LightCycler®

Roche

Digital LightCycler® System

Safety Guide

Publication version 2.0

Software version 1.1

Publication information

Publication version	Software version	Revision date	Change description
1.0	1.0	February 2022	First version
1.1	1.0	September 2022	Information on safety labels on analyzer updated. What is new in publication version 1.1 (9)
2.0	1.1	March 2024	The following information was added, updated, and/or extended: Cover, colors, and fonts of the publication. Electronic user documentation from the navify Portal. Temperature specifications for thermal cycler units. Center wavelengths and bandwidths for 6 excitation filters and 6 emission filters. Firefox version. What is new in publication version 2.0 (9)

Revision history

Edition notice

This publication is intended for users of the Digital LightCycler® System.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

Where to find information

The **User Assistance** contains all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- Software reference
- Configuration information
- Background information

The **Safety Guide** contains important safety information. You must read the Safety Guide before operating the instruments.

The **User Guide** focuses on routine operation and maintenance. The content is organized according to the normal operation workflow.

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eLabDoc

Electronic user documentation can be downloaded using the eLabDoc e-service on navify Portal:

www.navifyportal.roche.com

For more information, contact your local affiliate or Roche Service representative.

Table of contents

Preface 7
Intended use 7
Symbols and abbreviations 7
What is new in publication version 2.0 9
What is new in publication version 1.1 9
Introduction 11
Safety classifications 12
Safety precautions 13
Installation and transport 13
Safe and proper use of the system 13
Operating conditions 14
Electromagnetic compatibility 15
Warning messages 17
Electrical safety 17
Caution messages 18
Personal injury 18
Incorrect, invalid, or delayed results 20
Waste handling 26
Notices 27
Delay 27
Loss of supplies 28
Unauthorized access to personal information 29
Damage to the instruments 29
Safety labels on the system 31
About safety labels on the system 31
List of safety labels on the system 31
Location of safety labels on the partitioning engine 32
Location of safety labels on the analyzer 33
Safety information for disposal 34
System specifications 35
General specifications 35
General specifications of the system 35
General specifications of the analyzer 35
General specifications of the partitioning engine 36

Electric power supply 36
Electric power supply for the analyzer 36
Electric power supply for the partitioning engine 36
Environmental conditions for the system..... 37
Dimensions and weight..... 38
Dimensions and weight of the analyzer.... 38
Dimensions and weight of the partitioning engine 38
Required space 38
Space required around the analyzer..... 39
Space required around the partitioning engine..... 39
Radio equipment specifications 39
Thermal cycler units specifications 40
Detection unit specifications 40
Supported characters in ASTM messages 41
List of available consumables and reagents..... 41
Computer specifications 43
Specifications for the development software... 43
Specifications for the web application 43

Preface

Use this publication together with the Digital LightCycler® System User Guide or User Assistance.

Operation and maintenance actions are described in the User Guide and User Assistance.

In this section

Intended use (7)

Symbols and abbreviations (7)

What is new in publication version 2.0 (9)

What is new in publication version 1.1 (9)

Intended use

The Digital LightCycler® System supports a semi-automated workflow to run Polymerase Chain Reaction (PCR) based Nucleic Acid Testing (NAT). The system performs digital endpoint PCR analysis of microfluidic partitions, combining the functionalities of instrumentation, consumables, reagents, and data management to provide an efficient workflow from sample partitioning to result interpretation.

The Digital LightCycler® System is a semi-automated system for detection and absolute quantification of nucleic acid target copy number, intended for in vitro diagnostic use by professional users in diagnostic and screening laboratories.

The system is comprised of the Digital LightCycler® Analyzer, the Digital LightCycler® Partitioning Engine, and specified consumables, core reagents and application software. All assays are developed independently of the Digital LightCycler® System.

Symbols and abbreviations

Product names

Except where the context clearly indicates otherwise, the following product names and descriptors are used.

Product name	Descriptor
Digital LightCycler® System	system
Digital LightCycler® Partitioning Engine	partitioning engine
Digital LightCycler® Analyzer	analyzer
Digital LightCycler® Analyzer Software	analyzer software
Digital LightCycler® Web Application	web application
Digital LightCycler® Development Software	development software
Digital LightCycler® Universal Nanowell Plate	universal nanowell plate
Digital LightCycler® High Resolution Nanowell Plate	high resolution nanowell plate
Digital LightCycler® High Sensitivity Nanowell Plate	high sensitivity nanowell plate
Digital LightCycler® Partitioning Fluid	partitioning fluid
Digital LightCycler® Partitioning Fluid Waste Bottle	liquid waste bottle
Digital LightCycler® 5x DNA Master	DNA master reagent
Digital LightCycler® 5x RNA Master	RNA master reagent

Product names

Abbreviations The following abbreviations are used.

Abbreviation	Definition
AC	Alternating current
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
CFR	Code of Federal Regulations
CISPR	Comité International Spécial des Perturbations Radioélectriques (International Special Committee on Radio Interference)
DC	Direct current
EC	European Community
EMC	Electromagnetic compatibility
ft	Foot
GB	Gigabyte
HL7	Health Level Seven
IEC	International Electrical Commission
in	Inch
IP	Internet protocol
ISO	International Organization for Standardization
IVD	In vitro diagnostic
IVDR	In vitro diagnostics regulation
LAN	Local area network
lbs	Pound

Abbreviations

Abbreviation	Definition
LIS	Laboratory information system
PCR	Polymerase chain reaction
RAM	Random access memory
RF	Radio frequency
RFID	Radio frequency identification
UPS	Uninterruptible power supply
WLAN	Wireless LAN

Abbreviations

What is new in publication version 2.0

Layout

The cover page, the colors, and the fonts of the publication were updated.

Electronic user documentation

Electronic user documentation can be downloaded using the eLabDoc e-service on navify Portal.

eLabDoc (4)

Thermal cycler units

The temperature specifications for the thermal cycler units were added.

Thermal cycler units specifications (40)

Excitation filters and emission filters

The center wavelengths and bandwidths for the 6 excitation filters and 6 emission filters of the detection unit of the analyzer were added.

Detection unit specifications (40)

Firefox version

Use Firefox ESR 102.12.0 for the web application.

Specifications for the web application (43)

What is new in publication version 1.1

Safety labels on the analyzer

The information on safety labels on the analyzer was updated.

List of safety labels on the system (31)

Location of safety labels on the analyzer (33)

Introduction

⚠ General attention

To avoid serious or fatal injury, read this publication thoroughly before you use the system.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the system in a way that is not described in this publication.
- Keep this publication in a safe place to ensure that it is not damaged and remains available for use.
- This publication must always be easily accessible.

Safety classifications

The safety precautions and important user notes are classified according to the applicable standards. Familiarize yourself with the following meanings and icons:

⚠ Safety alert

- The safety alert symbol is used to alert you to potential physical injury hazards. Obey all safety messages that follow this symbol to avoid possible damage to the system, injury, or death.

These symbols and signal words are used for specific hazards:

⚠ 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 a hazardous situation which, if not avoided, may result in damage to the system.

Important information that is not safety relevant is indicated with the following icon:

Tip...

...indicates additional information on correct use or useful tips.

Safety precautions

⚠ **To avoid serious or fatal injury, read and comply with the following safety precautions.**

In this section

Installation and transport (13)

Safe and proper use of the system (13)

Operating conditions (14)

Electromagnetic compatibility (15)

Installation and transport

Errors in installation

Error during installation of a new system or new parts can cause malfunctions.

- Leave installation activities to Roche Service representatives.

Damage during transport

Damage during transport can cause malfunctions.

- Do not attempt to relocate or transport the system. Leave relocation and transportation to Roche Service representatives.

Safe and proper use of the system

Missing personal protective equipment

Working without personal protective equipment means danger to life or health.

- Wear appropriate personal protective equipment, including, but not limited to, the following items:
  - Eye protection
  - Lab coat
  - Lab gloves
- Follow laboratory best practices and regularly change lab gloves to minimize the risk of infection and contamination, especially after contact with waste or sample material.

Exchange or removal of parts

Unauthorized exchange or removal of system parts can damage the system or stop it from functioning correctly.

- Do not exchange or remove any part of the instruments. Leave replacement of all instrument parts to Roche Service representatives.

Non-specified consumables

Use of non-specified consumables can lead to incorrect results or damage the system.

- Only use consumables approved for the system.
- Refer to the User Assistance for a list of the available consumables.

Operating conditions

Unsuitable operating conditions

Operation outside of the specified ranges may lead to incorrect processing or malfunction of the system.

- Consult the specifications.
- Use the system indoors only. Avoid proximity to heat sources and high radiation, and avoid humidity outside of the specified range.
- Ensure that the system's ventilation openings always remain unobstructed.
- In case of an emergency, use the power inlets of the partitioning engine and the analyzer as the points where to quickly disconnect the instruments from the mains outlets. Ensure that the power inlets are always easily accessible.

Environmental conditions for the system (37)

- Refer to the User Assistance for an overview of the partitioning engine and the analyzer.

Power interruption

A power failure or momentary drop in voltage may damage the system or lead to data loss.

- Operate with an uninterruptible power supply (UPS). The specification of the UPS must comply with the power requirements for the instruments. If the UPS can barely supply the required power, the instruments may automatically shut down. Do not connect other devices to the UPS.
- Ensure periodic maintenance of the UPS.
- Perform regular backups of results.
- To shut down the instruments, follow the shutdown procedures in this publication. Only if immediate shutdown is required, use the power switch of the partitioning engine or the power button of the analyzer. If you use the power switch or power button, all processes are aborted. The data (e.g., partitioning data or results) for all currently processed samples may be lost.
- Refer to the User Assistance for the required electric power supply and for the procedures to shut down the partitioning engine and the analyzer.

Electromagnetic compatibility

The system complies with the emission and immunity requirements described in the parts IEC 61326-2-6 and IEC 61326-1.

The system complies with the emission requirements described in FCC CFR 47, Part 15 Class A.

The system has been designed and tested to CISPR 11 Class A.

In a domestic environment, the system may cause electromagnetic interference, in which case you must take measures to mitigate the interference.

Non-approved accessories, transducers, and cables

Use of non-approved accessories, transducers, and cables can result in increased electromagnetic emissions and decreased electromagnetic immunity of the system. It can also result in improper operation.

- Only use accessories, transducers, and cables specified or provided by the manufacturer of this system. For more information, contact your Roche Service representative.
- Only use cable length which complies with EMC testing:
  - USB 2.0: < 3 m
  - LAN/Ethernet: < 30 m (longer cable might reduce speed performance)
  - AC power input: < 30 m (longer cable can reduce the voltage of the system)

Electromagnetic fields

Strong electromagnetic fields can result in degradation of the system performance.

- Evaluate the electromagnetic environment before operating the system.
- Do not use portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm to any part of the system, including cables specified by the manufacturer.
- Do not operate this system close to sources of strong electromagnetic fields (for example, unshielded intentional RF sources), as they may interfere with proper operation. The distance of 30 cm for portable RF devices (mobile phones, Wi-Fi) is considered as normal electromagnetic fields for the system.
- Do not use the system in proximity (< 30 cm) to sources of strong electromagnetic radiation (for example, microwave ovens, hand-held radio transmitters, electric motors, RFID emitters), as they can interfere with proper operation.
- If it is suspected that electromagnetic interference affects the performance, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

Warning messages

⚠ List of warning messages

Failure to observe warning messages may result in death or serious injury.

- Before operating the system, read the warning messages carefully.

Electrical safety

Electric shock

Removing the covers of electronic equipment can cause electric shock.

- Do not remove any cover of the system except those covers specified in the instructions.
- Do not exchange or remove any part of the instruments. Leave replacement or repair of all instrument parts to Roche Service representatives.

Fire and burns

Alcohol is a flammable substance.

- Keep all sources of ignition (such as sparks, flames, or heat) away from the system when you perform maintenance that involves alcohol.
- When you use alcohol on or around the system, use no more than 20 mL at a time.

Caution messages

⚠ List of caution messages

- Before operating, read the caution messages carefully. Failure to observe them may result in minor or moderate injury.

In this section

Personal injury (18)

Incorrect, invalid, or delayed results (20)

Waste handling (26)

Personal injury

Sharps, rough edges, and/or moving parts

Personal injury and infection due to sharps, rough edges, and/or moving parts.

- Laboratory best practices can reduce the risk of injury.
- Be aware of your laboratory environment, well-prepared, and follow this publication. Some areas of the partitioning engine and the analyzer may have sharps, rough edges, and/or moving parts.
- Wear personal protective equipment to minimize the risk of injury from bodily contact with such parts, especially in less accessible areas, or while cleaning the partitioning engine or the analyzer.
- Your personal protective equipment should be appropriate to the degree and type of potential hazard, e.g., suitable lab gloves, eye protection, lab coat, and footwear.

Skin inflammation or injury

Direct contact with master reagents or other working solutions may cause skin irritation, inflammation, or burns.

- When you handle master reagents, exercise the precautions required for handling laboratory reagents.
- Wear appropriate personal protective equipment.
- Observe the instructions given in the Instructions for Use.
- Observe the information given in the Safety Data Sheets (available for Roche Diagnostics reagents and cleaning solutions).
- If master reagents or cleaning solutions come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant.
  Consult a physician.

Moving drawers

The nanowell plate drawer of the partitioning engine and the nanowell plate stack drawer of the analyzer open and close during operation. An opening drawer may strike you. A closing drawer may pinch your fingers.

- Keep away from the nanowell plate drawer of the partitioning engine and the nanowell plate stack drawer of the analyzer during operation.
- Do not try to close the nanowell plate drawer of the partitioning engine or the nanowell plate stack drawer of the analyzer manually by pushing against it.
- Leave sufficient free space around the partitioning engine and the analyzer to allow for unobstructed movement of the nanowell plate drawer and the nanowell plate stack drawer.

Sharp aspiration needle

The aspiration needle in the partitioning engine is sharp. Contact with the aspiration needle may result in personal injury.

- Carefully follow the instructions in this publication for replacing the bottles on the partitioning engine and for decontaminating the aspiration needle.
- When replacing the bottles on the partitioning engine or when decontaminating the aspiration needle, pay extra attention to the aspiration needle.

Refer to the User Assistance for the procedures to replace the bottles and to decontaminate the aspiration needle.

Incorrect, invalid, or delayed results

Use of incorrect nanowell plate type

The nanowell plate types are indistinguishable by their overall appearance. Using the wrong type of nanowell plates may cause incorrect, invalid, or delayed results.

- To identify the nanowell plate type, refer to the color-coded label of the nanowell plate.
- White label = Universal nanowell plate
- Violet label = High resolution nanowell plate
- Light-blue label = High sensitivity nanowell plate
- Refer to the User Assistance for details on the nanowell plates.

Improper handling of nanowell plates

Scratches, finger prints, dust, or other artifacts on the nanowell plate lanes compromise the image integrity, which may cause incorrect, invalid, or delayed results.

- Open the packing of the nanowell plates only immediately before use.
- Do not leave the nanowell plates in the open for any length of time.
- Do not touch the nanowell plate lanes.
- Handle the nanowell plates by the long sides of the nanowell plate frames only.
- Wear lab gloves when handling the nanowell plates. Regularly change lab gloves.

Untested computer configuration

Accessing the web application from a computer with an untested configuration may compromise the performance of the web application, which may cause invalid or delayed results.

- Observe the specifications for the computer used to access the web application.
- Refer to the User Assistance for the specification for the web application.

Pipetting errors

Pipetting errors, e.g., confusing the positions of the reaction mixtures on a nanowell plate, may cause incorrect results.

- Carefully enter the sample IDs and nanowell plate IDs when creating a sample setup in the web application.
- Use the sample setup report from the web application as a guide for pipetting and for verification of the sample setup in the analyzer software.
- If a pipetting error may have occurred, invalidate the affected nanowell plate lane in the web application before starting the run on the analyzer.

- Refer to the User Assistance for the procedure to invalidate nanowell plates and/or nanowell plate lanes.

Incorrect nanowell plate ID

If the analyzer cannot read a nanowell plate ID automatically, you must enter the nanowell plate ID manually. Entering an incorrect nanowell plate ID may cause incorrect, invalid, or delayed results.

- When you must enter a nanowell plate ID manually, ensure that you scan or enter the correct nanowell plate ID.
- Refer to the User Assistance for the procedure to resolve a nanowell plate ID reading error.

Contamination of the partitioning engine

The partitioning fluid bottles and the liquid waste bottles are indistinguishable by their overall appearance. Loading a liquid waste bottle in the position of the partitioning fluid bottle may contaminate the partitioning engine, which may cause incorrect, invalid, or delayed results.

- Store partitioning fluid bottles and liquid waste bottles in a way to allow for proper distinction.
- Mark all waste bottles with a permanent marker as waste bottles. Mark empty or expired partitioning fluid bottles as waste bottles immediately after unloading them from the partitioning engine.
- Dispose of liquid waste bottles according to local regulations directly after unloading them from the partitioning engine.
- If you inadvertently loaded a liquid waste bottle in the position of the partitioning fluid bottle, immediately unload it again.
- Before loading a partitioning fluid bottle and using the partitioning engine again after incorrect loading, decontaminate the aspiration needle.
- If you inadvertently loaded a partitioning fluid bottle after incorrect loading without decontaminating the aspiration needle, do not use the partitioning engine. Immediately unload the partitioning fluid bottle again and dispose of it according to local regulations.
- Decontaminate the aspiration needle following the decontamination procedure.
- Refer to the User Assistance for the procedure to decontaminate the aspiration needle.

Unpartitioned nanowell plate lanes

Even if a nanowell plate lane contains a reaction mixture, the nanowell plate lane may remain unpartitioned on the partitioning engine. Processing nanowell plates with unpartitioned nanowell plate lanes that contain reaction mixtures on the analyzer may contaminate the analyzer, which may cause incorrect results.

- Before unloading a partitioned nanowell plate from the partitioning engine, always check the partitioning status of the nanowell plate lanes by means of the color of the partitioning indicators.
- If a partitioning indicator of a nanowell plate lane that contains a reaction mixture remains gray, discard the nanowell plate according to local regulations.
- Do not load nanowell plates with unpartitioned nanowell plate lanes that contain reaction mixtures on the analyzer.

Refer to the User Assistance for details on the partitioning indicators.

Leakage of sample material from nanowell plates

Pipetted and partitioned nanowell plates do not have a physical barrier against leakage of the reaction mixtures from the nanowell plates. Leakage of the reaction mixtures from the nanowell plates may contaminate the laboratory, which may cause incorrect, invalid, or delayed results.

- After unloading the nanowell plates from the analyzer, immediately place them in a resealable plastic bag that you keep sealed.
- Dispose of the plastic bag that contains the nanowell plates according to local regulations.

Delayed processing of partitioned nanowell plates

Delayed processing of partitioned nanowell plates on the analyzer may cause degradation of biological material and/or invalidation of the nanowell plates, which may cause incorrect, invalid, or delayed results.

- Only pipette and partition nanowell plates if you can directly run them on the analyzer afterwards.
- Ensure that you start the run directly after loading the analyzer.
- For diagnostic runs, observe that there may be a time limit configured in the analysis packages between partitioning and processing of a nanowell plate. If the time limit is exceeded, the nanowell plate is invalidated and cannot be processed anymore.

Incorrect run type

Starting a development run on nanowell plates that are designated for a diagnostic run, may cause invalid or delayed results.

- As an administrator, assign the appropriate user roles to the user accounts.

Refer to the User Assistance for user management.

Missing measurements

Missing measurements (e.g., because of incomplete loading of the analyzer or invalidated nanowell plate lanes) that are needed for result calculation may cause invalid or delayed results.

- Ensure that you load all nanowell plates of a sample setup on the analyzer (except invalid nanowell plates) to enable result calculation.
- Take extra care to avoid wrongly invalidating a nanowell plate lane that is required for result calculation.
- If you must invalidate a nanowell plate lane or if the sample setup contains invalid nanowell plates that cannot be processed on the analyzer, consider the implications for result calculation (e.g., missing measurements from nanowell plate lanes that contain controls, are part of merged lanes, or contain reaction mixtures for a different test).

Invalidated controls

If you invalidate a nanowell plate lane that contains a control, the system automatically invalidates all final results of the sample setup for the affected targets, which may cause delayed results.

- Take extra care to avoid wrongly invalidating a nanowell plate lane that contains a control.
- If you must invalidate a nanowell plate lane that contains a control, consider the implications for the final results of the sample setup.

Not supported characters in sample IDs

The system uses CP-1252 (code page 1252) to encode and decode ASTM messages.

If you connect the system to an LIS via the ASTM protocol, characters outside of code page 1252 (e.g., Unicode characters) are not supported in the transmissions to the LIS. Using unsupported characters in sample IDs may cause incorrect transmission of the sample IDs to the LIS, which may cause invalid or delayed results.

- If you use Unicode characters in your sample IDs, connect the system to an LIS via HL7 protocol.
- If you connect the system to an LIS via ASTM protocol, only use characters in the range of 0x21 (exclamation mark "!") to 0x7D (closing curly bracket "}") of the CP-1252 character encoding for sample IDs.

Incorrect assignment of partitioning engine to analyzer

An analyzer only processes nanowell plates that were partitioned on an assigned partitioning engine. If the partitioning engine you used to partition the nanowell plates is not assigned to the analyzer you want to process the nanowell plates on, the information from the partitioning engine may be lost, which may cause invalid or delayed results.

- Ensure that the partitioning engine is assigned to the analyzer.
- Pay extra attention to the assignment of the partitioning engines to the analyzers in a multiple instrument configuration (multiple partitioning engines and multiple analyzers).

Refer to the User Assistance for the procedure to assign partitioning engines.

Weak passwords

Weak passwords may allow unauthorized access to the system, data manipulation or loss, or unauthorized access to personal information, which may cause incorrect, invalid, or delayed results.

- Use strong passwords.
- Do not share passwords.
- Do not write down passwords.
- Do not share user accounts.
- As an administrator, ensure that the global password policy configured in the analyzer software enforces safe password handling.

Refer to the User Assistance for the password settings.

Compromised data security

Unprotected IT infrastructure and unrestricted physical access to the system and attached infrastructure may allow for infection with malicious software, manipulation of system components, or misuse of the system. Infection with malicious software, manipulation, or misuse may cause incorrect, invalid, or delayed results, or unauthorized access to personal information.

- Ensure that attached networks are secure and monitored for security breaches. Customers are responsible for the security of their local network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the system from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.
- The Roche-provided firewall is mandatory and part of the system.
- Ensure that other computers and services on the network are properly secured and protected against malicious software and unauthorized access.
- Restrict physical access to the system and all attached IT infrastructure (computer, cables, network equipment, etc.).
- If parts of your network, which the system uses to exchange data, are connected by WLAN, secure the WLAN.
- Ensure that any external storage devices (such as USB flash drives) connected to the system are free of malicious software.

Unprotected export files

Insecure transfer or storage of backup files and archive files may allow for data manipulation, which may cause incorrect, invalid, or delayed results.

- Ensure that backup files and archive files are transferred securely, are stored in a secure location, and are protected from any unauthorized access and disaster.
- Ensure that any external storage devices (such as USB flash drives) that contain backup files and archive files are protected against unauthorized access.

Incorrect handling of master reagents

Incorrect handling of master reagents may lead to incorrect results.

- Adhere to the storage conditions defined in the Instructions for Use for the reagents and controls. The system does not allow the use of expired master reagents.
- Do not use master reagents that have been dropped on the floor or compromised in any other way.
- Do not manipulate supplies in any way not specified in the user documentation, Instructions for Use, or labels.

Waste handling

Environmental harm

The system generates waste. Improper disposal may contaminate the environment.

- Dispose of waste according to local regulations.

Notices

List of notices

Failure to observe the notices may result in damage to the system.

- Before operating, read the notices contained in this summary carefully.

In this section

Delay (27)

Loss of supplies (28)

Unauthorized access to personal information (29)

Damage to the instruments (29)

Delay

Incorrect loading of the partitioning engine

The partitioning fluid bottles and the liquid waste bottles are indistinguishable by their overall appearance. Loading a liquid waste bottle in the position of the partitioning fluid bottle may contaminate the partitioning engine, which may cause a time delay.

- Store partitioning fluid bottles and liquid waste bottles in a way to allow for proper distinction.
- Mark all waste bottles with a permanent marker as waste bottles. Mark empty or expired partitioning fluid bottles as waste bottles immediately after unloading them from the partitioning engine.
- Dispose of liquid waste bottles according to local regulations directly after unloading them from the partitioning engine.
- If you inadvertently loaded a liquid waste bottle in the position of the partitioning fluid bottle, immediately unload it again.
- Before loading a partitioning fluid bottle and using the partitioning engine again after incorrect loading, decontaminate the aspiration needle.
- If you inadvertently loaded a partitioning fluid bottle after incorrect loading without decontaminating the aspiration needle, do not use the partitioning engine. Immediately unload the partitioning fluid bottle again and dispose of it according to local regulations.
- Decontaminate the aspiration needle following the decontamination procedure.

Refer to the User Assistance for the procedure to decontaminate the aspiration needle.

Loss of supplies

Incorrect loading of the partitioning engine

The partitioning fluid bottles and the liquid waste bottles are indistinguishable by their overall appearance. Loading a partitioning fluid bottle in the position of the liquid waste bottle contaminates the partitioning fluid and the partitioning fluid bottle.

- Store partitioning fluid bottles and liquid waste bottles in a way to allow for proper distinction.
- Mark all waste bottles with a permanent marker as waste bottles. Mark empty or expired partitioning fluid bottles as waste bottles immediately after unloading them from the partitioning engine.
- If you inadvertently loaded a partitioning fluid bottle in the position of the liquid waste bottle, immediately unload it again.
- Do not use the partitioning fluid bottle anymore. Instead, treat the contaminated partitioning fluid bottle as waste and dispose of it according to local regulations.

Unauthorized access to personal information

Compromised data security

Unrestricted physical access to the system and attached infrastructure, and unprotected IT infrastructure may allow for infection with malicious software, manipulation of system components, or misuse of the system. Infection with malicious software, manipulation, or misuse may cause incorrect, invalid, or delayed results, or unauthorized access to personal information.

- Do not install and/or execute any other software on the analyzer.
- Restrict physical access to the analyzer and all attached IT infrastructure (computer, cables, network equipment, etc.).
- Ensure that attached networks are secure and monitored for security breaches. Customers are responsible for the security of their local network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the system from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.
- The Roche-provided firewall is mandatory and part of the system.
- Ensure other computers and services on the network are properly secured and protected against malicious software and unauthorized access.
- If parts of your network, which the system uses to exchange data, are connected by WLAN, secure the WLAN.
- Ensure that any external storage devices (such as USB flash drives) connected to the analyzer are free of malicious software.

Unprotected export files

Insecure transfer or storage of backup files and archive files may allow data manipulation, which may cause unauthorized access to personal information.

- Ensure that backup files and archive files are transferred securely, are stored in a secure location, and are protected from any unauthorized access and disaster.

Damage to the instruments

Circuit breakers and fuses

Improper use may result in damage to the system.

- If a circuit breaker trips or a fuse blows, contact your Roche Service representative.

Mechanical stress

Shock, vibration, or pressure can damage the system.

- Keep sources of vibration away from the instruments.
- Do not place objects on top of the instruments.

Safety labels on the system

In this section

About safety labels on the system (31)

List of safety labels on the system (31)

Location of safety labels on the partitioning engine (32)

Location of safety labels on the analyzer (33)

About safety labels on the system

The system has warning labels to draw your attention to areas of potential hazard. The following list explains the meanings of the labels at the locations where you find the labels.

The safety labels on the system comply with the following standards: ANSI Z535, IEC 61010-2-101, IEC 61010-1, IEC 60417, or ISO 15223-1.

Only Roche Service representatives may replace damaged labels. For replacement labels, contact your Roche Service representative.

List of safety labels on the system

General warning

Potential hazards located near this label may lead to death or serious injury.

Refer to the user documentation for instructions on safe operation.

Moving parts

There is a risk of hand injuries from moving parts near this label.

Keep hands away from moving parts.

No heavy load

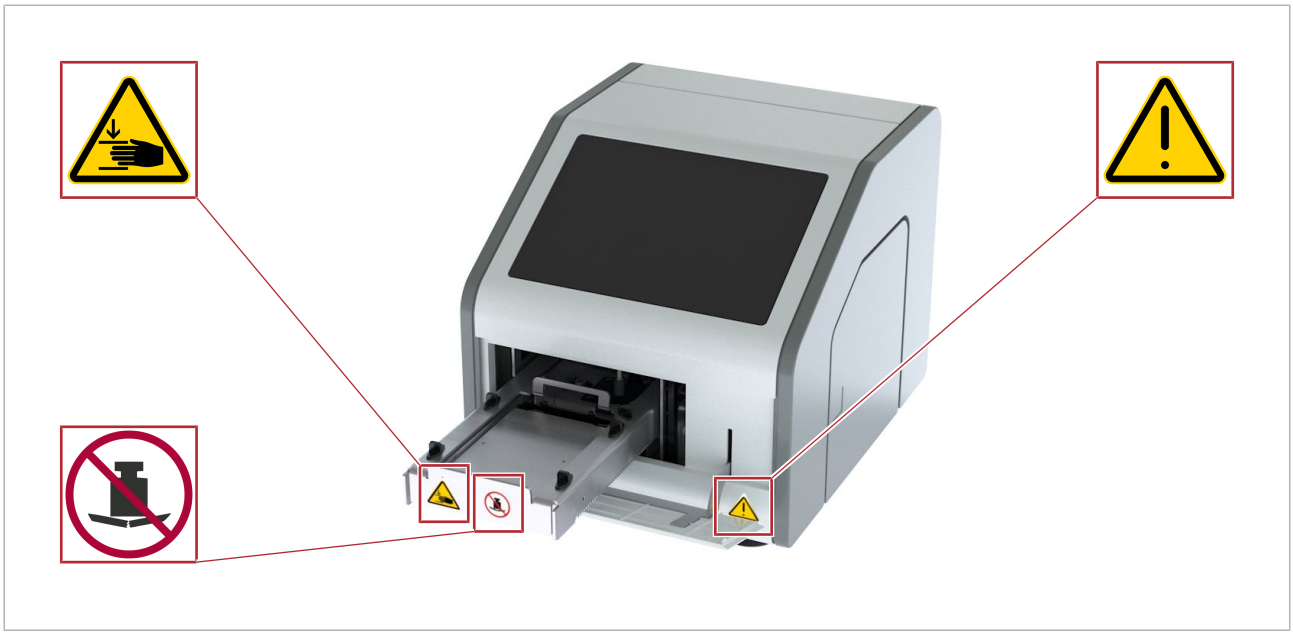
There is a risk of instrument damage near this label.

Do not place heavy objects on the instrument part.

Unplug

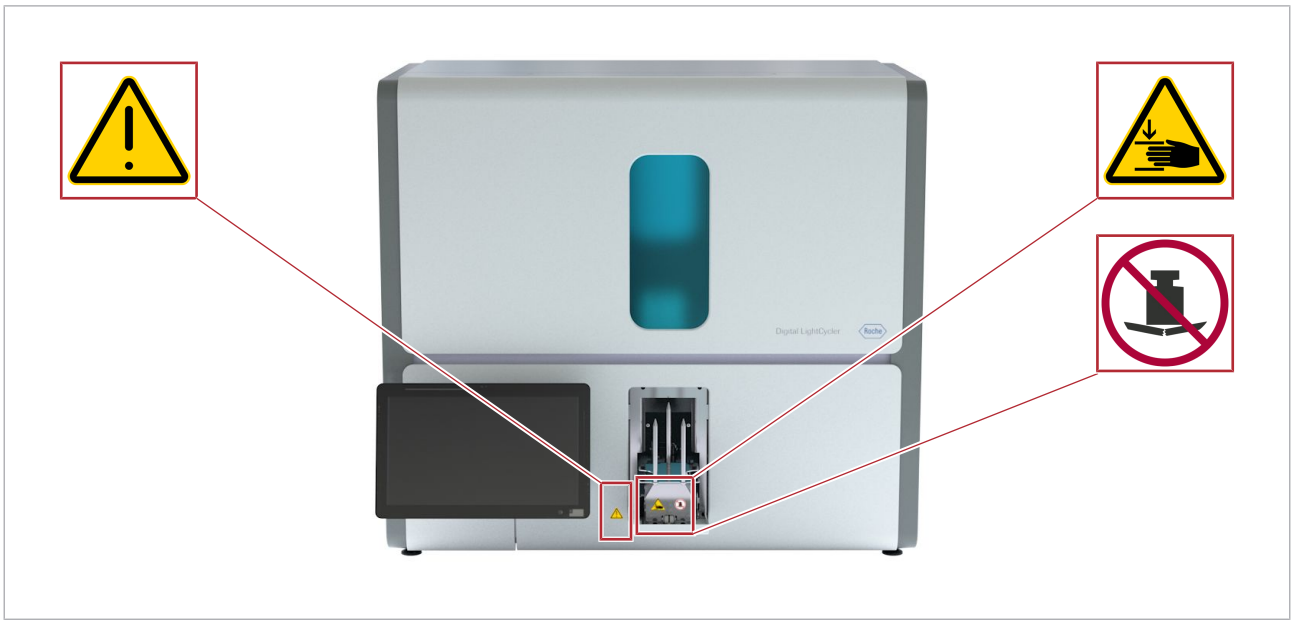
Unplug the mains cable from the mains outlet before performing any service activities.

Location of safety labels on the partitioning engine



Safety labels on the partitioning engine (front view with open nanowell plate drawer)

Location of safety labels on the analyzer



Safety labels on the analyzer (front view with open nanowell plate stack drawer)

Safety labels on the analyzer (side view)

Safety information for disposal

Disposal

- Dispose of the system according to local regulations. For more information, contact your Roche Service representative.

System specifications

In this section

General specifications (35)
Electric power supply (36)
Environmental conditions for the system (37)
Dimensions and weight (38)
Required space (38)
Radio equipment specifications (39)
Thermal cycler units specifications (40)
Detection unit specifications (40)
Supported characters in ASTM messages (41)
List of available consumables and reagents (41)

General specifications

In this section

General specifications of the system (35)
General specifications of the analyzer (35)
General specifications of the partitioning engine (36)

General specifications of the system

The system has the following general specifications:

System	
Noise emission	< 60 db (A)

General specifications of the system

General specifications of the analyzer

The analyzer has the following general specifications:

Analyzer	
Throughput	Up to 3.5 hours for 1 to 6 nanowell plates

General specifications of the analyzer

Analyzer	
	Up to 5 hours for 7 to 12 nanowell plates

General specifications of the analyzer

General specifications of the partitioning engine

The partitioning engine has the following general specifications:

Partitioning engine	
Throughput	Up to 5 minutes for 1 nanowell plate
	Up to 60 minutes for 12 nanowell plates

General specifications of the partitioning engine

Electric power supply

In this section

Electric power supply for the analyzer (36)

Electric power supply for the partitioning engine (36)

Electric power supply for the analyzer

The electric power supply for the analyzer must fulfill the following requirements:

		International (Europe)	US / Canada
Voltage		100-240 V AC ± 10%	
Frequency		50-60 Hz	
Current		15-6.25 A	
Installation	Installation category	Installation Category II (IEC 61010-1)	
	Protection class	Protection Class I	

Electric power supply for the analyzer

Electric power supply for the partitioning engine

The electric power supply for the partitioning engine must fulfill the following requirements:

	International (Europe)	US / Canada
Voltage	24 V DC	
Current	4 A	

Electric power supply for the partitioning engine

The power supply (AC adapter) of the partitioning engine must fulfill the following requirements:

		International (Europe)	US / Canada
Input voltage		100-240 V AC ± 10%	
Input frequency		50-60 Hz	
Input current		1.6 A	
Output voltage		24 V DC	
Output current		5 A	
Installation	Installation category	Installation Category II (IEC 61010-1)	
	Protection class	Protection Class I	

Power supply (AC adapter) of the partitioning engine

Only use the power supply (AC adapter) that is delivered together with the partitioning engine.

Environmental conditions for the system

The location must comply with the following conditions:

		International (Europe)	US / Canada
Ambient temperature	During operation	15 to 30 °C	59 to 86 °F
	During storage	5 to 40 °C	41 to 104 °F
	During transportation	-20 to 60 °C	-4 to 140 °F
Ambient humidity	During operation	20 to 80% (non-condensing)	
	During storage	15 to 85% (non-condensing)	
	During transportation	10 to 90% (non-condensing)	
Altitude above sea level		Up to 2000 m	Up to 6561 ft
Pollution degree		2	

Environmental conditions

Never operate the system if one of the environmental conditions is not fulfilled.

Other environmental conditions

- Indoor use only
- Horizontal installation space

- Dust-free environment with adequate ventilation
- No direct sunlight
- No perceptible vibration
- No equipment generating electromagnetic waves in the near vicinity
- No machines discharging ultrahigh frequencies (e.g., electric discharger)

Dimensions and weight

In this section

Dimensions and weight of the analyzer (38)

Dimensions and weight of the partitioning engine (38)

Dimensions and weight of the analyzer

The analyzer has the following dimensions and weight:

	International (Europe)	US
Height	90 cm	35.4 in
Width	100 cm	39.4 in
Depth	60 cm (without monitor)	23.6 in
Weight	200 kg	440 lbs

Dimensions and weight of the analyzer

Dimensions and weight of the partitioning engine

The partitioning engine has the following dimensions and weight:

	International (Europe)	US
Height	25 cm	9.8 in
Width	25 cm	9.8 in
Depth	30 cm	11.8 in
Weight	11 kg	24 lbs

Dimensions and weight of the partitioning engine

Required space

In this section

Space required around the analyzer (39)

Space required around the partitioning engine (39)

Space required around the analyzer

Do not operate the analyzer if there is insufficient free space around it.

	International (Europe)	US
Front	30 cm	12 in
Back	0 cm	0 in
Left side	50 cm	20 in
Right side	30 cm	12 in
Top	50 cm	20 in

Space required around the analyzer

Space required around the partitioning engine

Do not operate the partitioning engine if there is insufficient free space around it.

	International (Europe)	US
Front	20 cm	8 in
Back	10 cm	4 in
Left side	0 cm	0 in
Right side	30 cm	12 in
Top	20 cm	8 in

Space required around the partitioning engine

Radio equipment specifications

The partitioning engine contains radio equipment:

	Partitioning engine
Frequency	13.56 MHz

Radio equipment specifications of the partitioning engine

	Partitioning engine
Maximum radio-frequency power	< 500 mW
Number of RFID readers	1 (MUX 1 to 2)
Number of RFID antennas	2

Radio equipment specifications of the partitioning engine

Thermal cycler units specifications

The following table lists the temperature specifications for the thermal cycler units:

	Temperature	Description
Temperature range	37 °C to 99 °C	
Accuracy and homogeneity	± 0.5 °C	For a single thermal cycling position in a thermal cycler unit
	± 0.6 °C	Across all thermal cycling positions in both thermal cycler units when heated to the same temperature

Thermal cycler units specifications

Detection unit specifications

The following table lists the center wavelengths and bandwidths for the 6 excitation filters and 6 emission filters that are part of the detection unit of the analyzer:

Channel	Excitation filter	Emission filter
	Center wavelength / bandwidth [nm]	
1	435/21	488/15
2	492/20	526/20
3	543/13	570/17
4	576/23	607/10
5	630/10	660/20
6	682/24	727/36

Detection unit specifications of the analyzer

Supported characters in ASTM messages

The system uses CP-1252 (code page 1252) to encode and decode ASTM messages. Characters outside of code page 1252 (e.g., Unicode characters) are not supported and are replaced by a "?" (question mark) in ASTM messages.

If you connect the system to an LIS via the ASTM protocol, only use characters in the range of 0x21 (exclamation mark "!") to 0x7D (closing curly bracket "}") of the CP-1252 character encoding for sample IDs.

List of available consumables and reagents

Below is a list of globally available consumables and reagents. For ordering information, contact your local sales representative.

Image of product	Product name
	Digital LightCycler® Universal Nanowell Plate
	Digital LightCycler® High Resolution Nanowell Plate
	Digital LightCycler® High Sensitivity Nanowell Plate
	Digital LightCycler® Partitioning Fluid
	Digital LightCycler® Partitioning Fluid Waste Bottle
	Digital LightCycler® 5x DNA Master

Available consumables and reagents

Image of product	Product name
	Digital LightCycler® 5x RNA Master

Available consumables and reagents

Computer specifications

In this section

Specifications for the development software (43)

Specifications for the web application (43)

Specifications for the development software

	Minimum	Recommended
Computer	Operating system: Windows 10	
	Intel i5 processor	Intel i7 processor or higher
	8 GB RAM	16 GB RAM or more
Monitor resolution	1366 × 768	1920 × 1080

Specifications for the development software

Specifications for the web application

	Specification
Browser	Firefox ESR 102.12.0
Monitor resolution	1920 × 1080

Specifications for the web application

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