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SENTiNAT® 200

Operator's Manual

SENTINEL DIAGNOSTICS

Ver. OM_1N200S_4.0_2022

CE

Important Notice

Table of Contents

1 Information about Safety and Security

SENTiNAT® 200 is a pipetting instrument. This Operator's Manual is designed to help you get the most out of your SENTiNAT® 200.

ATTENTION

You must carefully read through the entire manual before beginning to operate your instrument. This first section must be read with particular attention. It contains important information about the use of the SENTiNAT® 200 and this manual.

1.1 About this Manual

This manual refers to the SENTiNAT® 200 Software 1.0.4 (in the following summarized as SENTiNAT® 200 Software) for the SENTiNAT® 200.

NOTE

Refer to the contents of the Data Storage Device (see Section 2.5 SENTiNAT® 200 Software).

This manual helps users operate the SENTiNAT® 200 correctly and safely. To achieve this goal, the manual describes the various components of the SENTiNAT® 200 and their functionality. The manual describes both the hardware and software of the SENTiNAT® 200 in depth, enabling the user to operate the instrument.

After introducing you to the various parts of the SENTiNAT® 200, the manual will describe step-by-step how to operate the instrument. After you have read through this manual, you should be capable of operating the SENTiNAT® 200.

Warnings and ***Notes*** are part of this manual to emphasize important and critical instructions. Symbols used in this manual for these warnings and notes are:

ATTENTION

Any special problems, warnings or important information will be accompanied by this symbol. Read these items carefully and follow the instructions provided.

NOTE

Information is provided to the programmer that is useful but not essential to the task at hand.

[...] Push buttons and their corresponding descriptions.

"**...**" Descriptions for all kinds of entry fields, control fields, check boxes, lists, etc.

___ Underlined texts are references to manuals, figures, sections, etc.

1.2 Additional SENTiNAT® 200 Manuals

Sample methods of typical applications guide you through the programming. A detailed software reference for the SENTiNAT® 200 can be found in the Help Function of the SENTiNAT® 200 and MIC Software.

1.3 SENTiNAT® 200 Intended Use

The SENTiNAT® 200 analyzer is an automated analyzer intended for the determination of analytes in human specimen. For the specific purpose refer to the assay's intended use. For In Vitro Diagnostic use only. For laboratory professional use only.

More information:

The SENTiNAT® 200 is a system used for the pipetting of liquid sample material and reagents, including the reconstitution of lyophilized reagents. The SENTiNAT® 200 is used for sample preparation in clinical, genetics and microbiology applications (e.g. for infectious diseases analyses and pharmacogenomics). The SENTiNAT® 200 must be operated using disposable tips and therefore provides the highest flexibility for carryover-free pipetting.

Applications are:

- NA extraction (only)
- NA extraction, qPCR setup and qPCR amplification

ATTENTION

Modification of any kind to the instrument configuration will result in the loss of Conformity to IVD Regulation 2017/746/EU.

1.4 Component List

A. Consumables

REF	Description	Package size
DS0001	Tips 1000 (1 pack x 8 boxes x 96 tips)	3840
DS0002	Tips 300 (1 pack x 5 boxes x 96 tips)	5760
DS0003	Tip 50 (1 pack x 5 boxes x 96 tips)	5760
DS0005	Deepwells (1 x 32 plates)	32
DS0009	HAMILTON MICRO-TUBES+V-CAPS	960
1N1008	Elution plate	20
DS0004	Microlab STAR Biohazard Plastic Liner for Waste Container	200

B. Accessories

REF	Description	Package size
1N1005	Magnetic Plate	1
SP0300	Lane cable	1
186731	Loading Tray (with protectors)	1
182176	Teaching Needle	4
355171	Cable USB 2.0 A-B 3m FERRIT	1
363013 (281093)	Fuse 6.3 AT (600VA)	2
173229	Volume Verification Solution	1
173400	SMP_CAR_24_A00, 4PCS	1
173410	SMP_CAR_32_A00, 3PCS	1
182085	Tip Carrier, Landscape	1
185437 (2/2)	Hamilton Liquid waste assembly (without Tip Waste block)	1
187001	Landscape Shaker Carrier Base	1
188049	MultiFlex PCR Module 96	3
188053	MultiFlex Carrier Base (portrait orientation)	1
188133	MultiFlex module bracket 7T	2
188248	MultiFlex Tip Park Module w Drip Pan Option	1
188293	MultiFlex Deepwell position (XXL)	2
188319	Hamilton Heater Shaker, flat bottom Adapter (APE)	1
3963343	Standard PC Win 10, US	1
815119	ADAPTER MN NUCLEOMAH SEP	1
815641	Teaching Plate	1
830480	SMP_CAR_32_D10_5_B00	2
830666	MIC4Hamilton (Magnetic Induction Cycler)	2
10076818	RGT_CAR_5R_CLAMP_A00	2
10103937	MIC-Carrier	1
10104116	Miniplate carrier	3
10111596	Starlet Ture rechts	1
DS0010	Waste container rectangular	1

1.5 Intended User Group Profiles and User Environment

1.5.1 User Group Profile

Title of user group	**Demographic data (Age range, Gender, specific physical attributes)**	**Typical tasks (supported by the medical device)**	**Expected qualification, expected job experience**
Primary user: Laboratory Operator	• Age: approx. 20-65 Years • Gender: All • Specific physical attributes: Education in Good Laboratory Practice (GLP)	Operating the pipetting instrument and user maintenance	• Knowledge of all reference documents • Knowledge of good laboratory practice • Knowledge of the SENTiNAT® 200 Software • Knowledge of the SENTiNAT® 200 • Trained for operation
Secondary user: Field Service Engineer	• Age: approx. 20-65 Years • Gender: All • Specific physical attributes: Education in service techniques	Service tasks, Preventive maintenance, Maintenance & Verification	• Completed training as a Service Engineer • Good English skills

1.5.2 User Environment

Title of user group	Organizational / social environment during task completion	Physical environment during task completion	Typical equipment used (in conjunction with the medical device)
Primary user: Laboratory Operator	Education in Good Laboratory Practice (GLP) and the Laboratory Operator of the SENTiNAT® 200 must have attended an official training course.	*In-Vitro* Diagnostic environment	Labware (Sample tubes, Reagent container, etc.) Liquids Cleaning agent Personal protection clothing (Lab gloves, etc.)
Secondary user: Field Service Engineer	Trained Field Service Engineer, education how to operate and repair / maintain the SENTiNAT® 200 Customer-oriented, flexible and communicative	Different environments, depending on customer site	Tools, Service Manual, adjustment equipment, spare parts, etc.

1.6 Operation

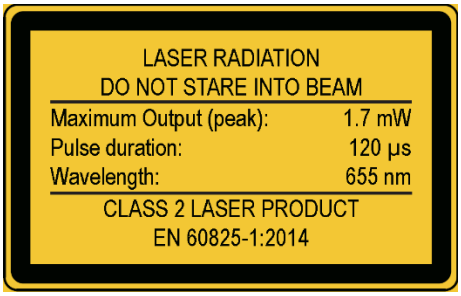
The operator of the SENTiNAT® 200 must have attended an official training course. The procedures contained within this manual have been tested by the manufacturer and are deemed to be fully functional. Any deviation from the procedures provided here could lead to erroneous results or malfunction.

During instrument operation, stand clear of all moving parts and the working deck of the instrument. In general, never lean over or into the instrument while it is in operation.

Please check which barcode reader is installed in your SENTiNAT® 200:

ATTENTION: LASER BEAM

The Barcode Scanner on the Autoload of the SENTiNAT® 200 has a Class II Laser Diode. Do not stare into the beam.



Barcode Scanner

NOTE

The Barcode Scanner on the Autoload of the SENTiNAT 200 has a Class I Laser Diode.

Barcode Scanner

NOTE

Do not put your fingers or hand between any of the barcode readers and sledge, as there is the possibility of squeezing, bruising or crushing.

If the SENTiNAT® 200 is used in a manner not specified by SENTINEL, the protection provided by the equipment may be impaired.

The SENTiNAT® 200 is operated by means of control software. Specific methods, programmed by specially trained method programmers according to Assay descriptions serve as job instructions for the control software. The operator should not modify methods, except in consultation with the persons responsible for the programming and/or the Assay supplier. Improper method changes can lead to false results.

In order to ensure error-free operation of the instrument, the content of the maintenance and verification procedures needs to be understood. In addition, the mandatory verification process must be carried out within the required timeframe, and the verification process must be documented.

1.7 Malfunction / Troubleshooting

ATTENTION

For SENTiNAT® 200 malfunction and for troubleshooting, contact your local SENTINEL Representative.

1.8 Training

Training courses will be held by your SENTINEL representative. Please feel free to contact your SENTINEL representative to arrange for an operator training course.

1.9 Legal Regulations

All local, state and federal laws which prescribe the use, application, and/or the handling of dangerous materials in connection with the instrument must be strictly followed.

1.10 Safety Precautions and Hazards

The following section describes the main safety considerations, electrical and biological, in operating this product and the main hazards involved.

ATTENTION

- Only authorized personnel may have access to the instrument.
- The laboratory or operator of the instrument is responsible for ensuring that the environmental conditions for safe operation of the instrument are met at all times.
- The laboratory or operator is responsible for any improper handling. It must be ensured that untrained or unauthorized personnel cannot manipulate or interfere with the instrument while it is in use.

ATTENTION

Read the following safety notices carefully before using the SENTiNAT® 200.

1.10.1 General Precautions

1.10.1.1 Instrument Installation and Relocation

The SENTiNAT® 200 must be installed or relocated by a Trained Field Service Engineer. Installations of instrument options and accessories are also performed by a Trained Field Service Engineer.

ATTENTION

The SENTiNAT® 200 conforms to European norms regarding interference immunity. However, if the SENTiNAT® 200 is subjected to electromagnetic fields or if static electricity is discharged directly onto the SENTiNAT® 200, its Liquid Level Detection ability may be negatively affected. It is therefore recommended that the SENTiNAT® 200 be kept away from other equipment that emits too high electromagnetic fields (EMC) in the laboratory, and that static electricity is minimized in its immediate environment.

Electromagnetic Emission Class A (EMC)

SENTiNAT® 200 is considered as a Group 1 ISM (industrial, scientific and medical radio-frequency equipment) class A device measured according to EN 55011.

This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

NOTE

During operation, the SENTiNAT® 200 must be shielded from direct sunlight and intense artificial light. The instrument must be positioned in the laboratory in a way permitting personnel to access the front and sides of the instrument in order to operate, maintain, open and close the protective covers. Accordingly, to calculate how much space is needed, consider the dimensions of the instrument (see Section 7.1.1 Dimensions and Weights) and sufficient space for a person to move and work comfortably.

ATTENTION

Never lift a fully installed instrument to transport it from one place to another. It must be re-installed in the new work location by a trained Field Service Engineer.

ATTENTION

The instrument weighs more than 150 kg. Necessary precautions must be taken when transporting the instrument.

1.10.1.2 Maintenance, Service and Repair

Only trained Field Service Engineers are authorized to perform mechanical maintenance on the SENTiNAT® 200.

For repair or shipment, all mechanical parts must be put in their rest positions. A SENTiNAT® 200 sent away for repair must also be decontaminated (see Section 6 SENTiNAT® 200 Decontamination) if it was in a laboratory environment with infectious or hazardous materials. The SENTiNAT® 200 must be repacked in the original shipping crate only by a trained Field Service Engineer (contact your local representative). There must be no containers or tips on the SENTiNAT® 200 during transportation.

The HAMILTON trained Field Service Engineer and the laboratory share the responsibility for the Installation Qualification (IQ) and the Operation Qualification (OQ), i.e. Verification and Training. The Process Qualification (PQ) is the responsibility of SENTINEL.

Only original SENTiNAT® 200-specific parts and tools may be used with the SENTiNAT® 200 (e.g. Carriers, Racks, CO-RE Tips, and Tip Waste Container). Commercially available Liquid Containers, such as Microplates and Tubes, may of course be used.

A breakdown of the power supply during a run may cause the loss of data. If data loss is unacceptable, use an independent power supply or an Uninterruptible Power Supply (UPS).

1.10.1.3 Operating the Instrument

When using the SENTiNAT® 200, Good Laboratory Practices (GLP) must be observed. Suitable protective clothing, safety glasses and protective gloves must be worn, particularly when dealing with a malfunction of the instrument where the risk of contamination from spilled liquids exists (see Section 1.9.5.2 Safety Measures).

ELECTROSTATIC DISCHARGE

Electrostatic discharge can cause damage to the instrument and can influence labware behavior and stability, therefore avoid any electrostatic charge onto labware and disposable tips during handling and manual loading of these, either to or from the SENTiNAT® 200.

ATTENTION

During instrument operation, stand clear of all moving parts and the working deck of the instrument. Never lean over or interfere with the instrument while it is in operation! Never reach into a running instrument with your hand(s)!

If not followed as mentioned above, there can be injuries or contamination!

ATTENTION

If the SENTiNAT® 200 is used in a manner not specified by SENTINEL, the protection provided by the equipment may be impaired.

ATTENTION

Any persons operating the SENTiNAT® 200 and the PC running the SENTiNAT® 200 Software must have attended a certified training course. Any departure from the procedures provided here could lead to erroneous results or a SENTiNAT® 200 malfunction.

1.10.1.4 Switching on the SENTiNAT® 200

The power switch is located on the left-front frame. When switched OFF, the power switch is toggled to the down position and the light within the switch is not illuminated. To switch ON the power switch, toggle the switch to the up position. The switch's internal light will be illuminated.

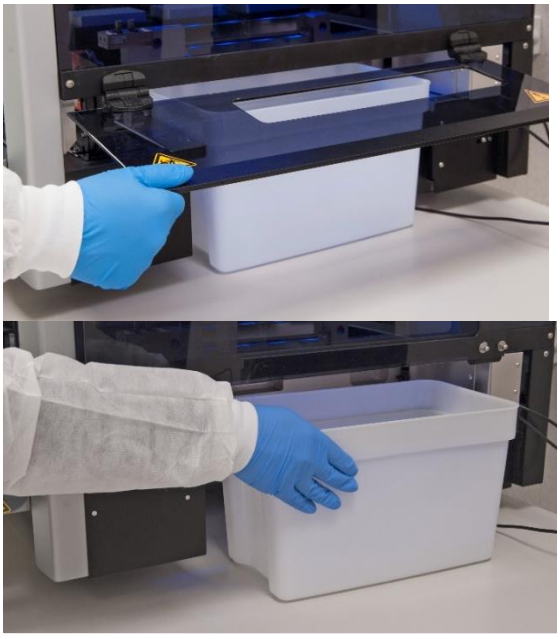
Power Switch OFF

Power Switch ON

1.10.1.5 Waste Container

Tip Waste Container:

- The Tip Waste Container collects used tips for disposal
- Open flap with one hand
- Take container out
- Flap will close as soon as it is held by the operator
- Empty container
- Open flap with one hand
- Put container inside
- Flap will close as soon as it is held by the operator
- The Tip Waste Container must be managed as biohazardous
- The Tip Waste is always to be regarded as contaminated



ATTENTION

The tip waste container is always to be regarded as contaminated.

1.10.1.6 Method Programming

All programs and methods for SENTiNAT® 200 are pre-installed and can be used via the SENTiNAT® 200 Software.

Program and method updates will be provided online or by a local representative.

Pay close attention to all instructions and parameters provided in test kit package inserts when using the SENTiNAT® 200.

ATTENTION

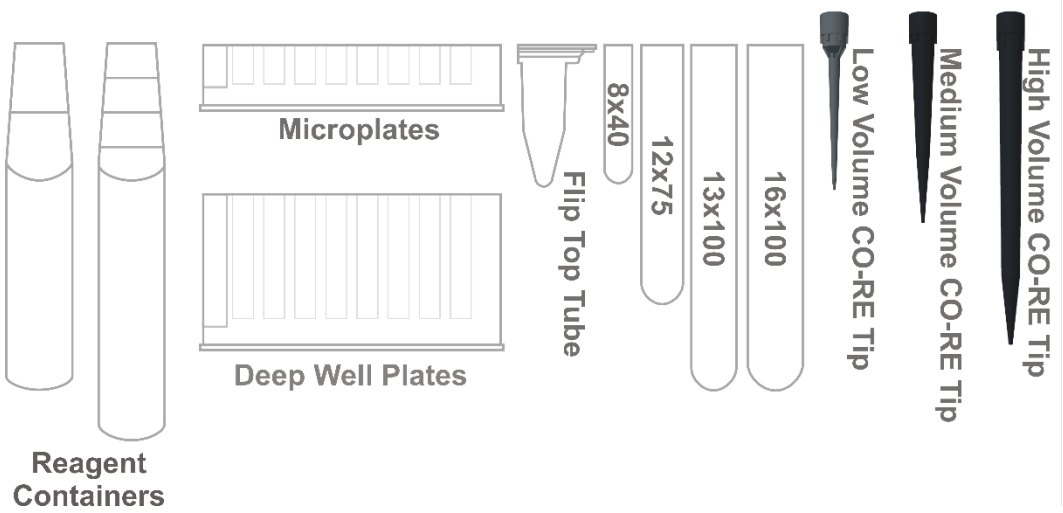
Only use Validated Methods!

NOTE

When working with samples, which will be used in particularly sensitive tests, take into account the evaporation and condensation that may occur while the method is running. There should be no delays between aspirate and dispense of samples.

If sampling aggressive liquids, use filter tips. Also use filter tips for tasks which are sensitive to cross-contamination (aerosols).

The inner diameter of sample tubes, reagent vessels, etc. must be greater than the diameter of the utilized disposable tip at its maximum immersion depth. This measure will avoid any collisions between labware such as sample tubes, reagent vessels, etc., disposable tips and the pipetting channel. For additional information and proper tip selection, refer to Section 2.3 Disposable Tips.



ATTENTION

Never disable any safety measure.

1.10.1.7 Loading

Do not exchange positions of sample or reagent tubes or switch microplates after they have been identified by the barcode reader. This could result in incorrect test data or instrument crash.

Microplates must be placed on the carrier such that well A1 is in the position defined in the deck layout of the method.

When pouring liquid into the containers, ensure that there is no foam on the surface of the liquid. Note that foam may cause pipetting problems.

Do not overfill reagent containers, tubes or other liquid containers.

Do not mix tip size and type (e.g. with or without filter or different volumes) in the same tip rack.

Do not fill up partially consumed tip racks with tips from another rack. Tips must be loaded in the tip racks as they are provided in the original packaging. They are individually labeled with a barcode for identification.

1.10.1.8 Work Routine

Periodic maintenance (daily maintenance, weekly maintenance, six-monthly maintenance) is a mandatory part of the work routine, and is guided by the user software.

ATTENTION

If the system is paused, do not wait too long before resuming the run. Loss of liquid from a full tip may result in invalid data.

Verify that the front cover and side doors are closed before starting a run.

Discard used tips and do not reuse them. Do not empty the tip waste during a run.

Do not try to open the front cover or the side doors during a run. It may cause an abort of the run. Do not leave tips on the pipetting channels for a long period of time (for example, overnight). This may cause damage to the CO-RE O-rings. A daily maintenance procedure will eject the tips.

Verify that the instrument arm does not move while loading the MIC with tubes from the left side with the side doors open.

1.10.2 Biohazard Precautions

BIOHAZARD WARNING

If the SENTiNAT® 200 becomes contaminated with biohazardous or chemical materials, it must be cleaned in accordance with the maintenance procedures (see Section 4 Maintenance and Section 6 SENTiNAT® 200 Decontamination). Observe and carry out the maintenance procedures provided. Failure to do so may impair the reliability and correct functioning of the SENTiNAT® 200.

If working with biohazardous samples, observe and carry out the maintenance procedures, paying particular attention to cleaning and decontamination. Wear gloves when handling the X-Arm and pipetting channels, the carriers, racks, containers and tips.

Avoid touching tips discarded into the laboratory-supplied waste container. Any surfaces on which liquid is spilled must be decontaminated.

Do not use disinfecting materials, which contain hypochlorite (e.g. Javel water, Chlorox) or other bleaching fluids.

If working with biohazardous or chemical materials, the user must not touch them. The SENTiNAT® 200 will drop its used tips into a Tip Waste Container, which must be emptied during the daily maintenance or as soon as it is full.

1.10.3 Computer Precautions

Use the necessary precaution to guard against software viruses. Use only manufacturer's original installation 'data storage device' sets for the Operating System. Use only the original SENTINEL SENTiNAT® 200 Software supplied on a data storage device. Any manipulation of the SENTiNAT® 200 Software data files or other information determining or affecting SENTiNAT® 200 functions can result in erroneous test results or instrument failure. Only the SENTiNAT® 200 Software may be used to control the SENTiNAT® 200.

For reasons of data safety and integrity, use of an Uninterruptible Power Supply (UPS) is recommended, since a loss of power may cause data to be lost or corrupted.

To avoid computer breakdowns, configure a hard disk of sufficient space in the computer. Ensure that there is always enough storage capacity on your hard drive. Delete log files from time to time. Generated data within the Log Files Directory (e.g. traces, TADM data and pipetting files) must be backed up onto the laboratory's host device and deleted from the control PC's hard disk at weekly intervals. Also see Section 1.9.3.1 End-User Computing Policy.

1.10.3.1 End-User Computing Policy

Scope:

This policy applies to end-user computing devices that connect to a SENTINEL Automated System.

All customer employees, members, users, and third-parties utilizing computer devices connecting to a SENTINEL System, assume the responsibility for the security and privacy of information contained within.

Policy:

End-User Computing Device Policy:

- With finalization of the technical installation of the SENTINEL system, the full responsibility and reliability for the computing device is transferred to the end-user of the system.
- Hence, SENTINEL is not responsible for:
  - Administration of the PC, e.g. user rights, user levels, privacy.
  - Data safety, data integrity.
  - PC maintenance.
  - Appropriate security measures, e.g. against threads via the network / internet.
  - Data backup and recovery.
  - Disaster Recovery
  - Operating System updates and security patches.
  - Cyber security
  - Computer security
- If SENTINEL delivers a PC as part of the instrument, a Warranty Agreement will be included by the PC manufacturer. That warranty includes hardware only and excludes explicitly any support for the topics mentioned above.

1.10.4 Electrical Safety Precautions

Before removing a mechanical or electrical component, the SENTiNAT® 200 must be switched off and disconnected from the main electricity supply and from the PC.

Any installation and de-installation of an electrically powered SENTiNAT® 200 component must be performed by a trained Field Service Engineer.

ATTENTION

This is equipment for a professional healthcare environment. It has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

SENTiNAT 200 is a Class A, Group 2 device in accordance with EN 55011 and CISPR11 and complies with the IEC 61326-2-6 EMC Collateral standard (Class A). The user is responsible to ensure a compatible electromagnetic environment for the equipment is maintained, so that the device will perform as intended. The electromagnetic environment must be evaluated prior to operation of the device.

Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.

1.10.5 Hazards

Location and explanation of warning and attention labels:

<table>
<tr><td>  </td><td colspan="3">Moving Parts
Be aware of moving parts (arm, pipetting heads, Gripper, etc.) inside transparent covers.
During instrument operation, stand clear of all moving parts and the working deck of the instrument. Never lean over or interfere with the instrument while it is in operation! Never reach into a running instrument with your hand(s)!
If not followed as mentioned above, there can be injuries or contamination!
A run is aborted if the cover is opened.</td></tr>
<tr><td>  </td><td colspan="3">Biohazard Warning
Deck may contain biohazardous or chemically contaminated materials.</td></tr>
<tr><td>  </td><td>Power Connection
Connect only to earth-grounded outlet.</td><td>  </td><td>Biohazard Warning
Waste may contain biohazardous or chemically contaminated materials.</td></tr>
<tr><td>  </td><td>Connection to PC
Use only the appropriate shielded cables.</td><td>  </td><td>Moving Parts
Moving arm inside transparent cover. Aborts the run if the cover is opened.</td></tr>
<tr><td>  </td><td>USB Connection
Having a total cable distance of more than 5m, signal loss can occur.</td><td>  </td><td>Hot Surface
Avoid contact with the HHS. Surfaces are hot and may cause personal injury if touched.</td></tr>
<tr><td>  </td><td>Biohazard Warning
Deck may contain biohazardous or chemically contaminated materials.</td><td>  </td><td>Pipetting Arm
Do not move Pipetting Arms by hand.</td></tr>
<tr><td colspan="4">Laser device designated for use solely as a component of the overall automated pipetting instrument and therefore is not within the scope of FDA Section 1040.11 for complete laser products. Laser devices are only to be installed, repaired, or replaced by a trained Field Service Engineer.</td></tr>
</table>

1.10.5.1 Substance-Related Hazards

ATTENTION

Chemical, biological and radioactive hazards can be associated with the substances used or the samples processed with the instrument. The same applies to waste disposal. The handling of substances and the disposal of waste may be subject to local, state or federal law or regulations with regard to health, environment or safety.

- *Always be aware of possible hazards associated with these substances*
- *Use appropriate protective clothing, goggles and gloves*
- *Strictly observe the corresponding provisions*

ATTENTION

Caustic substances can cause burns and eye injury.

- *Always be aware of possible hazards associated with these substances*
- *Avoid exposure to caustic substances*
- *Use appropriate protective clothing, goggles and gloves*

ATTENTION

Fire Hazard.

- *Use caution when using flammable or explosive fluids or vapors. There is a high risk of damage to health and to the instrument. The instrument is not explosion-proof nor is it for use in Ex zones.*

1.10.5.2 Safety Measures

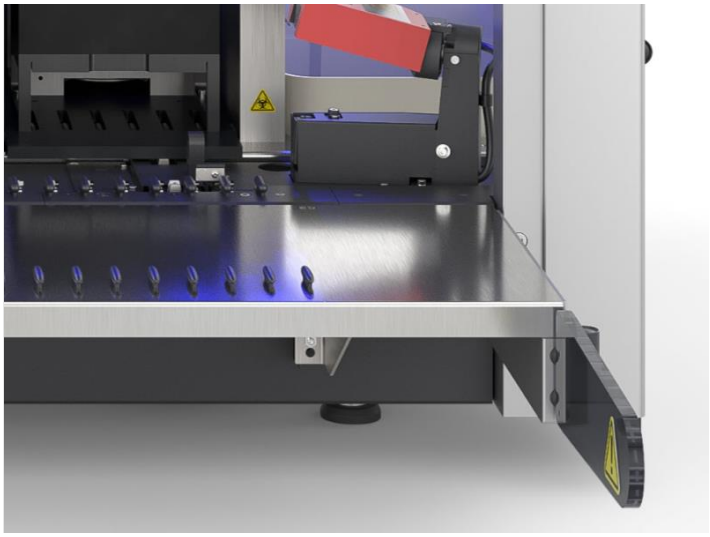
- **Access to Power Switch/Power Cord**

  Ensure there is enough room to access the power switch and power cord.

- **Working Area**

  The safety concept assumes that the doors are always closed and locked during normal operation.

- **Autoload Loading Tray and Side Guards**



The side guards are intended to draw attention to the Loading Tray area where racks and carriers, which extend beyond the edge of the Loading Tray, are being loaded and unloaded by the Autoload.

- **Surrounding Area**

Make sure the ventilation outlets of the instrument are not impaired by obstacles placed in the surrounding area.

ATTENTION

Rapid temperature changes or direct sunlight may affect certain functions such as barcode reading and pipetting accuracy.

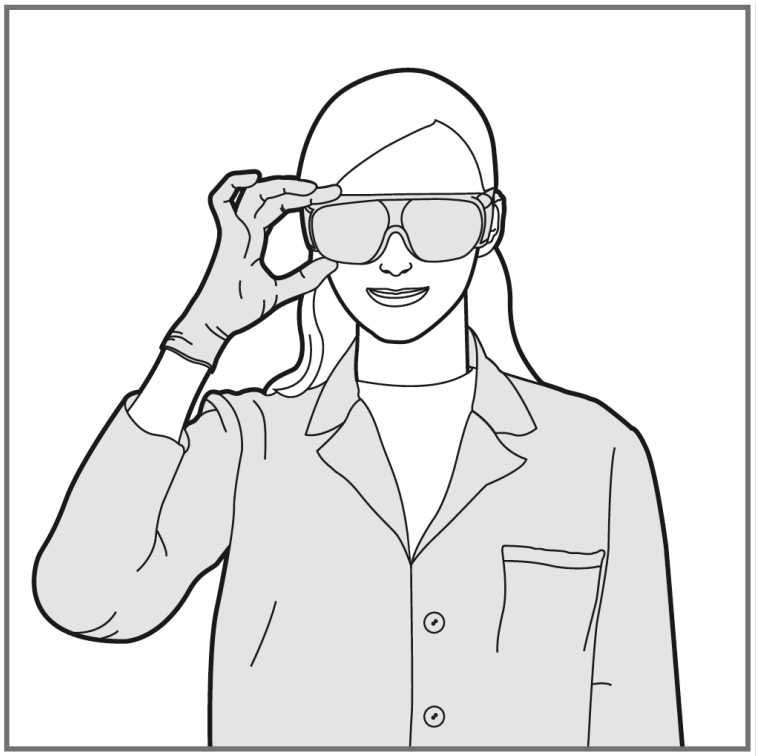
- *Do not open windows next to the instrument*
- *Do not expose the instrument to direct sunlight or intense artificial light or laser during operation*

Use appropriate:

Protective clothing

Goggles

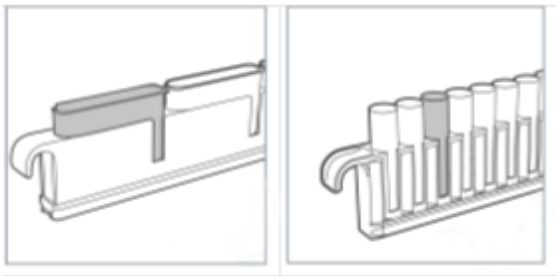
and Gloves.



1.10.5.3 Loading Reagents and Samples

Loading Reagents and Samples:

- The 1T Reagent Racks and 1T Sample Racks can tip over during sample and reagent loading and unloading



ATTENTION

Secure 1T Reagent Racks and 1T Sample Racks to prevent the risk of spillage of reagents or samples.

1.10.5.4 Loading Tray

Loading Tray:

- The instrument loading tray is a part of the instrument and must be treated with care.

ATTENTION

Risk of damage to equipment. Leaning onto the instrument loading tray will lead to damage of the loading tray.

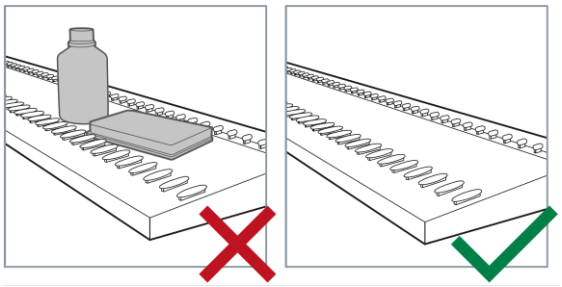
- *Do not lean onto the loading tray.*

ATTENTION

If you are making manipulation below the instrument (e.g. to store or retrieve consumables from under the workbench), when lifting, take care not to hit your head on the Loading Tray.

Foreign object damage:

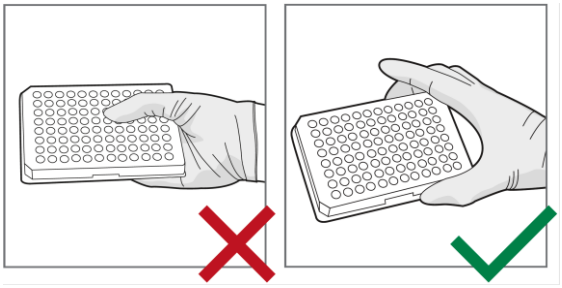
- Make sure that the loading tray has been cleared of foreign objects before running the instrument
- Foreign objects may obstruct the instrument and lead to damage to the equipment



1.10.5.5 Holding Labware

Holding Labware:

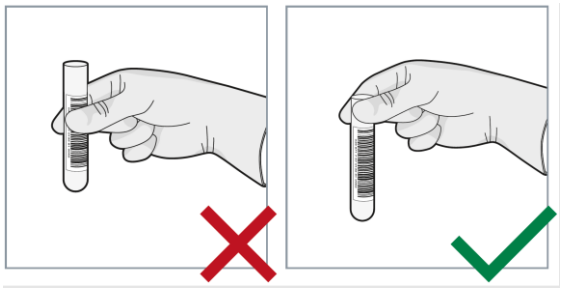
- Hold microplates by their sides



1.10.5.6 Holding Tubes

Holding Tubes:

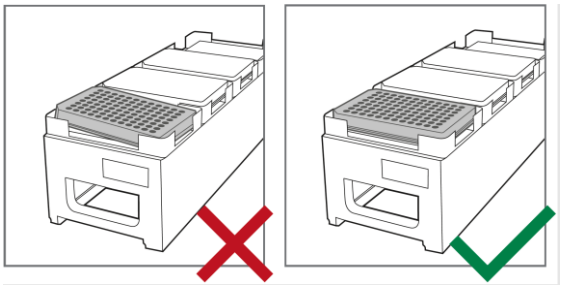
- Avoid holding tubes on barcodes
- Hold the tubes as shown



1.10.5.7 Placing Labware

Placing labware onto carriers:

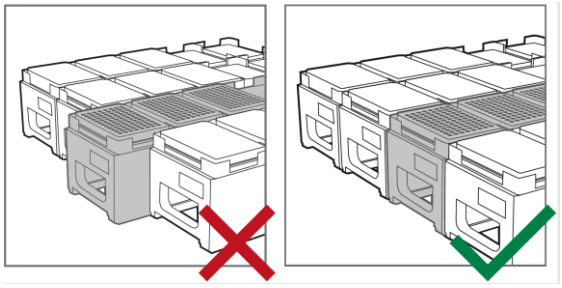
- Make sure labware is placed onto the carrier correctly
- Incorrectly placed labware will lead to collision or malfunction



1.10.5.8 Loading Plate Carriers

Loading Plate Carriers:

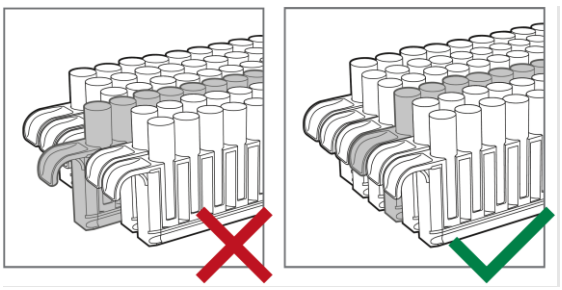
- Make sure the carriers have been pushed to the mechanical stop of the instrument
- Incorrectly positioned carriers will lead to malfunctions or collision



1.10.5.9 Loading Tube Carriers

Loading Tube Carriers:

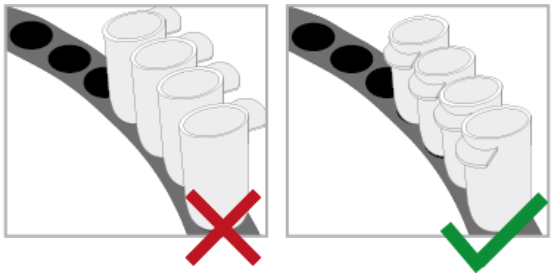
- Make sure the tube carriers have been pushed to the mechanical stop of the instrument
- Incorrectly positioned tube carriers will lead to malfunctions or collision



1.10.5.10 Loading MIC PCR tubes

Loading PCR tubes:

- Make sure that PCR tubes are correctly set
- Incorrect assembly of PCR tubes may lead to incorrect results and MIC rotor contamination
- Fill all unused positions with empty tubes

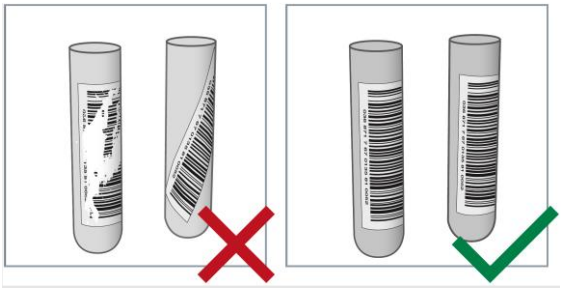


1.10.5.11 Barcodes Placement

Barcode quality:

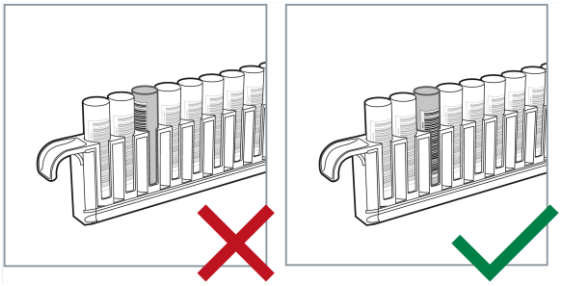
- Make sure that all barcodes are readable, as well as correctly applied
- Unreadable, scratched, smudged or incorrectly positioned barcodes on tubes will not be processed

Refer to the barcode types and quality requirements in Section 7.2 Autoload: Barcodes and Reader Specifications.



Barcode orientation:

- Make sure all tube barcodes have the correct orientation
- Incorrectly placed tube barcodes will not be readable

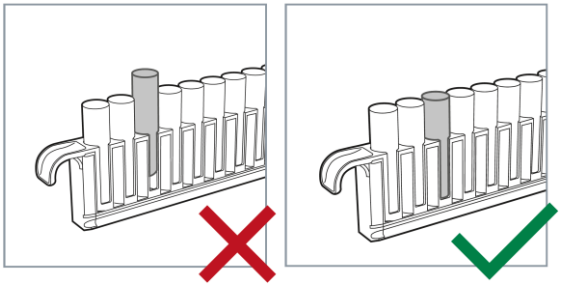


1.10.5.12 Tube Placement

Tube position:

When placing tubes into tube carriers:

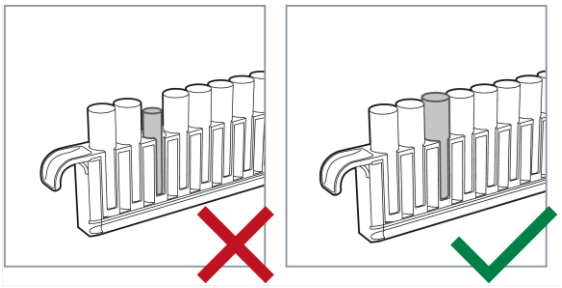
- Make sure the tubes are pushed all the way down into the tube carrier
- Incorrectly placed tubes may lead to malfunctions



Tube height:

When placing tubes into tube carriers:

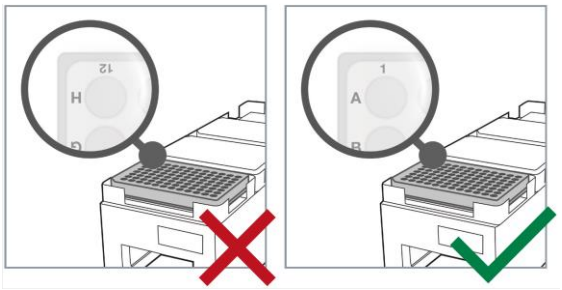
- Make sure that all tubes placed into the tube carrier are the same height
- Different tube heights will lead to incorrect calculation of sample volumes and lead to malfunctions



1.10.5.13 Labware Orientation

Labware orientation on carriers:

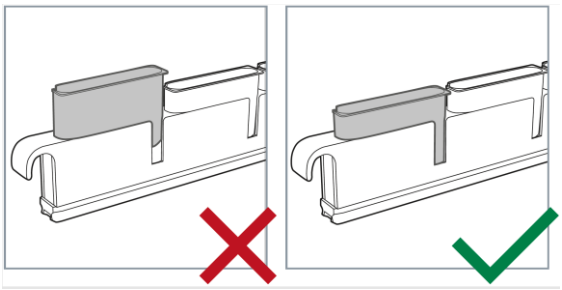
- Make sure plates have the correct orientation on the carrier
- The well position A1 has to be in the upper-left



1.10.5.14 Trough Position

Placing troughs into trough carriers:

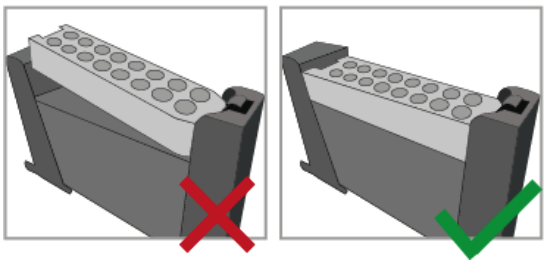
- Make sure the troughs are pushed all the way down into the carrier
- Incorrectly placed troughs will lead to spillage and/or malfunctions



1.10.5.15 Miniplate position

Placing miniplates into miniplate carriers:

- Make sure the miniplates are pushed all the way down into the carrier
- Incorrectly placed miniplates will lead to spillage and/or malfunctions



1.10.6 Reporting Serious Incidents

Any serious incident or near incident that has occurred in relation to the SENTiNAT® 200 must be reported to SENTINEL and to the competent authority of the Member State in which the operator is established.

Contacting SENTINEL is possible, either by contacting a local SENTINEL representative or by utilizing SENTINEL's webpage, which can be found on the last page of this Operators Manual.

2 Description of the SENTiNAT® 200

The SENTiNAT® 200 is a robotic pipetting instrument used for pipetting liquid samples in automated processes.

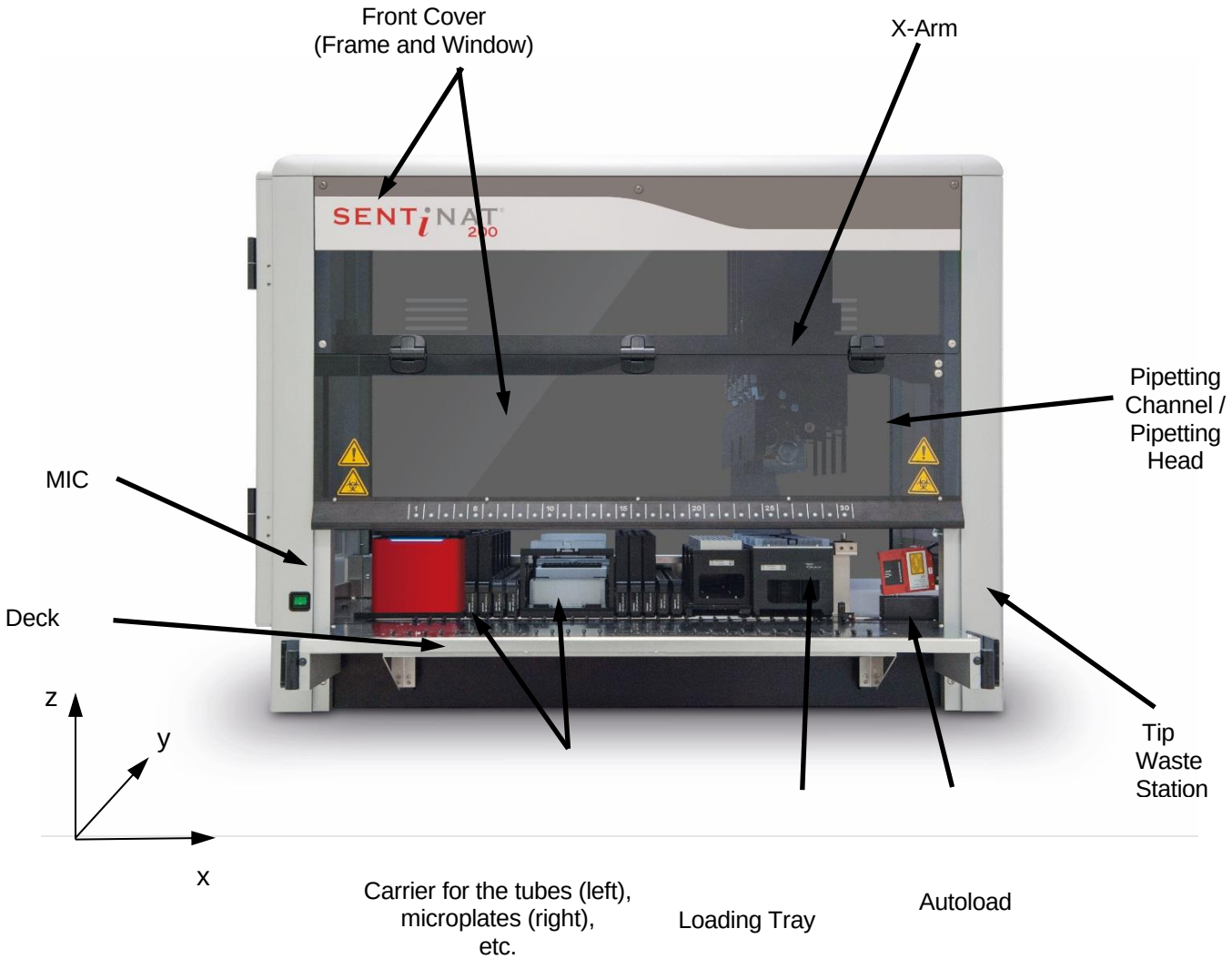
Pipetting means transfer of a discrete quantity of liquid from one container to another. A pipetting operation is achieved by aspirating (drawing) liquid from a source container, then transferring and dispensing (dropping) it into a target container.

The Components and Modules described in this section are either factory-installed and / or installed by a HAMILTON trained Field Service Engineer.

Other Components / Configurations / Accessories than applicable in this section, are not foreseen as being SENTiNAT® 200-compliant.

2.1 Platform

The SENTiNAT® 200 work surface, called a 'deck', is for placing loadable carriers hold reagent containers, such as tubes, Microplates, and other kinds of Labware.



The instrument deck is divided into 30 equal tracks (T) for loading carriers in pre-determined positions. This eliminates the need for the precise measurement of positions. A total of 25 SBS

(Standard format of the Society for Biomolecular Screening) positions can be placed onto a SENTiNAT® 200 Deck.

The deck has partitions of 22.5 mm, which is equivalent to 1-T (track). The labware carriers are adapted to those partitions, e.g. 1-T carriers for sample tubes, or 6-T carriers for microplates or CO-RE tips, etc. An additional partition provides space for the tip waste station.

2.1.1 Autoload

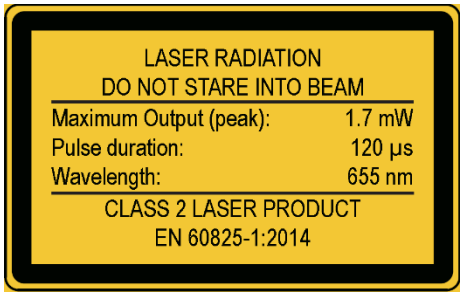
The Autoload is a device enabling automatic loading of carriers onto the SENTiNAT® 200 Instrument deck:

- Moves in the x-direction
- Shunts carriers on and off the deck
- Reads barcodes of carriers, tubes, and microplates

Please check which barcode reader is installed in your SENTiNAT® 200:

ATTENTION: LASER BEAM

The Barcode Scanner on the Autoload of the SENTiNAT® 200 has a Class II Laser Diode. Do not stare into the beam.



Barcode Scanner

NOTE

Do not put your fingers or hand between any of the barcode readers sledge, as there is the possibility of squeezing, bruising or crushing.

NOTE

The Barcode Scanner on the Autoload of the SENTiNAT® 200 has a Class I Laser Diode.

Barcode Scanner

NOTE

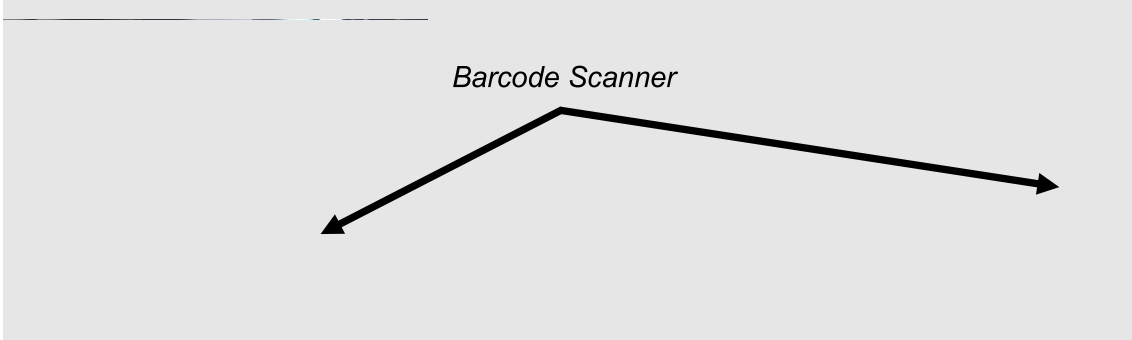
Do not put your fingers or hand between the Barcode Reader and Sledge, as there is the possibility of squeezing, bruising or crushing.

The following Carrier and Labware can be handled by the Autoload:

- Carrier Types:
  Tip Carrier, Plate Carrier, Sample Tube Carrier, Reagent Carrier, Stacker Carrier. See Section 8.1 Appendix A: Ordering Information for information regarding carrier types.
- Sample Tubes:
  See Section 8.1 Appendix A: Ordering Information for information regarding carrier types holding sample tubes.
- Reagent Containers:
  See Section 8.1 Appendix A: Ordering Information for information regarding carrier types holding reagent containers.
- CO-RE Tips:
  See Section 8.1 Appendix A: Ordering Information for information regarding carrier types holding CO-RE Tips.

There is a presence sensor that identifies whether tubes are present on a sample carrier.

Carrier identification by barcodes, and reading of barcodes on plates and tubes, is only possible in combination with the Autoload.



The Autoload, including the Barcode Reader, is shown reading horizontally for microplates and vertically for carriers and tubes

The following barcode symbologies can be read by the Autoload:

ISBT Standard	Code 128 (Subset B and C)
Code 39	Codabar
Code 2 of 5 interleaved	UPC A/E
JAN/EAN 8	

Barcodes must be black bars on a white background. SENTINEL recommends using the barcode type Code 128 (Subset B and C).

NOTE

In addition, barcodes must have a minimum readability (i.e. good contrast, size, correct orientation and distance between bars) to be fully functional.

Ensure the correct barcode orientation for tubes and plates (see specifications).

For details of barcodes, see the specifications provided in Section 7.2 Autoload: Barcodes and Reader Specifications.

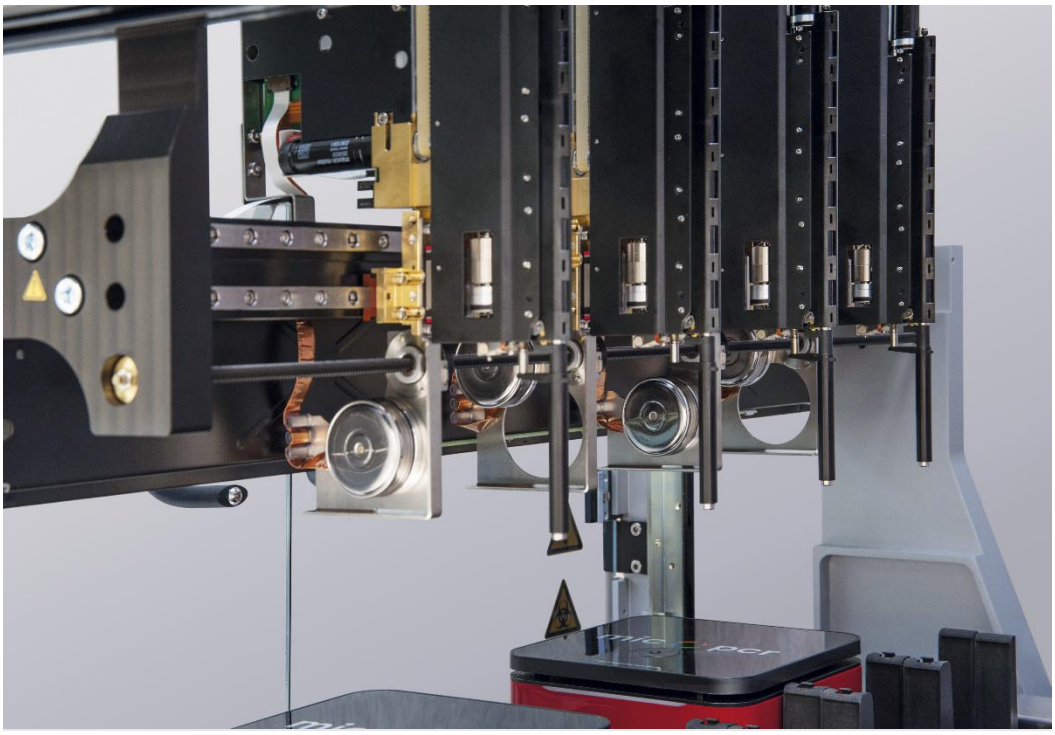
2.1.2 Pipetting Channels

The SENTiNAT® 200 is equipped with four 1000 µl pipetting channels.

2.1.2.1 1000 µl Pipetting Channels

The SENTiNAT® 200 is available with four 1000 µl pipetting channels, working in parallel for simultaneous transfer of liquids. Each pipetting channel moves independently on the Y-Axis, as well as on the Z-Axis. Each pipetting channel uses its own high-precision motors and electronics to reach any position on the deck without the need of teaching.

The 1000 µl pipetting channels work with a nominal volume of 1000 µl, support pipetting with disposable CO-RE tips.

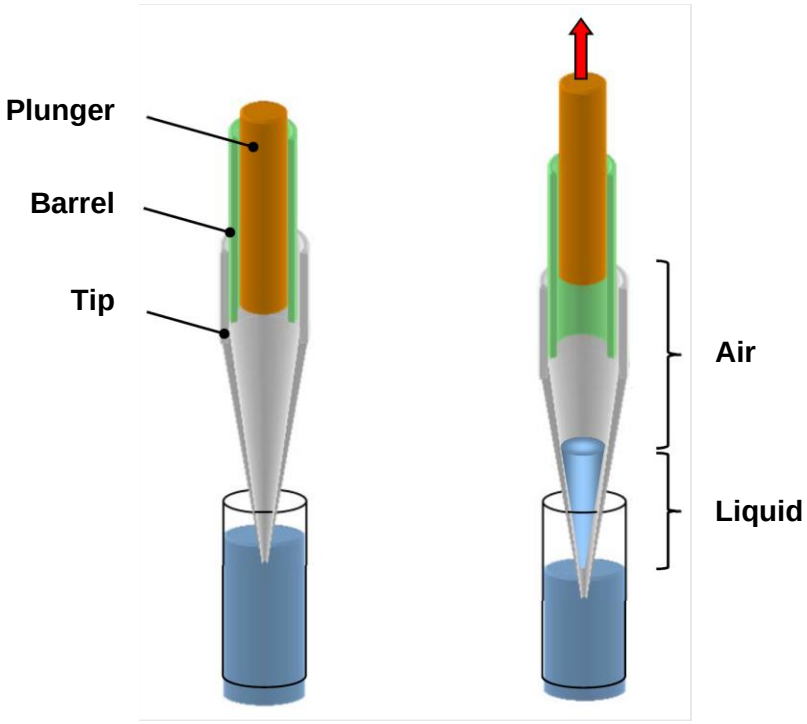


The minimum distance between two 1000 µl pipetting channels on the Modular X-Arm is 18 mm.

The pipetting channels have a set ‘traverse height’ of 245 mm above the origin or 145 mm between the top of the disposable tip and the deck of the instrument. This means that when a pipetting channel is to move from one location on the deck to another, it automatically does so at that particular height. This is a safety precaution, so that pipetting channels will not collide with any items that may be on the deck.

2.1.3 The Air Displacement Pipetting Principle

The SENTiNAT® 200 is based on the **air displacement pipetting** principle, comparable to the functionality of handheld pipettes. Air displacement means that the liquid is aspirated into and dispensed from a disposable tip or needle by the movement of a plunger. Between the plunger and the liquid surface is air. No system liquid of any kind is involved in the SENTiNAT® 200.



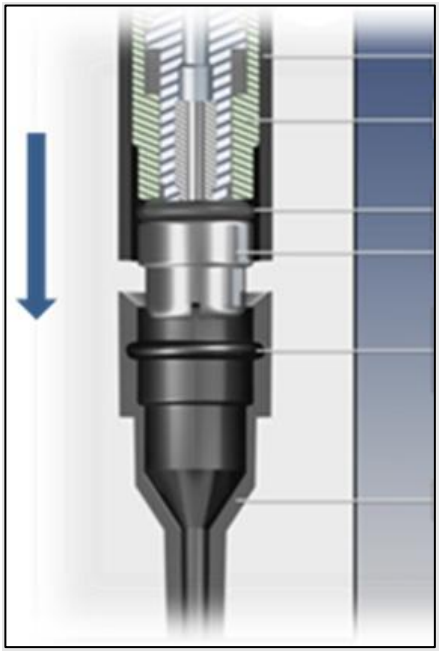
The air displacement pipetting principle

2.1.4 Liquid Level Detection

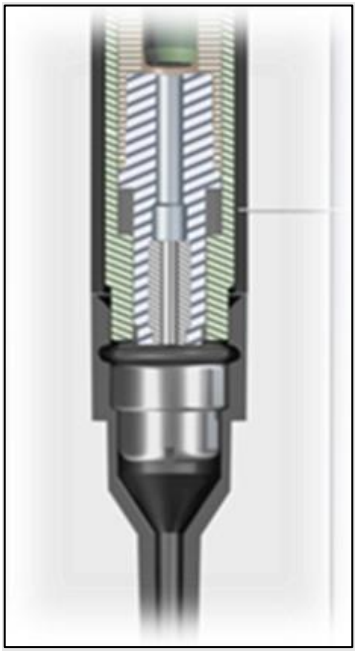
SENTiNAT 200 single pipetting channels (1000 µl) offer two modes of Liquid Level Detection (LLD): Capacitance- and pressure-based. The capacitive LLD (cLLD) detects conductive liquids. The pressure-based LLD (pLLD) detects all liquids including non-conductive solvents. If required for the application, capacitance and pressure-based LLD may be combined as Dual LLD (e.g. foamy samples).

2.1.5 Tip Pick-up with the CO-RE Technology

The first task for the SENTiNAT® 200 pipetting head is to pick up a HAMILTON disposable tip. Due to the unique (CO-RE) Compression-induced O-Ring Expansion technology, precise tip attachment and positioning is achieved. The system requires no vertical force for tip attachment or tip ejection, thus eliminating mechanical stress and improving overall system reliability along with pipetting speed and capability.



1. Tip Ejection Sleeve
2. Pressure Sleeve
3. O-Ring (unsqueezed)
4. Stop Disk
5. Groove for the O-Ring Expansion
6. Disposable Tip



Patent Numbers: EP11712400B2 (CH, DE, FR, GB) US7033543
DE199117375 US2006233669
JP3977597

NOTE

The principle of the CO-RE technology has the following advantages:

- *Enables coupling of disposable tips or washable needles within the same run*
- *Allows the use of different sizes of tips on the same pipetting head in the same run*
- *Picking up a Gripper and other tools is possible with a pipetting channel*
- *Prevents aerosols upon tip ejection*

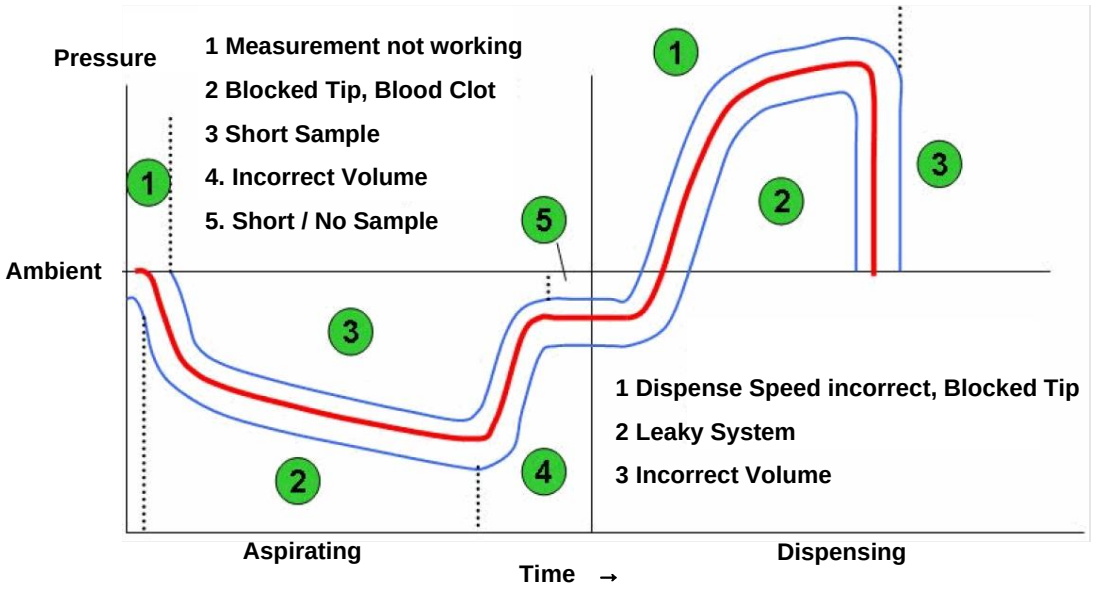
ATTENTION

Only HAMILTON CO-RE tips should be used for coupling to the pipetting heads of the SENTiNAT® 200. Other tips may cause contaminated or damaged pipetting channels and may lead to erroneous results.

2.1.6 Total Aspiration and Dispense Monitoring: TADM

During crucial sample transfers, the SENTiNAT® 200 can monitor aspiration and dispense steps in real-time. TADM verifies that a sample has been transferred by using a traceable digital audit trail.

TADM is available for individual pipetting channels.



Patent Numbers: EP1412759B1 (BE, AT, CH, DE, ES, FR, GB, IE, IT, NL, SE)
JP4328531
HK1067407
US6938504

2.2 Accessories

Accessories are defined as additional automation components. They provide a high degree of adaptability and permit customization for multiple applications.

2.2.1 CO-RE Gripper

The CO-RE Gripper is the plate-handling tool picked up by two pipetting channels during a run.

The CO-RE Gripper transports microplates, lids for microplates, archive plates etc. to and from positions on the deck of the SENTiNAT® 200. Plates can be gripped in landscape or portrait format within the working area. The rotation of plates is not an option.

CO-RE Gripper holder with jaws for the 1000 µl pipetting channels (inner positions)

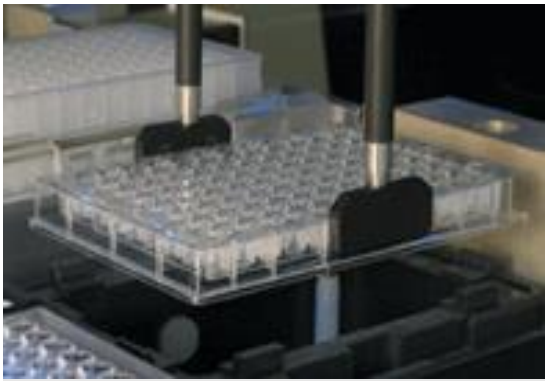


Plate being moved with CO-RE Gripper using 1000 ε l p i p e t t i n g c h

The CO-RE Gripper holder for the two different gripper jaws is mounted on the waste block, so it does not occupy any plate position.

2.2.2 HAMILTON Heater Shaker

The HAMILTON Heater Shaker (HHS) is designed to heat and shake microplates in SBS format. Loading and unloading as well the independent heating or shaking function of the HHS is fully controlled by the SENTiNAT® 200 Software.

Before shaking, the plates are locked and positioned in the center of the HHS. When the shaking process has finished, the plates are unlocked and can be easily removed from the Heater Shaker, using the CO-RE Grippers (do not move/remove plates manually from the HHS).

The HHS adapters fitted to your plate type allow optimal heating of your samples. The maximum set temperature of the HHS is 105 ˚C. To ensure reliable heating performance, two sensors permanently control the temperature, which guarantees the abidance of the user-defined temperature range. In addition, a cut-off temperature will protect your samples from over-heating.

HHS with standard universal flat bottom adapter

ATTENTION

Only labware which complies with the HHS dimensions can be used in order to prevent any loss of plates and/or liquids.

When shaking labware, the velocity must be adjusted to the type of labware and the volume within the labware to prevent cross-contamination due to spillages.

Flammable liquids must not be heated by the HHS, as they may cause fire.

Make sure that the plate used with the HHS is heat-resistant (maximum temperature 105 °C).

NOTE

An efficient heating of the liquid is only achieved if the appropriate adapter for the labware is used. The heating time and the maximum temperature, which can be reached for the liquid inside the plate, is dependent upon the amount of liquid, the size and weight of the used labware, the shape of the adapter used and the heating effectiveness between the plate and the adapter.

The maximum speed of the HHS depends upon the eccentric tappet and the labware used. Shaking can be performed clockwise or counter-clockwise.

ATTENTION

When working with toxic chemicals or samples, which will be used in particularly sensitive tests, take into account the evaporation that may occur while the HHS is running.

Be aware that heating of liquids will affect the pipetting process, as well as shaking the labware can influence the precision of pipetting.

ATTENTION

When shaking labware, the velocity has to be adjusted to the type of labware and the volume within the labware to prevent cross-contamination due to spillages.

NOTE

The HHS is intended to be used in combination with a SENTiNAT® 200 only!

Do not use the HHS as a stand-alone device.

ATTENTION

Before connecting or disconnecting the HHS from or to a SENTiNAT® 200, make sure that the SENTiNAT® 200 is switched off. Only when the SENTiNAT® 200 is switched off is it safe to connect or disconnect the HHS. Not obeying this instruction may result in damage to the HHS.

Do not touch the HHS by hand during run time and also not shortly after finishing a run, as it may be hot. Wait until the HHS has cooled down to room temperature.

2.2.2.1 Operating the HAMILTON Heater Shaker

The HHS is fully controlled by the SENTiNAT® 200 Software.

ATTENTION

When working with samples used in particularly sensitive tests, take into account the evaporation that may occur while the HHS is running. Be aware that heating of liquids will affect the pipetting process, also that shaking the labware can influence the precision of pipetting.

ATTENTION

When shaking labware, the speed has to be adjusted to the type of labware and the volume within the labware to prevent cross-contamination due to spillage.

ATTENTION

Do not touch the HHS while running, and shortly after finishing a run, as it may be hot. Wait until the HHS has cooled down to room temperature, which can take up to 1 hour.

NOTE

The maximum shaking speed of the HHS depends upon the orbit and the type of labware used (see Section 7.4.3 HAMILTON Heater Shaker Specifications).

NOTE

An efficient heating of the liquid is only achieved if the appropriate adapter for the labware is used. The heating time and the maximum temperature, which can be reached for the liquid inside the plate, is dependent upon the amount of liquid, the size / weight of the labware used, the size / weight of the used adapter and the connection between the plate and the adapter.

Further information about the maximum shaking speed for MTPs and DWPs can be found in Section 7.4.3 HAMILTON Heater Shaker Specifications.

2.2.3 Multiflex Carrier Base

This carrier base will occupy 7 tracks of the SENTiNAT® 200 deck.

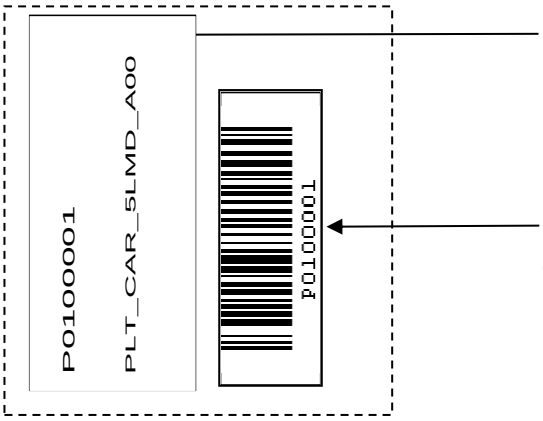
Carrier base with multiple modules

2.2.4 Carriers

Labware is placed on special carriers which are loaded onto the SENTiNAT® 200 deck.

Every carrier is equipped with at least 2 labels, one identification label and one barcode label. The identification label is readable by the operator; it contains the carrier name and barcode information. The carrier name on the identification label is the one used by the SENTiNAT® 200 Software.

The barcode label is for purposes of automatic identification.



Carrier barcode labels

Identification label on the front side of the carrier:

- carrier identification number
- carrier name

Carrier barcode label at the back of the carrier with carrier identification number:

- character 1 to 3: carrier type
- the rest is serial numbering

Identification label on the front

Carrier barcode label at the back

Location of Carrier Labeling

2.3 Disposable Tips

HAMILTON's CO-RE tips are the only tips developed to meet the demands of the most flexible and reliable automated pipetting tasks. Pipetting channels lock into the tip rather than the standard method of forcing a tip onto a mandrel (see Section 2.1.5 Tip Pick-up with the CO-RE Technology). This design assures superior tip alignment, seals the tip to the pipette channel, eliminates tip distortion, and mitigates aerosol contamination.

The use of non-HAMILTON tips is not supported on the SENTiNAT® 200. Non-HAMILTON tips do not have the annular space necessary to receive the O-ring. This may result in non-intended deformation of the O-ring and the tip material itself. It may lead to misalignment of the tip, improper sealing, reduced O-ring lifetime, improper drop-off, and potential aborted runs from randomly dropped tips. Therefore, HAMILTON does not support the use of non-HAMILTON tips on the SENTiNAT® 200.

ATTENTION

Only HAMILTON disposable tips and needles should be used for coupling to the pipetting channels and pipetting heads of the SENTiNAT® 200. Other tips may cause contaminated or damaged pipetting channels.

NOTE

Pipetting specifications are only guaranteed when using HAMILTON Tips.

HAMILTON's proprietary technologies for tip attachment (CO-RE) and air displacement pipetting together with the use of HAMILTON tips facilitate maximum pipetting accuracy and reliability.

HAMILTON disposable CO-RE tips are produced under clean room conditions (Class 8), based on ISO 14644 standards. "Biological purity tested" tips are free of DNA, DNase/RNase, PCR inhibitors and endotoxin (non-pyrogenic). In addition to these criteria, "Biological purity^{PLUS}" tips are sterile, in accordance with ISO 11135, and free of ATP.

Filter tips are available for preventing aerosol contamination.

Conductive (black) tips specifically designed for cLLD.

NOTE

Make sure to match the tip type(s) used with the method and channel(s) / probe head(s). Please refer to Section 2.1.5 Tip Pick-up with the CO-RE Technology.

NOTE

Be aware that different tip classes (with and without filter, black or clear, non-sterile versus irradiated, etc.) can have different performance when pipetting liquids. Pipetting parameters and liquid class settings may have to be adjusted when changing from one tip type to another, in order to achieve accuracy and precision, which is within published specifications.

NOTE

All new or special tip types require additional settings (such as configuration file entries, liquid classes, etc.) in the SENTiNAT® 200 Software. Please consult a local SENTINEL representative for the implementation of non-standard tips.

2.3.1 Shelf Life

The shelf life of any disposables, such as tips, containers, labware, etc. is provided on the corresponding packaging.

2.3.2 CO-RE Tips for 1000 µl Pipetting Channels

Disposable CO-RE tips for the 1000 µl pipetting channel are available in 4 different sizes with filter:

- Low volume CO-RE tip, 0.5 - 50 µl
- Medium volume CO-RE tip, 10 - 300 µl
- High volume CO-RE tip, 10 - 1000 µl

ATTENTION

To avoid any cross-contamination use only tips with filter.

ATTENTION

Only HAMILTON disposable CO-RE tips should be used with the SENTiNAT® 200. Non-HAMILTON tips may cause contamination or damage of the pipetting channels or may lead to incorrect pipetting.

ATTENTION

Use caution when using the low volume CO-RE tips, 0.5-50 µl and medium volume CO-RE tips, 10-300 µl on the same system. Do not mix up one tip type with the other during the process of loading the deck. The wrong tip causes either bad pipetting results or damaged pipetting channels.

NOTE

The tip type is printed in plain text on the barcode label of the tip rack for visual identification (e.g. 50 µl for CO-RE low volume tips).

2.3.2.1 Low Volume CO-RE Tip

The low volume CO-RE tip, 0.5-50 µl with filter, is available as conductive (black) tip for use with cLLD. It is compatible with Total Aspiration and Dispense Monitoring (TADM). The low volume CO-RE tips come in trays of 96 tips. One blister pack contains 5 trays. The trays are barcode-labeled for automatic identification during the loading process.

Low Volume CO-RE Tip, 0.5 ï 50 µl

Light Red Label

Tip Tray and Color Code Label for Low Volume CO-RE Tips, 0.5 ï 50 µl

2.3.2.2 Medium Volume CO-RE Tip

The medium volume CO-RE tip with filter, 10-300 µl, is available as conductive (black) tip for use with cLLD. It is compatible with Total Aspiration and Dispense Monitoring (TADM). The medium volume CO-RE tips come in trays of 96 tips. One blister pack contains 5 trays. The trays are barcode-labeled for automatic identification during the loading process.

Clear and Conductive CO-RE Tip, 10 ï 300 µl

Yellow Label

Tip Tray and Color Code Label for CO-RE Tips, 10 ï 300 µl

2.3.2.3 High Volume CO-RE Tip

The high volume CO-RE tip with filter, 10-1000 µl, is available as conductive (black) tip for use with cLLD, with filter. It is compatible with Total Aspiration and Dispense Monitoring (TADM). The high volume CO-RE tips come in trays of 96 tips. One blister pack contains 5 trays. The trays are barcode-labeled for automatic identification during the loading process.

Conductive CO-RE Tip, 10 ï 1000 µl

Tip Tray and Color Code Label for CO-RE Tips, 10 ï 1000 µl

2.4 MIC PCR instruments

The MIC PCR instruments are 2 installed Real-Time PCR thermalcycler installed on the SENTiNAT® 200. Each MIC is capable of performing 48 samples and is provided with 4 fixed reading channel.

Protocol and settings of the instrument is automatically performed by the SENTiNAT application Software.

For PCR reaction, dedicated PCR tubes have to be used.

ATTENTION

MIC rotors have to be always balanced while in use. Before starting a reaction, verify that all 48 positions in each instrument are occupied by a PCR tube.

2.5 Computer Requirements

The SENTiNAT® 200 and its accessories are controlled by dedicated SENTiNAT® 200 Software, which controls all functions for daily work routine, method programming, running methods and other services.

The SENTiNAT® 200 and the computer are linked via Universal Serial Bus Interface (USB).

For the recommended PC model refer to Section 7.1.4 Computer Requirements (Computer included in shipment).

To avoid data loss, we recommend an Uninterruptible Power Supply (UPS) for the PC.

2.6 SENTiNAT® 200 Software

The SENTiNAT® 200 Software provides everything to control the SENTiNAT® 200.

It is a Windows-based, menu-driven interface allowing the user to run the SENTiNAT® 200.

The SENTiNAT® 200 Software allows running different methods for aspirating and dispensing liquids, also to control accessories.

NOTE

SENTiNAT® 200 functionality has been verified using Windows 10. Running the SENTiNAT® 200 under any other Operating System may lead to severe problems and/or malfunction.

For more details regarding SENTiNAT® 200 Software, refer to your local SENTINEL representative.

The customer only needs to ensure that a suitable control PC is available for installation of the SENTiNAT® 200 Software. The SENTiNAT® 200 will be unpacked and installed and the initial set-up will be performed by a HAMILTON trained Field Service Engineer, according to the IQ Form.

NOTE

Any other software installed and running on the computer in parallel to SENTiNAT® 200 may have a negative impact on the performance of the IVD-R Software.

2.7 Power / Voltage

Make sure that the SENTiNAT® 200 is connected to a 115 or 230 VAC (50 Hz or 60Hz) socket. The SENTiNAT® 200 automatically recognizes any voltage within that range, without user intervention.

We recommend using an Uninterruptible Power Supply (UPS) for the SENTiNAT® 200.

Ensure that the instrument is correctly grounded when connected to the power supply.

The main plug is on the left-hand front side of the instrument.

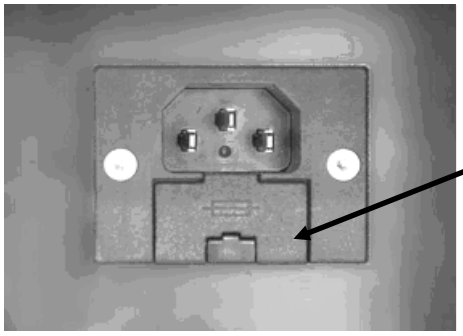
The fuses for the instrument are placed in the main power socket (see picture below).

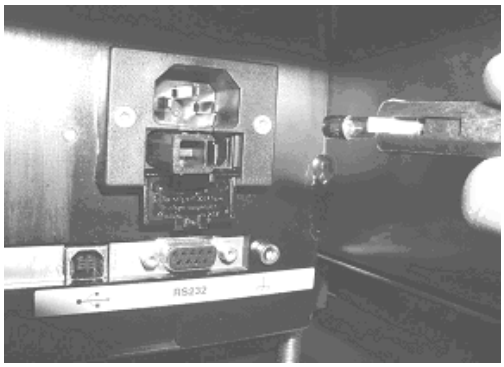
During installation / IQ, the appropriate fuse is selected by the HAMILTON trained Field Service Engineer.

Plug the main cables for the computer and the instrument into the same electrical outlet. Connect them only to a grounded outlet.

ATTENTION

Do not exchange the supplied/installed power cord. In case of damage or loss of the power cord, consult a local SENTINEL representative for a replacement. If replacing the power cord by inadequately-rated power cords, the protection provided by the equipment may be impaired.





Fuses

Access to the Fuses

ATTENTION

When replacing a fuse, make sure to use the appropriate fuse (see Section 7 Technical Specifications) and place it into the main power switch before switching on the instrument.

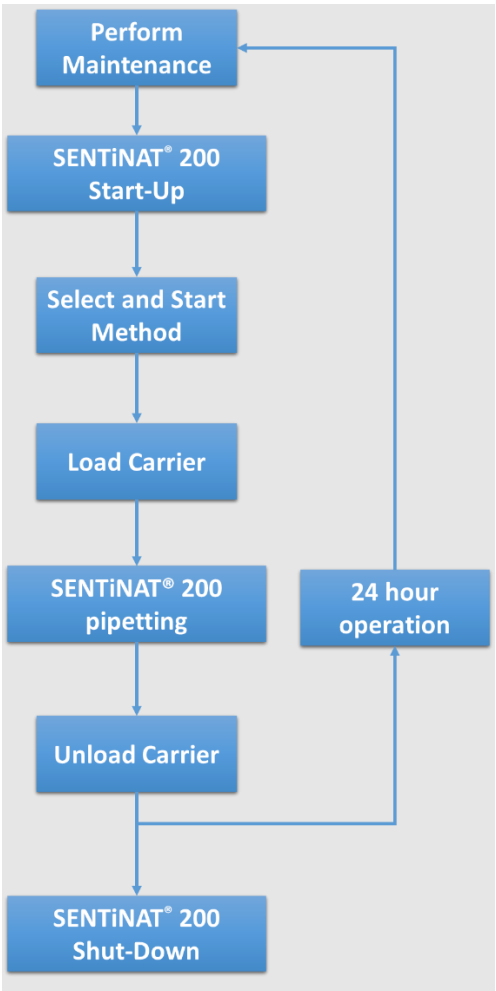
3 Routine Use

NOTE

This section can vary, due to different applications and method programming.

3.1 Daily Work Routine

Below is a flow chart indicating the logical flow of the daily work routine using the SENTiNAT® 200. Each of these steps is explained in detail in the following pages.



To perform the periodic maintenance, see Section 4 Maintenance.

3.2 Starting the SENTiNAT® 200 Application

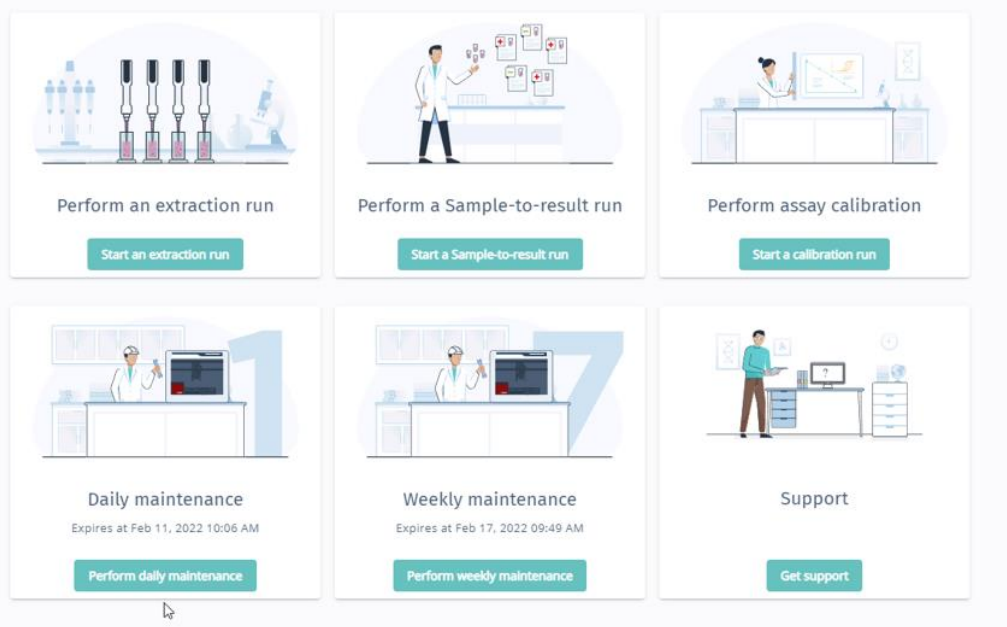
Turn on the SENTiNAT® 200 and the connecting PC and enter your username and password.

The Run Control enables the execution of methods.

It may be started by double-clicking:

1) The "**UgenTec SENTiNAT200 Bridge**" shortcut on the Desktop.
2) The Hamilton "**Star Instrument Host**" shortcut on the Desktop.

Keeping both the shortcuts opened, open the browser at the following website: http://localhost:8100/runs/selection
The following window will appear on the Desktop:



3.3 Selecting a Method

It is possible to perform a Sample-to-result run or an extraction run.

Prior to a sample measurement, a valid calibration curve needs to be registered for each quantitative method.

Before starting a new Sample-to-result run or extraction only, a daily or weekly maintenance run is required.

Make sure the lids of both PCR cyclers (MIC) are closed before starting maintenance. Performing maintenance while a PCR cycler lid is open will severely damage the instrument.

To perform the periodic maintenance, see Section 4 Maintenance.

ATTENTION

It is important to ensure that adequate amounts of the correct liquids are placed in the correctly labeled containers.

When pouring reagents into the reagent containers, ensure that there is no foam on the surface of the liquid.

Do not overfill reagent containers: fill approximately 10 mm below the top of the container to avoid spilling liquids.

Handle labware (tips, microplates, tubes, etc.) with care to avoid spilling liquids.

Always use the proper labware (tips, microplates, tubes, etc.) corresponding to the definitions of the methodôs layo

Position microplates correctly such that well #A1 is placed according to the deck layout.

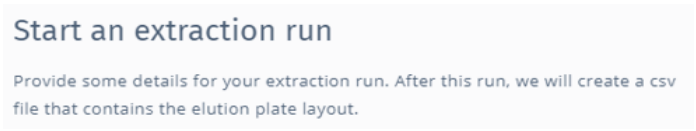
Handle any 1-track carrier (such as a sample carrier) with particular care, as this type of carrier can fall over and cause injury or contamination. Position it on the Autoload Tray (see figure below), or place several carriers together to minimize this risk.

Always make sure that all MIC rotor positions are full. Before starting a run, fill all empty positions with empty tubes.

MIC driver checks that the tubes are not full before start of the run. There is an error message when the tube is full.

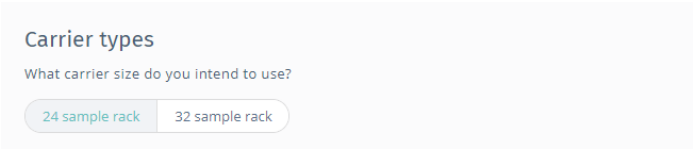
At the end of the run, discard all used tubes containing the reagent.

3.3.1 Performing an Extraction run

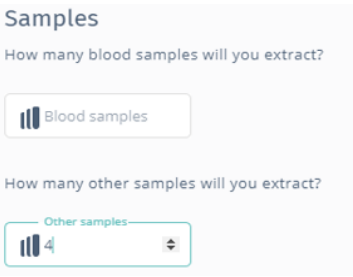


According to the sample tube, select the Carrier types:

- 24 sample rack can be used for sample tube 17x100
- 32 sample rack can be used for sample tube 13x100



NOTE: 1 type of carrier can be selected at a time. Different types of sample tubes have to be loaded in separate runs.



Insert the number of samples in the correct box based on the type sample (Blood samples or other samples).

NOTE: It is possible to upload a maximum of 48 samples per run.

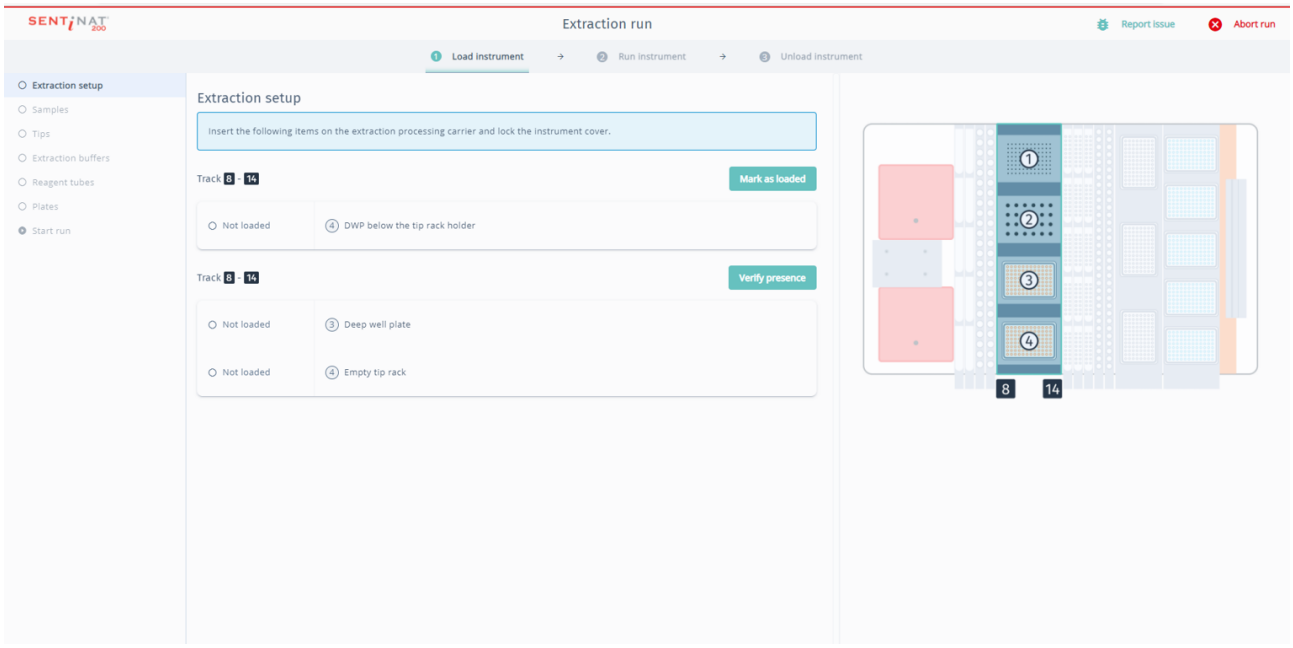
NOTE: SENTiNAT® 200 requires at least 700 µl of sample volume. Samples with less volume cannot be processed by SENTiNAT® 200.

Press the “Start my extraction run” button to proceed. Samples can be loaded both in track 6 or 7.

The correct position is highlighted by LEDs on the instrument. Alternatively, all carriers can be placed directly in their correct positions on the Autoload Tray.

3.3.1.1 Extraction setup

Follow the instruction setup and load a Deep Well Plate in position 3 and 4 and an empty tip rack in position 4. DWP in position 3 will be use for the DNA/RNA extraction, DWP in position 4 will be used to collect drops from tips parked during the washing with buffers. Confirm pressing corresponding bottom when done.



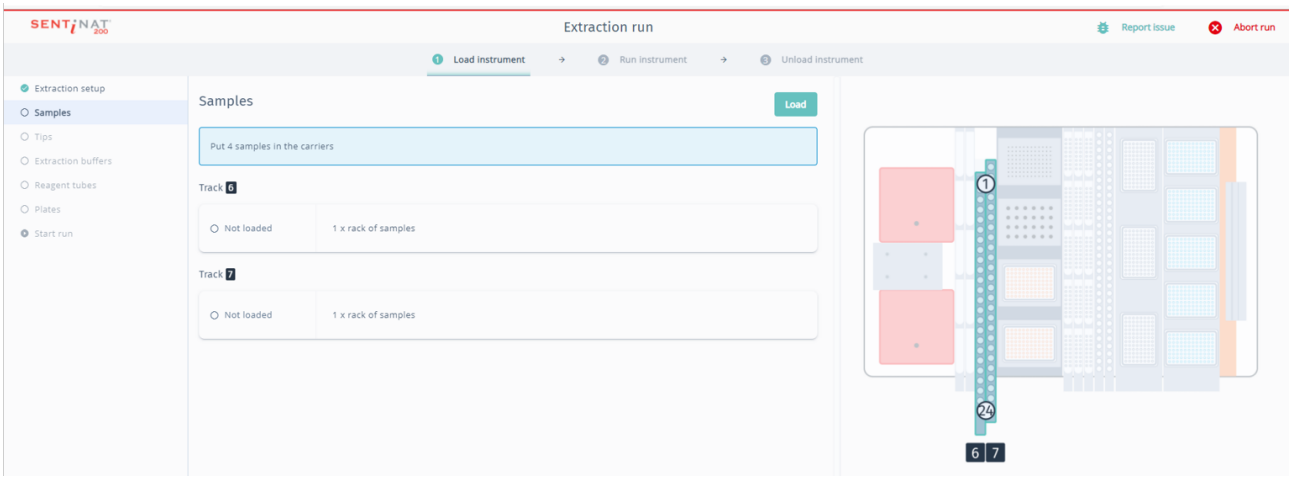
3.3.1.2 Sample:

The software provides information regarding the position of the rack. Specimens can be loaded in tracks 6 or 7.

One rack has to be assigned to the specific primary sample tube. Only one type of rack (32 or 24 tubes) can be loaded in a run.

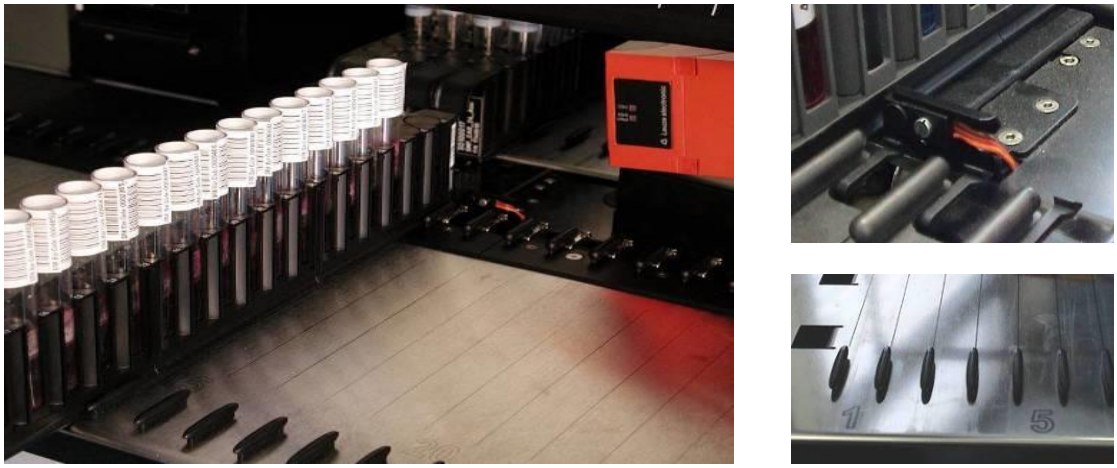
NOTE: Whole blood samples have to be analyzed in a dedicated run. Do not load other sample type in a dedicated whole blood rack.

NOTE: Verify that the barcode on the tube can be read from the autoloader reader.



Insert the carriers into the tracks between the front and rear slide blocks of the Autoload Tray until they touch the stop hooks on the far side of the Autoload Tray.

Press the Load button, in order to load samples.



Slide Blocks and Stop Hooks for Carriers

ATTENTION

Make sure the carriers are inserted completely until they touch the stop hooks on the Autoload Tray.

Make sure there are no carriers loaded on the same tracks, as already loaded carriers on the deck (indicated by LEDs).

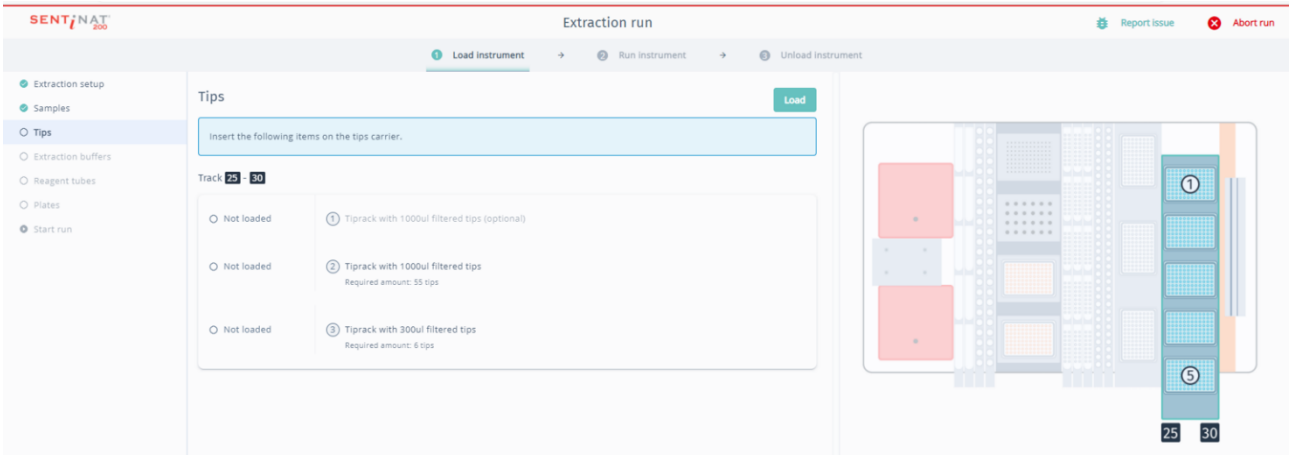
3.3.1.3 Tips:

Follow software instructions to correctly load the tip racks:

- Tip racks with 1000 µl tips can be loaded in position 1 and 2.
- Tip racks with 300 µl tips can be loaded in position 3.

NOTE:

- The barcode of the racks must be on the right side.
- Depending upon the sample's number, some tip racks could be optional.

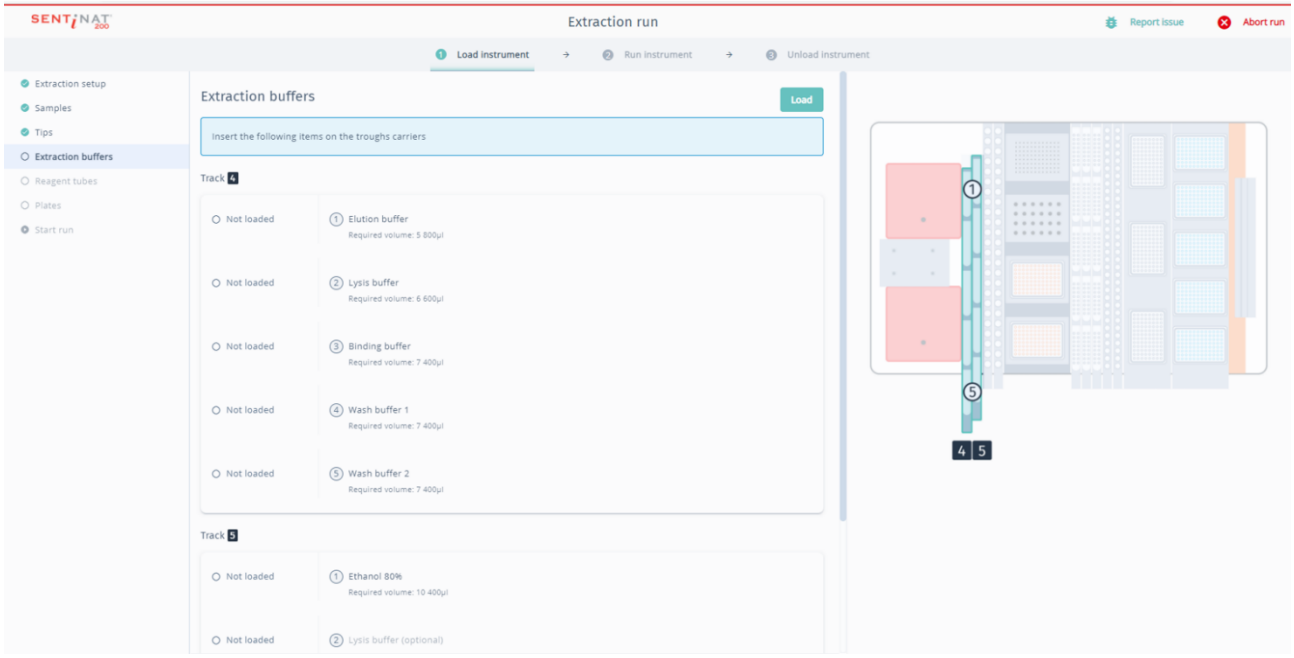


3.3.1.4 Extraction buffers:

Dedicated barcoded carriers with the extraction buffers are included in the extraction kit. Following the instruction reported on the software, load the carrier in the described position.

A complete set of extraction buffers can be loaded for up to 24 samples. In case more than 24 samples have to be extracted, a new set of trough buffers must be loaded in track 5 (Lysis buffer, Binding buffer, W1and W2).

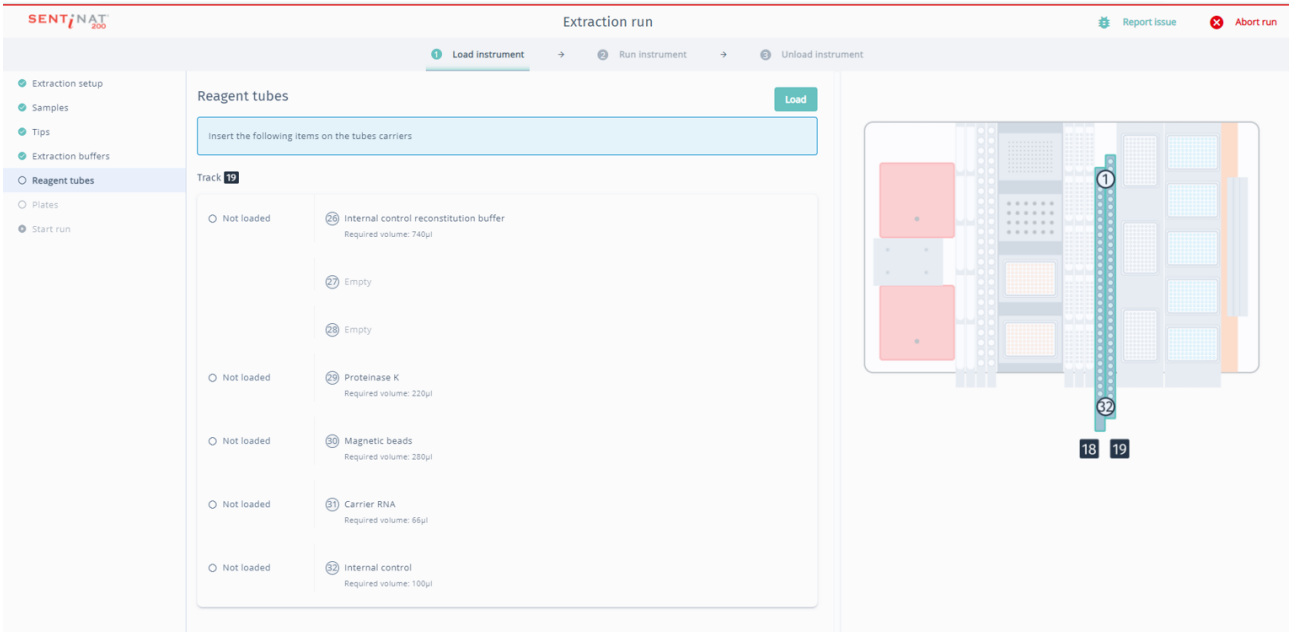
NOTE: Already used troughs for Lysis buffer, Binding buffer, Wash buffer 1 and 2 can only be loaded on the carrier at track 4.



3.3.1.5 Reagent tubes:

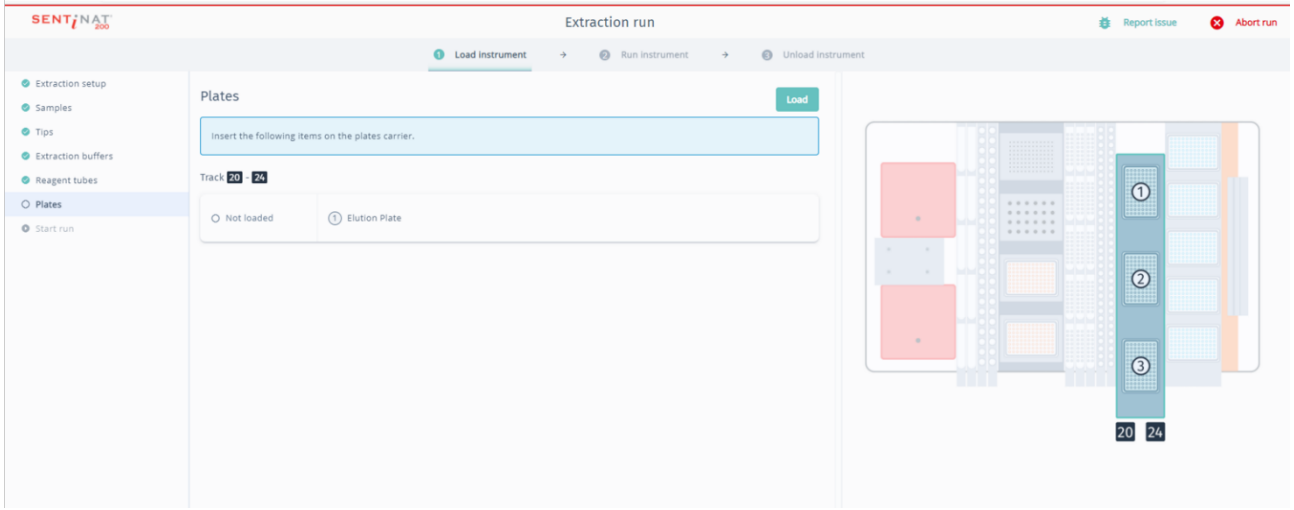
The software provides the list of the reagent tubes to load in track 19. The reagent tubes required are, Proteinase K, Carrier RNA, Beads and Internal control.

NOTE: Use the same lot of reagent buffer.



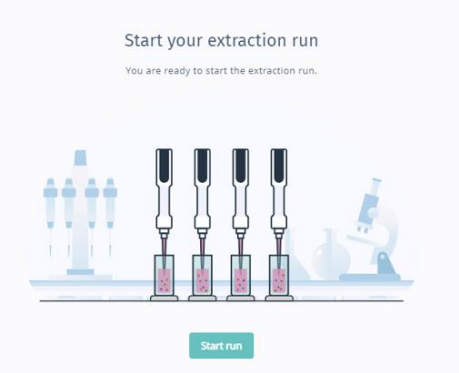
3.3.1.6 Plates:

Please load the Elution Plate in position 1 of the track 20-24.



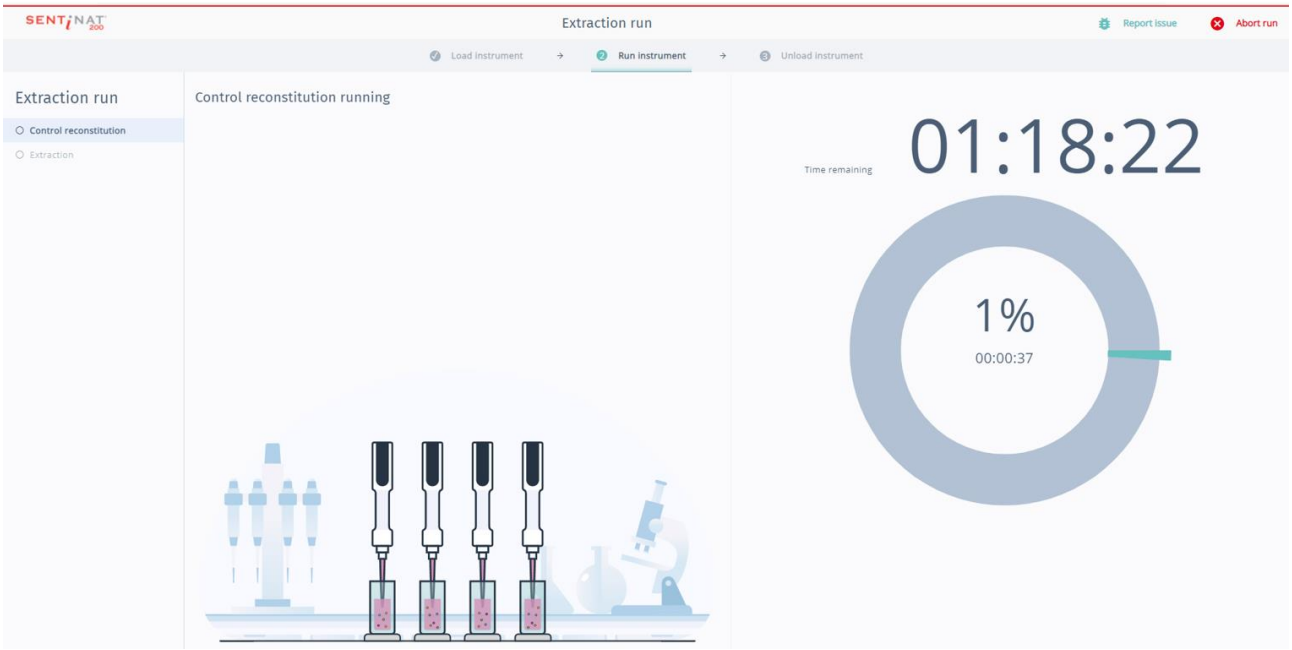
3.3.1.7 Start the run

The system is ready and the session can be started.



As soon as the run is started, a counting timer with will appear in the window.

Information regarding the ETA (Estimated Time of Arrival), procedure and completion percentage are reported.

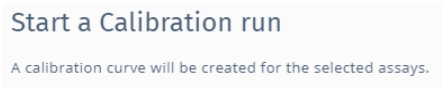


ATTENTION

An abort may cause the loss of data. Therefore methods once aborted cannot be resumed.

An aborted run (e.g. one stopped by pulling out an inserted carrier) cannot be restarted.

3.3.2 Performing an assay calibration



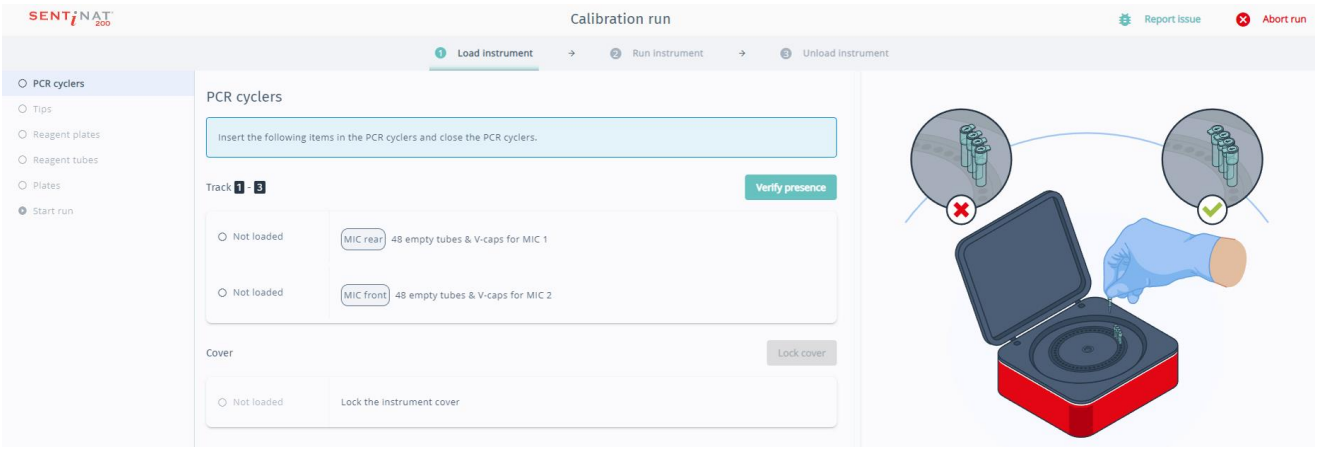
Select the Assay or Assays to be calibrated.

NOTE: It's possible to select up to 3 different assays to be calibrated in one run. Both MIC are calibrated in the same run.

3.3.2.1 PCR cycler:

Load 48 empty tubes and V-cap first in the front MIC and in the rear MIC; it is very important that the system is balanced, so please fill completely all the 48 positions of the MIC with the tubes even if the number of calibrator dilutions is lower. Please insert the tubes in the correct side as shown in the picture.

Once the empty tubes are loaded, press the Verify Presence button and lock the MIC cover.



3.3.2.2 Tips:

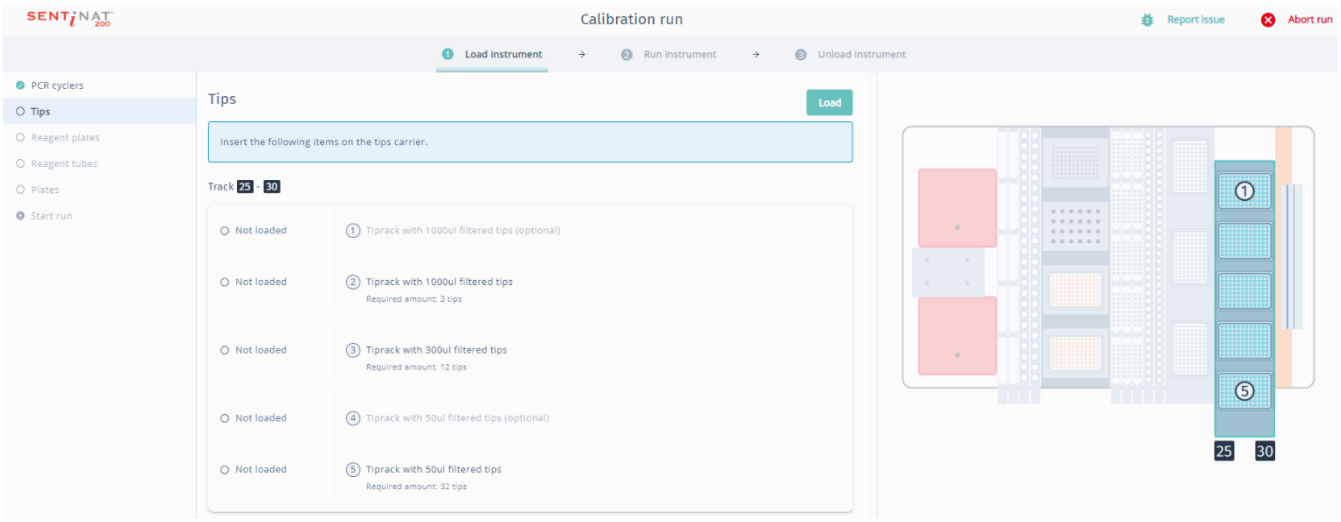
Follow software instructions to correctly load the tip racks:

- Tip racks with 1000 µl tips can be loaded in position 1 and 2.

- Tip racks with 300 µl tips can be loaded in position 3.
- Tip racks with 50 µl tips can be loaded in position 4 and 5.

NOTE:

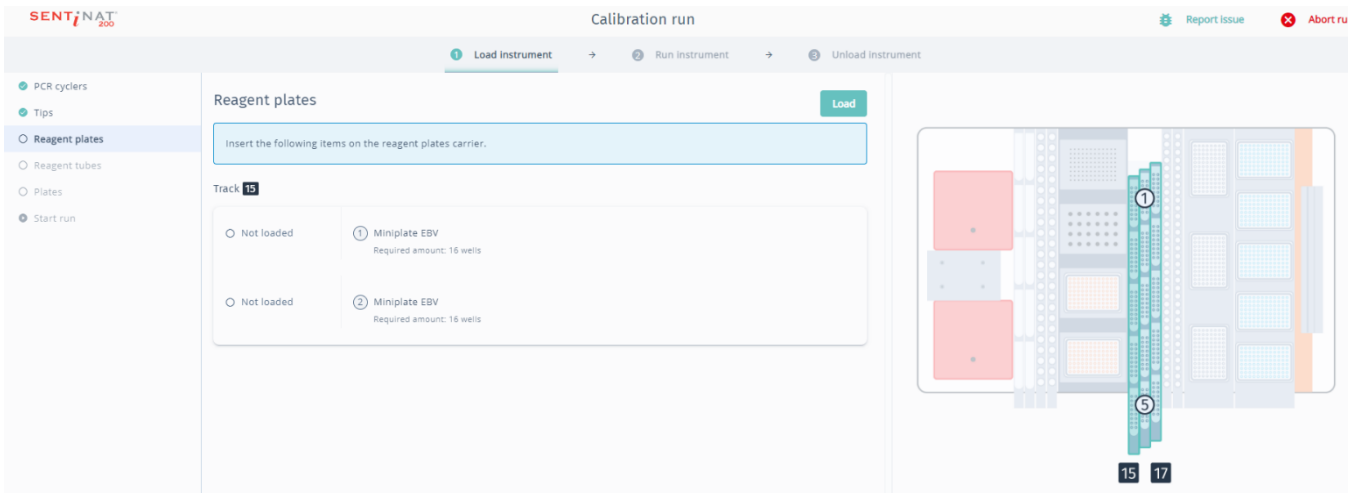
- The barcode of the racks must be on the right side.
- Depending upon the number of Assay Calibrations performed, some tip racks could be optional.



3.3.2.3 Miniplates:

According to the number of the programmed Assay Calibrations, load the miniplates starting from position 1 of track 15, following the indication shown by the software.

Up to 15 miniplates can be placed from track 15 to track 17.

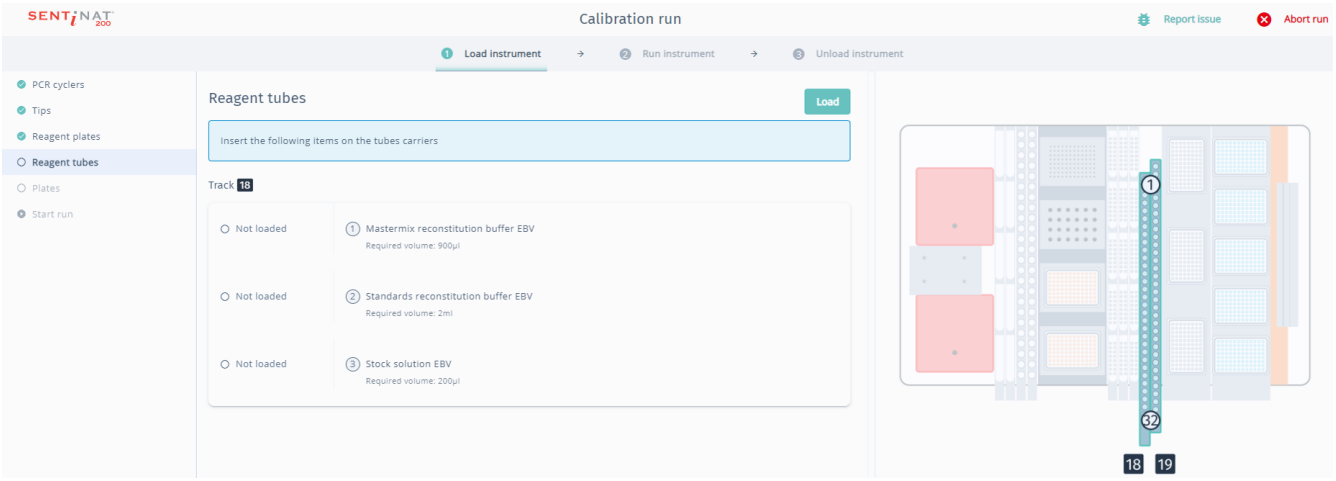


NOTE: Use only SENTINEL miniplates. Other consumables could not fit properly in the adaptor.

3.3.2.4 Reagent tubes:

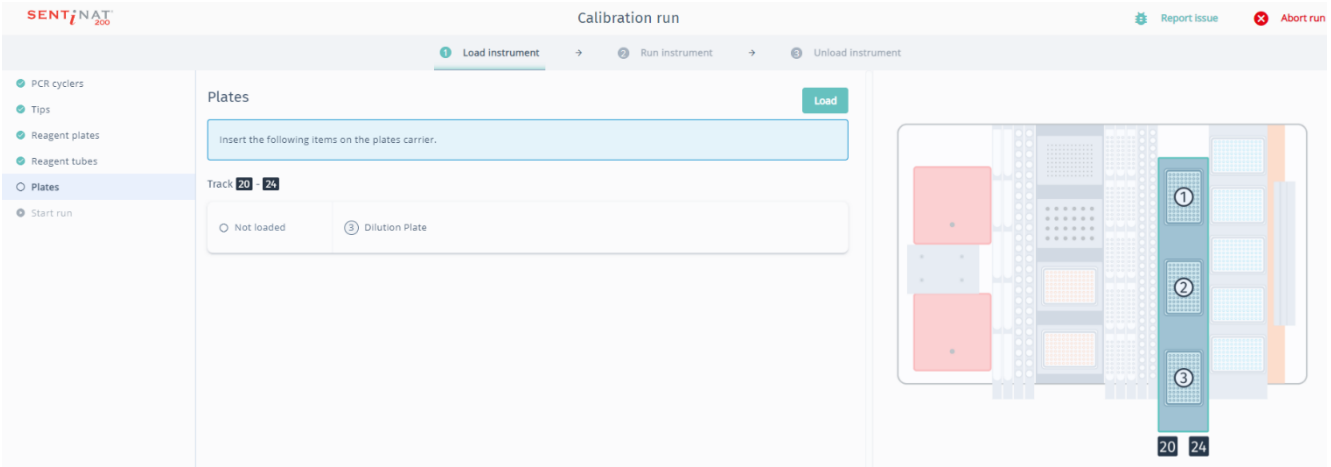
The software provides the list of the reagent tubes to load in tracks 18 and 19. The reagent tubes required are the Mastermix Reconstitution buffer, the Standard Reconstitution Buffer and the Calibrator stock solution.

NOTE: Use the same lot of reagent (Miniplates and Mastermix Reconstitution buffer).



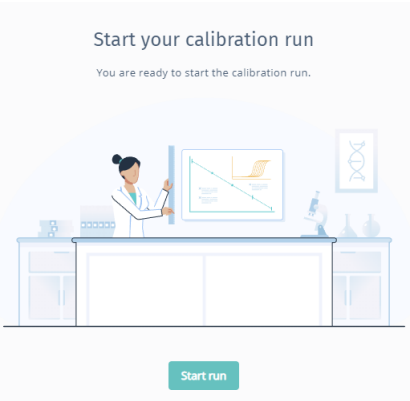
3.3.2.5 Plates:

Please load the Dilution Plate in position 3 of the track 20-24.



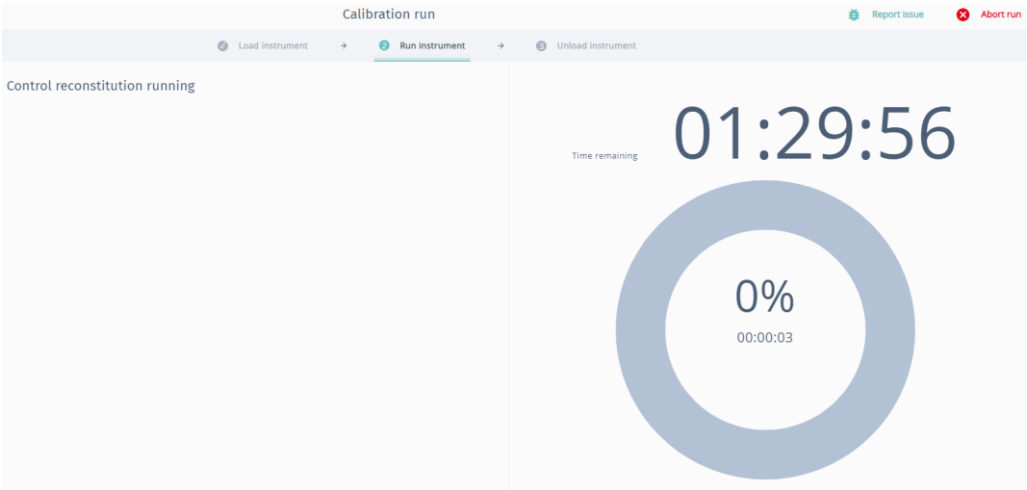
3.3.2.6 Start the run

The system is ready and the session can be started.



As soon as the run is started, a counting timer with will appear in the window.

Information regarding the ETA, procedure and completion percentage are reported.

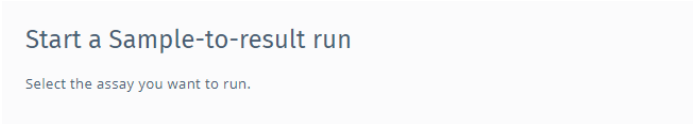


ATTENTION

An abort may cause the loss of data. Therefore methods once aborted cannot be resumed.

An aborted run (e.g. one stopped by pulling out an inserted carrier) cannot be restarted.

3.3.3 Performing a Sample-to-result run

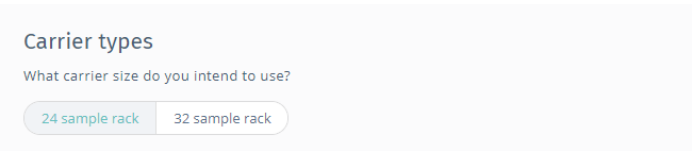


Select the Assay or Assays to be performed.

NOTE: In case of more Assays, only Assays requiring the same PCR protocol can be used in the same run.

According to the sample tube, select the Carrier types:

- 24 sample rack can be used for sample tube 17x100
- 32 sample rack can be used for sample tube 13x100



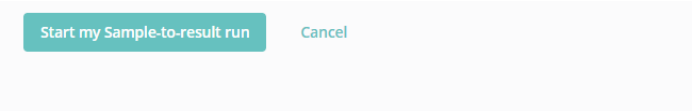
NOTE: 1 type of carrier can be selected at a time. Different types of sample tubes have to be loaded in separate runs.

Insert the number of samples.

NOTE: It is possible to upload a maximum of 48 samples per run.

NOTE: SENTiNAT® 200 requires at least 700 µl of sample volume. Samples with less volume cannot be processed by SENTiNAT® 200.

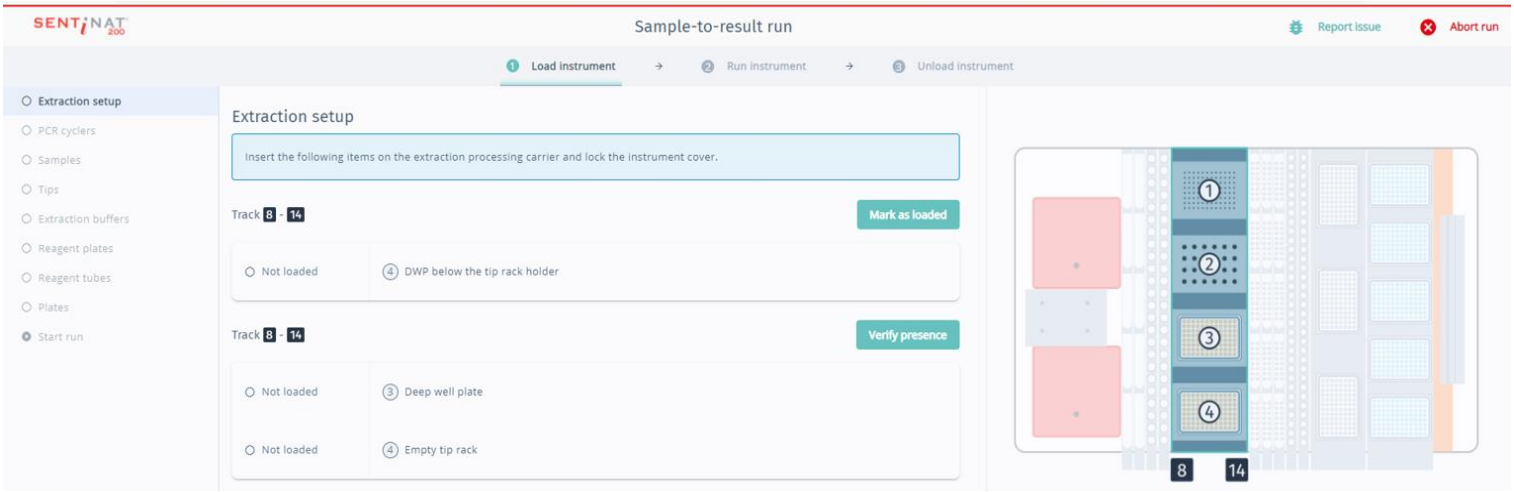
Press the “Start my Sample-to-result run” button to proceed. Samples can be loaded both in track 6 or 7.



The correct position is highlighted by LEDs on the instrument. Alternatively, all carriers can be placed directly in their correct positions on the Autoload Tray.

3.3.3.1 Extraction setup

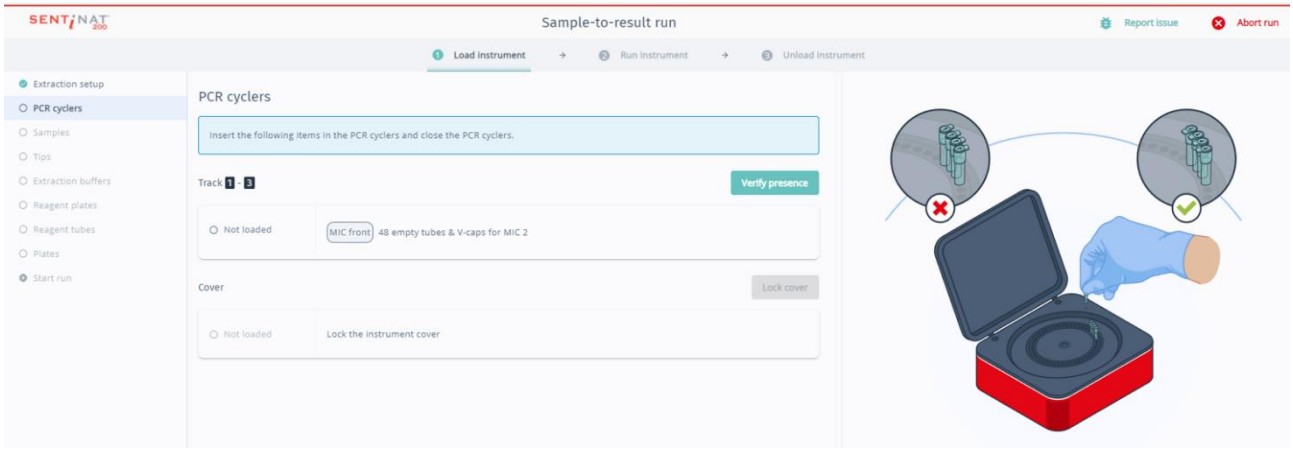
Follow the instruction setup and load a Deep Well Plate in position 3 and 4 and an empty tip rack in position 4. DWP in position 3 will be use for the DNA/RNA extraction, DWP in position 4 will be used to collect drops from tips parked during the washing with buffers. Confirm pressing corresponding bottom when done.



3.3.3.2 PCR cycler:

Load 48 empty tubes and V-cap first in the front MIC and eventually in the rear MIC; it is very important that the system is balanced, so please fill completely all the 48 position of the MIC with the tubes even if the number of samples is lower. Please insert the tubes in the correct side as shown in the picture.

Once the empty tubes are loaded, press the Verify Presence button and lock the cover.



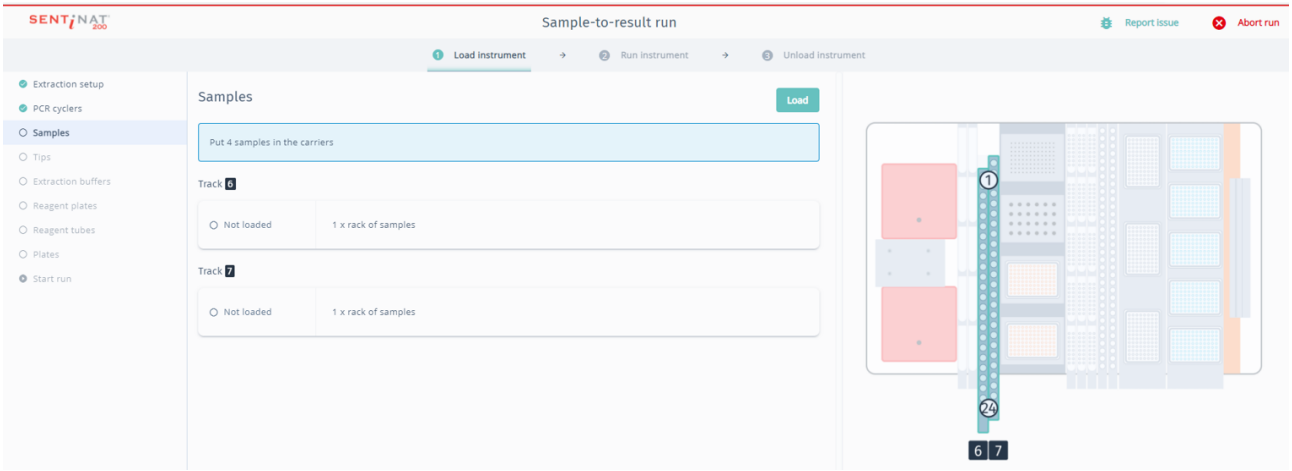
3.3.3.3 Sample:

The software provides information regarding the position of the rack. Specimens can be loaded in tracks 6 or 7.

One rack has to be assigned to the specific primary sample tube. Only one type of rack (32 or 24 tubes) can be loaded in a run.

NOTE: Whole blood samples have to be analyzed in a dedicated run. Do not load other sample type in a dedicated whole blood rack.

NOTE: Verify that the barcode on the tube can be read from the autoloader reader.



Insert the carriers into the tracks between the front and rear slide blocks of the Autoload Tray until they touch the stop hooks on the far side of the Autoload Tray.

Press the Load button, in order to load samples.

Slide Blocks and Stop Hooks for Carriers

ATTENTION

Make sure the carriers are inserted completely until they touch the stop hooks on the Autoload Tray.

Make sure there are no carriers loaded on the same tracks, as already loaded carriers on the deck (indicated by LEDs).

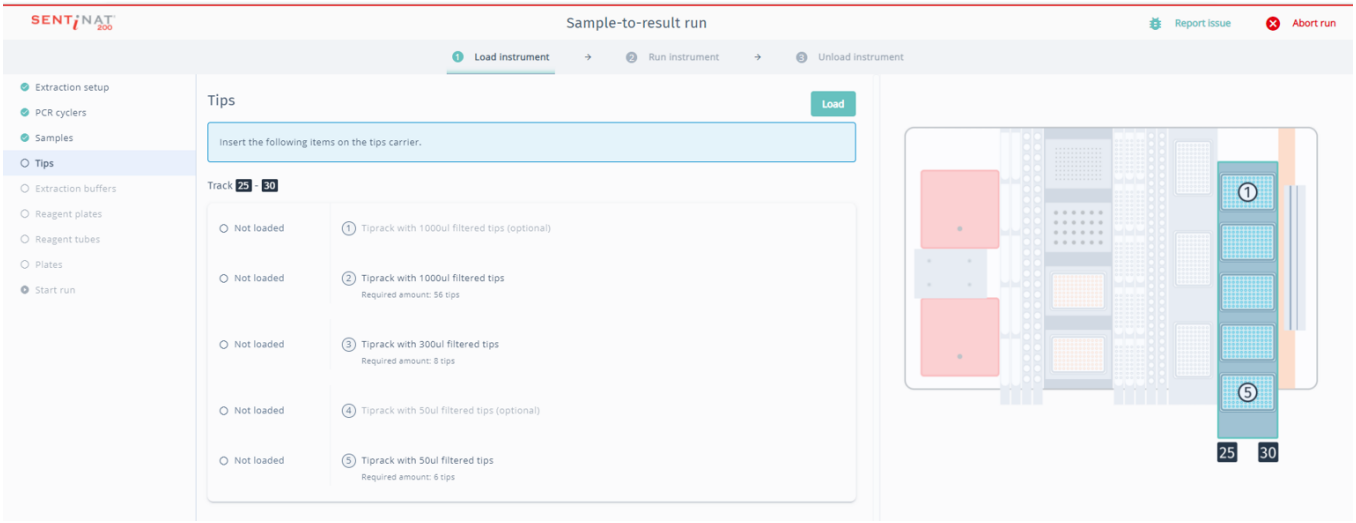
3.3.3.4 Tips:

Follow software instructions to correctly load the tip racks:

- Tip racks with 1000 µl tips can be loaded in position 1 and 2.
- Tip racks with 300 µl tips can be loaded in position 3.
- Tip racks with 50 µl tips can be loaded in position 4 and 5.

NOTE:

- The barcode of the racks must be on the right side.
- Depending upon the sample's number, some tip racks could be optional.

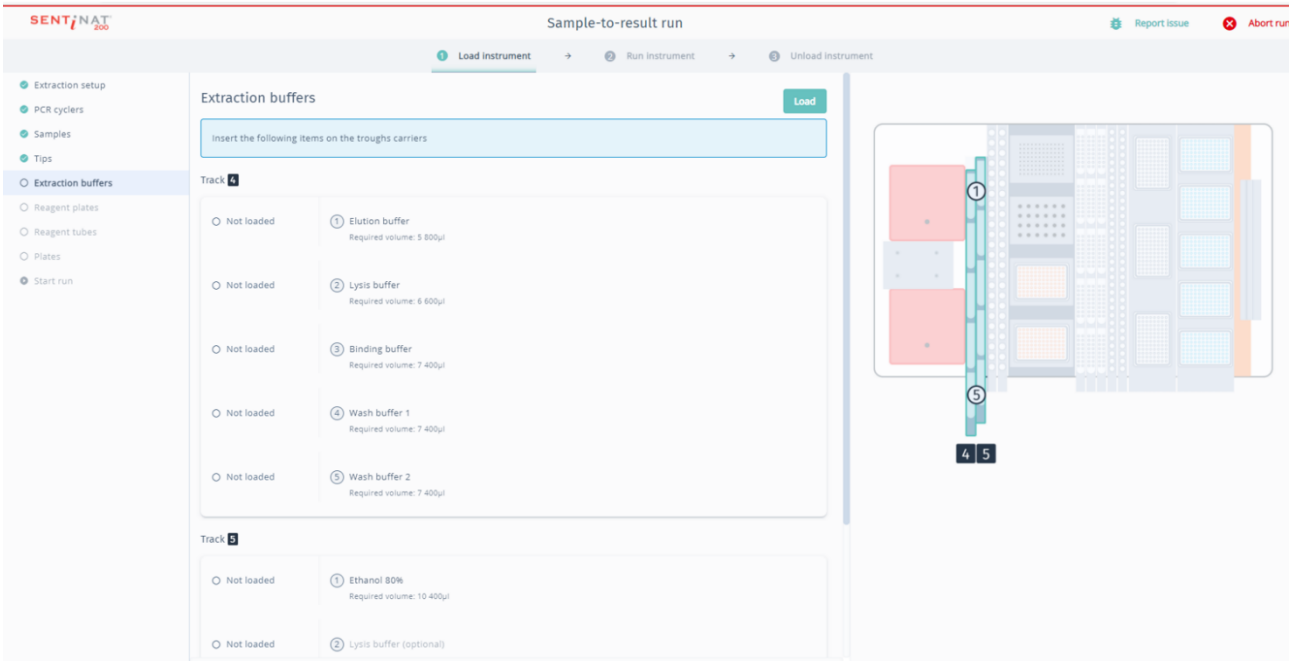


3.3.3.5 Extraction buffers:

Dedicated barcoded carriers with the extraction buffers are included in the extraction kit. Following the instruction reported on the software, load the carrier in the described position.

A complete set of extraction buffers can be loaded for up to 24 samples. In case more than 24 samples have to be extracted, a new set of trough buffers must be loaded in track 5 (Lysis buffer, Binding buffer, W1and W2).

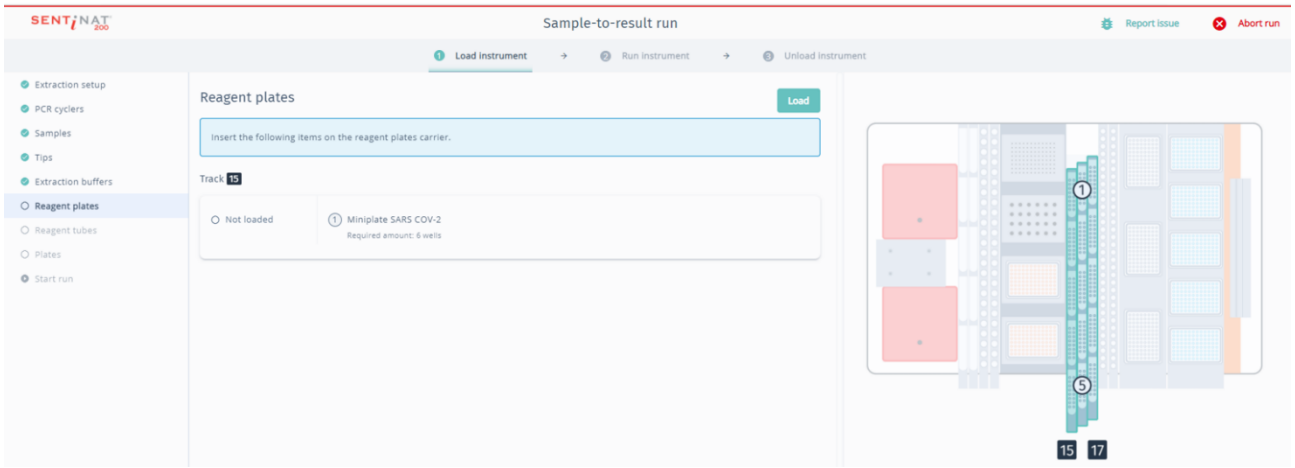
NOTE: Already used troughs for Lysis buffer, Binding buffer, Wash buffer 1 and 2 can only be loaded on the carrier at track 4.



3.3.3.6 Miniplates:

According to the number of samples and the programmed Assays, load the miniplates starting from position 1 of track 15, following the indication shown by the software.

Up to 15 miniplates can be placed from track 15 to track 17.



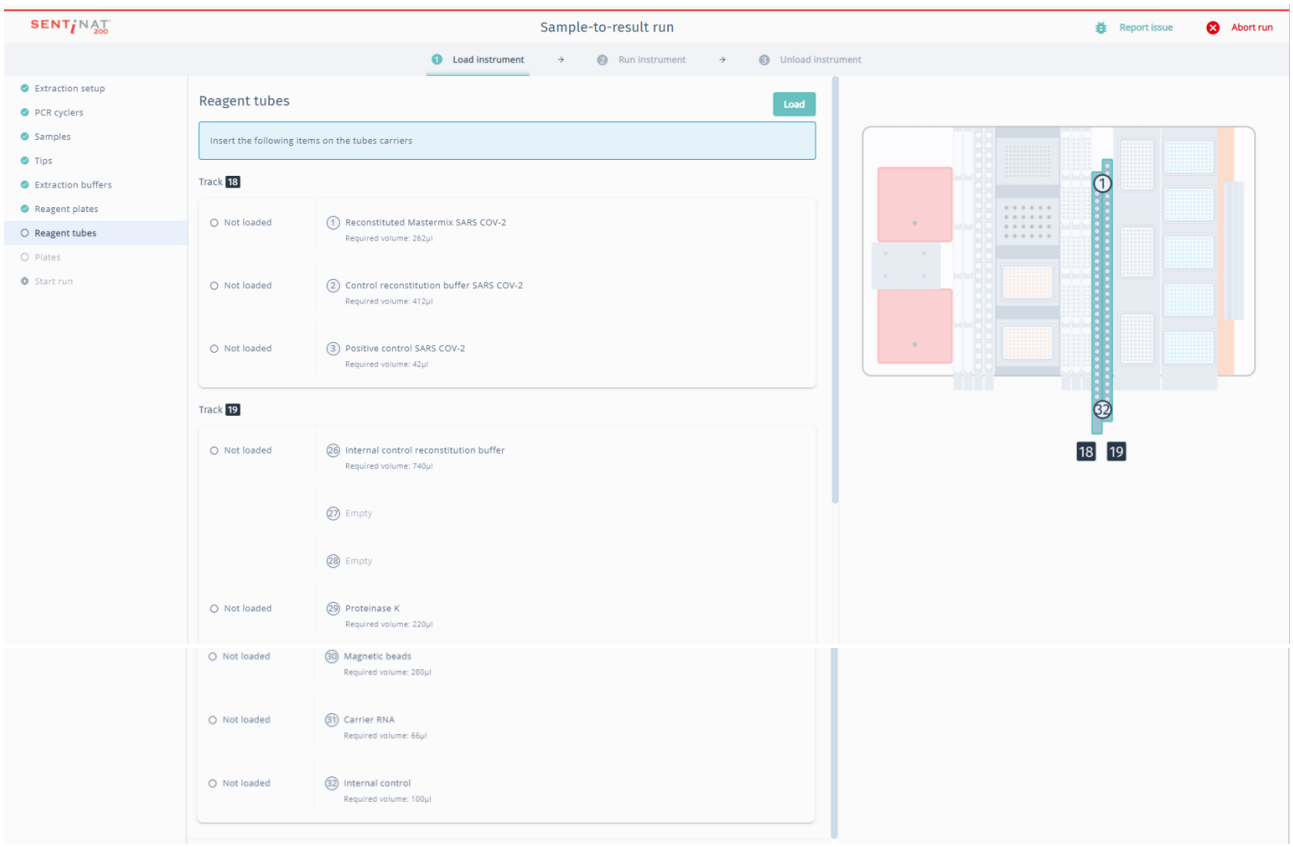
NOTE: Use only SENTINEL miniplates. Other consumables could not fit properly in the adaptor.

3.3.3.7 Reagent tubes:

The software provides the list of the reagent tubes to load in track 18 and 19. The reagent tubes required are the Master mix Resuspension buffer, the Control Reconsitution Buffer, Positive Control, Proteinase K, CarrierRNA, Beads, and Interna control.

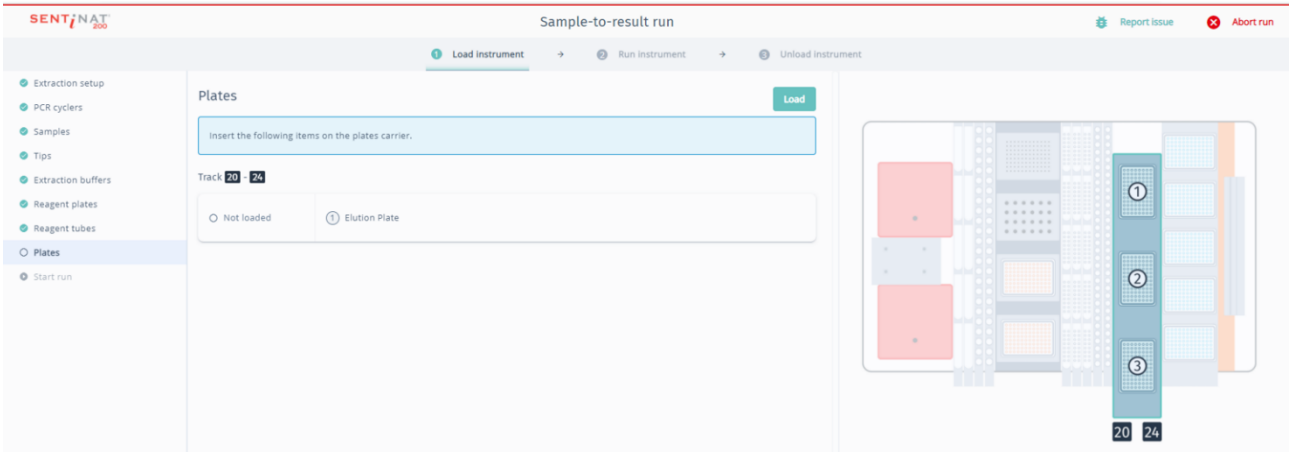
According to the programmed Assays, more than one Positive Control can be required.

NOTE: Use the same lot of reagent buffer.



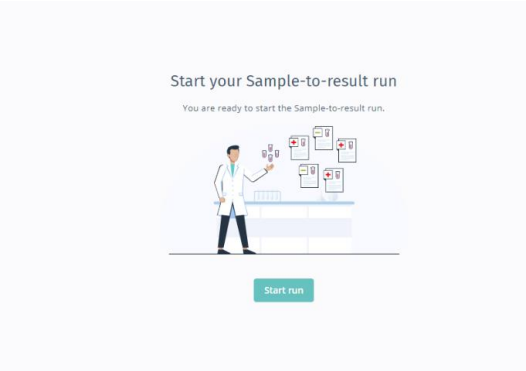
3.3.3.8 Plates:

Please load the Elution Plate in position 1 of the track 20-24.



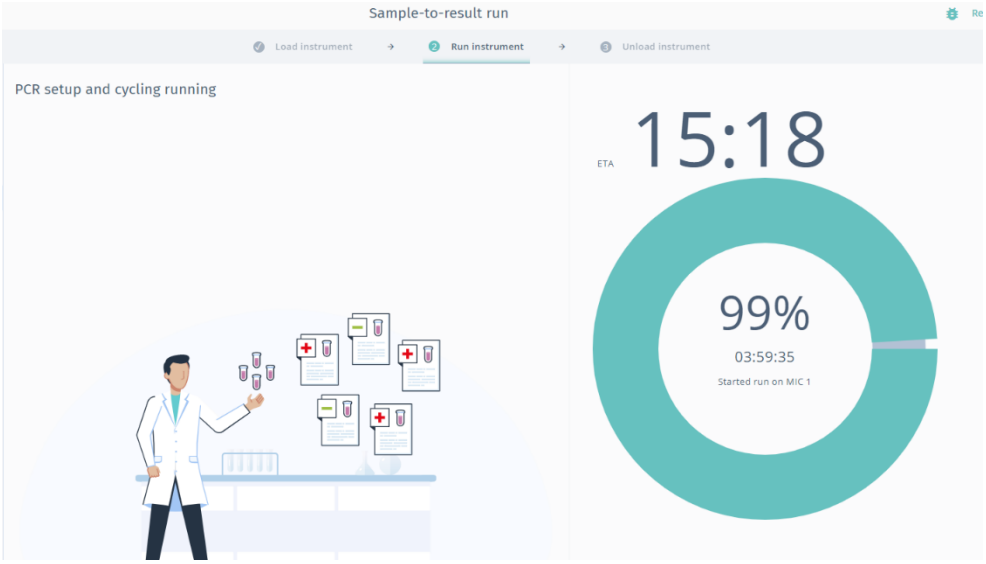
3.3.3.9 Start the run

The system is ready and the session can be started.



As soon as the run is started, a counting timer with will appear in the window.

Information regarding the ETA, procedure and completion percentage are reported.



ATTENTION

An abort may cause the loss of data. Therefore methods once aborted cannot be resumed.

An aborted run (e.g. one stopped by pulling out an inserted carrier) cannot be restarted.

4 Maintenance

Periodic maintenance routines are mandatory, guided by the SENTiNAT® 200 Software, need to be run in order to ensure the safe and reliable operation of your SENTiNAT® 200 and the accessories.

This section provides instructions on all extended maintenance work to be performed, in order to keep SENTiNAT® 200 instruments in perfect working condition or to restore them to a state in which they maintain the specified performance.

4.1 Maintenance Intervals

In order to maintain the SENTiNAT® 200 in good condition, the following maintenance intervals are foreseen:

- **Daily**: Before SENTiNAT® 200 start-up or shut-down. A Daily Maintenance is valid for 24 hours.
- **Weekly**: At the end of the week before the SENTiNAT® 200 is shut-down. A Weekly Maintenance is valid for 7 days.
- **Six-monthly**: Preventive maintenance service carried out by a trained Field Service Engineer.

  This is based on a maximum usage of 8 h per day and 5 days per week. Higher numbers of hours per week will make shorter maintenance intervals necessary.

NOTE

If the operator decides not to run either daily or weekly maintenance before shut-down, these routines must be executed at the next run start.

If any parts of the instrument, carriers, or racks have become contaminated, the weekly maintenance procedure must be performed.

The expiration date of the daily or weekly maintenance is not calculated from the date and time of the execution of the maintenance in question, but from the date and time of the start of the first method after having completed the maintenance. Immediately after completion of maintenance, the expiration date is not yet defined.

4.2 Materials Required

- Disposable latex gloves
- Protective glasses
- Lab coat

4.2.1 Cleaning Agents

According to the degree of contamination, the following cleaning agents are suitable for cleaning the parts of the SENTiNAT® 200. It is recommended to clean only the described part.

Suitable Cleaning Agents	Concentration	Risk to instrument	Other comments
Water	Distilled or de-ionized water	-	-
Alcohol	70% ethanol 70% 2-Propanol (isopropanol).	Dissolve plastics, stress crack on transparent plastics	-
Detergents	Mild detergent Special detergents	Check before with vendor of the agents	-
Tissue	-	-	Use lint-free tissues only

ATTENTION

Strong detergents may dissolve carrier and worktable surface coatings. Use only cleaning agents that are suitable for Laboratory instruments.

The vendor of this disinfectant and cleaning agent can provide more information.

Do not clean electronics, as this can damage the instrument. Pay very close attention to the exposure times listed by the cleaning agent manufacturer.

Failure to follow manufacturers' recommendations can lead to incomplete cleaning and disinfection.

In some cases, other decontamination procedures may be desirable (e.g. for reliably destroying infectious materials or DNA/RNA).

Many of these decontamination procedures are very aggressive and can cause damage to the SENTiNAT® 200. Please follow the guidelines provided below. If using other decontamination procedures not listed here, be aware that they may increase service and maintenance requirements and may make shorter maintenance intervals necessary.

ATTENTION

Use cleaning, disinfecting and decontaminating fluid in accordance with the manufacturer's instructions. Do not use materials which contain hypochlorite (e.g. Javel water, Chlorox), or bleaching fluids.

Prepare disinfectant fluids according to their labeling.

4.3 Cleaning Parts of the Instrument

Instrument Part	Cleaning Agent
Stop-disk and Tip Eject Sleeve on the Pipetting Head	Water, alcohol, mild detergent
Waste Station	Water, alcohol, mild detergent
Deck	Alcohol, mild detergent
Housing	Alcohol
Metal parts	Alcohol
Carriers	Alcohol, mild detergent
Racks	Alcohol, mild detergent
Needles	Alcohol
Autoload or other Scanner	Alcohol

ATTENTION

Cleaning procedures others than described are not recommended (e.g. washing of carriers in washing machines, autoclaving of instrument components, etc.).

4.4 Surface Decontamination using Liquids

If using other liquids or sprays for surface decontamination, follow the manufacturer's instructions. Pay particular attention to potential corrosiveness (e.g. acidic or alkaline solutions and oxidizing agents). Use of such agents may increase service and maintenance requirements (O-rings exchange, greasing of spindles, etc.) and may make shorter maintenance intervals necessary. Do not use disinfecting materials which contain hypochlorite (e.g. Javel water, Chlorox) or bleaching fluids. If possible, use non corrosive, neutral liquids.

4.5 Decontamination using Gases

Should decontamination by fumigation be necessary, SENTINEL recommends using ethylene oxide. Be aware that ethylene oxide fumigation may increase service and maintenance requirements (O-rings exchange, greasing of spindles, etc.) and may make shorter maintenance intervals necessary. SENTINEL does not carry out such fumigation procedures, so please use a third-party contractor for such service.

Fumigation using hydrogen peroxide (H_2O_2) is not recommended as it leads to bleaching or discoloration of many instrument materials. Be aware that hydrogen peroxide fumigation may increase service and maintenance requirements (O-rings exchange, greasing of spindles, etc.) and

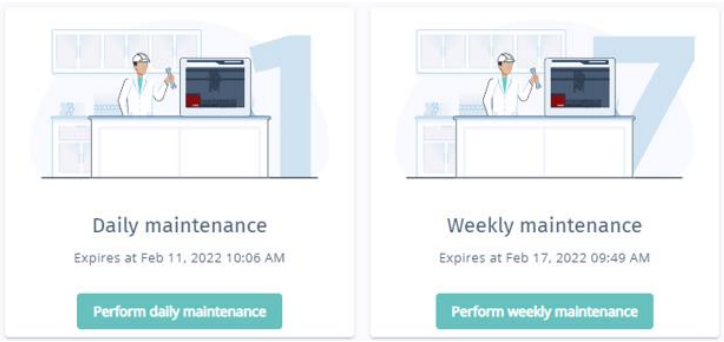
may make shorter maintenance intervals necessary. SENTINEL does not carry out such fumigation procedures, so please use a third-party contractor for such service.

Do not use formaldehyde fumigation or chlorine oxides (chemical compounds of chlorine and oxygen such as bleach). They are not suitable for the SENTiNAT® 200 because of chemical reaction and corrosion (for chemical compatibility, see Section 8.3 Appendix C: Chemical Compatibility).

4.6 Maintenance Procedures

The operator will be guided by the SENTiNAT® 200 Software through the maintenance procedures.

Daily maintenance and weekly maintenance must be performed before starting a new run. A reminder is shown in case the maintenance has expired. Press the button in order to perform a daily or weekly maintenance and follow the instructions.



ATTENTION

Always wear disposable gloves during maintenance.

Do not clean the instrument in the vicinity of open flames or devices which could create sparks. Do not use hot air blowers to dry the instrument. The liquids used for cleaning are flammable.

This manual provides indications regarding general disposal of waste. In addition, any regulations specific to the country of operation must be taken into account and observed.

Routine Completion

A maintenance routine is completed once the procedure has been fully executed and the results are within the specifications.

Aborting Maintenance Procedures

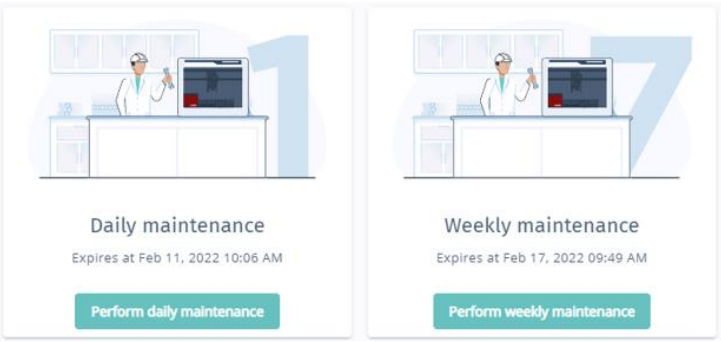
Aborting a maintenance procedure will lead to a ‘failed’ status, and maintenance will need to be started again.

4.6.1 Daily Maintenance

The following tasks belong to the daily maintenance:

- Checking if the deck is clean
- Emptying the tip waste
- Checking the tightness of the pipetting channel
- Verifying the cLLD function

To execute the Daily Maintenance procedure, click on the the "**Perform daily maintenance**" Icon in the software.

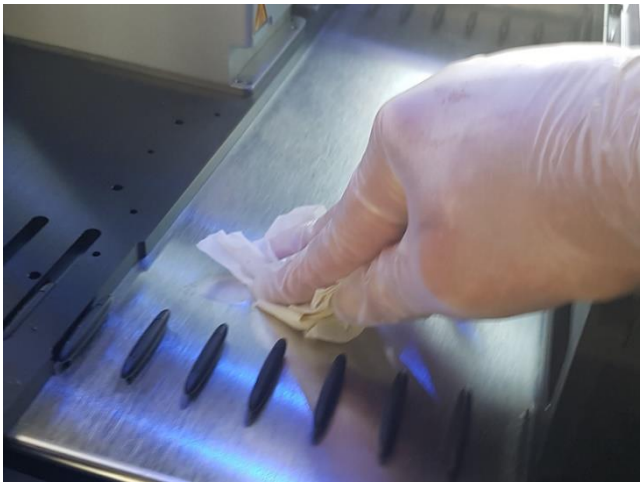


The front cover (i.e. the hinged Plexiglas window that shields the instrument in front) can be opened for user intervention.

4.6.1.1 Desk cleaning check

Once the maintenance procedure has started, the X-Arm moves to the left side. The operator now has access to the deck to check whether cleaning is needed.

- If the deck is clean, continue with the daily maintenance.
- If the deck needs to be cleaned, the daily maintenance can be interrupted. Instead of the daily maintenance, carry out the weekly maintenance.

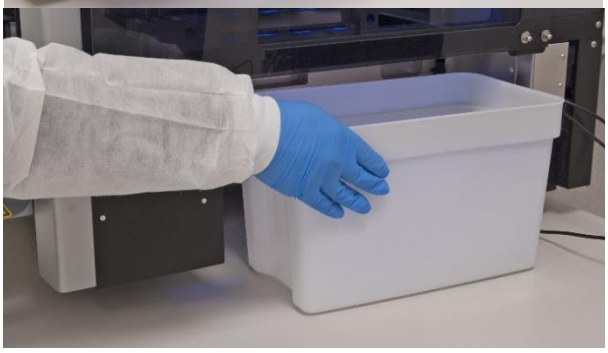


Continuing the daily maintenance procedure will lead the user to the next maintenance task. The tip waste container needs to be emptied. Dispose of the contents with the rest of the laboratory's contaminated waste.

4.6.1.2 Tip Waste Container

The Tip Waste Container collects used tips for disposal. To empty the container the following step has to be performed:

- Open flap with one hand
- Take container out
- Flap will close as soon as it is held by the operator
- Empty container
- Open flap with one hand
- Put container inside
- Flap will close as soon as it is held by the operator
- The Tip Waste Container must be managed as biohazardous



ATTENTION

The Tip Waste Container and its contents must be considered as biohazardous.

Emptying the waste container during a run may lead to contamination through used tips dispatched from the instrument.

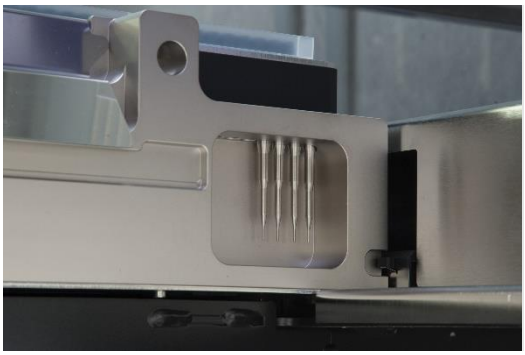
Only use the tip waste container provided with the instrument which has the SENTiNAT® 200 WASTE FLAP. Other types of waste containers require a risk assessment. By the laboratory and the protection provided by the Instrument may be impaired.

Implementing any mechanisms that hold the waste flap open or partially open is a violation of the protection provided; Sentinel CH SpA rejects any responsibility.

SENTiNAT® 200 is equipped with a WASTE FLAP. The Waste Frame with the Tip Waste Bag / Tip Waste Chute is out of the instrument configuration, is not compliant and must not be used
If used, it poses a hazard to the user, and the protection provided by the equipment will be impaired.

4.6.1.3 Pipetting channels check

For the next steps, the maintenance needles are required.

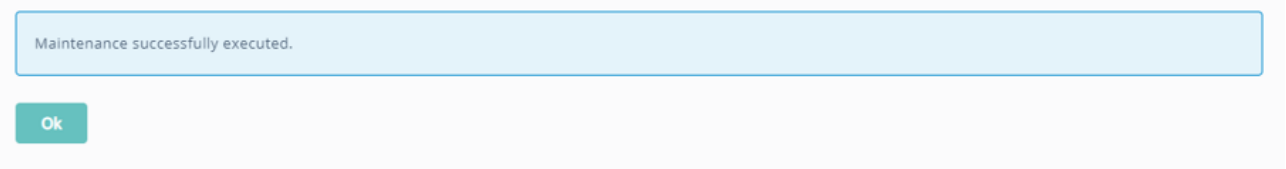


Maintenance Needles 1000 µl Pipett

The procedure continues with the tightness check of the pipetting channels. The X-Arm will travel to the right side to pick up the maintenance needles. Two checks are performed with the pipetting channels; the over-pressure and under-pressure check.

For the capacitive liquid level detection (cLLD) check, the needles are picked up again. One pipetting channel after the other is checked for proper cLLD function.

The end of the daily maintenance is displayed.



The daily maintenance process status is saved on the instrument

NOTE

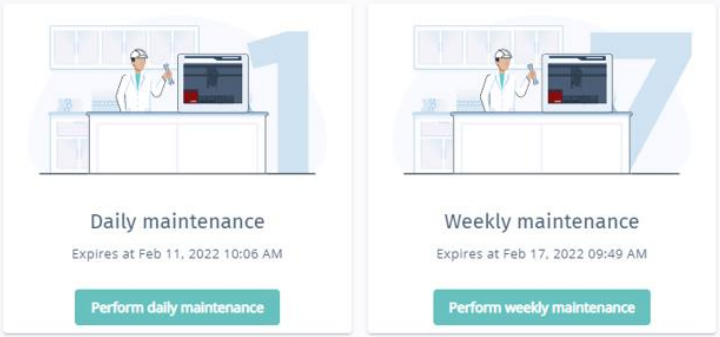
If any parts of the instrument (e.g. carriers or racks) have become contaminated, the weekly maintenance procedure must be performed.

4.6.2 Weekly Maintenance

The following tasks are carried out with the weekly maintenance:

- Operation performed by the technician before the automated weekly maintenance
  - Cleaning the deck and carriers
  - Checking the condition of the carriers
- Emptying and cleaning of the tip waste
- Checking the tightness of the pipetting channel
- Verifying the cLLD function
- Operation performed by the technician after the automated weekly maintenance:
  - Cleaning of the pipetting head: stop disk, O-ring, tip eject sleeve
  - Cleaning of the covers, Autoload protecting ribbon

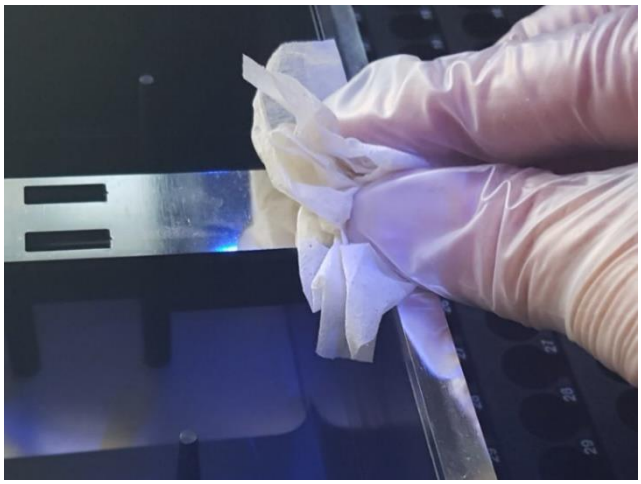
To execute the Weekly Maintenance procedure, click on the the "**Perform weekly maintenance**" Icon in the software.



Clean all carriers and all modules with an appropriate cleaning agent as described in Section 4.3 Cleaning Parts of the Instrument and leave them to dry. If they are heavily soiled, these carriers may be immersed in the cleaning agent (see Section 4.2.1 Cleaning Agents).

4.6.2.1 Carriers check

Examine each carrier for scratches on the barcode and any signs of damage. If damage is apparent, replace with new carriers.



NOTE

Carriers must be completely clean and dry before re-using.

Continuing the weekly maintenance program will advise the Autoload to move to the right-hand side of the instrument.

4.6.2.2 Deck cleaning

Open the front cover and wipe the deck with a cloth saturated with an appropriate cleaning agent, as described in Section 4.3 Cleaning Parts of the Instrument. The slide blocks in particular must be checked for cleanliness. Close the front cover.

ATTENTION

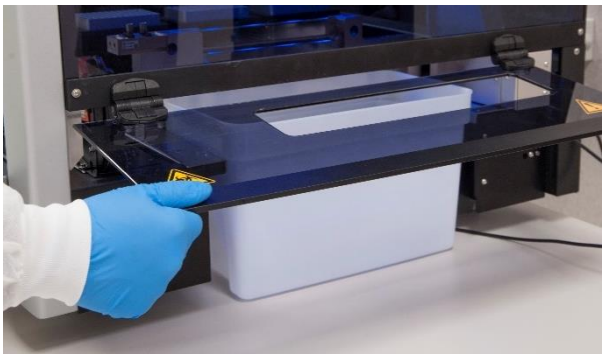
Do not spray directly at the Autoload unit or at electrical boards or connectors.

1. The next step of the maintenance procedure will advise the Autoload (if configured) to move to the left-hand side of the instrument. The tip waste needs to be emptied and cleaned. Dispose of tip waste with the rest of the laboratory's contaminated waste. Remove container and discard the plastic in the laboratory's contaminated waste.

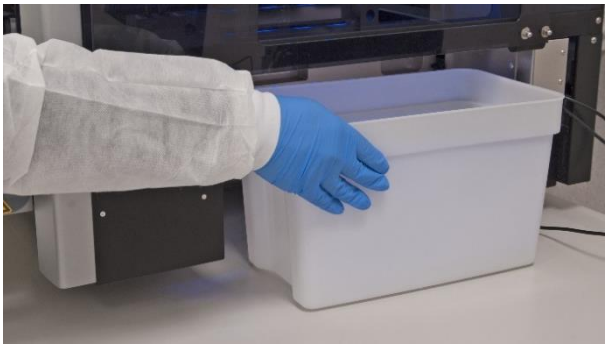
4.6.2.3 Tip Waste Container

The Tip Waste Container collects used tips for disposal. To empty the container, the following step has to be performed:

- Open flap with one hand
- Take container out
- Flap will close as soon as it is held by the operator
- Empty container
- Open flap with one hand
- Put container inside



- Flap will close as soon as it is held by the operator
- The Tip Waste Container has to be managed as biohazardous

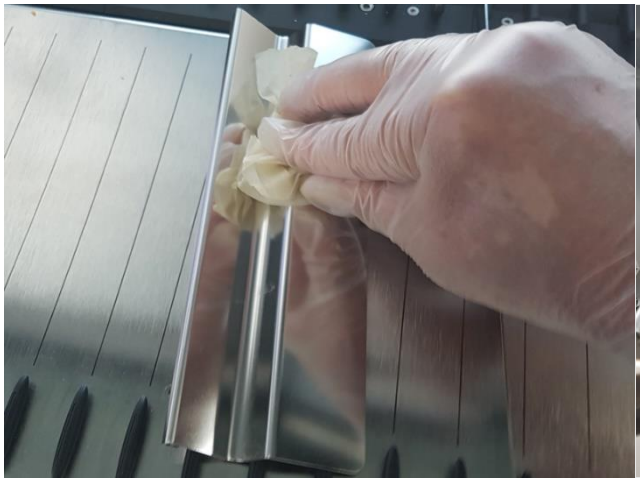


The Tip Waste is always to be regarded as contaminated.

4.6.2.4 Tip eject plate cleaning

Remove the tip eject plate of the waste station and clean it with an appropriate cleaning agent, as described in Section 4.3 Cleaning Parts of the Instrument.

Put the clean tip eject plate back in place.



ATTENTION

The tip eject plate is always to be regarded as contaminated.

4.6.2.5 Maintenance needles cleaning

Clean the maintenance needles.

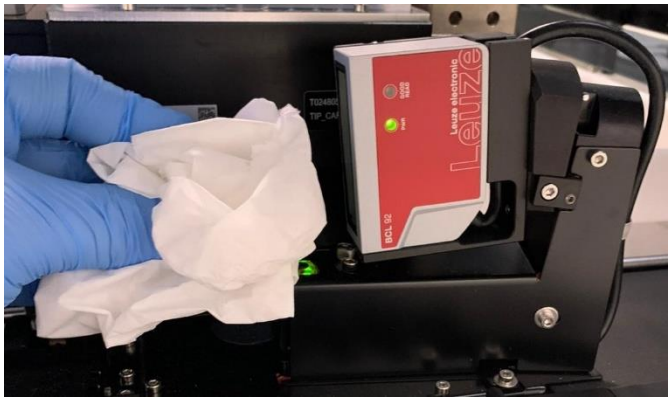
1000 µl Maintenance Needles

ATTENTION

Do not wet the maintenance needles inside.

4.6.2.6 Barcode reader check and cleaning

To prevent unreliable barcode reading, check the laser scanner window of the barcode reader and clean it with a lint-free cloth or Q-tips lightly, using ethanol (70%).



ATTENTION

The laser scanner window must be completely dry and free from dust and fibers before the instrument can be reused.

4.6.2.7 Autoload ribbon cleaning

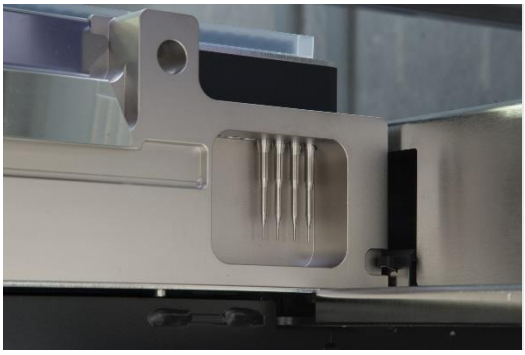
Clean the Autoload protecting ribbon with a lint-free cloth and the appropriate cleaning agent and wipe without exerting pressure (see Section 4.3 Cleaning Parts of the Instrument).

ATTENTION

Do not spray directly at the Autoload unit or at electrical boards or connectors.

4.6.2.8 Pipetting channels check and cleaning

For the next steps, the maintenance needles are required.

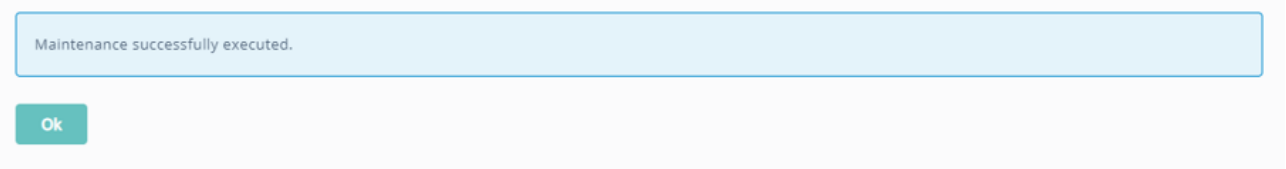


Maintenance Needles 1000 µl Pipett

The procedure continues with the tightness check of the pipetting channels. The X-Arm will travel to the right side to pick up the maintenance needles. Two checks are performed with the pipetting channels; the over-pressure and under-pressure check.

For the capacitive liquid level detection (cLLD) check, the needles are picked up again. One pipetting channel after the other is checked for proper cLLD function.

The end of the daily maintenance is displayed.

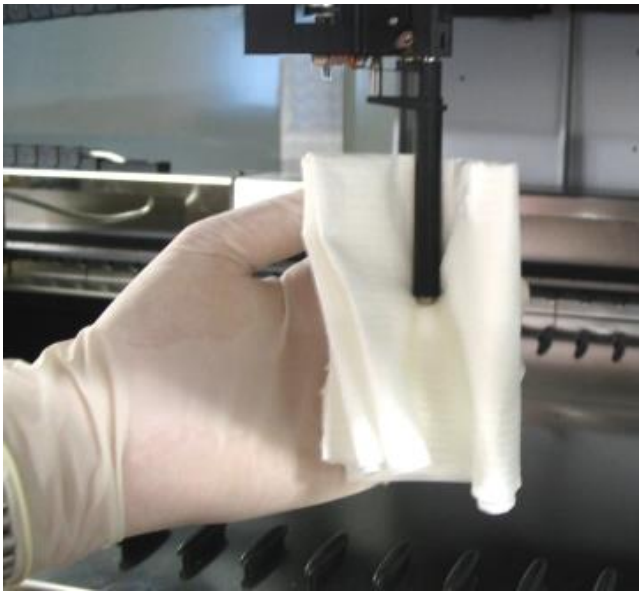


The weekly maintenance process status is saved on the instrument

NOTE

If any parts of the instrument, carriers or racks have become contaminated, the weekly maintenance procedure must be performed.

Clean the tip eject sleeve (outer part of the pipetting heads) with a lint-free cloth and the appropriate cleaning agent (see Section 4.3 Cleaning Parts of the Instrument).

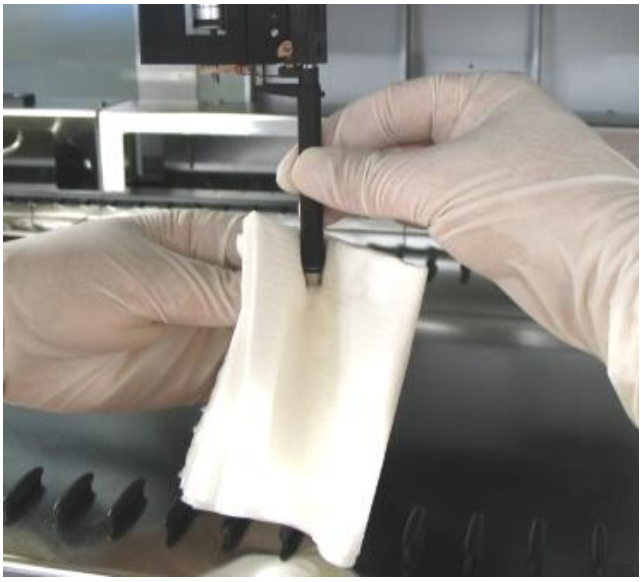


ATTENTION

Take care that no liquid gets inside the pipetting channel.

Whenever it is necessary to move the pipetting channels on the X-Arm, move them gently by pushing close to their Y-slide. Never force them, as this may lead to damage. If possible, switch on the instrument, as this will result in a smoother motion when the pipetting channels have to be moved on the X-Arm.

Clean the stop disk and the O-rings (outer part of the pipetting heads) with a lint-free cloth and the appropriate cleaning agent (see Section 4.3 Cleaning Parts of the Instrument).



ATTENTION

Take care that no liquid gets inside the pipetting channel.

Whenever it is necessary to move the pipetting channels on the X-Arm, move them gently by pushing close to their Y-slide. Never force them, as this may lead to damage. If possible,

switch on the instrument as this will result in a smoother motion when the pipetting channels have to be moved on the X-Arm.

4.6.2.9 Cover cleaning

Clean the front and side covers with a lint-free cloth and the appropriate cleaning agent and wipe dry (see Section 4.3 Cleaning Parts of the Instrument).

Clean the X-guide shaft behind the upper-front cover with a dry cloth at least once a month.

4.7 If Maintenance Fails

If an error is encountered during a maintenance procedure, try to resolve the problem and restart the maintenance procedure. If you cannot resolve the error yourself, contact your local SENTINEL representative.

5 Verification

The SENTiNAT® 200 must be verified by a HAMILTON trained Field Service Engineer upon initial set-up, and thereafter at regular intervals. If any verification procedures are due and have not been successfully completed, it is not possible to start a run or method.

6 SENTiNAT® 200 Decontamination

The following is the recommended procedure for decontaminating the SENTiNAT® 200:

- Clean the front and side cover with an appropriate cleaning agent (see Section 4.2.1 Cleaning Agents).
- Open the front cover and wipe the deck with a cloth saturated with an appropriate cleaning agent (see Section 4.2.1 Cleaning Agents). The slide blocks in particular must be checked for cleanliness.
- Remove the tip eject plate of the tip waste station and clean it by using an appropriate cleaning agent (see Section 4.2.1 Cleaning Agents).
- Clean the tip waste station by using an appropriate cleaning agent (see Section 4.2.1 Cleaning Agents).
- Remove the frame that holds the waste plastic bag in place and discard the plastic bag in the laboratory's contaminated waste. Place the tip eject plate back in place.
- Clean the tip eject sleeve (outer part of the pipetting channels) with a lint-free cloth and the appropriate cleaning agent (see Section 4.2.1 Cleaning Agents).
- Clean all carriers with an appropriate cleaning agent (see Section 4.2.1 Cleaning Agents). and let them dry. If they are heavily soiled, these carriers can be immersed into the cleaning agent (see Section 4.2.1 Cleaning Agents).

7 Technical Specifications

7.1 SENTiNAT® 200

7.1.1 Dimensions and Weights

Dimensions

SENTiNAT® 200	Width:	1124 mm
	Height:	903 mm
	Depth:	795 mm (without loading deck, i.e. transport size) 1010 mm (with loading deck) 1200 mm (with loading deck and carriers on loading deck)
	Work Area Dimensions:	width: 675 mm (30 tracks) , depth: 465 mm, height: 136 mm

Weights

SENTiNAT® 200	Approximately 150 kg

7.1.2 Operating- and Environmental Conditions

Maximum Power Consumption	≤ 600 VA
Voltage	115 VAC / 230 VAC ± 10 %
Frequency	50/60 Hz
Delayed Action Fuse	115 VAC: 6.3 A (T6.3AL250) 230 VAC: 3.15 A (T3.15A250)
Installation Category	Installation Category II (Overvoltage category)
Pollution Degree	2
Temperature Range	15 °C – 30 °C, Indoor Use Only
Relative Humidity	15 % – 85 %, no condensation
Noise Level	< 65 dBA (according DIN EN ISO 7779) Acoustics - Measurement of Airborne Noise Emitted by Information Technology and Telecommunications Equipment
Altitude	Up to 2000 meters above sea level

7.1.3 Transportation and Storage

Temperature Range	-25 °C – +70 °C, Indoor Storage Only
Relative Humidity	10 % – 90 %, no condensation, indoors

7.1.4 Computer Requirements (Computer included in shipment)

Recommended Minimum System Requirements	≥ 4GB RAM, ≥ 250GB HD, ≥ 16x DVD DirectX 9 Graphics device Windows 10 Professional or Enterprise, 32-Bit or 64-Bit
Communication	≥ 5 USB ports, ≥ 2 RS232 ports

7.2 Autoload: Barcodes and Reader Specifications

Carriers, containers, racks and tip racks will be identified by a barcode, which a reader, mounted on the Autoload slide, scans. The system allows for the specification of ranges (barcode mask) for plausibility checking of barcode information.

7.2.1 Barcode Symbologies

SENTINEL recommends use of the following 3 types of barcode symbologies:

- Code 128 (subset B and C)
- Code 39
- Codabar

For the highest reading safety, SENTINEL recommends the use of barcode type Code128 (subset B and C).

NOTE

Enable only barcode types which will be used on the system. Disabling the unused barcode types will improve the reliability of the readings.

7.2.2 Reading Accuracy

The rate of inaccurate readings of sample plates and container barcodes is less than 1 ppm.

The above-mentioned specification is valid under the following conditions:

- Barcode Symbology Module: ISBT Standard
- Code Density: 0.0065” (0.1651 mm)
- Print Quality: as defined in Section 7.2.4 Barcode Specifications
- Recognized errors are defined as an accurate reading

7.2.3 Barcode Scanner Specifications

Based on the Barcode Scanner supplied on the instrument:

Type:	Class II Laser Diode
Wavelength:	655 nm
Pulse Duration:	120 µs
Maximum Output (peak):	1.7 mW
Nominal Ocular Hazard Distance (NOHD):	≤ 0 mm
Applied Standard:	IEC/EN 60825-1:2007
Remarks:	The barcode scanner fulfills the requirements of IEC/EN 60825-1:2014 Laser Class I, but the label refers to IEC/EN 60825-1:2007 only. A statement is available upon request.

Type:	Class I Laser Diode
Wavelength:	655 nm
Pulse Duration:	continuously
Applied Standard:	IEC/EN 60825-1:2014

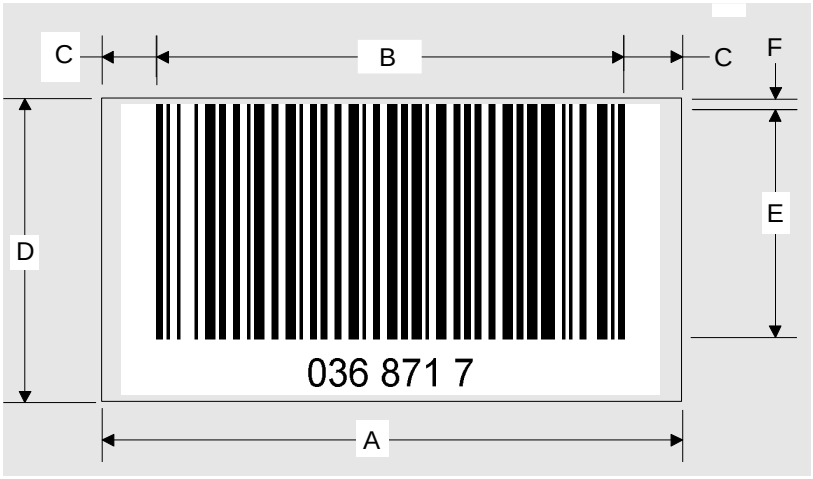
7.2.4 Barcode Specifications

Specification	Description	
Length of String	Maximum 20 characters excluding start, stop and check characters, depending on the code length (see label dimensions).	
Code Density, Tolerance	Minimum module width (X dimension) including a print tolerance: ≥ 0.0065" (0.1651 mm) Maximum module width (X dimension) including a print tolerance: ≤ 0.02" (0.508 mm) Best reading performance with X dimension between 0.0075” (0.1905 mm) and 0.01" (0.254 mm)	
Check Character	Code 128	One character
	Code 39	None, optional check character to be checked within programming
	Codabar	None, optional check character to be checked within programming
Quiet Zone	≥ 10 times the X dimension, but at least 3 mm.	
Print quality	The barcode print must be of a high quality. A printed barcode with an ISO/EC 15416 Grade 4 (A) or 3 (B) is required. Offset, typographic, intaglio and flexographic printing are suitable. Mechanical dot matrix and thermo matrix printing are not suitable. The surface may be treated, sealed or plastic-coated.	

7.2.5 Sample Barcodes

Barcode Specifications

For general barcode specifications, see Section 7.2.4 Barcode Specifications.

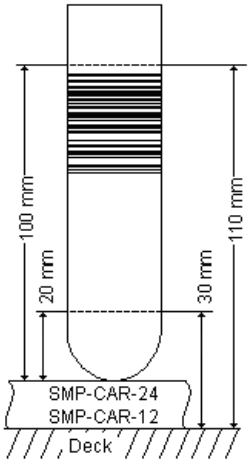


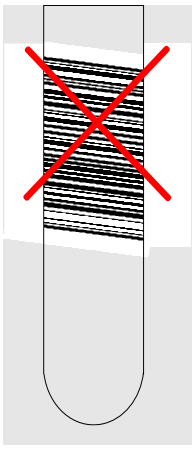
Dimension		Min.	Max.
A	Label Length	–	80 mm
B	Code Length	–	74 mm
C	Quiet Zone	3 mm	–
D	Label Width	12 mm	–
E	Code Width	12 mm	–
F	Distance from Code to Label Edge	–	1 mm

Positioning Barcode Labels

The label must be attached within a range of between 20 mm to 100 mm from the bottom of the sample tube.

The label must fit tightly at an angle of approximately 90° to the sample tube.





The label must fit tightly over its entire length.

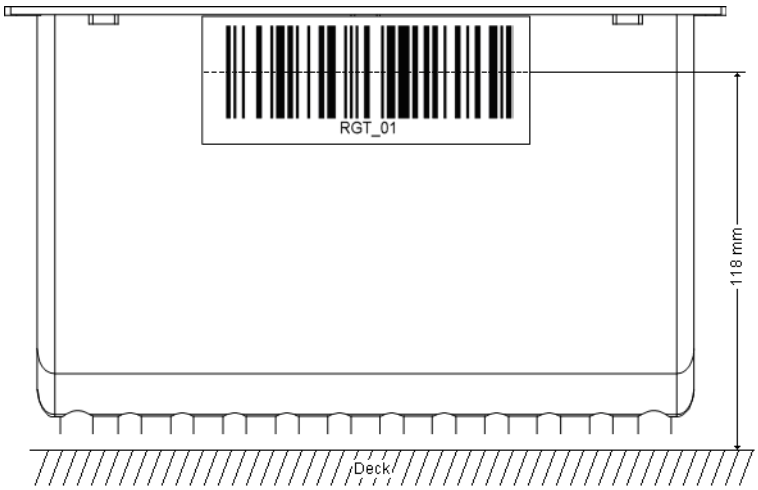
7.2.6 Reagent Barcodes

Label Specification

For general barcode specifications, see Section 7.2.4 Barcode Specifications.

Dimension		Min.	Max.
A	Label Length	–	66 mm
B	Code Length	–	60 mm
C	Quiet Zone	3 mm	–
D	Label Width	15 mm	–
E	Code Width	12 mm	–
F	Distance from Code to Label Edge	–	1 mm

Positioning Barcode Labels:



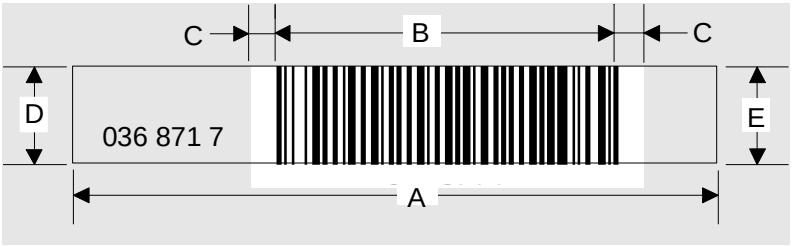
The label must be positioned on the upper edge, in the middle of the container.

The label must fit tightly over its entire length.

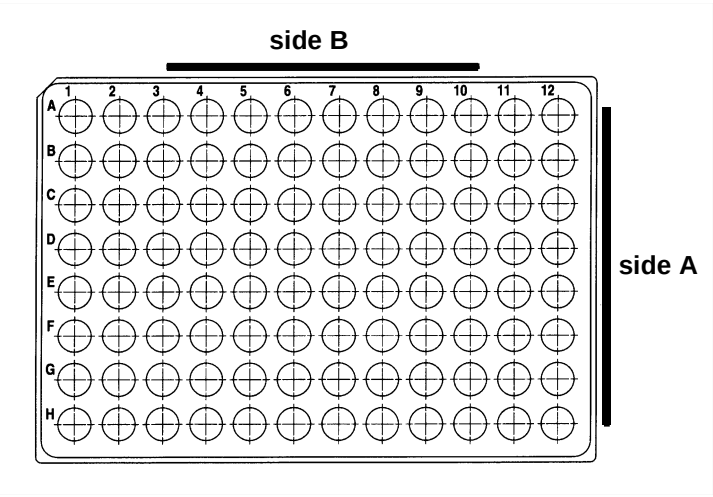
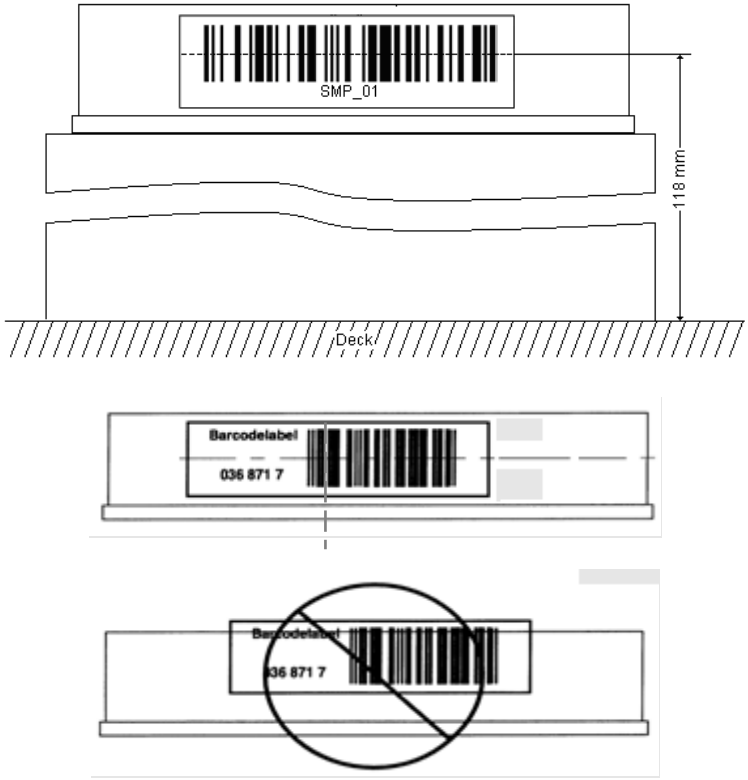
7.2.7 Plate Barcodes

Label Specification

For general barcode specifications, see Section 7.2.4 Barcode Specifications.



Dimension		Min.	Max.
A	Label length	–	66 mm
B	Code length	–	30 mm
C	Quiet zone	3 mm	–
D	Label width	10 mm	–
E	Code width	7 mm	–
	Distance from Code to Label Edge (if necessary)	–	1 mm

Positioning Barcode Labels: The barcode must fit on side B of the plate.	
The barcode must be positioned in the middle of the plate. The barcode must be centered and parallel to the edge of the plate. The barcode label must not protrude above or below the edge of the plate.	

7.3 Pipetting Channel Specifications

7.3.1 Tip Size for 1000 µl Pipetting Channel

Available CO-RE Tips	Volume
Low volume CO-RE tip (with filter)	0.5 - 50 µl
Medium volume CO-RE tip (with filter)	10 - 300 µl
High volume CO-RE tip (with filter)	10 - 1000 µl

7.3.2 Pipetting Specification for 1000 µl Pipetting Channel

Volume	Tip Size (with and without Filter)			Accuracy	Precision
	50 µl	300 µl	1000 µl	[%]	[%]
10	X	X	---	± 10	5.0
50	X	X	X	± 5	2.5
100	---	X	X	± 5	2.0
200	---	X	X	± 5	1.5
1000	---	---	X	± 5	1.5

7.3.3 Applied statistics:

$$\text{Precision} = \frac{s}{\bar{x}} \bullet 100\%$$

$$Accuracy = \frac{\bar{x} - x_t}{x_t} \bullet 100\%$$

$$\bar{x} = \frac{\sum_{i=1}^{n} x_i}{n}$$

$$s = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1}}$$

n = number of measured values

x_i = volume dispensed in pipetting cycle i [µl]

x_t = nominal volume [µl]

s = standard deviation [µl]

$\bar{x}$ = mean [µl]

Test conditions:

The Pipetting Specifications listed above are valid under the following conditions and obtained from measurements at HAMILTON Bonaduz.

1000 µl Pipetting Channel	
Test method	Gravimetric testing at HAMILTON. The scatter of the test method must be less than 1/6 of the specified precision (for one channel).
Accuracy / Precision	The values provided refer to the use of 8 pipetting channels.
Test size	≥ 10 single pipettings per pipetting channel with disposable CO-RE tips (pick-up and dispense; tip used only once) and specified volume.
Test mode	Volumes ≥ 20 µl as jet dispense, < 20 µl as (liquid) surface dispense
Test temperature	20 °C ± 2 °C
Test fluid	Deionized water with 0.1% NaCl, 0.01 % Tween®

7.4 Accessories Specification

7.4.1 CO-RE Gripper Specifications

Labware Format:	Microtiter footprint Plate Height ≤ 43 mm		
Positioning:	Reproducibility: X/Y/Z = ± 0.5 mm		
Movement Range:			
X:	Track 1 – n (depending on instrument type)		
Y:	Depending on # of pipetting channels and front channel used		
Z:	Lowest position = 15 mm over the deck work surface		
Gripper Opening:	**Minimum Opening**	**Maximum Opening**	**Arm Type**
	9 mm	Dependent upon the travel range on the pipetting arm	Modular Arm
Gripping Force:	5 N – 16 N (default 9 N)		
Transport Mass:	300 g (filled Deep Well Plate)		
Maximum Modules per System	2 Channels per System		

7.4.2 HAMILTON Heater Shaker Specifications

	Width	Height	Depth
Dimensions	150 mm	90 mm	105 mm
Weight	2500 g		
Labware [2]	Universal flat bottom adapter for 96 MTP (customized adapter available upon request)		

[2] Maximum weight including adapter 500g

Temperature Control	From 5 °C above ambient temperature to 105 °C			
Heater Specifications [3]	Set temperature	Time to reach set temperature	Deviation to set temperature	Deviation on heating plate
	37 °C	< 3min	± 1.0 °C	± 2.0 °C
	60 °C	< 10min	± 1.5 °C	± 3.0 °C
	90 °C	< 20min	± 2.0 °C	± 4.0 °C
	105 °C	< 35min	± 2.5 °C	± 5.0 °C

[3] Measured with HHS equipped with universal flat bottom adapter

Shaking Directions	Clockwise and counter-clockwise				
Shaking Orbit	2.0 mm, 3.0 mm				
Maximum Rotation Speed	2500 rpm (with 2.0 mm orbit)				
	2400 rpm (with 3.0 mm orbit)				
Shaker Specifications [4]	Set rotation speed		Deviation to set rotation speed		
	30 rpm		± 1.5 rpm		
	500 rpm		± 25 rpm		
	1000 rpm		± 50 rpm		
	2000 rpm		± 100 rpm		
Maximum Shaking Speed (rpm's)	Orbit	MTP	DWP	Tubes	Customized
	1.5 mm	n/a	2000	1800	n/a
	2.0 mm	2500	2000	n/a	2000
	3.0 mm	2400	1800	n/a	1800

[4] Measured with HHS equipped with universal flat bottom adapter

Operating- and environmental conditions	Maximum Power Consumption	140 VA
	Installation Category	Installation Category II (Overvoltage category)
	Pollution Degree	2
	Temperature Range	15 °C – 30 °C, Indoor Use Only
	Relative Humidity	15% – 85%, no condensation
	Noise Level	< 65 dBA at max speed (in accordance with DIN EN ISO 7779) Acoustics - Measurement of Airborne Noise Emitted by Information Technology and Telecommunications Equipment
	Altitude	Up to 2000 m above sea level
	Communication	CAN via TCC connector or USB
Storage and Transportation:	Temperature Range	-25 °C – +70 °C
	Relative Humidity:	10% – 90%, no condensation

8 Appendices

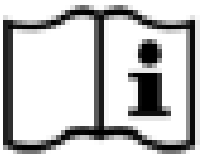
8.1 Appendix B: Regulatory Affairs

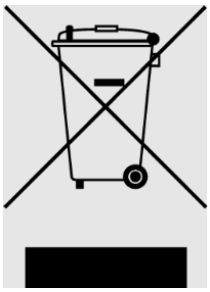
CE conformity is issued and maintained for the SENTiNAT® 200. See the Declaration of Conformity provided with the instrument, as well as the information in the following sections.

8.1.1 Explanation of the Type Plate

The Legal Manufacturer is indicated on the type plate. The content of the type plate is explained in the following table:

Legal Manufacturer 	HAMILTON Bonaduz AG Via Crusch 8 CH-7402 Bonaduz Switzerland
Importer 	Sentinel CH. SpA Via Robert Koch 2 20152 Milan Italy
Country of Origin	Made in Switzerland (fixed data, related to legal manufacturer)
Brand name (for example)	**SENTiNAT® 200** based on MICROLAB STAR IVD-R
	Manufacturing date (variable data, added during production)

	Part Number Variable data related to the platform or the dedicated instrument configuration.
	4-digit serial number Biunique serial number defines the final configuration of the instrument (variable data added during production)
	**GTIN (Global Trade Item Number**) is a unique identifier for trade items, developed by GS1 (fixed data, related to the platform configuration).
	Consult instructions for use
Authorized representative in the European Community/European Union 	Johner Medical GmbH Frankfurt Office Niddastr. 91 D-60329 Frankfurt am Main
	States that the instrument fulfils the legal requirements in Europe. See Section 8.2.2 EU Declaration of Conformity. Each Legal Manufacturer issues its own Declaration of Conformity.
	Indicates that SENTiNAT® 200 is intended to be used as an *In-Vitro* diagnostic medical device.

	25 years of safe use period under Chinese RoHS law SJ/T 11364-2014, see Section 8.2.8 RoHS Reduction of Hazardous Substances.
	WEEE symbol (crossed-out wheelie bin) indicates that in Europe the device must be recycled in accordance with the EU's Waste, Electronic & Electrical Equipment (WEEE) directive. See Section 8.2.6.1 Recycling of a ML STAR IVD-R according to WEEE.
The NRTL symbol depends upon the legal product manufacturer. It is to declare that safety standards are met according to **US** and **Canadian** standards, and the respective NRTL performs regular factory inspections.	
Hamilton Bonaduz AG **Made in Switzerland**	
	

8.1.2 SENTiNAT® 200 EU Declaration of Conformity

SENTiNAT® 200 is compliant with:

IVD Regulations 2017/746/EU, Class A IVD device

RoHS Directive 2011/65/EU and 2015/863/EU

Each individual instrument includes a printed Declaration of Conformity, indicating the European Regulations and Directive to which it is compliant.

8.1.3 Radio Interference (USA and Canada)

This equipment has been tested and found to comply with the limits for a Class “A” digital device, pursuant to both Part 15 of the FCC Rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the present user manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at their own expense.

Pursuant to the Canadian Radio Interference Regulations, ICES-001 Notice for Industrial, Scientific and Medical Radio Frequency Generators, this ISM apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations. Please note that this requirement is only for generators, which operate at over 10,000 Hz.

8.1.4 Applied Company Quality Management Systems

Applied company quality management systems EN ISO 9001 and EN ISO 13485 and 21 CFR (USA) and CMDR (Canada).

Legal Manufacturer	HAMILTON Bonaduz AG Via Crusch 8 CH-7402 Bonaduz Switzerland
Certification Body ISO 13485	TÜV Rheinland LGA Products GmbH Tillystrasse 2 D-90431 Nürenberg Germany
Certification Body ISO 9001	TÜV Rheinland LGA Products GmbH Tillystrasse 2 D-90431 Nürenberg Germany

8.1.5 Declaration of Quality

Each individual instrument includes a Declaration of Quality. It will be filled out according to the results of the final inspection and is valid for the specific instrument serial number entered.

Each individual instrument includes a printed Declaration of Quality, including the results of the final inspections and the instrument identification. It proves the pipetting performance achieved during final inspection.

8.1.6 Disposal

After the lifetime of the instrument has terminated, please contact Sentinel CH SpA for disposal regulations (see section 8.1.6.2 European: WEEE Declaration). Give due regard to the parts labeled with the biohazard warning symbol Section 1.9.5 Hazards. Only Hamilton trained field service engineers are authorized

8.1.6.1 Americas/Pacific Rim

After the life cycle of the IVD-R has ended, disposal must be considered. The customer is responsible for proper disposal of electronic devices per local regulations.

8.1.6.2 European: WEEE Declaration

The recycling of an instrument is in accordance with EC directive WEEE.

The European Community and the Directive 2012/19 requires from manufacturers or its Authorized representatives in the EU to organize and to perform the proper disposal and recycling of the waste of electrical and electronic equipment (WEEE). Since the SENTiNAT® 200 is based on the ML STAR IVD-R it will run through the same organization.

In case a disposal of the instrument is needed, please contact a Hamilton subsidiary or the Technical Support of Hamilton Bonaduz AG. They will organize the pickup of the decontaminated instrument at your premises and its proper recycling (see below). The contact details may also be found on the Hamilton website: https://www.hamiltoncompany.com/.

Recycling Process

The recycling process is as follows:

- Request for the collection of the decontaminated Hamilton instrument with Hamilton Bonaduz AG or a Hamilton subsidiary
- Decontamination of instruments and accessories, and documentation (see below)
- Preparation for transport:
- Packing of instrument and accessories, as needed
- Provide proof of the decontamination with shipment
- Note: Instruments with a weight of over 30 kg need to be fixed on a euro pallet. Instruments below 30 kg can be packed in a cardboard or plastic box. A signed copy of the decontamination document needs to be added to the outer part of the shipping box or instrument
- Pick-up and disposal of the instrument and accessories

Responsabilities

Ordering Party	Proof of decontamination of instrument for transport Note: The cost for decontamination and preparation for shipment is paid by the ordering party. On request, Hamilton offers to take care of that part of the recycling process.
Hamilton Bonaduz AG	Transport Organize the disposal in accordance with the WEEE directive Disposal

8.1.7 RoHS Compliance

Since June 2011 the SENTiNAT® 200 is in compliance with RoHS Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) and its amendments.

Since July 2016 the SENTiNAT® 200 is in compliance with RoHS II Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS II) and its amendments.

8.1.8 RoHS Reduction of Hazardous Substances

As indicated in Section 8.2.2 EU Declaration of Conformity, the European RoHS compliance is stated on the EU Declaration of Conformity.

Regarding **Chinese RoHS**, there are some substances above the limits of the Chinese RoHS legislation SJ/T 11364-2014. This is indicated with 25 years of safe use period, as indicated by the respective sign and declared in the following table in both English and Chinese.

Part Name	Toxic or hazardous Substances and Element					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr6+)	Polybrominated Biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Plastics						
Enclosure / Plastics parts	O	O	O	O	O	O
Mechanical parts						
Aluminum alloy parts	X	O	O	O	O	O
Steel alloy parts	X	O	O	O	O	O
Copper alloy parts	X	O	O	O	O	O
Electrical Units						
PCBs components / Sensors	O	O	O	O	O	O

Part Name	Toxic or hazardous Substances and Element					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr6+)	Polybrominated Biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Power Supply	O	O	O	O	O	O
Cables						
Connecting cables	X	O	O	O	O	O
Motors						
Motors / Pumps / Fans	X	O	O	O	O	O

O: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is **below** the limit requirement in SJ/T11364-2014.

X: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part **may be above** the limit requirement in SJ/T11364-2014.

部件名	毒性或危害物质和元素					
	铅 (Pb)	铬 (Hg)	镉 (Cd)	六价铬 (Cr6+)	多溴化联苯 (PBB)	多溴化二苯基以太 (PBDE)
塑料						
封入物/塑料零件	O	O	O	O	O	O
机械部分						
铝合金零件	X	O	O	O	O	O
钢合金零件	X	O	O	O	O	O
铜合金零件	X	O	O	O	O	O
电子部分						
PCB 板和组件/传感器	O	O	O	O	O	O
电源	O	O	O	O	O	O
电缆						
连接电缆	X	O	O	O	O	O
马达						
马达/泵/风扇	X	O	O	O	O	O

O: 表示该部件中所含这种毒性或危害物质及所有与之同类的物质含量低于 SJ/T11364-2014 要求的界限值 。

X: 表示该部件中所含这种毒性或危害物质及所有与之同类的物质含量至少有一种可能高于 SJ/T11364-2014 要求的界限值 。

8.2 Appendix C: Chemical Compatibility

8.2.1 Abbreviations of Materials used in the Following Table

1.4310	X10CrNi18-8 steel	PE	Polyethylene
1.4435	X2CrNiMo18-14-3 steel	PEEK	Polyetheretherketone
AA 5083 0	Aluminum	PMMA	Polymethyl-metharcylate
EPDM	Ethylene-propylene-elastomer	POM	Polyoxymethylene
FPM	Fluoroelastomer	PP	Polypropylene
FFKM	Kalrez	PTFE	Polytetrafluorethylene
FFPM	Per-Fluor-elastomer	PVC	Polyvinylchloride
FKM	Viton	PVDF	Polyvinylidenefluoride
NBR	Acrylnitril-butadiene-rubber	SI	Silicone

The table for chemical compatibility is based on information from different manufacturers. The results refer to laboratory tests with raw materials. The results with these materials are often associated with effects that cannot be observed under laboratory conditions (e.g. temperature, pressure, tension, chemical influences of substances, design features, etc.). The results listed may be considered only as a guideline. In case of doubt we recommend significant tests. The chemical resistance is not sufficient for an evaluation of a particular material for a product. Particular regulations (e.g. explosion prevention in the case of flammable liquids) have to be taken into account.

8.2.2 Chemical Resistance of the SENTiNAT® 200

	Materials																Overall resistance
Chemical	1.4034	1.4301	1.4305	1.4404	1.4435	PE	PP	PTFE	PEEK	FKM	FFKM	EPT	ZrO_2	PVDF	PMMA	AA6023 TTG	Instrument
Acetic acid, 20%	2	1	1	1	1	1	1	1	1	2	1	1	0	0	0	0	1
Acetic acid, glacial	2	1	1	1	1	1	1	1	1	4	1	1	0	0	0	0	1
Acetone	1	1	1	1	1	2	1	1	1	4	1	1	0	0	0	0	1
Acetonitrile	1	1	1	1	1	1	3	1	0	2	0	3	0	0	0	0	3
Ammonium hydroxide, 5%	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	1
Chloroform	1	1	1	1	1	3	3	1	1	1	1	4	0	0	0	0	4
Deionized water	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	1
Dimethyl formamide	1	1	1	1	1	1	1	1	1	3	1	1	0	0	0	0	1
Dimethyl sulfoxide	1	1	1	1	1	1	1	1	0	0	0	1	0	0	0	0	1
Ethyl acetate	1	1	1	1	1	2	1	1	1	4	1	1	0	0	0	0	1
Hexane	1	1	1	1	1	3	2	1	1	1	1	4	0	0	0	0	4
Hydrochloric acid, 5%	4L	2L	3L	2L	2L	1	1	1	1	1	1	1	1	0	0	0	1
Hydrochloric acid, 20%	4L	3L	3L	2L	2L	1	1	1	1	1	1	1	1	0	0	0	1
Hydrogen peroxide, 10%	1	1	1	1	1	2	2	1	1	2	2	2	1	0	0	0	2
Isopropyl alcohol	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	1
Methanol	1	1	1	1	1	1	1	1	1	2	1	1	0	0	0	0	1
Methylene chloride	1	1	1	1	1	4	3	1	2	2	1	4	0	0	0	0	4
Nitric acid, 5-10%	1	1	1	1	1	1	1	1	1	1	1	3	1	0	0	0	3
Nitric acid, 70%	1	1	1	1	1	3	4	1	1	2	1	3	1	0	0	0	3
Phosphate buffer	1	1	1	1	1	1	1	1	0	1	1	1	0	0	0	0	1

	Materials																Overall resistance
Chemical	1.4034	1.4301	1.4305	1.4404	1.4435	PE	PP	PTFE	PEEK	FKM	FFKM	EPT	ZrO_2	PVDF	PMMA	AA6023 TTG	Instrument
Phosphoric acid, 85%	3	2	3	2	2	1	1	1	0	1	1	1	1	0	0	0	3
Potassium hydroxide conc.	3	1	2	1	1	1	1	1	1	3	1	1	1	0	0	0	2
Sodium acetate	1	1	1	1	1	1	1	1	0	4	1	1	0	0	0	0	1
Sodium borate	1	1	1	1	1	1	1	1	0	1	1	1	0	0	0	0	1
Sulfuric acid, 1-75%	4	2	3	2	2	1	1	1	2	1	1	1	1	0	0	0	3
Urine	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	1
Triethylamine	1	1	1	1	1	0	4	1	0	4	0	4	0	0	0	0	4
Toluene	1	1	1	1	1	3	3	1	1	1	1	4	0	0	0	0	4
Sodium hydroxide, 5%	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1
Formic acid, 5%	3	1	2	1	1	1	1	1	1	2	1	1	0	0	0	0	2
Sodium hypochloride, 10%	3L	2L	2L	1L	1L	1	1	1	0	1	1	1	0	0	0	0	1
Ethanol	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	1
N-Hexan[1] [2]	0	0	0	0	0	2/3	2/3	0	0	0	0	0	0	1/1	(3)	1/1	
Ethyl-Acetate[2] [3]	0	0	0	0	0	1/3	1/3	0	0	0	0	0	0	3/3	0	1/1	
Methanol[2] [3]	0	0	0	0	0	1/1	1/1	0	0	0	0	0	0	1/1	(3)	1/0	
Acetonitrile (100%)[2] [3]	0	0	0	0	0	1/1	3/4	0	0	0	0	0	0	1/1	(3/4)	(1)	
Methylene Chloride[2] [3]	0	0	0	0	0	0/0	(3)	0	0	0	0	0	0	(2)	(3)	1/1	
Formic Acid (0.1%)[3]	0	0	0	0	0	1/1	1/2	0	0	0	0	0	0	1/1	(3)	(3)	
Ammonia (0.1%)[3]	0	0	0	0	0	1/1	1/1	0	0	0	0	0	0	(2)	2/2	1/1	

[1] flammable

[2] Resistance: two values are given for each medium: *left number = value at +20°C / right number = value at +50°C.*

Effects (key to codes in above table):

0 = No data available / no statement possible
1 = Very stable / suitable, No effect, little or no noticeable change
2 = Good resistance / suitable, Slight corrosion or discoloration
3 = Partially resistant, Moderate corrosion or other change in physical properties or dimensions; not recommended for continuous contact
4 = Not resistant, Severe corrosion or physical change; prolonged contact not recommended
K = No general specifications possible
L = Danger of pitting / corrosion
() = Estimated

8.3 Appendix D: Glossary

Term	Definition
Air Displacement Tip	HAMILTON CO-RE disposable tip
Aliquot	Aliquots are identical small volumes of liquid.
Aspirate	To draw up liquid into a pipetting device.
Autoload	Hardware assembly that enables the automatic loading of the SENTiNAT® 200. It consists of a loading head movable in Y direction, which draws the carriers into the SENTiNAT® 200 and reads the barcodes on them.
Barcode Mask	The barcode mask defines the basic structure of a barcode. It is a pattern to which a barcode must conform. The assignment of a specific Labware item can be done in this manner. The barcode mask can require a barcode to contain specific strings at fixed positions. It can also contain wildcards.
Barcode Reader	Device for reading sample/plate Barcodes. Part of the Autoload.
Carrier	Unit for loading plates, tubes and tips on the SENTiNAT® 200 deck. Loading process is carried out by the autoload unit.
Container	A container defines a tube, vessel or a single well of a plate.
Container identification	Barcode for the identification of a container. Serves for a unique identification of a vessel, e.g. a sample test tube.
Deck	The work surface (work area) of the SENTiNAT® 200. The area where the pipetting channels perform liquid handling or transport steps. The deck is divided into tracks, which are occupied by labware.
Deck Layout	A collection of labware placed upon a deck.
Dispense	To distribute quantities of liquid from a pipetting device.
Docking Station	The long bar at the back of the SENTiNAT® 200 for guiding the cables and the tubing for accessories.
EMC	Electromagnetic Compatibility (EMC) is the ability of electrical equipment and systems to function acceptably in their electromagnetic environment, by limiting the unintentional generation, propagation and reception of electromagnetic energy, which may cause unwanted effects such as electromagnetic interference (EMI) or even physical damage in operational equipment.

Term	Definition
Firmware	Lower Level program code that is carried out on the processors of the SENTiNAT® 200.
Front Cover	Protective covering for the SENTiNAT® 200, featuring a hinged front window made of transparent Plexiglas. With this option and assembly, the work surface of the SENTiNAT® is covered in such a way that it is shielded from user intervention and other outside influences (such as dust). At the same time, it protects the user from the movements of the SENTiNAT® 200.
Hardware Error	Type of error that is caused by a technical problem with the hardware.
HHS	HAMILTON Heater Shaker. Unit to heat and/or shake microplates in SBS format.
Instrument	Hardware of the SENTiNAT® 200 (mechanics, electronics, and firmware).
Instrument Steps	The commands made available by the firmware for controlling the SENTiNAT® 200.
IVD	*In-Vitro* Diagnostics.
Labware	Refers to movable items to be placed on the SENTiNAT® 200 deck, such as carriers, containers, or racks.
LIA *CLIA*	Lumino
LIMS	Higher level data processing system, generally known as Laboratory Information Management System, also LMS.
Liquid	Includes all kinds of liquids, among which are included reagents, controls, standards, wash fluids.
LLD	*Liquid Level Detection ï* Detection of liquid surface which may be achieved either by pressure or capacitive signal detection.
Loading/Unloading	The process by which plate, tube and tip carriers are brought on and off the SENTiNAT® 200 deck. This is automatically performed via Autoload unit.
Loading Trays	Hardware unit. The carriers can be placed on it and held outside the SENTiNAT® 200. The loading tray is attached to the SENTiNAT® 200, to support the automatic loading and unloading process.
Method	The method contains all instructions that must be executed during a run.
SENTiNAT® 200 *Software*	Software to run the SENTiNAT® 200.

Term	Definition
MTP (Microtiter Plate)	In general, a microtiter plate is assumed to have 96 wells (8 x 12) 9 mm wide. There are also plates with 384 wells (16 x 24 / 4.5 mm), or others with a different size
NRTL	Nationally Recognized Testing Laboratory
Pause	Interruption of processing. The current processing steps are completed.
Pipetting	Transfer of liquids from one container to another.
Pipetting Arm	Assembly equipped with the pipetting device and/or plate handler, as well as the common X-drive.
Pipetting Channel	Hardware assembly including the function of picking up a tip aspirating, dispensing, tip eject, liquid level detection and the Y/Z-movements
Pooling	Pipetting of different liquids in one well; 1, 2, 3…to n and n to 1, 2, 3...
Processing Step	Defines what must be carried out on the SENTiNAT® 200, as well as the location it must be carried out and possible interaction with other system components or labware. The action is defined in accordance with the methods, the loading and the tasks.
PN	Part number
Rack	Group of containers, as DWP, MTP, etc.
Rack Identification	Barcode for rack identification
Random Access	Means that every channel can access any position anywhere on the work area.
Run	Execution of the processing steps defined in the method with the aim of processing one or more liquids and containers (e.g. MTP). The run is a series of timed commands, in order to carry out processing on the SENTiNAT® 200 according to the processing plan. The run can include a reloading of elements.
Run Abort	Cancelled run by the user or by the SENTiNAT® 200
Run Visualization	Visualization of the current run, reporting the status of the SENTiNAT® 200.
Sample	Refers to a liquid in a unique identified container which is to be processed.
Side Guards	The side guards are intended to draw attention to the Loading Tray area where racks and carriers, which extend beyond the edge of the Loading Tray, are being loaded and unloaded by the Autoload.

Term	Definition
Stacker	Storage unit for racks
TADM	Total Aspiration and Dispense Monitoring. The pressure inside each individual pipetting channel is monitored, during aspiration and dispensing.
Tip	Disposable tip for pipetting
Tip Rack	Frame that holds the tips.
Tip Waste	Location for ejected tips. The Tips will be collected either into a tip waste bag or by a tip waste chute into a tip waste container.
Touch-Off	Type of dispensing where the tip approaches the bottom of the empty container so close as to allow the dispensed droplet to have simultaneous contact with the tip and the container bottom.
Trace	Record of the status during processing
Tube	A container for liquid, usually having a circular cross-section, and a cylindrical length section.
Waste Station	A device on the SENTiNAT® 200 deck to collect used disposable tips.
Well	The individual container of an MTP or a DWP.
Well Type	Geometrical shape of the well, such as U, V or flat.
Work Area	The area of the SENTiNAT® 200 to which access is provided during the processing. Elements to be pipetted or handled can be placed in this area.
Worklist	Information according to which a method is to be executed on the SENTiNAT® 200. A worklist may contain different parameters (e.g. Pipetting volume, heating temperature, shaking speed, etc.).

8.4 Appendix E: Manual Update Information

Modifications of the Operator's Manual are listed here.

Date of Change	Revision	Description of Change
05/2021	01	Complete new release
04/2022	02	Update of: Intended use (section 1.3), new barcode pictures and information (sections 1.5 / 2.1.1 / 7.2.3); new software version (section 1.1); symbols table.
06/2022	03	Update Software version (section 1.1); Update of Barcode Scanner sections 1.5/2.1.1/7.2.3; Introduction of section 3.3.2 Performing an assay calibration.
01/2022	04	Addition of paragraph 1.4 Component List; Update of: Tip Waste Container (Section 4.6.1.2); Disposal (Section 8.1.6); Americas/Pacific Rim (Section 8.1.6.1); European: WEEE Declaration (Section 8.1.6.2).

This Operator's Manual is valid for SENTiNAT® 200.

Note: changes in comparison to the previous version are indicated by a vertical bar in the text margin.

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