diatron

Kleeya®

User Manual

EDITION: Date: December 2020
Document no.: 1000027791_B
Version 2

SOFTWARE: User Software Version 1.0

Original Document

CE

We reserve the right to make changes in the course of technical development without previous notice.

STRATEC SE
Gewerbestraße 37
75217 Birkenfeld
Germany

TABLE OF CONTENTS

Intentionally left blank.

1 INTRODUCTION

This manual was created to assist the laboratory user with the utilization of the KleeYa instrument.

1.1 INTENDED USE

The KleeYa instrument is a fully automated chemiluminescence platform enabling the complete automation for immunoassay, like performing the sample processing (sample pre-dilutions, sample and reagent dispensing, incubations, wash processes) as well as the measurement and evaluation. Individual assays are carried out in disposable cuvettes.
The instrument is controlled via the PC software. This software, allows the user to process the pre-defined assays. The clear structure with intuitive user-guidance allows simple and quick operation of daily routine jobs.
The KleeYa instrument is designed for continuous loading and works on a sample-by-sample basis.

The device must be validated in the specific application according to laboratory practice and state-of-the-art before putting into service and after changes. Use of kits or kit components on the KleeYa instrument is only allowed after validation. Hazardous substances on the KleeYa instrument is in the responsibility of the user.

1.2 TYPOGRAPHICAL CONVENTIONS

The warnings, notes and symbols described hereafter are used in the current manual, on the instrument and on its packaging.

1.2.1 TERMINOLOGY

As used in this instruction manual in general and with regard to safety information, safety messages and warnings in particular, the following words have the following meanings:

May	This word is understood to be permissive. You can do what is mentioned.
User	To be qualified for instrument operation, you shall read and understand the written instructions in this instruction manual. The term “User” in this manual refers to any person who uses the instrument for its intended use.
Field service engineer	The term “Field service engineer” in this manual refers to a field service engineer authorized by the manufacturer.
Shall	This word is understood to be mandatory. You must do what is required.
Should	This word is understood to be advisory. It would be a good idea to do what is described and it is recommended that you comply.

1.2.2 DISPLAY OF WARNINGS AND NOTES

DANGER
Danger indicates a hazardous situation that, if not avoided will result in death or serious injury.

WARNING
Warning indicates a hazardous situation that, if not avoided, could result in death or serious injury.

CAUTION
Caution indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE
Notice indicates information considered important, but not hazard-related (e.g. messages related to property damage). The non-observance of a safety instruction can result in damage of the instrument or an adverse effect on the instrument function.

INFO
The non-observance of information can result in an adverse effect on the instrument function (result deterioration).

1.2.3 USED WARNING SYMBOLS

Biohazard!

Caution, hot surface!

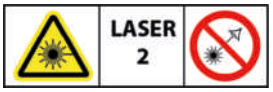
Caution, risk of danger to person or damage to equipment! Consult instructions for use!

Disconnect mains power connector before servicing

Electrical hazard!

Floor-level obstacle!

Laser hazard!



Mechanical hazard!

No heavy load

No stepping on surface/drawer!

1.2.4 OTHER SYMBOLS

CE mark

Certification label of the Nemko North America, Inc.

The instrument is a class 1 laser product according to IEC 60825-1:2014. It also complies with 21 CFR 1040.10 and 1040.11 except for conformance with IEC 60825-1 Ed. 3., as described in Laser Notice No. 56, dated May 8, 2019.

Consult instructions for use!

Date of production

Electrostatic discharge (ESD)

Expiration date

Fuse

Humidity limitations

ID number

In Vitro Diagnostic

Lot number

Manufactured by

Restriction of certain Hazardous Substances (RoHS) in electronic equipment

Serial number

Disposal of electrical and electronic equipment

In the European Union, electrical and electronic equipment shall not be disposed with other household-type waste. It shall be collected separately. Please observe the relevant legal regulations effective in your country.

Temperature limitations

1.2.5 SPECIAL TYPES

LEDS AND SIGNAL LAMPS

LEDs (light emitting diode) and signal lamps are printed in gray blue type.
Example: Power LED, Error LED

MENU ITEMS AND FIELDS

Menu items and fields are printed in gray bold type.
Example: **File** Menu

BUTTONS

Buttons are printed in gray blue bold type.
Example: **Open** button.

KEYS

Keys are printed in gray slanted type.
Example: Press *Enter*

FILE EXAMPLES

File examples are printed in typewriter font.
Example: `DRIVER=C:\SERVICE\DRIVERS`

1.3 QUALIFICATION FOR USER

1.3.1 QUALIFICATION FOR BASIC USER

Medical laboratory assistant capable of performing laboratory examinations of sample fluids and tissue, in order to prevent, identify and treat diseases.

REQUIRED KNOWLEDGE

- Ability to follow basic laboratory procedures and techniques.
- Ability to solve (troubleshoot) technical problems.
- Ability to operate laboratory instruments.
- Ability to perform basic instrument maintenance.

The user shall be properly trained in the function of the instrument, as well as in how to handle potentially hazardous specimens and reagents, in order to safely operate the instrument.

1.3.2 ADDITIONAL QUALIFICATION FOR ADVANCED USER

Associate's degree or equivalent college courses or technical school or two year's related experience and/ or training or an equivalent combination of education and experience.

REQUIRED KNOWLEDGE

- Ability to follow complex laboratory procedures and techniques.
- Familiarity with all relevant safety rules and accident-prevention regulations.
- Familiarity with the chemical manufacturer's safety-data sheets.
- Advanced troubleshooting skills needed to solve technical problems.
- Ability to perform complex instrument maintenance.

1.4 SAFETY INSTRUCTIONS

The aim of this section is to bring the user's attention to the few residual risks that exist despite the constructive protective measures taken.
The following safety instructions shall be observed at all times, both before and during operation and during maintenance.

Handling of the user manual
The user manual is provided for your safety and gives important instructions for the handling of the instrument described.

- Read all instructions!
- Keep the manual nearby the instrument.
- The user manual shall be accessible to the user at any time.

The KleeYa instrument is designed and manufactured in accordance with the safety requirements for electronic and medical instruments. It is the users responsibility to comply with local and national law's regulations and laboratory procedures for installation and operation of the instrument.
The manufacturer has done everything possible to guarantee that the equipment functions safely, both electrically and mechanically. The instruments are tested by the manufacturer and supplied in a condition that allows safe and reliable operation.

1.4.1 GENERAL SAFETY

⚠ WARNING

Non-observance of safety instructions

The non-observance of safety instructions may result in serious personal injury and material damage.

- Follow all safety instructions included in this manual.
- Follow all warnings marked on the instrument.

⚠ WARNING

Improper use of the instrument

Improper use of the instrument can cause personal injury, produce erroneous results and produce damage to the instrument.

- The handling and maintenance of the instrument shall be performed only by trained and authorized personnel.
- Before operating the instrument, the instruction for use manual shall be completely read and understood.
- Only use the instrument in accordance with the intended use as described in this manual.
- Use only the approved consumables and accessories described herein (e. g. Anchor® Tips, cuvettes etc.).
- The manufacturer assumes no liability for any damage, including those to third parties, caused by improper use or handling of the instrument.

⚠ WARNING

Missing, improperly opened, damaged or opened protective covers

To avoid serious injuries with deadly consequences due to electric shock or injuries by the instrument (e.g. contusion, cuts etc.), protective covers may only be opened or removed for certain maintenance procedures and with the highest level of caution.

- Only perform maintenance procedures described in this manual.
- Make sure that nobody is working on the instrument and that all covers are attached and closed before reconnecting the instrument to the mains supply.
- Make sure that all covers are attached and intact before switching on the instrument.
- Switch off the instrument, separate it from the mains supply and protect the instrument against restarting, if protective covers/gears are missing or damaged.
- Make sure that the motion of the pipettors or incubator has stopped before opening covers and/or accessing the working area of the instrument.
- Avoid touching the pipettors or incubator and other moving parts while the instrument is in operation.
- Perform all maintenance procedures with the highest level of caution.

⚠ WARNING

Overheating

Improper placing of the instrument may cause fire or serious instrument damage in case of overheating.

- Do not block or cover ventilation slots.
- The air shall be able to circulate.

⚠ WARNING

Sharp edges

Sheet metal parts and circuit boards located behind protective covers might have sharp edges. Contact might lead to injuries.

- Wear cut resistant gloves!
- Use caution at corners and edges!

⚠ WARNING

Unauthorized changes to the instrument

Any changes to the instrument that are not authorized by the manufacturer will lead to the loss of the validity of the conformity to the applicable regulations the manufacturer has declared. In this case, the customer is responsible for the fulfillment of the applicable regulations.

- Do not perform unauthorized changes.

NOTICE

Interference by mobile phones

Mobile phones can affect the correct function of the instrument.

- Do not use mobile phones next to a running instrument.

INFO

Laboratory equipment

The instrument has been designed and developed as laboratory equipment in accordance to the requirements of the EC directive 98/79/EC (IVD directive, directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices). In order to assure compliance, applicable standards recorded in the list of standards harmonized for the IVD directive were observed. The application of this product for in vitro diagnostics purposes requires a separate conformity assessment according to EC directive 98/79/EC for the complete system into which it will be incorporated and/or has to be used in combination with (e.g. reagent).

1.4.2 ELECTRICAL SAFETY

Non-observance of rules and regulations

Non-observance of rules and regulations will cause serious personal injury with deadly consequences and material damage.

- National rules and legal regulations for the safe electrical operation of the instrument shall be observed.

Improper connection of mains supply

Improper connection of the instrument and the peripheral devices to the mains supply can cause serious personal injury with potentially deadly consequences and material damage (e.g. fire).

- Only use grounded connection and extension cables with sufficient capacity (voltage and current) to connect the instrument and any peripheral devices to the mains power supply.
- Never remove ground connections.
- Grounding of the instrument and its peripheral devices to the same protective earth potential shall be ensured.
- The use of a multi-outlet power strip is not allowed!
- Only use power cables that fulfill the minimum requirements for this instrument.

Damaged power cables

Damaged power cables will cause serious personal injury with potentially deadly consequences and material damage (e.g. fire).

- Damaged power cables shall be replaced immediately!
- No objects may be placed on the power cables.
- Power cables shall be laid so that they cannot be squeezed or damaged.
- Power cables shall be laid so that they do not lay in accessible or drivable areas.

Defective instrument

Any defective instrument will result in serious injuries with deadly consequences and material damage (e.g. fire).

- Immediately disconnect the defective instrument from the mains supply, if a safe usage is no longer possible.
- Secure the defective instrument against reconnection.
- Label the defective instrument clearly as being defective.

Electric shock by electrical devices on wet surfaces or due to spilled liquid

Working with electrical devices on wet surfaces (floors, work table) or due to spilled liquid will cause serious injuries with deadly consequences and material damage due to electric shock.

- Only work on dry surfaces (floors, work table).

Emergency shutdown in case of functional disorder

Functional disorder of the instrument will cause electrical shock, burns, cuts or bruises.

- Pull out the mains plug to separate the instrument from the mains supply!

Blockade of access to mains supply

Improper placing of the instrument can cause accidents with serious injuries with deadly consequences, fire or serious instrument damage because the instrument cannot be separated from the mains supply.

- Make sure the mains plug is easily accessible.

Electrostatic discharge

Electronic components can be damaged or destroyed by electrostatic discharge.

- Use protective measures against electrostatic discharge.

1.4.3 BIOLOGICAL SAFETY

DANGER

Risk of infection!

The instrument shall be treated as potentially infectious. Improper handling of infectious parts will cause skin irritations, illnesses and possible death.

- Strictly follow the local and national provisions, legislation and laboratory regulations.
- Use appropriate gloves!
- Use an appropriate lab coat!
- Use an appropriate eye protection (e.g. protective glasses)!
- Avoid contact between skin/mucous membrane and samples/test reagents or parts of the instrument.
- Clean, disinfect and decontaminate the instrument immediately if potentially infectious material has been spilled.
- Do not use broken or chipped tubes or bottles.
- Observe the instructions in the package inserts for correct use of reagents.
- Observe the legal regulations for the handling of infectious material.
- Never use bio-hazardous liquids for testing the instrument!
- The instrument shall be cleaned, disinfected and decontaminated before servicing!

NOTICE

Organic solvents

Reagent containers and tubes for system liquid and waste can be seriously damaged by organic solvents and become unusable.

- Never use organic solvents.

1.4.4 DISPOSAL AND DECONTAMINATION

⚠ WARNING

Infectious waste

Potential infectious material and all parts that may come in contact with potential infectious material will cause severe environmental contamination.

- Strictly follow the local and national provisions, legislation and laboratory regulations.

⚠ WARNING

Misuse of battery

The product may contain an internal lithium manganese dioxide, vanadium pentoxide, or alkaline battery or rechargeable battery. There is risk of fire and explosions which can lead to burns if the battery pack is not handled properly.

- Do not attempt to recharge the battery.
- Do not expose to temperatures higher than 60°C (140°F).
- Do not disassemble, crush, puncture, short external contacts, or dispose of in fire or water.
- Spare batteries shall match the values (nominal voltage, nominal current, and type) specified by the manufacturer.
- Dispose used batteries according to the local and national provisions or legislation.
- Change of the PC battery shall be executed only by authorized service personnel.

NOTICE

Disposal of non-contaminated parts

Material out of use (e.g. packaging material) should be properly disposed. Material that might be used should be kept to avoid future transportation damage.

- Strictly follow the local and national provisions, legislation and laboratory regulations.
- Keep the packaging to allow for safe transportation in case the instrument shall be shipped at some future date.

NOTICE

Handling of decontamination products

Pay attention to managing the decontamination products, because they are harmful as indicated on the bottle.

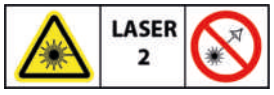
- Strictly follow the local and national provisions, legislation and laboratory regulations.
- Do not use improper decontamination products. We recommend Liquinox® or 70% ethanol to decontaminate the instrument.
- Use 0.5% sodium hypochlorite for soaking the sample racks.
- Only use decontamination liquid in accordance with the instructions for use!

1.5 POSITIONS OF SAFETY LABELS AND TYPE LABEL

Missing warnings

Missing or unreadable warning labels or type labels will result in non-identified dangers. This could result in serious personal injury and material damage.

- Check the instrument for missing or unreadable warning labels and type labels.
- Missing or unreadable warning labels or type labels shall be replaced.

1.		General warning label: • on the left and the right pipettor arm • inside the instrument, to the right and left of the Dispense Cartridges area • on the instrument side behind the wash buffer/system liquid containers drawer cover • on the instrument side behind the liquid waste containers drawer cover
2.		Biological hazard label: • on the sample/Anchor® Tips loading bay flap • on the solid waste flap • under both containers in the liquid waste containers drawer • on the instrument side behind the liquid waste containers drawer cover • on both liquid waste containers
3.		Disconnect mains power connector before servicing label: • next to the power cable on the back side • on the cover of the electronic compartment
4.		Laser hazard label: • on the top of the double ring incubator
5.		Laser hazard label: • on the side of the double ring incubator
6.		Hot surface warning labels: • next to both pipettor X-motors
7.		Mechanical hazard label: • on the left and right side of the top cover holder • on the cuvette module
8.		Floor-level obstacle label: • on the left and right side of the wash buffer/ system liquid containers drawer • on the left and right side of the liquid waste containers drawer
9.		No heavy load label: • on the reagent loading bay flap • on the sample/Anchor® Tips loading bay flap
10.		No stepping on surface/drawer label: • under the containers in the wash buffer/ system liquid containers drawer • under the containers in the liquid waste containers drawer

11.	-	Type label: • next to the power cable on the back side

Table 1-1: Labels

1.6 RADIO INTERFERENCES

INFO

Electromagnetic Compatibility (EMC)

This instrument complies with the emissions and immunity requirements as described in standard IEC 61326-2-6. This instrument has been developed and tested according to CISPR11 Class A. It may cause radio interference in domestic environments.

- If the instrument causes radio interference, you may need to take measures to eliminate the interference.
- The electromagnetic environment shall be evaluated before setup and operation of the instrument,
- Do not use the instrument in the proximity of sources with excessive electromagnetic radiation (e.g. unshielded, deliberately operated high frequency sources) since they could interfere with the proper operation of the instrument.

1.7 CYBERSECURITY

1.7.1 INTRODUCTION

The KleeYa main software (= specific KleeYa instrument software, PC software, which is used to control the instrument) is intended to be used in a defined and controlled environment. Access to the KleeYa main software is allowed only to trained and authorized users.
Nevertheless, despite the above mentioned, usage of the system may undergo the risk of illicit, criminally motivated, unauthorized access, leading to possible data loss, corruption or unauthorized distribution.
Furthermore, updates to the software modules provided with the system (e.g. Operating System, OS = system software that manages computer hardware. The KleeYa Operating System is Windows) must be distributed under controlled process pre-defined by **STRATEC**, to ensure that the KleeYa System still behaves according to its intended use after the update.
This chapter describes the policy followed by **STRATEC** and partners regarding Cybersecurity of the KleeYa System. It is described how software elements can be updated and the consequences of the installation of additional third party elements.

1.7.2 DEFINITION

Cybersecurity is generally understood as the protection of computer systems from adverse effects on assets including hardware, software or electronic data, as well as from disruption or misdirection of the services they provide.
In general, Cybersecurity is a shared responsibility of all stakeholders, meaning anyone who touches the data.
Cyber risks for medical devices are grouped in the following three key concepts:

1. **Confidentiality** of information at rest and in transit. This means in detail that sensitive data need to be prevented from being seen or accessed by non-authorized users, while ensuring that those that have legitimate, like trained and authorized users, have access to the data.
2. **Integrity** of data, which is necessary to ensure information authenticity and accuracy (i.e. non-repudiation) – or more specifically that data remains accurate and consistent throughout its life cycle.
3. **Availability** of the processes, devices, data, and connected systems, refers to the importance of keeping computer systems available and accessible when required by the activity.

1.7.3 USER TRAINING AND EDUCATION

Only trained and authorized end-users shall operate the KleeYa System, since these users are supposed to follow the intended use of the KleeYa System. Trained and authorized end-users are responsible for information security.
In order to minimize the risks, users need to be trained on a regular basis on Cybersecurity best practices.**STRATEC** recommends to provide security awareness trainings for employees that operate the KleeYa System and to make background checks prior to authorizing access to key personnel. This shall include in detail:

1. Create awareness and deepen the understanding of Cybersecurity for all users.
2. Ensure that all personnel understand their roles and responsibilities with regard to Cybersecurity.
3. Users must not install unauthorized applications (further details see sections below).
4. Users must not use any unauthorized media or device.
5. Ensure that all personnel strictly follows the security recommendations.

INFO

This policy applies to all employees, contractors, and anyone who has permanent or temporary access to the KleeYa System (including software and hardware).

1.7.4 IDENTIFICATION OF THREATS AND HAZARDS

This chapter explains the impact of different threats and hazards to cybersecurity according to NIST Special Publication 800-30 Revision 1, Guide for Conducting Risk Assessments, September 2012, pp. 6-7 and Appendix D-2.
A threat is any circumstance or event with the potential to adversely affect organizational operations and assets, individuals, other organizations, or the Nation through an information system via unauthorized access, destruction, disclosure, or modification of information, and/or denial of service.
A threat source is an actor (causal agent) with the intent and method targeted at the exploitation of a vulnerability or a situation and method that may accidentally exploit a vulnerability. In general, types of threat sources include: (i) hostile cyber/ physical attacks; (ii) human errors of omission or commission; (iii) structural failures of organization-controlled resources (e.g., hardware, software, environmental controls); and (iv) natural and man-made disasters, accidents, and failures beyond the control of the organization.

Type of threat source	Description	Examples
ADVERSE • Individual • Outsider • Insider • Trusted insider • Privileged insider • Group • Ad hoc • Established • Organization • Nation-State	Individuals, groups, organizations, or states that seek to exploit the organization's dependence on cyber resources (i.e., information in electronic form, information and communications technologies, and the communications and information-handling capabilities provided by those technologies).	1. Obtaining unauthorized access to sensitive system files based on known system vulnerabilities. 2. Malware, like a virus or worm could take down servers and could transmit data to a computer criminal. This could cause unexpected negative behavior of the KleeYa System. 3. Corruption of data and files on the KleeYa System leading to an unexpected behavior and malfunctioning of the system.
ACCIDENTIAL • User • Lab Administrator • Field Service Engineer	Erroneous actions taken by individuals in the course of executing their everyday responsibilities.	1. Revelation of classified data 2. Entry of erroneous data 3. Accidental data deletion or modification a. The file is deleted or moved to another location. b. The file are changed or deleted in such a way causing the system to use wrong data. 4. Data storage in unprotected areas 5. Failure to protect information
STRUCTURAL • IT Equipment • Storage • Processing • Communications • Display • Sensor • Controller • Environmental Controls • Temperature/Humidity Controls • Power Supply • Software • Operating System • Networking • General-Purpose Application • Mission-Specific Application	Failure: equipment, environmental controls, or software due to aging,resource depletion, or other circumstances which exceed expected operating parameters.	1. Uncontrolled installation or update of software can lead to unexpected behavior or malfunctioning of the KleeYa System.

Type of threat source	Description	Examples
ENVIRONMENT • Disaster (natural or man-made)	Natural disasters and failures of critical infrastructures on which the organization depends, but which are outside the control of the organization. Note: Natural and man-made disasters can also be characterized in terms of their severity and/or duration. However, because the threat source and the threat event are strongly identified, severity and duration can be included in the description of the threat event.	-

Table 1-2: Type of threat source

1.7.5 UNAUTHORIZED LOCAL ACCESS

Usage of the KleeYa System is restricted to trained and authorized users, following the intended use of the KleeYa System.
Unauthorized users could access or damage a computer system without the owner's informed consent. Consequences can be software and deletion of data, corruption or unauthorized distribution.

The following access control measures to ensure that only authenticated and authorized users have access to the KleeYa System are implemented (A) and recommended (B):

A) Features implemented

1. The KleeYa System can only be operated and accessed by entering a user identifier (“user name” and “password”).
2. Each user name is unique.
3. The “password” must be at least seven (7) characters long (if password policies are enabled).
4. All user accounts are generated with “strong passwords”, which force the user to the following (if password policies are enabled):
   - Usage of at least one upper case character
   - Usage of at least one lower case character
   - Usage of at least one none alpha numeric character
   - Usage of at least one numeric character
5. The KleeYa System automatically disconnects the user after a predetermined period of inactivity. This session expiration time can be defined in “settings”. As a default value, five minutes are defined for the KleeYa System. It is not recommended to set this time to more than five minutes.
6. End-users have no means to overcome the KleeYa software application, i.e. they have only restricted access to the Operating System and specific predefined applications, via the kiosk (desk shield) mode.

B) Recommended actions/behavior

All passwords are to be treated as sensitive, confidential information.

1. Access; only allow legitimate and trained users access to the KleeYa System with a password.
2. Individuality; each user shall have its own user name. Do not reuse the password for personal access for the KleeYa System.
3. Sharing passwords; passwords shall not be exchanged between authorized users.
4. Recording passwords; do not write down or otherwise record passwords, where they are accessible or recognizable by anyone else. This includes storage on personal computers.
5. Remember password features shall not be used on any application or the KleeYa System.
6. An account management process shall be implemented.
7. Limit the number of privileged accounts to those who have a legitimate activity.
8. Disable accounts immediately upon termination of an employee or contractor. Disabling instead of deleting accounts allows preservation of audit trails should an investigation be necessary.
9. Password change; passwords should be changed periodically as required.
10. Logout when you expect to be away from the KleeYa System for an extended period of time.

1.7.6 UNAUTHORIZED ACCESS VIA THE NETWORK

In case the computer of the KleeYa System is connected to a network, it is possible that unauthorized access is made by criminally motivated hackers and theoretically the software and data could then be modified in an unpredictable way, potentially leading to software malfunction, software and data loss, corruption or unauthorized distribution.

In order to avoid such a scenario, the integrated firewall of the Operating System is activated, denying remote access in accordance with the intended use of the KleeYa System. This integrated security measure controls network traffic to and from a computer.

1.7.7 REMOTE ACCESS

The KleeYa System might be connected to servers used by **STRATEC** or its contractual distribution partners for the purpose of health monitoring, troubleshooting in case of issues, standard customer support and software updates. In order to allow such additional services, software installation on the computer of the KleeYa System might be required.

However, such a connection is only be available in dedicated countries in alignment of the technical infrastructure and the respective regulations.

If such an application is installed on the KleeYa System the remote connection will be hosted by communication channels undergoing cryptography, which prevent

access and observation by unauthorized personnel. Thus, access and espionage by unauthorized persons is prevented.

1.7.8 EXTERNAL MEDIA AND DEVICES

Working with the computer of the KleeYa System can lead to voluntary or involuntary introduction of malicious software, like viruses, worms, spywares. Malwares are designed to infiltrate or damage a computer system without the owner's informed consent. As a result software and data loss, corruption or unauthorized distribution might occur.

The introduction of such malicious software might occur via the network or via a local USB device.

Modification of the KleeYa System, e.g. the installation or enabling of third-party software including software patching, should always be under explicit guidance of **STRATEC**. It is important to understand that any invalidated modification of the KleeYa System (e.g. product firewall changes, software patches, security software, utilities, games, music files, other software programs, etc.) can adversely affect system performance or safety in unpredictable ways.

In order to avoid such issues, the user has access to the KleeYa main software and a kiosk mode with highly reduced functionality, only. In general, the system is hardened and uses a whitelisting program to prevent access by unauthorized third party software or malware. Within the kiosk mode, the user will be able to use additional software tools provided with the KleeYa System like a program to update or downgrade the firmware supplied together with the reagent racks.

Additional functionalities as defined below will be available for network administrator.

1.7.8.1 CONNECTION TO A LOCAL AND/OR NETWORK PRINTER

The KleeYa System can either be connected to a local printer or to a network printer leading to the following risks:

1. **Local printer:** If the KleeYa System shall be connected to a local printer, the installation of printer drivers might be required. Each installation of a printer driver can theoretically affect the performance of the system negatively.
2. **Network printer:** If a network printer shall be used on the KleeYa System, the installation of printer drivers not being available on the KleeYa System might be required. Each installation of a printer driver can theoretically affect the performance of the system negatively.

No printer is validated by **STRATEC** on the KleeYa System against the intended use. **STRATEC** does not take any responsibility in regards to risks arising out of the installation of a printer driver.

For the installation of printer drivers **STRATEC** recommends relying on the Operating System printing service and to privilege printer drivers from the Operating System.

The installation of printer drivers shall only be performed by network administrators with deep understanding of potential security risks and not by end-users. Therefore, a dedicated access profile will be provided by **STRATEC**.

1.7.8.2 CONNECTION TO A KEYBOARD AND MOUSE

The KleeYa System provides easy an intuitive menu navigation by touch-screen, thus neither the usage of a mouse nor a keyboard is required.
If for whatever reason, a mouse or a keyboard shall be connected to the KleeYa System **STRATEC** recommends, the following hardware, being validated against the intended use together with the KleeYa System:

Keyboard:

- Logitech K120
- HP KUJ-0316
- Dell KB 216t

Mouse:

- HP 505062-001
- HP 590509-002
- Dell MS 116t

The installation of drivers for keyboard and mouse not being validated by **STRATEC** together with the KleeYa System can theoretically affect the performance of the KleeYa System negatively - although the risk might be considered as low.
In case under consideration of the aforesaid, additional drivers for keyboard and mouse shall be used on the KleeYa System, **STRATEC** recommends to rely on the Operating System services and to privilege drivers from the Operating System.
STRATEC does not take any responsibilities for the installation of other keyboards and mice than the ones validated in line with the KleeYa System.

1.7.8.3 FIREWALL AND ANTIVIRUS SOFTWARE

The typical approach for providing optimal security for systems is a combination of network firewall, personal firewall and an integrated antivirus software. However, the implementation of such a setup needs to be treated differently and independently for an analyzer, operated in an IVD environment, which is verified and validated in the predefined delivery status like the KleeYa System.

1. **STRATEC** does not take on any responsibility for network firewalls installed on the end-user sites. The network firewall of end-users will be installed by network administrators. **STRATEC** has no control on the network firewall in terms of adequateness and update frequency thus **STRATEC** cannot take any responsibility in this respect.
2. **STRATEC** does not take on any responsibility for antivirus software installed on the end-user sites. Antivirus software must be updated periodically in order to work efficiently. In a best-case scenario, these updates must be performed on a daily basis. The following requirements and associated risks might arise:
   a. All KleeYa Systems without any exception would need to be connected to the internet.
   b. In order to update the antivirus software, the computer of the KleeYa System needs to be connected to the internet permanently. If the computer is disconnected a potential security hole can open, allowing malware to be activated.
   c. Updates of the antivirus software are managed by the supplier of the aforementioned software, which is not **STRATEC**. Each antivirus software can unexpectedly recognize files as malware and delete them, even if they are essential for the proper performance of the complete KleeYa System, leading e.g. to malfunctioning of the software.

Additionally updates of the antivirus software might affect the performance of the computer of the KleeYa System negatively, leading to a disruption of timing and failures in the subsequent data analysis processes.

d. **STRATEC** is not the manufacturer of the antivirus software and cannot predict the effects updates would have on the functionality and performance of the KleeYa System. Therefore, **STRATEC** would need to update verification and validation of the complete KleeYa System continuously with each virus update in order to ensure a validated environment, which is not feasible.

STRATEC strongly recommends not to install additional firewalls and antivirus software on the KleeYa System!

For end-users (laboratory operators), the following approach has been realized:

1. Operating System service and ports, not being mandatory for the validated applications in regards to the intended use of the KleeYa System will be blocked.
2. Operating System integrated firewall is activated and configured such that all remote access to the system is denied. Additionally, a whitelisting program (Applocker) is installed avoiding unauthorized access.
3. On the Operating System, the AutoRun for all USB storage devices will be disabled. The end-user will only have the option to open files stored on a USB stick for the import and export of data in regards to the intended use of the KleeYa System. If a USB stick is inserted the end-user assumes full responsibility that the stick is not infected with viruses, Trojans or spyware.

In case it is urgently necessary to install laboratory specific firewall or antivirus software on the KleeYa System, access to the Operating System might be generated for network administrators of the laboratory via dedicated access pathway. However, it needs to be clearly understood that the aforementioned risk will appear and **STRATEC** cannot take over any responsibilities for a system, which has left the validated environment.
If you believe that additional firewall or antivirus software is necessary for you, please contact your distributor directly to discuss further steps.

1.7.9 SECURITY UPDATES OF THE KLEEYA SYSTEM

STRATEC will provide security patches of the Operating System addressing security vulnerabilities once a year or in addition in particular critical cases, like worldwide cyberattacks e.g. through ransomware worms.
If you like to exploit the possibility of getting periodical security patches of the Operating System, please contact your distribution partner directly.
Security patches of the Operating System might negatively affect the performance of the KleeYa System and therefore lead to malfunctioning. Therefore, the complete KleeYa System would leave the controlled validated environment, if these updates are installed in an uncontrolled manner without involvement of **STRATEC**.

If for whatever reason network administrators decide to install security patches of the Operating System without known consent of **STRATEC**, the administrator bears full responsibility for the further correct functionality of the KleeYa System. **STRATEC** will not take over any responsibility for a System that was modified without consent.

1.7.10 PRIVACY OF DATA ON THE KLEEYA SYSTEM

The KleeYa System generates analytical results in accordance with its intended use. This data is exposed to the risk of being spread through the following personnel, which are directly or indirectly involved in technical activities on the KleeYa System in a laboratory environment:

- **STRATEC** specialists
- **STRATEC**'s contractual distributions partners
- Distribution partners of **STRATEC**'s contractual distributions partners

These groups might get in contact during customer support or maintenance activities.

The KleeYa System does not store any specific patient information like last and surname. A sample identifier (SID), an anonymous sequence of alphanumeric characters is used instead and stored on the system. End-users are obliged only to use SIDs not referring to the patient; such traceability shall be kept on the laboratory tracing systems.

Therefore, there will not be the option to go back on the KleeYa System itself from health data to the SID and from the SID.

1.7.11 INCIDENT RESPONSE

STRATEC recommends to implement Cybersecurity structures (Cybersecurity incident management/process) as defined below.

Cybersecurity incident management is the process of identifying, managing, recording and analyzing security threats or incidents in real-time if applicable. Security incident management seeks to give a robust and comprehensive view of any security issues (Cybersecurity event and or a Cybersecurity incident) within an IT infrastructure. A Cybersecurity incident can be policy violations and unauthorized access to data that have a significant probability of compromising business operations and threatening information security. Whereas a Cybersecurity event is an identified occurrence of a system, service, or network state, indicating a possible breach of information security, failure of controls, or a previously unknown situation that may be security relevant

Cybersecurity incident management process typically starts with an alert that an incident has occurred and engagement of the incident response team, a team of appropriately skilled and trusted members of the organization that handles incidents during their life-cycle. From there, incident responders will investigate and analyze the incident to determine its scope, assess damages, and develop a plan for mitigation.

This means that a multi-faceted strategy for security incident management must be implemented to ensure the IT environment is truly secure. The ISO/IEC Standard 27035 outlines a five-step process for security incident management, including:

1. Prepare for handling incidents.
2. Identify potential security incidents through monitoring and report all incidents.
3. Assess identified incidents to determine the appropriate next steps for mitigating the risk.
4. Respond to the incident by containing, investigating, and resolving it
5. Learn and document key takeaways from every incident.

Once a Cybersecurity incident has been detected, **STRATEC** recommends to immediately contact your legal counsel and to initiate these ten steps:

1. Record the date and time when the breach was discovered.
2. Alert and activate everyone on the response team to begin executing the preparedness plan.
3. Secure the premises around the area where the data breach occurred to help preserve evidence.
4. Stop additional data loss. Take affected computer systems off-line.
5. Document everything known about the breach.
6. Interview those involved in discovering the breach and anyone else who may know about it.
7. Review protocols regarding disseminating information about the breach for everyone involved in this early stage.
8. Assess priorities and risks based on what you know about the breach.
9. Inform the proper authorities, including your regulator and you distribution partner.
10. Notify law enforcement, if needed, to begin an in-depth investigation.

2 INSTRUMENT DESCRIPTION

2.1 INSTRUMENT OVERVIEW

ENVIRONMENT

Compliance with the conditions required in terms of environment and electrical supply needs to be ensured in order to maintain the performance of the KleeYa instrument and to guranatee operators safety.
The following environmental conditions are required for operating:

- Ensure a surrounding temperature of 18°C to 30°C (64.4°F to 86°F).
- The Humidity shall be 20 - 80 % non-condensing.
- A clearance of a minimum of 15 cm (5.9 in) from the rear panal to ensure that the ventilation slits are not blocked to allow heat evacuation.
- Avoid exposure to direct sunlight

INTERLOCK

The interlock protective device (i.e cover sensor) of the cover is designed in such a way that it always gives a stop command to the instrument when the cover is open. This protective behavior applies even if the interlock protective device is out of order.
Only the service technician can temporarily disable this protective behavior for diagnostic, service or maintenance purposes.

UPS

The instrument is able to rely on an external Uninterruptable Power Supply (UPS) interfaced to the instrument PC to prevent susceptibility to power interruption. If you would like to use an external UPS please contact your distributor for discussion and setup.
STRATEC is not responsible for an Uninterruptable Power Supply (UPS) used with a KleeYa System.

Figure 2-1: KleeYa *instrument*

1	Loading slot for cuvette stacks
2	Reagent pipettor with steel needle (SPOLV)
3	Cooled reagent loading bay for Reagent Cartridges
4	Dispense Cartridges
5	Double ring incubator with washers and measurement unit (luminometer)
6	Sample pipettor with Anchor® Tip adapter
7	Sample loading bay (for samples, calibrators, or controls)
8	Anchor® Tips loading bay
9	Touch screen
10	System liquid container with purified water
11	Wash buffer container

12	Solid waste bag
13	PC (with own power switch)
14	Liquid waste containers
15	Power switch of the instrument (behind the touch screen on the instrument)

INFO

Mains plug
The mains plug can be found on the back of the instrument.

CONTAINER NOTATION

Figure 2-2: Container notation (e.g. system liquid containers)

1	Intermediate container (not removable)
2	Main container (removable)

The main container is connected to the intermediate container via a plug connection. The main container can be removed by lifting it in front approx. 2 cm (0.8 inch) and then pulling it forward. The plug connection seals itself automatically.

2.2 MODULES

TOUCH SCREEN AND PC

The system is provided together with the user software, which is located on the PC of the KleeYa instrument. The user software provides access to the options and information required to operate the KleeYa instrument and is handled via a touch screen. All work processes and results are managed by the user software and stored on the PC.
Optionally, the user software can communicate with devices in the laboratory network via the PC.

REAGENT LOADING

The cooled reagent loading bay is used to load Reagent Cartridges via a special rack. The reagent rack has a RFID label reader on each cartridge position to read information (e.g. ID, filling level) from the Reagent Cartridges.

SAMPLE LOADING

The sample loading bay is used to load test tubes via a special rack. The sample loading bay has a camera reader to read the information on the 1D or 2D barcode from the test tubes (samples, calibrators, or controls).

CUVETTE LOADING

Stacks of cuvettes are inserted via a funnel into the cuvette loader and stored in a magazine. Single cuvettes are automatically separated and inserted into the incubator for further processing.

PIPETTORS

The instrument has two independent pipettors to pipette reagents, samples, calibrators or controls into the cuvettes in the incubator. The left pipettor for reagents has a steel needle. The right pipettor for samples, calibrators or controls uses Anchor® Tips (disposable tips). The reagent pipettor can be cleaned automatically with system liquid.

INCUBATOR/ WASHER

The incubator/washer module consists of two rings with 36 cuvette positions each.
The outer incubator ring has two pipetting positions for reagent and sample pipetting into the cuvette.
The inner washer ring contains three wash stations and allows up to five wash steps for each cuvette. Magnetic particles are separated on the wall of the cuvette by magnets located at the wash positions and washed by dispense of wash buffer from the three wash stations. The inner washer ring contains also further incubation positions.
Cuvettes are transferred with cuvette pushers between the two rings and into the measurement unit that is located in the center of the rings.

DISPENSE CARTRIDGES

The Dispense Cartridges provide the Trigger Solutions (substrates) needed to initiate the chemiluminescence reaction on the KleeYa instrument. The nature of the trigger solutions might differ in conjunction with the detection system used by the vendor of the respective KleeYa assays. The KleeYa instrument provides two possible

locations for the insertions of the Dispense Cartridges. Depending on the assay either two or just one Dispense Cartridge (Trigger Solution) might be needed.
The Dispense Cartridges are placed on actuators on the measurement unit and dispense Trigger Solution into the cuvette from above.
Please refer to the instruction for use of the corresponding assay for details.

MEASUREMENT UNIT

Cuvettes are transferred from the washer ring into a rotor inside the measurement chamber. After dispense of a trigger reagent the rotor moves in front of a photomulitiplier tube (PMT). Here a second trigger reagent can be dispensed (if necessary, depending on the used detection system). Then the PMT creates a signal in relative light units that depends on the amount of light created by the chemiluminescence immunoreaction.

SYSTEM LIQUID

The system liquid container (10 l) together with an intermediate container (3.3 l) allows the refilling of purified water without interruption of the operation of the KleeYa instrument. A sensor hereby controls the current liquid level and requests the user to refill purified water at a certain residual volume. For refilling, the user removes the system liquid container (10 l) and returns it after refilling to its original position.

WASH BUFFER

The wash buffer container (10 l) together with an intermediated container (3.3 l) allows the refilling of wash buffer without interruption of the operation of the KleeYa instrument. A sensor hereby controls the current liquid level and requests the user to refill wash buffer at a certain residual volume. For refilling, the user removes the wash buffer container (10 l) and returns it after refilling to its original position.

WASTE

The KleeYa instrument is equipped with a container with a solid waste bag (foil bag) for the solid waste (cuvettes and Anchor Tips). To allow continuous operation during the exchange of the solid waste bag, the KleeYa instrument is provided with a small intermediate container. In this small intermediate container, the accumulating solid waste is collected during the replacement of the solid waste bag. After replacement, the solid waste automatically falls into the new solid waste bag.
The system is provided with two independent liquid waste containers (2x 10 l). As soon as one of the two containers is full, the system automatically switches to the second container and the user is requested to empty the relevant container. This can be done during operation.

HAND-HELD BARCODE SCANNER (OPTIONAL)

A hand-held barcode scanner can be optionally connected to the KleeYa instrument for scanning 1D and 2D barcodes. With this barcode scanner, for example, a recalibrator barcode containing a master curve can be scanned from the package insert. In addition, a barcode of a sample tube can be scanned separately if it was not recognized by the instrument scanner.

Intentionally left blank.

3 BASIC FUNCTIONS

3.1 TOUCH SCREEN

For convenient interaction with the KleeYa instrument a touch screen is provided. All inputs can be made with a stylus (tip R0.8 or over) or a finger directly on the touch screen.Use:

- Touch screen keyboard (alphanumeric inputs, e.g. A - Z, 0 - 9, etc.)
- Single click and double click:
  - Single click: Tap the screen with your stylus/finger once.
  - Double click: Tap the screen with your stylus/finger twice. Do not wait between the first and the second touch.
- Touch screen gestures:
  - Move entries in a list: Swipe with your stylus/finger from bottom to top or from top to bottom.

NOTICE

Damage of touch screen while operating

Improper use could damage the touch screen surface.

- Never use sharp edged or hard articles.
- Keep the surface clean (see chapter 5.2.3 on page 5-5).
- Operate with your finger without applying excessive pressure.

3.2 MENU BARS (OVERVIEW)

The user software provides access to the options and information required to operate the KleeYa instrument. Various fuctions of the instrument can be controlles via three menu bars. All functions of the instrument can be controlled via these menu bars.

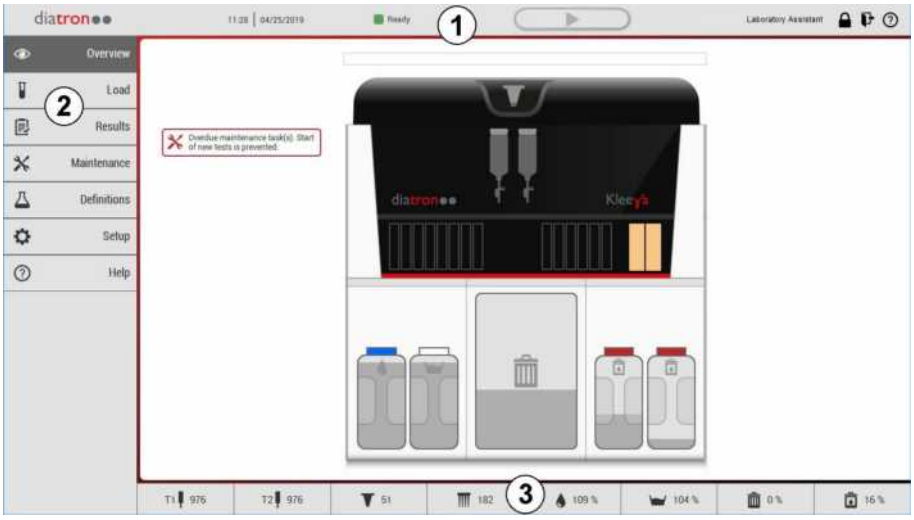


Figure 3-1: Menu bars

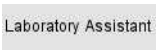
1	Top menu bar (see chapter 3.2.1 on page 3-3)
2	Main menu bar (see chapter 3.2.2 on page 3-4)
3	Resources menu bar (see chapter 3.3 on page 3-5)

3.2.1 TOP MENU BAR

Shows the current time and date.

Shows the current system status (e.g. initializing, ready).

Start button to start a test run.



Shows the user, who is logged in.

Log off button to log off the current user. Started tests are executed further. Another user cannot use the instrument during this log off time.

Shut down button to shutdown and switch off the user software.

Help button to show the online help.

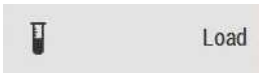
3.2.2 MAIN MENU BAR

Overview

This function/screen shows the status of all resources (Dispense Cartridges, cuvettes, Anchor® Tips, wash buffer, system liquid, solid waste and liquid waste) in the instrument. Additionally, these resources can be loaded and unloaded via this screen.

Open maintenance tasks or errors are also shown.

See chapter 3.3 on page 3-5 for detailed information.



Load

This function/screen gives an overview of all loaded samples, calibrators, controls and reagents. For samples, calibrators, and controls the assignment to assays (tests) are also shown. For reagents, extended information is shown.

The loading and unloading of samples, calibrators, controls and reagents is also possible.

See chapter 3.4 on page 3-42 for detailed information.

Results

This function/screen gives information about all results of the process, calibration curves, reports and the event log.

See chapter 3.5 on page 3-59 for detailed information.

Maintenance

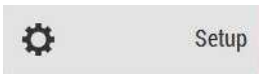
This function/screen gives an overview about the maintenance tasks, their status and allows to start these tasks.

See chapter 3.6 on page 3-75 for detailed information.

Definitions

This function/screen gives information about test definition, data reduction, and control definition.

See chapter 3.7 on page 3-78 for detailed information.



Setup

This function/screen gives information about the system settings, user accounts and report settings and allows to change it.

See chapter 3.8 on page 3-90 for detailed information.

Help

This function/screen shows the online help.

3.3 OVERVIEW

The **Overview** screen shows the status of all resources like Dispense Cartridges, cuvettes, Anchor® Tips, wash buffer, system liquid, solid waste and liquid waste and allows the loading and unloading. In addition, open maintenance tasks or event/ error messages are also shown.

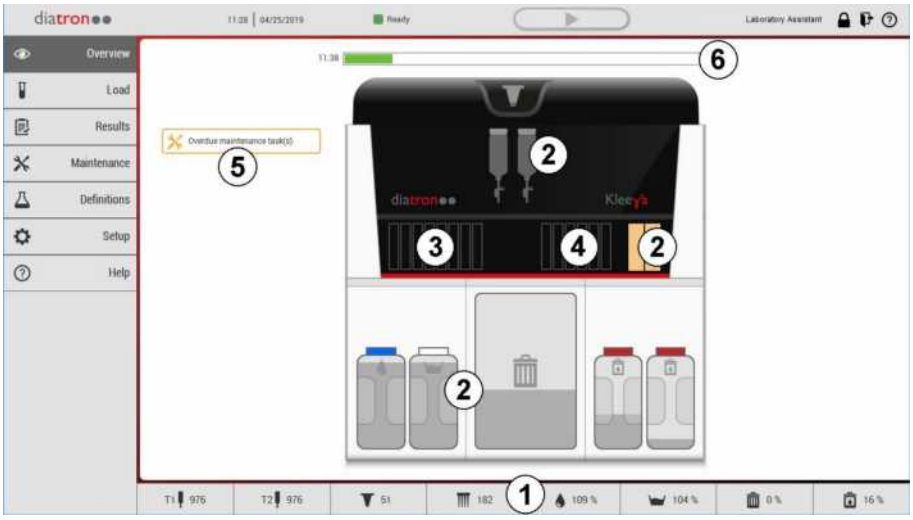


Figure 3-2: **Overview** *screen*

1	The **Resources menu bar** shows the state of the resources. Tap on the corresponding button for further information and to load or unload the corresponding resource.
2	The instrument symbol shows all resources. Tap on the corresponding button to get further information and to load or unload the corresponding resource.
3	The instrument symbol shows the reagent loading bay. Tap on the button to get further information and to load or unload reagent racks.
4	The instrument symbol shows the sample loading bay. Tap on the button to get further information and to load or unload sample racks.
5	The notification area shows messages that are relevant for starting test, e.g. open maintenance tasks and missing resources. Tap on the task or message to get further information.
6	The **Progress bar** shows the process timeline of all started tests.

PROCEDURE

1. Tap on the **Overview** button in the main menu bar or tap on a button in the resource bar to show the **Overview** screen.
2. **Load or unload resources**: Tap on a button in the resource bar (1) or tap on the corresponding symbol (2) on the displayed instrument surface (see below).
3. **Load or unload samples, calibrators, controls or reagents**: Tap on the corresponding symbol of the reagent bay (3) or sample bay (4) on the displayed instrument surface (see chapter 3.4 on page 3-42).
4. **Show open maintenance tasks**: Tap on a maintenance task (5, see chapter 3.6 on page 3-75).
5. **Show event/error messages**: Tap on an event/error message (5, see chapter 3.5.5 on page 3-72) in the notification area.

RESOURCES MENU BAR

Shows the available number of dispenses of Dispense Cartridge 1. To load or unload the Dispense Cartridge see chapter 3.3.1 on page 3-7.

Shows the available number of dispenses of Dispense Cartridge 2. To load or unload the Dispense Cartridge see chapter 3.3.1 on page 3-7.

Shows the number of loaded cuvettes. To load cuvette stacks see chapter 3.3.2 on page 3-18.

Shows the number of loaded Anchor® Tips and allows to load or unload Anchor® Tips (see chapter 3.3.3 on page 3-22).

Shows the liquid level of the system liquid container in percent. To load or unload the container see chapter 3.3.4 on page 3-29.

Shows the liquid level of the wash buffer container in percent. To load or unload the container see chapter 3.3.5 on page 3-32.

Shows the filling level of the solid waste bag in percent and allows to empty the bag (see chapter 3.3.6 on page 3-37).

Shows the liquid level of the liquid waste container in percent. To load or unload the container see chapter 3.3.7 on page 3-39.

3.3.1 LOAD OR UNLOAD DISPENSE CARTRIDGES

The **Trigger Solution** detail view shows the available number of dispenses of the loaded Dispense Cartridges. Additionally the expiration date, the lot number and the ID of both Dispense Cartridges are shown.
The KleeYa software reads the RFID label of the Dispense Cartridge and shows the information in the detailed view set. This includes the remaining dispense counters of all loaded trigger solutions. The counter decreases after every dispense.

⚠ WARNING

Hazardous liquids
Some trigger solutions also include hazardous liquids (e.g. DIATRON ACE system).

- If splashes of this liquids get into eye, immediate and thorough washing with water or a suitable buffer solution is recommended. If necessary, a physician should be consulted.
- Read always the consumable information (package insert) of the used Dispense Cartridges.

⚠ WARNING

Pooling
Trigger solution pooling is prohibited!

NOTICE

Consumable information (package insert)
Read always the consumable information (package insert) of the used Dispense Cartridges.

NOTICE

Storage and shelf life information
Please comply with the storage and shelf life information for the trigger solutions.

INFO

Loading and unloading restrictions
It is prohibited to reload Dispense Cartridges during a run.

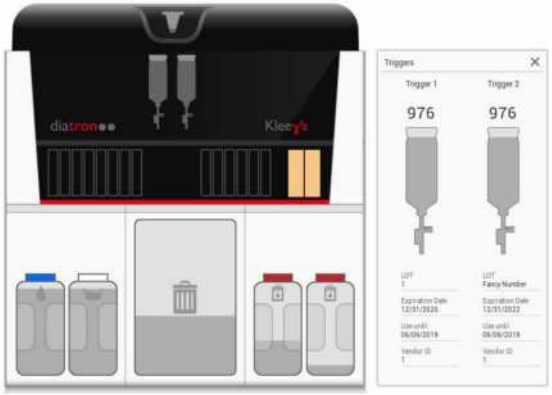


Figure 3-3: **Trigger Solution** *detail view*

The filling status of the Dispense Cartridges are additionally displayed in color:

- **Grey**: Liquid level ok.
- **Orange**: Liquid level low.
- **Red**: Dispense Cartridge empty.
- **Only borders of the cartridge**: Dispense Cartridge not loaded (removed).

Color coding for the DIATRON ACE system Dispense Cartridges and its position in the instrument:

- Trigger solution 1 - acid reagent (orange label) - position 1 (left position)
- Trigger solution 2 - base reagent (blue label) - position 2 (right position)

The RFID label on the Trigger solution Dispense Cartridges controls the correct positioning. An incorrectly positioned Trigger solution Dispense Cartridge is marked red and with an exclamation mark in the user software.

In case of usage of the Trigger Solutions system provided by DIATRON (ACE system), please note the important consumable information (package insert) before use:

- Trigger Solution 1 – Acid Reagent (see chapter 8.3.3 on page 8-9).
- Trigger Solution 2 – Base Reagent (see chapter 8.3.4 on page 8-13).

If you are using Dispense Cartridges from another vendor, please read the enclosed consumable information (package insert).

SHOW INFORMATION

1. Tap on one of the **Dispense Cartridge** buttons.
   The **Trigger Solution** detail view is shown on the **Overview** screen.

PREPARATION

DIATRON Trigger Solutions (Acridinium ester system):

1. Open the outer box with the Dispense Cartridges carefully.

Figure 3-4: Box

2. Remove both boxes with the Dispense Cartridges from the outer box.

Figure 3-5: Outer box

Figure 3-6: Both boxes with the Dispense Cartridges

3. Open the desired box with the Dispense Cartridges in the middle by removing the pierced strip.

Figure 3-7: Pierced strip of the box

4. Remove the upper part of the box.

Figure 3-8: Opened box

5. Open the inner foil package and remove the inside protective cardboard that stabilizing the Dispense Cartridge during transportation.

Figure 3-9: Opened foil

6. Remove only the Dispense Cartridge you want to use from the box.
   Store all other Dispense Cartridges in the box/according to information on label.
   Always store the Dispense Cartridges upright!

Figure 3-10: Stored Dispense Cartridges

UNLOADING

T1 500

1. Tap on one of the **Dispense Cartridge** buttons.
   The **Trigger Solution** detail view is shown on the **Overview** screen.
2. Open the instrument cover.
3. Pay attention to the correct Dispense Cartridge position.
4. Press the locking of the empty Dispense Cartridge together (1).

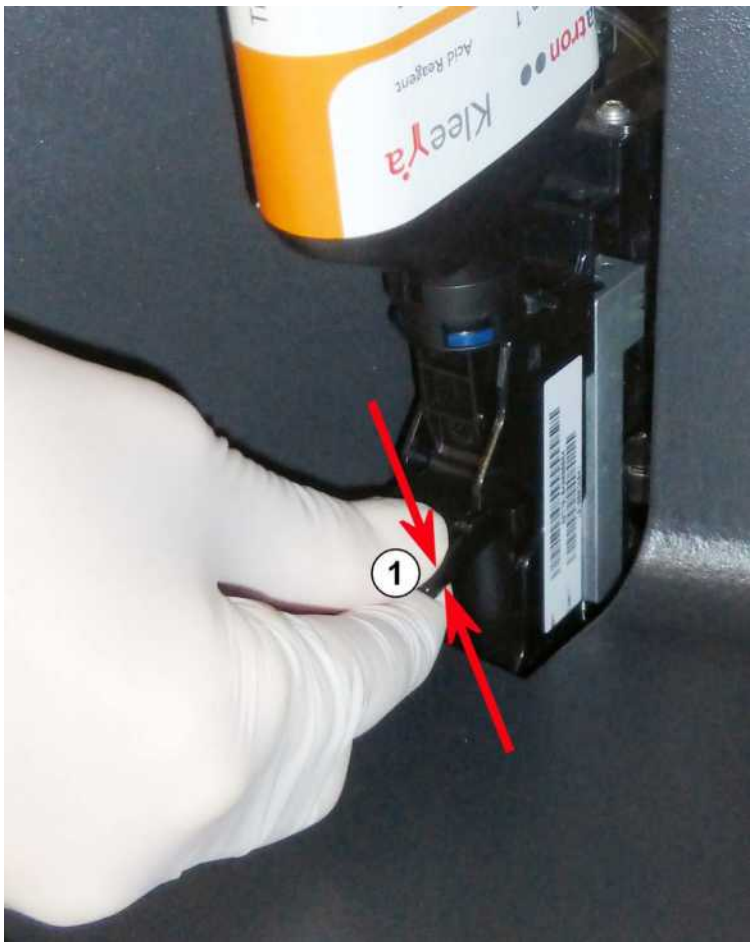


Figure 3-11: Unloading Dispense Cartridge 1

5. Drag them obliquely forward (2).

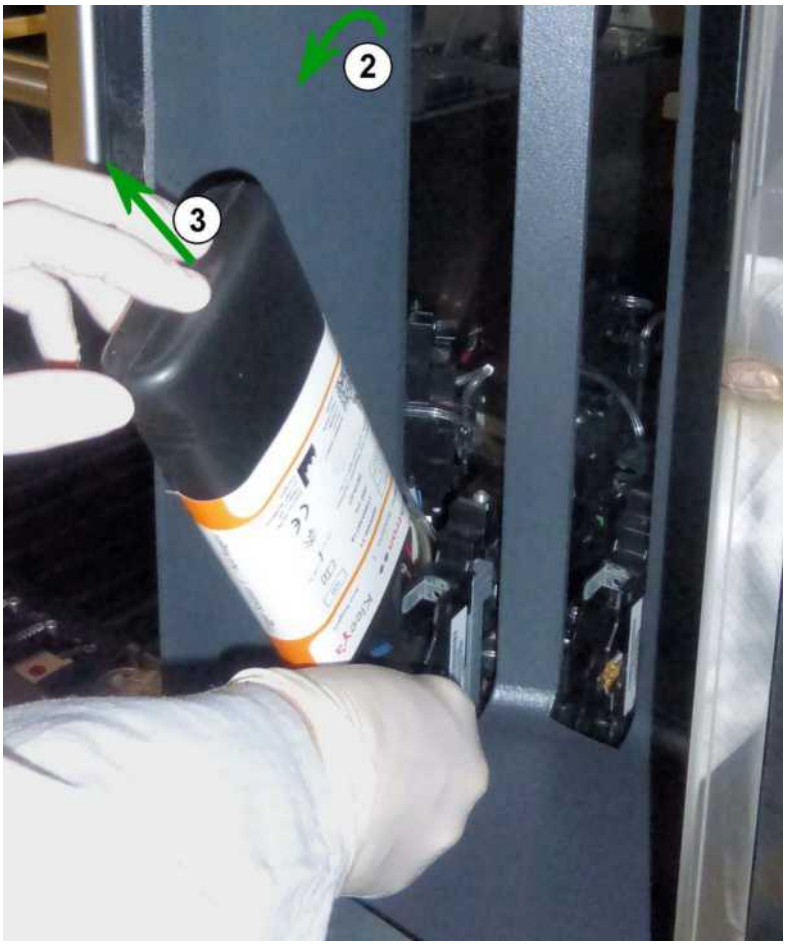


Figure 3-12: Unloading Dispense Cartridge 2

6. Remove the Dispense Cartridge (3).
7. Dispose the Dispense Cartridge.
8. Store the Dispense Cartridge according to the consumable information (package insert) or dispose it according to the local and national provisions, legislation and laboratory regulations.
9. Close the instrument cover or load a new Dispense Cartridge.

LOADING

1. Tap on one of the **Dispense Cartridge** buttons.
   The **Trigger Solution** detail view is shown on the **Overview** screen.
2. Open the instrument cover.
3. Remove the cap (1) from the new Dispense Cartridge.

Figure 3-13: Loading Dispense Cartridge 1

NOTICE

Recalibration
If the lot numbers change, it might be necessary to recalibrate the instrument depending on parameters set by the assay developer!

4. Insert the Dispense Cartridge port slanted into the correct position (2).

Figure 3-14: Loading Dispense Cartridge 2

5. Press the locking together (3).
6. Put up the Dispense Cartridge (4) and press it down slightly (5).

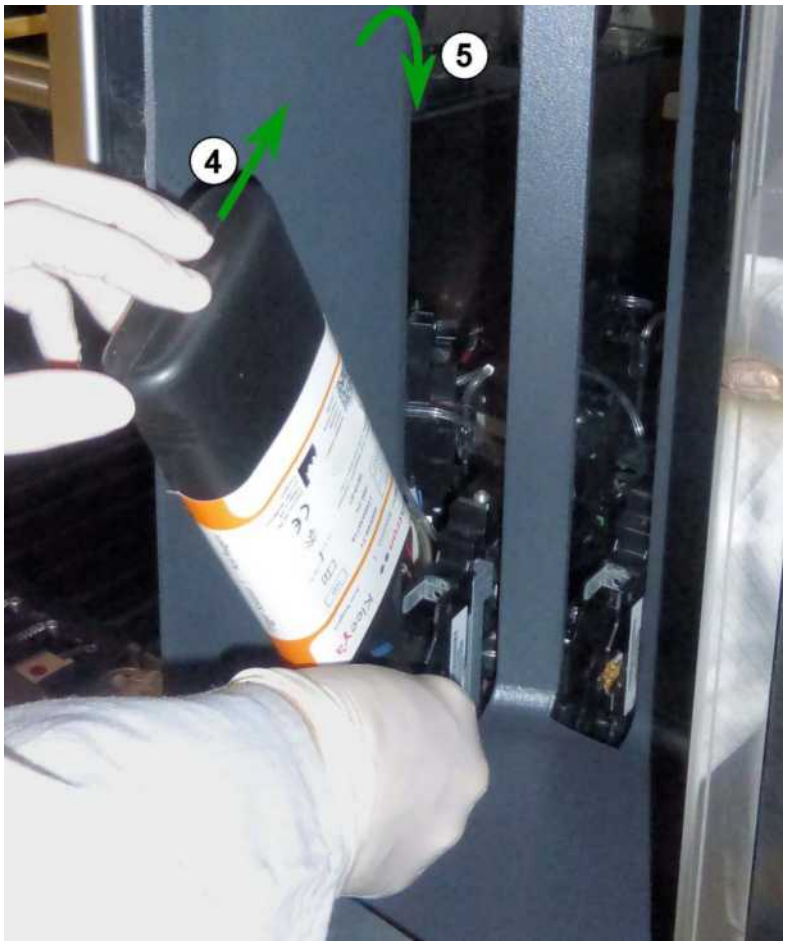


Figure 3-15: Loading Dispense Cartridge 3

7. Let the lock loose and make sure that it snaps into place.
8. If necessary, unload/load the other Dispense Cartridge.
9. Close the instrument cover.
10. Check the shown Dispense Cartridge values in the **Trigger Solution** detail view on the **Overview** screen.

3.3.2 LOAD CUVETTES

The **Cuvettes** detail view shows the number of loaded cuvettes and allows to load cuvette stacks.

⚠ WARNING

Cross-contamination by multi-use
Repeatedly use of single-use cuvettes will cause cross-contamination.
- Never reuse single-use cuvettes.

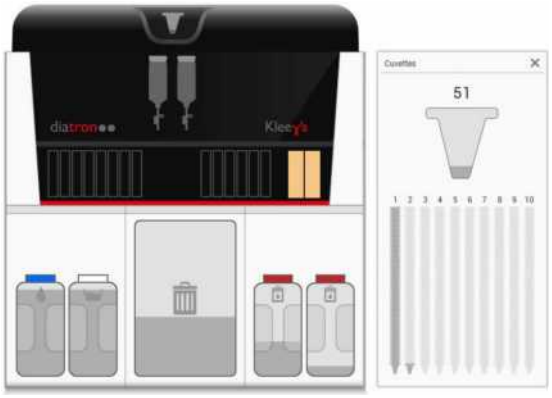


*Figure 3-16: **Cuvettes** detail view*

The filling status of the cuvettes are additionally displayed in color:
- **Grey**: Number of cuvettes is high enough.
- **Orange**: Number of cuvettes is low.
- **Red**: No or not enough cuvettes loaded.

After switching on the instrument, the exact number of cuvettes of an opened stack cannot be displayed. Cuvettes of an opened stack are counted as 1 until they are used up.

Please note the important consumable information (package insert) about the cuvettes before use, see chapter 8.3.2 on page 8-6.

SHOW INFORMATION

1. Tap on the **Cuvettes** button or on the corresponding symbol on the displayed instrument surface.
   The **Cuvettes** detail view is shown on the **Overview** screen.

PREPARATION

1. Open the box with the cuvette stacks carefully.

Figure 3-17: Box with cuvette stacks

2. Hold the cuvette bag on one corner and ensure that all cuvette stacks in the bag are below this area.
3. Remove the upper end of the bag with a scissors and discard the cut-off part.

Figure 3-18: Opening of the bag

LOADING

NOTICE

Cuvette handling
Hold the stack at the upper end. Don't touch the cuvette wall of the lowest cuvette!

1. Remove one cuvette stack from the bag.

Figure 3-19: Load cuvettes

2. Insert one cuvette stack into the loading slot for cuvette stacks.

Figure 3-20: Load cuvettes

3. Wait until the cuvette stack is completely loaded, the cuvette loading tower is turned, and the number in the cuvettes section is updated according to the new stack.
4. If desired or necessary, repeat the loading procedure.

3.3.3 LOAD OR UNLOAD ANCHOR® TIPS

The **Anchor® Tips** detail view shows the number of loaded Anchor® Tips and allows to load or unload Anchor® Tips.

⚠ WARNING

Cross-contamination by multi-use
Repeatedly use of single-use Anchor® Tips will cause cross-contamination.
- Never reuse single-use Anchor® Tips.

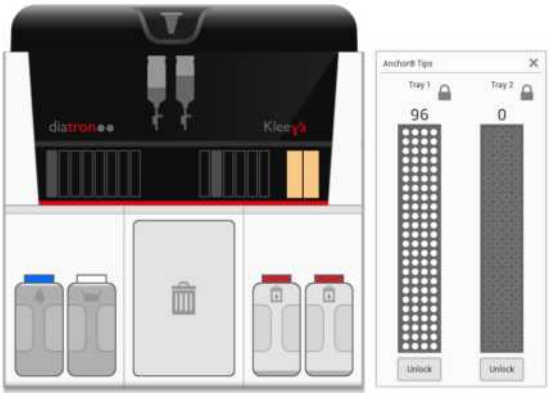


Figure 3-21: **Anchor® Tips** *detail view*

Please note the important consumable information (package insert) about the Anchor® Tips before use, see chapter 8.3.1 on page 8-3.

SHOW INFORMATION

96

1. Tap on the **Anchor® Tips** button or on the corresponding symbol on the displayed instrument surface.
   The **Anchor® Tips** detail view is shown on the **Overview** screen.

PREPARATION

1. Open the shipping box with the Anchor® Tips carefully.

Figure 3-22: Shipping box with Anchor® Tips

2. Remove one box from the shipping box.

Figure 3-23: Opened shipping box

3. Open the box with the Anchor® Tips tray boxes carefully.

Figure 3-24: Box with Anchor® Tips tray boxes

UNLOADING

1. Tap on the **Anchor® Tips** button or on the corresponding symbol on the displayed instrument surface.
   The **Anchor® Tips** detail view is shown on the **Overview** screen.
2. Open the sample/Anchor® Tips loading bay flap.

3. Tap on the **Unlock** button of the desired Anchor® Tips tray.
   The closed **Lock** symbol changes to a opened **Lock** symbol.
4. Pull out the drawer of the desired Anchor® Tips tray.

Figure 3-25: Loading bay drawer with empty Anchor® Tips tray

5. Remove the empty Anchor® Tips tray.

LOADING

NOTICE

Anchor® Tips handling
Don't touch the Anchor® Tips.
Insert the Anchor® Tips tray directly into the drawer.

1. If there is no tray in the station, the unloading procedure must still be carried out (see above).

2. Remove one Anchor® Tips tray box.

Figure 3-26: Anchor® Tips tray box

3. Open the Anchor® Tips tray box.
   Note that there are two Anchor® Tips trays in the box. The openings for them are at the top and bottom. Only one of the openings shall be opened at a time.

Figure 3-27: Anchor® Tips tray box

4. Remove the Anchor® Tips tray from the box.
   Note that the Anchor® Tips tray must only be held in the middle.

Figure 3-28: Correct handling of the Anchor ®Tips tray

5. Insert the full Anchor® Tips tray into the drawer.
   Notice: It is NOT possible to insert a partially filled Anchor® Tips tray into the drawer.

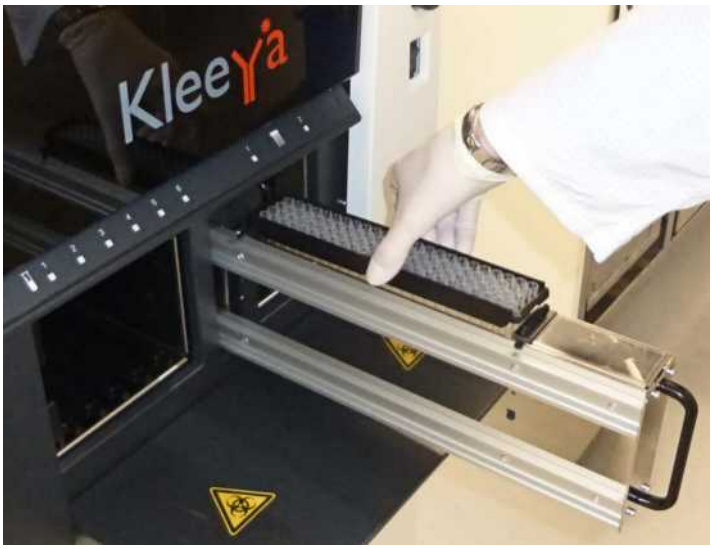


Figure 3-29: Loading bay drawer

6. Close the drawer.
   The opened **Lock** symbol changes to a closed **Lock** symbol.

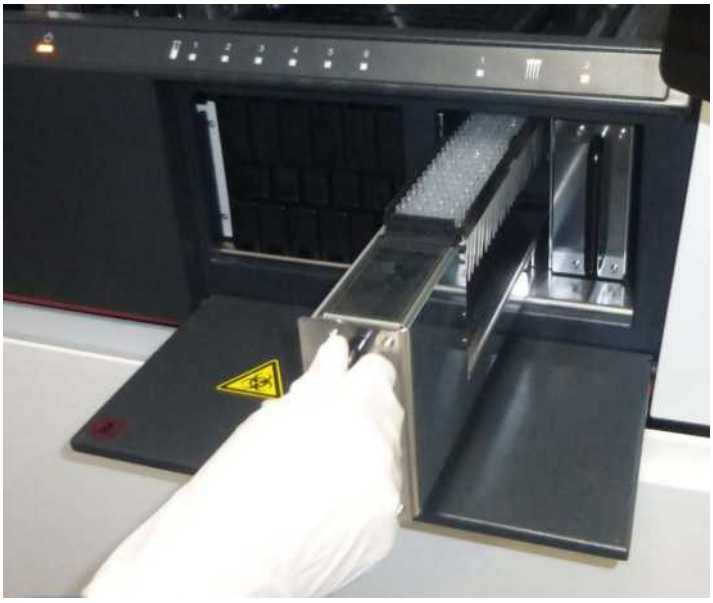


Figure 3-30: Load Anchor® Tips

7. Close the sample/Anchor® Tips loading bay flap.

3.3.4 LOAD OR UNLOAD SYSTEM LIQUID MAIN CONTAINER

The **Liquids** detail view shows the liquid level of the wash buffer main container, the system liquid main container and both liquid waste main containers in percent.

The instrument needs purified water (also called system liquid):
- to prime, fill and clean the reagent pipettor probe,
- to dilute reagents if requested.

Used system liquid shall comply with the definition of "Instrument Feed Water" according to CLSI standard for "Preparation and Testing of Reagent Water in the Clinical Laboratory" (4th Edition), including following characteristics:
- pH: 5.0 – 8.0
- conductivity: <2 µSi/cm
- resistivity: > 0.5 M Ohm*cm
- TOC: < 500 ppb
- SiO2: <1.0 ppm
- Bacteria: <10 CFU/m

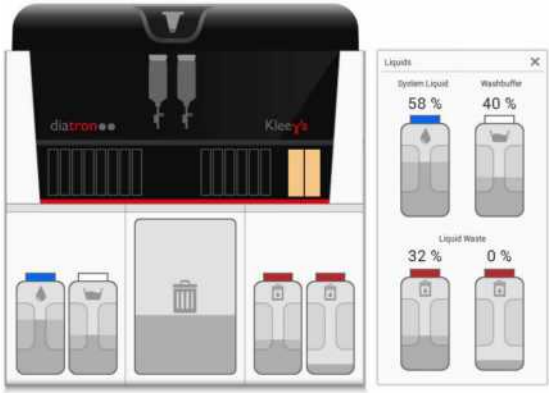


*Figure 3-31: **Liquid** detail view*

The filling status of the container is additionally displayed in color:
- **Grey**: Liquid level ok.
- **Orange**: Liquid level low.
- **Red**: The container is empty.

INFO

Re-usable containers
The system liquid main container is re-usable.

SHOW INFORMATION

1. Tap on one of the **Liquid container** buttons or on the corresponding symbols on the displayed instrument surface.
   The **Liquids** detail view is shown on the **Overview** screen.

UNLOADING

1. Pull out the wash buffer/system liquid containers drawer.
2. Raise the front of the (empty) system liquid main container approximately 2 cm (0.8 inch).

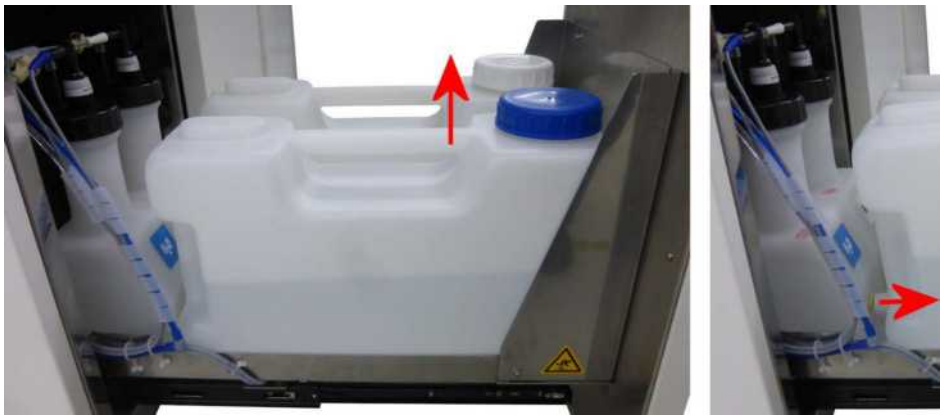


Figure 3-32: Unloading system liquid main container

3. Pull the system liquid main container forward and remove it.

LOADING

1. Prepare 10 l purified water.
2. Open the system liquid main container screw cap (blue cap) and pour in the purified water (outside the instrument).
3. Close the screw cap.
4. Insert the system liquid main container into the instrument.

Figure 3-33: Loading system liquid container

5. Move the system liquid main container connection port over the connection port of the intermediate container on the back side.

6. Press the system liquid main container on the front down.
7. Close the wash buffer/system liquid containers drawer.

3.3.5 LOAD OR UNLOAD WASH BUFFER MAIN CONTAINER

The **Liquids** detail view shows the liquid level of the wash buffer main container, the system liquid main container and both liquid waste main containers in percent.

⚠ WARNING

Pooling
Wash buffer pooling is prohibited!

NOTICE

Consumable information (package insert)
Read always the consumable information (package insert) of the used wash buffer.

NOTICE

Storage and shelf life information
Please comply with the storage and shelf life information for the wash buffer.

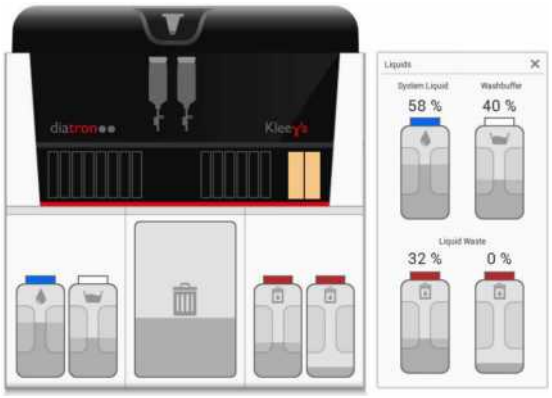


*Figure 3-34: **Liquid** detail view*

The filling status of the container is additionally displayed in color:

- **Grey**: Liquid level ok.
- **Orange**: Liquid level low.
- **Red**: The container is empty.

Please note the important consumable information (package insert) about the 5x TBS wash buffer before use, see chapter 8.3.5 on page 8-17.
If you are using wash buffer from another vendor, please read the enclosed consumable information (package insert).

INFO

Re-usable containers
The wash buffer main container is re-usable.

SHOW INFORMATION

1. Tap on one of the **Liquid container** buttons or on the corresponding symbols on the displayed instrument surface.
   The **Liquids** detail view is shown on the **Overview** screen.

PREPARATION

DIATRON 5x TBS wash buffer bottles:

1. Open the box with the 5x TBS wash buffer bottles carefully.

Figure 3-35: Box

2. Always store the 5x TBS wash buffer bottles upright!

Figure 3-36: Opened box

UNLOADING

1. Pull out the wash buffer/system liquid containers drawer.
2. Raise the front of the (empty) wash buffer main container approximately 2 cm (0.8 inch).

Figure 3-37: Unloading wash buffer main container

3. Pull the wash buffer main container forward and remove it.

MIXTURE

Prepare 10 l wash buffer:

1. Open the container screw cap (white cap) outside the instrument.
   5x TBS Wash Buffer provided by Diatron is color coded (white lid, corresponding to white lid on the wash buffer container in the KleeYa instrument (main and intermediate).
2. If there is still liquid in the container, empty it completely!
3. Open the **full** 5x TBS wash buffer bottle.
4. Fill the 5x TBS wash buffer completely into the **empty** wash buffer main container.

Figure 3-38: Fill in 5x TBS wash buffer

5. Fill the wash buffer main container with 8 l purified water up to the mark.

Figure 3-39: Fill in purified water

6. After completion of the wash buffer preparation, the cap must be placed lightly on the wash buffer main container to allow proper degassing of the wash buffer solution.
7. **Wait 2 hours** for the micro-bubbles to disappear from the solution before use.
8. Close the wash buffer main container screw cap.

LOADING

9. Insert the wash buffer main container into the instrument.

Figure 3-40: Loading wash buffer main container

10. Move the wash buffer main container connection port over the connection port of the intermediate container on the back side.
11. Press the wash buffer main container on the front down.
12. Close the wash buffer/system liquid containers drawer.

3.3.6 LOAD OR UNLOAD SOLID WASTE BAG

The **Solid Waste** detail view shows the filling level of the solid waste in percent and allows to empty the solid waste bag (foil bag).

Figure 3-41: **Solid Waste** *detail view*

To display the filling status of the solid waste bag the instrument counts the cuvettes and Anchor® Tips since the last emptying. The filling status of the solid waste bag is additionally displayed in color:

- **Grey**: Level ok.
- **Orange**: Level become full.
- **Red**: The solid waste bag is full.

NOTICE

Solid waste bag presence

The instrument does not monitor the presence of the solid waste bag!
It is strictly forbidden to use the instrument without a solid waste bag on.

- Check the presence of the solid waste bag before starting a run.

The instrument has a small intermediate container, which allows to change the solid waste bag during operation.

UNLOADING

1. Tap on the **Solid waste** button or on the corresponding symbol on the displayed instrument surface.
   The **Solid Waste** detail view is shown on the **Overview** screen.
2. Open the solid waste flap.

Figure 3-42: Solid waste bag

3. Unhook the full bag from the tensioner in the back of the flap.
4. Unhook the full bag from the front of the flap.
5. Remove the full bag.
6. Close the full bag.
7. Dispose the full bag according to the local and national provisions, legislation and laboratory regulations.

NOTICE

Do not close the solid waste flap during replacement of the solid waste bag.

LOADING

1. Insert the empty bag and hinge it into the holding clamps/sheet on the front of the flap.
2. Hinge it into the tensioner on the back of the flap.
3. Close the solid waste flap.
4. Tap on the **Yes** button to confirm emptying the waste bag.
   If you tap the **No** button, the instrument will not realize that the bag is empty.

3.3.7 LOAD OR UNLOAD LIQUID WASTE MAIN CONTAINER

The **Liquids** detail view shows the liquid level of the wash buffer main container, the system liquid main container and both liquid waste main containers in percent.

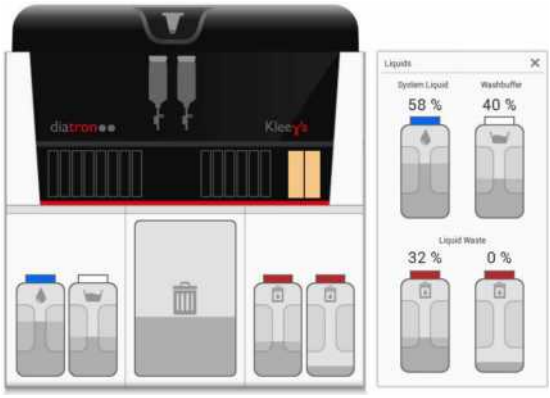


Figure 3-43: **Liquid** *detail view*

The filling status of the containers are additionally displayed in color:

- **Grey**: Liquid level ok.
- **Orange**: Liquid level high.
- **Red**: The container is full.

INFO

Re-usable containers
The liquid waste main containers are re-usable.

SHOW INFORMATION

1. Tap on one of the **Liquid container** buttons or on the corresponding symbols on the displayed instrument surface.
   The **Liquids** detail view is shown on the **Overview** screen.

UNLOADING

1. Pull out the liquid waste container drawer.
2. **Notice:** Pay attention to the control light on the connector and remove only unused liquid waste main containers (the control light is off).
   Pull the joint level sensor and liquid waste connector (1) out of the full liquid waste main container (5) and put the liquid waste connector in the tube (2) behind the containers.

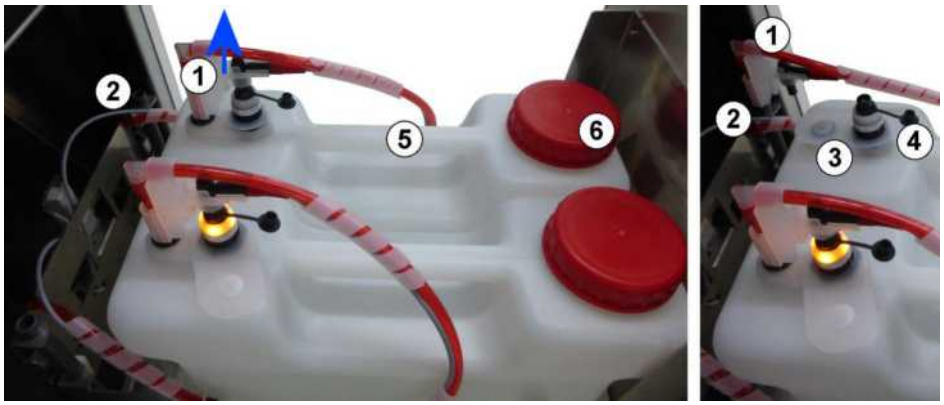


Figure 3-44: Unloading system liquid main container

3. Close the flat cap (3).
4. Close the connector cap (4).
5. Remove the full liquid waste main container (5).
6. Open the liquid waste main container screw cap (6).
7. Empty the liquid waste main container according to the local and national provisions, legislation and laboratory regulations.
8. Fill preferably 200 ml commercial hypochlorite or bleach into the empty liquid waste main container.
9. Close the screw cap (6).

LOADING

1. Insert the liquid waste main container (5) into the instrument.
2. Open the connector cap (4).
3. Open the flat cap (3).
4. Plug in the joint level sensor and liquid waste connector (1) into the liquid waste main container. The tube shall always be guided on the outside of the liquid waste main container, not in between both containers.

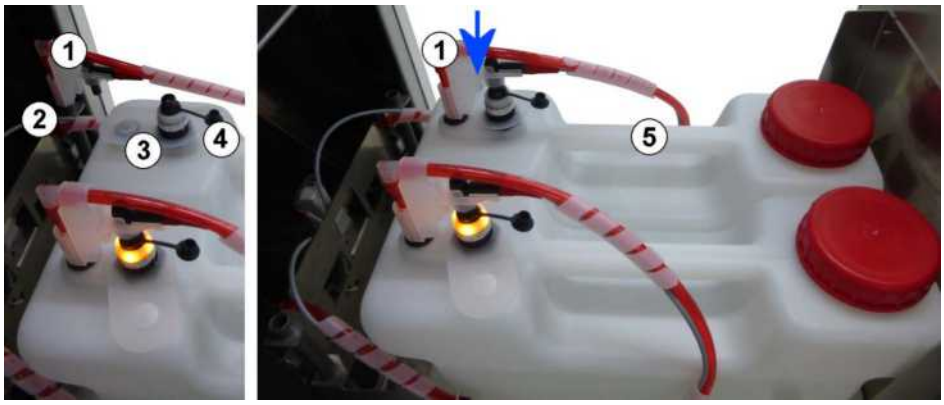


Figure 3-45: Loading system liquid main container

5. Close the liquid waste liquid container drawer.

3.4 LOAD

The **Load** screen gives an overview of all loaded samples, calibrators, controls, and assay reagents. The loading and unloading of samples, calibrators, controls, and reagents is also possible.

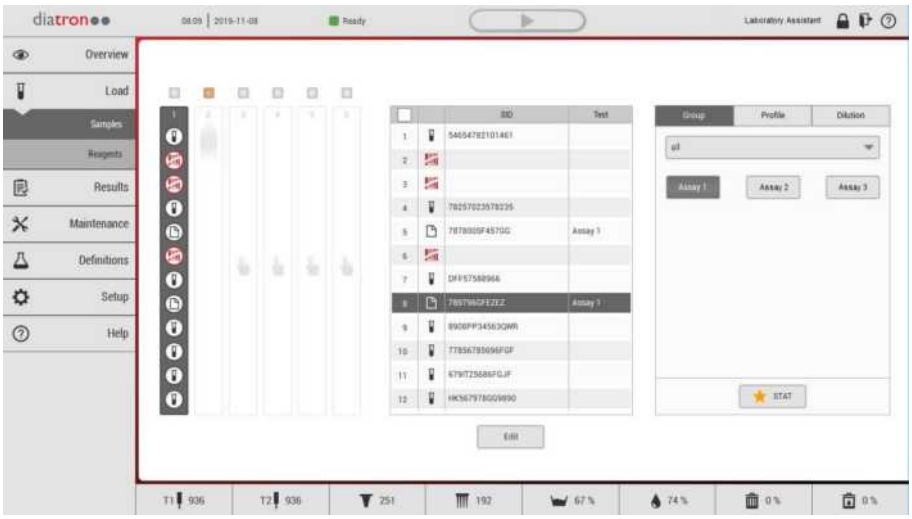


Figure 3-46: **Load** *screen*

PROCEDURE

1. Tap on the **Load** button in the main menu bar to show the **Load** screen.
2. Below the **Load** button appears a sub menu with further buttons:
   - **Samples**: Tap on the button to show the **Sample loading** screen (see chapter 3.4.1 on page 3-43). The screen shows information about the loaded samples, calibrators, and controls. It allows to associate tests to samples, calibrators, and controls.
   - **Reagents**: Tap on the button to show the **Reagent loading** screen (see chapter 3.4.2 on page 3-55). The screen shows information about the loaded reagents.

3.4.1 LOAD OR UNLOAD SAMPLES, CALIBRATORS, AND CONTROLS

Samples, calibrators, or controls are loaded into the sample loading bay within so-called sample racks.
For positive sample identification, the sample loading bay is provided with a camera (on the left hand side). By means of this camera, the barcodes, on the (test) tubes can be read and used for identification. Barcodes of calibrators additionally contain data for the corresponding master curve.
The sample loading bay supports loading of up to 6 sample racks each with up to 12 (test) tubes on individual lanes. On each rack a maximum of two recalibrator tubes containing a barcode with mastercurve information can be loaded at the same time. The other positions on the same rack can be loaded with tubes of any other barcode type. The state of each lane is indicated by its corresponding lane status indicator (LED).

⚠ WARNING

Use of sample racks
Insert the sample racks carefully to avoid spilling of liquid and tipping over of tubes.

⚠ WARNING

Improper loading or unloading of sample racks
Improperly loaded or unloaded sample racks can produce erroneous results due to incorrect pipetting activities.

- Only load and unload sample racks if you are explicitly requested to do so.
- Only load and unload sample racks on the specified lanes.
- Check the correct transfer or input of all reagent and sample names.

NOTICE

Handling and cleaning of optical surfaces
Improper optical surfaces (e. g. (e. g. camera, lenses, sensors)) could generally degrade the quality of images, data, etc.

- Do not touch any optical surfaces.
- Only clean the optical surfaces with a soft and lint-free cloth.
- Do not use any aggressive detergents or solutions (e.g. acetone).

NOTICE

Do always push in the sample racks into the sample loading bay with the handle or pull it out again with the handle.

INFO

Never load more than one sample rack at the same time! For proper barcode identification the sample racks must be loaded one after the other.

TUBE AND SAMPLE RACK SPECIFICATIONS

All used tubes (sample test tubes, calibrator tubes, or control tubes) must fulfill the following specifications:

	Tube height	Tube diameter	Sample rack type
1	92 - 100 mm	12 mm	A12
2	92 - 100 mm	13 mm	A13
3	92 - 100 mm	15 mm	A15
4	92 - 100 mm	16 mm	A16
5	75 mm (+ spacer in sample rack)	12 mm	B12
6	75 mm (+ spacer in sample rack)	13 mm	B13
7	75 mm (+ spacer in sample rack)	15 mm	B15
8	75 mm (+ spacer in sample rack)	16 mm	B16
9	30 mm (in 75 mm transfer tube)	10 mm	C10

Table 3-1: Tube specifications

A special sample rack (A12, A13, ... , C10) must be used for each type of tube (1-8) so that the instrument can correctly dispense liquid from the tubes.
Each (new) standard sample rack can be customized to a specific sample rack type according to its intended use/used tubes, see chapter 5.3.1 on page 5-11.

LED STATUS

The LEDs above sample loading bay lanes show the status of the sample rack in the lane:

LED	Lane	Notice
Off	Lane is empty Sample rack (samples, calibrators, or controls) is finished or unused	
Slow flashing	Sample rack can be loaded in the selected lane	
On	Sample rack (samples, calibrators, or controls) will scheduled or is processed	**Do not unload the sample rack!**
Fast flashing	Error	See error message!

Table 3-2: LED status

STATUS INFO

The **Load** screen shows the status of individual samples, calibrations, controls, and sample racks:

Symbol/Time	Description
	Selected lane to load a sample rack.
	Sample rack is finished (shown below the sample rack).
Time	Sample rack is processed until xx:xx o'clock (shown below the sample rack).
	Tap to select the lane.

Table 3-3: Status info for sample racks and lanes

Symbol	Description
	Calibration tube
	Control tube
	Empty position in the sample rack.
	Sample test tube assigned tests.
	Sample test tube with barcode/sample ID.
	Sample test tube with duplicate barcode/sample ID.
	Tube without or unreadable barcode/sample ID.
	STAT: Sample/calibration/control to be tested in priority. A STAT test is defined as a quick turnaround time, such STAT tests are ordered when the result is needed quickly for a decision regarding patient management. These emergency STAT samples can be programmed for all the sample tray positions. If the profiles are sent through by a centralized computer system, the category of STAT is already associated with the profile. The priority of any sample can be raised to STAT as long as it has not already been incorporated into the instrument workflow.

Table 3-4: Status info for (test) tubes

PROCEDURE/ SHOW INFORMATION

1. Tap on the **Load** button in the main menu bar to show the **Load** screen.
2. Tap on the **Samples** button below the **Load** button.

SAMPLE SAFETY

- **Traceability of the diagnostic results**
  For maintaining traceability of the diagnostic results, the sample should be handled according to the laboratories quality system as described in the local requirements.
- **Maintaining safety**
  For maintaining safety, the samples must fulfill the requested installation and operating conditions as stated in the instruction for use of the relevant assay.

- **Air bubble formation or clotting**
  Air bubble formation or clotting of the samples must be avoided as these may alter the liquid detection functionality and hence cause unreliable results. To avoid clots, the samples should be treated accordingly (e.g. centrifuged) prior to the use in the KleeYa instrument.
- **Sample volume**
  Check that the sample volume is sufficient to run the required amount of tests (as described in the instructions for use of the used kits).

LOADING

1. Check all samples for air bubbles before testing.
   Remove existing air bubbles!
2. Load all (test) tubes (with samples, calibrators, or controls) into the sample rack.
   Notice: Do not load more than two recalibrator tubes with barcodes containing mastercurve information on the same rack.
   Notice: Pay attention to the correct sample rack type!
   Ensure that the barcode labels face towards the left (open side of the sample rack).
3. Open the sample/Anchor® Tips loading bay flap.

4. Tap on the desired lane on the touch screen.
5. Wait until the camera has focused on the desired loading lane and the corresponding LED flashes slowly.
6. Push the sample rack carefully into the desired lane to avoid tipping over and spilling of tubes and press it against the pressure of the spring, until it engages with an audible click.
   - While the sample rack is introduced in the lane, the barcodes of the (test) tubes are read automatically.
   - Barcodes that have not been read automatically can be entered manually, see chapter 3.4.1.3 on page 3-53.
   - If the rack has been inserted properly, the LED goes off for this position, and starts flashing at the next free position that can be loaded.

Figure 3-47: Sample loading bay

7. Test and dilution assignment:
   a. Automatic test and dilution assignment: If the instrument is connected to a LIS- or LAS-system, the samples will be automatically assigned to one or more tests, see chapter 3.4.1.1 on page 3-49.
   b. Manual test and dilution assignment: It is always possible to assign samples to one or more tests manually, see chapter 3.4.1.2 on page 3-50.
8. If desired, load additional sample tube racks.
9. Close the sample/Anchor® Tips loading bay flap.

UNLOADING

1. Open the sample/Anchor® Tips loading bay flap.
2. Press the unused/finished sample rack a short-time against the pressure of the spring. The sample rack is set free.
   The corresponding LED over the sample loading lane must be off.
3. Remove the sample rack carefully.
4. Close the sample/Anchor® Tips loading bay flap.

NOTICE

Check sample rack
The sample rack should be checked at regular intervals for damages, wear and tear see chapter 5.2.5 on page 5-10.

3.4.1.1 AUTOMATIC TEST AND DILUTION ASSIGNMENT

If the instrument is connected to a LIS- system, the instrument will query the host for test orders automatically, when the sample rack is loaded.

INFO

Problems with the automatic test assignment

If the instrument is connected to a LIS-system, but the samples, calibrators, or controls won't be automatically assigned to one or more tests, then:

- Check if the test request was sent from the LIS-system to the instrument.
- Check the barcodes of the sample tubes, calibrator tubes, or control tubes.
- Check the connection to the LIS-system.

3.4.1.2 MANUAL TEST AND DILUTION ASSIGNMENT

It is possible to assign samples, calibrators, or controls manually to one or more tests. For any loaded sample rack, the sample rack details allow test order assignment.

In addition, a dilution factor can also be selected for samples, calibrators, or controls, if dilutions are intended for the respective assay. By default, the smallest selectable dilution factor (e.g. none - undiluted) is assigned.

Assign single tests or a set of tests?

When assigning tests to a sample, calibrator, or control, you can choose whether to select individual tests (**Group** tab (3)) or a whole set of tests (**Profile** tab (4)). A profile is a collection of several previously defined tests. With a profile it can be avoided that a single test is forgotten in case of repeated test requests.

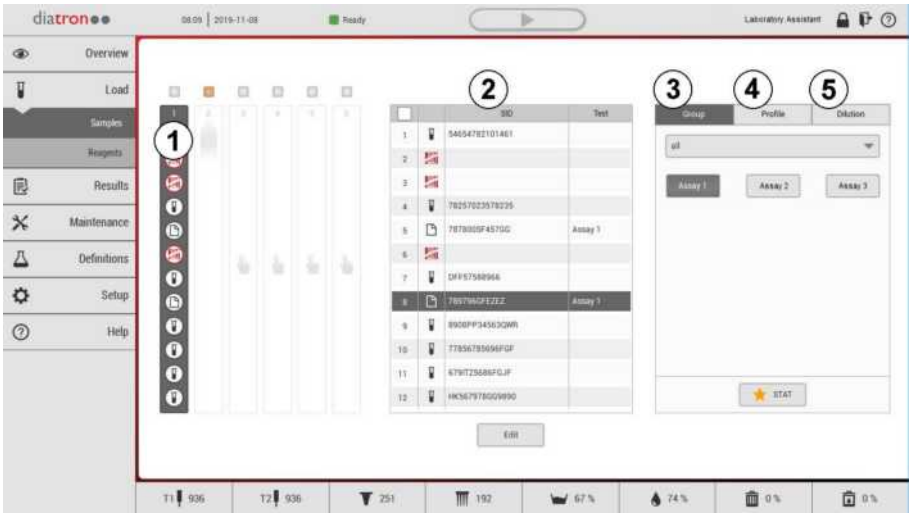


Figure 3-48: Inserted sample racks

1. Tap on the desired sample rack symbol (1).
   The user software shows in the middle of the screen all IDs of each test tube (2).
2. Tap on the desired sample ID, calibrator ID, or control ID.

Assign single test(s) or/and a set of tests:

Already assigned tests are marked dark.

3. Assign single test(s):
   a. Tap on the **Group** tab (3) on the right side of the screen.
   b. Tap on the selection list below the tabs to show a specific group of tests or all tests.
   c. Tap on the desired test.
      The test is assigned to the selected sample, calibrator, or control and displayed in the table line.
      An assigned test is marked in dark grey in the **Group** tab.
   d. Repeat the assignment for further tests.
4. Assign a set of tests:
   a. Tap on the **Profile** tab (4) on the right side of the screen.

b. Tap on the desired set of tests.
The set of tests is assigned to the selected sample, calibrator, or control and displayed in the table line.
An assigned profile is marked in dark grey in the **Profile** tab.
c. Repeat the assignment for further set of tests.

5. If necessary, tap on the **STAT** button to start the test(s) with high priority.
The **STAT** symbol is displayed in the table line and the **STAT** button is marked in dark grey.
A detailed explanation of **STAT** can be found in chapter 3.4.1 on page 3-43.
6. Repeat the procedure for other samples, calibrators, or controls.

DILUTIONS

It is also possible to change the dilution factor of a sample, calibrator, or control if the test allows dilution factors:

1. Tap on the desired sample ID, calibrator ID, or control ID.
2. Tap on the **Dilutions** tab (5) on the right side of the screen.
3. Tap on the desired test.

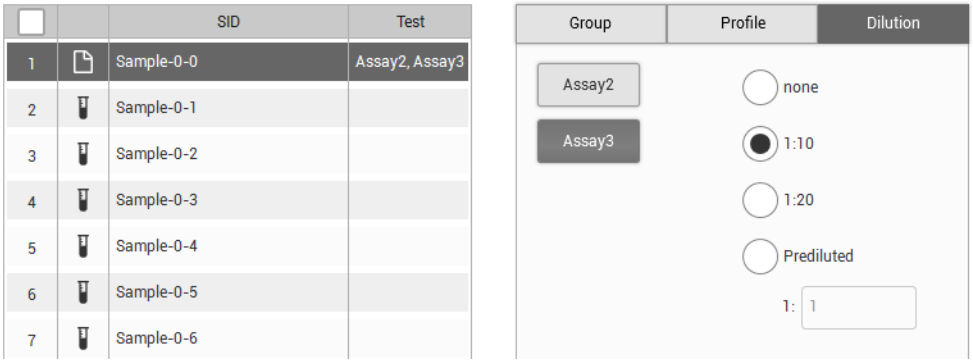


*Figure 3-49: **Dilution** tab*

4. Tap on the desired dilution factor.
The dilution factor is assigned to the selected sample, calibrator, or control.
5. Repeat the procedure for other samples, calibrators, or controls.

CANCEL AN ASSIGNMENT

Any assignment can also be canceled by selecting it again:

1. If not already selected, tap on the desired sample ID, calibrator ID, or control ID.
2. Assigned single test(s):
   a. Tap on the **Group** tab (3) on the right side of the screen.
   b. Tap on the selection list below the tabs to show a specific group of tests or all tests.
   All already assigned tests are marked dark gray in the **Group** tab.
   c. Tap on the desired test.
   The test assignment is canceled.
   d. If necessary, repeat the steps for further tests.
3. Assigned set of tests:
   a. Tap on the **Profile** tab (4) on the right side of the screen.
   All already assigned profiles are marked dark gray in the **Profile** tab.

b. Tap on the desired set of tests.
The set of tests assignment is canceled.
c. If necessary, repeat the steps for further set of tests.

4. If necessary, tap on the **STAT** button to cancel the assigment.

SELECT ALL OR SEVERAL

It is also possible to select all or several samples, calibrators, or controls to assign tests or STAT to them together:

1. Tap on the checkbox in the first column of table headings.
Instead of the position number in the lines an already marked checkbox appears.

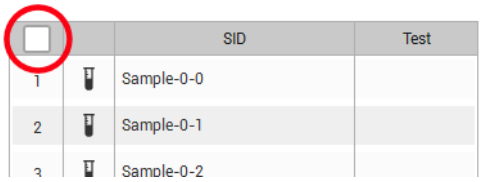


Figure 3-50: Top checkbox

2. If you wanted to select all samples, calibrators, or controls, you are now ready.
3. If you do not want certain samples, calibrators, or controls to be selected, you must tap on the respective checkbox to deselect them.
If you tap on the checkbox again, the respective checkmark is set again.

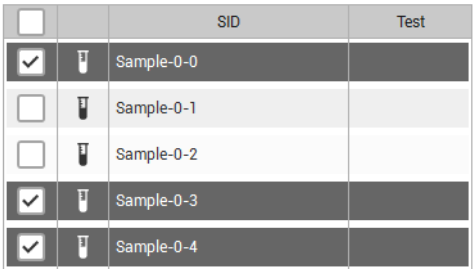


Figure 3-51: Checkboxes

4. If you want to deselect all lines, tap on the checkmark in the first column of table headings again.

3.4.1.3 MISSING ID (BARCODE ERROR)

In some cases it may happen that the barcode of a test tube cannot be read.

Troubleshooting:

CHECK BARCODE LABELS

1. Note the affected test tube position(s) on the screen and remove the affected sample rack.
2. Ensure that the barcode labels face towards the left (open side of the sample rack).
3. Check the barcode label of the affected test tubes:
   - on damages,
   - on wrinkle,
   - or on bad printing.
4. If possible, replace the affected barcode(s).
5. Insert the sample rack again.

EDIT SAMPLE ID(S)

If it is not possible to replace the barcode, it is possible to edit the ID of the affected test tube(s).

1. Tap on the desired sample rack symbol.
   The user software shows in the middle of the screen all IDs of each test tube.
2. Tap on the **Edit** button.
   The user software shows a screen to edit all unknown IDs.

Figure 3-52: Edit IDs screen

3. *Recall mode*: If you don't remember the barcode, you can use the *recall mode*:
   - **Don't** close the **Edit sample IDs** screen!
   - **Don't** change test tube positions!
   - Remove the affected sample rack.
   - Use the barcode labels for the next steps.
4. Tap on the field of the desired test tube with unknown ID.

5. Enter the ID.
   Calibrator IDs must start with $Cal.
   It is recommended to use max. 20 characters (letters, numbers, special characters) for the ID.
   Optionally, the barcode can also be scanned with a hand-held barcode scanner. The repeated entering of the ID is then not necessary.
6. Tap on the **Next** button.
7. Retype the ID.
8. Tap on the **Ok** button.
9. If necessary tap on the next marked test tube with unknown ID.
10. Insert the sample rack again.
    The user software closes the **Edit IDs** screen.
    All barcodes that were read automatically during the first rack insertion and all manually entered barcodes appear in the list.

Notice: The *recall mode* can be used any number of times **while** the **Edit IDs** screen is open.

3.4.2 LOAD OR UNLOAD REAGENTS

The reagent loading bay is used for loading reagents located in Reagent Cartridges into the instrument by means of so-called reagent racks. By means of the pipettor, the reagents can then be distributed in the course of a test run.
For positive reagent identification, the reagent loading bay is provided with a RFID label system. By means of this RFID label system, the RFID label, on the Reagent Cartridges can be read and used for identification. In addition, the system can read and write more information about the reagent (e.g. liquid level, expiration date).
The reagent loading bay supports loading of up to 8 reagent racks with 1 or 2 Reagent Cartridges on individual lanes.

⚠ WARNING

Improper loading or unloading of reagent racks
Improperly loaded or unloaded reagent racks can produce erroneous results due to incorrect pipetting activities.

- Only load and unload reagent racks if you are explicitly requested to do so.
- Only load and unload reagent racks on the specified lanes.
- Check the correct transfer or input of all reagent and sample names.

NOTICE

Do always push in the reagent racks into the reagent loading bay with the handle or pull it out again with the handle.

INFO

Never load more than one reagent rack at the same time! For proper RFID label identification the reagent racks must be loaded one after the other.

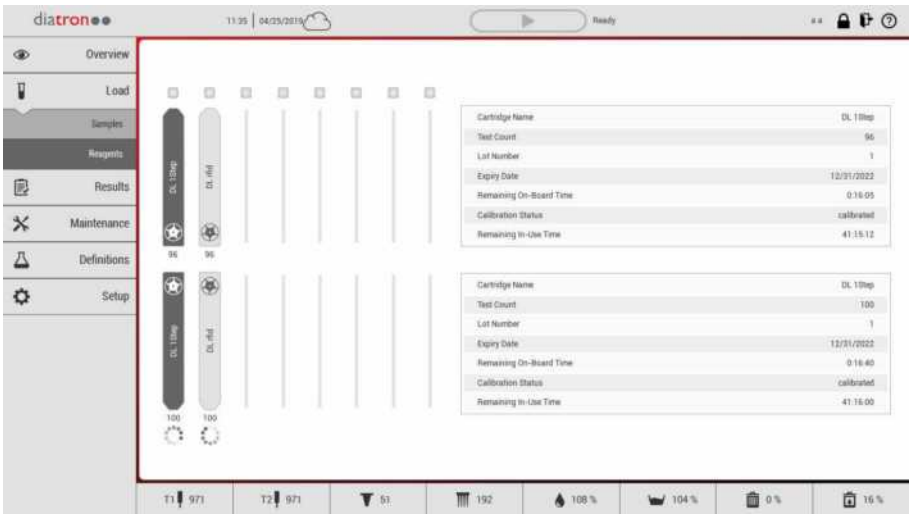


Figure 3-53: **Reagents** *screen*

STATUS INFO

The **Reagent** screen shows the status of individual Reagent Cartridges and reagent racks:

Symbol/Time	Description
	Please wait while the RFID label is read and the particles are shaken up.
	Shaking magnetic beads.
Name	Name of the Reagent Cartridge.
No cartridge	Empty position in the reagent rack.
Number	Number of remaining test count (shown below the Reagent Cartridge).
	Error: • Expiration date or the on-board stability is expired. • No valid calibration curve is available. • The remaining test count of the Reagent Cartridge are zero. See error message in the information box on the right side!

Table 3-5: Status info

PROCEDURE/ SHOW INFORMATION

1. Tap on the **Load** button in the main menu bar to show the **Load** screen.
2. Tap on the **Reagents** button below the **Load** button.

LOADING

Before a Reagent Cartridge is utilized, it must first be prepared. The mandatory instructions on the packaging box of the Reagent Cartridges must be strictly followed.

1. Remove the desired Reagent Cartridge from the package.
   Keeping the Reagent Cartridge in an upright position at all times.
2. Prepare the Reagent Cartridge according to the instruction for use of the relevant assay for details.
3. Load one or two Reagent Cartridges into the reagent rack.

Figure 3-54: Reagent rack with two Reagent Cartridges

4. Keep the rack straight and move it jerkily from top to bottom. This movement is intended to loosen the liquid from the sealing foil and the top edge. Repeat the jerky movement if necessary.
5. Remove the foil from the Reagent Cartridge(s).
6. Open the reagent loading bay flap.
7. Push the reagent rack carefully into the desired lane, press the white button (1) and press the handle against the pressure of the spring, until it engages with an audible click.
   While the reagent rack is introduced in the lane, the RFID label of the Reagent Cartridges are read automatically.

Figure 3-55: Reagent loading bay

8. Tap on the screen on the loaded reagent rack symbol to get information about the Reagent Cartridges.
9. Close the reagent loading bay flap.

UNLOADING

1. Open the reagent loading bay flap.
2. Press the white button (1) on the handle of the unused/finished reagent rack and press the handle a short-time against the pressure of the spring. The reagent rack is set free.
   Pay attention to the corresponding state of the reagent loading lane in the user software.
3. Remove the reagent rack carefully.
4. Close the reagent loading bay flap.
5. Store the Reagent Cartridge(s) according to the consumable information (package insert) or dispose it according to the local and national provisions, legislation and laboratory regulations.

3.5 RESULTS

The **Results** screen gives information about all results of the process, calibration curves, reports and the event log.
On the KleeYa instrument, it is not necessary to wait for the entire processing to be finished to view the results. As soon as the processing of one sample test, calibration, or control is finished, the instrument generates the result for it. The completed results can be accessed via the main category **Results** as well as its several sub categories.

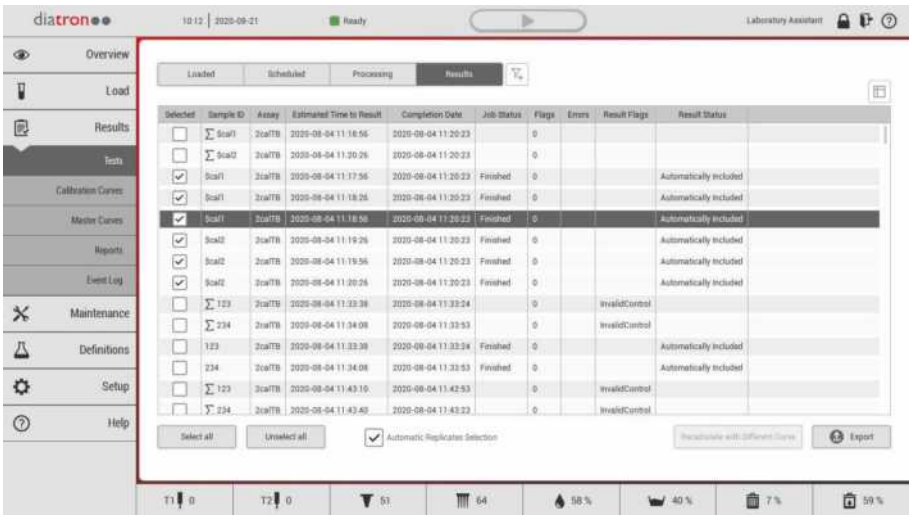


Figure 3-56: **Results - Tests** *screen*

PROCEDURE

1. Tap on the **Results** button in the main menu bar to show the **Results** screen.
2. Below the **Results** button appears a sub menu with further buttons:
   - **Tests**: Tap on the button to show the **Tests** screen (see chapter 3.5.2 on page 3-64). The screen shows information about all samples in different states.
   - **Calibration Curves**: Tap on the button to show the **Calibration Curves** screen (see chapter 3.5.3 on page 3-68). The screen shows information about the created calibration curves.
   - **Master Curves**: Tap on the button to show the **Master Curves** screen (see chapter 3.5.3 on page 3-68). The screen shows information about the created master calibration curves.
   - **Reports**: Tap on the button to show the **Reports** screen (see chapter 3.5.4 on page 3-70). The screen shows information about different reports (e.g. Sample Results Report).

- **Event Log**: Tap on the button to show the **Event Log** screen (see chapter 3.5.5 on page 3-72). The screen shows information about all events and errors.

See chapter 3.5.1 on page 3-61 for using filters or setting table columns.

3.5.1 FILTER AND TABLE HEADER

3.5.1.1 USE OF FILTER

The filter function makes it possible to focus on the results of highest interest.

PROCEDURE

New filter:

1. Tap on the **Add filter** button above the table to create a new filter.
2. Select the desired **Filter Type**.

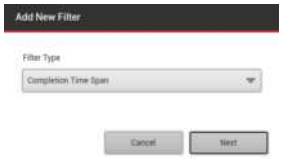


*Figure 3-57: **Add new Filter** window*

3. Tap on the **Next** button.
   Depending on the selected filter, a further window appears in which the corresponding filter value(s) can be entered.

Figure 3-58: Filter value window

4. Enter the desired filter value(s).
   The user software shows the filter result in the background.
5. Tap on the **OK** button to activate the filter.

Edit filter value(s):

1. Tap on the desired filter above the table.
2. Edit the filter value(s).
3. Tap on the **OK** button to activate the changed filter.

Delete filter:

1. Tap on the **X** button of the desired filter.

or

1. Tap on the desired filter above the table.
2. Tap on the **Delete** button.

Combine filters:
In order to get a detailed result list, different filters can be combined with each other. Functionality: The second filter is applied to the results of the first filter (AND combination). Further filters can also be added to the combination.

1. Create the first filter (see add).
2. Create the second filter (see add).
3. If necessary, create further filters.

3.5.1.2 CONFIGURE TABLE HEADER

The configure table header function makes it possible to define the column setup being most suitable for your application.

PROCEDURE

1. Tap on the **Configure table header** button above the table to show the **Configure Table Header** window.

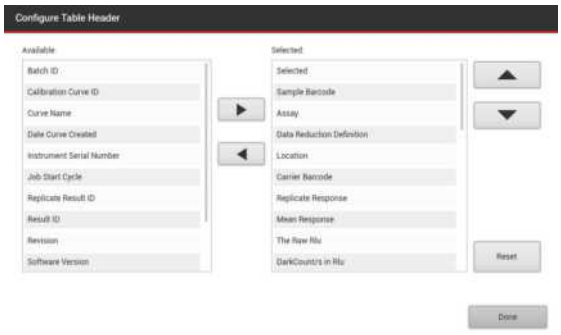


*Figure 3-59: **Configure Table Header** window*

Functions:

Available	Shows all available columns for the table.
	Moves a selected column entry from the **Available** table to the **Selected** table. Moves a selected column entry from the **Selected** table to the **Available** table.
Selected	Shows all chosen columns for the table. Only this columns will be shown in the table.
	Allows to change the order of the shown columns in the table. Select an entry in the **Selected** table. Tap on the **Up** or **Down** button to change the order.

2. Select the desired table columns.
3. Define the desired order of the columns.

4. Tap on the **Done** button to activate the configuration.

Reset the user configuration:

1. Tap on the **Configure table header** button above the table.
2. Tap on the **Reset** button to the table configuration back to the default configuration.

3.5.2 TESTS

The **Tests** screen shows all results since the last database maintenance. If filters are activated, only the respective results are displayed. The table contains information on all tests in each job status (scheduled, loaded, processing, finished, canceled, data reduction pending).

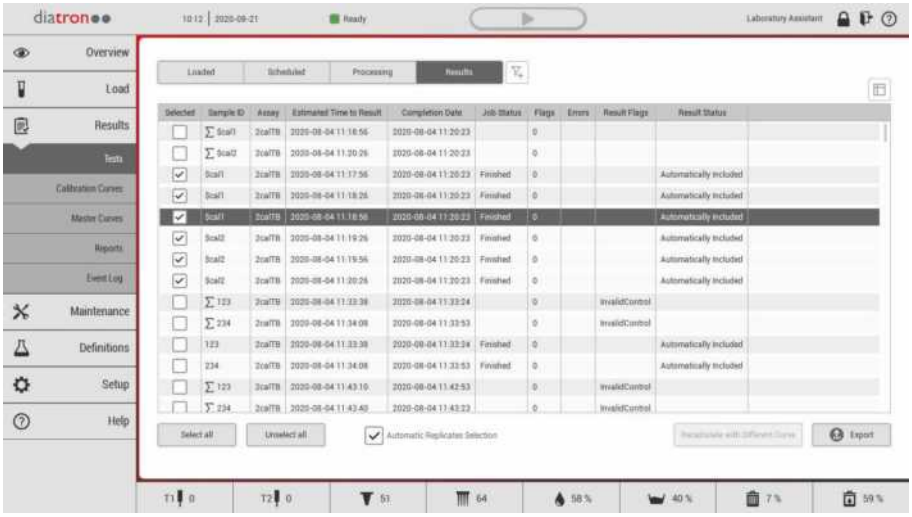


Figure 3-60: **Results - Tests** *screen*

GROUPS

The **Tests** screen is divided into four groups:

Loaded group	Shows all loaded samples, calibrators, or controls, their assigned tests and the position in the loading bay and rack. If multiple tests have been assigned, the sample is displayed multiple times. Empty positions on loaded racks are also shown but without Sample ID.
Scheduled group	Shows all scheduled samples, calibrators, or controls and their expected finalization. Additional information can be shown via column configuration.
Processing group	Shows all scheduled and currently processed samples, calibrators, or controls and their expected finalization. Additional information can be shown via column configuration.
Results group	Shows all samples, calibrators, or controls in all Job Status. Shows test results of finished tests. Additional information can be shown via column configuration.

Table (depending on the selected group and column configuration):

Selected	Allows to select one or more result lines.
Sample ID	Shows the ID of the sample, calibrator, or control.
Assay	Shows the assay used for the test. If several tests have been made with one sample, the test results appear in separate lines.
Estimated Time to Result	Shows until when the test result is expected.
Completion Date	Shows when the test result was available.
Result Flags	Shows all result flags.
Result Status	Shows the status of the test result.
Job Status	Shows the current test status (e.g. **Finished**).
Flags	Shows the number of flags for the test.
Errors	Shows the errors that occurred during the test.

Further columns that can be selected via the configure column function:

%CV Conc	Shows the %CV value of the concentration of all replicates for this assay.
%CV Response	Shows the %CV value of the replicate response calculated from all replicates for this assay.
Batch ID	Shows the batch ID (consecutive number).
Batch Name	Shows the batch name „Batch dd/mm/yyyy hh:mm“.
Calibration Curve ID	Shows the ID of the calibration curve that was used for result generation.
Carrier Barcode	Shows the sample rack type.
DarkCount /s in RLU	Shows the dark count value per second. Background value of the measurement unit which is used to correct the RLU value (Response = Raw RLU – Dark count). Dark count measurement is done for 0.5 s before each measurement.
Date Curve Created	Date and time when the calibration curve was created that was used for result calculation.
Dilution Description	Shows the dilution description „1:dilution factor“.
Dilution Factor	Shows the dilution factor.
Instrument Serial Number	Shows the serial number of the instrument.
Job ID	Shows the Job ID (consecutive number).
Job Start Cycle	Shows the Job Start Cycle (consecutive number).

Location	Shows the sample position (Lane, Position).
Mean Conc.	Shows the mean concentration of all replicates of the sample for this assay.
Mean Response	Shows the mean RLU value of all replicates of the sample for this assay (dark count corrected value).
Reagent Lots	Shows the lot number of the Reagent Cartridge(s).
Replicate Conc.	Shows the concentration of the sample in the unit defined by the assay developer.
Replicate Response	Shows the RLU value of the sample (dark count corrected value).
Result Label	Shows all result labels.
Sample Type	Shows the sample type (Specimen, Control, Calibrator, Recalibrator).
SD Conc.	Shows the standard deviation of the concentrations of all replicates of the sample.
SD Response	Shows the standard deviation of the response values of all replicates of the sample.
Test Order ID	Shows the test order ID (consecutive number).
The Raw RLU	Shows the raw RLU value without dark count correction.
Unit	Shows the concentration unit defined by the assay developer.
Used Reagents	Shows the names of all used reagents.
User Concentration	Shows the concentration of the sample in the user unit defined in **Definitions > Assays > General > Parameters**.
User Name	Shows the user who started the test.
User Unit	Shows the user unit defined in **Definitions > Assays > General > Parameters**.

Functions (depending on the selected group):

Select all	Select all run results.
Unselect all	Unselect all run results.
Automatic Replicates Selection	Selects all run result replicates of a sample.
Recalculate with Different Curve	Allows to recalculate the selected result with an other calibration curve. The result must be generated within the recalculation period which is set in the assay definition by the assay developer.
Export	Exports all selected run results as ".csv" file.

Allows the use of filters (see chapter 3.5.1.1 on page 3-61).

Allows to configure the table columns (see chapter 3.5.1.2 on page 3-62).

PROCEDURE

1. Tap on the **Results** button in the main menu bar to show the **Results** screen.
2. Tap on the **Tests** button to show the **Tests** screen.
3. Tap on the desired group to show the results of this group.
4. Tab on the desired line in the table to start further actions.

3.5.3 CALIBRATION AND MASTER CURVES

The **Calibration Curves** screen and the **Master Curves** screen show information of all created calibration curves and the underlying master calibration curves.

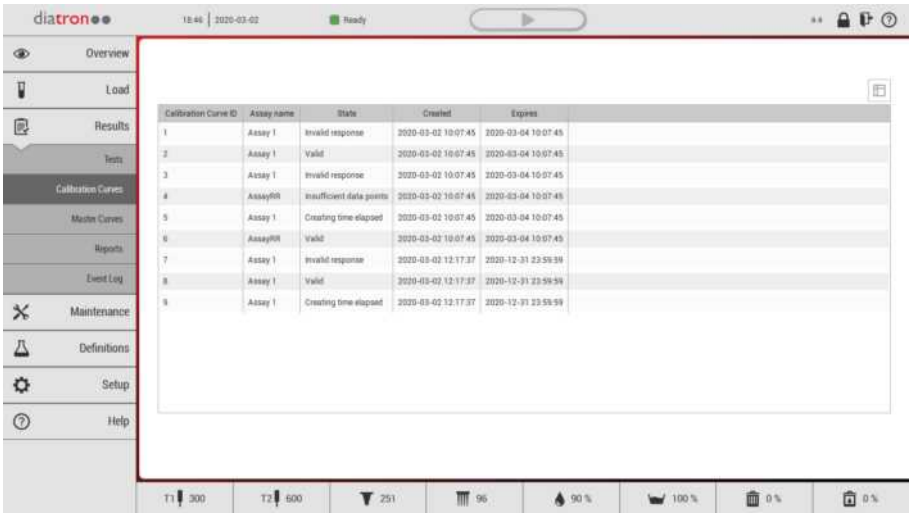


Figure 3-61: **Results - Calibration Curves** *screen*

Calibration curves (also standard curves or working curve) are used to compensate the differences between reagent lots, different analyzers and environmental conditions. To generate a calibration curve an assay calibration must be run and validated according to the indications reported in the instructions for use of the assay (indications may vary per assays).
The results are calculated in comparison to a calibration curve.

The specific reference curve (master curve) for a reagent lot is provided by the vendor of the Reagent Cartridge (see instruction for use of the relevant assay for details). If a new reagent lot is used, this curve must be loaded on the database and then adjusted by a calibration before sample results can be calculated.
The measuring signals of the calibrators allow the shift of all master curve points to a working curve, corresponding with the actual conditions during measurement.

The stored master curve is generally specified with a defined number of master curve base points.

- In dependence of the assay a pre-defined number of calibrators with known concentration values are measured. These measured signals (RLU) are compared with the master curve signal of the corresponding calibrator concentrations.
- The relative difference between the measured RLU and the master RLU of the calibrators is calculated.
- Based on appropriate compensation factors, a re-adjustment of the master curve points is made in order to achieve, the working curve.

Example:

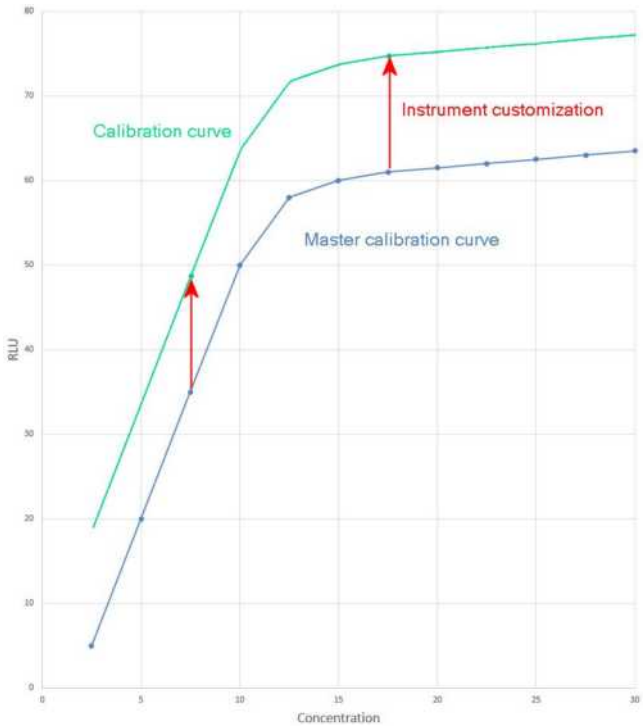


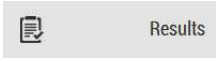
Figure 3-62: Calibration and master curves

A measured calibration curve can be exported and imported as master curve to transfer the data to different instruments as file. Alternatively, master curves can be delivered as 2D barcodes on the recalibrators with assay reagent kits (see instruction for use of the relevant assay for details, indications may vary per assays). A master curve always needs a recalibration on the instrument in order to create a valid calibration curve for dose calculation.

Functions:

	Allows to configure the table columns (see chapter 3.5.1.2 on page 3-62).
Import	*Only for Master Curves!* Allows the import of a master curve from a file.
Delete	*Only for Master Curves!* Allows the delete a selected master curve.

PROCEDURE



1. Tap on the **Results** button in the main menu bar to show the **Results** screen.
2. Calibration or master curves:
   - Tap on the **Calibration Curves** button to show the **Calibration Curves** screen.
   - Tap on the **Master Curves** button to show the **Master Curves** screen.

3.5.4 REPORTS

The **Reports** screen allows reports of results, calibration curves, used reagents, controls, messages, and maintenance as formatted output. The reports can be printed and/or saved as PDF or XLS files.

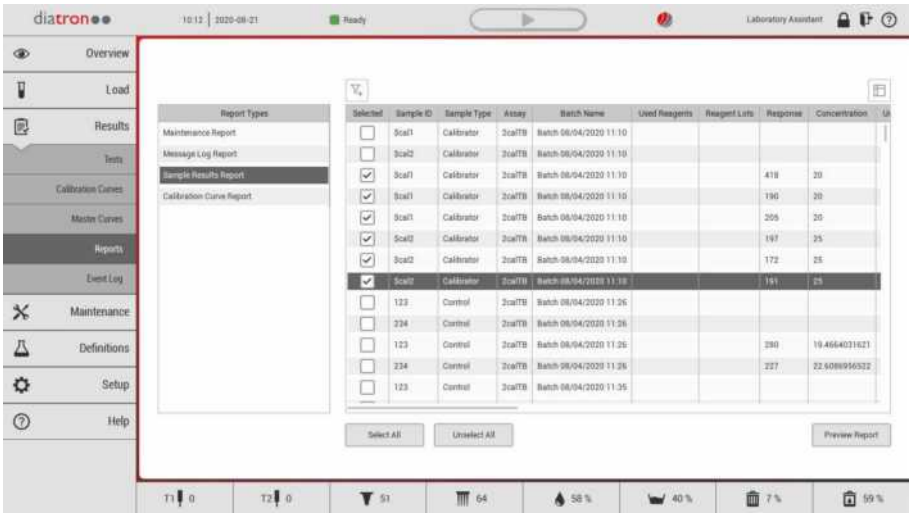


Figure 3-63: **Results - Reports - Sample Results Report** *screen*

GROUPS

The **Report** screen is divided into **Report Types** groups:

Maintenance Report group	Shows which maintenance tasks have been carried out.
Message Log Report group	Shows the event log as report.
Sample Results Report group	Shows all results of all performed tests.
Calibration Curve Report group	Shows the results of the last calibration curve.

Functions:

Select all	Select all entries.
Unselect all	Unselect all entries.
Preview Report	Generates a formated report of all selected entries. The reports can be printed and/or saved as PDF files.
	Allows the use of filters (see chapter 3.5.1.1 on page 3-61).
	Allows to configure the table columns (see chapter 3.5.1.2 on page 3-62).

PROCEDURE

1. Tap on the **Results** button in the main menu bar to show the **Results** screen.
2. Tap on the **Reports** button below the **Results** button.
   Next to the button appears another menu with the **Report Types** groups.
3. Tap on the desired **Report Types** group.
4. Tap on the desired entries or tap on the **Select All** button to select all desired entries.
5. Tap on the **Preview Report** button.

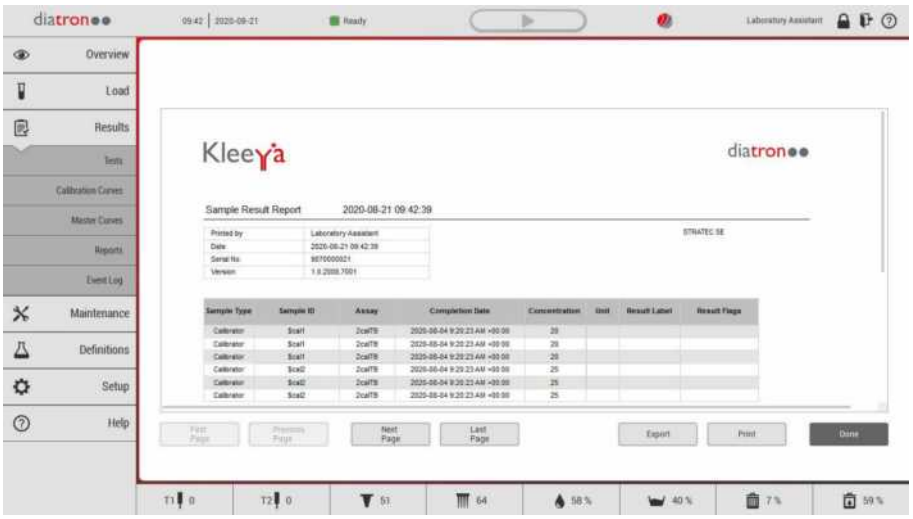


Figure 3-64: **Preview Report** *screen*

6. Use the functions of the **Preview Report** screen.

First Page	Shows the first page of the report.
Previous Page	Shows the previous page of the report.
Next Page	Shows the next page of the report.
Last Page	Shows the last page of the report.
Export	Exports report as PDF or XLS file.
Print	Prints the report.
Done	Returns to the previous report screen.

3.5.5 EVENT LOG

The **Event Log** screen shows all instrument messages (information, warning, or error messages). The newest message is on the top of the list.

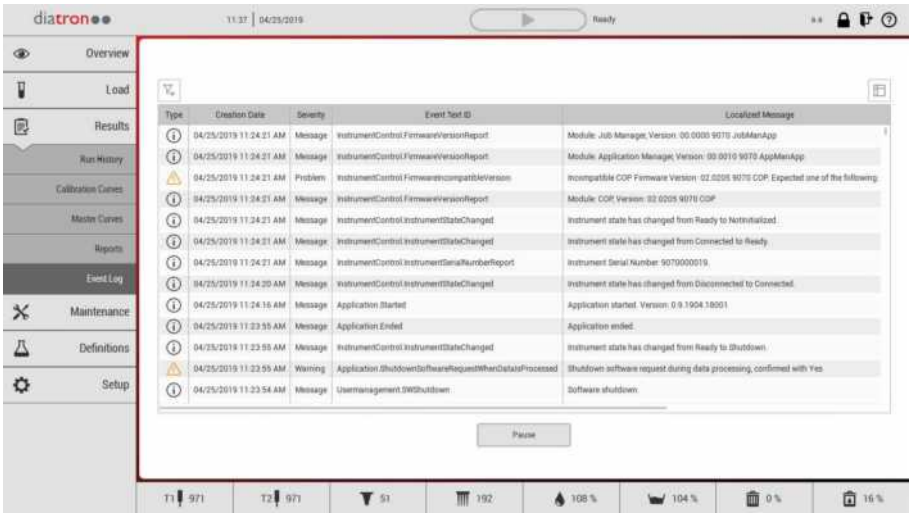


Figure 3-65: **Results - Event Log** *screen*

Functions:

Pause	This function allows you to interrupt the automatic updating of the table. This allows you, for example, to view older entries without the display jumping to the first line of the table when a new entry is made. New entries are not lost due to the interruption.
Resume	Starts the automatic updating of the table after the pause.
	Allows the use of filters (see chapter 3.5.1.1 on page 3-61).
	Allows to configure the table columns (see chapter 3.5.1.2 on page 3-62).

COLOR/SYMBOL CODE

All messages according to their increasing severity:

Information messages

An information message shows only information and no errors.

- The instrument works without problems
- An intervention of the user is not necessary

Warning messages

A warning message shows/requires:

- a problem of the instrument, which could be fixed. The instrument continues to work
- a problem that arises when the user does not intervene (e.g. a resource will be empty soon)
- the user should intervene as soon as possible

Error messages

An error message shows/requires:

- a failure (malfunction) of the instrument
- a stop of the instrument because of missing resources
- the user must intervene in all cases of an error message

PROCEDURE

Results

1. Tap on the **Results** button in the main menu bar to show the **Results** screen.
2. Tap on the **Event Log** button to show the **Event Log** screen.

3.5.5.1 MESSAGES IN THE NOTIFICATION AREA

The notification area on the **Overview** screen shows open maintenance tasks and event/error messages.

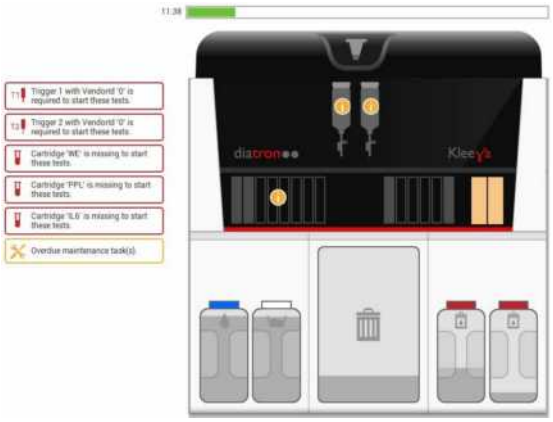


Figure 3-66: **Overview** *screen - messages*

COLOR/SYMBOL CODE

All messages according to their increasing severity:

Orange Orange notifications show/requires:

- a problem that arises when the user does not intervene (e.g. a resource will be empty soon)
- a maintenance task that is due but does not block sample processing
- the user should intervene as soon as possible

Red Red notifications show/requires:

- the reasons why no or not all tests can be started: e.g.
  - missing resources to start assigned tests
  - due maintenance tasks that block sample processing
- the user must intervene in all cases of a red notification

PROCEDURE

1. Tap on the **Overview** button in the main menu bar to show the **Overview** screen.
2. Tap on the task or message to get further information.

3.6 MAINTENANCE

The **Maintenance** screen gives an overview about the maintenance tasks (e.g. Start of Day Maintenance Task) and allows performing necessary maintenance tasks to obtain the KleeYa instrument performance.

INFO

Special access rights
In most cases, special access rights are required for the described functions (e.g. edit, delete).

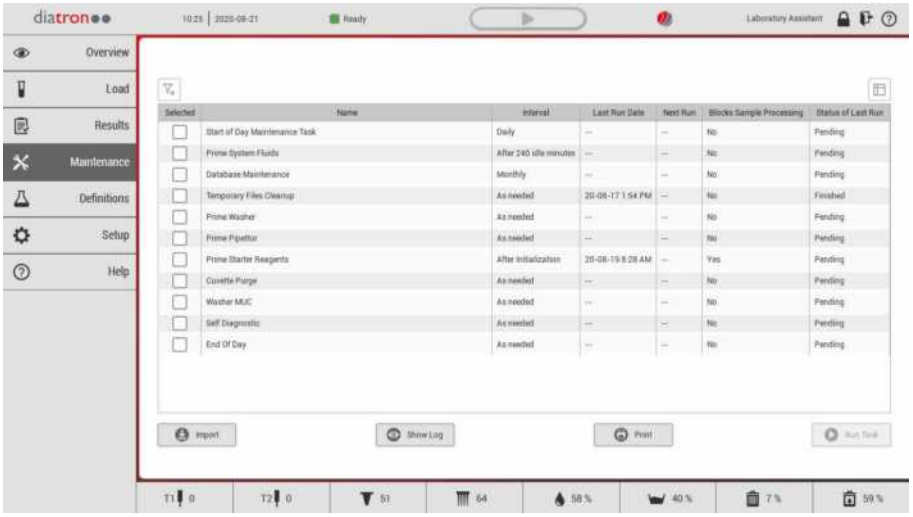


Figure 3-67: **Maintenance** *screen*

The **Maintenance** screen shows all available maintenance tasks with the most important details in a table. The table shows the following columns:

Selected	Tap on the box to tick a maintenance task. The tick can be removed again by tapping again. It is also possible to select several lines.
Name	Shows the name of the maintenance task.
Interval	Shows the necessary interval to run the maintenance task.
Last Run Date	Shows the date/time of the last run.
Next Run	Shows the date/time of the next scheduled run.
Blocks Sample Processing	Shows whether further processing of tests is blocked until the necessary open maintenance task is executed.

Status of the Last Run	Shows the state of the last run.
	Allows the use of filters (see chapter 3.5.1.1 on page 3-61).
	Allows to configure the table columns (see chapter 3.5.1.2 on page 3-62).

PROCEDURE

1. Tap on the **Maintenance** button in the main menu bar to show the **Maintenance** screen.
2. Tap on a button below the table to call various functions:
   Note that depending on the number of selected maintenance tasks, not all functions are available.

Import	Allows to import (new) maintenance tasks. Tasks with an existing name cannot be imported. In this case, the existing task must be deleted before it can be imported.
Show Log	Switches to the **Event Log** screen (see chapter 3.5.5 on page 3-72).
Print	Prints the maintenance tasks on the standard printer.
Run Task	Allows to start one or more selected maintenance tasks (see chapter 3.6.1 on page 3-77).

See chapter 3.5.1 on page 3-61 for using filters or setting table columns.

3.6.1 RUN OF A MAINTENANCE TASK

The **Perform Task** window shows details of a running maintenance task.

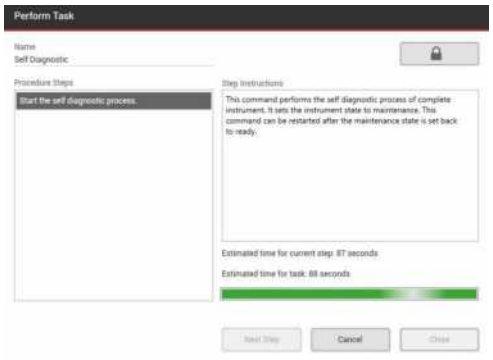


Figure 3-68: **Perform Task** *window*

Lock	**Log off** button to log off the current user. Started maintenance tests are executed further. Another user cannot use the instrument during this log off time.
Next Step	Some tasks may require confirmation before they are run. For example if results are deleted from view by execution of a maintenance task a message is shown and confirmation is given by tapping the **Next Step** button.
Cancel	Cancel the current running maintenance task. After canceling a maintenance task, the instrument starts initialization.
Close	Closes the window after processing or canceling.

PROCEDURE

1. Tap on the **Maintenance** button in the main menu bar to show the **Maintenance** screen.
2. Select one or more maintenance tasks
3. Tap on the **Run Task** button below the table to start the maintenance task(s).
4. Follow the maintenance instructions (step) on the screen.
5. Tap on the **Next Step** button to go to the next maintenance step.
6. Repeat the previous step for all maintenance steps.
7. Tap on the **Close** button after the last maintenance step.

3.7 DEFINITIONS

INFO

Special access rights
In most cases, special access rights are required for the described functions.

The **Definitions** screen gives information about assays, controls and data reduction.

PROCEDURE

1. Tap on the **Definitions** button in the main menu bar to show the **Definitions** screen.
2. Below the **Definitions** button appears a sub menu with further buttons:
   - **Assays**: Tap on the button to show the **Assay** screen (see chapter 3.7.1 on page 3-79). The screen allows to select an available assay and shows information about it or allows to edit it. It is also possible to import/ export assays from/to an external source or to add assays from scratch.
   - **Groups & Profiles**: Tap on the button to show the **Groups & Profiles** screen (see chapter 3.7.2 on page 3-82). The screen shows information on defined groups and profiles and allows to add/delete groups and profiles.
   - **Controls**: Tap on the button to show the **Controls** screen (see chapter 3.7.3 on page 3-84). The screen shows information about used controls and allows to edit/add controls.

3.7.1 ASSAYS

The **Assay** screen allows to select an assay from the assay list on the instrument and shows information about the selected assay or allows to edit assay parameters. On the Assay screen it is also possible to import assays from an external source.

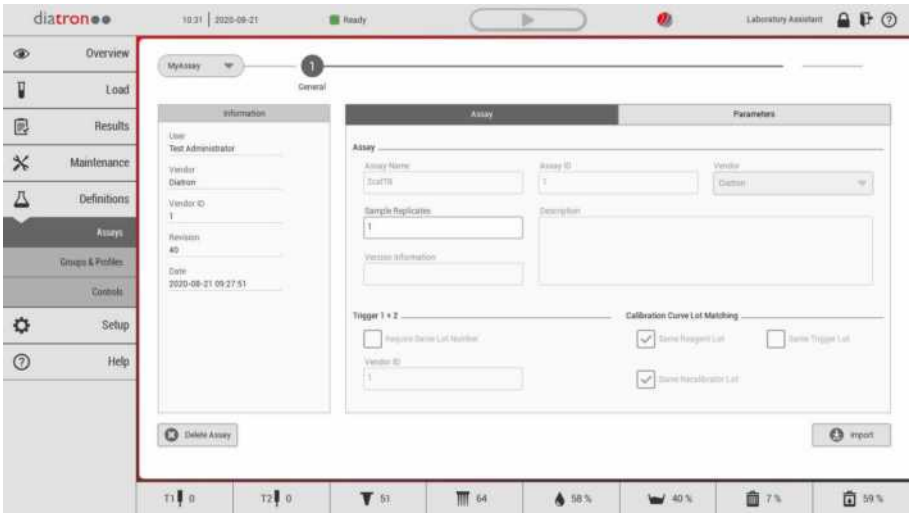


Figure 3-69: **Definitions - Assays** *screen*

Functions of the **Information** field:

User	Shows the user who created or last changed the assay.
Vendor	Shows the supplier of the assay.
Revision	Shows the revision number of the assay.
Date	Shows the date and time the assay was created or last modified.

INFO

Specifications
The following specifications of the assay shall be taken from the instruction for use or consumable information (package insert) of the relevant assay and Reagent Cartridges!

Assay sub tab (figure see above):
Functions of the **Assay** field:

Assay Name	Name of the assay. The assay name must be unique and must not be longer than 8 characters.
Assay ID	Shows the ID of the assay.

Vendor	Shows the supplier of the assay.
Sample Replicates	Number of sample replicates.
Version Information	Versions information entered by assay developer.
Description	Assay description entered by assay developer.

Functions of the **Trigger 1 + 2** field:

Require Same Lot Number	Allows to check the trigger LOT numbers. The assay is then only executed if the LOT numbers match.
Vendor ID	ID of the supplier.

Functions of the **Calibration Curve Lot Matching** field:

Same Reagent Lot	Allows to check the reagents LOT numbers. The assay is then only executed if the LOT numbers match.
Same Trigger Lot	Allows to check the trigger LOT numbers. The assay is then only executed if the LOT numbers match.
Same Recalibrator Lot	Allows to check the recalibrator LOT numbers. The assay is then only executed if the LOT numbers match.

Parameters sub tab (shows laboratory specific parameters):

Figure 3-70: **Parameters** *sub tab*

Functions of the **User Unit** field:

Enable	Enables laboratory specific unit different from the unit set by the assay developer.
User Unit	Unit that will be shown for assay results.
User Concentration	Factor for conversion from unit to user unit

Functions of the **Reruns** field:

Allows Reruns	Allows reruns of the assay. The rerun rules are set by the assay developer.

Functions of the **Laboratory Normal Result Range** field:
Laboratory specific result range: Different to the assay range but within the assay range set by the assay vendor.

Minimum	Lower limit of laboratory normal result range (must be equal or higher than lower limit of assay range).
Maximum	Upper limit of laboratory normal result range (must be equal or lower than upper limit of assay range).

Generals functions:

Delete Assay	Allows to delete the selected assay.
Import	Allows to import (new) assays. It is not possible to import an assay that has the same name as an existing assay. It is possible to give the assay a new name during import.

PROCEDURE

1. Tap on the **Definitions** button in the main menu bar to show the **Definitions** screen.
2. Tap on the **Assay** button to show the **Assay** screen.

View/edit an assay:

INFO

Editing assays is only possible if no results are available for this assay. Assays can only be edited if they have never been started or after database maintenance has been carried out.

1. Tap on the assay selector arrow (next to step 1) to select an assay.
2. View or edit the values of step 1 (General).
   Please note the following sub-chapters.
3. Tap on the next steps and view/edit the values.

3.7.2 GROUPS & PROFILES

The **Groups & Profiles** screen shows information on defined groups and profiles for tests (assays) and allows to add/edit/delete groups and profiles.
The **Groups & Profiles** screen is divided into two groups:

Groups	Shows all groups. A group allows the thematic sorting of single tests.
Profiles	Shows all profiles. There is the possibility to arrange several assays as a profile. If the user assigns assays to samples, they can select a profile instead of all affected assays. In this way, it is possible to simplify recurrently test arrangements.

Lists:

Groups/**Profiles**	Shows all groups or profiles.
Assays	Shows all available assays. Selected Assays have a dark background. The **Group Name**/**Profile Name** field allows to edit the name.
Selected Assays	Shows all selected assays of the chosen group or profile.

Functions:

Add	Allows to add a group or profile.
Delete	Allows to delete the selected group or profile.

PROCEDURE

1. Tap on the **Definitions** button in the main menu bar to show the **Definitions** screen.
2. Tap on the **Groups & Profiles** button to show the **Groups and Profiles** screen.
3. Tap on the **Groups** or **Profiles** button.

Add a group or profile:

1. Tap on the **Add** button.
2. Enter the new group or profile name.
3. Tap on the **Create** button.
   The new group or profile is added to the list.

Edit a group or profile:

1. Tap on the desired group or profile name.
2. If necessary, edit the group or profile name in the **Assays** area.
3. If necessary, select or unselect one or more test(s) in the **Assays** area.
   All assigned test(s) are displayed in the **Selected Assays** list.
   All assigned tests are marked dark gray in the **Assays** area.

Delete a group or profile:

1. Tap on the desired group or profile name.
2. Tap on the **Delete** button.

INFO

Edit or delete a group or profile

Editing a group/profile has no effect on assignments already created. Assignments between samples/calibrators/controls and groups/profiles are only realized via direct test assignments.

3.7.3 CONTROLS

The **Controls** screen shows information on defined controls and allows to add/ delete controls.
All Quality Control samples being used contain a fixed concentration (target value) for a specific analyte. By testing this sample with the analytical method it should produce an expected result. If one or more results of control samples have a difference from the expected results, an issue in the analytical system or method may be detected.
To find out if a control result indicates an analytical problem, the control results are evaluated based on either the target value range (defined by the actual manufacturer of the control material) or on “intra-laboratory” limits. Intra-laboratory limits have to be calculated for each combination of: Analyzer instrument, method (assay), control material and control material lot.

Before the control is utilized by the user, it must first be prepared. The instruction on the packaging box or the package insert must be strictly followed.

- Check that the control volume is sufficient to run the required amount of tests (as described in the consumable information (package insert) on the kits being used).
- Check the control specific consumable information (package insert) for control specific preparation.

Table:

Name	Shows the name of the control (1-20 characters).
Lot Number	Shows the LOT number of the kit. If it is a kit control the lot has to match with reagent lot. Controls are provided by various vendors. The system provides the possibility to define either controls connected to kit loaded on the instrument (lot number mandatory, kit control) or to define external controls from different vendors (routine). For details on the controls please refer to the instruction for use provided by the vendor of the control.
Control ID	Shows the unique ID of the control (barcode).
Expires	Shows the expiration date of the control.
Type	Shows whether it is a routine or kit control. After pressing the **Add** button the view switches to the **Details** view.

Functions:

Add	Allows to add a control.
Delete	Allows to delete the selected control.
Details	Allows to view details of the selected control.
Print	Allows to print the selected control.
Copy	Allows to copy the selected control with all its parameters except the control ID. After assigning a new **Control ID**, changes in the assay assignment can be made.
QC now	Starts the QC now software. The QC now software provides long-term statistics of control results. The button is only visible if the QC now software is installed on the instrument. QC now is a software add-on to the KleeYa instrument to support the Quality Control of all parameters performed on the KleeYa instrument. The main purpose of this add-on is to provide the user access to the performance of their Quality Control samples in order to control the integrity of the analytical results.
	Allows the use of filters (see chapter 3.5.1.1 on page 3-61).
	Allows to configure the table columns (see chapter 3.5.1.2 on page 3-62).

PROCEDURE

1. Tap on the **Definitions** button in the main menu bar to show the **Definitions** screen.
2. Tap on the **Controls** button to show the **Controls** screen.

Add a control (to manually add controls if no 2D Code on the control vial is provided)**:**

1. Tap on the **Add** button.
   The details view opens to enter the parameters for the new control (see chapter 3.7.3.1 on page 3-86).
2. Enter the name of the new control.
3. Select the type of the new control.
4. Enter the lot number.
5. Select the expiration date of the new control.
6. Enter the unique control ID (barcode). Via the control ID the sample will be recognized as the new control.
7. Tap on the **Add** button to be able to assign an assay and set the validation parameters (see chapter 3.7.3.1 on page 3-86).
   Repeat this step if the control is used in multiple assays.
8. Tap on **Close Details** to close the details view. The new control is visible in the list of all controls.

Show details of a control/edit a control:

1. Tap on the desired control in the table.
2. Tap on the **Details** button (see chapter 3.7.3.1 on page 3-86).

Delete a control:

1. Tap on the desired control in the table.
2. Tap on the **Delete** button.

3.7.3.1 DETAILS OF A CONTROL

The details screen shows all settings and assignments of a control.

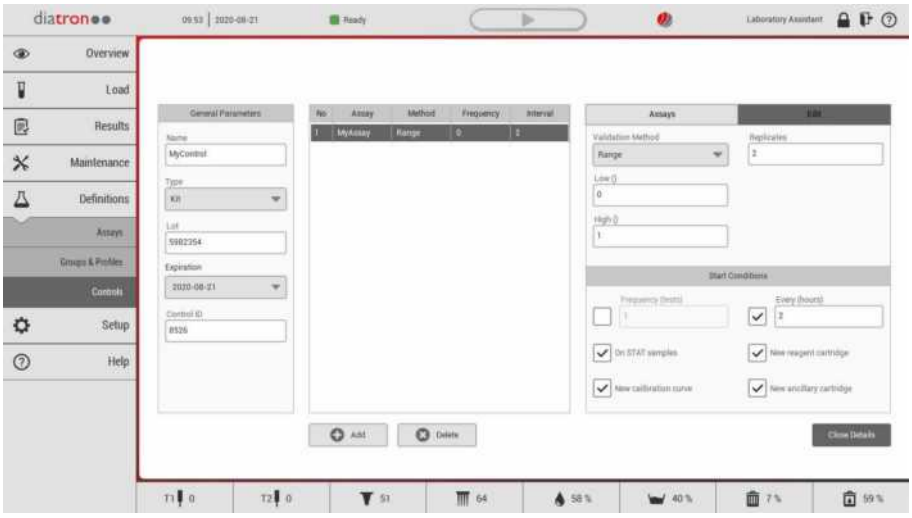


Figure 3-71: Details screen

General Parameters field:

Name	Name of the control.
Type	**Routine** control or control of a **Kit**.
Lot Number	LOT number of the kit. Must be entered for kit control and can be empty for routine control. Controls are provided by various vendors. The system provides the possibility to define either controls connected to kit loaded on the instrument (lot number mandatory, kit control) or to define external controls from different vendors (routine). For details on the controls please refer to the instruction for use provided by the vendor of the control. Only Controls with Lot number will be transfered to QC now. Enter any number for routine controls that shall be transferred to QC now.

Control ID	Unique ID (barcode) of the control.
Expiration	Expiration date of the control.

Assigned **Assay** list:

No	Sequential number of assigned assays.
Assay	Name of the assigned assay.
Method	Shows the chosen validation method (see **Edit** tab).
Frequency	Shows after how many tests (with the same assigned assay) a test with this control is performed.
Interval	Shows after how many hours a test with this control should be performed.

Functions:

Add	Allows to assign an assay.
Delete	Allows to delete the selected assay.
Close Details	Closes the details screen.

ASSAYS TAB

The **Assays** tab shows all available assays. The selected Assay has a dark background and is also shown in the assigned/selected **Assay** list line.

EDIT TAB

Validation Method

Allows to select the validation method from the drop-down menu:

- **Range**: Allows to define the concentration range for control validation. The control will be only valid if the measured concentration is within this range.
- **CV/SD**: Allows to define the concentration range for control validation. The control will be only valid within the concentration range mean +/- 2 SD. (E.g. mean=100; 2 SD=10 --> control will be valid if the concentration is in the range from 90 to 110.)
- **CV%**: Allows to define the Coefficient of Variation in % for control validation. The control will only be valid if the CV% of replicates does not exceed this value.
- **Cutoff**: Allows to select a cutoff value for the control type. A negative control will only be valid if its concentration is below the cutoff value. A positive control will only be valid if its concentration is above the cutoff value.

Validation method parameters

Validation method **Range** (Accuracy Control):

- **Low (concentration unit)**: Specifies the lower concentration range value.
- **High (concentration unit)**: Specifies the higher concentration range value

Validation method **CV/SD** (Precision Control):

- **Mean ()**: Allows to define the expected concentration of the control.
- **2 SD ()**: Allows to define the allowed deviation from the expected control concentration.

Validation method **CV%** (Precision Control):

- **%**: Allows to define the maximum CV% between the replicates of the control.

Validation method **Cutoff** (Accuracy Control):

- **Value ()**: Allows to select the cutoff value for the control.
- **Control Type**: Allows to select the control type: positive **Pos** or negative **Neg** control.

Replicates

Specifies the number of replicates. Some methods require more than one replicate.

Start Conditions field:

Frequency (tests)	Specifies after how many tests (same assay) a test with this control should be performed.
Every (hours)	Specifies after how many hours a test with this control should be performed.
On STAT samples	Performs a test with this control if STAT samples are used.
New reagent cartridge	Performs a test with this control when the reagent cartridge has been replaced.
New calibration curve	Performs a test with this control when a new calibration curve has been recorded.
New ancillary cartridge	Performs a test with this control when the ancillary cartridge has been replaced.

PROCEDURE

Add an assay and specify the conditions:

1. Tap on the **Add** button.
2. Tap on the **Assays** tab.
3. Tap on the desired assay in the list.
4. Tap on the **Edit** tab.
5. Choose the validation method.
6. Specify all parameters of the chosen validation method.
7. Choose one or more start conditions.

3.8 SETUP

INFO

Special access rights
In most cases, special access rights are required for the described functions.

The **Setup** screen gives information about the instrument settings, user accounts and report settings and allows to change it.

PROCEDURE

1. Tap on the **Setup** button in the main menu bar or tap on a button in the resource bar to show the **Setup** screen.
2. Below the **Setup** button appears a sub menu with further buttons:
   - **System Settings**: Tap on the button to show the **System Settings** screen (see chapter 3.8.1 on page 3-91). The functions of the screen allows to view or change the instrument settings.
   - **Account Management**: Tap on the button to show the **Account Management** screen (see chapter 3.8.2 on page 3-92). The functions of the screen allows to view or change the access rights of existing or new users.
   - **Report Settings**: Tap on the button to show the **Report Settings** screen (see chapter 3.8.3 on page 3-94). The functions of the screen allows to customize the report settings.

3.8.1 SYSTEM SETTINGS

The functions of the **System Settings** screen allows to view or change the instrument settings.

Functions:

AUTOMATIC LOCK OUT TIME

Enable Automatic Lock out	Enables automatic logout of the current user if the user has not worked with the software for a defined period of time. Started tests are executed further. Another user cannot use the instrument during this log off time.
Lock out Time	Shows the time in minutes that must elapse before the user is logged out. It is possible to change the time.

PASSWORD

Enable the Password Policies	Allows only passwords with at least 7 characters. The password must contain at least one or more of the following characters: • upper case character, • lower case character, • numeric digit, and • special character (e.g. #!$%_-).
Change Password	Allows to change the current password.

DATABASE BACKUP PATH

Database Backup Path	Not used in current software version.

3.8.2 ACCOUNT MANAGEMENT

The functions of the **Account Management** screen allows to view or change the access rights of existing or new users.
Functions:

Add	Allows to add an new user account. The user name shall be unique.
Delete	Allows to delete a selected user.
Change Password	Allows to change the password of the selected user

USER NAME

Shows a list of all registered users. However, only those users are displayed who have the same or less rights than yourself.
Click on an user name to show the details in the **Settings** area.

SETTINGS

User Name	Shows the unique user name in the user software.
First Name	First name of the user.
Last Name	Last name of the user.
Role	Defines the access rights for the user account: • Laboratory User • Laboratory Administrator
Disable Account	Disables the selected user account.

Functions	Lab. User	Lab. Admin.
Start a test run	X	X
Start maintenance tasks	X	X
Add/Edit/Delete maintenance tasks	-	Only import
Show test results/ calibration curves / master curves	X	X
Generate reports	X	X
Show event log	X	X
Show assays and laboratory specific parameters	X	X
Import assays and edit laboratory specific parameters	-	X
Add/Edit/Delete controls	X	X
Add/Edit/Delete groups & profiles	-	X
System settings	-	X

Functions	Lab. User	Lab. Admin.
Account management	-	Restricted to same or role with lower rights
Report settings	-	X

Table 3-6: Roles and rights

3.8.3 REPORT SETTINGS

The functions of the **Report Settings** screen allows to customize the report settings.
Functions:

REPORT HEADER CUSTOMIZATION

Company Name	Name of the laboratory.
Company Logo	Logo of the laboratory
Change Logo	Allows to change the laboratory logo. Tap on the button to select a picture file on the PC.

3.9 TROUBLESHOOTING AND ERROR MESSAGES

INFO

Troubleshooting manual

Please refer to the separate KleeYa Troubleshooting Manual on error messages and troubleshooting.

Intentionally left blank.

4 USE OF THE INSTRUMENT

4.1 SAFETY AND HINTS

DANGER

Emergency shutdown in case of functional disorder
Functional disorder of the instrument will cause electrical shock, burns, cuts or bruises.
- Pull out the mains plug to separate the instrument from the mains supply!

WARNING

Erroneous operation of the instrument or the software
Malfunctions can cause serious injuries with deadly consequences or damage of the instrument.
- Closely follow the steps contained in the individual instructions.
- Check correct data input.
- Check process of loading.
- In case of constantly erroneous operation call service.

WARNING

Liquid in instrument
Liquid which gets into the instrument can cause illnesses with deadly consequences in case of contact. The instrument can be damaged by liquids.
- Switch off the instrument.
- Separate the instrument from the mains supply.
- Wear suitable protective clothing.
- Clean, disinfect or decontaminate and dry the instrument according to the applicable local and national provisions, legislation and laboratory procedures.

WARNING

Cross-contamination by multi-use
Repeatedly use of single-use Anchor® Tips, cuvettes, or test tubes will cause cross-contamination.
- Never reuse single-use Anchor® Tips, cuvettes, or test tubes.

4.2 BRIEF SEQUENCE PLAN

Start-up	• Switch on the instrument • Switch on the PC.	chapter 4.3 on page 4-3

Preparations	• Load full Dispense Cartridges:
	• Load cuvette stacks
	• Anchor® Tips:
	  • Unload empty Anchor® Tip trays
	  • Load full Anchor® Tip trays
	• Fill wash buffer container with wash buffer
	• Fill system liquid containers with purified water
	• Waste:
	  • Empty liquid waste containers
	  • Empty solid waste bag
	• Run open maintenance tasks.
		chapter 4.4 on page 4-4

Load reagents and samples	• Load test tube rack(s) • Assign tests • Load reagent rack(s)	chapter 4.5 on page 4-6
Start test run	• Start test run	chapter 4.6 on page 4-6
Results	• View results	chapter 4.7 on page 4-7
Unload and reload samples and reagents	• Unload finished test tube rack(s) • Reload test tube racks	chapter 4.8 on page 4-8
Reload resources	• Reload resources	chapter 4.9 on page 4-9
Event/error messages and special tasks	• Event/error messages • Maintenance tasks	chapter 4.10 on page 4-10
Shut down	• Shut the PC down • Switch the instrument off	chapter 4.11 on page 4-11

4.3 START-UP

1. Close all instrument flaps.
2. Switch on the instrument.
3. Pull out the liquid waste containers drawer to access the PC.
4. Switch on the PC.
5. Close all drawers.
6. Wait until the KleeYa user software has been started.
7. Enter your **Username**.

Figure 4-1: **Log in** *window*

8. Enter your **Password**.
9. Tap on the **Enter** button.
10. Wait until the instrument is initialized.

4.4 PREPARATIONS

1. Tap on the **Overview** button in the main menu bar.

DISPENSE CARTRIDGES

2. Check the number of available number of dispenses of the Dispense Cartridges.
3. If necessary, load full Dispense Cartridges (see chapter 3.3.1 on page 3-7).

CUVETTES

4. Check the number of available cuvettes.
5. If necessary, load cuvette stacks (see chapter 3.3.2 on page 3-18).

ANCHOR® TIPS

6. Open the sample/Anchor® Tips loading bay flap.
7. Pull out both drawers of the Anchor® Tips trays.
8. Check the number of available Anchor® Tips.
9. If necessary, load full Anchor® Tip trays (see chapter 3.3.3 on page 3-22).
10. Close the drawers.
11. Close the sample/Anchor® Tips loading bay flap.

WASH BUFFER

12. Check the level of the wash buffer container.
13. If necessary, unload/fill/load the wash buffer container (see chapter 3.3.5 on page 3-32).

SYSTEM LIQUID

14. Check the level of the system liquid container.
15. If necessary, unload/fill/load the system liquid container (see chapter 3.3.4 on page 3-29).

SOLID WASTE

16. Check the level of the solid waste bag.
17. If necessary, unload/load the solid waste bag and confirm that you emptied the solid waste (see chapter 3.3.6 on page 3-37).

LIQUID WASTE

18. Check the level of the liquid waste container.
19. If necessary, unload/empty/load the liquid waste container (see chapter 3.3.7 on page 3-39).

MAINTENANCE TASKS

20. Start the daily maintenance task "Start of Day Maintenance Task" and fulfill all instructions (see chapter 5.2.1 on page 5-4 and chapter 3.6.1 on page 3-77).
21. If necessary, run all required maintenance tasks.

4.5 LOAD SAMPLES AND REAGENTS

1. Tap on the **Load** button in the main menu bar to show the **Load** screen.
2. Tap on the **Samples** button below the **Load** button.
3. Load all test tubes into sample rack(s).
4. Load the sample rack(s), one after the other, into the sample loading bay (see chapter 3.4.1 on page 3-43).
5. If necessary, assign desired tests and dilutions to the samples.
6. Tap on the **Reagents** button below the **Load** button.
7. Load all necessary Reagent Cartridges into reagent rack(s).
8. Load the reagent rack(s), one after the other, into the reagent loading bay (see chapter 3.4.2 on page 3-55).

4.6 START TEST RUN

1. Tap on the **Start** button to start the test run.

4.7 RESULTS

View or export results as list:

1. Tap on the **Results** button in the main menu bar to show the **Results** screen.
2. Tap on the **Test** button to show the **Tests** screen with a table of all tests (finished and in process) with numerous information (e.g. the status, raw results and calculated concentration, flags), see chapter 3.5.2 on page 3-64.
3. Tap on the **Results** group to show the results of all finished tests.
4. If necessary filter the results to see only relevant tests.
5. Selected results (tick first column) can be exported to .csv via the **Export** button.

View or export results as formated report:

1. Tap on the **Results** button in the main menu bar to show the **Results** screen.
2. Tap on the **Reports** button to show the **Run History** screen with a table of all tests (finished and in process) with numerous information (e.g. the status, raw results and calculated concentration, flags), see chapter 3.5.2 on page 3-64.
3. Tap on the **Reports** button below the **Results** button.
   Next to the button appears another menu.
4. Tap on the **Sample Results Report** button to show a table of all tests (finished and in process) with numerous information (e.g. the status, raw results and calculated concentration, flags), see chapter 3.5.4 on page 3-70.
5. If necessary filter the results to see only relevant tests.
6. Tap on the desired entries or tap on the **Select All** button to select all desired entries.
7. Tap on the **Preview Report** button.
8. Use the functions of the **Preview Report** screen to export or print the report.

4.8 UNLOAD AND RELOAD SAMPLES AND REAGENTS

UNLOAD

1. Remove unused/finished sample rack(s) carefully (see chapter 3.4.1 on page 3-43).
   The corresponding LED over the sample loading lane must be off.
2. Remove the unused/finished reagent rack(s) (see chapter 3.4.2 on page 3-55)
   Pay attention to the corresponding state of the reagent loading lane in the user software. The square above the lane must be gray.

RELOAD

1. Tap on the **Load** button in the main menu bar to show the **Load** screen.
2. Tap on the **Samples** button below the **Load** button.
3. Load all test tubes into sample rack(s).
4. Load the sample rack(s), one after the other, into the sample loading bay (see chapter 3.4.1 on page 3-43).
5. If necessary, assign desired tests and dilutions to the samples.
6. Tap on the **Reagents** button below the **Load** button.
7. Load all necessary Reagent Cartridges into reagent rack(s).
8. Load the reagent rack(s), one after the other, into the reagent loading bay (see chapter 3.4.2 on page 3-55).

4.9 RELOAD RESOURCES

1. Tap on the **Overview** button in the main menu bar.

DISPENSE CARTRIDGES

2. Check the position of the empty Dispense Cartridge (see chapter 3.3.1 on page 3-7).
3. Unload the empty Dispense Cartridge.
4. Load a full Dispense Cartridge.

CUVETTES

5. Load cuvette stacks (see chapter 3.3.2 on page 3-18).

ANCHOR® TIPS

6. Check the position of the empty Anchor® Tip tray (see chapter 3.3.3 on page 3-22).
7. Unload the empty Anchor® Tip tray.
8. Load a full Anchor® Tip tray.

WASH BUFFER

9. Unload/fill/load the wash buffer container (see chapter 3.3.5 on page 3-32).

SYSTEM LIQUID

10. Unload/fill/load the system liquid container (see chapter 3.3.4 on page 3-29).

SOLID WASTE

11. Unload/load the solid waste bag (see chapter 3.3.6 on page 3-37).

LIQUID WASTE

12. Unload/empty/load the liquid waste container (see chapter 3.3.7 on page 3-39).

4.10 EVENT/ERROR MESSAGES AND MAINTENANCE TASKS

EVENT/ERROR MESSAGES

- Check all event/error messages (see chapter 3.5.5 on page 3-72).

MAINTENANCE TASKS

- Start the daily maintenance task "End of Day Maintenance Task" and fulfill all instructions (see chapter 5.2.1 on page 5-4 and chapter 3.6.1 on page 3-77).
- If necessary, run all required maintenance tasks (see chapter 5 on page 5-1 and chapter 3.6 on page 3-75).

4.11 SHUT DOWN

1. Tap on the **Shutdown** button.
2. Tap on the **Yes** button to confirm the warning message.
3. Wait until the PC is shutdown (touch screen is black).
4. Switch off the instrument.
5. Remove all sample racks.
6. Remove all reagents and store them or dispose it *.
7. Remove both Dispense Cartridges and store them or dispose it *.

**) Store them according to the consumable information (package insert) or dispose it according to the local and national provisions, legislation and laboratory regulations.*

Intentionally left blank.

5 MAINTENANCE AND SERVICE

NOTICE

Unchecked instrument

Only checked instruments enable correct operation.

- Pay attention to the Operation Qualification (OQ) form .
- Check the instrument after installation, maintenance or repair.

5.1 SAFETY AND HINTS ABOUT CLEANING/ DECONTAMINATION

⚠ DANGER

Electric shock or mechanical injury by mains supply

If the instrument is not separated from the mains supply before performing maintenance, this will cause serious injuries with deadly consequences due to electric shock. Additionally, there is the danger that the instrument could start and cause injury (e.g. contusion, cuts etc.) to the person working with the instrument.

- Switch off the instrument, separate it from the mains supply and protect it against restarting.
- Make sure that nobody is working on the instrument and that all covers are attached and closed before reconnecting the instrument to the mains supply.
- Only start cleaning, disinfection, decontamination, maintenance or repair work when instrument is secured.

⚠ WARNING

Defects in the liquid system

Defect or leaky tubes, valves or pumps lead to deterioration of the pipetting results and consequently corruption of final results. Furthermore incorrectly flushed tips can cause mixing up of sample material.

- Check the instrument for drops and pooling of liquid on surfaces.
- Check tubes, valves or pumps periodically.

⚠ WARNING

Unapproved or improper maintenance work

Unapproved or improper carried out maintenance work will result in serious personal injury and material damage.

- Follow all safety instructions in chapter 1.4 on page 1-8 and this chapter.
- Take off watches and jewelry before performing any maintenance works.
- Only perform maintenance procedures described in this manual.
- Closely follow the steps contained in the individual instructions.
- For maintenance, only use the parts mentioned in this instruction.
- Tests and maintenance specified by the manufacturer shall be performed to ensure the safe operation of the instrument and the proper functioning of the instrument.
- All service and maintenance which are not described in this instruction shall be performed by qualified and authorized field service engineers.
- Any changes made to the instrument that are not authorized by the manufacturer will void the manufacturer's warranty.

NOTICE

Cleaning, disinfection or decontamination

Observe the following aspects during cleaning, disinfection or decontamination because otherwise breakdowns or damage can be the result.

- Disinfect or decontaminate components with a suitable disinfection or decontamination method.
- Only use liquid cleaning, disinfection or decontamination solutions with a moistened cleaning tissue.
- Use only approved cleaning, disinfection or decontamination solutions and methods.
- Avoid cleaning, disinfection or decontamination solutions to come into contact with bearings and guides, as otherwise the greasy film may dissolve!
- Do not use cleaning, disinfection or decontamination solutions in the proximity of circuit boards, light barriers and acrylic glass surfaces!
- Do not pour or spray liquid cleaning, disinfection or decontamination solutions into the instrument.
- Do not autoclave containers and components for liquids or waste.

NOTICE

Handling and cleaning of optical surfaces

Improper optical surfaces (e. g. camera, lenses, sensors) could generally degrade the quality of images, data, etc.

- Do not touch any optical surfaces.
- Only clean the optical surfaces with a soft and lint-free cloth.
- Do not use any aggressive detergents or solutions (e.g. acetone).

NOTICE

Damage of touch screen while cleaning

Improper cleaning could damage the touch screen surface.

- Use a soft and lint-free cloth with neutral detergent or with ethanol to clean the touch screen.
- Do not use any chemical solvent, acidic or alkali solution.
- If dust is accumulated on the case surface, remove it by using a special vacuum cleaner for computers.

5.2 MAINTENANCE AND CLEANING

5.2.1 DAILY MAINTENANCE

Start of Day

DURATION 6 min

PROCEDURE

1. Start the daily maintenance task "Start of Day Maintenance Task" and fulfill all instructions (see chapter 3.6.1 on page 3-77).

End of Day

DURATION 4 min

PROCEDURE

1. Start the daily maintenance task "End of Day Maintenance Task" and fulfill all instructions (see chapter 3.6.1 on page 3-77).
2. Insert the maintenance cartridge on position 1 (left position) and an empty cartridge on position 2 (right position).
   Both cartridges must have a RFID label with a test count of at least 4 to start the task.

5.2.2 WEEKLY MAINTENANCE

DURATION 10 min

TOOLS

- Soft and lint-free cloths

PROCEDURE

1. Wipe the steel needle (SPOLV) of the reagent pipettor with a soft and lint-free cloth.
2. Wipe the surfaces in the interior of the instrument with a soft and lint-free cloth.
   Do not clean the pipettor guide rods!

5.2.3 MONTHLY MAINTENANCE

DURATION

1 hrs 30 min (weekly + monthly maintenance), without the duration of the maintenance task "Database Maintenance"

TOOLS

- Soft and lint-free cloths
- Sodium hypochlorite (0.5-0.9%)
- Distilled water
- Hypochlorite solution (0.1%)
- Additional intermediate container
- Clean and empty container

PROCEDURE

Surfaces and containers:

1. Wipe the surfaces of the instrument with a soft and lint-free cloth.
2. Pull out the wash buffer/system liquid containers drawer.
3. Clean the system liquid container, system liquid intermediate container, wash buffer container, and wash buffer intermediate container each with:
   a. Fill 1 l sodium hypochlorite (0.5-0.9%) and rinse out.
   b. Fill 1 l of distilled water and rinse (repeat 3 times).
4. Close the wash buffer/system liquid containers drawer.
5. Pull out the liquid waste containers drawer.
6. Clean the waste liquid containers and waste liquid intermediate container each with:
   a. Fill 1 l sodium hypochlorite (0.5-0.9%) and rinse out.
   b. Fill 1 l distilled water and rinse (repeat 3 times).
   c. Fill 1 l hypochlorite solution (0.1%) and rinse out.
7. Close the liquid waste containers drawer.
8. Start the maintenance task "Monthy Maintenance Task" (see chapter 3.6 on page 3-75).

Washers:

1. Fill the additional intermediate container with 4 l sodium hypochlorite (0.5-0.9%).
2. Pull out the wash buffer/system liquid containers drawer.
3. Place the additional intermediate container to the left of the drawer.
4. Open the cap (1) of the intermediate wash buffer container (2) behind the wash buffer container. Make sure that the inner part of the cap (1) with the connections does not rotate with the outer part.

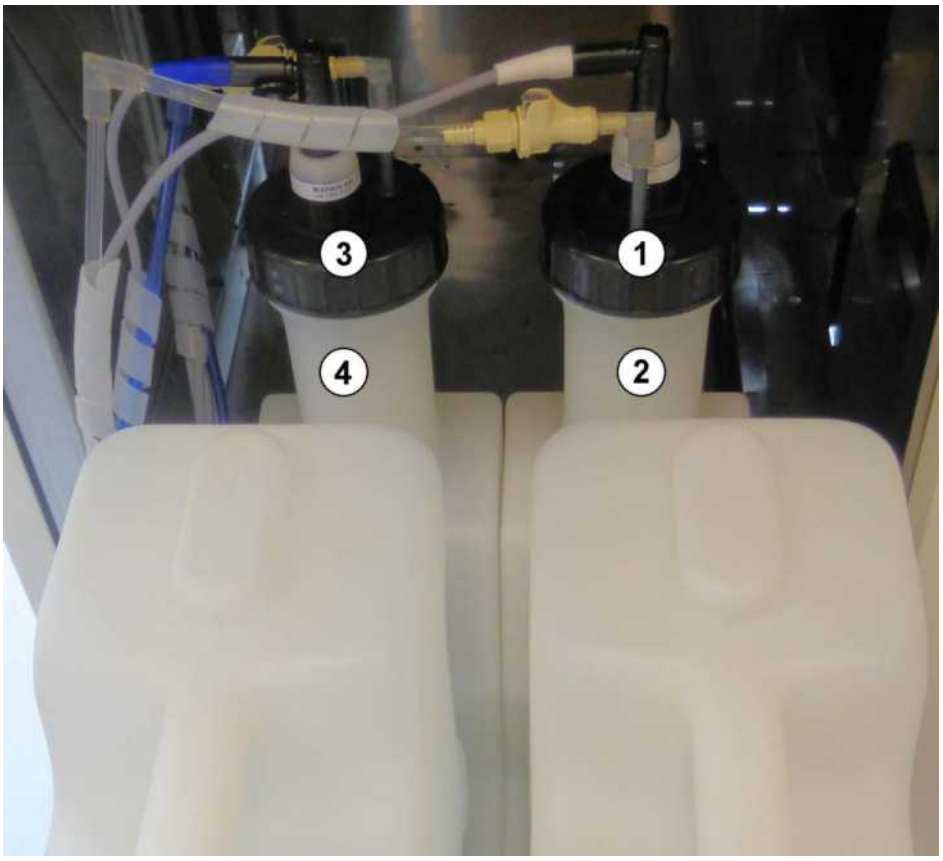


Figure 5-1: Wash buffer/system liquid containers

5. Put the cap (1) on the additional intermediate container and tighten it loosely.
6. Prime the washers (cleaning):
   a. Start the maintenance task "Prime Washer".
   b. Wait 5 minutes **after** finishing the task.
   c. Repeat the cleaning procedure **4** times in total.
7. Open the cap (3) of the intermediate system liquid container (4) behind the system liquid container. Make sure that the inner part of the cap (3) with the connections does not rotate with the outer part.
8. Place the cap (3) in a suitable clean and empty container.
9. Open the cap (1) of the additional intermediate wash buffer container.
10. Put the cap (1) on the intermediate system liquid container (4) and tighten it loosely.
11. Prime the washers (flushing):
    a. Start the maintenance task "Prime Washer".
    b. Wait 1 minutes **after** finishing the task.
    c. Repeat the cleaning procedure **8** times in total.
12. Open the cap (1) of the intermediate system liquid container (4).
13. Put the cap (1) on the intermediate wash buffer container (2) and tighten it by hand.
14. Put the cap (3) on the intermediate system liquid container (4) and tighten it by hand.
15. Start the maintenance task "Prime Washer" to fill the washers with wash buffer.

16. Close the wash buffer/system liquid containers drawer.
17. Remove the additional intermediate container.

Database:

1. Start the maintenance task "Database Maintenance".

5.2.4 QUARTERLY MAINTENANCE

DURATION

2 hrs 12 min (weekly + monthly maintenance)

TOOLS

- Soft and lint-free cloths
- Liquinox®
- Distilled water

PROCEDURE

1. Moisten a soft and lint-free cloth with Liquinox® and wipe the steel needle (SPOLV) of the reagent pipettor.
2. Moisten a soft and lint-free cloth with distilled water and wipe the steel needle (SPOLV) of the reagent pipettor.
3. Wipe the steel needle (SPOLV) of the reagent pipettor dry with a soft and lint-free cloth.
4. Fill the additional intermediate container with 4 l sodium hypochlorite (0.5-0.9%).
5. Pull out the wash buffer/system liquid containers drawer.
6. Place the additional intermediate container to the left of the drawer.
7. Open the cap (1) of the intermediate system liquid container (2) behind the system liquid container. Make sure that the inner part of the cap (1) with the connections does not rotate with the outer part.

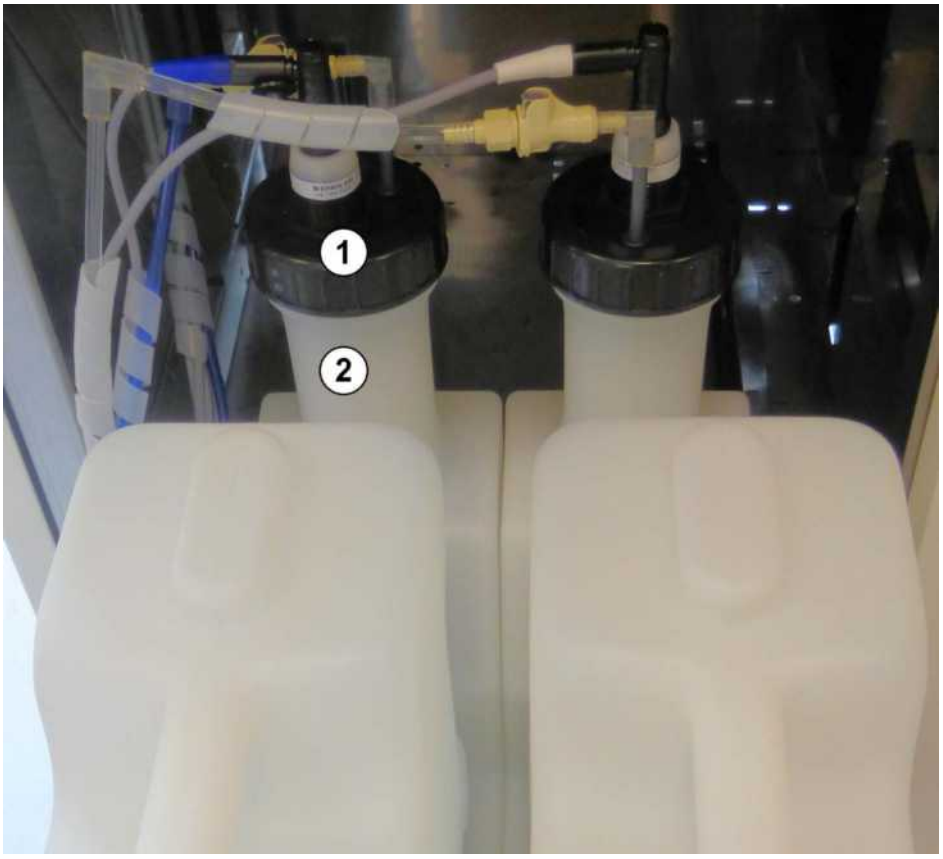


Figure 5-2: Wash buffer/system liquid containers

8. Put the cap (1) on the additional intermediate container and tighten it loosely.
9. Prime the steel needle (SPOLV) (cleaning):
   a. Start the maintenance task "Prime Pipettor".
   b. Wait 5 minutes **after** finishing the task.
   c. Repeat the cleaning procedure **3** times in total.
10. Open the cap (1) of the additional intermediate wash buffer container.
11. Put the cap (1) on the intermediate system liquid container (2) and tighten it by hand.
12. Prime the steel needle (SPOLV) (flushing):
   a. Start the maintenance task "Prime Pipettor".
   b. Wait 1 minutes **after** finishing the task.
   c. Repeat the cleaning procedure **6** times in total.
13. Close the wash buffer/system liquid containers drawer.
14. Remove the additional intermediate container.

5.2.5 CHECK SAMPLE RACK

Depending on the frequency of their usage, the sample racks will show signs of wear and tear at the push-push snap in site (yellow circles). If there is too much wear observable the sample racks shall be exchanged. Sample racks that do not snap in smoothly anymore must be exchanged immediately. Otherwise the push-push mechanism at the sample bay can be damaged.

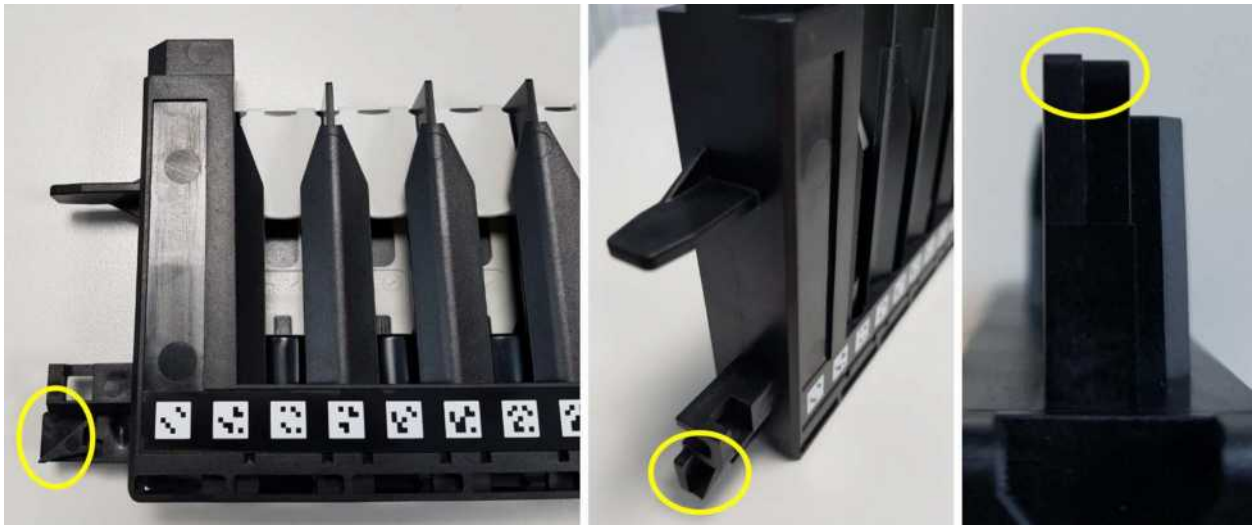


Figure 5-3: Check positions

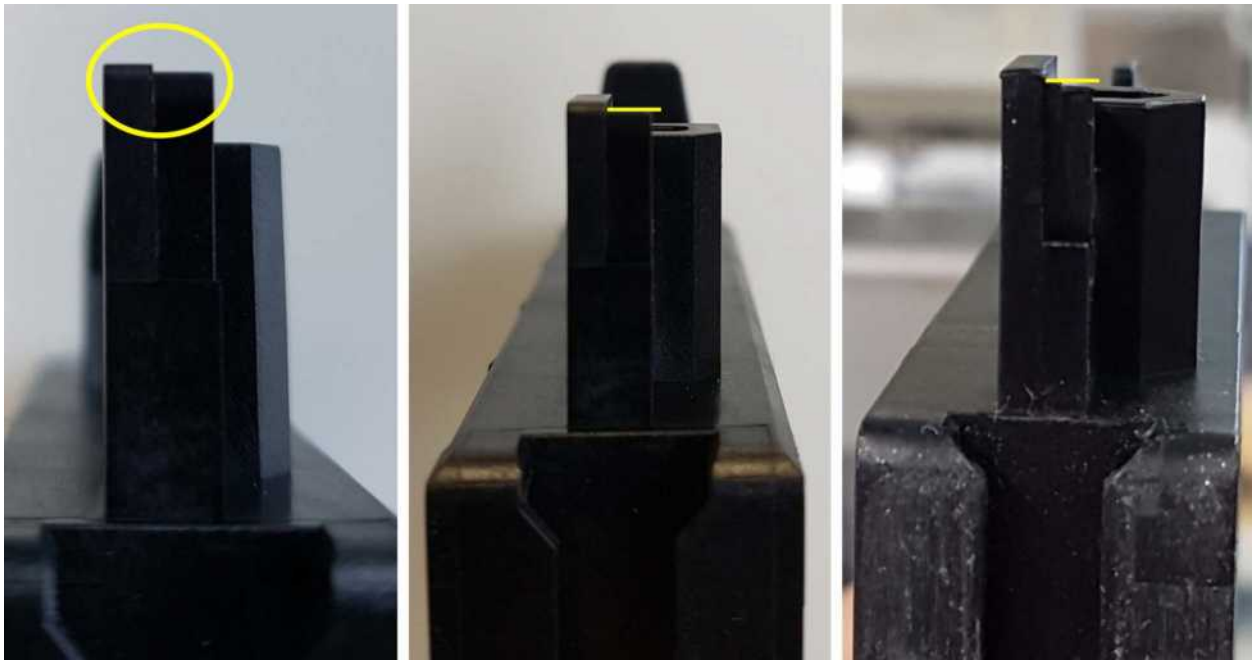


Figure 5-4: Wear and tear (center: new sample rack, right: old sample rack)

Newly ordered racks must be labeled with the respective label and equipped with spacers if necessary (see chapter 5.3.1 on page 5-11).

5.3 SERVICE

5.3.1 TUBE AND SAMPLE RACK SPECIFICATIONS

Each tube type (see chapter 3.4.1 on page 3-43) requires a dedicated sample rack type with a specific label and in special cases also with spacers:

- Sample rack types (label) (see chapter 5.3.1.1 on page 5-11)
- Spacers for sample racks (see chapter 5.3.1.2 on page 5-14)

5.3.1.1 SAMPLE RACK TYPES (LABEL)

Each tube type requires a dedicated sample rack type. The sample rack must be labeled with the respective rack label according to the sample tubes that shall be used within the rack. Only the tubes of this type can be used within each rack type.

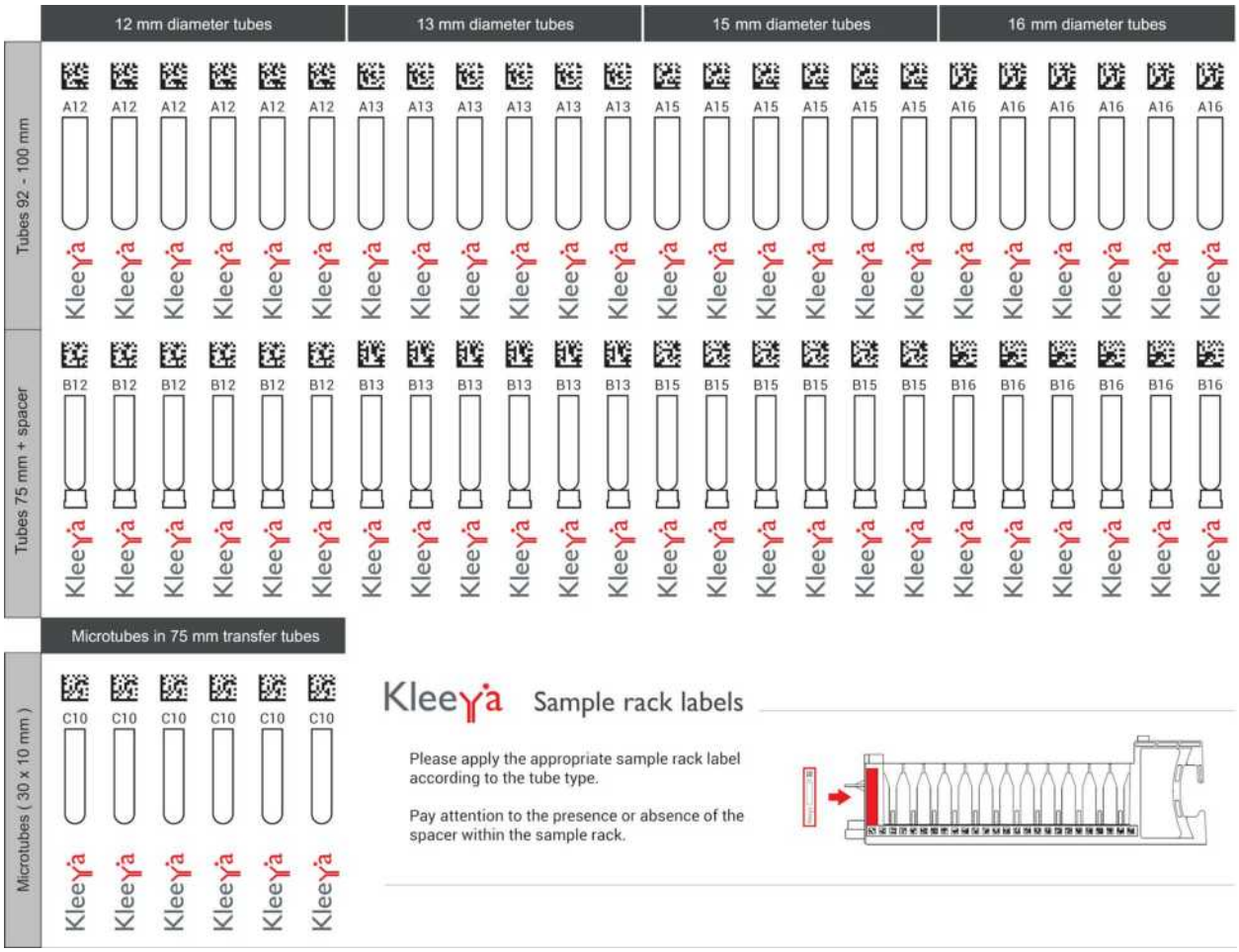


Figure 5-5: Sample rack labels

ADD A LABEL

1. Place the sample rack so that you can stick the label on the front position.

Figure 5-6: Label position

2. Carefully remove the desired label from the label sheet.

Figure 5-7: Sample rack label

3. Note that the 2D barcode on the label must face up (in the picture on the right).
   Stick the label straight into the recess.

Figure 5-8: Glued label

4. If necessary, add spacers to the sample rack (see chapter 5.3.1.2 on page 5-14).

5.3.1.2 SPACERS FOR SAMPLE RACKS

For 75 mm tubes an additional spacer is required in the sample position of a sample rack. Please note that all sample positions must be equipped with a spacer.
There are no spacers for 30 mm tubes. These tubes require a transfer tube.

ADD SPACERS

Remove the white springs from all 12 sample positions:

1. Use a pen or something similar to loosen the springs at the backside of the rack.

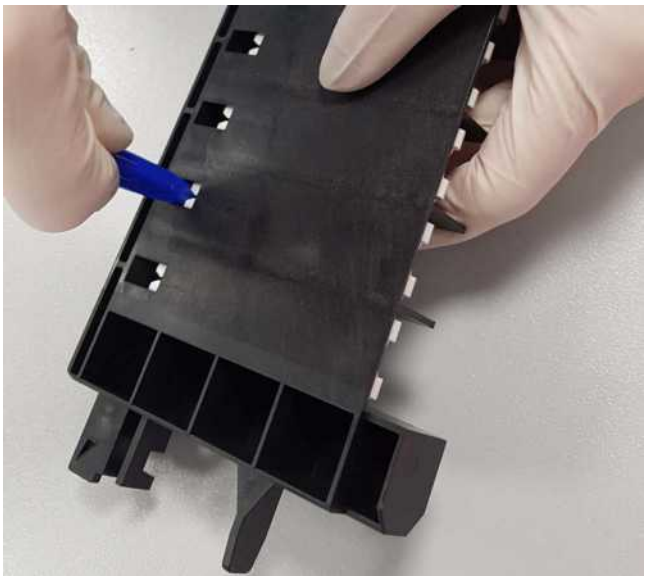


Figure 5-9: Loosen spring 1

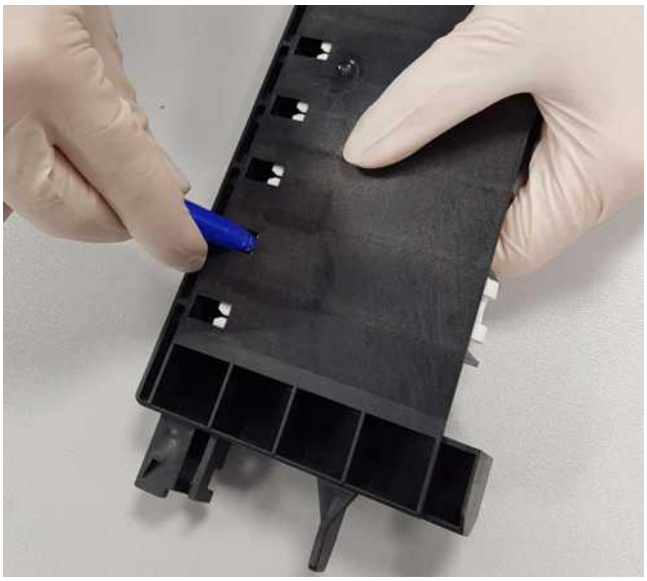


Figure 5-10: Loosen spring 2

2. Use the pen to remove the spring from the front by pushing it upwards.

Figure 5-11: Remove spring

3. Repeat the steps to remove all springs.

Insert the spacers into all 12 sample positions:

4. Place the spacer into the sample position and move it downwards with your fingers.
   Use your finger to move the spacer along the protruding spring guide. The spacer must be pushed to the front to make sure it does not collide with the spring guide.

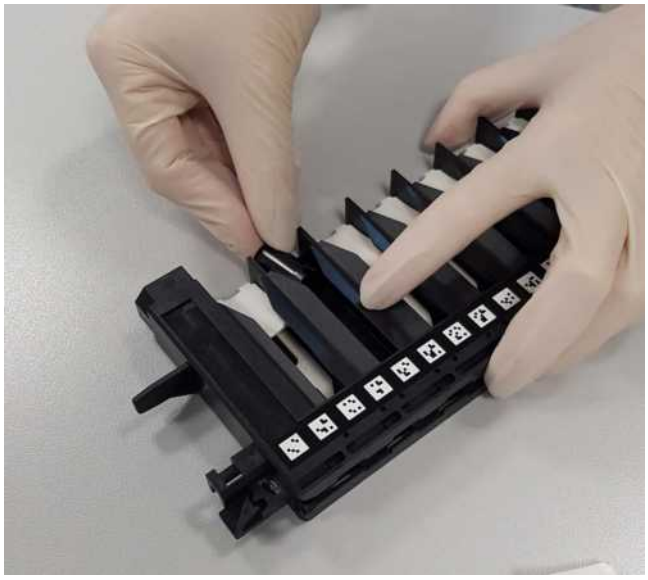


Figure 5-12: Insert spacer

Figure 5-13: Bottom position

5. Make sure that the spacers are pushed to the bottom of the rack and sit plain inside the rack.
   If necessary use the pen, your finger or a sample tube and push down the spacer.
6. Repeat the steps to insert all spacers.

Re-insert the springs into all 12 sample positions:

7. Place the spring into the sample position from above.
   Make sure the spring runs under the spring guide when pushing it down. The spring snaps into place with a click. When correctly inserted the springs are all at the same height about 1 mm lower than the back of the rack.

Figure 5-14: Insert spring

8. Repeat the steps to insert all springs.

Check:

9. Check all sample positions for correct mounting of spacers and springs. Spacers must be pushed to the bottom and sit plain inside the rack. All springs must be inserted and correctly snapped in.
   Example (in the figure from left to right):
   - all is well
   - the spacer does not fit properly
   - the spring is not properly snapped in

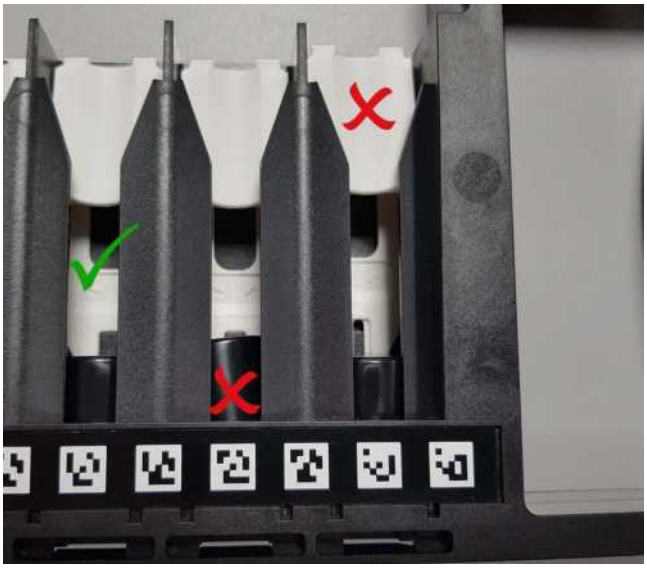


Figure 5-15: Check

Sample rack type label:

10. Stick the correct type label onto the sample rack (see chapter 5.3.1 on page 5-11 and chapter 5.3.1.1 on page 5-11).

5.3.2 AUTOMATIC INSTRUMENT CHECKS/ INITIALIZATION

The instrument performs some checks during power up and initialization automatic system. For each module, the instrument carried out dedicated sequences for integrity check.

Those include amongst others:

- **Measurement unit**
  Luminometer (start module), lift (moves lift, check drive and light barrier), Rotor (moves rotor, check drive and light barrier), bubble sensor (start sensor)
- **Reagent bay / Reagent rack**
  Bay cooling (checks connection), rack shaker (check shaker movement, check drive and sensor)
- **Sample loading**
  Shutter (closes shutter, check drive and light barrier)
- **Camera reader for sample recognition**
  Mirror drive (move mirror, check drive and hall sensor)
- **Frontcover**
  LEDs, buzzer, and interlock (initialize), aspirate (start module)
- **Cabinet**
  Level monitor (check level sensors, container connection), flooding sensor (check sensor if it's flooded or not)
- **Incubator**
  Incubator (check movement and light barriers)
- **Disposable Dispense Cartridge Actuator (DDCA)**
  DDCA (check movement and light barriers)
- **Washer**
  Lift (move lift, check drive and light barrier), bubble sensor (start sensor), valve (check)
- **Pipettor**
  Both X-/Y-/Z-drives (check movement and light barrier), reagent and sample pipettor (check communication)
- **Cuvette loader**
  Pusher (move pusher, check drive and light barrier, carousel (move carousel, check drive and light barrier)

Intentionally left blank.

6 INSTALLATION AND REMOVAL OF THE INSTRUMENT

6.1 INSTALLATION OF THE INSTRUMENT

⚠ WARNING

Instability of instrument
Due to improper placing of the instrument, the instrument can tilt and fall down. The user can be heavily injured or the instrument can be seriously damaged.
- Observe the technical specifications of the instrument (see chapter 7.4 on page 7-3).
- Position the instrument on a stable floor with an adequate load-bearing capacity.

⚠ CAUTION

Installation by unauthorized personnel
Improper installation can cause damage or malfunctions.
- Installation shall be executed by authorized field service engineer.

INFO

Installation qualification (IQ)
After the installation, the user of the instrument receives an installation qualification which documents the proper installation of the instrument.

INFO

Microsoft software license terms (EULA)
Please note the enclosed Microsoft software license terms for the Microsoft Windows embedded operating system.

Check the scope of delivery for completeness by means of the packing list (see enclosed packing list).

6.2 REMOVAL OF THE INSTRUMENT

NOTICE

Removal by unauthorized personnel

Improper removal will cause damage.

- Removal shall be executed by authorized field service engineer.

NOTICE

Omitted reinstallation

If the instrument moves within the plant, the authorized service personnel shall perform a complete reinstallation. If this reinstallation is omitted, this will cause damage of the instrument or irregular pipetting performance!

- Reinstallation shall be executed by authorized field service engineer.

7 TECHNICAL DATA

INFO

Specification
Values are achieved under optimal conditions and can vary depending on environmental conditions, instrument status and processing conditions! Specifications are subject to change with notice according to STRATEC`s “Change control system”.

7.1 POWER REQUIREMENTS

Instrument:	
Voltage:	100 V - 240 V ±10%
Frequency:	50 - 60 Hz
Input current:	5 - 2.1 A
Fuses:	primary 250 VAC / T6.3AH

Computer:	
Voltage:	100 V - 240 V ±10%
Frequency:	50 - 60 Hz ±5%
Input current:	3 A

7.2 LASER OF THE INCUBATOR MODULE

The instrument is a class 1 laser product and incorporates the following laser source:

Maximal output power:	< 1 mW
Wave length:	650 nm

7.3 COMPUTER AND CONNECTIONS

Hardware:	
The following specifications are the minimum requirements.	
Processor:	Pentium, 3.2 GHz or better
Memory (RAM):	4 GB
Hard disk:	500 GB or more
Ports:	• 1 Gigabit Ethernet port • 4 or more USB ports
Modem:	External modem via USB or internal PCI card modem
Monitor/Graphic card:	Resolution: 1366 x 768 pixel or more 18.5 inch
Power consumption:	Separate power supply, see chapter 7.1 on page 7-1

Software:	
Operating system	Microsoft® Windows® 10 (UK English)

7.4 INSTALLATION DIMENSIONS AND WEIGHT

Dimensions with touch screen and opened top cover:

Width:	175 cm (68.9 in)
Depth:	110 cm (43.3 in)
Height:	173 cm (68.1 in)

Dimensions without touch screen:

Width:	133 cm (52.4 in)
Depth:	70 cm (27.6 in)
Height:	147 cm (57.9 in)

Instrument weight:	277 kg (610.7 lb)

7.5 ENVIRONMENTAL CONDITIONS

The following table shows the range of conditions needed to run the system safely.

Environmental condition:	The system is made for Indoor use only.
Temperature:	Operating: 18°C to 30°C (64.4°F to 86°F) Storage: 5°C to 40°C (41°F to 104°F) Transport: -20°C to 60°C (-4°F to 140°F)
Humidity:	Operating: 20 - 80 % non-condensing Storage: 10 - 85 % non-condensing Transport: 10 - 90 % non-condensing
Pollution degree:	2
Overvoltage category:	II
Limit class:	Class A (For industrial use. Domestic use restricted)
Sunlight:	No direct sunlight May mislead optical sensors and affect performance
Altitude	Up to 2000 m (6562 ft) above mean sea level
Dust:	No excessive dust

7.6 NOISE

70 dB(A), distance 1 m (39.4 in)

7.7 PACKAGING

Number of Boxes:	3 (2 pallets)

Box A:	
Contents:	Instrument
Dimensions (WxDxH):	145 cm x 80 cm x 172 cm (57.1 in x 31.5 in x 67.7 in)
Weight:	347 kg (765 lb)

Box B and Box C:	Two boxes are packed together on a pallet.
Contents:	Box 2/3: Covers Box 3/3: Touch screen, PC
Dimensions (WxDxH):	148 cm x 80 cm x 140 cm (58.3 in x 31.5 in x 55.1 in)
Weight:	131 kg (288.8 lb) {121 kg + 11 kg (266.8 lb + 24.0 lb)

Intentionally left blank.

8 APPENDIX

8.1 ACCESSORIES AND CONSUMABLES

NOTICE

Non-recommended accessories and consumables
The usage of non-recommended accessories and consumables can produce erroneous results or damage to the instrument.
- Use only the accessories and consumables described herein.

ACCESSORIES

- Containers:
  - Liquid waste main container
  - System liquid main container
  - Wash buffer main container
- Hand-held barcode scanner
- Reagent rack
- Sample rack
- User Manual

CONSUMABLES

- Anchor® Tips trays with 96 Anchor® Tips (300 µl)
- Stackable Cuvette with 50 cuvettes per stack
- Dispense Cartridges
  - Trigger Solution 1 – Acid Reagent
  - Trigger Solution 2 – Base Reagent
- Reagent Cartridges
- 5x TBS wash buffer
- Waste bags

8.2 SPARE PARTS

See separate spare parts list.

8.3 IMPORTANT CONSUMABLE INFORMATION

See integrated original documents in the next sub-chapters.

8.3.1 ANCHOR® TIPS TRAYS/ANCHOR® TIPS

Name:	Anchor® Tips, 300 uL
Purpose:	Vessels used to transport sample from the laboratory container to the cuvette with an automated pipetting system in the KleeYa Evaluation Unit | single use
Ident No.:	Anchor® Tips, 300 uL – Ident No.:10036506
Packaging units:	Anchor® Tips, 300 uL, Set of 5760 pieces
Material:	PP medical grade

1 INTENDED USE

The intended use is as a vessel for the transfer of liquids.
The Anchor® Tips are intended exclusively for single use only and for application by qualified staff.
Anchor® Tips are designed to be used with an automated pipetting system in the KleeYa instrument in line with *in vitro* diagnostic analyses.

INFO

The Anchor® Tips, 300 uL complies with the In Vitro Diagnostic Medical Devices Directive (98/79/EC) and is classified as "other IVD product".

For more information about the Anchor® Tips, 300 uL please refer to the KleeYa User Manual.

⚠ WARNING

Handling

This instruction is provided for your safety and gives important instructions for the handling of the article.

- Read all instructions (including KleeYa User Manual)!
- Do not use damaged articles!
- Do not use any articles whose direct packaging is damaged!
- Do not use any articles whose expiration date has been exceeded!
- Never reuse single-use articles! Repeatedly use of single-use articles might cause cross-contamination. Furthermore, correct product performance is not guaranteed anymore.

2 SPECIFICATIONS

Nominal volume:	300 uL
Nominal length:	55 mm

3 USE

With two independent drawers for Anchor® Tips trays, a continuous refilling of tips and therefore an uninterrupted operation of the KleeYa System is possible.

Every drawer can be filled with one Anchor® Tip tray with 96 tips each. The KleeYa System's software monitors the loading of the trays.

The Anchor® Tips trays are inserted into the Tip Loading Bay of the KleeYa System. The Tip Loading Bay has the capacity to hold up to two tip trays.

For further instructions for use see KleeYa User Manual "3.3.3 Load Or Unload Anchor® Tips".

4 ENVIRONMENTAL CONDITIONS

Temperature 	Operating: 18°C to 37°C (64,4°F to 98,6°F) Storage: 2°C to 32°C (35,6°F to 89,6°F) for a maximum of 2 years Transport: -10°C to 60°C (14°F to 140°F) for a maximum of 3 days
Humidity 	Operating: 20 – 80 % non-condensing Storage: 20 - 80 % non-condensing for a maximum of 2 years Transport: 10 - 90 % non-condensing for a maximum of 3 days
NOTICE	Protect from sunlight and UV rays!

5 DISPOSAL AND DECONTAMINATION

NOTICE

Disposal of non-contaminated parts

Material out of use (e.g. packaging material, units with damaged direct packaging) should be properly disposed according to local waste disposal regulations.

⚠ WARNING

Disposal of contaminated parts

Potential infectious material will cause severe environmental contamination.

Strictly follow the local and national provisions, legislation and laboratory regulations.

6 SUPPORT

NOTICE E-mail: Support.KleeYa@diatron.com

7 MANUFACTURER

STRATEC Consumables GmbH
Sonystrasse 20
5081 Anif
Austria
Internet: www.stratec.com/solutions/consumables

CE IVD

8.3.2 STACKABLE CUVETTE

Name:	Stackable Cuvette, 1 mL
Purpose:	Reaction vessel for liquids | single use
Ident No.:	Stackable Cuvette, 1 mL – Ident No.:10033666
Packaging units:	Stackable Cuvette, 1 mL, Set of 3000 pieces
Material:	PP medical grade

1 INTENDED USE

The intended use is as a reaction vessel for liquids.
They are intended exclusively for single use only and for application by qualified staff.
The cuvette is designed to be used for automated analytical systems, e.g. KleeYa System in line with *in vitro* diagnostic analyses.

INFO

The Stackable Cuvette, 1 mL complies with the In Vitro Diagnostic Medical Devices Directive (98/79/EC) and is classified as "other IVD product".

For more information about the Stackable Cuvette 1mL please refer to the KleeYa User Manual.

⚠ WARNING

Handling

This instruction is provided for your safety and gives important instructions for the handling of the article.

- Read all instructions (including KleeYa User Manual)!

- Do not use damaged articles!
- Do not use any articles whose direct packaging is damaged!
- Do not use any articles whose expiration date has been exceeded!
- Never reuse single-use articles! Repeatedly use of single-use articles might cause cross-contamination. Furthermore, correct product performance is not guaranteed anymore.

2 SPEFICIFATIONS

Nominal volume:	1 mL
Processing volume:	600 uL
Residual volume:	≤ 10 uL

3 USE

Stackable Cuvettes are loaded stack-wise into the KleeYa System. Through an opening in the top cover the system is fed with cuvettes. Stackable Cuvettes can be loaded during the run. The KleeYa System has the capability to host of up to 500 cuvettes.

For further instructions for use see KleeYa User Manual “3.3.2 Load Cuvettes”.

4 ENVIRONMENTAL CONDITIONS

Temperature 	Operating: 2°C to 37°C + 3°C (35,6°F to 98,6°F + 5,4°F) Storage: 2°C to 32°C (35,6°F to 89,6°F) for a maximum of 2 years Transport: -10°C to 60°C (14°F to 140°F) for a maximum of 3 days
Humidity 	Operating: 20 – 80 % non-condensing Storage: 20 - 80 % non-condensing for a maximum of 2 years Transport: 10 - 90 % non-condensing for a maximum of 3 days
NOTICE	Protect from sunlight and UV rays!

5 DISPOSAL AND DECONTAMINATION

NOTICE **Disposal of non-contaminated parts**

Material out of use (e.g. packaging material, units with damaged direct packaging) should be properly disposed according to local waste disposal regulations.

⚠ WARNING **Disposal of contaminated parts**

Potential infectious material will cause severe environmental contamination.

Strictly follow the local and national provisions, legislation and laboratory regulations.

6 SUPPORT

NOTICE	E-mail: Support.KleeYa@diatron.com

7 MANUFACTURER

Manufactured in Germany for STRATEC Consumables GmbH.

STRATEC Consumables GmbH
Sonystrasse 20
5081 Anif
Austria
Internet: www.stratec.com/solutions/consumables

CE IVD

8.3.3 TRIGGER SOLUTION 1 – ACID REAGENT

Name:	PACKAGE INSERT for TRIGGER SOLUTION 1 – ACID REAGENT
Purpose:	This solution is intended to generate a luminescent signal during a chemiluminescence immunoassay reaction in the "KleeYa" instrument.
Product code:	226491-T1
Product size:	3 x 270 mL

1 INTENDED USE

INFO **For in vitro diagnostic use only.**

For professional use.

Trigger Solution 1 – Acid Reagent, Trigger Solution 2 – Base Reagent ("Trigger Solutions") are required to generate the luminescent light signal in the fully automated chemiluminescence immunoassay (CLIA) analyzer "KleeYa". The Trigger Solutions are designed for the flash system, which implies the usage of an acridinium-labeled conjugate. The acridinium ester label undergoes an oxidative reaction when exposed to peroxide (Trigger Solution 1 – Acid Reagent) and an alkaline solution (Trigger Solution 2 – Base Reagent). The oxidized product is in an excited form. The return to its ground state is indicated by the emission of light, which is measured in a few seconds and is expressed in relative light units (RLU) by the "KleeYa" instrument.

Please refer to the "KleeYa" instrument's Instruction for Use for further information.

2 INGREDIENTS

The Trigger Solution 1 – Acid Reagent is supplied as a 3 x 270 mL ready to use reagent.

Brand name	Ingredients
Trigger Solution 1 – Acid Reagent	• hydrogen peroxide • nitric acid 0.5%

3 SAFETY INSTRUCTIONS

- For hazard and precautionary statements, please refer to the Safety Data Sheet (SDS).This instruction is provided for your safety and gives important instructions for the handling of the solution.
- Read Safety Data Sheet!
- Use routine laboratory precautions. Do not eat, drink, or smoke in designated work areas.
- Wear disposable gloves and laboratory coats when handling specimens and kit reagents. Avoid contact with eyes, skin and clothing.
- Avoid swallowing and contact with mucous membranes.
- In case of eye contact rinse immediately with plenty of water and consult a physician. Remove contact lenses, if present and easy to do. Continue rinsing.
- In case of skin contact wash skin immediately with plenty of water. In case of skin irritation or allergic reactions see a physician.
- Move to fresh air in case of accidental inhalation of vapors or decomposition products.
- If swallowed do NOT induce vomiting. Drink plenty of water and seek medical advice. Beware of aspiration if vomiting does occur.
- Do not use damaged, broken or chipped Dispense Cartridges.
- Do not use reagent once frozen.
- Do not mix the remains of reagents.
- Follow Good Laboratory Practices (GLP) when handling the reagents.
- Strictly follow the local and national provisions, legislation and laboratory regulations.

4 REAGENT PREPARATION AND USE

The Trigger Solution 1 – Acid Reagent is ready for use.

Prior to usage, allow the Trigger Solution 1 – Acid Reagent to reach room temperature (20-25 °C).

Inspect the Trigger Solution 1 – Acid Reagent prior to use.

Do not use any articles whose direct packaging is damaged!

Do not combine Trigger Solution 1 – Acid Reagent from different production lots.

Do not use any articles whose expiration date has been exceeded!

Whenever the Trigger Solution 1 – Acid Reagent and Trigger Solution 2 – Base Reagent are replaced, follow the procedure described in the “KleeYa” instrument’s Instruction for Use.

To avoid any mix-up, the labels for the Trigger Solutions are marked with Trigger Solution 1 – Acid Reagent (orange) and Trigger Solution 2 – Base Reagent (blue). Follow the color marking on the label when you place the bottles in the device. Correct positioning is essential.

In case you observe any leakage, remove the Trigger Solution 1 – Acid Reagent from the "KleeYa" instrument and use a new Dispense Cartridge.

Prime the new Trigger Solutions completely through the reagent lines.

Do not shake violently to avoid bubble formation.

5 ENVIRONMENTAL CONDITIONS

	Storage Conditions
Temperature:	Operating/After opening: 15°C to 25°C (59°F to 77°F) Usage: 15°C to x 25°C (59°F to 77°F) Storage: 4°C to 25°C (40°F to 77°F)
Shelf life:	Trigger Solution 1 – Acid Reagent is stable until the expiration date on the label (one year after manufacturing). Do not use reagent beyond the expiration date printed on the label!
In-use stability:	30 days after opening Discard opened Dispense Cartridge after 30 days!
Notes:	Protect from direct sunlight! Do not freeze!

Appropriate precautions and good laboratory practices must be followed during storage, handling and disposal of the Trigger Solution 1 – Acid Reagent. Refer to the SDS associated with the Trigger Solution 1 – Acid Reagent.

6 DISPOSAL AND DECONTAMINATION

NOTICE **Disposal of non-contaminated parts**

Material out of use (e.g. packaging material) should be properly disposed.

Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any local, State and Federal authority requirements / regulations.
Dispose of surplus and nonrecyclable products via a licensed waste disposal contractor.

7 MANUFACTURER

Diatron MI Plc.
Táblás u. 39.
H-1097 Budapest
Hungary
Phone number: +36 14369800
E-mail: Support.KleeYa@diatron.com
Internet: www.diatron.com

CE IVD

Release date 01.04.2020 version 02

8.3.4 TRIGGER SOLUTION 2 – BASE REAGENT

Name:	PACKAGE INSERT for Trigger Solution 2 – Base Reagent
Purpose:	This solution is intended to generate a luminescent signal during a chemiluminescence immunoassay reaction in the "KleeYa" instrument.
Ident No.:	226491-T2
Product size:	3 x 270 mL

1 INTENDED USE

INFO **For in vitro diagnostic use only.**

For professional use.

Trigger Solution 1 – Acid Reagent, Trigger Solution 2 – Base Reagent ("Trigger Solutions") are required to generate the luminescent light signal in the fully automated chemiluminescence immunoassay (CLIA) analyzer "KleeYa". The Trigger Solutions are designed for the flash system, which implies the usage of an acridinium-labeled conjugate. The acridinium ester label undergoes an oxidative reaction when exposed to peroxide (Trigger Solution 1 – Acid Reagent) and an alkaline solution (Trigger Solution 2 – Base Reagent). The oxidized product is in an excited form. The return to its ground state is indicated by the emission of light, which is measured in a few seconds and is expressed in relative light units (RLU) by the "KleeYa"instrument.

Please refer to the "KleeYa" instrument's Instruction for Use for further information.

2 INGREDIENTS

The Trigger Solution 2 – Base Reagent is supplied as a 3 x 270 mL ready to use reagent.

Brand name	Ingredients
Trigger Solution 2 – Base Reagent	• cetyltrimethylammonium surfactant • sodium hydroxide 0.25N

3 SAFETY INSTRUCTIONS

- For hazard and precautionary statements, please refer to the Safety Data Sheet (SDS).This instruction is provided for your safety and gives important instructions for the handling of the solution.
- Read Safety Data Sheet!
- Use routine laboratory precautions. Do not eat, drink, or smoke in designated work areas.
- Wear disposable gloves and laboratory coats when handling specimens and kit reagents.
- Avoid contact with eyes, skin and clothing.
- Avoid swallowing and contact with mucous membranes.
- In case of eye contact rinse immediately with plenty of water and consult a physician. Remove contact lenses, if present and easy to do. Continue rinsing.
- In case of skin contact wash skin immediately with plenty of water. In case of skin irritation or allergic reactions see a physician.
- Move to fresh air in case of accidental inhalation of vapors or decomposition products.
- If swallowed do NOT induce vomiting. Drink plenty of water and seek medical advice. Beware of aspiration if vomiting does occur.
- Do not use damaged, broken or chipped Dispense Cartridges.
- Do not use reagent once frozen.
- Do not mix the remains of reagents.
- Follow Good Laboratory Practices (GLP) when handling the reagents.
- Strictly follow the local and national provisions, legislation and laboratory regulations.

4 REAGENT PREPARATION AND USE

The Trigger Solution 2 – Base Reagent is ready for use.

Prior to usage, allow the Trigger Solution 2 – Base Reagent to reach room temperature (20-25 °C).

Inspect the Trigger Solution 2 – Base Reagent prior to use.

Do not use any articles whose direct packaging is damaged!

Do not combine Trigger Solution 2 – Base Reagent from different production lots.

Do not use any articles whose expiration date has been exceeded!

Whenever the Trigger Solution 1 – Acid Reagent and Trigger Solution 2 – Base Reagent are replaced, follow the procedure described in the “KleeYa” instrument’s Instruction for Use.

To avoid any mix-up, the labels for the Trigger Solutions are marked with Trigger Solution 1 – Acid Reagent (orange) and Trigger Solution 2 – Base Reagent (blue). Follow the color marking on the label when you place the bottles in the device. Correct positioning is essential.

In case you observe any leakage, remove the Trigger Solution 2 – Base Reagent from the "KleeYa" instrument and use a new Dispense Cartridge.

Prime the new Trigger Solutions completely through the reagent lines.

Do not shake violently to avoid bubble formation.

5 ENVIRONMENTAL CONDITIONS

	Storage Conditions
Temperature:	Operating/After opening: 15°C to x 25°C (59°F to 77°F) Usage: 15°C to x 25°C (59°F to 77°F) Storage: 4°C to 25°C (40°F to 77°F)
Shelf life:	Trigger Solution 2 – Base Reagent is stable until the expiration date on the label (one year after manufacturing). Do not use reagent beyond the expiration date printed on the label!
In-use stability:	30 days after opening Discard opened Dispense Cartridge after 30 days!
Notes:	Protect from direct sunlight! Do not freeze!

Appropriate precautions and good laboratory practices must be followed during storage, handling and disposal of the Trigger Solution 2 – Base Reagent. Refer to the SDS associated with the Trigger Solution 2 – Base Reagent.

6 DISPOSAL AND DECONTAMINATION

NOTICE **Disposal of non-contaminated parts**

Material out of use (e.g. packaging material) should be properly disposed.

Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any local, State and Federal authority requirements / regulations.
Dispose of surplus and no recyclable products via a licensed waste disposal contractor.

7 MANUFACTURER

Diatron MI Plc.
Táblás u. 39.
H-1097 Budapest
Hungary
Phone number: +36 14369800
Email: Support.KleeYa@diatron.com
Internet: www.diatron.com

CE IVD

Release date 01.04.2020 version 02

8.3.5 5X TBS WASH BUFFER

Name:	**PACKAGE INSERT for 5x TBS WASH BUFFER**
Purpose:	This solution is intended to wash-off excess acridinium ester conjugate, non-bound components and background molecules during a chemiluminescence immunoassay reaction in the KleeYa analyzer.
Product code:	TWB5
Product size:	4 x 2 L (5x concentrated)

1 INTENDED USE

INFO **For in vitro diagnostic use only.**

For professional use.

The product is intended as a wash buffer for the chemiluminescence reaction in the fully automated chemiluminescence immunoassay analyzer "KleeYa".

The 5x TBS Wash Buffer is designed for the flash system, which implies the usage of an acridinium-labeled conjugate.

The 5x TBS Wash Buffer is used to wash-off excess conjugate and background molecules during the immunoassay reaction.

Please refer to the KleeYa instrument's Instruction for Use for further information.

2 INGREDIENTS

The 5x Wash Buffer is supplied as a 2 L concentrated Tris-buffered saline solution (5x) being sufficient for preparing 10 L of working solution.

Brand name	Ingredients
5x TBS Wash Buffer	• Tris base < 4 % • NaCl < 5% • Preservatives < 0.2 % • Surfactants < 0.5 %

3 SAFETY INSTRUCTIONS

- For hazard and precautionary statements, please refer to the Safety Data Sheet (SDS).This instruction is provided for your safety and gives important instructions for the handling of the solution.
- Read Safety Data Sheet!
- May cause an allergic skin reaction.
- Improper handling of solution can cause skin, eye irritations.
- Avoid contact with eyes, skin and clothing.
- In case of eye or skin contact flush eyes with copious amounts of water for several minutes or wash skin area with water.
- Wear laboratory gloves, lab coat and eye protection when handling the reagent.
- Follow Good Laboratory Practices (GLP) when handling the reagents.
- Keep the reagent container closed when not in use.
- Do not use solution if direct packaging is damaged!
- Strictly follow the local and national provisions, legislation and laboratory regulations.

4 REAGENT PREPARATION AND USE

Prior to dilution, allow the 5x TBS Wash Buffer to reach room temperature (20-25 °C).
Fill the full bottle of 5x TBS Wash Buffer (2 L) into the 10 L container of the fully automated chemiluminescence immunoassay analyzer "KleeYa" and add 8 L of DI water (until the indication line on the 10 L tank)in order to get 10 L of 1x TBS Wash Buffer. Always add the 5x TBS Wash Buffer before the DI water in order to ensure optimal blending of reagents. Precaution should be taken to minimize foaming. Avoid vigorous agitation by adding the DI water slowly.

After completion of the wash buffer preparation, the cap must be placed lightly on the container to allow proper degassing of the wash buffer solution. Wait 2 hours for the microbubbles to disappear from the solution before use.

Avoid any dust or microbial contamination of the 10 L container, 5x TBS Wash Buffer and DI water.

Do not mix the remains of 1x TBS Wash Buffer from different 10 L containers.
Do not use 5x TBS Wash Buffer once frozen.

Do not use the 5x TBS Wash Buffer after expiry.

If the solution remains in the tank after the end of onboard stability the solution shall be discarded, the tank shall be cleaned according to the Instructions for Use.

5 ENVIRONMENTAL CONDITIONS

	Storage Conditions
Temperature:	Operating/After opening: +15 °C to +30 °C (59 °F to 86 °F) Storage: +4 °C to +32 °C (40 °F to 89 °F) Transport: +4 °C to +32 °C (40 °F to 89 °F)
Shelf life:	2 years after the date of manufacture.
In-use stability:	30 days (in diluted, ready to use form)

Appropriate precautions and good laboratory practices must be followed during storage, handling and disposal of the 5x TBS Wash Buffer. Refer to the SDS associated with the 5x TBS Wash Buffer.

6 DISPOSAL AND DECONTAMINATION

⚠ DANGER **Hazardous waste**

Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 91/689/EEC.

NOTICE **Disposal of non-contaminated parts**

Material out of use (e.g. packaging material) should be properly disposed.

Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any local, State and Federal authority requirements / regulations.
Dispose of surplus and nonrecyclable products via a licensed waste disposal contractor.

7 MANUFACTURER

Diatron MI Plc.
Táblás u. 39.
H-1097 Budapest
Hungary
Phone number: +36 14369800
E-mail: support@diatron.com
Internet: www.diatron.com

Release date 2020-04-01 version 02

Intentionally left blank.

9 CONTACT

GERMANY

STRATEC SE
Gewerbestraße 37
75217 Birkenfeld
Germany
Phone: +49 (0) 7082 7916-0
Fax: +49 (0) 7082 7916-999
E-Mail: info@stratec.com
Internet: www.stratec.com

Intentionally left blank.

10 GLOSSARY

Anchor® Tip	Disposable tip
CE	Conformité Européenne (European conformity)
CFR	Code of Federal Regulations (Codes of FCC, US government)
Fatal Error	An unexpected and non-recoverable termination of instrument operation including, but not limited to assay processing,maintenance, service, start-up, and shut-down.
FCC	Federal Communications Commission, US government
Host	In computer networking a host is a main computer (e. g. server, central computer).
ID	Identification (Number).
IVD	In-vitro Diagnostic
LAN	A Local Area Network is a computer network.
LAS	Laboratory Automation System
LED	Light Emitting Diode
LIMS	A Laboratory Information Management System (LIMS) is computer software that is used in laboratories for the management of samples, laboratory users, instruments, standards and other laboratory functions such as invoicing, plate management, and work flow automation.
LIS	A Laboratory Information System, is a class of software which handles receiving, processing and storing information generated by medical laboratory processes.
LIS01-A2	Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems
LIS02-A2	Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems
ms	Milli seconds (1000 ms = 1 s)
nm	A nanometer is a unit of length in the metric system. (1 nm = 0.000001 mm = $1*10^{-9}$ m = $39.37*10^{-9}$ inch)
PC	Personal Computer
PS2	The PS/2 (PS2) connector allows the connection of a keyboard or a mouse to a computer.
RAM	Random access memory When the computer is shut down, anything contained in RAM is lost.

Recall mode	During recall mode, the sample rack can be removed from the instrument to resolve problems with the barcode. The position of the test tubes shall not be changed.
RFID	Radio frequency identification
RLU	Relative light unit
RoHS	Restriction of Hazardous Substances
RS232	Serial bus standard to connect devices to a computer.
STAT	Short turnaround time (sample to be tested in priority)
USB	The Universal Serial Bus is a serial bus standard to connect devices to a computer.
V	Voltage
VGA	The Video Graphics Array is a standard interface to connect a screen to a computer.
µl	A microliter is a unit of volume in the metric system. (1 µl = 0.001 ml = $1*10^{-6}$ l)

11 INDEX

M

N

O

P

Q

R

S

T

U

W

Intentionally left blank.