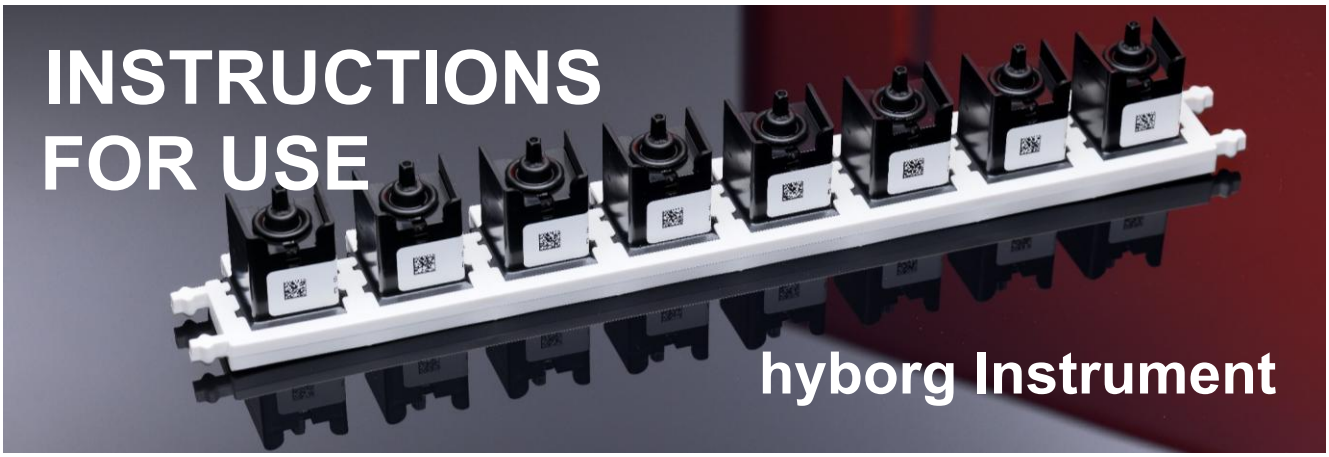


hyborgDxRED2-3_instructions for use_E_2026_08_31
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Products belonging to Risk Class A (according to IVDR – EU 2017/746)

hyborg Dx RED2 (including hyborg software)	*Basic UDI-DI 912012773HDR-001XD*	*GTIN / UDI-DI 09120127730015*
hyborg Dx RED3 (including hyborg software)		*GTIN / UDI-DI 09120127730787*

Analysis system for processing multiplex hybcell tests including software.

System Liquid	*Basic UDI-DI 912012773HDR-005XM*	*GTIN / UDI-DI 09120127730022*
PE-Buffer		*GTIN / UDI-DI 09120127730138*
CS-Buffer		*GTIN / UDI-DI 09120127730503*

Buffers for hyborg Dx RED and hybcell tests

Service and replacement parts

hyborg Scanner		*GTIN 09120127730343*
Waste Bottle		*GTIN 09120127730831*
Rack		*GTIN 09120127730220*
hyborg Service-Kit		*GTIN 09120127730381*
hybcell Control xC		*GTIN 09120127730121*

The instructions for use describe the *hyborg Dx RED2/3* instrument and the **instrument software in its version 1.9.0.**

The language setting on which these instructions for use are based is ***en (English)***.

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Version information

Version	Document and Changes	Modified	Approval
001	**CUBE-MA-16025-V01-E CE-IVD hyborgDx – CUBE-MA-16025-V01-E CE-IVD hyborgDx V02** First draft, introduction of the disclaimer. The removal of the symbol for liquids used by the hyborg. Use of images from the updated hyborg software. Added chapters, “Diagnose the status of instrument hardware or electronics” and “Granting a Support member remote access to the instrument”.		
002	**CUBE-MA-16025-V01-E CE-IVD hyborgDx V02 - CUBE-MA-18003-V01-E CE-IVD hyborgDxRED2** Formatting of the first page to include better images and the month of document release. Modified disclaimer report. Added images to chapters, “Diagnose the status of instrument hardware or electronics” and “Granting a Support member remote access to the instrument”. Improvement of the troubleshooting chapter to add more images on handling the hyborg, added a new subchapter “Empty Liquids / Full Waste” and finally, the removal of the subchapter involving the error lamp.		
003	**CUBE-MA-18003-V01-E CE-IVD hyborgDxRED2 - CUBE-MA-20009-V03-E CE-IVD hyborgDxRED2** Introduction to subchapters “Manage Liquids (buffers)”, “Check system pressure”, “Control hybcell and quality assurance” and “Show log, usage and this manual” whilst removal of subchapter “Granting a support member access to the instrument” from the Tools chapter. The Troubleshooting subchapter now has added subchapters “Granting a support member access to the instrument” and “Empty Liquids / Full waste”.		
004	**CUBE-MA-20009-V03-E CE-IVD hyborgDxRED2 - CUBE-MA-21010-V04-E CE-IVD hyborgDxRED2** The chapter “Basic hybcell processing” now has updated images as a result of hyborg software updates. Accompanied with the rearrangement of some subchapter content.		
005	**hyborgDxRED2_instruction for use_E_2022_05_18** Renaming of the documents instead of manual, now called instructions for use. The previously named chapter “Switching on” is now referred to as “Preparatory treatment”. This chapter now has additional information. Introduction of the subchapter “Serious Incidents / vigilance” into the Troubleshooting chapter.		
006	**hyborgDxRED2_instruction for use_E_2023_04_25** Introduction of the GTIN into the main page and product page.		
007	**hyborgDxRED2_instruction for use_E_2023_10_13** The buffers and rack are now introduced in the main page of the IFU including their GTIN numbers, together with that, GTIN is now referred to as UDI-DI.		
008	**hyborgDxRED2_instruction for use_E_2024_01_03** Updated images throughout the IFU related to the hyborg software updates and year 2024. Reports have also been updated both software and PDF versions. Into the chapter Troubleshooting, a new subchapter “Barcodes on liquid bottles not readable” has been introduced.		

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009	**hyborgDxRED2_instruction for use_E_2024_04_25** The chapter Troubleshooting, subchapter “Barcodes on liquid bottles not readable” now has introduced barcodes in multiple languages, French, German, Italian, Spanish, and UK. Lastly, an appendix “Pre-installation form Cube Dx hyborg connectivity” is now added into the last page of the IFU.		
010	**hyborgDxRED2_instruction for use_E_2024_11_07** The chapter “hyborg packaging for transport” is renamed, and it now has step by step instructions on how to pack the hyborg for transportation. Introduction of a new Chapter “Connectivity” which was previously in the appendix.		
011	**hyborgDxRED2_instruction for use_E_2026_07_07** New order of chapters and sometimes renaming of headings, trying to unify the format of IFUs (with the ones for test kits). Adding of chapters, revision of description of software function. Changing to RustDesk.	CRE,	BNU
012	**hyborgDxRED2-3_instruction for use_E_2026_08_31** Inclusion of *hyborg Dx RED3*.	CRE	BNU

Paper copies of the instructions for use can either be printed or requested from Cube Dx at *support@cubedx.com*. Previous versions of the instructions for use may as well be requested.
Please save any eIFUs locally after downloading for offline access.

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IVD CE

1. Warnings and Safety Information

Please read this user manual carefully before using the instrument for the first time!

Intended for **professional IVD use only**. ***hyborg Dx RED2*** and its variant ***hyborg Dx RED3*** bear the **CE mark** according to regulation **(EU) 2017/746**.

Improper use of the instrument, which does not comply with the instructions in this user manual, may compromise the intended protective effect and/or the performance of the instrument.

The instrument has to be checked annually according to ÖVE/ÖNORM E8701 or DIN VDE 0701-0702 by the operator.

Note that the hyborg Dx RED meets standards of emissions and immunity in accordance with EN 61326-2-6, electrical safety standards in accordance with EN 61010-1, EN 61010-2-010, EN 61010-2-051, EN 61010-2-101 as well as laser safety standards in accordance with EN 60825-1.

When working with *hyborg Dx RED*, please adhere to the **generally accepted rules of conduct in laboratories**.

Replacement parts and accessories may only be supplied by the manufacturer and its distribution partners. The use of non-OEM replacement parts and other accessories will lead to a forfeit of warranty.

Installation of the instrument may only be carried out by authorized personnel. Note that (premature) installation and commissioning of the instrument by the user is not permitted and will lead to a forfeit of warranty.

Always wear **disposable gloves** when operating the instrument, and also **safety glasses** when handling hyborg liquids. It is recommended to wear a **lab coat** as well. The liquid in the waste container (marked with red dot) is potentially infectious.

Within the hyborg Dx RED **parts are moving**. You may jam your fingers in the instrument drawer if you handle the instrument carelessly. Keep your hands and fingers out of the instrument's drawer when it is closing!

Also comply with the **test-specific instructions for use** relevant for the respective product.

The **housing** of the *hyborg Dx RED* protects users from laser radiation, moving parts and contact with the heated parts of the instrument. Note that you must not remove the housing during routine operation! Safe and proper operation of the hyborg is guaranteed only when the provided housing is in place.

Do not use the *hyborg Dx RED* close to sources of strong electromagnetic radiation, since this may disrupt proper operation.

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2. Explanation of symbols

Below symbols are depicted in this (and other) instructions for use, on product labels or other product documentation.

Symbol	Explanation
	CE mark. In vitro diagnostic medical instrument.
	Manufacturer.
	Date of manufacture.
	Protected by a fuse.
	Connect to the mains supply (alternating current).
	Use by date.
	Temperature limit for storage.
	Sufficient for <n> tests.
	In-use stability in <n> months.
	Reference to the instructions for use (www.cubedx.com/documents).
	**Follow the instructions for use!** The instructions for use include information for safe use. Position: instrument front.
	**Biological hazard!** Samples processed by the hyborg are potentially infectious. Position: instrument front and waste bottle position.
	**Hot surface!** The heating elements built into the instrument become hot during operation. The elements are located inside the instrument and are accessible, if the cover is removed (for maintenance, error handling…). Position: cover of optical module.
	**Attention, general hazard area!** The instrument processes samples that are potentially infectious. Wear disposable protective gloves and safety glasses when handling the waste. Moving parts within the instrument might inflict injuries. Be careful not to jam your fingers or hands in the drawer. Position: instrument front.
	The laser beam is completely covered within the instrument. The cover has no outlet openings through which laser light can penetrate. The laser is constantly on during the scanning process. Position: instrument front.
	**Attention, laser radiation!** The instrument contains a laser source. Position: cover of optical module.
	By removing the case of the optical module, exposure to laser radiation of class 3B is possible. Position: cover of optical module.

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3. Intended Use(s)

hyborg Dx RED2/3

hyborg Dx RED 2 and *hyborg Dx RED 3* and their software are automated in vitro diagnostic (IVD) devices designed to process and analyse microarray tests, conducted by using *hybcell* test cartridges. The instrument facilitates the detection and/or measurement of analytes based on the specific *hybcell* tests utilized. *hyborg Dx RED* is not limited to any particular analyte, as the range of analytes detectable depends solely on the selected *hybcell* tests, not the device itself.

Depending on the *hybcell* tests used, the instrument can perform various functions, such as screening, monitoring, diagnosis, diagnostic aid, therapy-accompanying diagnostic, prognosis, or prediction. The context in which diagnostic information is provided depends on the *hybcell* tests employed, and the instrument is not limited to any specific clinical or diagnostic context.

The *hyborg Dx RED* can deliver qualitative, semi-quantitative, or quantitative results, depending on the configuration of the processed hybcell tests. The instrument is suitable for processing a wide range of sample types and is not restricted to any specific sample material, target population, or medical condition.

This device is exclusively intended for professional users in a clinical or laboratory setting.

Buffers: System Liquid, PE-Buffer and CS-Buffer

System Liquid, PE-Buffer and *CS-Buffer* are essential accessories for use with *hyborg Dx RED* instruments and ensure optimal performance during the automated processing and analysis of *hybcell* test cartridges.

- *System Liquid* ensures that fluid transport in the *hyborg Dx RED* runs smoothly. It removes any residual buffer in the tubing to prevent microbial growth within parts of the instrument and the build-up of salt deposits.
- *PE-Buffer* (or Primer Extension Buffer) provides a specific chemical environment necessary for DNA-based hybcell microarray tests conducted by the instrument.
- *CS-Buffer* (or Compact Sequencing Buffer) provides a specific chemical environment necessary for DNA-based hybcell microarray tests conducted by the instrument.

All buffers are critical for the accurate detection and measurement of analytes, as they support the overall diagnostic process carried out by *hyborg Dx RED*, they are suitable for qualitative, semi-quantitative, or quantitative analyses, depending on the exact product configuration applied. These accessories are not limited to any particular analyte, sample matrix, or diagnostic function, as their use depends on the hybcell tests employed. The buffers are suitable for various diagnostic applications, such as screening, diagnosis, monitoring, prognosis, prediction, and therapy-accompanying diagnostics.

The *System Liquid, PE-Buffer* and *CS-Buffer* are intended for professional users in clinical or laboratory settings, in conjunction with *hyborg Dx RED*. They may not be used separately in other contexts or with other diagnostic platforms.

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4. General Instrument Description

hybcell technology

hybcell enables both challenging immunologic (protein) as well as comprehensive genetic (DNA) tests on a single platform. Fundamental to the quality of any test is molecular interaction under defined and reproducible physical and chemical conditions. *hybcell technology* provides fast results with reduced hands-on time which results in quicker diagnosis and direct patient benefit.

Microarrays are an established core technology within the R&D community and are a very powerful method for the detection of molecular interactions. In principle, certain detector molecules, such as antibodies or DNA oligos are immobilised on a surface, which can either be a simple glass slide or a proprietary chemical or biological coating. The detector molecules bind certain compounds in the test sample and a biological readout detects the interaction. A core component of all microarray systems is a software package which interprets the large amount of data generated in parallel by the multiple spots (e.g. antibodies, antigen, DNA oligo) on the array's surface.

hybcell is the world's first cylindrical microarray. Advantages of *hybcell* are a very reproducible and fast binding or hybridisation process. *hybcell* tests are easy to use, as *hyborg Dx RED* processes the samples automatically.

As opposed to carrying to standard two-dimensional formats, *hybcell* is shaped as a cylinder and made up of following components:



Lid: The lid is used to seal the *hybcell* and to prevent cross-contamination.

Tray: The tray holds the other components together and protects the *hybcell*.

Core: The core is the heart of *hybcell* and carries test-specific spots on its surface.

Tube: This transparent cylinder contains the liquid sample once filled into the cartridge. The Core rotates within the Tube (and therefore within the sample).

hybcell and its components

hyborg Dx RED and Buffers

The *hyborg Dx RED* (instrument) and its software are intended to process and analyze different *hybcell* tests. The instrument and the software enable the user to automatically perform *hybcell* tests according to configured work-flows - coded in software protocols – with little variations in timing, heating, liquid dispensing or scanning. These protocols are imported to the software. hybcell tests are either based on DNA, proteins or other biomolecules.

The hyborg provides possibilities for heating and cooling the sample, to add liquids, to stir the solution by rotating the hybcell and fluorescence scanning the hybcell surface (a cylindrical microarray). The instrument is not intended to be used with any accessories other than those provided by the manufacturer.

For proper operation of the instrument *System Liquid* has to be connected. This buffer is used for flushing the tubing (including valves and other parts of the fluid system) after each hybcell test, during initialisation, when triggered by the user via the software or during shut-down. *System Liquid* prevents salt build-up and the growth of microorganisms in the fluid system.

PE-Buffer and *CS-Buffer* are a specific buffer required by DNA-based hybcell tests. These buffers contribute to the stabilization and integrity of analytes during testing as well as enabling a homogenous distribution of PCR amplicons across the surface of the *hybcells*.

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Accessories

Accessories to be used in combination with *hyborg Dx RED* include particular liquids (*System Liquid, PE-Buffer, CS-Buffer*), a waste container (*Waste Bottle*) and a device holding the hybcells in position (Rack) once transferred to the instrument. All accessories are provided by Cube Dx or respective distribution partners. However, note that especially DNA-based *hybcell tests* may require DNA extraction and PCR from the initial sample as well. Therefore DNA extractors or (q)PCR instruments or thermocyclers might be needed as well.

Test-specific necessary accessories are described in the instructions for use of these tests. Be aware that only specific accessories / instruments might be validated for a test.

Consumables and wear parts (*hybcells*, buffers, tubing, racks, etc.) may only be purchased from Cube Dx and its contracted distribution partners. Service and maintenance may only be done by authorized personnel.

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5. Technical Specification

hyborg Dx RED (instrument) and hyborg Software		
	hyborg Dx RED 2	**hyborg Dx RED3**
Weight	Instrument: ~ 45 kg (without liquids) Packed instrument: ~ 70 kg	Instrument: ~ 55 kg (without liquids) Packed instrument: ~ 80 kg
Dimensions (depth / width / height)	Instrument: 574 / 620 / 503 mm Shipping crate: 700 / 740 / 660 mm	Instrument: 572 / 645 / 499 mm Shipping crate: 680 / 720 / 640 mm
Ambient conditions	indoor use, not for wet locations, pollution degree 2 in accordance with IEC 60664-1 / DIN EN 60664-1 ambient temperature 0 to 40° C, humidity 30 to 80 % rHu altitude < 2000 m sea level	
Electromagnetic compatibility (EMC)	Moderate disturbances accepted (laboratory environment)	
Power supply	100 to 240 VAC (16 A) (overvoltage category II) 50 - 60 Hz	
Power consumption	Max. 480 W	
Appliance class	Class I (protective conductor)	
Fuses	10A delay-action fuse	
Liquids	Maximum 4 liquids: ▪ Liquid 1 – *PE-Buffer* ▪ Liquid 2 – *CS-Buffer* ▪ *System Liquid* ▪ Waste	
Automatic cleaning	After each run	
Heating	4 to 95° C	
Optic module (laser)	Laser class 1, classified in accordance with IEC 60825-1:2014. Laser output power: <0.39 mW; wavelength: 640 nm. The light source itself can be classified as class 3B in accordance with IEC 60825-1:2014. The instrument has no outlet openings through which laser light can penetrate. The laser is constantly on during the scanning process.	
Sound pressure level during operation	< 70 dB	
Rated operating pressure	~ 100 mbar	

Technical data

hyborg Dx RED is designed for 24 hours / 7 days operation.

The instrument is intended to be used several times a day with several samples per run.

Up to 24 hybcells can be processed per run. Processing time is test-specific.

The instrument may only be used by properly trained operators (authorized training by Cube Dx or its distributors).

Instrument Access / Connections

hyborg Dx RED provides different user accesses (compare pictures below).

The drawer is the main access and opens and closes to load and unload up to 24 *hybcells* (for *hyborg Dx RED2* provided in 3 Racks, each holding up to 8 *hybcells* / samples).

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On the left-hand side of the instrument different buffers (liquids) are connected / refilled / disposed: Liquid 1, Liquid 2 and system liquid, waste.

The cover is not intended to be removed during routine operation. However, it can be opened with a tool for service and maintenance reasons.



hyborg Dx RED2



hyborg Dx RED3

Different connectors are located on the right-hand side of the instrument. They are used to connect the barcode reader or additional peripheral instruments (e.g., keyboard, computer mouse, ethernet cable, etc.)

The power cable is connected on the right-hand side as well, close to the main switch.

The pictures below show the open drawer and a *Rack* loaded with *hybcells*. Whereas *hyborg Dx RED2* works with up to 3 Racks made of plastics and holding 8 hybcells each (in total 24 hybcells), *hyborg Dx RED3* offers a single metal rack, holding up to 24 hybcells.

Opening and closing the drawer is managed by the software. Whereas *hyborg Dx RED2* moves the drawer in and out automatically, *hyborg Dx RED3* is unlocking / locking the drawer and the user has to move the drawer in and out into its closed and open position by pushing or pulling the drawer.

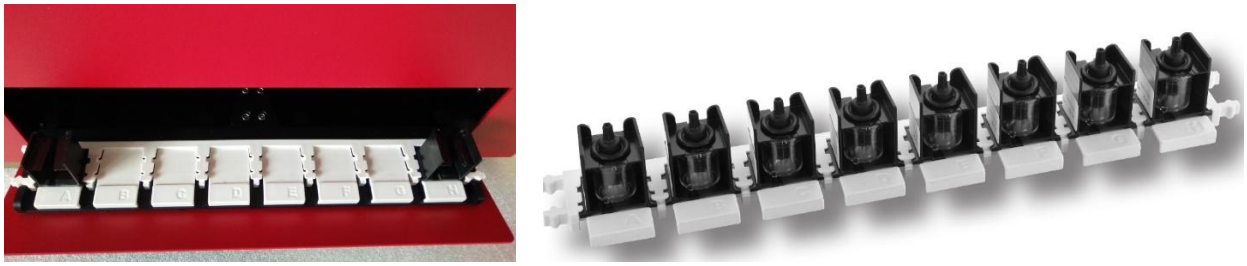
As the samples pipetted into the hybcells are **potentially infectious**, wear disposable gloves at any time when inserting and removing racks!

For *hyborg Dx RED2* the barcode on the *hybcell* must face the inside of the instrument. For *hyborg Dx RED3* the barcode on the hybcells must face the outside of the instrument. The design of the *Rack* should safeguard, that it is inserted correctly into the drawer (left and right end different). **Therefore, do not use excessive force to insert *Racks*!**

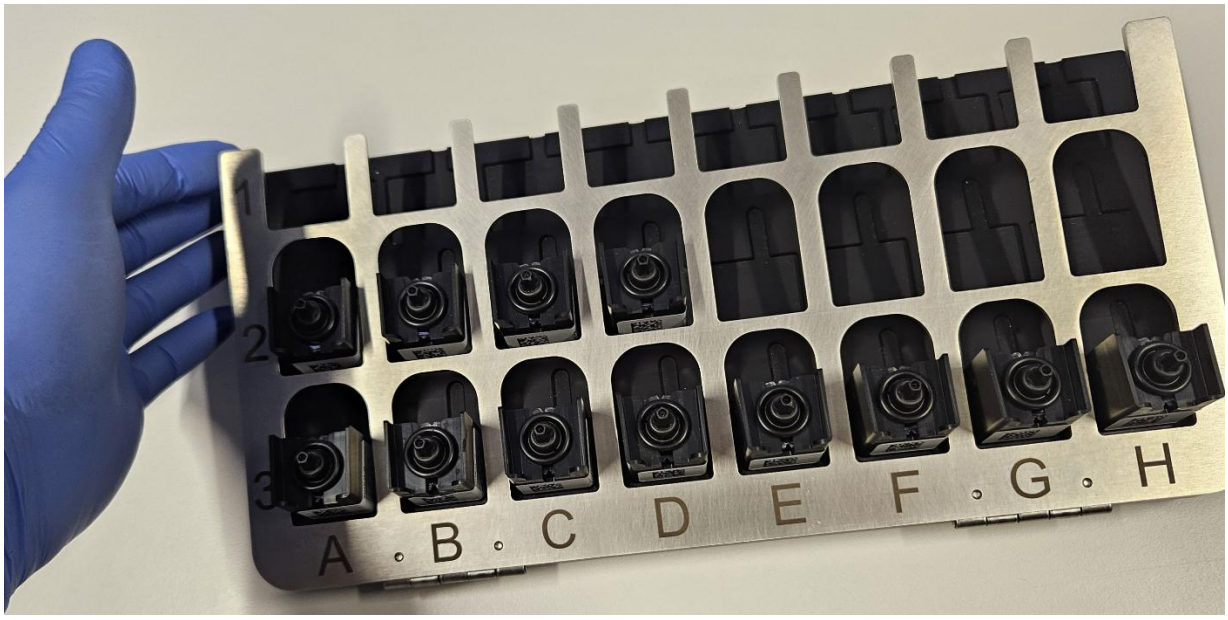
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***hyborg Dx RED2: Open drawer and Rack with hybcells,* barcodes face the inside of the instrument.**



hyborg Dx RED3: Metal rack loaded with hybcell. Cover must be closed and barcodes face outside of instrument.

Electricity is supplied using the power cable included within the delivery of an instrument.

Disconnect *hyborg Dx RED* from the power grid, if removing the cover (for repairs, service..)! Unplug the power cable to disconnect.

Data ports

The instrument can be connected to the intra-/internet using either a standard ethernet cable or via WLAN using a wireless adapter (USB).

The instrument provides following data ports:

- USB 2.0 (for validated accessory only)
- Ethernet (RJ-45) (for maintenance and service activities only)

The USB interfaces are used to connect different accessories to the instrument. Make sure to use only accessories, which are either supplied with the instrument or validated for the use with *hyborg Dx RED* (e.g. barcode reader). The use of non-validated accessories may worsen the performance of the instrument.

The instrument does not need to be connected to a network / the internet to achieve its intended use. However, a permanent internet connection facilitates the periodic update of *hybcell* protocols and enables remote access.

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6. Packaging and Transport

Before you start, ensure that:

- all required tools are available and maintained,
- all required materials are available in sufficient quantities, and
- that you have read and understood the instructions completely.

If *hyborg Dx RED* was operated in a (clinical) laboratory before it is packed and transported, a decontamination procedure has to be undertaken first. (see Maintenance, Cleaning and Decontamination).

Required material

- (Wooden) transport box
- 7 x 40cm angle profiles
- 2 x lashing strap
- Bag(s) for accessories, cables..
- 2 x shock indicator
- 2 x tilt indicator
- transport instructions (form)
- Optional: stretch film

Packaging

The following images show the packaging for the *hyborg Dx RED2* device.

The packaging for the *hyborg Dx RED3* device is the same as the example shown here.

1. Disconnect accessories and cables and put them in a bag: e.g. keyboard, mouse, WLAN stick (USB), barcode scanner, power cable. Empty all bottles (e.g. System Liquid, PE-Buffer,..) and put the bottles back in their positions. Empty the waste.
2. Thread the lashing straps through the provided holes of the bottom of the packaging crate. If there are no wholes in the box, the straps are routed around the outside.

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3. Place the *hyborg Dx RED* in the middle of the bottom of the packaging crate and position the 40cm angle profiles under each side of the instrument (4x).



4. Arrange the side panels around the instrument. Pay attention to the orientation of the handles so that they can fold down. The lashing straps are on the outside of the side panels.



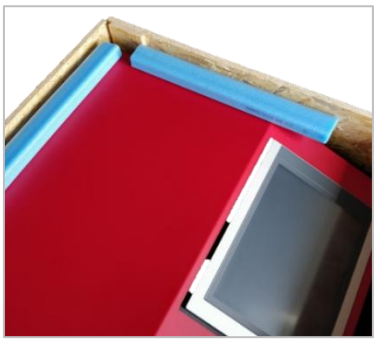


5. Place three 40cm angle profiles on the top edges (on both sides and at the back).

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6. Put the bag with the accessories onto the slant holding the instrument's screen. Before doing that, put some soft packaging material on the slant to protect the surface of the instrument.



7. Thread the lashing straps into the provided holes of the top cover and put the top cover onto the packaging crate. If there are no such holes provided, the straps are routed around the outside.



8. Attach the transport instructions on the top cover of the packaging crate and tighten the lashing straps (using the attached ratchet spanners). If available, you can attach two shock indicators (No. 1, 'SHOCKWATCH') and tilt indicators (No. 2, TILTWATCH') each. Place the shock indicators on diagonally opposite corners. Place the tilt indicators on a long and a short side each.

No. 1

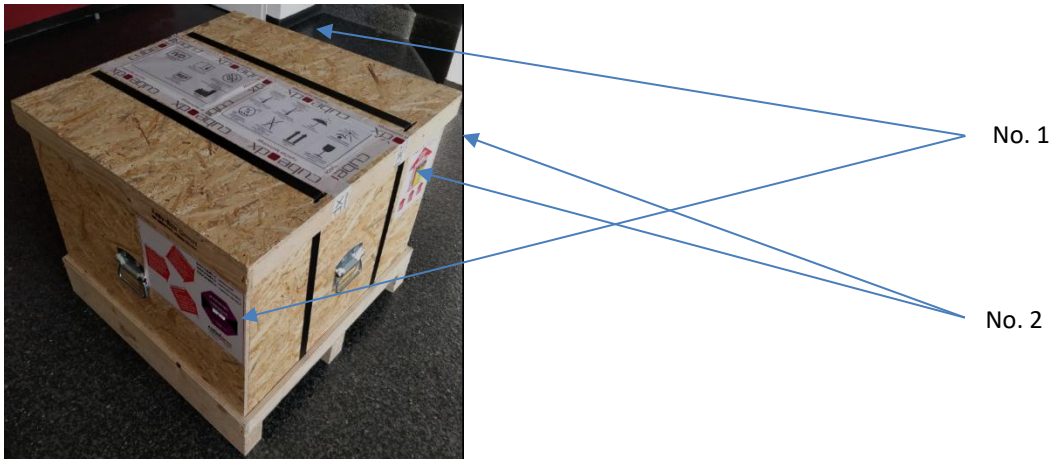


No. 2



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Optional: Wrap the transport box with stretch film in multiple layers.

The checklist below summarizes the most important steps to prepare *hyborg Dx RED* for transportation.

Item	Check
hyborg Dx RED placed in the middle?	☐
7 x 40cm angle profiles placed?	☐
Accessories added?	☐
Transport box firmly lashed?	☐
Shock indicator attached?	☐
Tilt indicator attached?	☐

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7. Product Components

hyborg Dx RED2:



- *hyborg Dx RED2* (GTIN / UDI-DI 09120127730015)
  - 1 x instrument *hyborg Dx RED2*
  - 1 x *hyborg Scanner*
  - 1 x power cable
  - 4 x glass bottles (1 *Waste Bottle*, 3 empty bottles for liquids)
  - 1 x *Rack* (see below)

hyborg Dx RED3:



- *hyborg Dx RED3* (GTIN / UDI-DI 09120127730787)
  - 1 x instrument *hyborg Dx RED3*
  - 1 x *hyborg Scanner*
  - 1 x power cable
  - 4 x glass bottles (1 *Waste Bottle*, 3 empty bottles for liquids)

Buffers:



- *System Liquid* (GTIN / UDI-DI 09120127730022)
  - 1 x 1 L *System Liquid* (in a bottle)
- *PE-Buffer* (GTIN / UDI-DI 09120127730138)
  - 1 x 1 L *PE-Buffer* (in a bottle)
- *CS-Buffer* (GTIN / UDI-DI 09120127730503)
  - 1 x 1 L CS-Buffer (in a bottle)

Service and replacement parts:



- *hyborg Scanner* (GTIN 09120127730343)
  - 1 x USB-barcode scanner validated for use with *hyborg Dx RED*
- *Waste Bottle* (GTIN 09120127730046)
  - 1 L glass bottle to collect liquid waste
- *Rack* (GTIN 09120127730220)
  - 5 x *Rack* to hold up to 8 hybcells each



- *hyborg Service-Kit* (GTIN 09120127730381)
  - 2 x air filter fleece
  - 1 x air filter pressure line
  - 3 x rubber bottle seal
  - 1 x non-return valve



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- 1 x set of spare screws
- Different replacement tubings
- 1 x single piece of *hybcell Control xC*
- 1 x service label

- *hybcell Control xC* (GTIN 09120127730121)
  - 24 x *hybcell Control xC* (24 *hybcells* separately sealed in plastic foil)
  - 24 x *Lid* (1 bag with 24 *Lids*)



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8. Storage, Transportation, Shelf Life and Disposal

All products have to be kept dry and should be protected from excessive sunlight. The maximum shelf life of products is only guaranteed if the products are kept at the required temperatures during transportation and storage. The expiry date of the products is printed on the product labels.

Products	Shelf life	In-use	Temperatures [°C]			Disposal
	[months]	[weeks]	Storage	Transport	In-use	
hyborg Dx RED2	--	--	0 to 40°C	-10 to 40°C	0 to 40°C	--
hyborg Dx RED3	--	--	0 to 40°C	-10 to 40°C	0 to 40°C	--
System Liquid	36	8	8 to 25°C	4 to 40°C	8 to 25°C	Ordinary sewage
PE-Buffer	36	8	8 to 25°C	4 to 40°C	8 to 25°C	Ordinary sewage
CS-Buffer	36	8	8 to 25°C	4 to 40°C	8 to 25°C	Ordinary sewage
hyborg Scanner	--	--	-40 to 70°C	-40 to 70°C	0 to 50°C	--
Waste Bottle	36	--	8 to 25°C	4 to 40°C	8 to 25°C	Potentially infectious
Rack	120	--	8 to 25°C	4 to 40°C	8 to 25°C	--
hyborg Service-Kit	120	--	8 to 25°C	4 to 40°C	8 to 25°C	--
hybcell Control xC	24	--	8 to 25°C	4 to 40°C	8 to 25°C	--

Disposal of buffers and liquid waste

All remains of buffers (System Liquid, PE-Buffer, CS-Buffer) and the liquid waste can be disposed without any special procedures into the ordinary sewage. Flush the drain with water afterwards (for approximately 1 minute).

You can re-use any of the glass bottles (from System Liquid, PE-Buffer, CS-Buffer or Waste Bottle) to connect to the liquid waste position (marked red). Before re-using any bottle, empty it, rinse it with water and wash it in the laboratory dishwasher. Before connecting the Waste Bottle again, clean the inside and outside of the connector of the instrument with a towel soaked in 80% ethanol.

Currently, Cube Dx does not provide any tests that use primary human samples as a direct input for hybcells. However, if the instrument is used for research and primary human samples are run directly in the hybcell cartridges on the instrument (e.g. saliva, urine, blood, etc.), the waste is potentially infectious and has to be treated accordingly.

Incoming inspection upon receipt of an instrument

When receiving the *hyborg Dx RED*, the packaging should be checked for visible damage. Any obvious damage has to be reported to the carrier immediately.

The packaging should be equipped with two shock and two tilt indicators each. These are located on the outside of the packaging, and indicate whether the product experienced any mechanical hits or was tilted over:

- Shockwatch L 65: If the force of any shock applied to the packaging exceeds the defined limit, the indicator tears and the released liquid irreversibly changes colors of the indicator (to red).
- Tiltwatch: The indicator field turns red when the packaging is inclined more than 7°.

The indicators are not colored red if the conditions during the whole transportation stayed within specifications. If the indicator is colored red, accept the delivery but make sure the carrier confirms the activation of the indicators, best in writing.

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Until the instrument is installed, store the *hyborg Dx RED* in a dry location free at ambient temperature (between 0 and 40°C).

If you need to transport the *hyborg Dx RED* yourself, please note that it weighs approximately 80 kg (with its packaging). Use the handles on the packaging or other appropriate transportation aids (e.g., a lift truck) to move the instrument with its packaging. When moving or lifting the hyborg without packaging, lift the instrument by grabbing the base plate on the bottom of the instrument.

If you want to move the *hyborg Dx RED* from one location to another, make sure that the instrument is turned off and the drawer is closed.

If you prepare for disposal, sending or repair, decontaminate the instrument first (see *Maintenance, Cleaning and Decontamination).*

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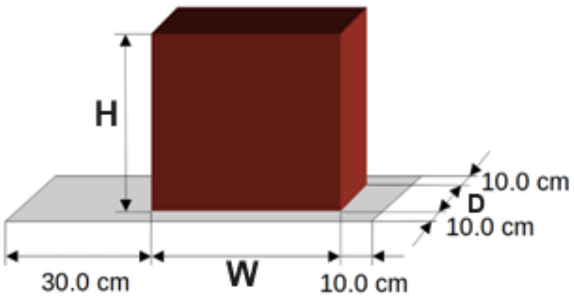
IVD CE

9. Installation

Installation must only be carried out by authorised personnel!

Requirements

The *hyborg Dx RED* has to stand on an even, dry, and stable ground near a wall socket. It requires approximately 100 cm of bench (depth approximately 70cm) – see footprint on the right.



There should be at least 10 cm of free space towards the top. Make sure to keep 10 cm distance at the back of the instrument for air circulation. At least 30cm of space should remain to the left of the instrument to allow the exchange of liquid bottles.

Electrical power supply (100 to 240 VAC, 50 to 60 Hz, 16 A) – electrically fused - is required to operate *hyborg Dx RED*.

The instrument stands on 4 pedestals. Each of these pedestals is carrying a weight of up to 15 kg. Make sure to keep the distance between the ground plate of the instrument and the work bench clear for air circulation.

Installation

- Unpack the instrument by removing the lashing straps and lifting the top of the wooden box. Then remove the side parts of the wooden box. Check for visible damages.
- Place the *hyborg Dx RED* on its workspace.
- Connect the power cable.
- Connect the barcode reader (USB).
- Connect the necessary buffers:
    - System Liquid, yellow (must be full),
    - PE-Buffer, blue (for tests based on RNA or DNA),
    - CS-Buffer, green (for tests based on RNA or DNA),
    - Waste Bottle, red (must be empty).
- Optional: connect the instrument to the Ethernet (Intra- / Internet), either via cable or using an USB-WLAN adapter (and connect the instrument via the Windows settings to the wireless local network.
- Qualify the performance of the instrument (either by setting up your own evaluation procedure or by following the suggestions of Cube Dx).

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10. Connectivity

If the *hyborg Dx RED* is connected to the internet, following use cases are possible. More information about connectivity (how to establish, how to use) can be found in Cube Dx' guidline *hyborg Dx RED2_3_guidline connectivitydatamanagement_E_2026_05_20.pdf* (download from Cube Dx' website).

Remote support

Cube Dx is using RustDesk to offer remote support. Rustdesk enables Cube Dx and its sales and service partners to provide fast and targeted support. In case of any support request by the user, remote access can help in most of the cases quick and with comparable little effort. In case of hardware problems remote access might help to identify the root cause of the problem and therefore keep repairs efficient and fast. In case of software issues, most of these issues can be solved remotely.
RustDesk ensures data privacy and security by routing all traffic through a server hosted by Cube Dx with end-to-end encryption (Ed25519 and ChaCha20-Poly1305). Third party access is ruled out. For network configuration, it utilizes TCP ports 21115 to 21119 and UDP port 21116 for core routing and relay services.

(Automated) protocol update

If connected, *hyborg Dx RED* will download new *hybcell* protocols autonomously from our website under https://www.cubedx.com/protocols. The software uses TCP-Port **443** and checks every 24 hours or during instrument startup for new protocols. The update can as well be triggered from the user via the software (tab *Protocol*). Without the automated protocol download, the user must download and import *hybcell* test protocols using an USB drive (for each new hybcell lot).

HL7 and LIMS connection

The hyborg software can upload hybcell test results to an internal hospital or laboratory information system (LIMS) by configuring the HL7 interface (server name or IP address and port required) on the *Options* tab of the hyborg software. If configured and active, the hyborg software sends an *HL7 ORU R30 Unsolicited Point-Of-Care Observation Message* to the specified destination.

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11. Maintenance, Cleaning and Decontamination

Maintenance and Repair

Cube Dx recommends an annual inspection and preventive maintenance done by authorized service personnel of either Cube Dx or distributors.

Operators in Austria and Germany are obliged to execute recurring safety checks according to the Medical Instrument Operator Regulation (Medizinproduktebetreibergesetz). These checks have to be executed by the operators themselves (visual check, measurement of earthing and insulation resistance as well as leakage currents).

In order to ensure full functionality of the instrument, *hybcell Control xC* should be processed regularly. See section *Using hycell Control (xC) for periodic instrument check-up* under section *Tools* for further information

Only authorizes service personnel may repair the instrument. If the instrument is repaired or modified by non-authorized personnel, any warranties are waived immediately.

Cleaning and Decontamination

The instrument could come into contact with infectious or bio-hazardous materials. Therefore, wearing personal protective gear is recommended during operation and cleaning, for example gloves, googles, face mask.

The tubing inside the instrument is cleaned with *System Liquid* after each run.

Cleaning the instrument's surface regularly (e.g. once per week), before service or maintenance or before preparing the instrument for transport is recommended. When cleaning surfaces (except the touchscreen), cleaning products should be used that contain only **alcohol or aldehyde** as **active cleaning ingredient**. Avoid using other detergents that could damage or harm parts of the instrument. Use a cloth dampened with water, special screen cleaning solution or ethanol when cleaning the touchscreen.

Before cleaning, ensure the instrument is switched off to prevent malfunctions (if for example controls are accidentally operated). Apply the liquid to the cloth first and refrain from spraying it directly onto the instrument. Avoid using harsh solvents, chemicals, abrasives, compressed air, or hot steam on the instrument.

Decontamination

In case of potential contamination due to spills of infectious material on the instrument, before maintenance or service, before repairs, before transportation, or after prolonged periods of inactivity (e.g., 3-4 weeks) the instrument has to be contaminated.

1. Remove all bottles and dispose their content.
2. Clean the outside (surface) of the instrument (see above) with a cloth soaked in an ethanol solution.
3. Open the drawer and wipe the surfaces where the hybcells are placed with the same cloth.
4. If any other parts from the inside seem to be contaminated, follow the same procedure for these parts (if you can reach those parts through the opening of the drawer).

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12. Changing Windows settings

Some settings, for example date and time, the standard printer or a WLAN connection are configured in the underlying operating system of *hyborg Dx RED*.

The instrument's underlying operating system is Windows.

When working with the instrument software, access to Windows settings is not possible as the instrument's software covers the whole screen.

To access Windows, connect a USB keyboard to any of the available USB ports.

By pressing the Windows button of the keyboard, the task bar and file explorer of Windows are shown.



Once access to the operating system is established, the necessary settings can be done, files can be downloaded or uploaded and updates can be made.

Common settings:

- Date and Time: Windows → Settings → Time and Language → Date and Time
- Select / configure printer: Windows → Settings → Bluetooth and Devices → Printers and Scanners
- Connect WLAN: Task bar → Globe symbol → WLAN symbol → Select WLAN

For more detailed help refer to Windows help.

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13. Basic Instrument Operations

Start-up, Status Information

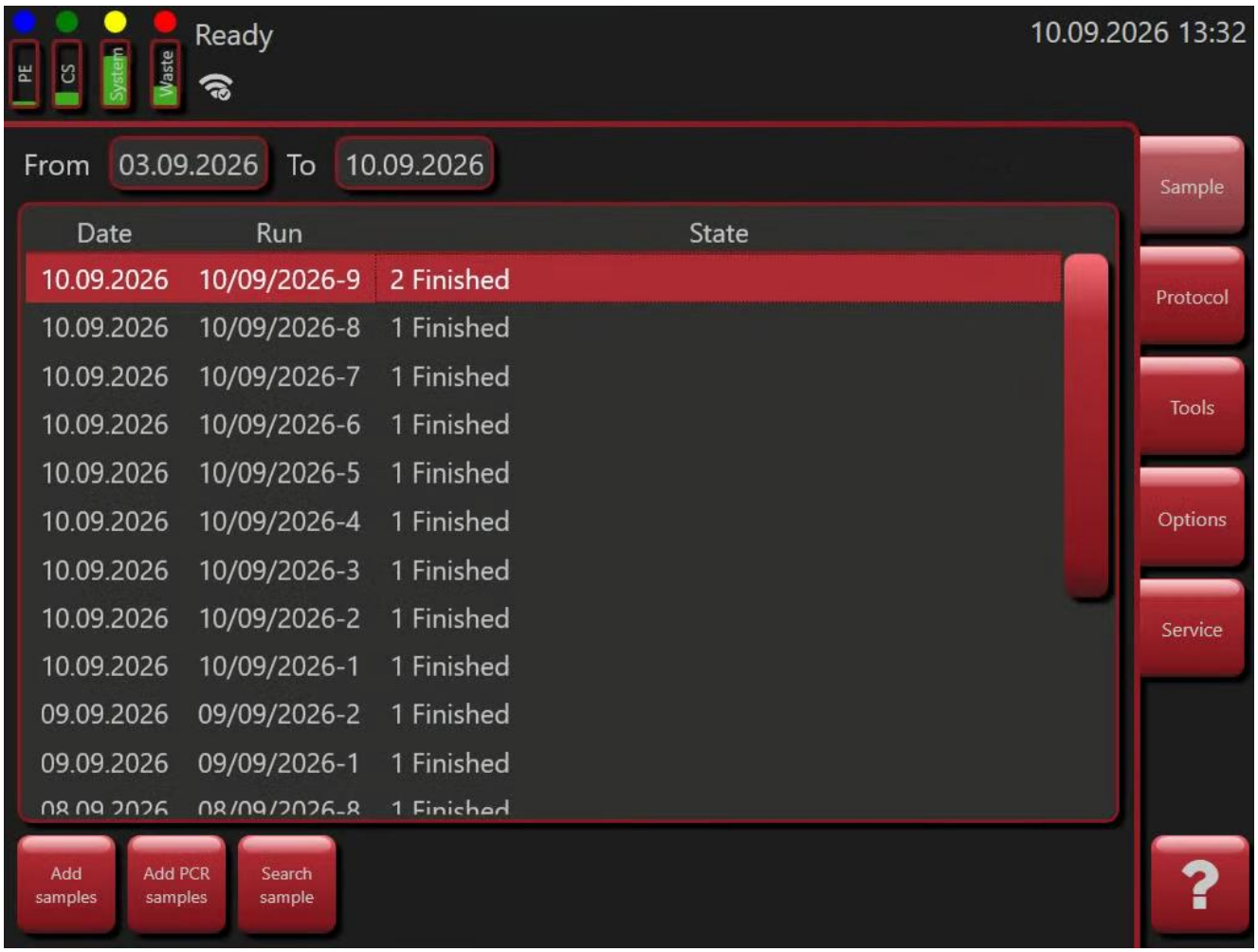
To start-up the instrument, switch it on, using the main switch on the right-hand side of the instrument. Wait until boot and initialization routines are completed.



Main switch on right side of instrument

hyborg Dx RED starts with its initialization routine (homing all axis, checking for “lost” hybcells and flushing the tubing). This routine takes approximately 3 minutes. After the initialization process the hyborg is ready for operation, which is indicated in the header of the screen: “Ready”.

After start-up of the software and initialization of the instrument, the *Sample* screen is shown. This page is the starting point for creating runs and viewing results.



***Sample* screen.**

Status Information

The header of all top-level screens (*Sample, Protocol, Tools, Options* and *Service*) shows status information:

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- Filling level of all four liquids (Waste, System Liquid, Liquid 1, Liquid 2) as bar graphs (liquid = a coloured bar, empty = black bar). The display of Liquid 1 and Liquid 2 can be disabled under the *Options* screen. The names of the liquids are extracted from the barcodes of the liquids which are scanned during the changing of liquids (see *Tools*)
- Instrument status:
    - *Connecting*: The instrument software is connecting to the hardware of the instrument.
    - *Checking*: The software is running an initialisation routine (Homing, checking liquids..)
    - *Device init failed*: The initialisation routine could not be finished successfully.
    - *Ready*: The instrument is ready for operation (initialisation successful, buffers connected..)
    - *Analyzing*: Currently a hybcell test is in progress.
    - *Cleaning*: The procedure for cleaning the tubing of the instrument is in progress.
    - *Controlling*: Currently a *hybcell Control xC* or a fluidics check is in progress.
    - *Drawer open*: The drawer has been opened and is now open.
    - *Aborting*: Analysis aborted by user.
    - *Escaping*: Analysis aborted by user after current sample.
    - *Skipping*: Analysis of current sample is aborted by user and resumed with next sample.
    - *Offline*: While using hyborg Software in Demo mode.
    - *Error*: An error occurred.
    - *Unknown*: The software cannot assign a clear state of the instrument.
- Date and Time.
- Established internet connection:
    -  indicates that the instrument is connected to the internet (either via cable or WLAN).
    -  indicates that no connection to the internet is established. Be aware, that the sensing of a connection can be delayed for up to 2 minutes.

Navigation to top-level screens

On the right-hand side of all top-level screens, navigation buttons to all other top-level screens are displayed. The top-level screens are:

- *Sample* (see above): Create and manage *hyborg* runs and display results for samples
- *Protocol*: Check, import and delete protocols.
- *Tools*: Different functions like managing liquids, QA, operation of drawer, re-analysing scans, shut-down, etc.
- *Options*: Set and change different instrument, software and report options.
- *Service*: Service purposes only (restricted access (password)), not considered in this manual.

Content-specific operators

On the bottom of the top-level screens, specific operators (buttons) are displayed to trigger different context-related actions.

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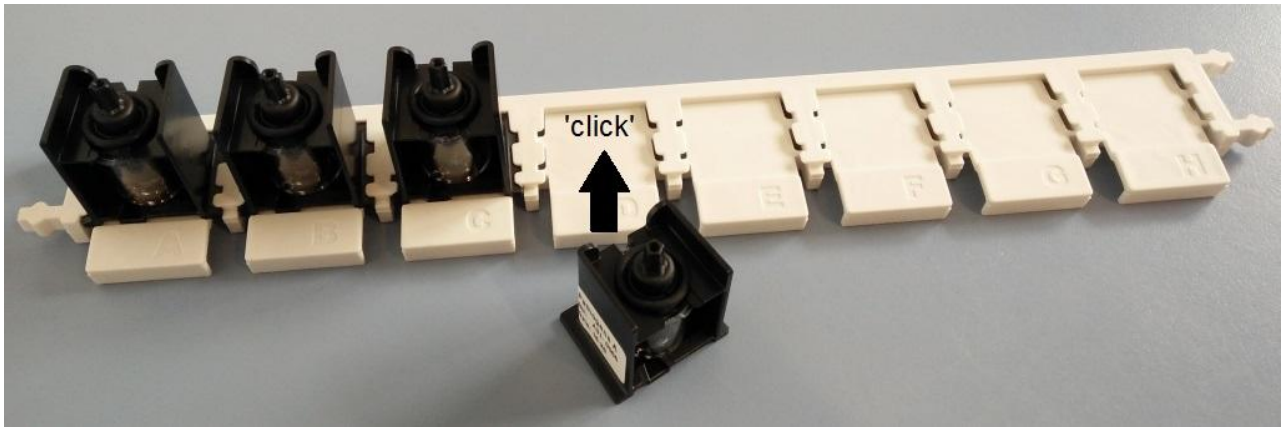
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Create and Start a Run

hyborg Dx RED2

Each *hybcell* is fixated to a *Rack* (offering 8 positions each), which holds the *hybcell* firmly. The barcode of the *hybcell* must face towards the inside of the instrument. During fixation of the *hybcell* to the *Rack* - when the *hybcell* reaches its final position – a 'click'-sound is audible. The drawer is opened and up to three *Racks* are inserted in the *Rack* positions. The *Racks* only allow the loading in a fixed position, so do not use too much force for the loading.



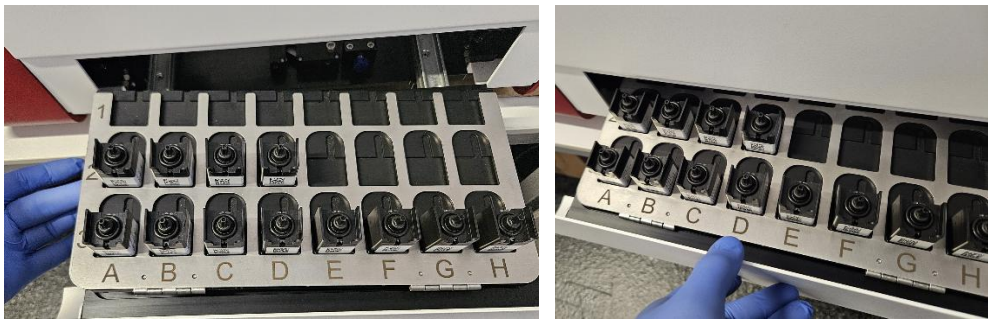
Each hybcell has to be inserted into a position of the *Rack*.

hyborg Dx RED3

The metal rack is taken out of the instrument and the cover opened. *hybcells* are carefully put on their positions and the cover of the rack is closed. The barcode of the *hybcell* must face towards the outside of the instrument. The drawer is opened and the metal rack is inserted in its position again. The metal rack only allows the loading in a fixed position, so do not use too much force during loading.



Load metal rack: open cover, place *hybcells* in position, close cover.



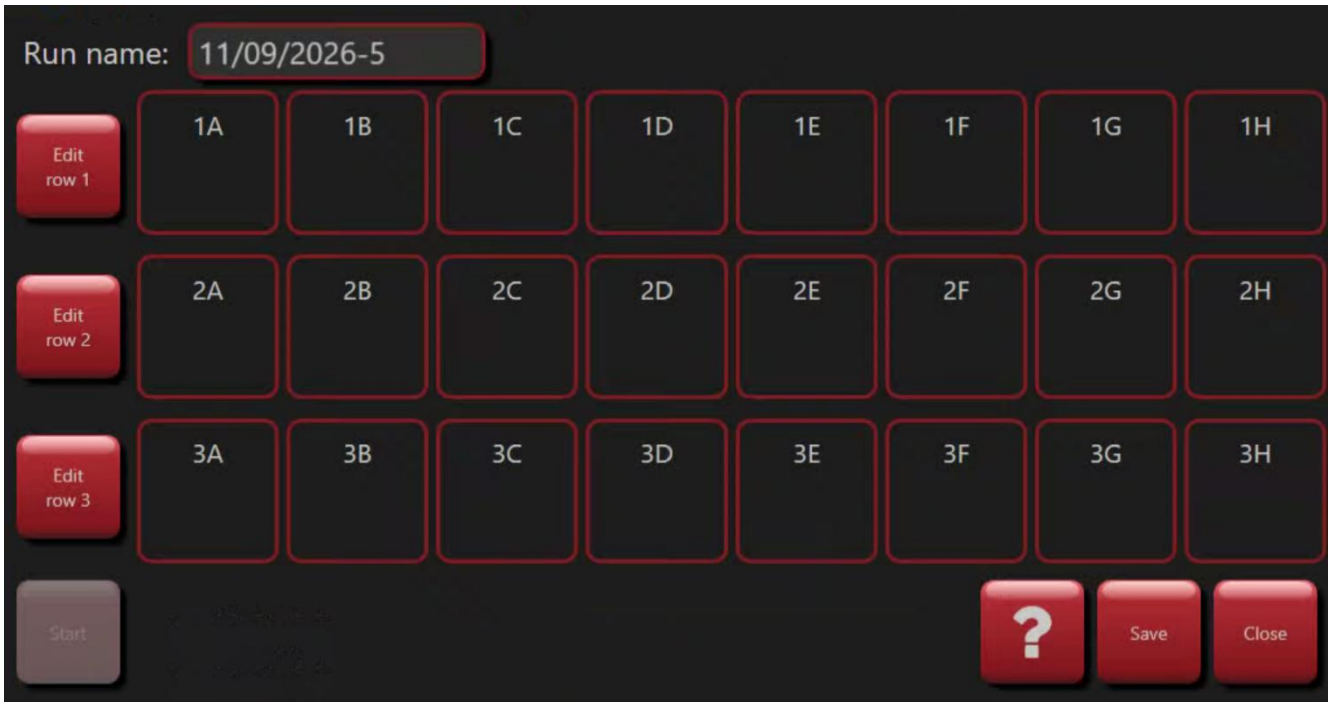
Load metal rack into instrument: open drawer, place metal rack in instrument (letters and numbers still to read), close drawer.

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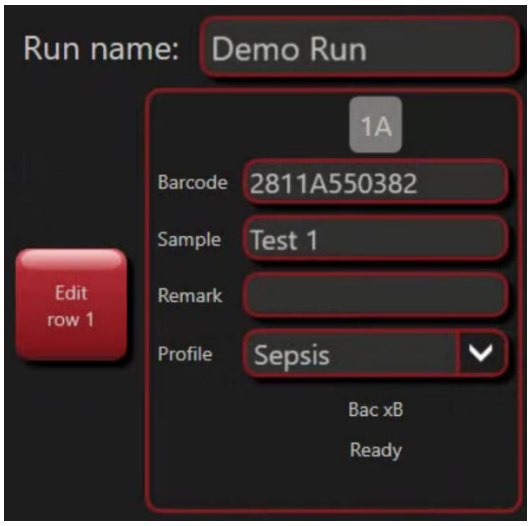
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To define a new run or new samples within a run, make sure the *Sample screen* is opened and press the *Add samples button*.



***Add Samples Screen* after pressing the *Add samples button* from the *Samples Screen* (creating or editing runs/samples).**



Adding samples to a run on a specific Rack position after clicking the position (creating or editing runs/samples).

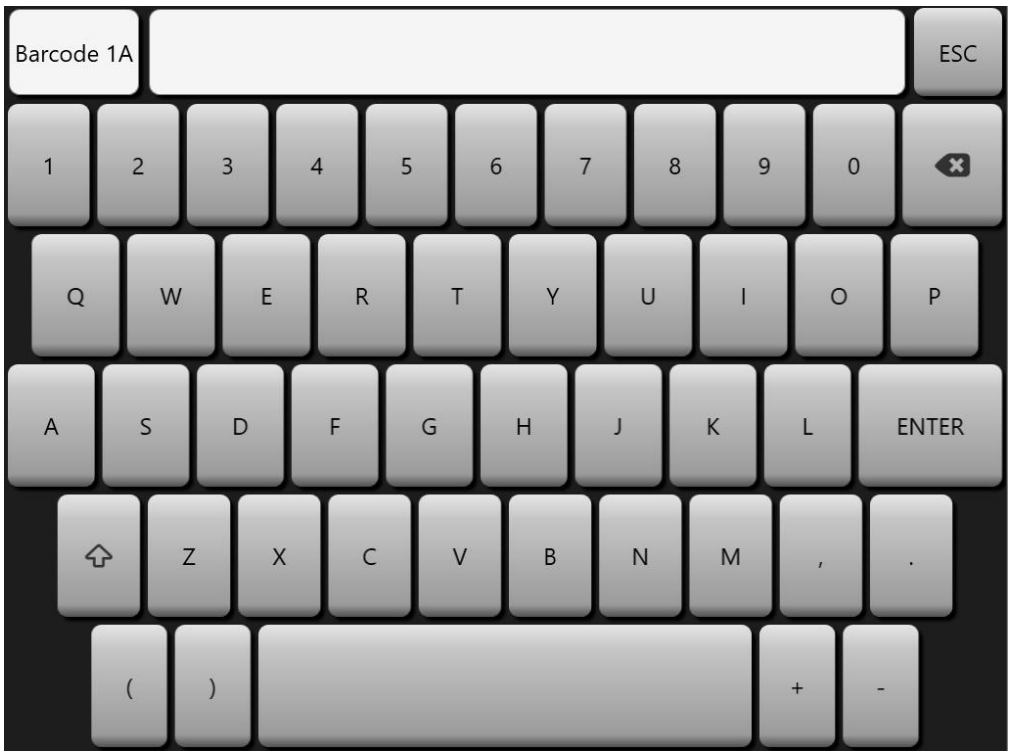
Barcode (mandatory)

Each *hybcell* test is assigned to a unique identifier, printed as a barcode on the backside of the *hybcell*. This barcode contains a reference to the protocol which will be processed (which must be available to the software), the expiry date (calendar week) and a serial number. The barcode can be read with the handheld barcode scanner (USB) shipped with the instrument. However, typing the code with the virtual keyboard (or an attached USB-keyboard) is possible as well.

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Virtual keyboard (on the touchscreen).

Sample (mandatory)

The sample ID is chosen by the user (or is defined by the user's organization). It identifies the sample and is associated with the result. This ID must be unique for the particular run. The ID can be as well read from a barcode on the sample container.

Remark (optional)

A remark can be added by the user. This remark will be displayed on the later report.

Profile (optional)

Profiles might be defined for a test. A profile defines a subset of possible results, that will be presented on the report. In other words, some possible results are not displayed, as these might be considered as not relevant for the selected profile. This can make sense, if a test with a very broad panel (e.g. different bacteria) delivers possible results, that might not be of clinical relevance for certain types of samples.

Run

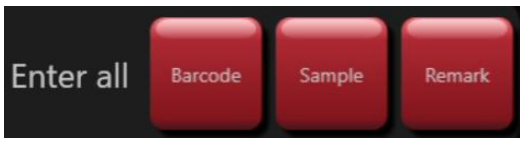
The name of the run can be modified. If not modified, the run is named with the current date and a consecutive number.

The order of data input is defined from sample 1 (barcode, sample, remark, profile) to sample 2 (barcode, sample, remark, profile) to sample 3 and so forth. For reasons of streamlining the workflow, the user can choose to enter all barcodes (hybcell IDs) for a row first, by pressing the *Edit row 1 (or 2 / 3)* and then the *Barcode* button. Same can be done for sample and remark by pressing the *Sample* button, respectively the *Remark* button.

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Up to 24 hybcells might be assigned for a single run (barcode and sample ID). The run is started by clicking the *Start button* which is presented at the bottom left corner of the screen .



The drawer opens (*hyborg Dx RED2*) or is released (*hyborg Dx RED3*) and the *Rack(s)* with the prepared *hybcells* are placed on their designated positions in the drawer. To avoid mix-ups of samples when using *hyborg Dx RED2*, ensure that the positions of *hybcells* in the *Rack* and the position of the *Racks* in the drawer matches the assigned positions.

The *Rack* is inserted into the instrument, with the *hybcell* barcodes either facing towards the inside of the instrument (*hyborg Dx RED2*) or outside the instrument (*hyborg Dx RED3*).



***hyborg Dx RED2*: The barcodes of *hybcells* must face the inside of the instrument.**



***hyborg Dx RED3*: The barcodes of *hybcells* must face the outside of the instrument.**

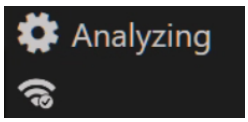
After loading the *Rack(s)* into the drawer, the run is started by confirming and clicking the *OK button*. The instrument will close the drawer and start the sequential processing of the *hybcells*.

The instrument status displayed in the header of the screen will change to *Analyzing* (see above).

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If the run should not be started immediately, but later, the run can be saved by clicking the *Save button*. If the created run should be discarded, the *Close button* has to be clicked.



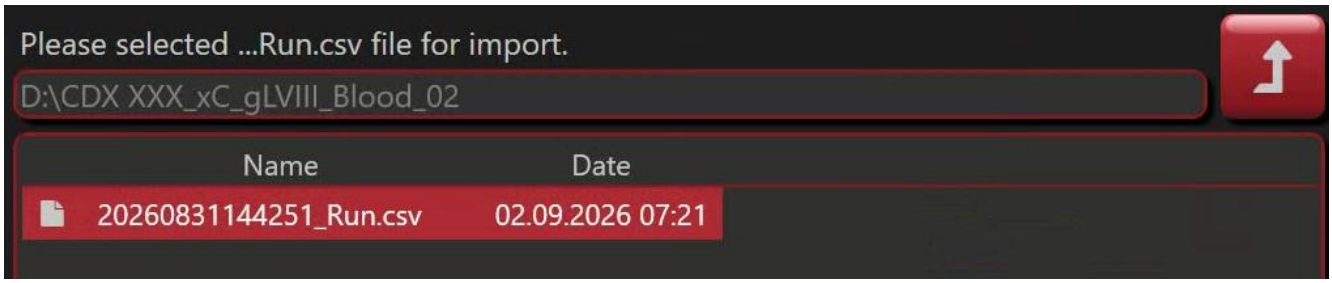
Importing PCR data and Create a Run

DNA-based *hybcell* tests utilize in most cases PCR amplicons as samples. If working with *geneLEAD VIII* (gLVIII) from Precision Science Systems Ltd. (PSS, Japan) for the PCR part of the test, exported PCR data from gLVIII can be used to create a new run for *hyborg Dx RED*.

How to export PCR data from gLVIII is explained in the instructions for use of the instrument. The result of the export is a CSV file (.csv) with the suffix "_Run" in the file name, for example "20260831144251_Run.csv" (among other files). The export files have to be exported to an USB drive as the same drive is used to import the data to *hyborg Dx RED*.

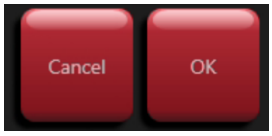
After the USB drive is connected to the instrument, the procedure is started by clicking the *Add PCR samples button* from the Sample Screen.

A Windows like file explorer is displayed. Navigate to the file which is basis of the intended import (click a folder to enter or use the up-button to exit the current folder..) and select the file by clicking on it (will be highlighted).



Select PCR run for import .

To confirm the import click the *OK button*.



The import file is read and the PCR data for the single samples is presented (sample ID, date of execution of the PCR, type of test/PCR including PCR lot (if such data is available) and result (e.g. Cts, Tms..)).

The status of two checkboxes for each PCR sample decides how the PCR data for the respective sample is treated on the instrument.

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PCR data of an imported PCR run and selection for a run (or only to be stored).

The order presented by the import data is the one which has been configured for the PCR run (Track 1 to Track 8 from top down).

After import the *Save checkbox* is active for all imported PCR samples. So, all imported results will be saved in the instrument's database by default. If PCR data for single samples should not be saved, deactivate the respective *Save checkbox*.

By activating the *Run checkbox* the sample is selected for the *hyborg* run. After import of the run, some PCR samples are already selected for follow-up *hybcell* testing. This selection is based on rules set out in PCR-protocol specific lot data, which is available to the instrument (see *Managing Protocols*).

For some samples a warning in regard of missing lot information can be displayed (in yellow, below the information on the PCR test used). Either there is no data on the necessary lot provided on the instrument (Warning: *Lot xxxx not recognized*) or the user did not enter lot information for the PCR run on the PCR instrument (Warning: *No lot*).

If a user wants to add or correct information on the PCR sample (e.g. name, lot information) and result or if a user is unsure whether to test a sample with *hybcell* or not, detailed PCR data can be shown after clicking the *Details button*.

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PCR details for a sample (displayed after clicking the *Details button*).

Depend on the PCR test the amplification curve or the amplification and melting curve for the sample are displayed. Calculated values for Ct (Cycle threshold) and if applicable one or more Tms (melting temperatures are displayed and represented on the respective curves.

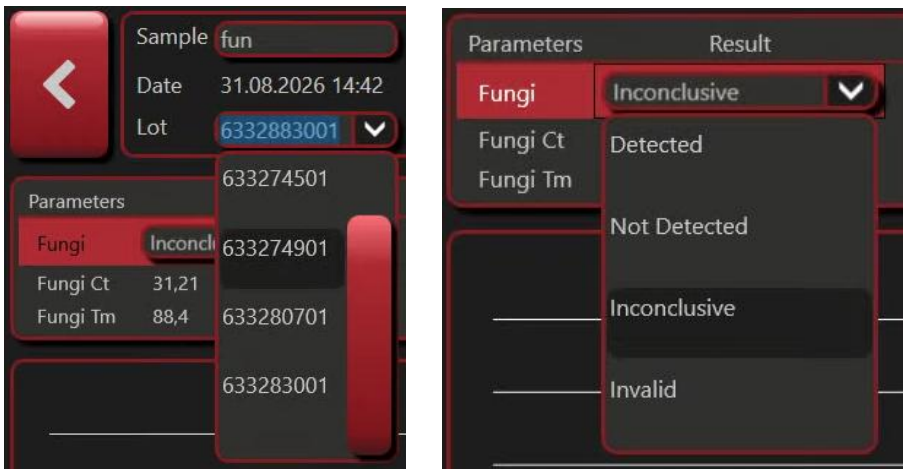
Based on these values, most protocols derive a suggestion on how the qualitative PCR result should be displayed. For these qualitative results basically four possibilities are provided:

- *Detected*: The PCR result is considered positive for the target → follow-up hybcell
- *Not Detected*: The PCR result is considered negative for the target → no hybcell
- *Inconclusive*: The PCR data does not allow definitive PCR results → follow-up hybcell
- *Invalid*: Controls failed, no Cts, Tms could be calculated → no hybcell

The suggested qualitative result, the sample name and the lot information can be changed by the user either by entering a new sample name or by select a new result or lot information from a dropdown menu.

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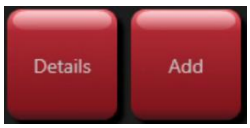
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Changing suggested data for a PCR sample by using dropdown menus.

Once the details for the PCR sample have been reviewed and the necessary changes have been made, the *Details view* can be closed by clicking the *Close button*.

As the intended *hybcell* run might include samples from several PCR runs, the import can be repeated for another run by clicking the *Add button*.



The same selection of samples for this PCR run can be made as for the one before (and adding data from PCR runs can be repeated).

Once all samples are selected, the process of importing is concluded with clicking the *OK button*.



For the suggested *hybcell* run, a new order is presented and any gaps (=samples of PCR runs which are not tested with *hybcell*) are filled up.

Please, be careful with the order of samples and *hybcells* when filling the amplicons into the *hybcells*!

The run will be created with the sample names imported from the PCR data.



Run with the predefined samples from the PCR run(s).

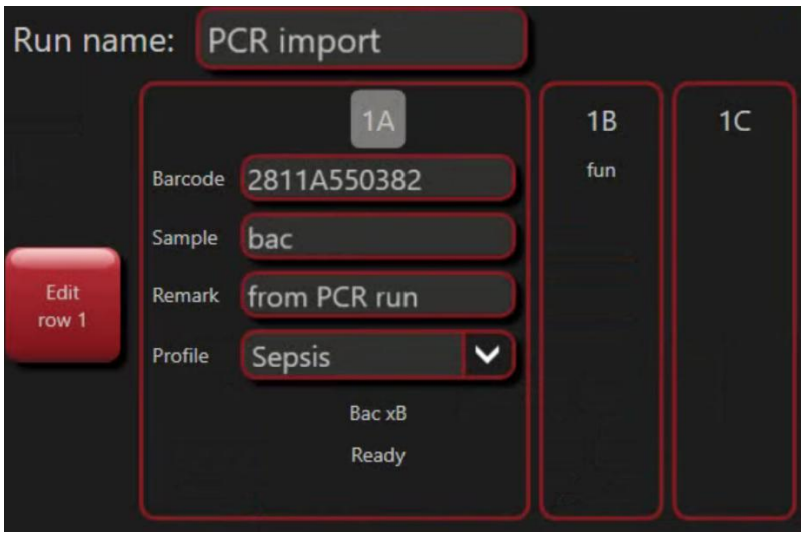
To complete the *hybcell* run, the *hybcell's* barcode must be associated with the sample (mandatory). A remark and the selection of a profile can be added optionally.

The name of the run can be modified. If not modified, the run is named with the current date and a consecutive number.

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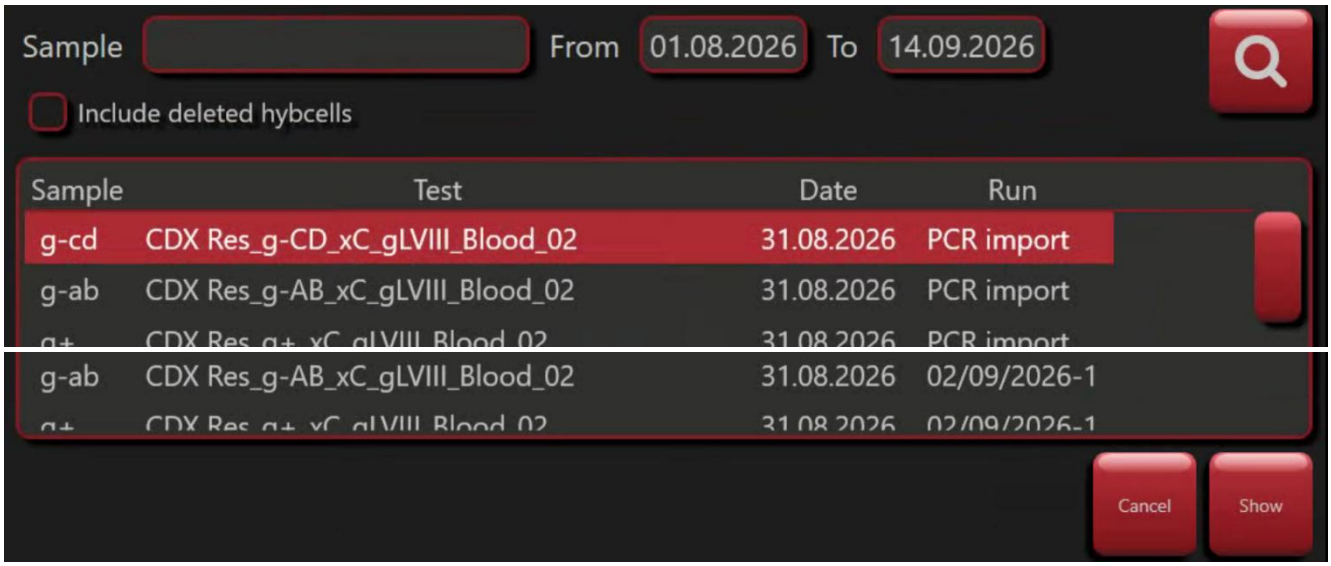


Open run with barcode of the *hybcell* added, profile selected and remark inserted.

Once all samples of the run are defined, the run is either started by clicking the *Start button*, saved for a later start by clicking the *Save button* or discarded by clicking the *Close button* (see above).

Search for Samples

By clicking the *Search sample button* options to search for samples (processed or ready) are displayed. The search can be made by typing (parts of) the sample name into the *field Sample*. The display of samples can be limited to those for a certain period. The start and end of the period can be tailored by changing the data of the *From* and *To fields*. If the *checkbox Include deleted hybcells* is active, deleted *hybcell* tests are shown in the results as well. In such cases the date for the PCR run is considered for the search (which might differ from the date the run was imported).



Results and options displayed in the *Search screen* (condensed).

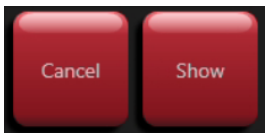
Once the samples for which the search criteria match are found and displayed on the screen, a sample can be chosen by clicking on the line representing the sample.

Clicking the *Show button* opens the result for the sample (either the *hybcell* or the PCR result, see below).

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Display (Check Plausibility), Print, Export, Delete or Upload Results

Once the samples of a run are processed, results can be displayed, checked for plausibility, printed, exported, deleted or uploaded to a LIMs system using HL7 messages.

First step is to select the run by clicking on it in the *Samples* screen (see above). The different *hybcell* tests will be displayed, each with a checkbox for selection (and cancelling the selection). Furthermore a color-coded square display the status of the test (and the status is displayed in the footer of the sample area as well).

- *Ready* (grey): The *hybcell* test is ready for processing (no result yet)
- *Processing* (light green): The *hybcell* test is currently processed (no result yet)
- *Successful* (dark green): The *hybcell* test was successfully processed (result available)
- *Control failed* (orange): The *hybcell* test was processed, but a control failed (no result)
- *Aborted* (red): The *hybcell* test was aborted by the user or due to an instrument error



Example of a sample that was successfully processed and one for which controls failed.

Samples can be selected or being removed from the selection by clicking the checkbox on the right-upper corner of the sample area. Clicking the *Invert selection button* inverts the current selection.

Different functions are applied to the current selection when clicking on the respective buttons.

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Print

To print reports for the selected tests, press the *Print button*. The print is directed to the standard printer defined in the settings of the operating system (Windows) of the instrument.

Sample #	AMPLICON SCAN BAC XC A	**Test**	hybcell Bacteria DNA xC (1)
Date	10.09.2026 10:23	**Profile**	Sepsis (08.09.2026)
Remark	2836A250020	**hybcell**	2830A250053
Liquids	2: CS-Buffer (503283901) / S: System Liquid (022284801)		

Controls		
Controls	PASSED	

Parameters	Result	Representation
Internal Control (IC)	Detected	
BACTERIA	Detected	
Staphylococcus aureus	Detected	100 — 99999

Negative Parameters

Acinetobacter baumannii, Aerococcus urinae, Aerococcus viridans, Aeromonas, Alcaligenes, Anaerococcus, Bacteroides fragilis, Bordetella pertussis/parapertussis, Borreliella, Burkholderia cepacia complex, Burkholderia pseudomallei, Capnocytophaga, Cardiobacterium hominis, Cardiobacterium valvarum, Citrobacter freundii, Citrobacter koseri, Clostridium perfringens, Corynebacterium diphtheriae, Corynebacterium jeikeium, Corynebacterium ulcerans, Cronobacter sakazakii, Cutibacterium avidum, Eikenella corrodens, Enterobacter asburiae/cancerogenus, Enterobacter cloacae, Enterobacter cloacae complex, Enterobacter hormaechei, Enterobacter kobei/ludwigii, Enterobacter roggenkampii, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Finegoldia magna, Francisella tularensis, Fusobacterium, Fusobacterium necrophorum, Fusobacterium nucleatum, Granulicatella adiacens, Haemophilus influenzae, Haemophilus parainfluenzae, Helicobacter pylori, Kingella kingae, Klebsiella aerogenes, Klebsiella michiganensis, Klebsiella oxytoca, Klebsiella pneumoniae complex, Legionella pneumophila, Leptospira, Listeria, Moraxella catarrhalis, Morganella morganii, Mycoplasmoides pneumoniae, Neisseria meningitidis, Nocardia, Pantoea agglomerans, Parvimonas, Pasteurella multocida, Prevotella intermedia, Proteus, Proteus mirabilis, Providencia stuartii, Pseudomonas aeruginosa group, Salmonella enterica, Serratia marcescens, Staphylococcus lugdunensis, Stenotrophomonas maltophilia group, Streptococcus agalactiae, Streptococcus anginosus group, Streptococcus dysgalactiae, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus salivarius, Vibrio vulnificus, Yersinia enterocolitica subsp. enterocolitica, Yersinia enterocolitica subsp. palearctica

Example of a printed report (pdf).

Export

The *Export button* is only active, if an USB drive is connected to the instrument. When clicking the *Export button* the results of the selected tests are stored in a predefined folder structure on the USB drive:

hyborg → Export: PDF-reports of the results are stored.

hyborg → Support: ZIP-file containing several files including raw data of the result. The ZIP-file might be requested by technical support in case of required troubleshooting

Delete

The sample can be deleted by clicking on the *Delete button*. The samples are not shown in the *Sample screen* anymore. However, results for samples of the run can still be searched for (and found) in the *Search view*.

HL7 Upload

Pressing the *HL7 Upload button* loads the results into connected LIMS system via HL7. *hybcell* results and PCR results can be uploaded separately.

For detailed results, click on the respective sample to open the *Result screen*.

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Possible result of a processed sample.

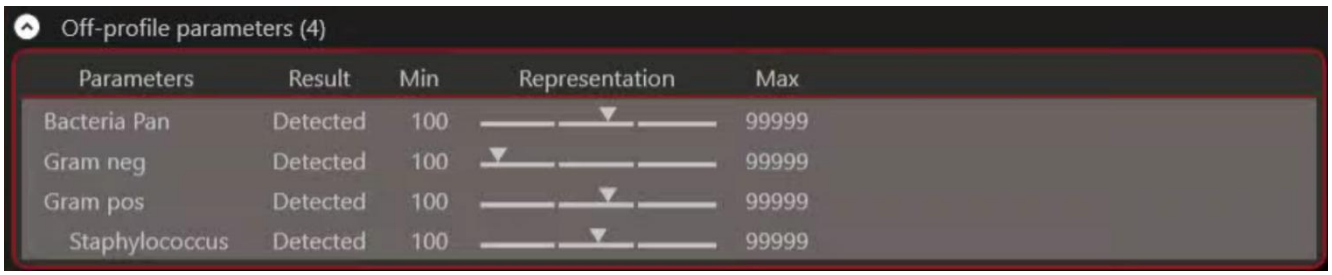
All reports are divided into sections.

- **Header**: general information about the sample, the *hybcell*, buffers / liquids and date and time.
- **Controls**: summary of results for several controls. If all controls have passed, the result for Controls is *PASSED*. If one or several controls have failed, the result is *FAILED* or *INVALID* and some explanation for each failed control is displayed.
- **Results:**
    - Name of the tested criteria, as defined in the protocol (e.g., bacterial species, inflammatory marker, etc.)
    - Test-specific result, for example a qualitative result like *Detected* / *Not detected*.
    - Representation (test specific) of the measurement with minimum value, maximum value and a graph indicating, where the actual value lies within a logarithmic scale (indicated by a triangle).
- **Off-profile parameters,** hide or show by clicking the *Arrow* button beside the section heading: if using profiles, results not part of the profiles (but of the test) are displayed in this section.

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Example of off-profile parameter.

- **Negative parameters,** hide or show by clicking the *Arrow* button beside the section heading: all results of a test that are classified as “negative / not detected” are displayed in this section.

If the displayed result is part of a run with more then one result, *Navigation Arrows* are displayed and active on one or both sides of the header. By clicking on an active *Navigation Arrow*, the next result of the run is displayed.

Several functions can be executed by clicking the provided buttons.

Show PCR result

Whenever PCR data for the sample is available, the *Show PCR result button* will be active and clicking on it shows details on the PCR result associated with the sample (see above).

Expert mode

If a test result does not seem to be plausible, the expert mode can be used to see the raw data. Clicking on the *Expert mode button* opens the TIFF of the fluorescence scan of the *hybcell’s* surface. Depending on the type of the test, different criteria have to be met. However, the scan should never show larger “clouds” of fluorescence or irregular stains or spots across the surface. This mode should only be used by experiences users.



Example of a scan (raw data) of *hybcell’s* surface – signal intensities are transformed into false-colour representation, circles indicate the expected positions of the different probes).

The user can use the *Zoom buttons* (+/-) to zoom in and out. Original size is restored by pressing the *Default view button*. By clicking the *Close button* expert mode is ended and the result view is entered again.

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Selected

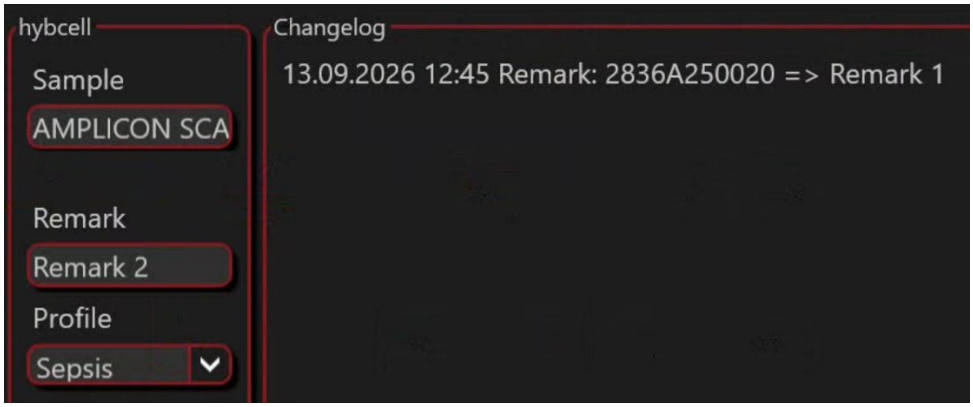
This button changes its name from *Selected* to *Not selected* and vice versa when clicking on it. This selection refers to the run overview and samples can for example being reviewed and selected for later HL7 upload or other functions.

Export – HL7 Upload – Print - Delete

These buttons have the same functionality as in the *Run view* (See above).

Edit

After a test was processed, the sample name / ID, the remark and the selected profile can be changed by clicking the *Edit button*. The dialogue below is displayed together with a change log to help the user to track any changes made.



Example of a sample edited after it was processed.

Once changes were made to the sample information, the *Show changelog button* will appear in the line with additional buttons (which are accessible via the button with the three dots). Clicking the *Show changelog button* will show which changes have been made so far (see above).



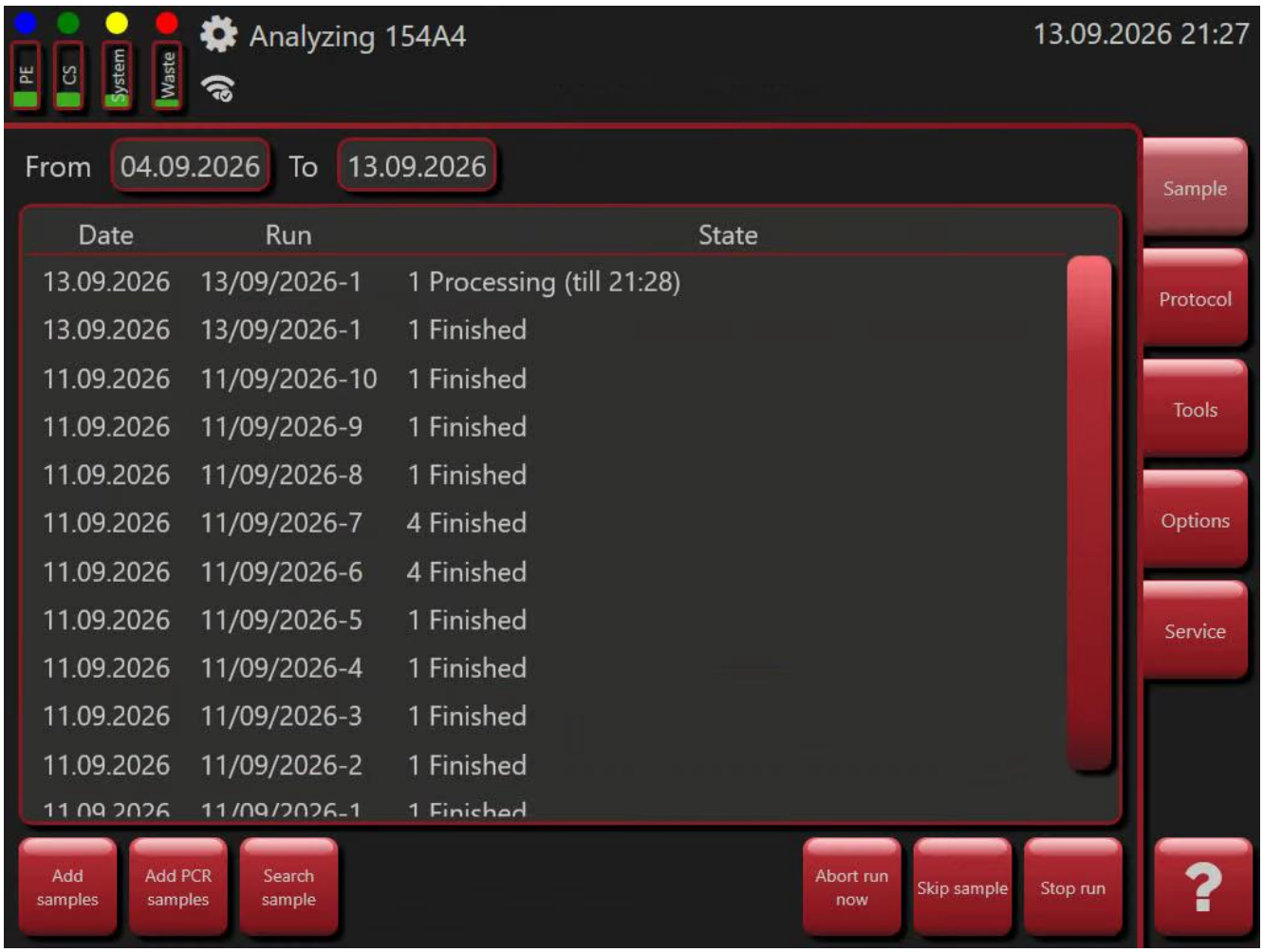
Additional buttons displayed after clicking the *Dots button*.

Skip Sample, Stop or Abort Run

Whenever processing a run is ongoing, some options to stop or abort the processing are displayed in the footer of the screen.

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Options to skip processing of the current sample or stopping / aborting the run.

Abort run now

If processing of the run should be stopped immediately, the *Abort run now button* can be clicked. Be aware that the result for the active test is then invalid. Remaining tests of the run (not processed) keep their *Ready status* and can be processed later. Results from samples that have already been processed are retained.

Skip sample.

By clicking the *Skip sample button* the currently processed *hybcell* test is stopped and the next *hybcell* test of the run is started. Be aware that the result of the skipped sample will be invalid.

Stop run

If clicking the *Stop run button*, the currently active test is processed until its end. The result of this test should be valid (if no other reasons invalidate the test). Then processing of the run is halted, remaining tests keep their *Ready status*. Use this option, if you want to process samples with higher urgency after stopping the run.

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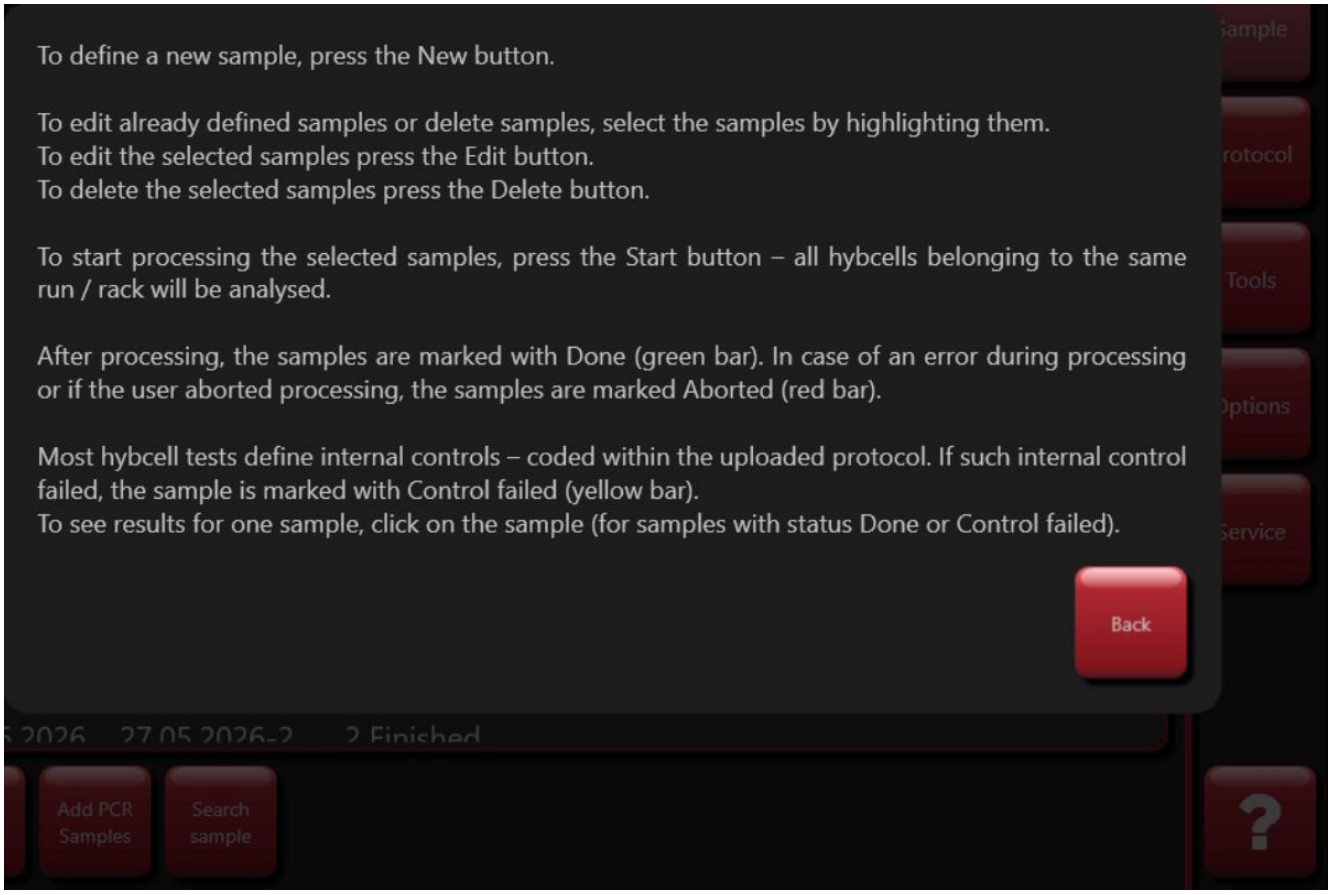
14. Built-in help

The software provides contextual help. Whenever the *Help button* is displayed, a text related to the current screen is shown after clicking.



The *Help button*.

Below an example of contextual help for the *Sample screen*.

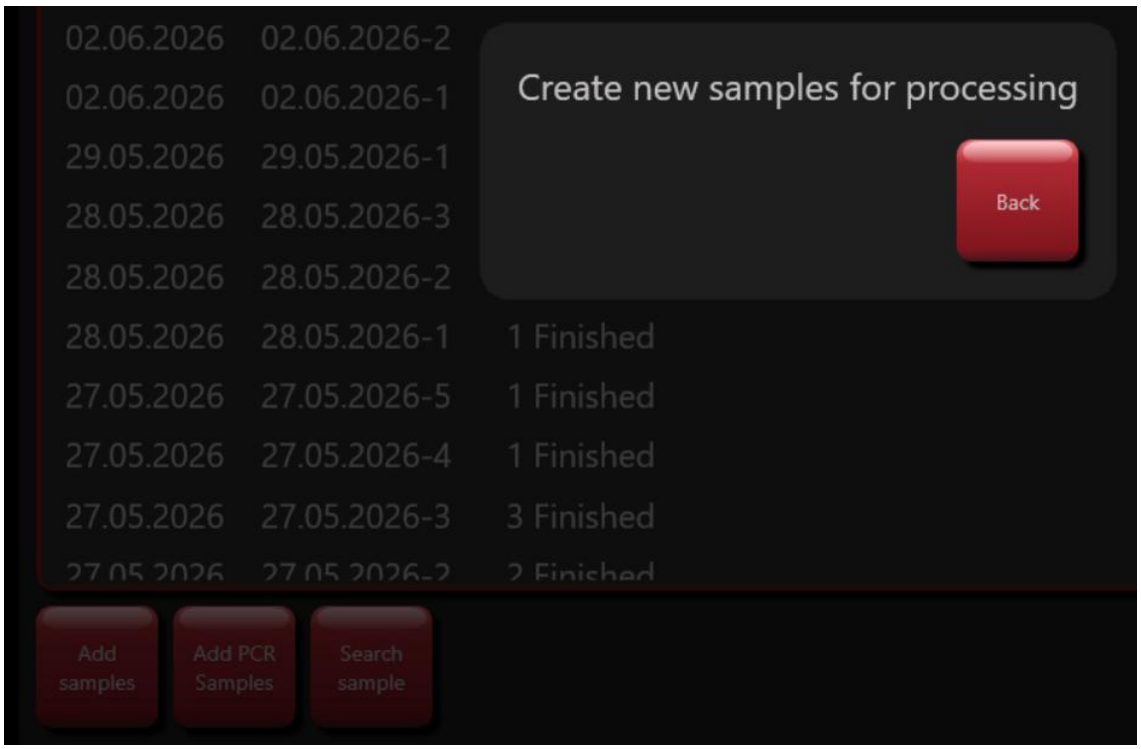


Contextual help for the *Sample screen*.

Furthermore, many of the displayed software buttons display a brief explanation of the function behind the button. By clicking and holding the button for about 2 seconds the help text is displayed.

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Contextual help for the *Add samples button* of the *Sample screen*.

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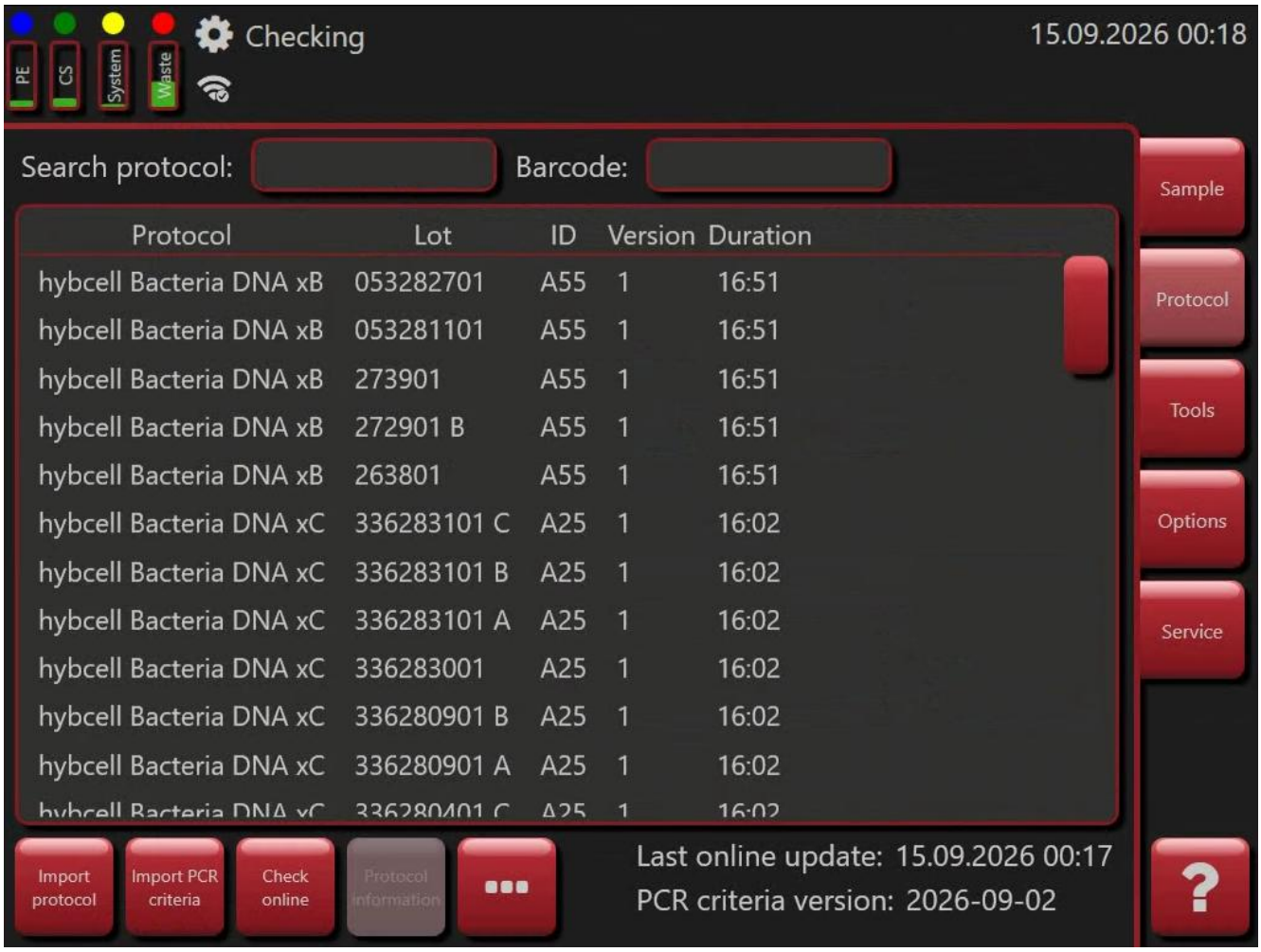
15. Managing Protocols

The *Protocol screen* is entered by clicking the *Protocol button* on the right-hand side of the screen (see above).

Protocols are encrypted xml-files, that are configured and provided by Cube Dx. They are test and production lot specific and contain information on the processing steps for the test done by the instrument, e.g., heating and cooling cycles, rotation of the *hybcell*, exchange of liquids or fluorescence scanning.

Furthermore, the *protocol* contains information on the microarray grid on the *hybcell's* surface. Any parameter (e.g., bacterial species, a single inflammatory biomarker) is represented by one or more spots of that grid. Which spots are associated with which parameter is as well coded in the specific protocol, along with rules how to calculate the outcome / result for the parameters based on the raw data (fluorescence signal).

PCR criteria is a xml-file that contain information on the interpretation of PCR results based on specific PCR lots. Slight variations of the features of different lots of PCR enzymes and primer and probe concentrations result in slight variations of Cts and Tms for different product lots. Therefore, for each lot of the PCR products specific information for optimal differentiation of criteria (for example cut-off between *Detected / Not detected)* is provided in the xml-file.



***Protocol screen* with available *protocols* (for the specific *hyborg*).**

A *protocol* has a name and is associated to a production lot and an ID – which is as well part of the *hybcell* barcode. Furthermore, a version number and the duration of processing the protocol are shown.

For each new production lot, an updated *protocol* is issued and provided.

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The footer displays, when protocols and the PCR criteria file was last updated via the internet. The version of the PCR criteria file is shown as well.

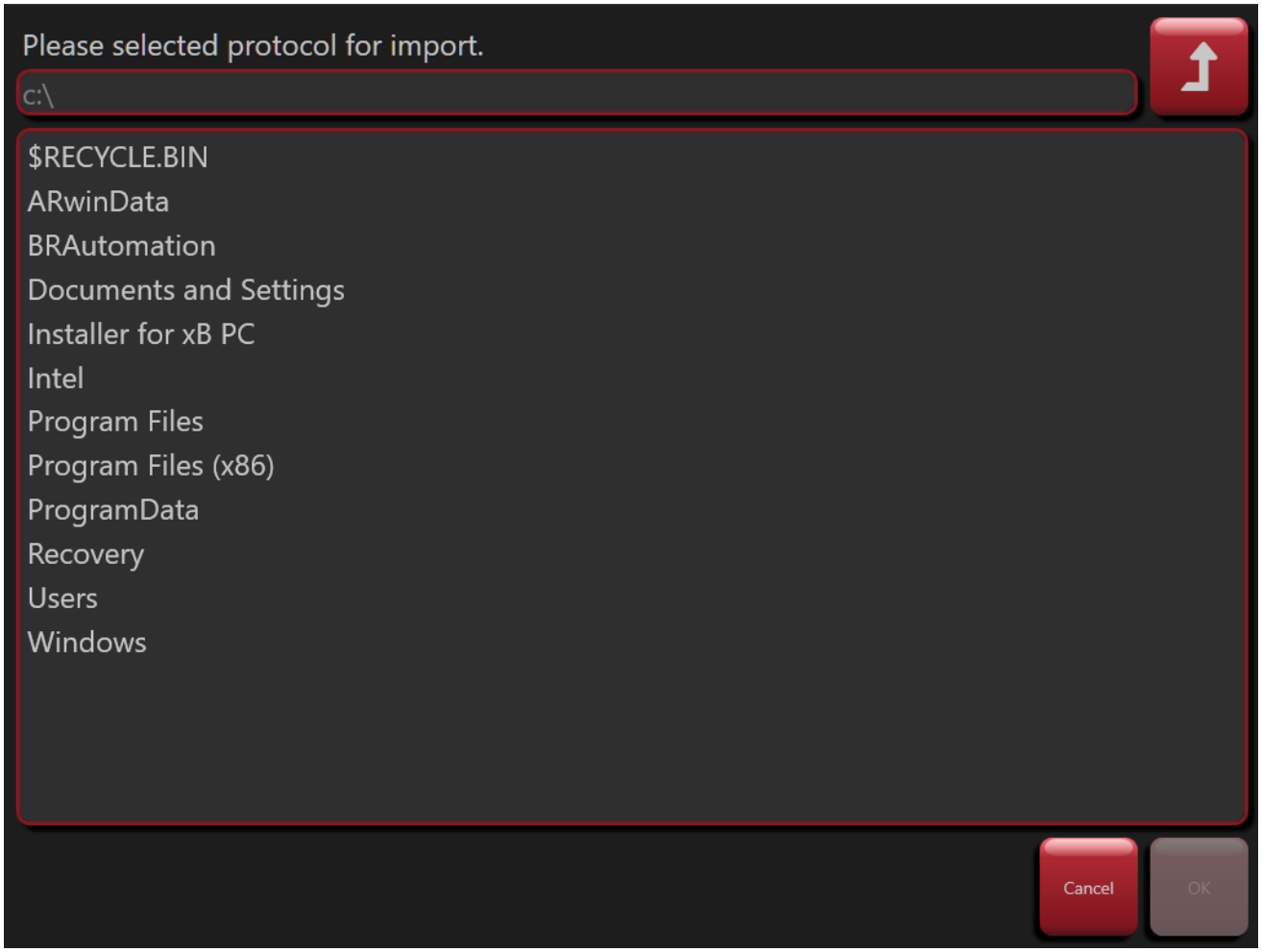
Import or Delete Protocols, View Details

Protocols and the PCR criteria file (.zip) can be downloaded from Cube Dx' website: www.cubedx.com/protocols.

Before the protocols can be imported, they have to be unzipped and stored on a USB drive. The USB drive has to be connected to the instrument.

To import a new protocol, press the *Import protocol button*. A file selection dialogue appears.

To import a new PCR criteria file, press the *Import PCR criteria button*. A similar file selection dialogue appears.



File selection of protocol to be imported (file extension .hyb).

Navigate to the folder (USB drive) the protocol or PCR criteria file is stored in. The file extension of the protocol must be ".hyb". The file extension of the PCR criteria file must be ".zip". Select the protocol file and click the *Ok button*.

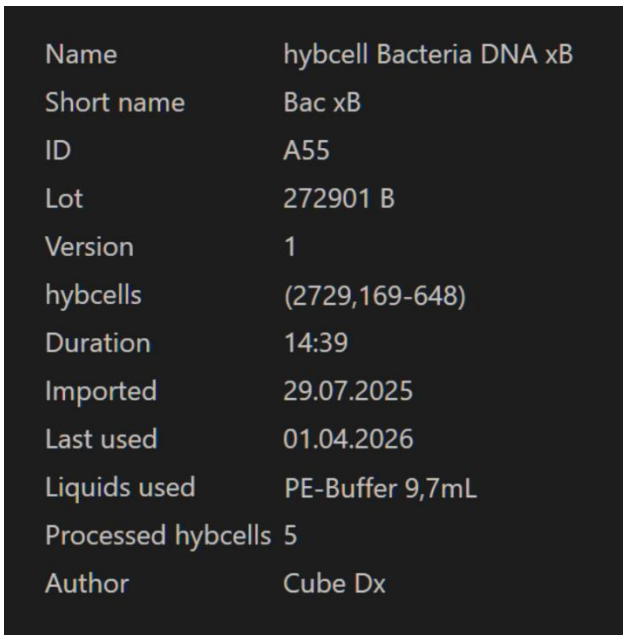
If the instrument is connected to the internet new and updated protocols and PCR criteria files can be imported automatically by clicking the *Check online button*. The update via this function might take a few seconds.

Click on the *Protocol Information button* to see further details of the protocol (e.g., short name or the protocol, author, duration, lot ID, used barcodes of hybcells, used liquids, etc.).

Below an example for detailed lot information.

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Details of a protocol.

To delete an outdated protocol, select the protocol by clicking on it. Press the *Delete protocol button*. This button is displayed after pressing the *'…'-button*.



Define, Change or Delete Profiles

Some *hybcell* tests might be used for different diagnostic uses and not all parameters (e.g. different bacterial targets) are relevant for all uses. Therefore, the scope of results on a report can be narrowed – either by Cube Dx as default or by the user. This narrowing is done by defining profiles and to select the parameters which should be considered for the report. The remaining parameters are then termed as off-profile parameters and can be shown in a different section of the report (dependent on the settings, compare *Options*).

Profiles are associated with the ID of protocols (3-digit alphanumeric number, e.g. A55).

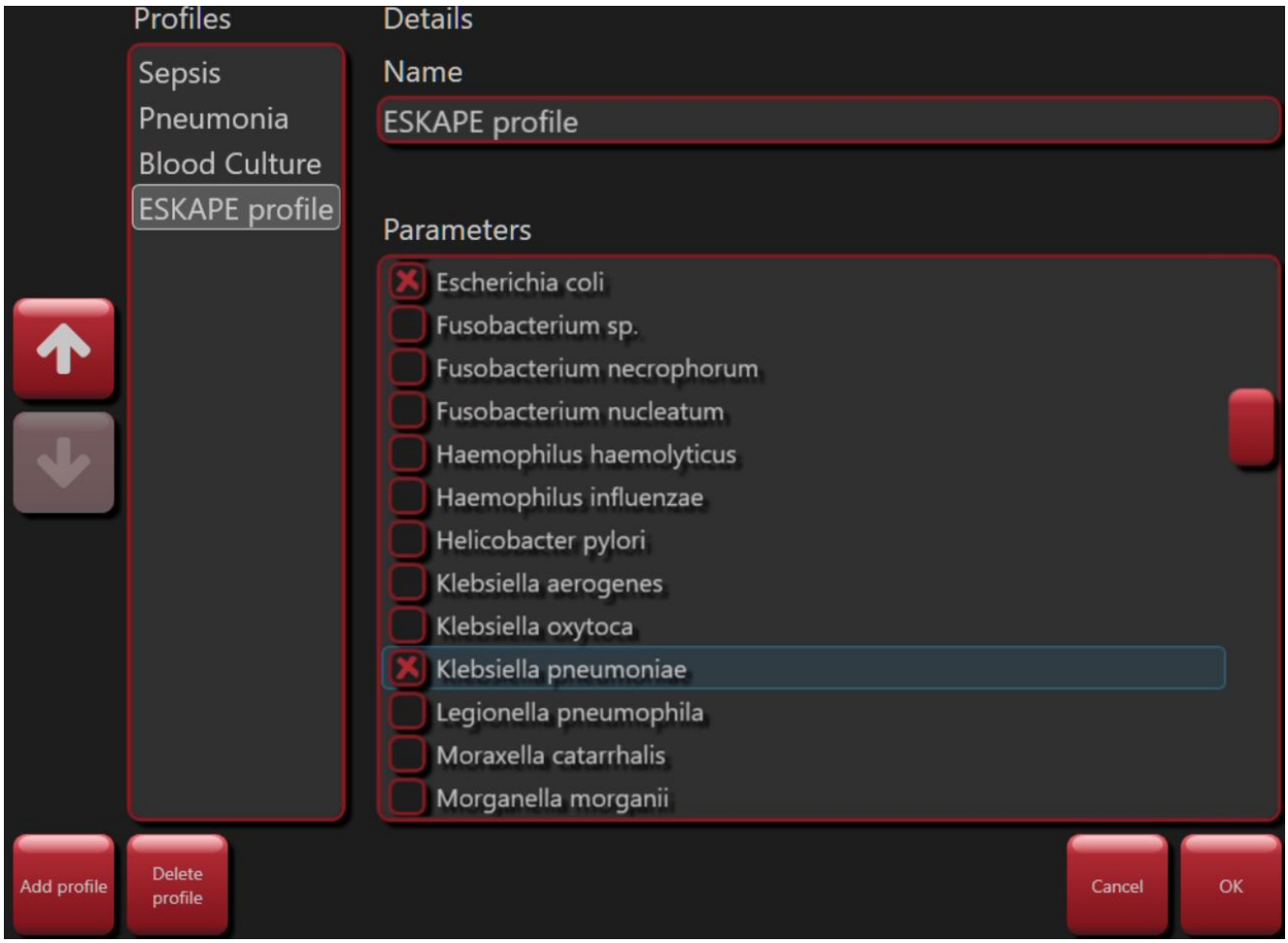
To create, change or delete profiles to a protocol, a protocol has to be selected by clicking on it and then clicking the *Define profiles button*. This button is displayed after pressing the *'…'-button*.

Below screen will be displayed.

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Definition of profiles.

The already defined profiles are displayed in the *Profiles column*. By clicking the *Add profile button* a new profile is created. The name of the profile can be changed in the *Name field*. Selecting the relevant parameters for the profile (from all available parameters of the test) is done by activating the checkbox of the parameter.

The *up and down arrows* on the left-hand side of the *Profiles column* move the selected profile up or down. The order of profiles from top to bottom will be displayed to the user in the same order for the selection of profiles.

Profiles that have been created by the user can be deleted by selecting the profile and clicking on the *Delete profile button*. Note: profiles provided by Cube Dx that come with the protocols cannot be deleted (in the example above: Sepsis, Pneumonia, Blood Culture).

By leaving the screen clicking the *Cancel button*, all changes made (adding, changing or deleting profiles) are not saved. Leaving by clicking the *Ok button* saves all changes.

Define, Change or Delete own Parameters

Own parameters can be defined by combining available parameters (with help of basic arithmetic operators and some functions). The result can be classified as well (defining two or more classes).

To define own parameters, click the *Define parameter* button. This button is displayed after pressing the *'…'-button*.

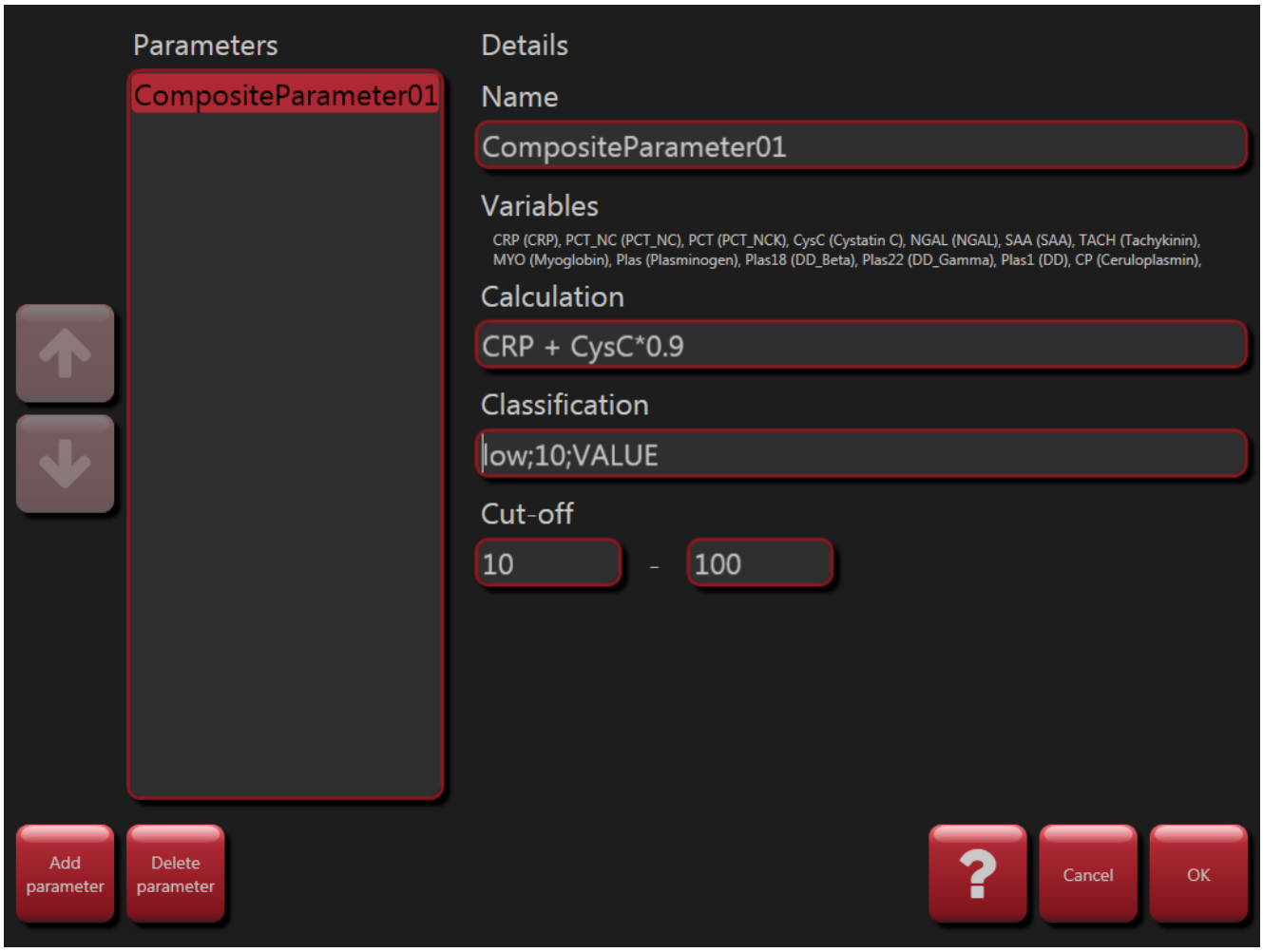
Assign a name to the parameter and define the combination and classification. The variables available for the combination are displayed under *Variables* and are the *Parameters* defined as possible results. A *Classification* of the results is defined by a string of any length, separated by semicolons. This string alternates between class

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names and their threshold values. If the value *VALUE* is entered, the calculated value (from *Calculation*) is specified at this point. In the example below, for instance, the value 'low' would be output for values between 0 and 10, and the calculated value for values greater than 10. Finally, the *Cut-off* range defines the range within which the standard values for the parameter lie (from – to) and are displayed accordingly in the report.

Cube Dx provides an overview on available operators and functions in the annexes of this instructions for use.



Definition of own parameters.

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16. Tools

The software offers functionalities to maintain the instrument, assist in trouble shooting, manage liquids, provide logged and system information and to start and manage *hybcell Control (xC)*. The *Tools screen* is entered by clicking the *Tools button* on the right-hand side of the screen.



The *Tools screen*.

Using *hycell Control (xC)* for periodic instrument check-up

hybcell Control xC is a special-purpose *hybcell* test to check basic functionalities of *hyborg Dx RED*. These functionalities are transport of liquids, temperature control, *hybcell* handling and taking a fluorescence scan of the *hybcell's* surface.

To start the check, the field beside the text *Control barcode* has to be selected / activated and the barcode of *hybcell Control (xC)* has to be read.

If a valid barcode (=barcode of *hybcell Control (xC)*) was scanned the procedure is started by clicking the *Start control button* that has popped up.

The software will ask the user to insert the hybcell on position A1 into the instrument (the same as for ordinary *hybcell* tests as well, see *Basic Instrument Operations*)

The result of *hybcell Control (xC)* is added to the list of previously done check-ups (at the top of the list). By clicking the result, details of the results are shown.

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Parameters	Result	Cut-off
Versions		
Software	1.8.2.24	
Firmware	04	
Hardware	C1	
Robotics		
Take hybcell	PASSED (1)	0,5 - 1,5
Return hybcell	PASSED (1)	0,5 - 1,5
Fluidics		
Pressure	PASSED (94)	90 - 115
Airtightness	PASSED (0,030)	-1 - 0,2
Level 1	PASSED (1)	0,5 - 1,5
Level 2	PASSED (1)	0,5 - 1,5
Level System	PASSED (1)	0,5 - 1,5
Level Waste	PASSED (1)	0,5 - 1,5
Tubing 1	PASSED (4,53)	2 - 20
Tubing 2	PASSED (5,05)	2 - 20
Waste	PASSED (240)	15 - 20000

Example of a report on a *hybcell Control xC*.

If the control failed, repeat the check-up. If the control failed several times in a row, contact Cube Dx or the responsible distribution partners.

Specific features

With help of specific features the instrument can be maintained and minor issues can be solved.

Open (and Close) the Drawer

To open and close the drawer – for example to remove (part of) a *hybcell* after an instrument error - press the *Open drawer button*. The software prompts the user to wait, until the drawer is opened. After pressing the *Ok button*, the drawer is closing again.

Clean and Empty Tubing

To prevent the tubing from clogging – e.g. due to a build up of salt sediments from the buffers – the tubes are flushed with *System Liquid* after each run. However, to repeat such cleaning, click the *Clean tubing button* to start the cleaning routine. The tubing will be emptied after the cleaning procedure.

Repeat Initialization

After an error occurred, or to move the axis back to the initial position, the initialization routine (after power on) can be repeated. Press the *Initialize instrument button* to initialize the instrument once again.

Check (System) Pressure

To check the system pressure, click the *Check pressure button*. With this function you can check if the pressure is constant after changing liquids. If the liquid bottle are not closed tightly enough or if there is an other pressure leak, the build-up of pressure will fail.

Shutdown

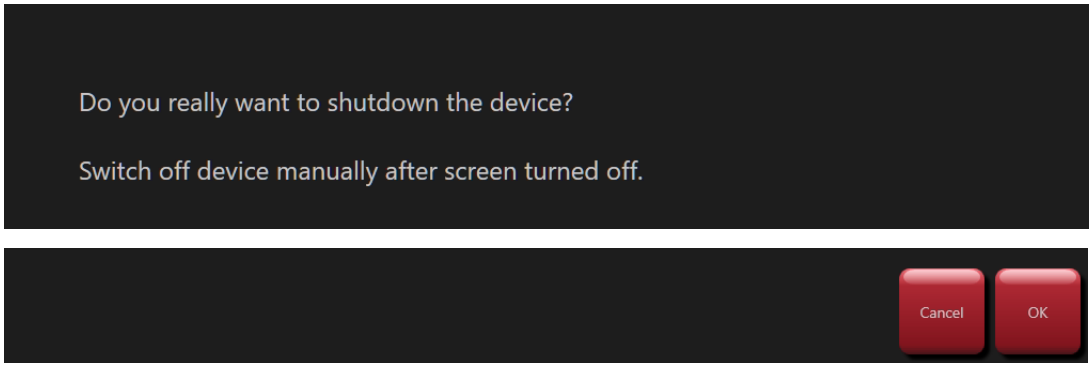
To shut down the hyborg software and the *hyborg Dx RED* – for example to pause operation for a longer period, press the *Shutdown button*. This button is only available / active, if the instrument is not processing a test or cleaning itself (see above). The user will be prompted to confirm the shutdown. Confirm the shutdown by pressing the *OK button*.

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After shutdown (black screen), turn off the main switch (on the right side of the instrument).

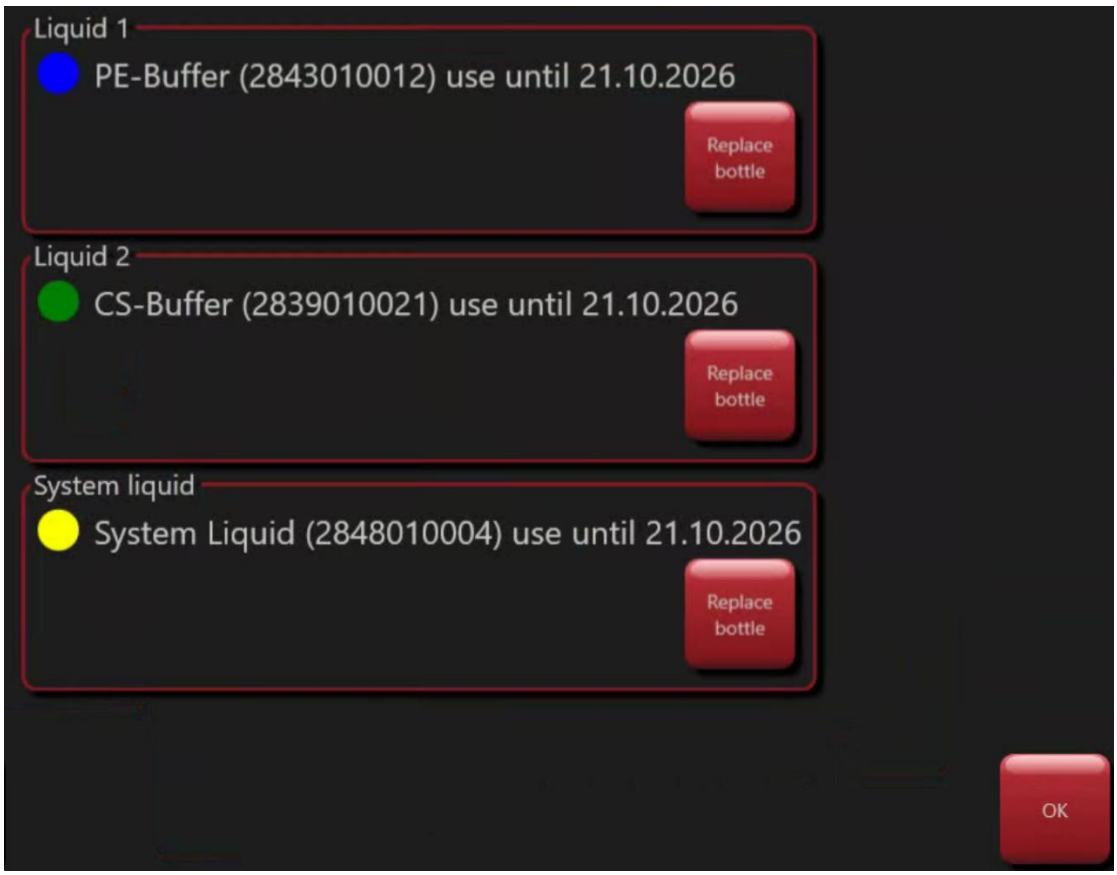


Confirming the shutdown of the instrument.

Manage Liquids (buffers)

To exchange buffers and manage liquids (bottles) of the *hyborg Dx RED*, click the *Manage liquids* button. The screen below will be displayed.

The currently connected liquids are shown, including a date until which the liquids can be used, depending on expiration date and in-use expiry, whichever occurs first.



The *Manage liquids screen*.

If a liquid is changed, the empty bottle has to be removed first. **When handling liquids, wear disposable gloves, protective glasses and a laboratory coat.** Prepare and open the new bottle. Remove the empty bottle from its mount and unscrew the connector. Connect the new bottle to the instrument by fastening the exposed connector to the new bottle. **Be aware that the sealing ring stays in place between the new bottle and the connector.** Put the bottle back in its mount. Be careful not to mix up the liquids. Colour-codes on the bottles and on the

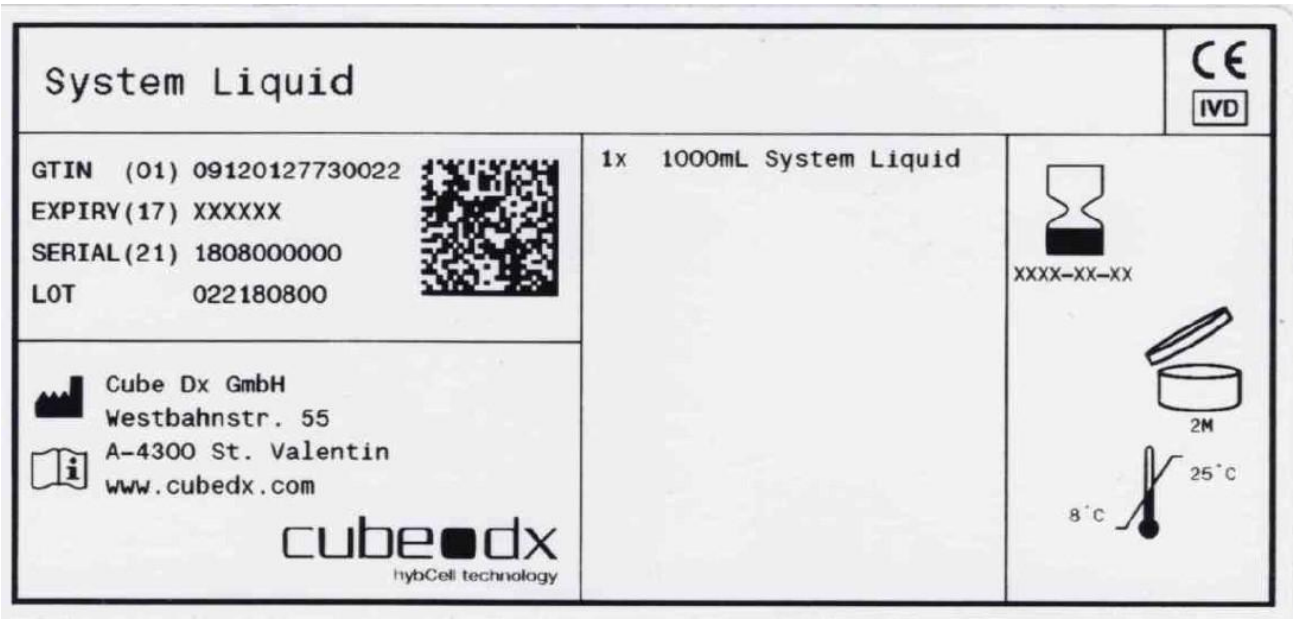
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instrument should guide you as well. Dispose any remaining liquid of the exchanged bottle (see *Storage, Transportation, Shelf Life and Disposal*).

- *PE-Buffer*: blue.
- *CS-Buffer*: green.
- *System Liquid*: yellow.
- *Waste Bottle*: red.

Click on the respective *Replace bottle button* and scan the barcode from the new bottle's label. The expiry date of the liquids is coded in the liquid barcodes and the software checks and displays the expiry of the liquids.



Label of System Liquid (example).

The level of liquid waste is monitored by the instrument and can be disposed whenever full (see Storage, Transportation, Shelf Life and Disposal).

Displaying Information

(Re-)Analyse Scan

Previously made fluorescence scans / tests (stored as .tif-files) might be analysed once again with different/varying protocols (e.g. to examine variations of different calculations).

To analyse scans once again, the scan itself (.tif-file) as well as the protocol (xml-file) have to be loaded from an external source (file system, e.g. from the instrument itself or via USB drive). After clicking the *Analyze Scan Button* the user is prompted to select the scan (.tif-file) and the protocol (xml-file).

Once finished, the analysis of the scan delivers the same formats as analysing regular results (see *Basic Instrument Operations*).

Version and MAC Information

After clicking the *Information button* below screen pops-up. It contains information about the last execution of the *hycell Control xC*, software version information and the MAC addresses (LAN / WLAN).

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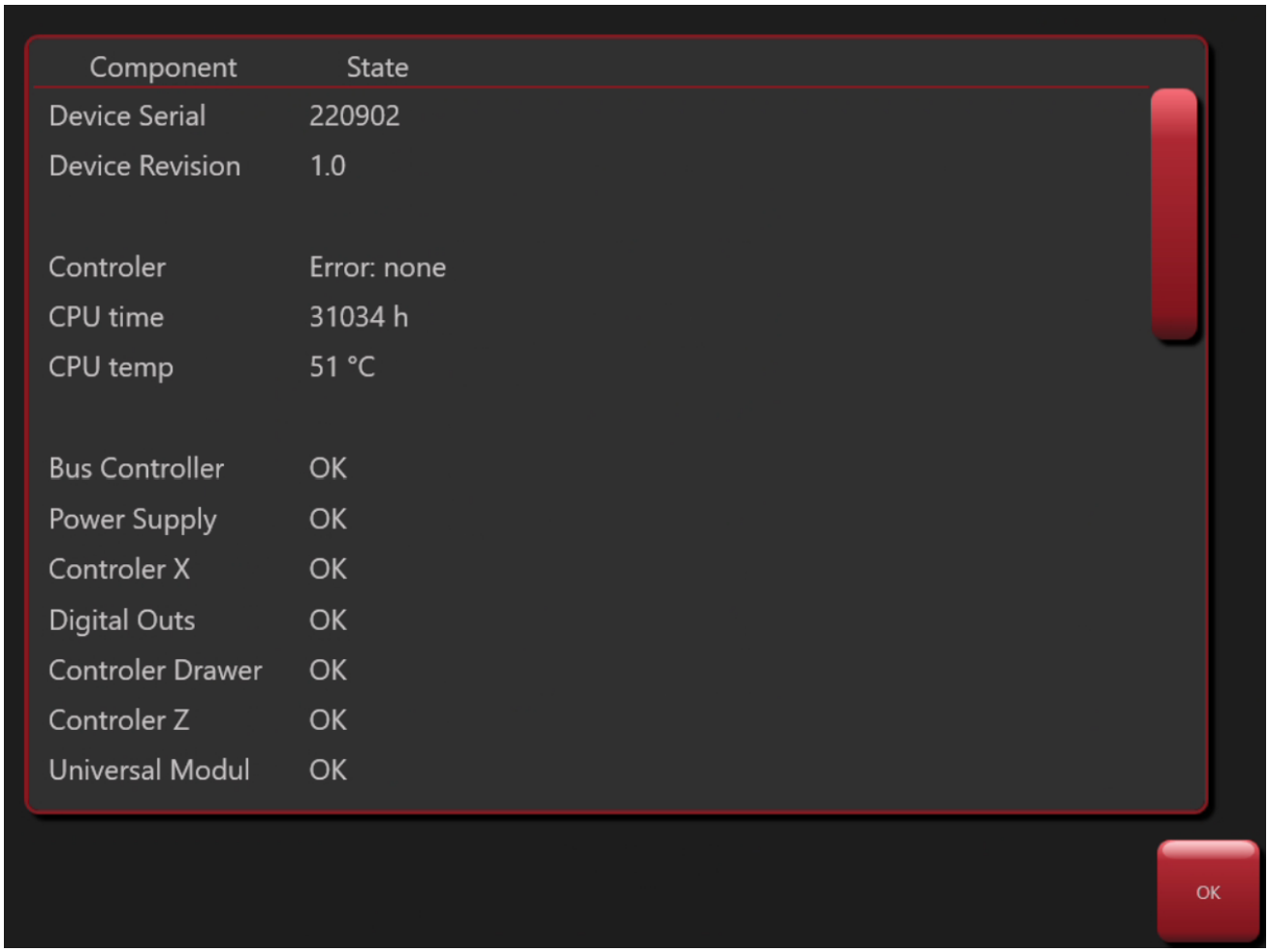
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Information on software versions and MAC addresses.

Hardware / Electronics Diagnostics

Pressing the *Instrument diagnose button* prompts a screen depicting the current status of hardware (electronics). This information should help during trouble shooting and service technicians might ask for this information. A scrollbar helps to go down the list and depict all available information.



Information on electronics status.

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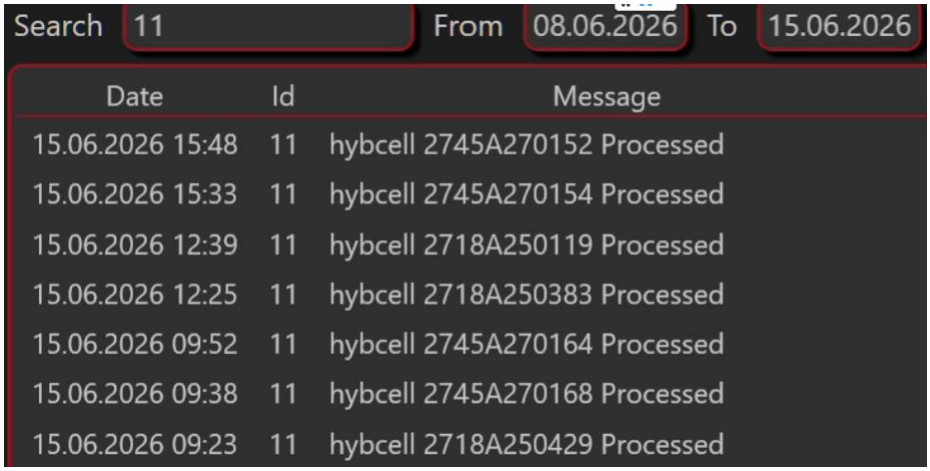
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Show Instrument Log

By clicking the *Show log button*, the log of the instrument is shown. The log lists relevant events with time stamp, ID and a descriptive message. The display can be limited by setting a time frame for events (*From…To*) and by a search function (e.g. searching for ID or parts of the message).

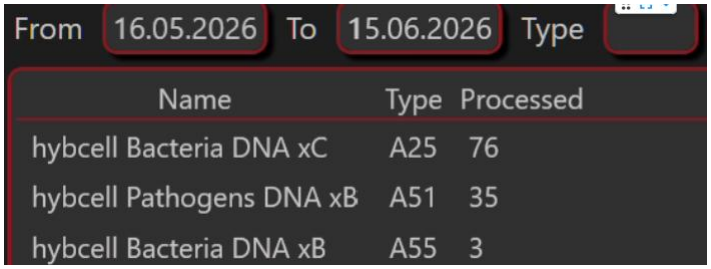
Examples of logged events are for example the start of the instrument and software, the processing of a *hybcell*, the exchange of liquids or instrument errors.



Example of the instrument log.

Overview of Usage

By clicking the *Usage overview button*, the frequency of different tests (protocols) run on the instrument is shown (name of test and protocol ID, number of tests processed). The calculation can be limited by setting a time frame for processed tests (*From…To*) and by a search function (limiting the type).



Overview on usage.

Open IFU

By clicking the *Show manual button*, this instructions for use (IFU) or an older version thereof are opened as pdf-file.

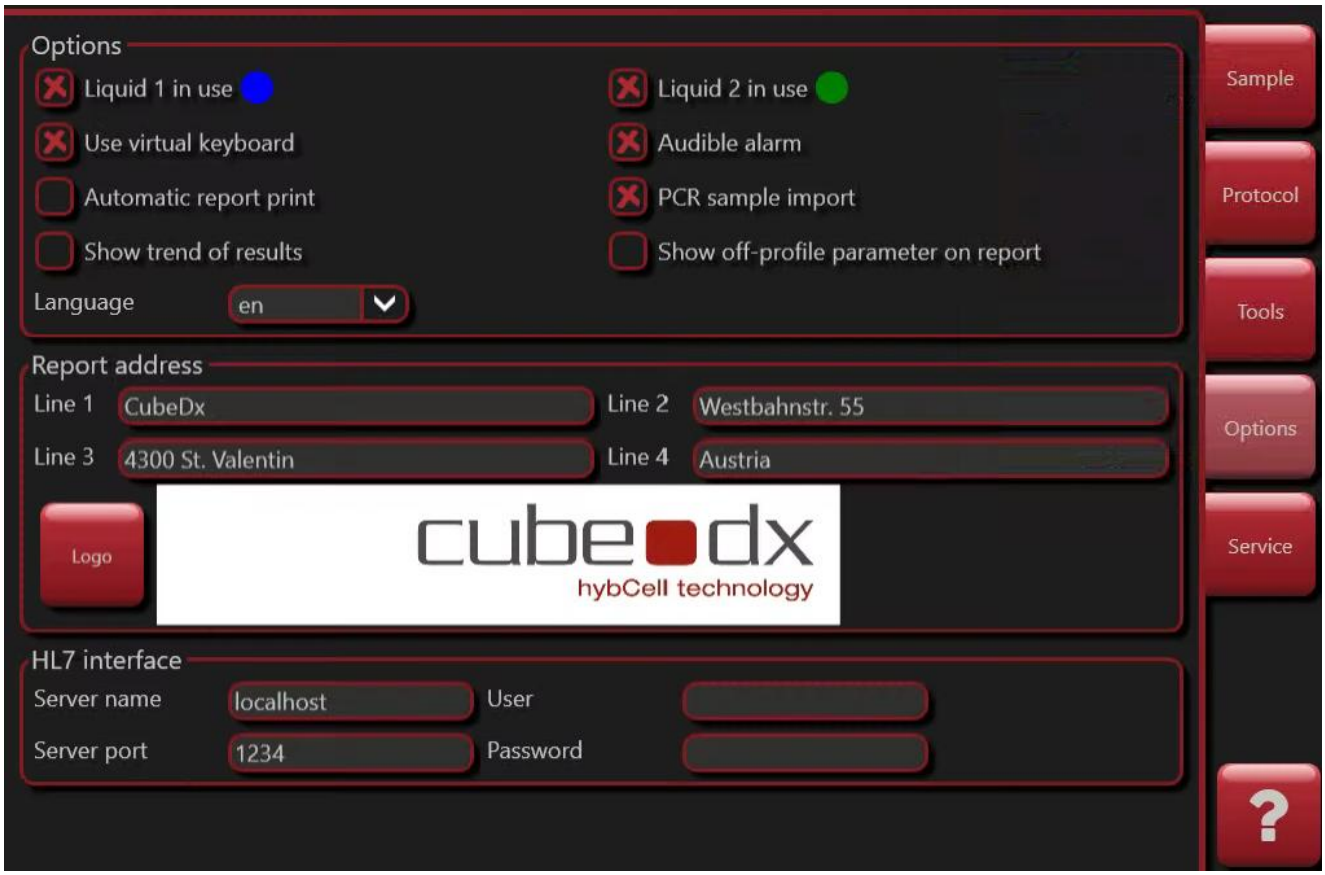
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17. Options

The software and *hyborg Dx RED* offer a few options to be set by the user. To open the options menu, click on the *Options button* (available from all main pages).



Instrument and software options.

Select and Unselect Options

Liquid 1 or Liquid 2 in use

By selecting or unselecting the checkboxes *Liquid 1 in use* or *Liquid 2 in use* defines, which connectors for different buffers are active. Which buffers are needed is defined by the used tests. If selected, the corresponding level sensors of the liquids are controlled and displayed by the software. During start-up of the instrument the flow-rate is checked.

Use virtual keyboard

If selected, text and numbers can be entered by the user via the touchscreen, with help of displaying a virtual keyboard when the user is prompted to input (textual) data.

Audible alarm

If selected, an audible alarm will be triggered in case of an error.

Automatic report print

If selected, reports are printed by the defined standard printer after processing of each *hybcell* / test automatically.

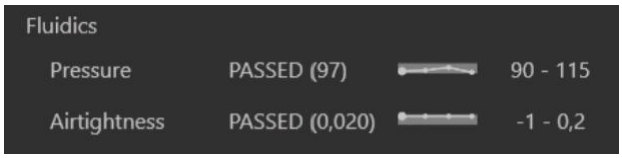
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Show trend of results

If selected, the results of the test and results of tests with the same sample name of the previous 30 days are displayed as a trend. An example of how such trends are used are the results for *hybcell Control xC* – the sample name is always the serial number of the instrument. Trends can help to understand the progression of a parameter or a condition.



Example of a trend of single parameters of the *hybcell Control xC* result.

Show off-profile parameter on report

If selected, the reports include the presentation of off-profile parameters (= parameters that have been defined as not being a relevant result in the clinical context) in a separate section of the report.

PCR sample import

If selected, PCR data can be imported via the *Sample Screen* (using the *Add PCR samples button*). If not selected, the *Add PCR samples button* is not displayed (and therefore not available for use).

Language

The language setting for the software can be changed with help of a dropdown menu. Currently available: English (*en*) and German (*de*).

Be aware that any changes are only active after a re-start of the instrument.

Report Address

Four lines can be used to display customer specific information on the header of the report. Furthermore, a jpg-file can be displayed as well – for example a logo of the customer. The logo-file can be changed by clicking on the *Logo button*. A file selection dialogue will be displayed that allows the user to navigate to and select the desired file.

Below an example of how the customer specific information would be displayed:

CubeDx GmbH
Westbahnstr. 55
4300 St. Valentin
Austria

cube dx
hybCell technology

Example of a header of a report (print).

HL7 Interface Settings

The settings under the section *HL7 Interface* configure a unidirectional HL7 interface (upload). Ask for support, if you want to use the HL7 interface.

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18. Troubleshooting

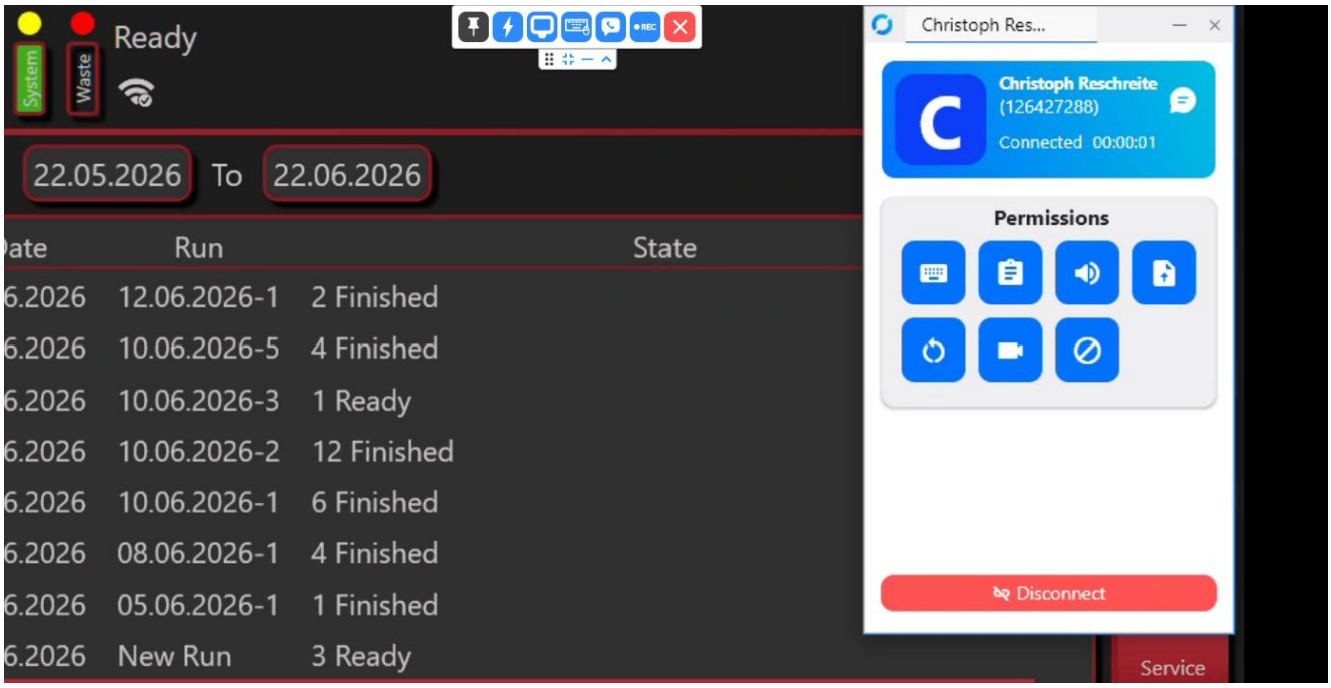
Make sure to shut down the *hyborg Dx RED* and disconnect the power supply cable any time you have to remove the cover of the instrument. (See the *Tools screen*, *Shutdown button* above).

All trouble shooting might only be done by trained operators (authorized training by Cube Dx or its distributors).

Granting Access to a Member of the Support Team

If the instrument is connected to the internet and the necessary ports are open a support member can establish remote access to the instrument. The remote access software explicitly asks for permission to access the instrument (dependent on settings) from outside for each remote access session.

So, a remote access session has to be planned and the user has to grant access to the instrument for the support member. More details on the used tool (Rustdesk) and possible set-ups of remote sessions can be requested by Cube Dx.



Example of a remote session.

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Removing hybcell Components from the Inside

If an error occurs that causes a *hybcell* part to be stuck in the analysis chamber or any another position, the instrument should remove these parts by itself. These *hybcell* parts will be moved behind the opening of the drawer. The drawer cover must be opened manually by the user and the *hybcell* parts must be taken out.



Open the drawer manually.



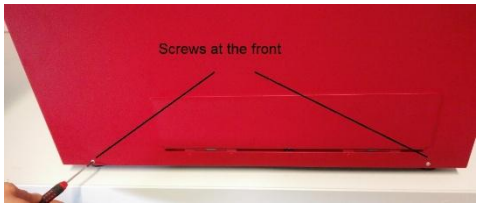
Remove hybcell parts.

It might be necessary to open the gripper. A popup window asks, if such opening is intended. If you confirm, the gripper opens automatically.

In rare occasions it might be necessary to remove hybcell parts manually from the inside of the instrument.

To do so, you can either access the shut-down instrument via the drawer, or you have to remove the instrument cover.

Before removing the cover, not only shut-down the instrument, but pull the power cable as well. You have to remove 4 screws (2 at the bottom of the front and 2 at the top of the rear) to be able to lift off the cover.



Remove two screws at the front.



Remove two screws at the rear.



Take off cover.

Wear protective gloves when you are taking out hybcell parts! Remove the hybcell parts and attach the cover once again.

Do not operate the instrument without cover! During start-up, the instrument will initialize again.

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No build-up of pressure / pressure system not airtight

A common reason that system pressure does not build-up is a leak in the pressure system caused by missing or not correctly aligned sealing rings between liquid bottle and connector. This error frequently occurs after changing liquids. So, the first connection to look at is always the one for which the liquid has been changed recently.

Open the connector once again and check for the presence of the sealing ring. The may either stick to the bottle or be inside the connector (see pictures below, be aware that the colour of the sealing ring might be of other colour than shown on the picture as well).

Check, that only **one** sealing ring is between bottle and connector. Check, that the sealing ring is put well on the bottom of the connector and that it is not pinched or edged. Connect the bottle once again and check system pressure (compare *Tools*)



Sealing ring (either in connector or on bottle).

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Barcodes on liquid bottles not readable

If the barcode on the bottles for the buffers is not readable by the software and the barcode reader, the empty bottle cannot be replaced by a new one. Please, check following possible causes:

- Buffers are single use and can only be scanned / used once by the software.
- Use the original barcode reader supplied with the instrument.
- If the barcode is damaged, please contact your local distributor.
- The language setting of the barcode reader must match with the language setting of the operating system (Microsoft).
- The barcode reader must be programmed to read the barcodes correctly. You may try to reprogram the reader by scanning following barcodes in this sequence:



ENTER/EXIT PROGRAMMING MODE



French (France)



German



Italian



Spanish



United Kingdom

Invalid Controls / Results

Invalid internal controls or little plausible test results may be due to incorrectly connected liquids or congested tubing. Check the connection of liquids and execute a *Clean tubing* command (see above). See the test manuals for more details.

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19. (Near) Incidents / Vigilance

Make sure to immediately report near incidents and incidents related with the use of the instrument to Cube Dx or respective distribution partners and the national competent authority.

Please follow the rules of national legislation about reporting (near) incidents.

In case of further questions or in case of problems with the instrument or the test(s), please contact:

- 

  Cube Dx GmbH
  Westbahnstraße 55, 4300 St. Valentin, Austria
  Contact information: www.cubedx.com

For additional information about instrument and software check our download area under

www.cubedx.com/documents.

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20. Service and replacement parts

hyborg Scanner (GTIN 09120127730343)

hyborg Dx RED is shipped with a handheld barcode scanner (either USB-connection or wireless). In case the scanner is broken or lost, replacement can be ordered at Cube Dx or its responsible distributor.

Waste Bottle (GTIN 09120127730831)

hyborg Dx RED is shipped with a waste bottle made of glass. When full, the bottle is disconnected from the instrument, emptied and connected again. In case the bottle is broken or lost, replacement can be ordered at Cube Dx or its responsible distributor.

Rack (GTIN 09120127730220)

Th *hyborg Dx RED2* is shipped with a package of *Racks* (5 pieces). *Racks* are support structures made of plastics that hold single *hybcells* that are prepared for testing. Over time these *Racks* wear off and might break. In case the *Racks* are broken or lost, replacement can be ordered at Cube Dx or its responsible distributor.

hyborg Service Kit (GTIN 09120127730381)

The *hyborg Service-Kit* contains all necessary material for the annual service as part of the recommended maintenance. This product is brought by the service engineers when they do the service. Therefore in most of all cases the responsible distributor takes care of providing the *hyborg Service Kit* along with the service.

hybcell Control xC (GTIN 09120127730121)

hybcell Control xC is used for a periodic check-up of the instrument (see *Tools*). In case you are run out of hybcell Control xC, replacement can be ordered at Cube Dx or its responsible distributor

Cube Dx does not recommend the user to stock any spare parts necessary for a possible repair.

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21. Annexes

Operators

When own parameters are defined (compare *Managing Protocols*) different parameters and expressions can be combined using operators. Each (class of) operator(s) has a specific precedence. The classification, available operators and the expression's priority (top down) is listed below.

Primary

- (,)
- values

2 * (3 + 2)

Multiplicative

- *, /, %

1 * 2 % 3

Additive

- +, -

1 + 2 - 3

Relational

- =, ==, !=, <>
- <, <=, >, >=

.1 < 2

Logical

These operators can do some logical comparison between other expressions:

- or, ||
- and, &&

true or false and true

The **and** operator has more priority than the **or**, thus in the example above, **false and true** is evaluated first.

Functions

When own parameters are defined (compare *Managing Protocols*) different parameters and expressions can be used in below functions.

Name	Description	Usage	Result
Abs	Returns the absolute value of a specified number.	Abs(-1)	1
Ceiling	Returns the smallest integer greater than or equal to the specified number.	Ceiling(1.5)	2

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Name	Description	Usage	Result
Exp	Returns e raised to the specified power.	Exp(0)	1
Floor	Returns the largest integer less than or equal to the specified number.	Floor(1.5)	1
IEEERemainder	Returns the remainder resulting from the division of a specified number by another specified number.	IEEERemainder(3, 2)	-1
Log	Returns the logarithm of a specified number.	Log(1, 10)	0
Log10	Returns the base 10 logarithm of a specified number.	Log10(1)	0
Max	Returns the larger of two specified numbers.	Max(1, 2)	2
Min	Returns the smaller of two numbers.	Min(1, 2)	1
Pow	Returns a specified number raised to the specified power.	Pow(3, 2)	9
Round	Rounds a value to the nearest integer or specified number of decimal places.	Round(3.222, 2)	3.22
Sign	Returns a value indicating the sign of a number.	Sign(-10)	-1
Sqrt	Returns the square root of a specified number.	Sqrt(4)	2
Truncate	Calculates the integral part of a number.	Truncate(1.7)	1
in	Returns whether an element is in a set of values.	in(1 + 1, 1, 2, 3)	true
if	Returns a value based on a condition.	if(3 % 2 = 1, 'value is true', 'value is false')	'value is true'

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