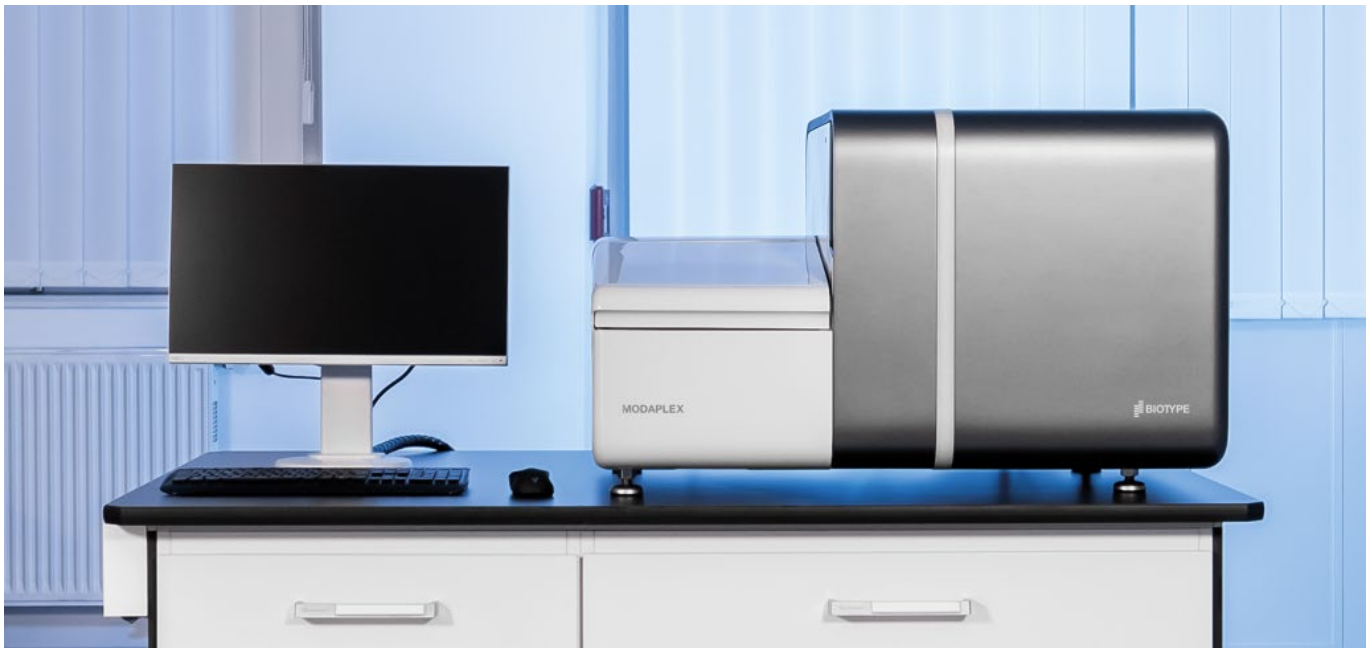
MODAPLEX

Original operating manual

User Manual



For Research Use Only

MPXHB01v6en
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BIOTYPE

Notice of Change

Please note the following adaptations compared to the previous handbook

Operator's Manual Version	Software Version	Revision Date	Change Description
1.0	11.10. (or higher)	31.08.2023	Initial version
2.0	11.10. (or higher)	29.09.2023	Adjustments in chapter 1.5 and 9
3.0	12.0. (or higher)	14.05.2024	Adjustments in chapter 3.3, correction of misspellings
4.0	12.0. (or higher)	23.10.2024	Chapter 7.6 for software updates added, Note for usage of MODAPLEX Gel added (chapter 3.6)
5.0	12.1. (or higher)	30.06.2025	Chapter 6 updated after MODAPLEX Controller update, explanation of new features
6.0	12.2 (or higher)	30.06.2026	Inclusion of the absorption buffer as a hazardous substance, adjustment of contact information, adjust controller information

For any further questions, please contact us:

at +49 351 8838 400 or

modaplex@biotype.de

Table of Contents

1. Document Information

The revision history of the MODAPLEX operator´s manual is listed on page one of the handbook.

1.1. Edition

This MODAPLEX Manual is intended for users of the MODAPLEX System and the MODAPLEX Software, which includes the MODAPLEX Controller and MODAPLEX Design and Analysis Software (Release version from 12.2). Please refer to the respective handbooks for MODAPLEX Kits provided by BIOTYPE.

We have made every effort to ensure that all the information contained in this publication is correct at the time of its release. However, the manufacturer of this product may need to update the publication's information because of product surveillance activities, which could lead to a new version of this publication.

1.2. Warranty

Any customer modification to the system renders the warranty or service agreement null and void. For conditions of warranty, contact your local sales representative or refer to your warranty contract partner. Always perform software updates according to the provided BIOTYPE recommendations.

1.3. Copyright

1.4. Trademarks

POP-7 is a registered trademark of Life Technologies Corp. (part of Thermo Fisher Scientific Corp.). BIOTYPE and MODAPLEX are registered trademarks of BIOTYPE GmbH. Other registered names, trademarks, etc. used in this document, even if not specifically marked as such, are not to be considered unprotected by law.

1.5. Declaration of Conformity

Europe – CE Declaration of Conformity

BIOTYPE GmbH declares under sole responsibility that the MODAPLEX instrument is in compliance with the relevant provisions of the following European Directives:

2014/30/EC	DIRECTIVE on the harmonisation of the laws of the Member States relating to electromagnetic compatibility
2014/35/EC	DIRECTIVE on the harmonisation of laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits
2019/19/EC	DIRECTIVE on Waste Electrical and Electronic Equipment (WEEE)
2011/65/EC	DIRECTIVE on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
94/62/EC	DIRECTIVE on packaging and packaging waste

Any modification to the product or use is not authorized by BIOTYPE GmbH and will invalidate the device EU Declaration of Conformity.

2. Safety and Regulatory Compliance

The instructions and safety information in this user manual must be followed to ensure safe operation of the MODAPLEX. The following types of safety information appear throughout the MODAPLEX User Manual. The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

2.1. Proper use

Use the device as recommended by BIOTYPE and in accordance with the instrument specifications provided (see Chapter 9). If the instrument is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired. When used as intended, this product presents no significant electrical, temperature, or other safety hazards.

2.2. Warning Symbols and Precautions

2.2.1. Safety Alert Terms

The MODAPLEX User Manual includes various types of safety information to ensure safe operation of the equipment. These are identified by the following safety alert terms:

Table 1: Safety alert terms

WARNING	
	The term WARNING indicates potentially hazardous situations that, if not avoided, could result in death or serious injury.
CAUTION	
	The term CAUTION indicates potentially hazardous situations that could result in minor or moderate injury. It may also be used to alert about unsafe practices.
NOTE	
	The term NOTE provides necessary information on the correct handling of the instrument, chemicals, and software.

2.2.2. Safety Labels

The following CAUTION symbols may be displayed on the instrument or appear in the software along with the safety symbols listed in the table below.

Table 2: Warning Symbols

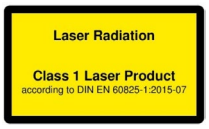
LASER CLASS 1	
	Laser Class 1 Product
LASER BEAM	
	Laser WARNING: This symbol warns operators about potential laser hazard. *Only visible for service technicians.*
HOT SURFACE	
	Temperature CAUTION: This symbol indicates that the labelled surfaces are too hot to touch, as some components may be heated to high temperatures.
SHARP ELEMENT	
	Sharp element CAUTION: This symbol alerts operators to sharp elements.
CORROSIVE	
  	Corrosive substance CAUTION: These symbols alert operators to corrosive substances.
WARNING	
	Acute and chronic aquatic toxicity CAUTION: This symbol alerts the operators to substances with acute and chronic aquatic toxicity.

Table 3: Mandatory signs

WARNING	
	Personal Protection CAUTION: Wear appropriate protective gloves.
GLASSES	
	Personal Protection CAUTION: Wear appropriate protective eyeglasses.
LABORATORY COAT	
	Personal Protection CAUTION: Wear appropriate protective laboratory coat.

2.2.3. Instrument Safety Warnings

Observe laser safety requirements as the instrument uses lasers.

WARNING	
	WARNING: Use of controls, adjustments or performance or procedures other than those specified herein may result in hazardous laser light exposure.

Under normal operating conditions, the instrument is safe and categorized as class 1. There are no laser safety precautions for the operator.

During some service operations, and/or when safety features are bypassed, the instrument is class 3B (extremely hazardous). Laser radiation of 50 mW at 488 nm and 100 mW at 639 nm (according to label on laser) may be accessible inside the optical module if the door interlocks are defeated and covers are removed.

Service operations on the optical module may only be performed by personnel that are trained and authorized by BIOTYPE.

Observe warnings to instrument handling.

CAUTION

Do not override any door sensor by technical means.

Overriding any door lock sensors may result in serious injury of the operator. Door sensors ensure the user's safety at all times.

CAUTION

The user shall not gain entry to the safety override keyhole. The use of the service key is limited to the service technician and any attempt to manipulate it might expose the user to a dangerous situation.

NOTE

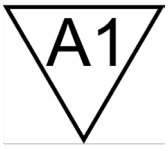
No items shall be dropped, placed, or intentionally left in the inside or on top of the instrument. The user is responsible for keeping the area surrounding the instrument unobstructed.

Observe warning and caution symbols on the instrument or components to prevent personal injury or impairment of the instrument.

CAUTION

Touching parts of the thermocycler can lead to skin damage due to hot surfaces.

NOTE



Correct orientation: Make sure that parts are inserted with correct orientation in the instrument. Incorrect orientation of parts can lead to instrument damage.

NOTE

Correct orientation CAUTION: Make sure that parts are inserted with correct orientation in the instrument. Incorrect orientation of parts can lead to instrument damage.

NOTE

The instrument contains electrical parts and must be disposed as electrical waste according to WEEE Directive.

2.2.4. Hazards Safety Warnings

Sample Area

CAUTION

Treat the area surrounding the PCR cycler with caution. Depending on the application, potentially hazardous components that are added to the PCR reaction might contaminate this area. Wear appropriate personal protective equipment (e.g., laboratory coat, gloves, protective eyeglasses).

NOTE

The materials and liquids that reach high temperatures in the thermal cycler do not show any danger from heating.

MODAPLEX Buffer and CE Plate

MODAPLEX Buffer acts as anode buffer for the CE process (within the CE Plate) and is used for the Capillary storage when the system idles. It contains EDTA (CAS: 10378-23-1), Chlormethylisothiazolinon (CAS: 26172-55-4) and Methylisothiazolinon (CAS: 2682-20-4). Please refer to the Material Safety Data Sheets for details on how to handle and dispose of chemicals.

CAUTION

	GHS05  **Danger**
H318	Causes serious eye damage.
P280	Wear protective gloves/protective clothing/eye protection/ face protection.
P305 +351 +338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

MODAPLEX Buffer may cause serious eye damage. Wear personal protective equipment such as lab coat, appropriate gloves, and protective eyeglasses when working with MODAPLEX Buffer.

Please refer to the Material Safety Data Sheets for details on how to handle and dispose MODAPLEX Buffer.

MODAPLEX Decon

MODAPLEX Decon is a Decontamination reagent for electrophoresis and contains 6 - 7.4 % sodium hypochlorite. Please refer to the Material Safety Data Sheets for details on how to handle and dispose of chemicals.

CAUTION

	GHS05 Danger 	GHS09 Danger 
H314	Causes severe skin burns and eye damage.	
H410	Very toxic to aquatic life with long lasting effects.	
EUH031	Contact with acids liberates toxic gas.	
P280	Wear protective gloves/protective clothing/eye protection/ face protection.	
P305 +351 +338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	

Decon solution may cause eye, skin, and respiratory tract irritation. Wear personal protective equipment such as lab coat, appropriate gloves, and protective eyeglasses when working with Decon solution.

Please refer to the Material Safety Data Sheets for details on how to handle and dispose Decon.

Waste Container

Special care is advised when emptying the MODAPLEX waste container as the solution contains up to 3 % sodium hypochlorite. Please refer to the Material Safety Data Sheets for details on how to handle and dispose the MODAPLEX waste.

CAUTION

The waste solution is a mixture of sodium hypochlorite, POP-7™ Polymer, and MODAPLEX buffer. Due to its chemical composition, this mixture MUST NOT be mixed with other solutions containing sodium hypochlorite. The waste solution must be disposed regularly. Liquid waste containing sodium hypochlorite **MUST NOT** be poured down the drain but disposed professionally.

Care should be taken to reduce the chance of splashing or spilling when transporting a full bottle.

Wear personal protective equipment such as lab coat, appropriate gloves, and protective eyeglasses when emptying the MODAPLEX waste.

2.2.5. Recommendations on good laboratory practice

Following guidelines shall be followed for good laboratory practice and for minimizing the hazards of chemicals:

- Treat liquids as potentially hazardous material.
- Do not use liquids in the Sample Plate that can ignite, evaporate, or produce toxic fumes when heated by the thermal cycler.
- Read and understand the Material Safety Data Sheets (MSDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials.
- Follow storage and handling instructions as described in IFU/Handbook for the assays.
- The user is responsible for disposal of waste. Comply with all local, state/provincial, or national laws and regulations related to chemical storage, handling, and disposal. If potentially hazardous waste is generated, categorize the waste.
- For disposal of the system or instrument parts refer to chapter 4.
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer's cleanup procedures as recommended in the MSDS.
- For cleaning the casing of the system, refer to chapter 7.2.
- Open and close vials containing reagents carefully.
- Do not expose reagents to light during storage.
- Do not use reagents beyond their expiration date.
- Do not mix reagents from other kits and/or other lots as this may compromise performance.
- The thermal cycler may still be hot after a run is completed: avoid direct contact. To avoid injury, close the doors with care so that the door(s) do not close on your hand.

CAUTION

PCR technology is extremely sensitive. To avoid potential cross-contamination, at least two distinct working areas should be available; one dedicated to the reaction set up and the second for the addition of sample to the reaction.

CAUTION

Do not touch the capillary ends and the electrodes of the capillary electrophoresis cartridge. Do not reuse the Polymerase Chain Reaction (PCR) plates or the capillary electrophoresis (CE) plates. Refer to the Material Safety Data Sheets (MSDS) if you spill any of the reagents or consumables.

Material Safety Data Sheets

Chemical manufacturers supply Material Safety Data Sheets (MSDSs) that provide safety information on how to store, handle, transport, and dispose the chemicals safely. With the first shipment of hazardous chemicals to new customers and with every update of the MSDS, the customer receives a current MSDS. Be sure to replace the appropriate MSDS in your files each time you receive a new MSDS packaged with a hazardous chemical.

2.2.6. Regulatory Compliance

The instrument has been tested and found to be compliant with the following requirements for safety and electromagnetic standards:

A) IEC 61010: Safety requirements for electrical equipment for measurement control and laboratory use

B) IEC 61000: Electromagnetic compatibility (EMC)

C) IEC 61326: Electrical equipment for measurement, control and laboratory use - EMC requirements

D) IEC 62311: Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)

E) IEC 61293: Marking of electrical equipment with ratings related to electrical supply - Safety requirements

F) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility

G) Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits

3. Introduction to the MODAPLEX System

3.1. Intended Use and Intended User

This manual describes how to operate the MODAPLEX System. Before operating the MODAPLEX, it is essential that users fully read and understand this user manual.

3.2. System description

The MODAPLEX System includes the following system components:

- Instrument with integrated PCR thermal cycler, capillary electrophoresis system and two lasers for the excitation of fluorescence in the analytes.
- Onboard reagents.
- User interface to the integrated PC consisting of monitor, keyboard, and mouse.
- Software for instrument control, running on the integrated PC.
- Design and Analysis software for a second workstation. This software supports Windows (10 & 11). Linux (tested on Debian ≥ 11) and iOS (Ventura ≥ 13.3.1) are available upon request.

3.3. Instrument description

The MODAPLEX is a sophisticated benchtop analysis instrument designed to perform real-time quantification of nucleic acids through the integration of two cutting-edge technologies: polymerase chain reaction (PCR) and capillary electrophoresis (CE). Known as MODAPLEX technology, it enables precise and accurate quantitative or qualitative measurements of results using BIOTYPE specific reagents. With its high multiplexing capabilities, the MODAPLEX allows for the simultaneous measurement of multiple relevant biomarkers within up to 48 wells, that makes MODAPLEX ideal for multi-gene testing and analysis of biomarker signatures.

In addition to its outstanding performance, the MODAPLEX offers users a rapid turnaround time and same-day results, thereby significantly reducing the waiting period for critical data. Its user-friendly interface and intuitive software make it easy to operate and its robust design ensures reliable and reproducible results.

3.4. MODAPLEX Technology

The MODAPLEX technology realizes real-time quantification procedure through the combination of PCR and capillary electrophoresis in one automated run.

During a MODAPLEX run, the genetic targets of interest are amplified in a PCR reaction. While the PCR reaction continues undisturbed, the amplified DNA fragments are electrokinetically injected into a capillary that is filled with a gel matrix. In this Gel, the DNA fragments are separated by size and quantitatively detected. This process is repeated consistently during the PCR. This way, real-time data is generated, thus enabling the simultaneous quantification of multiple targets.

In detail, a PCR Plate is prepared with one sample per well containing a primer mix with fluorescently labelled oligonucleotide primers. The PCR Plate is located within the thermal cycler module and PCR reaction is started. At specific PCR cycles, the capillaries of the CE module are inserted into the PCR Plate and via a high voltage applied

to an electrode in proximity to the capillary for a predetermined time, negatively charged DNA molecules are forced to enter the capillary. Subsequently, the capillaries are placed in the CE Buffer within the CE Plate and the CE separation is performed by applying high voltage to the CE Buffer. Meanwhile the PCR reaction continues. PCR cycling and CE separation are timed to match one complete CE separation within two PCR cycles by default. This timing can be changed by the user. Integrated lasers perform fluorescent detection of all amplicons. Quantification is performed by real-time sampling of the amplicons, which allows construction of amplification curves and calculation of threshold cycle (Ct). At the end of the PCR amplification, capillaries and electrodes are chemically decontaminated to remove the residual amplified PCR fragments and to recondition the capillary array for a new assay run.

The MODAPLEX technology allows assessment of multiple DNA or RNA targets independently and including all targets (sample template, controls, and internal calibration standards) within a single reaction well. In addition, multiple assays running on the same PCR program can be analysed simultaneously using the same plate and run.

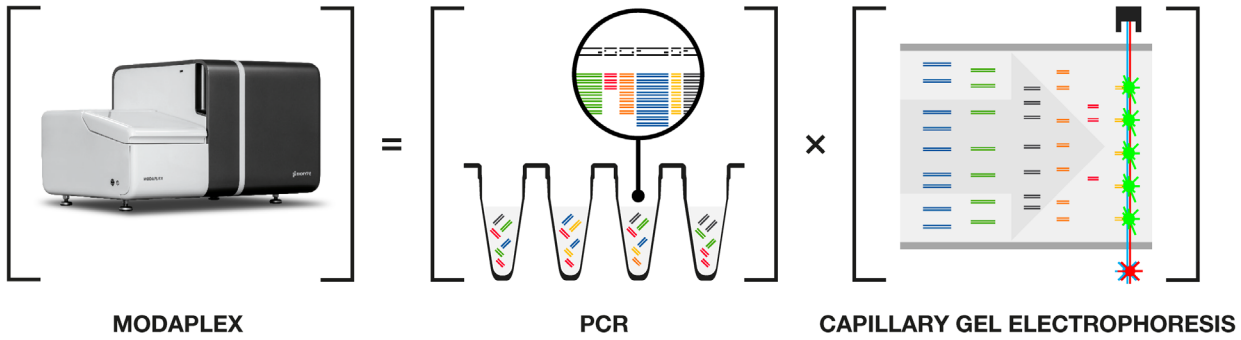


Figure 1: MODAPLEX Technology

3.5. Workflow

The MODAPLEX load-and-walk-away workflow is identical for all tests and combinations of tests. The workflow comprises three steps: PCR set-up, MODAPLEX run, and data analysis with MODAPLEX software.

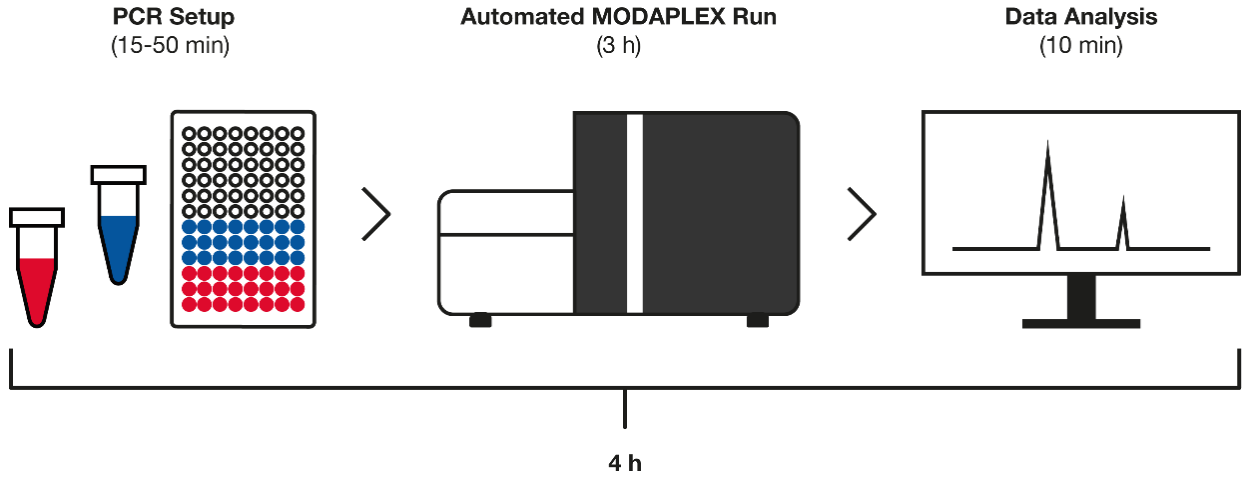


Figure 2: MODAPLEX workflow

3.6. MODAPLEX System Overview and Components

The MODAPLEX instrument consists of two functional modules: PCR thermal cycler (amplification module) and CE system with fluorescent detection (analysis module). Please refer to the figures below for the location of major system parts, components, and controls. Please refer to the tables below for a list of instrument parts and their function as well as consumables and their function.

Figure 3: MODAPLEX instrument, front side

Figure 4: MODAPLEX instrument, view with sample door open (left) and consumables door open (right)

Table 4: Instrument parts and functions

Part	Function
Carriage	Houses the thermal cycler, CE Tray and Idle Tray. Moves in the X (right/left) and Z (up/down) directions. Its purpose is to correctly position the PCR Plate, CE Plate, or Idle Tray in relation to the cartridge (CE system).
Cartridge	The Cartridge consists of the cartridge body, the capillaries, the capillary circuit board and the capillary window. It is the core part of the instrument where sample injection, CE separation and detection of amplified PCR products take place.
CE Tray	Houses the disposable CE Plate
Gel Cooling Chamber	Gel cooling ensures extended shelf life and consistent separation quality after the bottle has been opened.
Hold Down Plate	Fixes the Sample Plate in the thermal cycler.
Idle Tray	Houses the capillaries when the system is in idle mode or decontaminates the capillaries at the beginning and the end of each run. When the system is in idle mode, the idle tray contains MODAPLEX Buffer in which the capillaries are immersed to keep them from drying out. During a run, MODAPLEX Decon is pumped into the Idle Tray, and the capillaries are submerged in MODAPLEX Decon to prevent cross contamination and carryover. Both Buffer and Decon enter the Idle Tray at the same location. Contents of the Idle Tray are removed by a pump to the waste container.
Thermal cycler	Thermal cycler – holds PCR Plate. This is where thermal cycling as part of polymerase chain reaction occurs. Capillaries are submerged into the PCR Plate during sample injection – the process in which negatively charged particles are electrokinetically injected from the PCR solution into the capillary tips.

Table 5: Consumables and functions

Consumable	Function
10X Capillary Protection Buffer	Must be diluted 1:10 before use. 1X Capillary Protection Buffer acts protective medium for the cartridge capillaries and electrode during injection. It is filled in all empty wells (from A1-H6 when using a 48 capillary cartridge) of a PCR Plate before a run.
Aluminum Sealing Film	Referred as: foil* Protects the filled wells of the Sample Plate from contamination and spilling.
Mineral Oil	Prevents cross-contamination and evaporation during PCR and electrokinetic injection by overlaying PCR solutions.
MODAPLEX Buffer	Referred as: Buffer* Is filled into and flushes the anode chamber and Idle Tray.
MODAPLEX CE Plate	Referred as: CE Plate* Contains a medium, named CE Buffer, for generating an electrical current required for initiating and performing capillary electrophoresis. Half of the CE Plate is filled with CE Buffer, which corresponds to 48 wells from A1-H6.
MODAPLEX Decon	Referred as: Decon* Decontamination solution that destroys DNA and RNA from previous runs.

MODAPLEX PCR Plate	Referred as: Sample Plate* Referred as: PCR Plate* The wells of the MODAPLEX PCR Plate are filled with samples, controls or with 1X Capillary Protection Buffer. A maximum of 48 wells of the Sample Plate can be used for analysis, ranging from A1-H6.
MODAPLEX Size Standard	PCR reagent that creates peaks during CE that support correct assignment of target peaks.
POP-7™ Polymer for 3730/3730xl DNA Analyzers	Referred as: MODAPLEX CE Gel, Gel* Separation medium that fills the cartridge capillaries. Must be exchanged every two weeks if used for analysis, regardless of the expiration date indicated on the label. In idle mode, the Gel can remain in the system until a replacement is requested, due to low volume or expiry date.
Waste	Collects all liquids pumped through the instrument.

*Abbreviated consumable name used in the manual, software and on the instrument.

The following materials and consumables are necessary to run the instrument but are not part of the MODAPLEX system and must be ordered from BIOTYPE:

Table 6: Material and consumables not part of the system

Material/ Consumable	Article Number
10X Capillary Protection Buffer Kit	85-21001-1800
Aluminum Sealing Film	00-14X04-0100
Mineral Oil	00-04301-0025
MODAPLEX Buffer	00-14302-2000
MODAPLEX Cartridge 48 capillaries	84-20101-0048
MODAPLEX CE Plate	00-14306-0020
MODAPLEX Decon	00-14303-2000
MODAPLEX PCR Plate	84-20102-0025
MODAPLEX Hold Down Plate	84-20002-0001
POP-7™ Polymer for 3730/3730xl DNA Analyzers [Product of Life Technologies Corporation, provided by thermofisher.com with article number 4335615]	00-04305-0028

MODAPLEX system components:

The MODAPLEX system includes a keyboard, a mouse and a screen.

These are installed by the service technician authorized by BIOTYPE. Please contact BIOTYPE if you have any special needs, such as different keyboard layout.

NOTE

Only original peripherals shall be used with the system. Do not connect different peripherals without authorization.

MODAPLEX Assays

MODAPLEX assays are provided by BIOTYPE. Additional MODAPLEX assays can be developed by customers using the MODAPLEX system as enabling platform. Please contact BIOTYPE for further information.

4. System Transport, Installation, Relocation and Disposal

Only a service technician, authorized by BIOTYPE, shall transport, install, relocate, or dispose the system. Unauthorized movement or installation can cause personal injury, damage of the system, or affect calibration and may void the warranty and/or service contract.

CAUTION
Unauthorized movement or installation of the MODAPLEX instrument by users is prohibited and can cause personal injury.
NOTE
Only original parts shall be used with the system. Only original external cables provided with the instrument shall be used for the system.
NOTE
The fuse replacement must be done by technical maintenance personnel only and prohibited by user.

To ensure proper setup and optimal system performance, contact BIOTYPE customer support when any of the following conditions occur:

- The system needs to be installed or uninstalled.
- The system needs to be relocated within the laboratory facility.
- The system needs to be relocated for storage.
- The system needs to be packaged for transport or shipment to another location.

A relocation of the instrument might entail recalibrations of the optical and the motor system due to shocks arising from the transport and/or changed mechanical tensions in the new location. In addition, the air ventilation space must not be obstructed by moving other items close to the instrument.

NOTE
Before the system is relocated, decontaminate the external surfaces: • With a cloth or gauze moistened with 10 % household bleach solution. • With a cloth or gauze moistened with water or 70 % Isopropyl alcohol.

For system specifications including measurement and weight of the instrument, please refer to chapter 9. System Specifications.

System Disposal

Please contact BIOTYPE for system disposal.

The MODAPLEX Cartridge and the MODAPLEX Hold Down plate are user replaceable components. The installation and removal of these parts are described in chapter 7.3 (Cartridge Exchange) and chapter 6.8.1 (Removing Plates).

How to obtain support

Please contact BIOTYPE customer support in any case of system transport, installation, and relocation via Email at modaplex@biotype.de.

The instrument includes the software AnyDesk for remote support. The support person will request to start this software, if necessary. In order to launch AnyDesk, move the mouse to the bottom of the screen and click the AnyDesk icon. The software will display an address (9 digit number), which is necessary for a remote technician to access the instrument. Once authorization has been granted, the support person can access the software remotely.

5. System Software

5.1. MODAPLEX Controller Startup

The MODAPLEX Controller software is automatically launched after instrument startup. The launch of the software is indicated by a splash screen. After successful launch of the software, the system will be prepared for use. This process will start automatically after 60 sec, unless the **Cancel** button is pressed. It is also possible to start the process manually by clicking the **Start** button. If the system preparation is cancelled by the user, or fails due to hardware issues, the system status bar will display “Inoperable”.

After starting up successfully, the software and instrument are ready to use. This is also indicated by the LED strip lighting up in white colour. If the LED strip lights up in another colour, please see chapter 6.1.1.

It is not necessary and not advised to shut the system down manually, as the instrument performs regular idling routines and protects the cartridge from damage.

5.1.1. Accounts

The MODAPLEX instrument is operated using a limited user account for security reasons. Please contact BIOTYPE for configuration of the operating system using an administrative account.

5.2. Main System Screen

The Main System Screen is the first screen displayed when starting the software. This is the dashboard for any actions on the MODAPLEX instrument. The Main System Screen is structured by three navigation bars:

- Navigation Menus (on top),
- System Status Bar (at the bottom),
- Toolbar (left side).

The toolbar adapts according to the selected navigation menu.

Figure 5: MODAPLEX Controller, Main System Screen

Use the buttons on the toolbar to access different functions in the software. The following table gives an overview of the toolbar buttons and the associated functions.

Table 7: Toolbar Buttons

Button	Button Name	Function
	Create New …	Create a new Run Draft/ Assay Definition/ PCR-CE Protocol/ Analysis Protocol.
	Open Existing …	Open or import an existing Run Draft/ Completed Run/ Assay Definition/ PCR-CE Protocol/ Analysis Protocol.
	Save	Save entries.
	Enable Edit Mode	Save Symbol changes to Edit Symbol if saved files can be edited.
	Export	Export an existing Run Draft/ Completed Run/ Assay Definition/ PCR-CE Protocol/ Analysis Protocol.

	Prepare Instrument and Start Run…	Start the device preparation for the selected Run Draft.
	View Run Setup	View the run setup of the processing run.
	Abort Run	Abort the selected run.
	Remove Plates	Remove plates from the device.
	Exchange Cartridge Consumable Exchange and Waste Disposal	Initiate the exchange of the cartridge, consumables, or to dispose waste.
	Mark all entries read	Confirm all event log entries are read.
	Create new Assay Definition/ Run Definition from Microsoft Excel	Create a new Assay Definition (menu Protocol Definitions) or Run Definition (menu Runs) with information from a prepared Microsoft Excel template.
	Manage Existing...	Access the archive options of a Run Draft/ Completed Run/ Assay Definition/ PCR-CE Protocol/ Analysis Protocol.
	Duplicate as Run Draft	Click on symbol in Completed Run to create a Run Draft out of the selected Completed Run Revision.
	Open Run Revision in MODAPLEX Deep Dive	Open the Analysis Results in MODAPLEX Deep Dive software to view data. This button is only available in the MODAPLEX Design and Analysis Software.
	Unlock Doors	Unlock doors to clean the device. This button is only available in the MODAPLEX Controller software.

5.2.1. System Status Bar

The system status bar located at the bottom of all screens in the Controller software provides an overview of the instrument and consumables status.

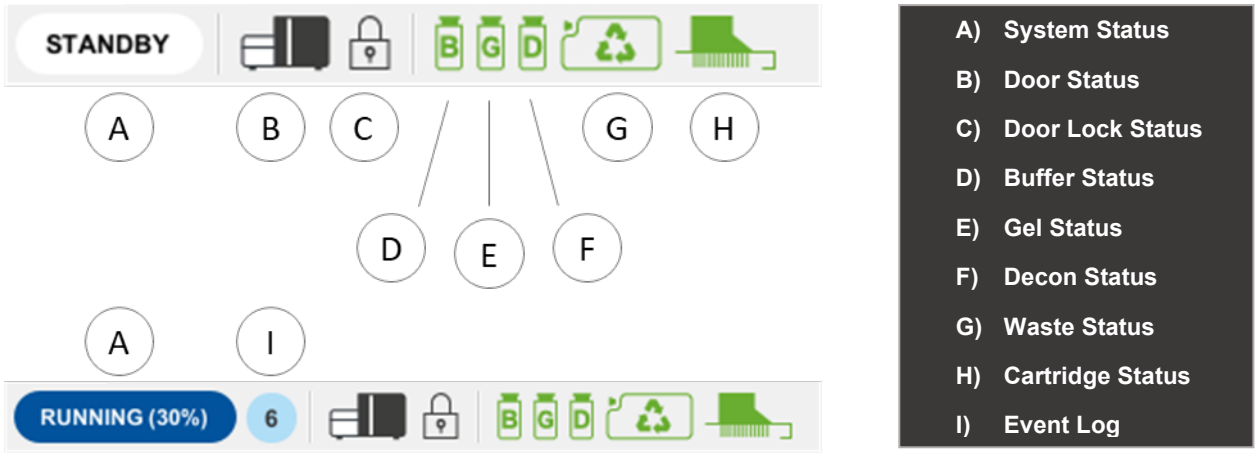


Figure 6: MODAPLEX Controller, System Status Bar

The symbol for instrument status shows one of the following conditions listed in table 8:

Table 8: Instrument status

Status	Symbol colour	Description
STANDBY	White	The device is in standby. A run could be started without prior instrument care.
RUNNING (48%)	Blue	A run is currently executed. The progress of the run is indicated as a percentage. This percentage starts at an initial level and increases with every CE separation performed. During data analysis the status progress remains at 100 %.
FINISHED	Green, flashing	The data analysis is finished.
BOTTLE FILL	Orange	This status is active, once there are fewer than two remaining runs left or the remaining idle time is less than 60 hours due to consumable filling levels.
WARNING	Orange	There is a warning that does not indicate a fatal error to the system. This status is active as soon as a consumable or the cartridge are expired, separations of the cartridge are exceeded, bad capillaries are detected, or the instrument service is overdue. If one of the before applies, a run cannot be started.
INOPERABLE	Red	The device is inoperable. No run can be started in this state. Possible reasons are: a blank or no cartridge is installed, at least one consumable is empty, the waste is full, the system was not successfully prepared for use (see MODAPLEX Controller Startup above) or Idling failed.
FAILED	Red, flashing	The Run or data analysis failed.

ERROR	Red, flashing	A serious problem (error) was logged and is displayed in the Event Log. Please refer to the error message displayed in the Event Log for further instructions. This status prevents the device from starting a run, change the cartridge and to perform a scheduled task (e.g. idling). Please contact our customer support (modaplex@biotype.de)

The door symbols adapt to the status of the sample and consumable door as shown in table 9:

Table 9: Status of the instrument doors and locks

Symbol	Status
	All doors closed
	Sample Door open
	Consumable Door open
	Doors locked
	Doors unlocked

NOTE	
	Do not attempt to open doors unless the door lock sign indicates that the door lock is open. In doubt, try to open the doors gently and without excessive force.

The lock symbol indicates the status of the doors by a closed or opened lock symbol. The status of the inserted bottles and the cartridge is indicated by the colour of the respective symbol as listed in table 10:

Table 10: Consumable Status

Consumable	Colour	Status
Buffer Decon Gel		OK
		Consumable is expired or fill level is low
		Bottle is empty, no bottle installed
Waste		OK

		Waste is full
Cartridge		OK
		Cartridge is expired, there are bad capillaries, or the number of separations is exceeded
		The cartridge memory chip is not readable, no cartridge inserted

5.3. Navigation Menus

The navigation menu includes four menus shown in the figure below.

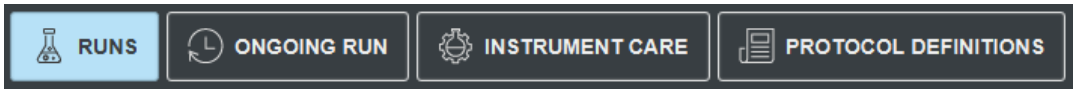


Figure 7: MODAPLEX Controller, Navigation Menus

For the MODAPLEX Design and Analysis Software the structure of the navigation menu differs, as described in chapter 6.10.2.

5.3.1. Runs

By opening the menu **Runs** the user has access to the run section. It consists of the two tabs **Drafts** and **Completed**. The tab **Drafts** is opened by default. It allows for the management of Run Drafts, including the preparation of new Run Drafts. Select the button for creating a new Run Draft or for opening an existing Run Draft either by using the toolbar or by clicking on the symbol in the middle of the dashboard. When switching to the tab **Completed**, completed runs can be managed accordingly.

5.3.2. Ongoing Run

The menu **Ongoing Run** provides an overview of the current run. The toolbar gives quick access to the actions **View Run Setup** (this links to the Runs menu), **Abort Run** and **Remove Plates**.

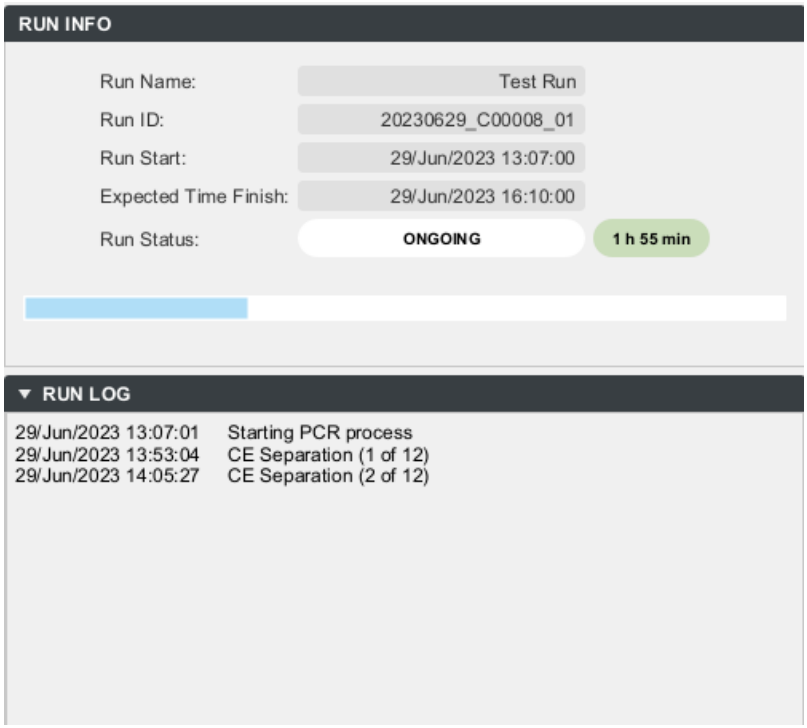


Figure 8: MODAPLEX Controller, Ongoing Run menu

5.3.3. Instrument Care

The menu **Instrument Care** provides access to the tabs **Event Log**, **Cartridge**, **Liquid Management**, **Maintenance** and **Settings**. Every tab, except the tab for Settings, gives detailed information on the instrument status. The status in the respective tab is colour coded:

- Green: OK
- Orange: preventive action suggested
- Red: corrective action required

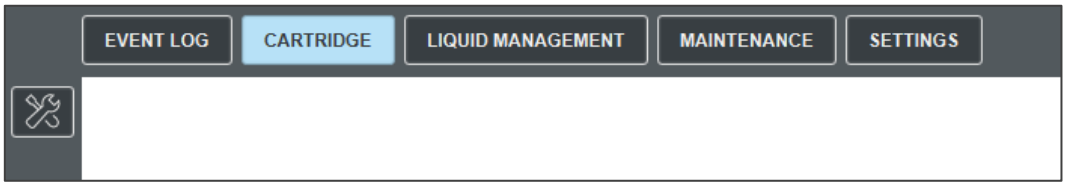


Figure 9: MODAPLEX Controller, Tabs of the Instrument Care menu

If a status turns orange or red in the tab for Cartridge or Liquid Management, the respective consumable should be replaced. Instructions for consumable replacement procedures are provided by selecting the tools-symbol within the toolbar. Please refer to chapter 7.4. Consumable Exchange and Waste Disposal for detailed instructions on these procedures.

5.3.4. Protocol Definitions

The tab **Protocol Definitions** lets the user manage, add and modify Assay Definitions, PCR-CE Protocols, and Analysis Protocols. Within the respective tab the user can create new or open existing files.

Please refer to chapter 6.3. Protocol Definitions for further instructions.

The software uses three different protocol types to operate MODAPLEX runs. The following protocol types exist:

Assay Definition

The Assay Definition is specific to a certain Assay Kit and is provided with the kit. It consists of a PCR-CE Protocol, an Analysis Protocol, and a target list.

PCR-CE Protocol

The PCR-CE Protocol contains settings for the instrument to operate a run, such as PCR settings and CE settings.

Analysis Protocol

The Analysis Protocol contains parameters for the analysis algorithm to analyse a run.

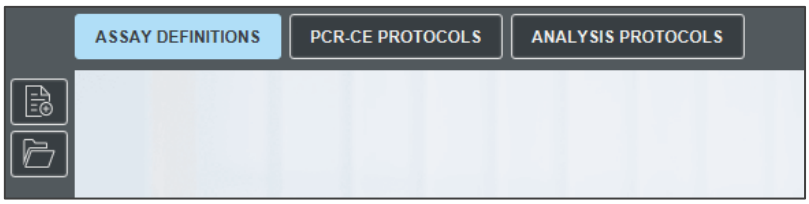


Figure 10: MODAPLEX Controller, Protocol Definitions menu

6. MODAPLEX Operation

This chapter provides detailed instructions on how to perform runs on the MODAPLEX instrument. It covers all steps from sample preparation procedures to starting runs using the MODAPLEX Controller software and transferring results to either the MODAPLEX Design and Analysis Software or the MODAPLEX Reporter. By following the step-by-step guidance, you will be able to carry out the necessary tasks with ease and accuracy.

Table 11: MODAPLEX Workflow

MODAPLEX Workflow			
1) Software and instrument preparation	a) System Status Check	Check system status in MODAPLEX Controller software, and ensure, that it is neither *Inoperable*, nor *Error*. Replace cartridge and consumables or dispose waste, if necessary.	**Chapter 6.1. Chapter 6.2.**
	b) Import / Create Assay Definition and protocols	Import or create Assay Definitions, PCR-CE Protocols and Analysis Protocols into the MODAPLEX Design and Analysis Software at the workstation prior to Run Draft creation. Alternatively, this step can be done in the MODAPLEX controller software, if the Run Draft creation will be done in the software installed on the instrument.	**Chapter 6.3.**
	c) Run Draft Creation	Create a Run Draft by applying Assay Definitions and setting the plate map. This step can be performed in the MODAPLEX Design and Analysis Software at the workstation prior to run preparations on the instrument. Afterwards, import the Run Draft into the MODAPLEX Controller software. Alternatively, Run Draft creation can be done in the MODAPLEX Controller on the instrument.	**Chapter 6.4.**
		⇩	
2) Laboratory work	a) Master mix Preparation	Prepare master mix according to MODAPLEX Assay Kit handbook.	**Chapter 6.5.**
	b) Sample Plate Preparation	Add master mix and samples to Sample Plate, according to MODAPLEX Assay Kit handbook. Add Capillary Protection Buffer to all empty wells according to cartridge size.	**Chapter 6.5.**
	c) CE Plate Preparation	Prepare CE Plate.	**Chapter 6.6.**
		⇩	
3) Start Run in Software	a) Initiate Run Start Procedure	Follow software instructions of MODAPLEX Controller to place Sample Plate, CE Plate and Hold-Down. Insert in the MODAPLEX.	**Chapter 6.7.**
	b) Finish Run Start Procedure	Finish the Run Start procedure of the software to start the run. The procedure will be finished once you entered your initials and finished the Run Start wizard. It might take a few minutes until this prompt appears. In case of any failure in the initiation procedure, you will be able to remove your Sample Plate from the instrument before resolving the issue.	**Chapter 6.7.**
		⇩	
4) Post Run Activities	a) Plate Removal	Remove plates from the MODAPLEX after the run has finished.	**Chapter 6.8.1. Chapter 6.8.2.**
	b) Export Run	Export Completed Run to a data storage device.	**Chapter 6.9.**

c) Data Evaluation		
MODAPLEX Reporter	Load completed runs of MODAPLEX assays into the MODAPLEX Reporter to get an assay specific report according to MODAPLEX Assay kit handbook.	
MODAPLEX Design and Analysis Software MODAPLEX Deep Dive	Analyse MODAPLEX data in MODAPLEX Design and Analysis Software and MODAPLEX Deep Dive.	**Chapter 6.10.**

6.1. Preparing the System

Before doing preparatory steps for a new run, the instrument status shall be checked directly on the instrument.

NOTE

Please check instrument status regularly as the MODAPLEX instrument SHOULD NOT be shut down if it is in regular usage. **Ensure that the instrument does not run dry at any time and that it is operated in full accordance with the instrument specifications during operation and idle modes.**

CAUTION

Do not override any door sensor by technical means.

Overriding any door lock sensors may result in serious injury of the operator. Door sensors ensure the user's safety at all times.

NOTE

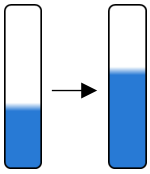
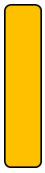
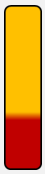
Please check the age of the MODAPLEX Gel on the system. If the gel has been installed for more than two weeks, replace the gel with a new bottle before performing a new analysis.

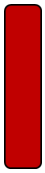
To confirm instrument status, view MODAPLEX Controller software and check the information in tab Instrument Care, described in Chapter 6.2.

6.1.1. LED strip and Instrument status

For a fast and easy assessment of the device status, the LED strip on the front of the instrument housing indicates this via a colour change. The following table indicates which colours occur:

Table 12: Colour-coding for LED strip status

LED Display	Status
	LED off/ The system should be only turned off by our service team.
	Standby / Quality Assurance Mode
	Running *The run progress is reported via the LED display.*
	Finished *The run is finished and analyzed successfully.*
	Failed *The run is finished but data analysis failed.*
	Low Consumables *This status is active, once there are fewer than two remaining runs left or the remaining idle time is less than 60 hours due to consumable filling levels.*
	Warning *A run cannot be started in this mode. Please exchange indicated consumables to return the system to an operational state.*
	Inoperable *The device is currently inoperable. No run can be started in this state. Please check the status bar to return the system to an operational state.*

LED Display	Status
	Error *A serious problem was logged. It is not possible to perform a run and to execute the quality assurance mode (e.g. idling)!* *Please contact our customer support (modaplex@biotype.de)*

For further information, please refer to the information provided by the instrument status bar in the controller application (Chapter 5.2.1).

6.2. Status of Cartridge and Liquids

Control the instrument status via the MODAPLEX Controller software in the Instrument Care menu and check the tab for Cartridge, Liquid Management and Maintenance. Verify that the onboard consumables are adequate for the run. Please replace onboard consumables if an orange or red status is present. Provided that every status is green, the operator can proceed with preparing a new run.

6.2.1. Cartridges

NOTE	
	Make sure that only unimpaired cartridges are inserted. The cartridge capillaries are fragile and must not be broken, the electrodes must not be bent. Using a broken cartridge may seriously damage the system.
CAUTION	
	Take care when handling the Cartridge for Cartridge replacement procedure. The Cartridge contains sharp parts, especially electrodes and capillaries, that might lead to operator injury when handled incorrectly.

For a view on the Cartridge status select the Instrument Care menu and then the Cartridge tab. The basic information of the current Cartridge is shown on top as well as the general status of the Cartridge. A Cartridge can be used for up to 50 runs. Completed and remaining runs are calculated and indicated. If the Cartridge is installed, it has an in-use stability of 6 months.

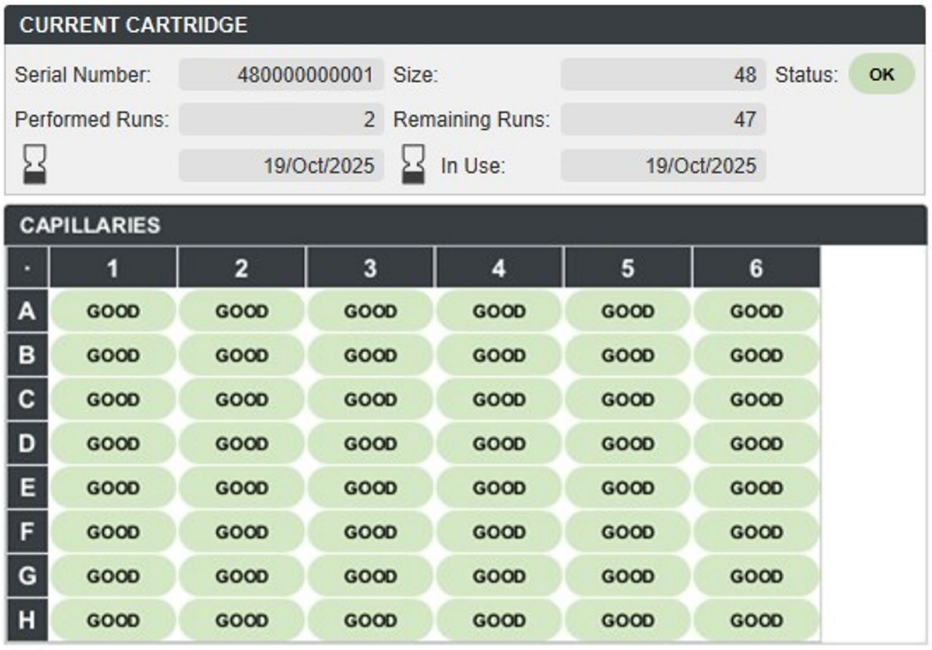


Figure 11: MODAPLEX Controller, Cartridge Tab within the Instrument Care menu

Status of Capillaries

The system distinguishes three capillary states. Each state is associated with a specific color and defines whether a capillary may be used for approved or not approved assay definitions.

Table 13: Capillary status

Status of Capillary	Colour	Validity	Use with approved Assay Definitions	Use with not approved Assay Definitions
Good	Green	Valid	Allowed	Allowed
Bad (user)	Yellow	Valid	Not allowed	Allowed (capillary status can be set by Technical Service manually if its performance does not resemble “good”.
Bad (soft)	Red	Invalid	Not allowed	Not allowed

Yellow-marked Bad (User) capillaries are valid but must not be used with approved assay definitions. Their use is restricted exclusively to not approved assay definitions.

Red-marked Bad (Soft) capillaries are classified as invalid and must never be used. They do not meet the technical requirements for reliable operation and therefore cannot be used in either approved or not approved assay definitions.

An exchange of the Cartridge is required if no remaining runs are left or its expiry date is exceeded. Please select the tool button to initiate the cartridge exchange process and refer to chapter 7.3. for detailed information on replacing the Cartridge.

6.2.2. Liquid Management

To get detailed status information about onboard liquids, open Liquid Management tab within Instrument Care menu.

For replacing liquid reagents or emptying the waste container, please refer to chapter 7.4 Consumable Exchange and Waste Disposal.

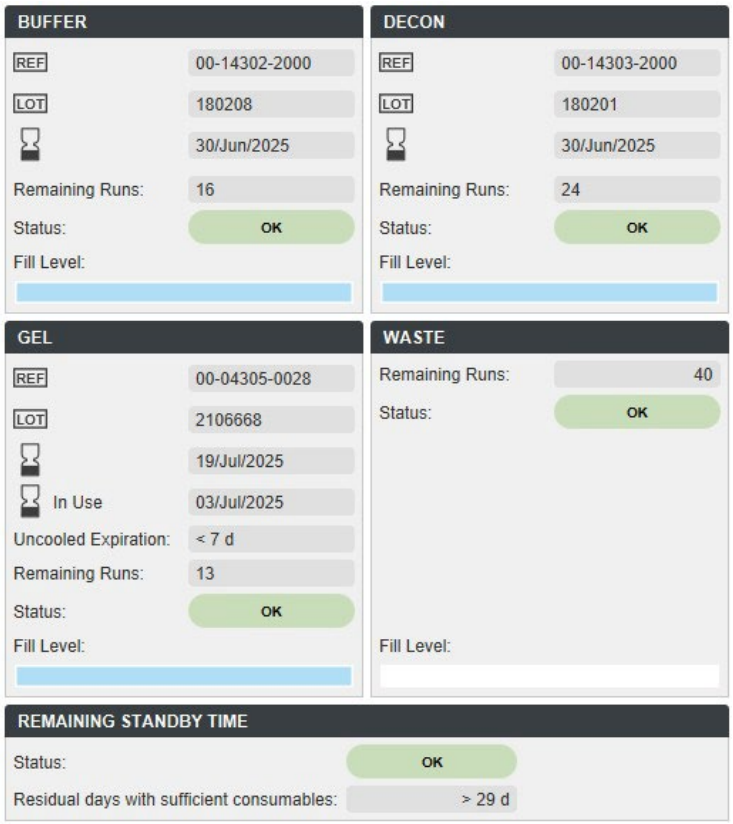


Figure 12: MODAPLEX Controller, Liquid Management tab in Instrument Care menu

The Liquid Management tab displays all relevant information about the installed reagents. The status of every liquid is highlighted in green, orange or red. A green status defines the filling state and expiry date as valid and sufficient. If the status turns orange or red, the consumable needs to be exchanged. Remaining runs are indicated according to expiring date and fill level. The fill level of consumables is calculated and visualized by the blue bar. The less blue within the bar, the less liquid is left. Note that a full blue bar in the section for waste means that the waste is full and must be discarded.

Note that the uncooled time of the Gel is tracked. If the tracked time reaches a duration of 7 days, the Gel status automatically switches to expired, even if the expiration date is not reached yet. The Gel must be replaced in this case. The remaining time before expiry without cooling is displayed next to “Uncooled Expiration” and decreases from <7 d to 0 d, when the cooling is inactive.

6.3. Protocol Definitions

Protocols and Assay Definitions can be imported or created in the MODAPLEX Design and Analysis Software at the workstation with subsequent Run Draft creation. Alternatively, protocol definitions can also be set in the MODAPLEX Controller on the instrument if the Run Draft is also created there.

Open the Protocol Definitions menu in the respective software to create new, open or manage existing Assay Definitions, PCR-CE Protocols and Analysis Protocols. The tabs for Assay Definitions, PCR-CE and Analysis Protocols are structured similarly.

If a BIOTYPE assay is run on the instrument, no protocol definitions need to be created by the user. BIOTYPE provides ready to use Assay Definition, PCR-CE Protocol and Analysis Protocol with purchased assays. These can be imported, as described below.

6.3.1. Opening existing files

If an existing protocol shall be opened, please click the button **Open Existing** in the toolbar of the respective tab. A window pops up as shown in figure 13. Select the respective button on top to scan a barcode or import from file if the protocol shall be imported from external source. In case the protocol is already available within the software, the user can also filter existing files by name, ID, creator and creation date. If filtering Assay Definitions, please select if only valid or expired files shall be filtered.

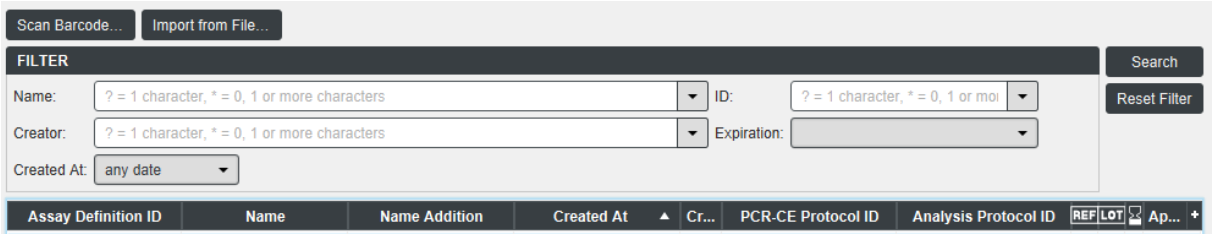


Figure 13: MODAPLEX Controller, Protocol Definitions – protocol import

Select the preferred file with a click on the line and click open to edit and/ or export the protocol.

If an Assay Definition is imported, the PCR-CE Protocol and the Analysis Protocol need to be imported also. Please note, that only Assay Definitions with the same PCR-CE Protocol can be loaded into a single Run Draft.

A complete Run Draft can be created in the MODAPLEX Design and Analysis Software at the workstation. When a Run Draft is imported into the MODAPLEX Controller on the instrument, the Assay Definition, PCR-CE Protocol and Analysis Protocol of that Run Draft are automatically imported into the software.

Once the Assay Definition including PCR-CE Protocol and Analysis Protocol have been imported into the software, a Run Draft can be created by adding only the respective Assay Definition. The corresponding PCR-CE Protocol and Analysis Protocol are linked to the selected Assay Definition and automatically added to the Run Draft.

6.3.2. Creating new files

For creating new Run Drafts, Assay Definitions, PCR-CE and Analysis Protocols, please select the upper button in the toolbar **Creating new** in the respective tab. Enter basic information and the parameters.

6.4. Run setup

As mentioned in chapter 6.3., Run Draft can be created in the MODAPLEX Design and Analysis Software at the workstation or alternatively, in the MODAPLEX Controller on the instrument.

To execute a MODAPLEX run, a Run Draft needs to be created. A Run Draft contains one tab for Run Information and one tab for the Plate Map. After the run is finished, a Completed Run is created, while the Run Draft stays

existing. You may reuse this Run Draft as a template for future runs. In the Completed Run, the user has access to the tabs Run Report, Run Log and Run Results.

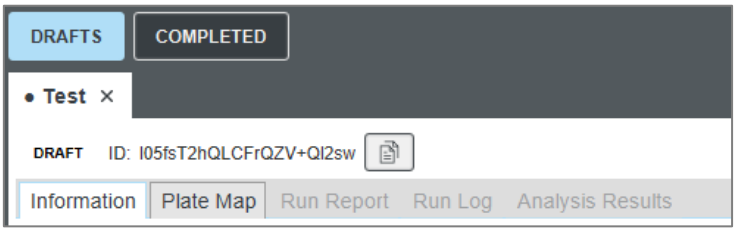


Figure 14: MODAPLEX Run Draft

Several Run Drafts can be opened simultaneously in separated tabs and processed. Each Run Draft tab is listed below the working tab.

6.4.1. Run Information

To load Assay Definitions, Analysis Protocol, and PCR-CE Protocol into a Run Draft, there are two options available. Either it can be scanned from QR codes contained in assay kits, or it can be loaded as files.

Load Assay Definition, Analysis Protocol and PCR-CE Protocol by barcode scanning (only available in MODAPLEX Controller)

Every MODAPLEX Assay Definition, Analysis Protocol and PCR-CE Protocol can be imported with a barcode. Different Assay Definitions may refer to the same Analysis and PCR-CE Protocol. In this case no rescanning of the Analysis and PCR-CE Protocol is necessary. The PCR-CE Protocol for MODAPLEX Assays provided by BIOTYPE is available with installation.

Select **Open existing** and click **Scan Barcode** within the opening dialog. Activate the barcode scanner and scan the barcode of the respective protocol provided with the assay kit. Click **OK** and complete the tab Run Information by entering name and creator (mandatory fields).

Load Assay Definition, Analysis Protocol and PCR-CE Protocol by importing from file

Select **Open existing** and click the button **Import from File** within the opening wizard. Select the desired file and confirm. Existing files from previous runs can also be searched by using the filter function. Click **OK** and complete the tab Run Information by entering name and creator (mandatory fields).

Imported Assay Definitions and their corresponding PCR-CE Protocol and Analysis Protocol are listed in the table. Select one to display detailed information including its ID on the right side.

Select **Remove Assay** to delete selected assay definitions.

6.4.2. Plate Map

The next step after completing the Run Information tab is to define the Plate Map.

At this point, the distribution of samples to the wells of the PCR Plate should be determined. Enter this information into the software. Each well, that will contain a sample, must be selected, named, and assigned with an Assay Definition and a well type. Check the assay handbook for existing requirements for the well types.

It is also possible to import the Plate Map information directly from a Microsoft Excel file via the button “Create new Run Definition from Microsoft Excel”. The Import file needs to be structured as followed:

- Column A: Well ID (e.g., A1 or A01)
- Column B: Well Name
- Column C: Unique Assay Definition ID
- Column D: Well Type (e.g., PC, NTC – correct spelling required)
- All data must be on the first sheet; cell order and empty cells do not matter

If you wish to copy data to the clipboard, or to remove assignments, you may use the **Toggle well selection** button on the upper left of the plate map. This button will select all previously unselected wells and unselect previously selected wells. You may then use the buttons **Copy Wells to Clipboard** or **Clear Selected Wells** to perform the respective action.

Define multiple wells at a time on the Plate Map:

- Select **Toggle well selection** (button with tick) to select all wells.
- Click on the number 1-6 to select a whole column.
- Click on the capital letter A-H to select a whole row.

If Run Information and Plate Map are completed, the Run Draft can be saved. Now the PCR and CE Plate can physically be prepared as described in the following chapters, before finally starting the run.

The Run Draft inclusive Run Information and Plate Map can be prepared within the MODAPLEX Design and Analysis Software before entering the lab. Import the Run Draft file to the software of the instrument as described above and initiate starting the run.

Please note, if a Run Draft is edited, a duplicate with a new ID will be created and renaming or revision of the Run Draft might be required.

6.5. Preparing the Sample plate

Generally, the operators should follow this procedure:

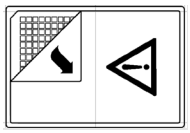
- Determine the number of samples, number and type of run controls, and number of unused wells for the run. Define and print out the Plate Map.
- Refer to appropriate IFU/Handbook to determine volumes of the individual components required to prepare the PCR master mix.
- In a clean work area, prepare the appropriate PCR reagents according to the IFU/Handbook.
- If required, prepare 1X Capillary Protection Buffer for the unused wells by diluting the 10X Capillary Protection Buffer 1:10 with distilled water. Each unused well requires at least 25 µL of 1X Capillary Protection Buffer. Prepare at least 10 % overage to the total volume of 1X Capillary Protection Buffer.
- Move to the template area.

- If required, follow assay IFU/handbook to add the appropriate amount of the Size Standard/ Calibrator mix to the PCR master mix.
- Aliquot appropriate volume of the PCR master mix to the appropriate wells according to the plate map.
- Add appropriate volume of the extracted sample, negative or positive control to the appropriate wells. Refer to the assay IFU/handbook for appropriate sample extraction protocol and assay controls.
- Add at least 25 µL of 1X Capillary Protection Buffer to all unused wells.
- Prepare the PCR Plate as specified by the assay IFU/handbook. This normally includes covering the PCR Plate with adhesive aluminum foil and spinning down briefly, followed by vortexing the plate gently, so that the reaction solutions do not get in contact with the foil cover and repeating the centrifugation step.
- Overlay all reaction wells and all unused wells that contain 1X Capillary Protection Buffer with a drop of mineral oil. Cover the PCR Plate with adhesive aluminum foil again and spin it down briefly.
- Transfer the Sample Plate to the working area of the instrument and proceed with starting the run.

NOTE
Note that the minimum reaction volume of 25 µL and the absolute technical minimum of 20 µL must be ensured considering pipetting errors.
NOTE
Make sure each well is covered with oil. The lack of oil coverage can lead to sample loss due to evaporation. As the instrument is unable to detect non-covered samples empty wells will cause instrument damage.
NOTE
Make sure the Sample Plate cover is removed before starting a run. Covered plates lead to damage of cartridge. The instrument has no sensor for detecting plate covers of the sample Plate that were not removed. The instrument is only able to detect CE Plate covers that were not removed.

6.6. Preparing the CE Plate

Prior to starting a run, take a new CE Plate stored in the fridge and spin down the CE Plate briefly. Transfer the CE Plate to the working area of the instrument.

NOTE	
	Make sure CE Plate cover is removed before starting a run. Covered plates lead to damage of cartridge.
NOTE	
	Warning label to remove CE Plate cover before starting a run is present on the CE Plates.

6.7. Start the Run

For starting a new run open a Run Draft and click on the green play button within the toolbar. A new window opens that guides the operator through 5 steps to check and prepare the instrument before the run starts. By selecting **Next** the user can proceed with the next step.

If the play button is colored red, a requirement on the Run Draft for starting the run is not met. Check your Run Draft to contain valid Assay Definitions only and minimum 1 well of each well type. Furthermore, the device status shall be “Standby” or “Bottle Fill”.

The wizard **Start Run** includes the following steps:

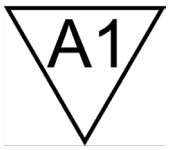
- **Step 1: Check Consumables**
  Check for green status of consumables. If necessary, initiate a procedure for replacing consumables during this step by pressing the button **Exchange consumables**.
- **Step 2: Check Run Setup**
  Control the status of the Assay Definitions.
- **Step 3: Confirm Manual Steps**
  Confirm the listed manual steps with a check mark.
- **Step 4: Insert Plates**
  Confirm correct insertion of CE and Sample Plates and close all doors of the instrument. Following, a short pre run check will take place.
- **Step 5: Start the Run**
  Enter the operator’s name and finish the process. The run will now start.

Note that the software verifies the filling level before each run in order to prevents the run to abort due to missing consumables.

Note that the Gel must be replaced after 2 weeks. During longer periods of Idle mode the Gel can remain in the system but must be replaced before an analysis is performed.

Note that CE Plate and Sample Plate must be inserted with the correct orientation into the instrument. The position of the well A1 of both plates must face the top right corner as indicated by the label on the MODAPLEX instrument. The Sample Plate needs to be fixed to the instrument using the MODAPLEX Hold Down Plate. Place the Hold Down Plate on top of the Sample Plate, then close the black frame-like thermocycler lid until it latches.

NOTE



NOTE Correct orientation: Make sure that parts are inserted with correct orientation in the instrument. Incorrect orientation of parts can lead to instrument damage.

Always use a fresh CE Plate provided by BIOTYPE.

6.7.1. View the Run Status

The run status can be monitored within the Ongoing Run menu and the current instrument mode can be seen at the System Status Bar.

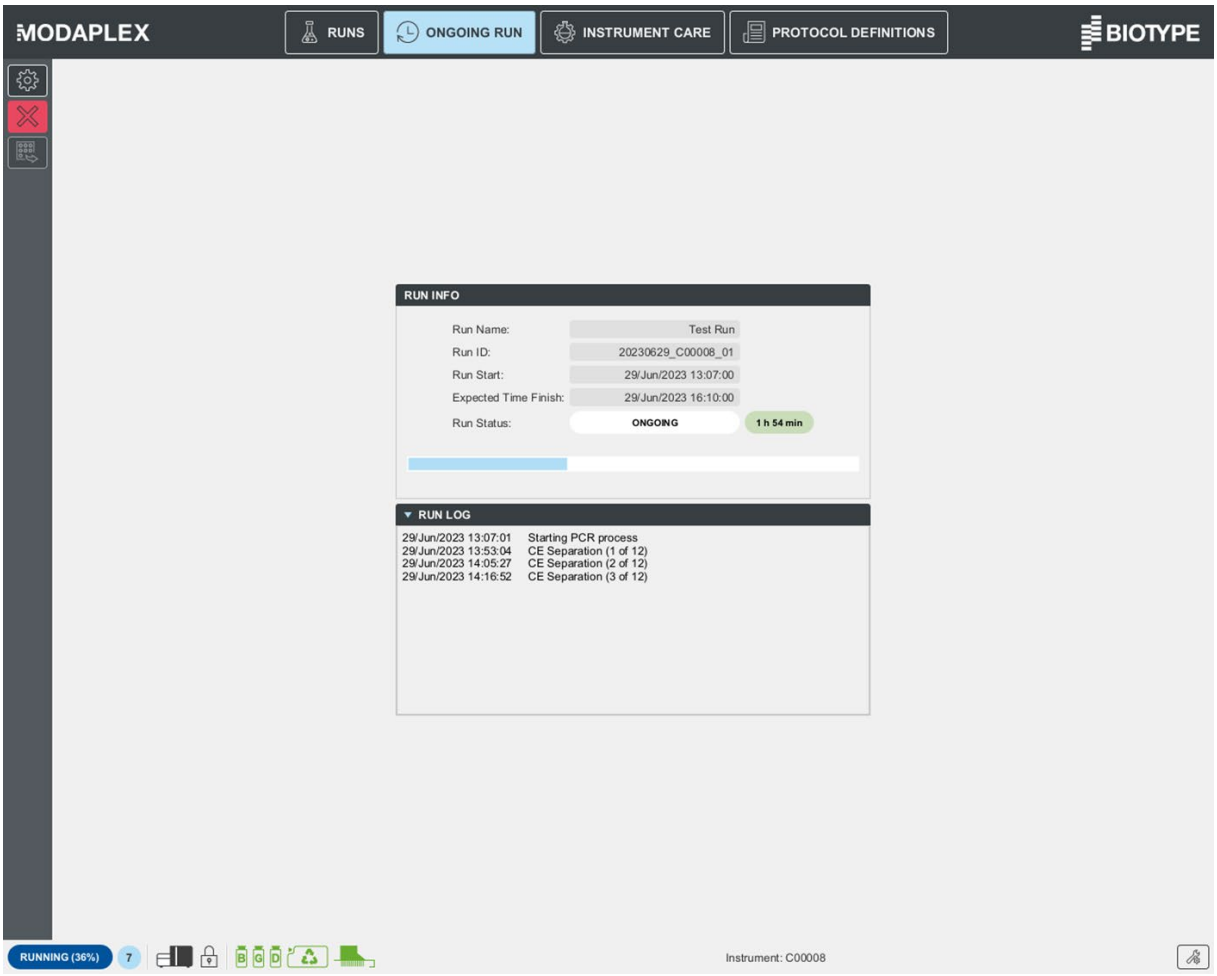


Figure 15: MODAPLEX Controller

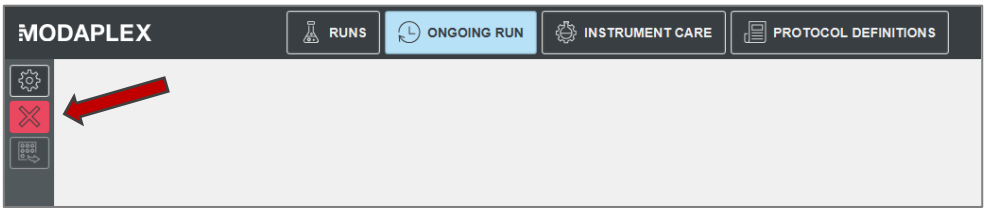


Figure 16: MODAPLEX Controller, Abort Run

6.7.2. Run Error

If a run fails, the LED strip turns blue and red, the System Status Bar indicates “Failed” and the Ongoing Run menu gives information about run status and run log.

Please contact BIOTYPE support if technical support is needed.

6.8. End of Run

A completed run is indicated with a successful run and analysis status shown in the tab Ongoing Run. Instrument status is also indicated by a flashing green “Finished” field on the left side in the System Status Bar. Moreover, the end of a run can also be seen on the LED strip of the instrument which turns blue and green.

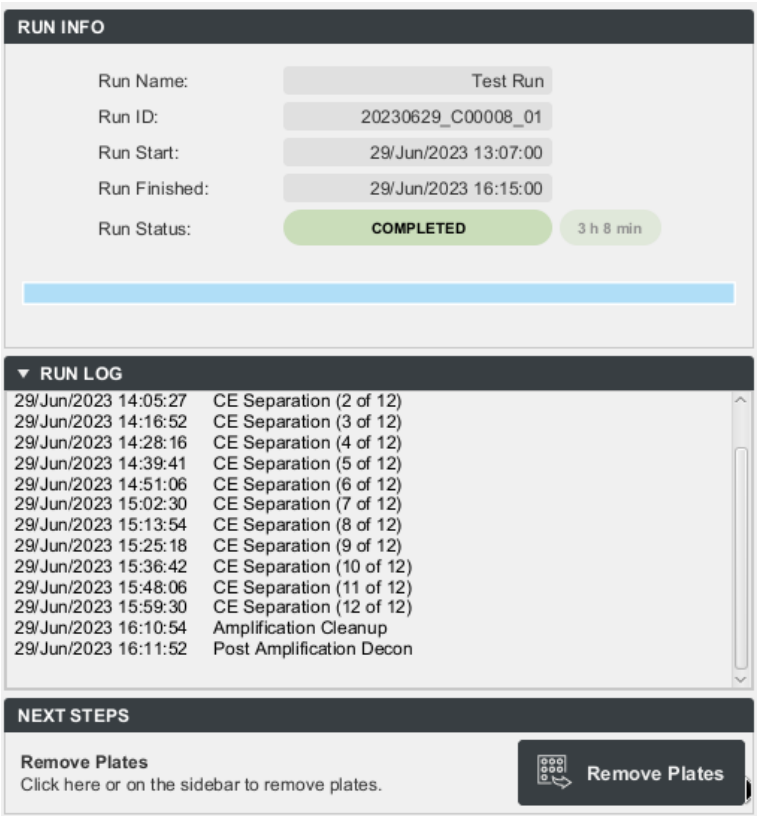


Figure 17: MODAPLEX Controller, Ongoing Run menu

6.8.1. Removing Plates

CAUTION

Touching parts of the thermocycler can lead to skin damage due to hot surfaces.

For removing plates, click on the button **Remove Plates** located under Run Log information in the Ongoing Run menu or in the toolbar in the Ongoing Run menu. The following window appears and the listed working steps need to be followed.

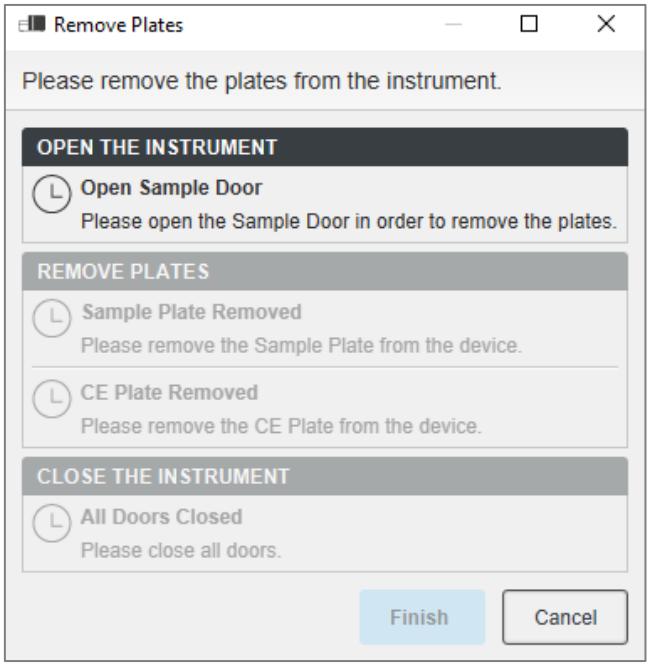


Figure 18: MODAPLEX Controller, Remove Plates wizard

Cover the CE and Sample Plates with aluminum foil to prevent PCR product from spilling and contamination. Dispose the CE and Sample Plate as laboratory waste according to institutional, local, and federal regulatory requirements.

Remove the MODAPLEX Hold Down Plate from the instrument by hand and proceed with decontamination as described below.

6.8.2. Decontamination of the Hold Down Plate

CAUTION

Decon solution may cause eye, skin, and respiratory tract irritation. Please refer to the Material Safety Data Sheets for details on how to handle and dispose of chemicals. Wear personal protective equipment such as lab coat, appropriate gloves, and eyewear when you work with Decon solution.

Please refer to the Material Safety Data Sheets for details on how to handle and dispose Decon.

CAUTION

Decontaminate the Hold Down Plate with following procedure:

- Prepare fresh 1/10 MODAPLEX Decon solution by diluting the MODAPLEX Decon 1:10 with distilled or deionized water.
- Fill a plastic tray with 1/10 diluted MODAPLEX Decon solution and submerge the Hold Down Plate in the solution for at least 30 minutes. Cover the plastic tray with the tray lid. The decontamination of the Hold Down Plate should not exceed 12 hours. Transfer the plate to a water bath to dilute the Decon solution adhered to the plate after removing the plate from the Decon bath. Rinse the decontaminated Hold Down Plate with deionized water and let it air dry. Wipe any residue from the end surfaces with a lint-free cloth. The Decon bath may be used for 2 weeks or up to 15 cleaning cycles. Dispose of diluted Decon in accordance with all applicable regulations for solutions containing sodium hypochlorite.

6.9. Accessing Results

After a run is finished, a Completed Run is created. It contains the original information of the Run Draft and is supplemented with new information about Run Report, Run Log and Analysis Results. How to view this information and proceed with data analysis is explained in the following chapters.

6.9.1. View Results of the current MODAPLEX Run

The results of the current MODAPLEX run are shown in the Completed Run menu within the Analysis Results tab once the run is completed.

When the run has finished, the Ongoing Run menu is shown by default. Click the button **View Run Setup** within the toolbar of the Ongoing Run menu for an automatic forwarding to the Run information of the Completed Run.

6.9.2. View the Results of a Previous MODAPLEX Run

To review results of a previous run, please select **Open Existing Run** within the toolbar of the Completed Runs menu and open the respective file. The results of the selected run are listed in the Run Results tab.

6.9.3. Run Report, Run Log and Analysis Results

In an opened Completed Run, the tabs Run Report, Run Log and Analysis Results are now accessible,

besides the initial tabs Run Information and Plate Map.

- The Run Report gives all relevant information for quality control of the performed run. It includes date, operator, reagents with lot and expiration date as well as consumable status.
- The Run Log tab lists the performed technical steps of the instrument with date and time.

- The tab Analysis Results gives an overview on generated data of the run. Results can be used for a first control. For further analysis, the results must be copied and opened with the analysis software. This is explained in the following chapters.

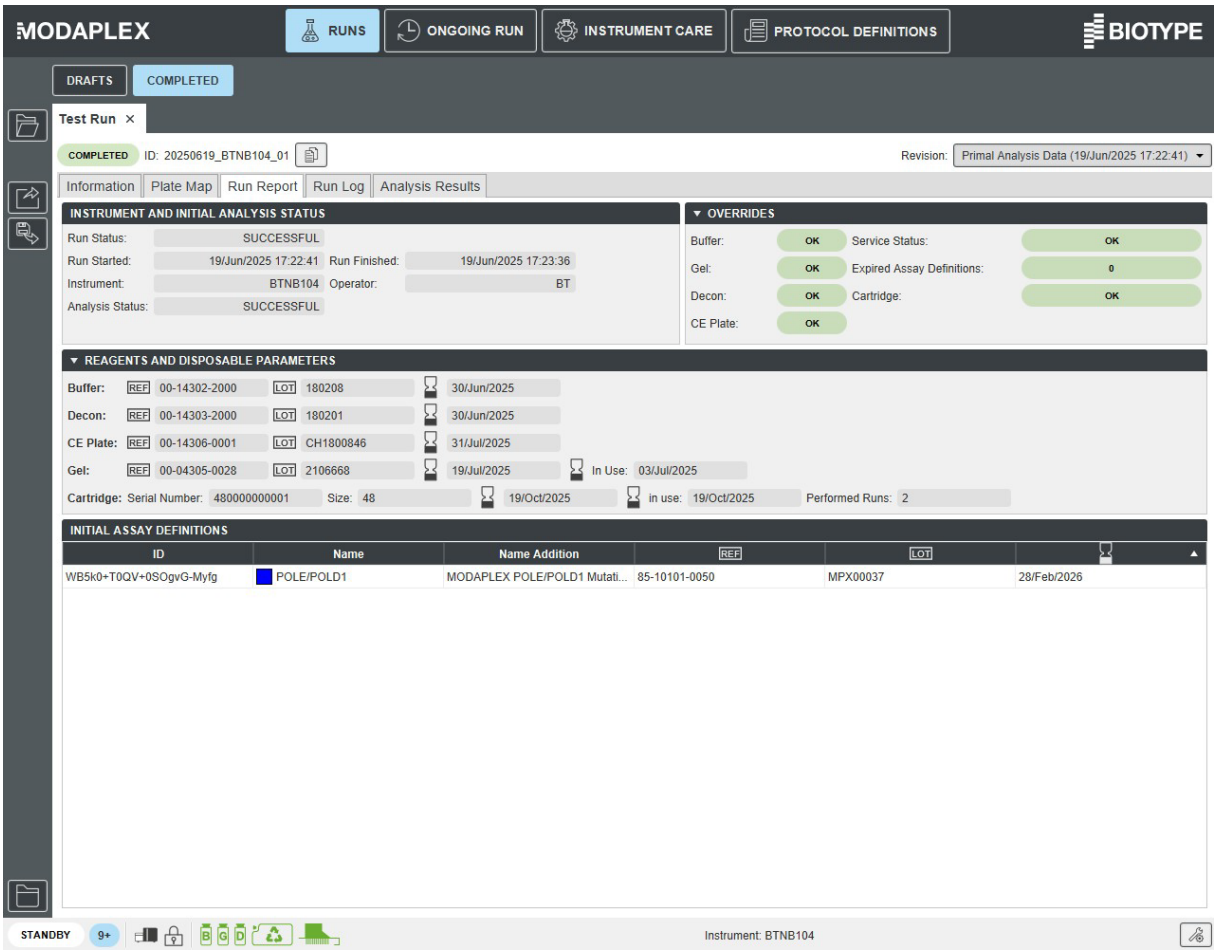


Figure 19: MODAPLEX Controller, Completed Run

The Run Information tab of the completed run can be used for a new Run Draft. Please select the button **Duplicate as Run Draft** in the toolbar and a new Run tab will open.

6.9.4. Loading Results to Storage Devices

There is a port for USB storage devices on the side of the MODAPLEX instrument. Connect the storage device to transfer results from the MODAPLEX to the working computer.

Figure 20: MODAPLEX instrument, port for storage devices

Run data of completed runs can be exported by selecting the **Export Run** button from the toolbar in the Completed Runs menu. Select the desired folder or export directly to the connected storage device.

6.9.5. MODAPLEX Hub: Transfer results and protocols via ethernet

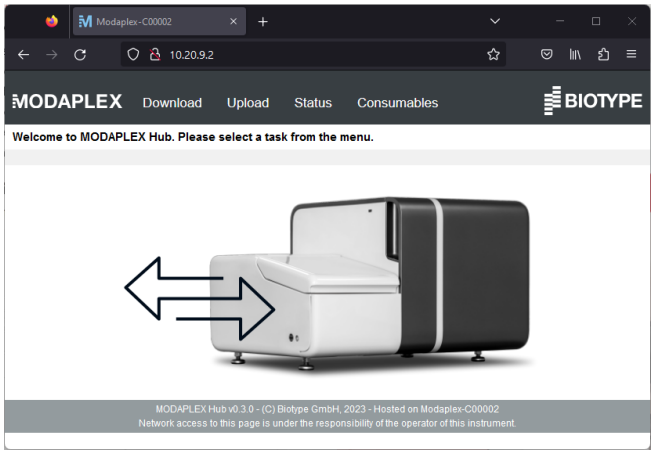
The MODAPLEX can also be connected to an internal network to transfer data via a web interface. Please contact BIOTYPE if you wish to use this feature.

Access MODAPLEX Hub for the instrument by entering the IP address of the instrument into the address bar of the web browser in the form “http://123.456.789.890”. If there are issues when opening the webpage, please make sure that the IP address is correct and accessible from your PC.

The Hub provides four main functions:

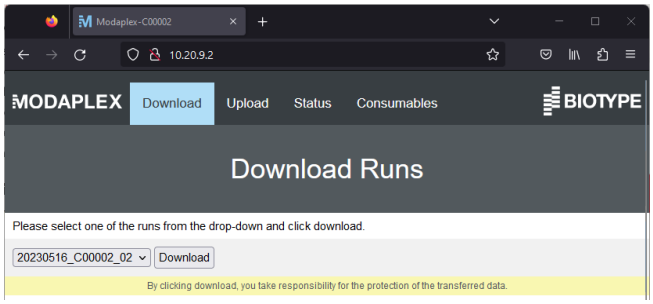
1) Download runs
2) Upload protocol definitions
3) Monitor the status of current and past runs
4) Monitor the consumable status

Click the respective item in the menu bar to access the desired function. Please see below for usage of these functions.



Download runs

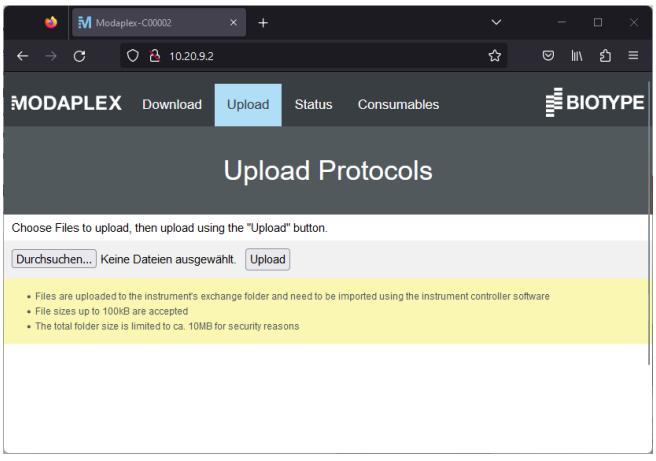
Follow the instructions on screen to download runs. Downloaded runs are provided as zip files. Only one download at a time is allowed by the server. There is a notification if another user is downloading a run at the same time.



Upload protocol definitions

When uploading protocol definitions, xml files and checksum files may be selected. After uploading the files, it is necessary to import the uploaded files using MODAPLEX Controller, see section 6.3. The files will appear in the file list on the uppermost folder level.

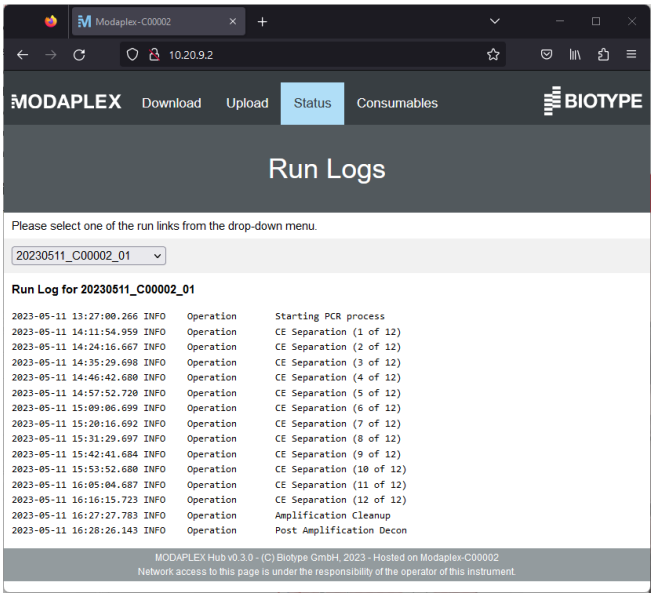
While it is sufficient to upload protocol definitions produced with the MODAPLEX Design and Analysis Software as single xml files, it is also possible to include the checksum file provided with each xml protocol. This allows the MODAPLEX Controller software to verify the integrity of the



file. There is a warning, that the protocol was potentially manipulated, if you decide not to include the checksum file.

Monitor the **status** of current and past runs

Select a run to display the logging information of a run. By default, the most recent run is displayed. The information displayed is identical to the text displayed in the run log section of a run. The display does not auto-refresh. Please use the refresh button of the browser to view the most recent data of the current run.

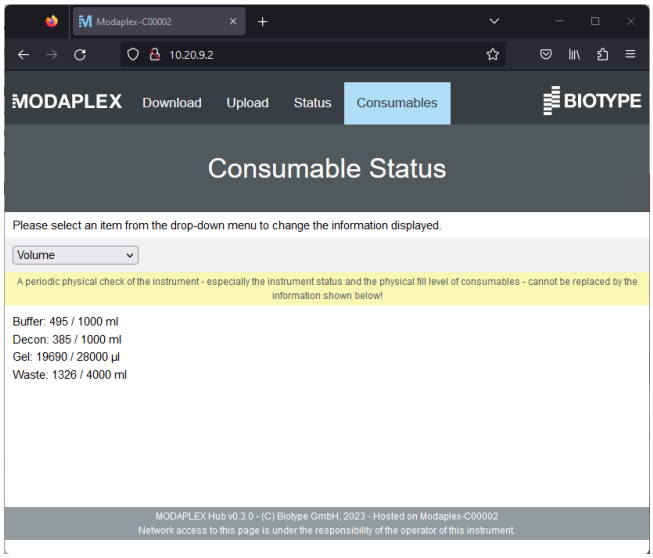


Monitor the **consumable** status

The following different properties may be displayed for the liquid consumables:

- Volume – the remaining volume in the bottle (for waste: remaining empty volume)
- Expiry – expiry dates for consumables, if applicable
- Reference Number – the reference number specified (e.g. by barcode scan), when installing the bottle
- Lot Number – the lot number specified (e.g. by barcode scan), when installing the bottle
- Last exchange (Gel) – the date of the last Gel exchange

Information that is not applicable for a bottle is displayed as N/A.



6.10. Software for Data Evaluation

For data evaluation of completed runs performed by MODAPLEX assay customers, please refer to:

- **MODAPLEX Reporter**

  Data interpretation according to MODAPLEX assay kit handbook

For data evaluation of completed runs performed by MODAPLEX assay developers, please refer to:

- **MODAPLEX Design and Analysis Software**

  Detailed data access via MODAPLEX Deep Dive

6.10.1. MODAPLEX Reporter

The MODAPLEX Reporter is used together with MODAPLEX assays. MODAPLEX assays provided by BIOTYPE are used with an assay specific MODAPLEX Reporter plugin.

The MODAPLEX Reporter will evaluate the data according to the assay settings and create a report. Transfer generated data of completed runs from MODAPLEX assays into the MODAPLEX Reporter to interpret the data.

6.10.2. Data Import

Save your completed run data in a folder of the computer with installed MODAPLEX Reporter. Import the data into the software according to the instructions given in the MODAPLEX assay kit handbook.

6.10.3. Reference

For instructions to MODAPLEX Reporter software, please refer to the respective MODAPLEX assay kit handbook.

6.10.4. MODAPLEX Design and Analysis Software

The MODAPLEX Design and Analysis Software shall be installed at the workstation, which is not connected to the MODAPLEX instrument. The MODAPLEX Design and Analysis Software has no access to the MODAPLEX instrument. Therefore, the functionalities are reduced compared to the MODAPLEX Controller software installed on the computer connected to the instrument. Accordingly, the Ongoing Runs and Instrument Care menus are missing and there is no System Status Bar.

The menus Runs and Protocol Definitions operate equally to the MODAPLEX Controller software. They can be used to prepare Analysis Protocols, PCR-CE Protocols and Assay Definitions, as well as Run Drafts. Additionally, files of completed runs can be loaded into the MODAPLEX Design and Analysis Software. By opening and editing a Completed Run, the Plate Map of the run can retroactively be changed. Assay Definitions can also be added or removed. Only Assay Definitions with the same PCR-CE Protocol can be used in a run. To complete the changes, the fields for Creator and Revision need to be filled before saving the changes to the Completed Run. After saving, a new analysis is automatically started and can be viewed in the menu Data Analysis, which is not available in the MODAPLEX Controller software.

The menu Data Analysis also offers the function Add Batch Reanalysis which enables the replacement of Assay Definitions of multiple runs.

The menu Settings provides access to system information in the About Section, the Assay Definition TrustStore, a function to export log files and the Preferences section to define the processor usage.

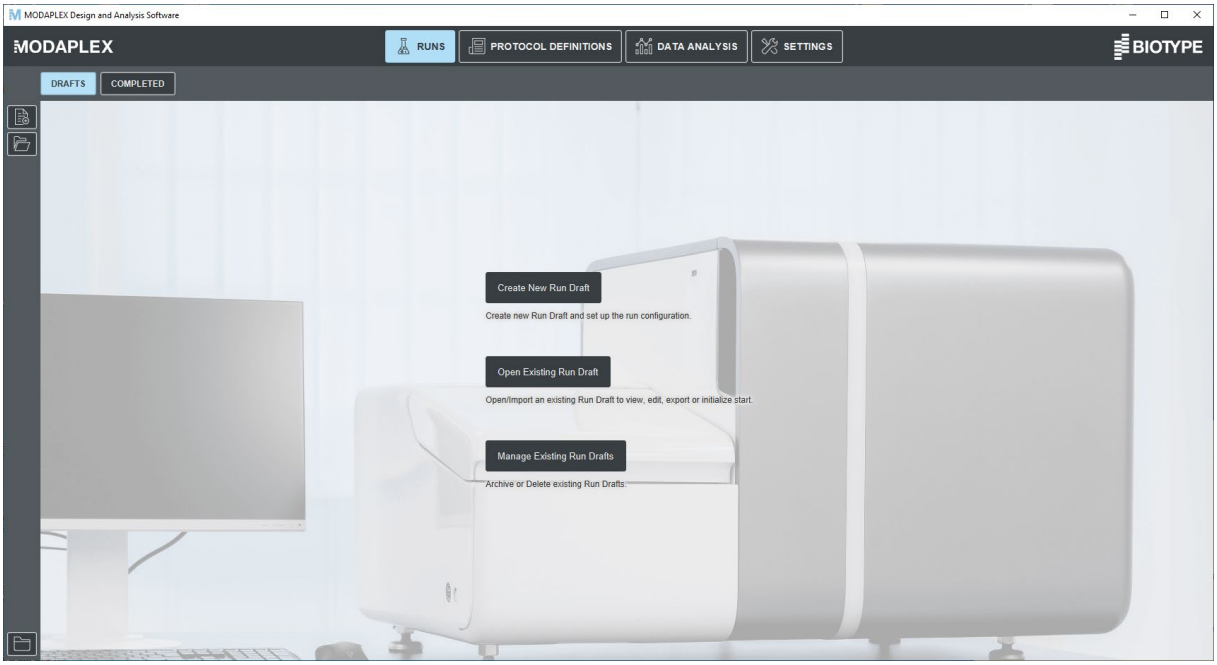


Figure 21: MODAPLEX Design and Analysis Software, Runs menu

6.10.5. Data Import

Save your completed run data in a folder on the computer with installed MODAPLEX Design and Analysis Software. Import the data into the software by selecting the button **Open Completed Run** in the Completed Run tab from the Runs menu.

6.10.6. MODAPLEX Deep Dive

The MODAPLEX Design and Analysis Software forwards to the MODAPLEX Deep Dive software used for detailed data access. For data access, click on the button **Open Run Revision** in Deep Dive located in the toolbar of the opened Completed Run. The MODAPLEX Deep Dive is primarily intended for customers using MODAPLEX as enabling platform and therefore creating PCR-CE Protocols, Analysis Protocols, and Assay Definitions for MODAPLEX assays, not provided by BIOTYPE.

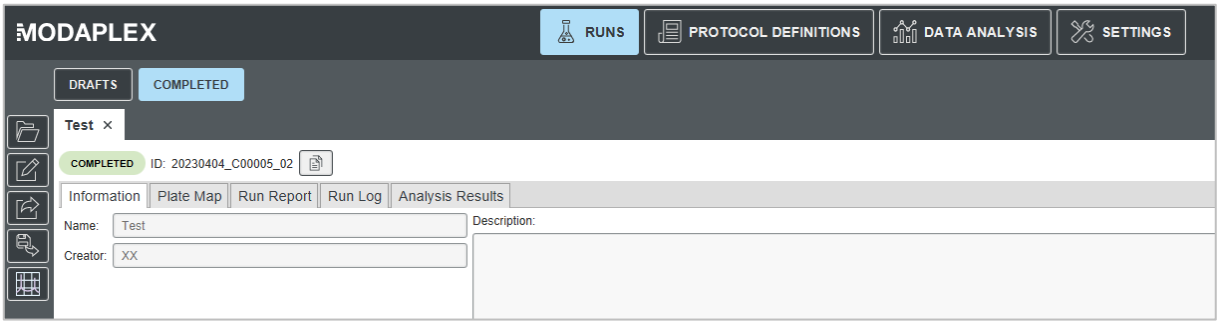


Figure 22: MODAPLEX Design and Analysis Software, the red arrow marks the button, which transfers to MODAPLEX Deep Dive for data access of completed runs.

Reference

For instructions on MODAPLEX Deep Dive software, please refer to the MODAPLEX Deep Dive Technical Note.

7. System Maintenance

This section provides information to the operator about replacing system reagents and performing routine maintenance for the instrument.

NOTE	
i	Only original parts shall be used with the system. Only original external cables provided with the instrument shall be used for the system.

NOTE	
i	The instrument or system parts must be marked as defective if they show visible external damage. It must not be used until repairing, testing and release by BIOTYPE service. The same is true for a partly disassembled instrument or known defective components.

7.1. Technical Maintenance

Please check the date for the next maintenance within the Instrument Care menu in the Maintenance tab. Do not use the instrument if the instrument status is overdue.

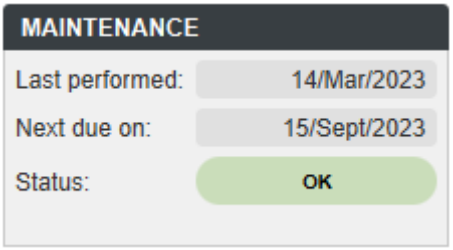


Figure 23: MODAPLEX Controller, Maintenance tab in Instrument Care menu

Technical maintenance of the MODAPLEX instrument is provided by BIOTYPE annually. The service engineer will set the date for the next service and the software will indicate that the service is due before the interval has passed.

Note that the technical maintenance of the MODAPLEX instrument is only done by a customer support technician authorized by BIOTYPE.

How to obtain urgent technical maintenance

Please contact BIOTYPE customer support in any case of urgent technical maintenance via Email at modaplex@biotype.de. For scheduled technical maintenance, BIOTYPE will contact the customer.

7.2. Cleaning the casing of the System

CAUTION

Decon solution may cause eye, skin, and respiratory tract irritation. Wear personal protective equipment such as lab coat, appropriate gloves, and protective eyeglasses when working with Decon solution.

Please refer to the Materials Safety Data Sheets for details on how to handle and dispose Decon.

CAUTION

To avoid damage, do not use MODAPLEX Decon solution or bleach on the electronic components such as the barcode scanner, monitor, keyboard, and mouse.

CAUTION

When using flammable cleaning reagents such as 70 % Ethanol, ensure sufficient ventilation and ensure that surfaces have dried before closing the sample or consumable door. Follow all safety instructions provided by the manufacturer of the cleaning agent.

NOTE

Do not use an excessive amount of liquid for the cleaning, especially with active power source. Cleaning of outside shall not be done during a run.

NOTE

Use the cleaning agents as described in this manual only. Use of cleaning agents not described in this manual can impair the instrument.

NOTE

Do not use organic solvents for cleaning of any parts of the Gel path, especially the tubing in the Gel cooling chamber. Notice that there is an extremely low solubility of urea in organic solvents that might cause quality issues with the capillary electrophoresis.

For maintenance procedures such as cleaning, please use the key button in the toolbar for opening and closing the doors.

Only following cleaning reagents shall be used for cleaning of instrument surfaces:

- 70 % Ethanol – for cleaning the housing of the instrument
- 1/10 diluted MODAPLEX Decon - for decontamination of the sample area

Before using any other cleaning reagents, please contact BIOTYPE customer support via Email at modaplex@biotype.de.

Clean the exterior and the surfaces of the system for routine cleaning of working areas in the lab or before the system is relocated. Following procedure shall be applied:

- Wipe the external surfaces of the instrument and peripherals (mouse and keyboard) with a cloth or gauze moistened with
    - 1/10 diluted MODAPLEX Decon solution.
    - 70 % Ethanol subsequently.
- Dry the external surfaces with a dry cloth or gauze.
- Wipe the surfaces around the MODAPLEX thermal cycler and the sample door first with a cloth or gauze moistened with 1/10 diluted MODAPLEX Decon solution followed by 70 % Ethanol.
- Make sure that all surfaces are left dry after cleaning.

Please contact BIOTYPE customer support via Email at modaplex@biotype.de, if there is any doubt about the compatibility of decontamination or cleaning agents.

7.3. Cartridge Exchange

NOTE	
	Make sure that only unimpaired cartridges are inserted. The cartridge capillaries are fragile and must not be broken, the electrodes must not be bent. Using a broken cartridge may seriously damage the system.
CAUTION	
	Take care when handling the cartridge for cartridge replacement procedure. The cartridge contains sharp parts, especially electrodes and capillaries, that might lead to operator injury when handled incorrectly.

For regular maintenance of the MODAPLEX instrument, review the System Status Bar or regularly check the Instrument Care menu in the MODAPLEX Controller software to review the status of the Cartridge. Please exchange the Cartridge, if the Cartridge symbol and the current Cartridge status is highlighted in yellow or red.

For the Cartridge exchange procedure, a MODAPLEX CE Plate is required.

For changing the Cartridge, refer to the tab Cartridge in the Instrument Care menu and select the button **Exchange Cartridge** in the toolbar. The Cartridge exchange wizard opens. Follow the given instructions in the wizard. If any liquid consumable is empty to perform the Cartridge exchange, an exchange can be initiated by selecting **Exchange Consumables** during the first step of the instruction. As soon as step 5 of instruction is finished, the Cartridge exchange is completed.

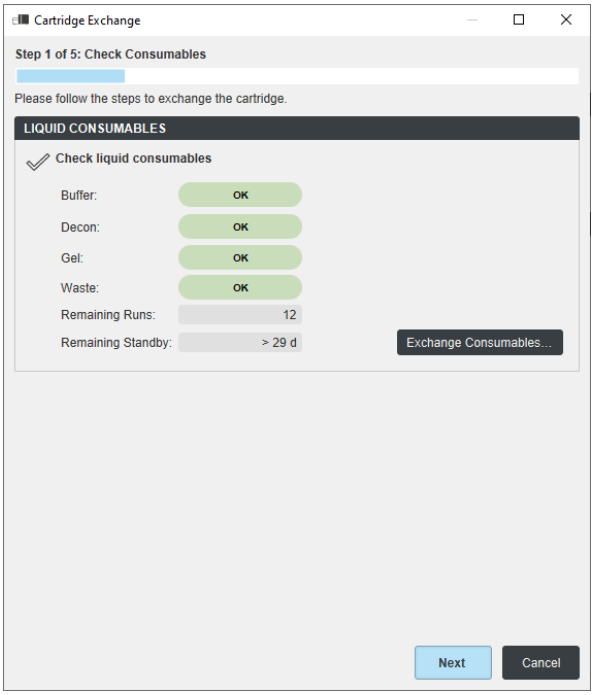


Figure 24: MODAPLEX Controller, Cartridge Exchange wizard

The data of the currently inserted Cartridge and the capillaries overview are now visible in the Cartridge tab. All data of the Cartridge are saved on a chip that can be read by the instrument and are sent to the software with installation. The first installation date of the Cartridge as well as performed runs will be saved automatically on the chip of the Cartridge. If a Cartridge is inserted a second time into the instrument or into another instrument, the saved data will appear with reinsertion of the Cartridge.

Water Wash Wizard

Use the Water Wash Wizard if you wish to entirely replace old Gel in the system with fresh Gel. This might become necessary if the instrument was unintentionally turned off for a period of time or if the BIOTYPE support team asks you to use the wizard for issue resolution. Use distilled or deionized water with this wizard. The use of third-party reagents is user responsibility.

7.4. Consumable Exchange and Waste Disposal

CAUTION

MODAPLEX Decon, Waste and MODAPLEX Buffer solution may cause eye, skin, and respiratory tract irritation. Wear personal protective equipment such as lab coat, appropriate gloves, and protective eyeglasses when working with Decon solution.

Please refer to the Material Data Safety Sheet for details on how to handle and dispose Decon.

CAUTION

The waste solution in the waste container contains sodium hypochlorite. Liquid waste containing sodium hypochlorite **MUST NOT** be mixed with any other laboratory waste known to contain guanidine thiocyanate (GuSCN).

Care should be taken to reduce the chance of splashing or spilling when transporting a full bottle.

Wear personal protective equipment such as lab coat, appropriate gloves, and protective eyeglasses when emptying the MODAPLEX waste.

NOTE

Never install used or partially filled bottles of consumables on the MODAPLEX system as this can lead to an instrument running dry.

Never install a used bottle as the accuracy of the expiry date might be impaired.

NOTE

Note that the CE Gel is cooled within the instrument. Do not interrupt the cooling chain unnecessarily before installing the Gel in the instrument. The shelf life of the Gel is strongly reduced if not cooled.

The Gel must be replaced after 2 weeks. During longer periods of Idle mode the Gel can remain in the system but must be replaced before an analysis is performed.

For regular maintenance of the MODAPLEX instrument, review the System Status Bar or regularly check the Instrument Care menu in the MODAPLEX Controller software to review the status of liquids and waste. Please exchange the liquid if its status is highlighted in orange or red.

For replacing MODAPLEX Buffer, Decon, or Gel and for emptying the waste bottle, the Liquid Management wizard is used for exchanging liquids by performing the following steps:

Liquid Management:

- Select the button **Consumable Exchange and Waste Disposal** in the toolbar
- CONSUMABLE: Scan your consumable to be installed by selecting the button **Scan Now** OR select the **Editing** button for manual consumable barcode input
- Confirm the lot of the new consumable
- WASTE: Select the button **Dispose Waste**

- Door for consumables is unlocked and can be opened
- Remove current bottle and replace with new bottle OR
- Dispose waste, rinse the bottle once with water and reinsert the bottle
- Confirm the exchange with the respective button
- Close the door

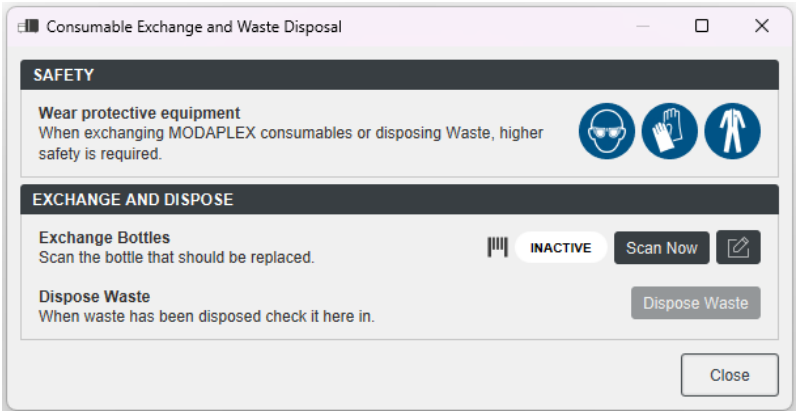


Figure 25: MODAPLEX Controller, Consumable exchange, and waste disposal wizard

Make sure that the consumable to be replaced is connected to the correct tubing. For security, replacements of multiple consumables must be done consecutively within the MODAPLEX Controller software. Please make sure that consumable bottles are sorted correctly for replacement procedure.

The barcode scanner only scans barcodes of BIOTYPE consumables. Do not install other consumables than consumables provided by BIOTYPE for MODAPLEX instrument.

Only replace Buffer with fresh and completely filled bottle. Risk of instrument running dry.

Only replace Decon with fresh and completely filled bottle. Risk of instrument running dry.

Only replace Gel with fresh and completely filled bottle. Instrument will not recognize empty Gel bottle before a run and you will lose your samples.

Only reinsert completely empty waste bottle. Make sure that the waste bottle is reinserted in the right orientation with the tubing at the upper part. Otherwise, waste will leak out if the tubing is at the lower part and must be opened for removal of the full waste bottle.

7.5. Shutting Down or Re-Starting the System

NOTE	
i	No self-directed shut down of the system shall be done by the operator permanently. Idling routines must run regularly to prevent the system fluids from crystallizing.

The MODAPLEX instrument should not be shut down if it is in regular usage.

Please contact BIOTYPE customer support via Email at modaplex@biotype.de if shutting down or re-starting the system is required.

7.6. Software updates

IT security is an ongoing process focused on protecting sensitive data and ensuring the integrity of technical instruments connected to IT systems. At BIOTYPE, we take IT security very seriously and provide thoroughly tested updates on a regular basis. Our customer support team will notify you as soon as software updates become available.

To maintain up-to-date IT security between service intervals, the instrument features a semi-automatic update process for both offline and online systems.

If your instrument is not connected to the internet (including cases where it is only connected to an internal network), you can install upgrades using a USB stick. BIOTYPE provides these USB sticks for upgrades, or alternatively, we will supply the necessary file contents along with instructions for preparing your own USB stick.

To install a security update, restart the instrument after optionally inserting the USB stick containing the offline update. To restart, press the power button located next to the USB port and then select the “Restart” option displayed on the screen. The available updates will be installed during the restart procedure. You can continue using the instrument immediately after the restart is complete.

Once you have performed the update, we kindly request that you notify us by sending a message to modaplex@biotype.de. This helps us track the update status of your instrument. Please also contact our customer support team with any comments or issues you encounter.

8. Error Conditions and Troubleshooting

The following error conditions can occur at the instrument and must be addressed as specified.

Table 14: Error conditions

Error	Action
Technical error conditions displayed in the Event Log (see chapter 5.3.3Instrument Care).	Each log item includes a description and a proposed action. In doubt, contact BIOTYPE for technical support.
The instrument ran dry due to insufficient Buffer or Decon fill level.	Replace the empty consumable using the wizard and attempt to start a run with an empty Sample Plate. If the first pre check sequence fails, retry. In case the condition persists, please contact BIOTYPE for technical support.
The Gel bottle is entirely empty and the Gel installation wizard reports pressure issues repeatedly when attempting to replace the Gel bottle.	The Gel line must be primed manually. Please contact BIOTYPE for technical support.
The instrument does not start any process because it reports open doors.	Make sure that both screws of the cartridge are properly secured and that the sample door and the consumable door are fully engaged. The instrument will not perform any action for safety reasons if one of these conditions is not met. A door sensor might be misaligned if the error persists. Please contact BIOTYPE support for re-alignment of the sensor.
A power outage occurred. The instrument is therefore turned off.	Restart the instrument by clicking the On/Off button next to the USB ports at the front left side of the instrument. Wait for the

Error	Action
	instrument to finish its startup sequence (Prepare for Use) and check for any remaining error condition.
The software is not visible anymore.	If there is a BIOTYPE icon on the bottom right of the screen, double-click it to reopen the minimized application. If this is not the case, you can restart the MODAPLEX controller software by moving the mouse to the bottom of the screen and clicking the icon for MODAPLEX controller software. In doubt, push the power button on the front-left side of the instrument, select Restart and wait for the software to re-open
My USB Stick is not detected by the instrument	Please make sure to use a USB stick with a common file system. In doubt, please format the USB stick with a FAT32 file system. It might take a few seconds before a USB stick is detected. Reopen the export or import file dialog to check if the USB stick was mounted in the meantime.
I managed to open the file browser of the operating system. Why can I not copy files to my USB stick?	Always use dialogs integrated into the MODAPLEX controller software for file operations. Operating system tools are only intended for service activities and file access is limited for the logged in user.
The warning “The Assay Definition/Analysis Protocol/.. was possibly manipulated” is displayed after opening a file.	Please ensure that you also have the corresponding checksum alongside the MODAPLEX file. The checksum is necessary to test for manipulation. If both files weren’t present at the same folder level by import, the file is possibly manipulated.
If the sample plate was inserted but isn’t detected	Wipe the end surfaces of the Hold down plate with a lint-free cloth to remove any dust or other residues that could block the sensor.

9. Systems Specifications

Table 15: Instrument specifications

Specification	Parameters
Size	Depth 600 mm Height 515 mm Width 908 mm
Weight	115* kg net without chemicals 118 kg gross, ready to use with maximum consumable filling levels (excluding monitor, keyboard, and mouse)
Space installation requirements	The system is a benchtop analyzer installed in laboratory rooms with appropriate clearance around the instrument and behind the instrument for proper cooling and airflow. The working envelope around the instrument allows for opening covers and easy operator access. Minimum workspace: Height: 551 mm Width: 908 mm Depth: 650 mm This does not include monitor, keyboard, and mouse.
Temperature	Operation within 18 °C to 27 °C
Relative Humidity	20 % to 80 %, non-condensing
Electric frequency	50 ± 5 Hz or 60 ± 5 Hz
Electric voltage	110 – 240 V ± 10 %
Electric power	110 V, 8 A / 240 V, 5 A The device may only be connected to power using the surge protection power strip provided by BIOTYPE. Please do not connect any other devices to this power strip.
Power cord rating	H05VV-F 3G with at least 1,0 mm² conductor cross-section with max. current capacity 10 A / 250 V
Fuse	For 110 V use: M 10 A H 250 V; for 240 V use: M 6 A H 250 V
Maximum altitude	The instrument can be used at altitudes of up to 1500 m.
Pollution	The instrument can be used in environments with pollution degree 2 according to EN 60664-1:2007, i.e., laboratories.

*estimated

NOTE	
	This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
NOTE	
	Only use power cords H05VV-F 3G with at least 1,0 mm² conductor cross-section with max. current capacity 10 A / 250 V
NOTE	
	Ensure free access to the power plug of the MODAPLEX instrument.

Table 16: PC Requirements for MODAPLEX Design and Analysis Software

Specification	Parameters
Operating System	Windows 10 Version 21H1 (MinVersion=10.0.19043, 64-bit), Version for macOS 13 (Ventura) available upon request
Java Version	OpenJDK 17 (bundled in Windows executable)
Storage capacity	16 GB hard-disk space
Main Memory	4 GB RAM

10. Glossary

Term	Definition
MODAPLEX technology	Technology that combines PCR and CE
Wizard	User interface in software that leads through a sequence of steps.

10.1. Abbreviations

Abbreviation	Definition
CE	Capillary Electrophoresis
DNA	Deoxyribonucleic acid
ID	Identification
IFU	Instruction for use
LED	Light-emitting diode
MPX	MODAPLEX

MSDS	Material Safety Data Sheets
PCR	Polymerase chain reaction
RNA	Ribonucleic acid

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