram-negative organisms, and 25 fastidious organisms were tested using Sensititre™ susceptibility plates in the ARIS HiQ™ system. Percent reproducibility was determined for each antibiotic/microorganism combination by calculating the number of isolates whose MICs fall within +/- one doubling dilution of the mode, out of the total number of isolates tested across days. The "best-case" scenario (i.e., assuming any off-scale result is within one well from the mode) was used when determining percent reproducibility. Percent reproducibility for all antibiotic/microorganism combinations tested met the acceptance criteria of >95% based on the "best-case" percent calculation.

Documentation and support

Related documentation

Document	Publication number
Sensititre™ SWIN™ Software System Instructions For Use	MAN0017791

Related products

For more information about the following products, go to **thermofisher.com/clinicalmicrobiology**.

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Index

R

S

T

U

V

W