HYRIS **bCUBEplus**
User manual
(English)

Version 1.0

CE IVD

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bCUBEplus (REF: H0006)

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About this Manual

This manual is referred to For the online use of the instrument using HYRIS bAPP™, please read the HYRIS bAPP™ section on our Help center (https://support.hyris.net). For the offline use of the instrument using HYRIS bPANEL™, please read the HYRIS bPANEL™ – User Manual guide.

Refer to the Help center (https://support.hyris.net) for updated information.

This manual is to be considered as a component of the equipment. When installing the equipment for the first time, the user should accurately check the content of the Manual in order to verify its integrity and completeness.
In the event the Instruction Manual should be ruined, incomplete or inadequate, please contact Hyris S.r.l. in order to immediately restore or replace the incompliant Manual.

The observance of the operating procedures and of the warnings described in this Manual is a basic requirement for the correct working of the equipment and to guarantee the operator's safety.

The Manual must be read in every part in front of the equipment before using it, in order to become familiar with the operating procedures, the commands, and the precautions for a correct and safe usage.

The HYRIS **bCUBEplus** User Manual should be kept, complete and readable in every part, in a safe place, and, at the same time, it should be rapidly accessible to the user when using the equipment.

Declaration of Responsibility by the Manufacturer

MANUFACTURER:
Hyris S.r.l.
Viale V. Lancetti 19
20158, Milan, Italy
Web: www.hyris.net

Hyris S.r.l. is responsible for safety, reliability and performances of the equipment only when the equipment is used in compliance with the following conditions:

- Calibrations, modifications or servicing must be performed by qualified staff expressly authorized by Hyris S.r.l.
- The equipment must be opened and its internal parts must be accessed to by maintenance qualified staff only expressly authorized by Hyris S.r.l.
- The environment where the equipment is used must be in compliance with the safety prescriptions.
- The electric wiring of the building must be designed according to the applicable safety standards and perfectly working.
- Parts of the equipment that can be replaced by the user and accessories must be replaced with items of the same kind and with the same characteristics.
- Usage and maintenance of the equipment and of its accessories must be performed in compliance with the instructions described in this Manual.
- This Manual must be kept complete and readable in every part.
- The equipment is used and serviced until its "End of Life".

IEC 61010-1 Standard Symbols

All the symbols reported in the following table, which are present on the equipment and/or any document/device to be used in conjunction with the equipment, comply with the IEC 61010-1 safety standards.

IEC 61010-1 SYMBOL	DESCRIPTION	POSITION
	The WARNING messages show in the manual in correlation with the description of procedures and operations, which could cause injury to the operator, if not correctly performed.	Symbol placed on items for which it is important to read the Operating Manual for relevant information (see WARNING paragraph).
	Direct current	Symbol placed on power adapter and on the identification label of the instrument

ISO 7000 Standard Symbols

SYMBOL	DESCRIPTION	POSITION
	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used	Symbol placed on shipping or storage boxes
	To indicate the acceptable upper and lower limits of relative humidity for transport and storage	Symbol placed on shipping or storage boxes

Other Symbols

SYMBOL	DESCRIPTION	POSITION
S/N	Serial number	Placed on the identification label on the instrument, identifies the serial number of the device
	Product reference	Placed on the identification label on the instrument, identifies the product model
	European Conformity	Placed on the identification label on the instrument, affirms compliance with the relevant EU legislation
	Date of manufacture	Placed on the identification label on the instrument, near the production year of the device
	Manufacturer	Placed on the identification label on the instrument, near the information about the legal manufacturer of the device
	Crossed-out wheeled bin	Placed on the identification label on the instrument, indicates the prohibition to throw the device in the household wheeled bin when at its “end of life”.
	Refer to the instructions for Use/functioning.	Placed on the identification label on the instrument, this symbol recommends to refer to the instruction manual before/during the use of the device
	Server connection	Placed on the top of the instrument, under the corresponding communication LED.
	Hot	Placed on the top of the instrument, under the corresponding communication LED.

	Internet connection	Placed on the top of the instrument, under the corresponding communication LED.

Safety Information

General Safety Information

In order to guarantee the user's safety as well as a correct working of the equipment, it is necessary to operate within the consented restrictions and adopt all the precautions listed below.

WARNING

Prior to usage, verify that all the safety requirements are satisfied. If not, the instrument must not be powered or connected to any other equipment.

WARNING

The operator working with HYRIS **bCUBEplus** must strictly follow all the indications contained in this manual. Hyris S.r.l. does not respond for improper use of the equipment: the instrument functioning, performance and safety are not assured in case of improper use. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

- Read the instruction manual before using the instrument. Operating the instrument before reading this manual can constitute a personal injury hazard. For safe use, do not operate this instrument in any manner unspecified in this manual. Only qualified laboratory personnel trained in the safe use of electrical equipment should operate this instrument. Always handle all components of the system with care and wear gloves.
- Do not open the cartridge lid when the analysis is running, as this can compromise the results of the experiment and the LEDs light can cause discomfort to the eyes of the operator.
- Warning about the risk of burning. While the analysis is running, enough heat is generated to cause serious burns. Always wait for the conclusion of the experiment in order to return to idle temperature before opening the lid and removing the cartridge.
- Do not operate after the equipment malfunctions or has been damaged in any manner. Return the instrument to the manufacturer for service for examination, repair, electrical or mechanical adjustment.

Electrical Safety

- Connect to the equipment the proper specified power supply only. In order to guarantee the electrical safety requirements, the power supply must be provided by means of the proper AC/DC adapter only. The power supply is provided by Hyris S.r.l. with the equipment. The compliant power supply model is the following one, with the input and output characteristics reported:

  Power supply

Manufacturer	CUI Inc
Model	SDI65-12-U
Input	100 ~ 240 V c.a.– 50-60 Hz
Output Voltage	12 VDC
Current Rating	5 A

WARNING

The equipment must be powered only with the power supply provided by the manufacturer in the equipment, no other power supplies are allowed due to the electrical safety of the power connection.

  Equipment electrical information:

Manufacturer	Hyris S.r.l.
REF	H0006
Input voltage	12VDC
Input current	4500 mA (Max)

  Please unplug the power supply when the equipment is not in use.
- Do not connect additional Multiple Portable Socket-Outlet or extension cord. Multiple portable socket-outlet or extension cord shall not be connected to the system.

- Observe the IEC 60950-1 standard in case of connection with other instruments. The connection of the equipment with other devices, for example with the dedicated computer, is allowed only when the safety requirements for the user and the environment are not compromised. If the Manual does not contain enough information about the possibility of interconnection with other devices, the user should contact the manufacturer to have information about the effects that coupling devices may have on the user and the environment.

- Replace damaged parts immediately. Cables, connectors, accessories, or other parts of the equipment must be replaced immediately when damaged or not working correctly. In these cases, contact the manufacturer.

- Do not connect items (accessories and peripherals) which are not specified as part of the system expressly indicated by Hyris S.r.l. In order to guarantee all the safety requirements, it is necessary to use only the accessories and peripherals specified in this Manual as part of the system, which have been tested with the equipment. The usage of accessories and consumer goods supplied by other manufacturers or not specifically indicated by Hyris S.r.l. does not guarantee the safety and the correct working of the equipment. Use only peripherals in compliance with the standards of the class they belong to.

- Check the functionality of the system before starting any usage. It is strongly recommended to check the overall functionality of the system before starting any usage. In case any anomalies or malfunctioning should be noticed, immediately switch off the system and ask for service to qualified personnel.

- Periodically check that all the system works regularly. It is strongly recommended to periodically check that all the system works regularly without any sign of malfunctioning. If any anomalies or flat traces should be noted act as in the previous warning.

Working Environment Safety

- The equipment is designed to be used in laboratory environment. The equipment is designed for professional laboratory use, according to IEC 61010 Part 1 – General requirements.
- The equipment and its internal parts are protected against the inflow of liquids according to IEC 61010 Part 1 – General requirements. The equipment is protected against the dripping, spraying and splashing of water and relevant harmful effects. Avoid submitting the equipment to the risk of water jetting or temporary and continue immersion because its protection degree does not guarantee protection of internal parts against ingress of liquids. Do not use the equipment where such risks are present. Devices in which liquids have accidentally penetrated must be immediately cleaned and checked by authorized qualified staff.
- Use the equipment within the environmental limits of specified temperature and humidity. The equipment is designed to work in normal environmental conditions that, in compliance with the IEC 61010 Part 1 – General requirements:
  - Indoor usage
  - Altitude up to 2000 m
  - Ambient Temperature range +5°C / +40°C
  - Maximum Relative Humidity 80% for temperatures up to 31°C, decreasing linearly to 50% relative humidity at 40°C.
- The equipment could heat up during its normal use. This aspect should be considered as a normal characteristic of the equipment due to the high integration of the electronic circuitry inside. The equipment heating up should not be considered as a potential fault or as a defect of the equipment itself.
- Make sure the electric wiring of the building is efficient before connecting the power supply to the mains. When the equipment is connected to the environmental mains, make sure that the building wiring is correctly functioning and efficient and compliant to the local regulations and standards.
- Be careful using the equipment in locations disturbed by strong magnetic fields. The equipment is compliant with the EMC requirements (Electromagnetic Compatibility) according to what specified by the standard IEC 61326 Part 1 – General Requirements In every case it is recommended to keep the equipment away from disturbance sources and induced electromagnetic fields surpassing the values prescribed by the standard in order to avoid any possible instabilities and malfunctioning of the equipment. For more detail about device classification and minimum distances, please refer to paragraph Electromagnetic compatibility of the present manual.
- Be careful using the equipment near short-wave or micro-wave devices. If the equipment is used in an area where there are also short-waves or micro-wave devices, it is necessary to remember that these may cause instability and interfere with the correct working of the equipment. Do not use the equipment near X-ray or diathermy devices.

Electromagnetic Compatibility

This laboratory device is designed for use in electromagnetic environments declared in compliance with the following international standards:

- IEC 61326-1: Electrical equipment for measurement, control and laboratory use – EMC requirements - Part 1: General requirements.

The operator must assure that the device is used in an environment compliant to this standard. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operations of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

For this purpose, the following measures must be taken:

- The floor should be in antistatic material (wood, ceramic, etc.). If covered by synthetic material, relative humidity should be maintained at least at 30%
- The quality of the electrical power supply and the mains frequency magnetic fields should be typical of domestic, commercial and hospital environments
- If the operator has to work without a break while power supply is interrupted, it is necessary to have power supplied through a UPS (Uninterruptible Power Supply) unit

Intended use

The HYRIS **bCUBE™** is an instrument designed to be used to perform amplification of genetic material by isothermal amplification or real-time PCR, and simultaneously verify the presence of a target DNA or RNA sequences via fluorescence detection. HYRIS **bCUBE™** shall be used in conjunction with the HYRIS disposable cartridges (16-wells and 36-wells) and the control software (HYRIS **bAPP™**) supplied by Hyris Srl.
For professional use only.

Module

HYRIS **bCUBEplus** is an optical, electrical and mechanical instrument which does the following:

- Hosts the disposable cartridge
- Controls the cartridge temperature
- Optically excites the probes contained in the samples and reads out the fluorescent signal

HYRIS **bCUBEplus** as a product includes its power supply and its Ethernet cable connection to Windows PCs and LAN.

Applied standards

- EN 61326-1:2021: Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
- EN 301 489-1 V.2.2.3: Electro Magnetic Compatibility (EMC) standard for radio equipment and service. Part 1: Common technical requirements. Harmonized standard covering the essential requirements of article 3.1b of directive 2014/53/EU
- EN 62311:2020: Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0Hz – 300 GHz)
- ETSI EN 300 328 V2.2.2: Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EY
- EN 62471:2010: Photobiological-safety
- EN 61010-1:2012: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
- EN 61010-2-010:2019: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials

Principle of operation

HYRIS **bCUBEplus** is a bio-molecular analysis tool designed to obtain DNA amplification and concurrent real-time detection. RNA amplification/detection is also possible using Reverse Transcription techniques.
DNA amplification can be obtained either via isothermal (LAMP) or thermal cycling (Real-Time PCR) protocols.
Target DNA detection is obtained via optical measurement of the sample fluorescence, coming by specific fluorophores present in the analysis mixture.
HYRIS **bCUBEplus** is designed to be used in conjunction with dedicated disposable cartridges, supplied by Hyris S.r.l. These cartridges can come in different versions, housing different numbers of reaction chambers (wells) and allowing different samples volume (10-30 µl).

WARNING

HYRIS **bCUBEplus** must be used only with original cartridges provided by Hyris S.r.l. Further details on the cartridge are available in Cartridge handling section.

HYRIS **bCUBEplus** can be controlled by Desktop PC / Laptop / Tablet / Smartphone, using Ethernet or WiFi connection.
HYRIS **bAPP™** software interface works online on most operating systems (Windows, Linux, MacOS, iOS, Android). It allows to create and manage custom recipes or launch analyses which are shared among a selected work group (**Swarm**).

HYRIS **bPANEL**™ software interface (for Windows PC / Tablet) allows the user to work totally offline, using recipes created with HYRIS **bAPP**™.

HYRIS bCUBEplus functions

HYRIS **bCUBEplus** is characterized by following features:

- Heating/Cooling the Hyris cartridge and its content according to the thermal protocol sent via HYRIS **bAPP**™ or HYRIS **bPANEL**™ in order to obtain DNA/RNA amplification
- Real time detection of fluorescences from DNA/RNA amplification in **FAM**™, **HEX**™ ,**CY5**™, **ROX**™
- Connection to Hyris Services for remote real time data monitoring through HYRIS **bAPP**™ web application
- Offline use through HYRIS **bPANEL**™
- Connection to internet using Ethernet or WiFi connection
- Real time device status communication through the Status LEDs on the top of the instrument
- Assisted results interpretation according to parameters set in related protocol sent by HYRIS **bAPP**™ or HYRIS **bPANEL**™

Limitations

- HYRIS **bCUBEplus** is a bio-molecular analysis tool for professional use only
- Detectable samples/wells is limited by the number of the Hyris Cartridge model used in the experiment
- HYRIS **bCUBEplus** connectivity to Hyris System can be limited by Company or Private network settings, like custom blocks or firewalls
- HYRIS **bCUBEplus** can work offline with HYRIS **bPANEL**™ for temporary internet connection unavailability. After one week of disconnection, internet connection is mandatory for continuing working with the device.
- HYRIS **bCUBEplus** can perform analyses only on available wavelengths (**FAM**™, **HEX**™, **CY5**™, **ROX**™), according to the HYRIS **bCUBEplus** model
- HYRIS **bCUBEplus** not provided with external battery.

Packing content

The following items will be found in the provided box:

- HYRIS **bCUBEplus** (Figure 1a)
- Ethernet cable (Figure 1b)
- Power Supply including European and North American power cords (Figure 1c). Characteristics:
  - Input: 100 ~ 240 V c.a. 1.4A 50/60Hz
  - Output: 12V DC 5A
  - Power: 60W
- USB stick with HYRIS **bPANEL**™ software installer and User Manual (Figure 1d)

Note: Please check the presence of all these items. Remove the items carefully from the shipping box and inspect them for any external damage. If any of the parts are missing or damaged, contact the manufacturer prior to installation.

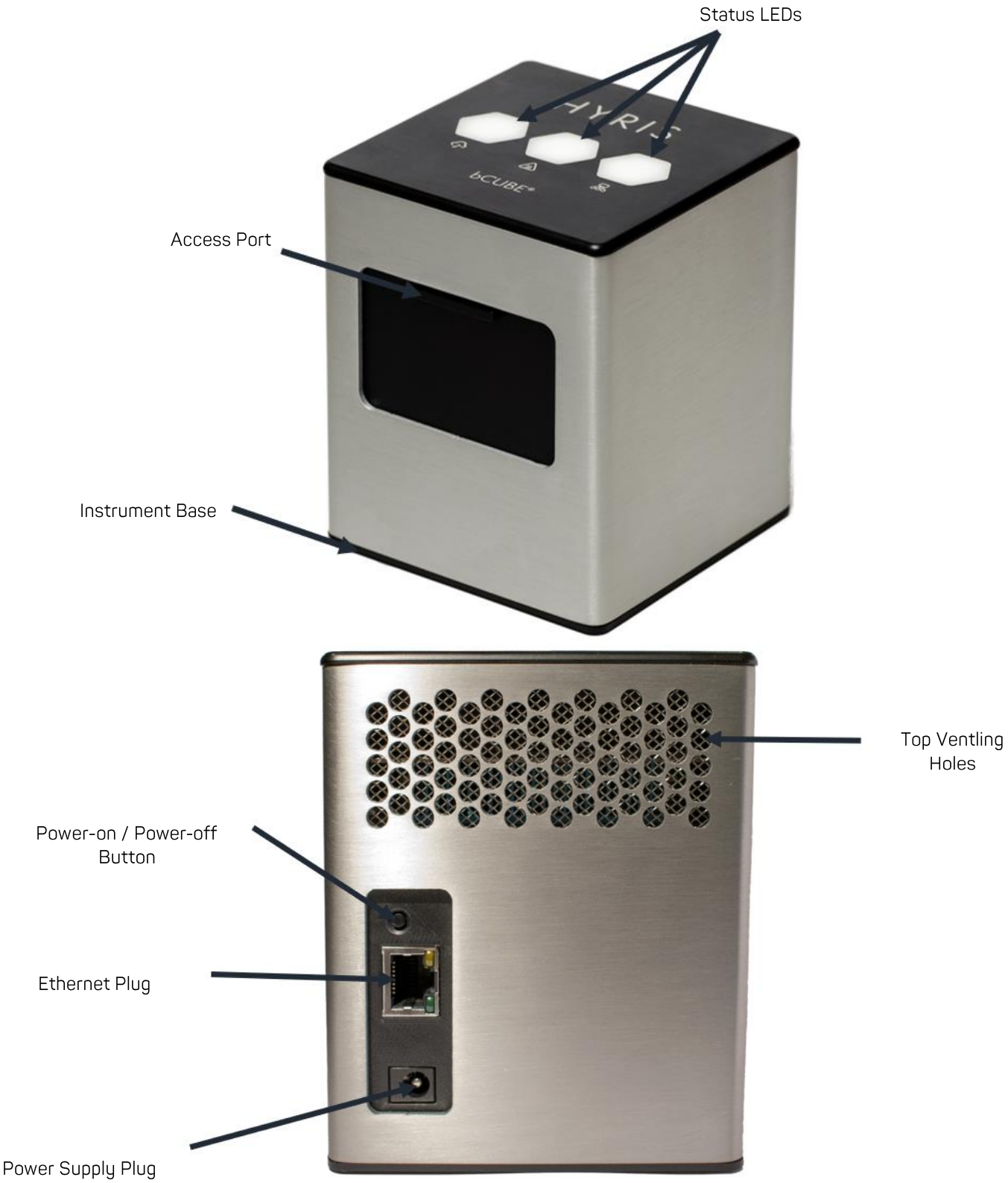
Disposal information

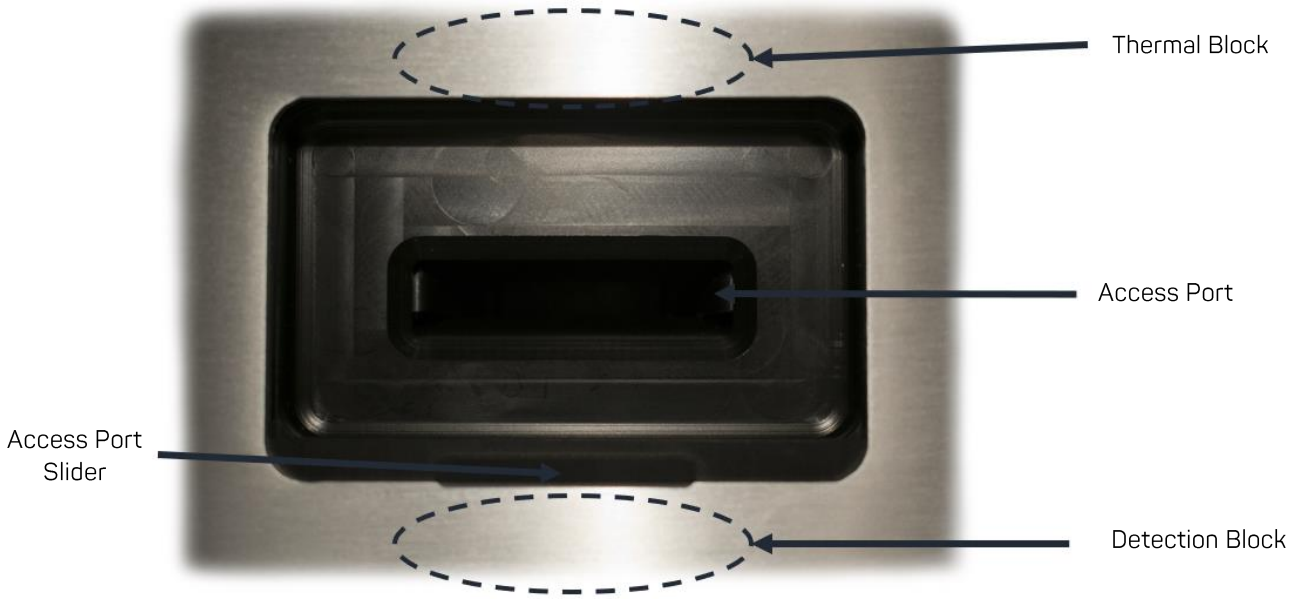
- Dispose of the used cartridges according to local, state and federal regulations
- Treat all human specimens and all consumables that have come into contact with the samples, including the cartridge, as capable of transmitting infectious agents
- Hyris Cartridges: dispose the cartridge as Routine biohazard waste
- HYRIS **bCUBEplus** : the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
- Refer to the datasheet of the Hyris developed assays (HYRIS **bKIT™**)

WARNING

Please refer to local codes and regulations for proper disposal/recycle requirements of packaging and consumer materials and of the device when at its "end of life".

HYRIS bCUBEplus Instrument Overview





Description of the features highlighted in the pictures above:

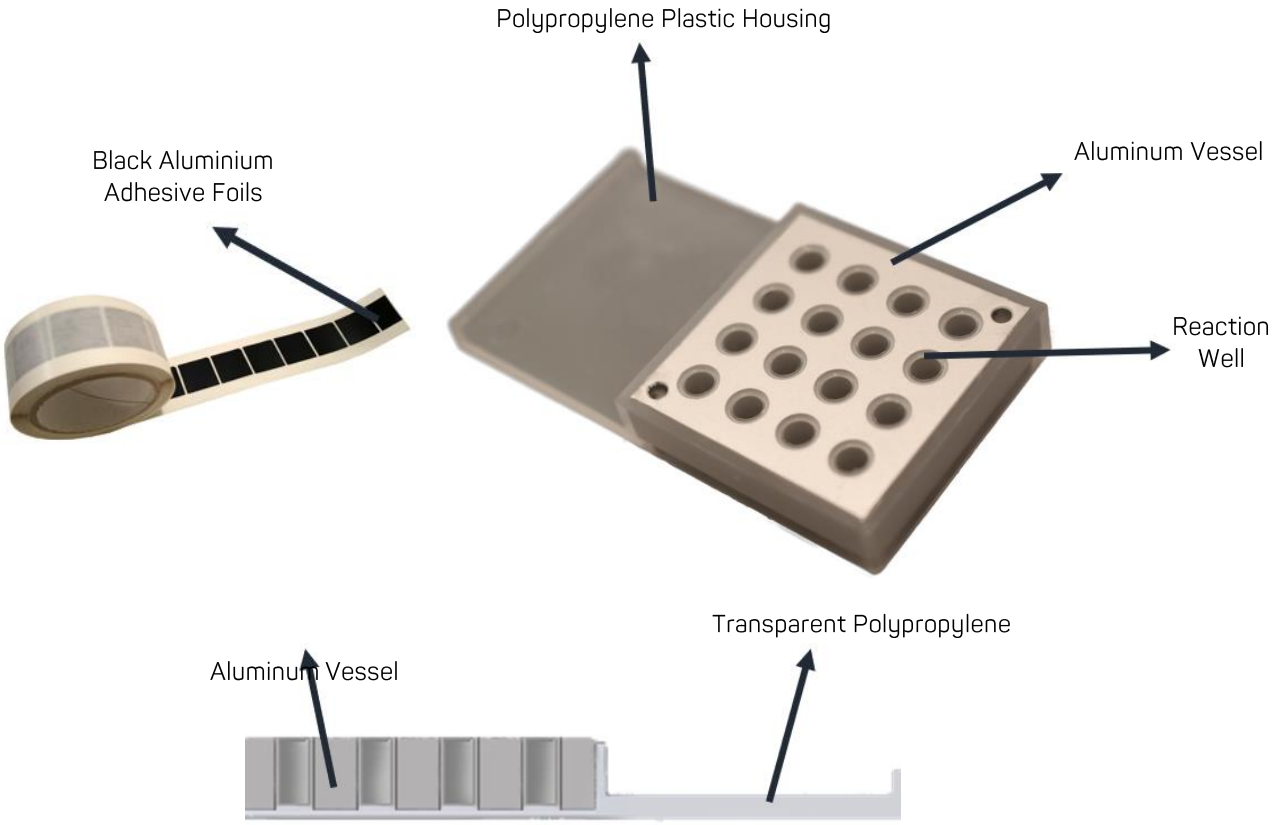
- Access Port Slider: opened to insert/remove the cartridge inside HYRIS **bCUBEplus** . To be kept closed during operations.
- Access port: insert the cartridge here. Always push the cartridge up to the end of the port.
- Thermal Block: precisely controls the temperature of the cartridge and contained samples. Heating/Cooling is obtained with a Peltier element.
- Detection block: features high brightness LEDs with dichroic filters for fluorophores excitation. Detection is obtained thanks to a CMOS sensor with dichroic filters matched to fluorophores emission wavelengths.
- Top venting holes: allow air exchange between the inside of the Instrument and the ambient
- Power supply Plug: insert here the 12 VDC adapter jack
- Power-on/Power-off button: press shortly to wake up the instrument from Stand-By. When the machine is running, long press (about 5 seconds) to safely power down the HYRIS **bCUBEplus**
- Ethernet Plug: insert here the Ethernet cable for Windows PC / Network communication
- Status LEDs: Give information about the status of the instrument

WARNING

Do not cover the top venting holes. Covering those areas may result in excess over-heating leading to instrument malfunctioning/failure.

Hyris Disposable Cartridge

HYRIS **bCUBEplus** is designed to be used in conjunction with special disposable cartridges supplied by Hyris S.r.l. A picture of the cartridge and a schematic cross section are reported below, with highlighted the main features.



The disposable cartridge is composed of an Aluminum Vessel, with trough holes forming Reaction Wells. These holes are sealed by the Polypropylene Housing, which contains the aluminum part. The transparent Polypropylene Housing bottom allows optical fluorescence detection from below the cartridge.
After the samples have been loaded in the Reaction Wells, the top of the cartridge should be sealed with one pre-cut Black Aluminum Adhesive Foil supplied by Hyris S.r.l.

WARNING

HYRIS **bCUBEplus** must be used only with original disposable cartridges provided by Hyris S.r.l. (contact manufacturer for applicable product codes). Do not use other cartridges. The use of other cartridges will compromise the security of the device and the results of the experiments.

System Requirements

In order to operate HYRIS **bCUBEplus** instrument, the user should have available:

- A PC / Laptop / Tablet / Smartphone (see HYRIS **bAPP™ – System Requirements** and HYRIS **bPANEL – System Requirements** sections in respective manuals for more info).
- Hyris Disposable Cartridge
- Stable internet connection for usage with HYRIS **bAPP™**.
- Windows PC / Tablet for usage with HYRIS **bPANEL™** software

See dedicate paragraphs for each of these bullets for more details.

HYRIS bCUBEplus functional operation

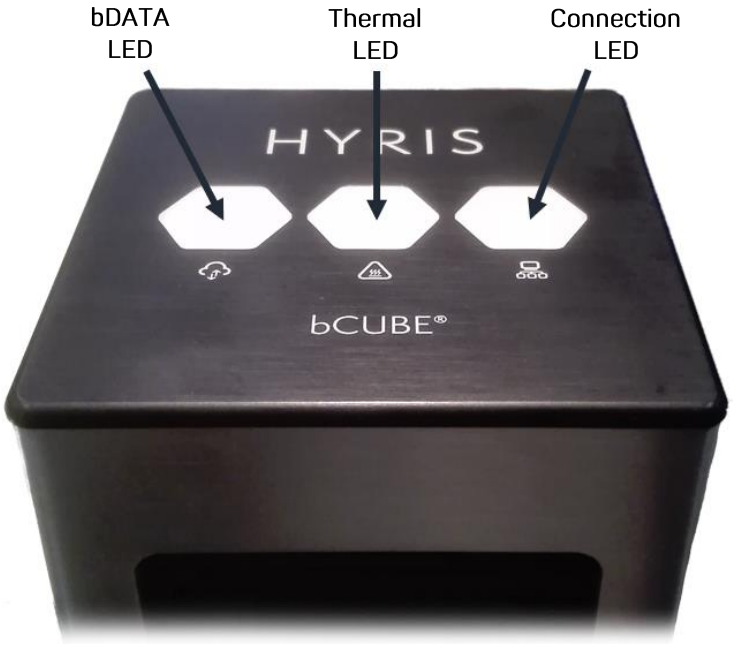
General Information

HYRIS **bCUBEplus** can be controlled either by a Windows PC, through Ethernet/WiFi connection using HYRIS **bPANEL**™ or dedicated HYRIS **bAPP**™.
This section of the manual will guide you through the complete procedure for setting-up and running an experiment in these two modes.
Before running an experiment, the user must verify that all the safety requirements are satisfied, according to the chapter Safety Information of HYRIS **bCUBEplus** User Manual.

Status LEDs

The status of the HYRIS **bCUBEplus** and its functioning are communicated to the user by the different color combinations of the Status LEDs on the top of the device.

- HYRIS **bDATA**™ **LED**: corresponding to the symbol, it indicates the connection status to Hyris server.
  Ready color: green
  When Ready color is on, HYRIS **bCUBEplus** is connected to HYRIS **bDATA**™
- **Thermal LED**: corresponding to the symbol, it indicates if the cartridge is hot or not.
  Ready color: orange
  When Ready color is on, the internal temperature of the HYRIS **bCUBEplus** is not hot. If cartridge is inserted, it can be safely handled
- **Connection LED**: corresponding to the symbol, it indicates the internet connection state of the HYRIS **bCUBEplus**
  Ready color: blue
  When ready color is on, HYRIS **bCUBEplus** is connected to a network



For a graphical representation, the symbol (from left to right: bDATA, Thermal and Connection LEDs) will be displayed in this document when color code explanation is required.

The table below shows a summary of the possible Status LEDs color codes.

bDATA LED:

LED color	Description	User behavior
	Power on/off	Machine is going to power on/off
	Booting	Wait for the power-up routine to complete (**Ready colors**)
	Ready	Ready for operation
	Experiment in progress	Wait for completion (**Ready colors**), do not remove the cartridge (hot!)
	System fault	Contact support@hyris.net
	Missing connection to HYRIS **bDATA™**	Server connection may be not available at the moment. Ready for operation.
	Missing connection for long time	HYRIS **bCUBEplus** is not connecting to Hyris server for long time. See "Troubleshooting" section. Ready for operation.
	HYRIS **bCUBEplus** disabled	HYRIS **bCUBEplus** disabled. Contact support@hyris.net

Thermal LED:

LED color	Description	User behavior
	Power on/off	Machine is going to power on/off
	Booting	Wait for the power-up routine to complete (**Ready colors**)
	Ready	Ready for operation
	Experiment in progress	Wait for completion (Orange or blinking Red-Orange color) do not remove the cartridge (hot!)
	System fault	Contact support@hyris.net
	Hot cartridge	Do not remove the cartridge: hot!

Connection LED:

LED color	Description	User behavior
	Power on/off	Machine is going to power on/off
	Booting	Wait for the power-up routine to complete (**Ready colors**)
	Network connection ok	Ready for operation. HYRIS **bCUBEplus** is connected to a network.
	Experiment in progress	Wait for completion (**Ready colors**) do not remove the cartridge (hot!)
	System fault	Contact support@hyris.net
	No connection	HYRIS **bCUBEplus** is not connected to any network. HYRIS **bCUBEplus** can't communicate. See "Troubleshooting" section

Status LEDs colors: typical conditions

As previously described, the Status LEDs can provide a detailed description of the HYRIS **bCUBEplus** state.
In order to simplify the decoding of the color codes, the typical color combinations are listed in the following table.

LEDs Colors	DESCRIPTION	INTERPRETATION
	• bDATA LED steady green • Thermal LED steady orange • Connection LED steady blue	• HYRIS **bDATA**™ connection OK • Cartridge not hot • Network connection OK
	• bDATA LED steady green • Thermal LED blinking orange and red • Connection LED steady blue	• HYRIS **bDATA**™ connection OK • WARNING: Cartridge hot • Network connection OK
	• bDATA LED blinking green and yellow • Thermal LED steady orange • Connection LED blinking red and yellow	• Missing HYRIS **bDATA**™ connection • Cartridge not hot • Missing network connection
	• bDATA LED blinking green and yellow • Thermal LED steady orange • Connection LED steady blue	• Missing HYRIS **bDATA**™ connection • Cartridge not hot • Network connection OK. HYRIS **bCUBEplus** can be used locally
	• bDATA LED multicolor • Thermal LED multicolor • Connection LED multicolor	• Experiment is running on HYRIS **bCUBEplus**

	• bDATA LED off • Thermal LED off • Connection LED off	• HYRIS **bCUBEplus** off

WARNING

Prior to usage, verify that all the safety requirements are satisfied. If not, the equipment must not be powered, or connected to any other instrument, until such safety conditions are restored.

Technical information

General Information

Product Name	**bCUBEplus**
Manufacturer	Hyris S.r.l.

Operating conditions

- Indoor use
- Temperature range: +5 to + 40 °C
- Maximum relative humidity
  - 80% for temperatures up to 31°C
  - 50% at 40°C (decreasing linearly)

Dimensions, Weight and materials

- Dimensions (W x L x H, mm): 100 x 100 x 120 approx.
- Weight: approx. 1.15 Kg
- Materials:
  - Casing, support mechanics: Anodized Aluminum
  - Internal plastic parts: Acetal resin
  - Cartridge: Aluminum and Polycarbonate or Aluminum and Polypropylene
  - Top LED diffusers: PMMA

AC/DC Power supply

HYRIS **bCUBEplus** must be used only in conjunction with the power supply specified below.

Model	SDI65-12-U
Manufacturer	CUI INC
Input Voltage	100-240 VAC – 50-60 Hz
Output Voltage	12 V
Current Rating (max)	5 A

Light Sources

HYRIS **bCUBEplus** uses high brightness LEDs as light sources, coupled with bandpass filters to achieve narrow wavelength spectrum. The instrument can drive up to 4 LEDs for each detection channel.
Information on Green LEDs:

Luminous flux (single)	114 lm
Dominant Wavelength	520-535 nm

Information on Blue LEDs:

Luminous flux (single)	45,7 lm
Dominant Wavelength	465-485 nm

Information on RED LEDs*:

Luminous flux (single)	62 lm
Dominant Wavelength	620-630 nm

Information on Blue (FAM™) Excitation filters:

Centre Wavelength	472 nm
Band width	30 nm

Information on Green (HEX™) Excitation filters:

Centre Wavelength	530 nm
Band width	11 nm

Information on RED (CY5™) Excitation filters:

Centre Wavelength	630 nm
Band width	20 nm

Information on Amber (ROX™) Excitation filters:

Centre Wavelength	570 nm
Band width	20 nm

HYRIS bCUBEplus Wiring / Installation / Power-Up

In order to power-up HYRIS **bCUBEplus** , do the following:

- Make sure your PC/Laptop has nothing connected to the Ethernet port (HYRIS **bCUBEplus** off and not connected)
- Connect the AC plug of the supplied 12 VDC Adapter to an AC outlet, with rating 5 A/90 ~ 264 V c.a., 60/50 Hz
- Connect the power jack of the 12 VDC Adapter to HYRIS **bCUBEplus** Power Supply Plug
- If Ethernet connection is required, connect one end of the Ethernet cable to the Windows PC Network Adapter (LAN) and the other end to HYRIS **bCUBEplus** Ethernet Plug.
- Press the Power-on/Power-off button on HYRIS **bCUBEplus** to switch the instrument on. Wait for the Status LEDs to show that the HYRIS **bCUBEplus** is ready.

WARNING

The equipment must be powered only with the power supply provided by the manufacturer in the equipment, no other power supplies are allowed to guarantee the electrical safety of the power connection.

WARNING

The equipment must be connected to a computer only with the Ethernet cable provided by the manufacturer in the equipment, no other Ethernet cables are allowed to guarantee the electromagnetic compatibility of the connection.

Preparing for operation

Before running an experiment, verify the following conditions:

- HYRIS **bCUBEplus** is cabled and powered as described in HYRIS **bCUBEplus** Wiring / Installation / Power-Up section
- HYRIS **bCUBEplus** is placed on a flat surface, in stable position

- The Status LEDs are indicating that HYRIS **bCUBEplus** is operative and can communicate to a device/web app.

Turning off HYRIS bCUBEplus

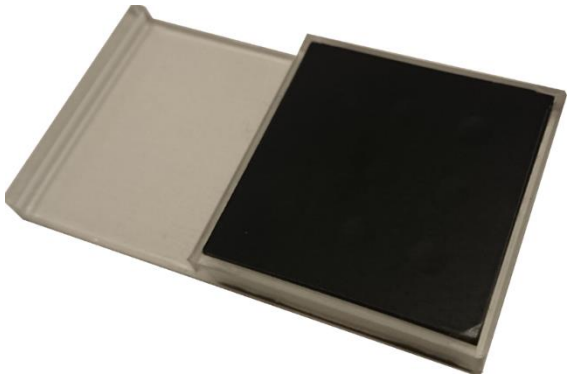
In order to switch off the instrument, keep pressed the Push Button present on HYRIS **bCUBEplus** until the Status LEDs turn yellow. Wait for the Status LEDs to turn off, then disconnect the power cord. Avoid to keep the power cord plugged while HYRIS **bCUBEplus** is not in operation, in order to save energy and lengthen the life of the internal battery.

Cartridge handling

Preparing the Cartridge

In order to prepare a Cartridge for an experiment, follow the procedure below:

- Take out a new cartridge from its clean envelope.
- Place the cartridge in a stable position on a flat surface.
- Fill in each of the reaction wells with the sample to be analyzed.
- Take note of the position of each sample.
- When all the samples have been loaded, carefully seal the top of the cartridge with one of the black aluminum foils supplied by Hyris S.r.l. Please, make sure that the foil surface is absolutely flat and free of folds, to guarantee optimum thermal contact between the thermal block and the cartridge.
- The Cartridge is now ready to be loaded.



Cartridge after sealing

Load the cartridge inside HYRIS bCUBEplus

In order to load a cartridge inside HYRIS **bCUBEplus** , follow this procedure:

- Open the **Access port slider**.
- Insert the cartridge in the **Access port.**
- Verify the correct cartridge placement by moving it back and forth: if it's correctly pressed up against the thermal block, some force will be necessary.
- Close the **Access port slider**.

Removing the cartridge

As soon as an experiment is completed, the cartridge is cooled down near to room temperature and can be removed. Never try to remove the cartridge while an analysis is running, as it gets hot during operation.
In order to remove the cartridge:

- Open the **Access port slider**
- Remove the cartridge by pushing the handle downward and, at the same time, pull it out of the instrument
- Close the **Access port slider**

Push the handle downward and pull the cartridge in order to extract it from HYRIS **bCUBEplus**

WARNING

Before launching the experiment on the HYRIS **bCUBEplus** , check the cartridge is fully pushed up to end run.

WARNING

Never tilt or flip the cartridge upside down or directly touch the wells.

WARNING

Never try to remove the cartridge while an analysis is running or while the central Status LED is blinking red and yellow, as it gets hot during operation and can cause injuries.

WARNING

Never use the same cartridge for multiple experiments. Contamination from past analysis will lead to incorrect results.

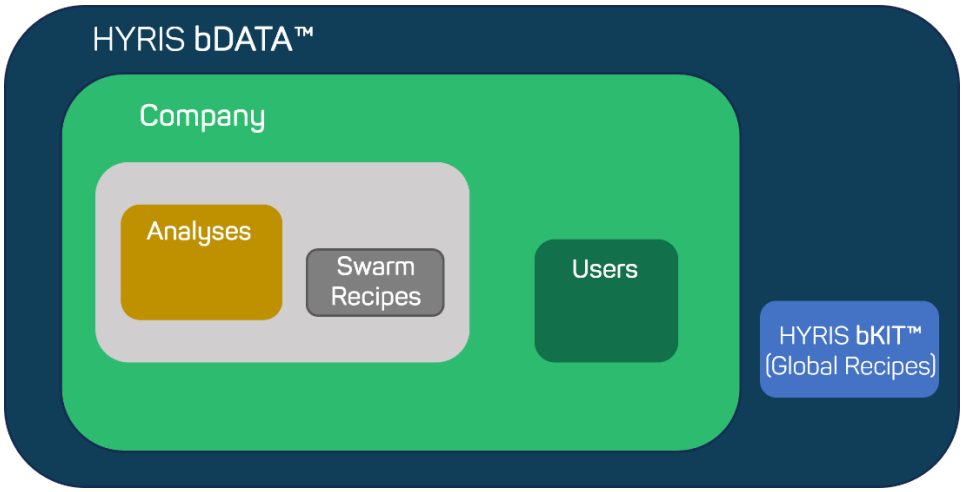
WARNING

For Cartridge disposal after use, please refer to the directives and regulations concerning disposable requirements of the country in which the device is used.

Hyris Network

Introduction

Hyris technology allows users to share analysis results all around the world in real time thanks to an organized structured online work environment: the HYRIS **bDATA**™.



Users and user profiles

After the purchase of the first HYRIS **bCUBEplus** by a customer, a **Company** is added to the HYRIS **bDATA**™. Each **Company** is identified with an account with **Administrator** permissions. The **Administrator** can create/delete **Users**, deciding each user's permissions, and **Swarms**.

- The **Swarm** is a container which collects **Analyses** and **Recipes**. Each company could create many **Swarms**, each of these storing different sets of **Analyses** and **Recipes**.
- The **User** is the operator which is supposed to operate with the HYRIS **bCUBEplus** .
  Each **User** is assigned by the **Administrator** to one or more **Swarms**, so that it's blind to other **Swarm**'s contents. On the contrary, the **User** can interact with **Analyses** and **Recipes** linked to its **Swarms** accordingly to its permissions.
- The **User** can finally interact only with the HYRIS **bCUBEs**™ which are assigned to the **Company**.

Different **Users** have different permissions according to the assigned role:

Role	Permissions
Administrator	• Create/Edit **Recipes** • Create/Edit **Users** • Create/Edit **Swarms** • Manager and Operator permissions
Manager	• Create/Edit **Recipes** • Create/Edit new **Analyses** • View all analyses in the assigned **Swarms**
Operator	• Create new **Analyses**
Reviewer (For Certifier Companies only)	• Create/Edit new **Analyses** • View all analyses in the assigned **Swarms** • Create/Edit **Recipes** • Certificate **Analyses**

The creation and management of different **Swarms**, **Recipes** and **Analyses** are performed using the online HYRIS **bAPP**™.

Connectivity

Introduction

In order to perform the above-mentioned functions, the connection of the HYRIS **bCUBEplus** with other devices is mandatory.

Important notice on Local Area Network connectivity

The remote access to the HYRIS **bCUBEplus** is possible only via the HYRIS **bDATA**™ service after authentication and restricted to allowed user accounts. Conversely, the connection to a HYRIS **bCUBEplus** within the same local network for loading protocols or reading data does not require authentication. For this reason, it is of extreme importance that the HYRIS **bCUBEplus** instruments are connected only to trusted networks with proper security controls in place.

LAN connection available

In case internet connection is available, HYRIS **bCUBEplus** can be controlled by both HYRIS **bPANEL**™ and HYRIS **bAPP**™ in real time and data can be shared online. Different connections modes are possible.

HYRIS bCUBEplus wired to Local Network

In case you connect your HYRIS **bCUBEplus** to your Local Area Network (LAN) with an Ethernet cable, no particular set-up is necessary. In order to control it from your PC with HYRIS **bPANEL**™, just make sure that your PC/Laptop is connected to the same network as HYRIS **bCUBEplus**

HYRIS bCUBEplus WiFi connection

In case you connect your HYRIS **bCUBEplus** to your Local Area Network (LAN) with a WiFi connection, no particular set-up is necessary. In order to control it from your PC with HYRIS **bPANEL**™, just make sure that your PC/Laptop is connected to the same network as HYRIS **bCUBEplus** . Please note that the selected WiFi's credentials have to be previously saved to HYRIS **bCUBEplus** .

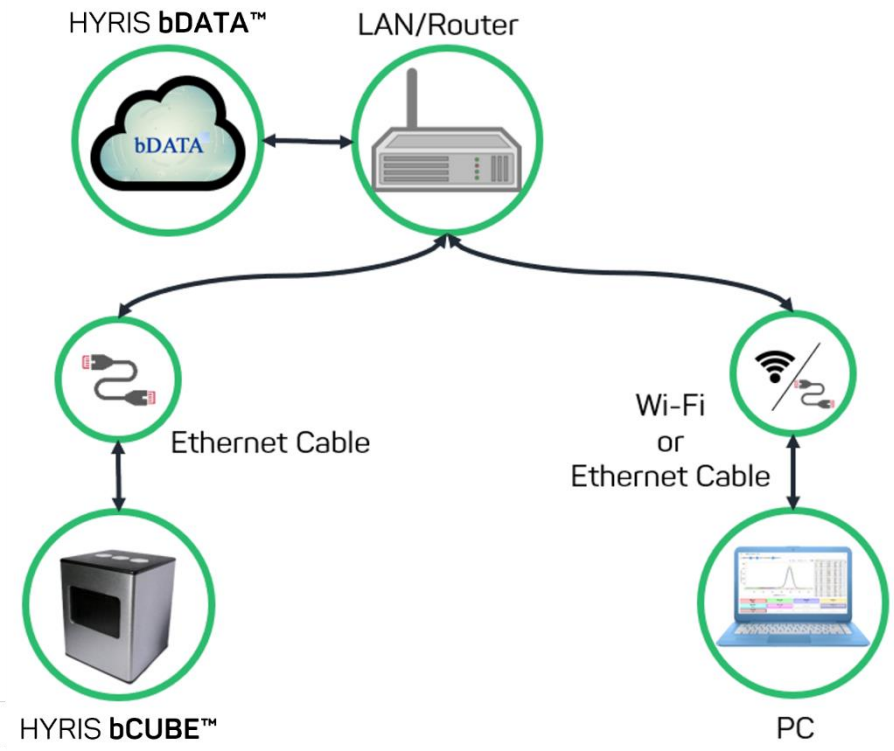
Possible configurations

Several configurations to connect HYRIS **bCUBEplus** to LAN are available:

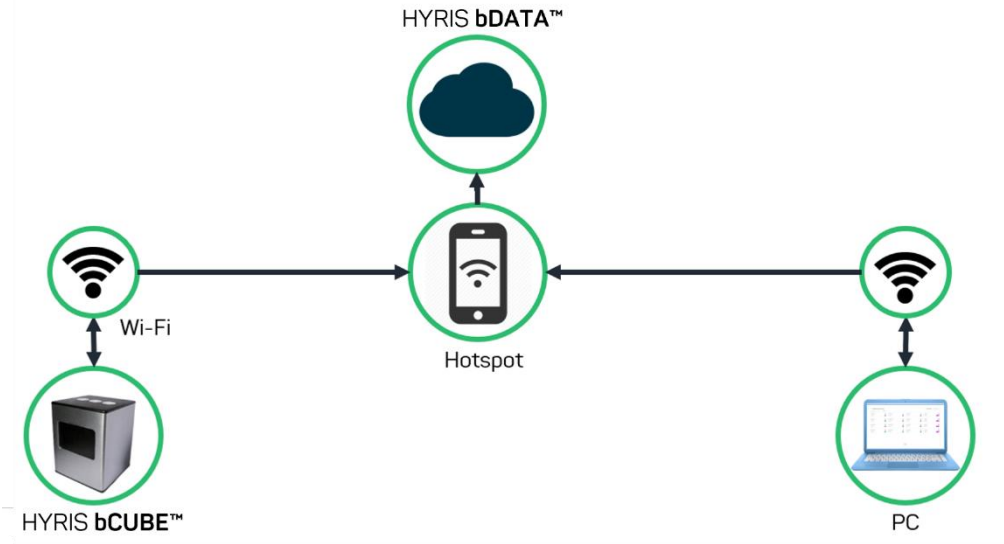
- HYRIS **bCUBEplus** WiFi is not already set up: HYRIS **bCUBEplus** is directly connected to the router or the PC via Ethernet cable and PC is connected to LAN via WiFi or to directly the router via Ethernet cable. This configuration is mandatory in case of first use of the device. To configure the WiFi set up of the HYRIS **bCUBEplus** , see the Set HYRIS bCUBEplus WiFi chapter.
- HYRIS **bCUBEplus** WiFi is already set up: the device is connected to LAN via WiFi and the PC is connected to LAN via WiFi or directly via Ethernet cable.
  Another option is to connect the HYRIS **bCUBEplus** to internet through a mobile phone hotspot

WARNING

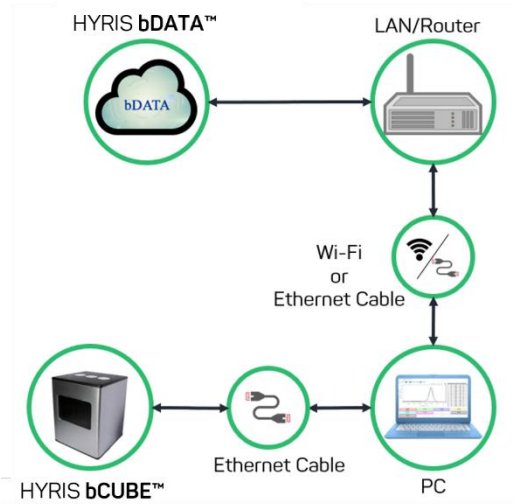
Check that the WiFi signal is stable and strong where HYRIS **bCUBEplus** is placed. If not, communication issues or delays may occur.



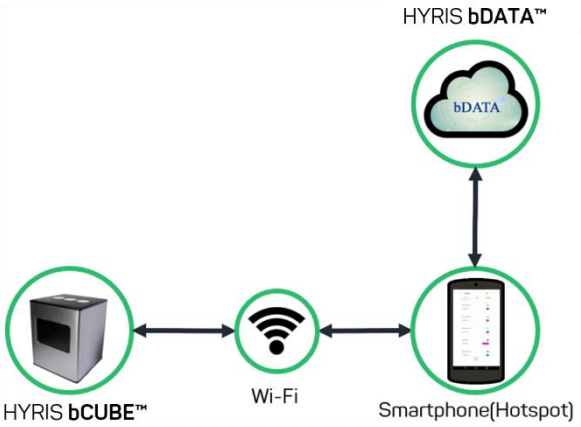
Both HYRIS bCUBEplus and PC connected to LAN via Ethernet cable or WiFi (RECOMMENDED)



Both HYRIS bCUBEplus and PC connected to Hotspot



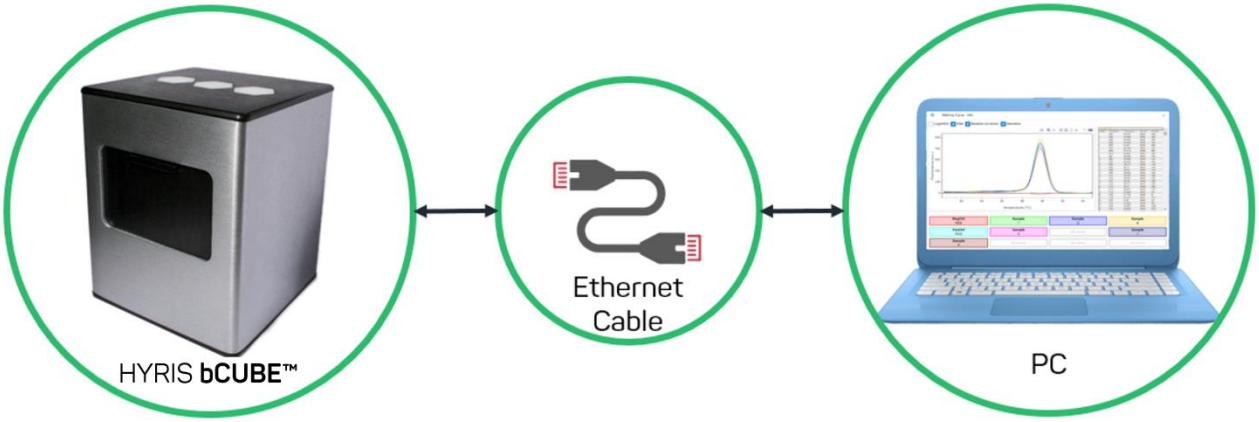
HYRIS bCUBEplus connected to PC via Ethernet cable, PC connected to LAN via Ethernet cable or WiFi – RECOMMENDED if WiFi is not already set up for the current LAN or if LAN ports are not accessible



HYRIS bCUBEplus connected and controlled by smartphone (hotspot)

Internet connection not available

If internet connection is not available, HYRIS bCUBEplus can be controlled and monitored by HYRIS bPANEL™ (see dedicated manual).



In this case, the Ethernet connection between the PC and the HYRIS **bCUBEplus** is mandatory.

WARNING

HYRIS **bCUBEplus** must be connected periodically to Hyris server in order to renew its license. Let it connect to the Internet as often as possible, especially just before planned offline use.

Set HYRIS bCUBEplus WiFi

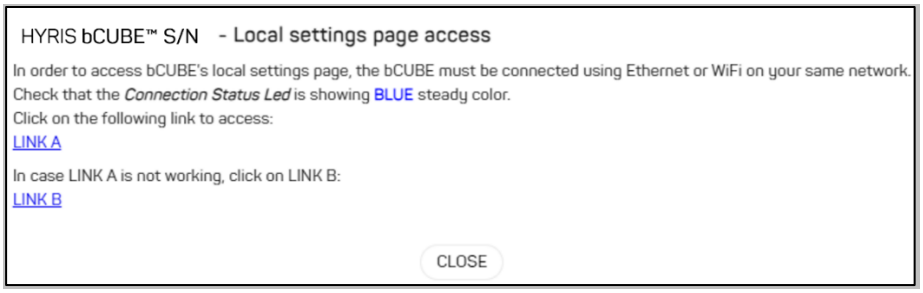
Two procedures are available for setting the WiFi credentials on the HYRIS **bCUBEplus** :

- In case the HYRIS **bCUBEplus** is already **Connected** and **Available**, the WiFi credentials can be directly set from the **Devices section** in HYRIS **bAPP™**
- In case HYRIS **bCUBEplus** is connected via Ethernet cable to PC as the only available first connection, WiFi credentials can be set through the **Local Settings page**

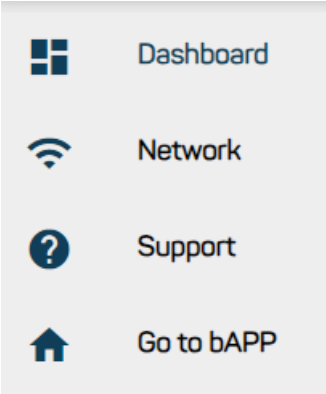
Local settings page

The **Local Settings page** is used to access the selected HYRIS **bCUBEplus** if the HYRIS **bCUBEplus** and the controlling device (PC or Smartphone) are connected to the same network.

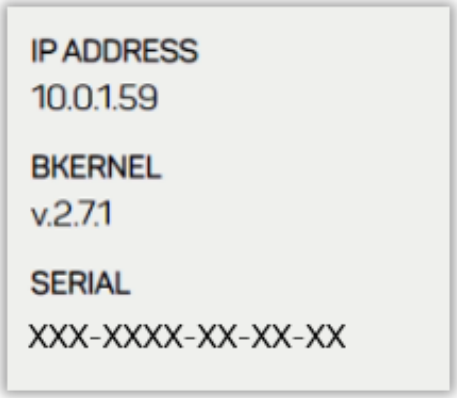
The access to this page can be performed by both clicking on the relative button  in the **Devices section** of the HYRIS **bAPP™** and select one of the suggested links (Link A or Link B)



or by typing the following link in any browser address bar: **http://*bCUBE_hostname*** (put the desired HYRIS **bCUBEplus** hostname, which can be provided by Hyris).
After access is achieved, the list of the available sections is shown on the top left of the screen:

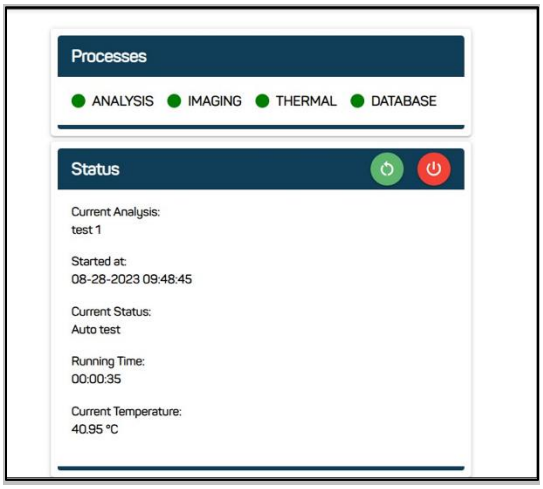


Also, general information about the HYRIS **bCUBEplus** is reported to the bottom left of the screen.



Dashboard

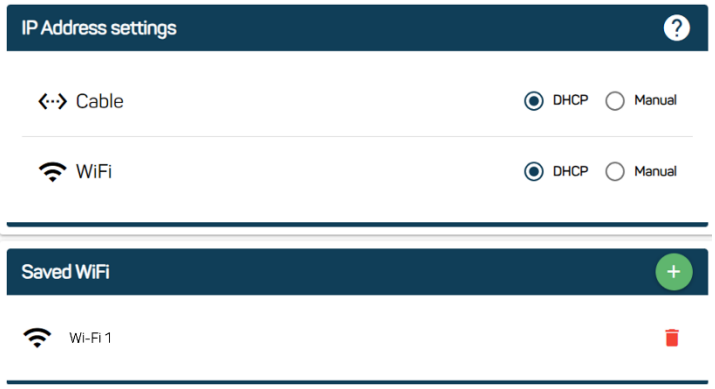
The general information about the HYRIS **bCUBEplus** is shown in the "**Status**" section.



Network

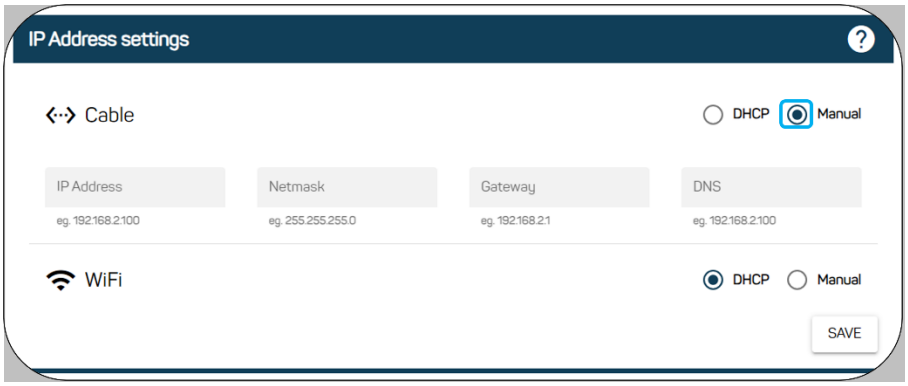
In this section, the user can manage the HYRIS **bCUBEplus** saved WiFi. The saved WiFi are listed. Following actions are allowed from this section:

- Manage the **IP Address settings**: switch from dynamic IP (**DHCP**) to static IP (**Manual)**
- Manage and add **Saved WiFi**
- See **DNS** and **Interfaces** status



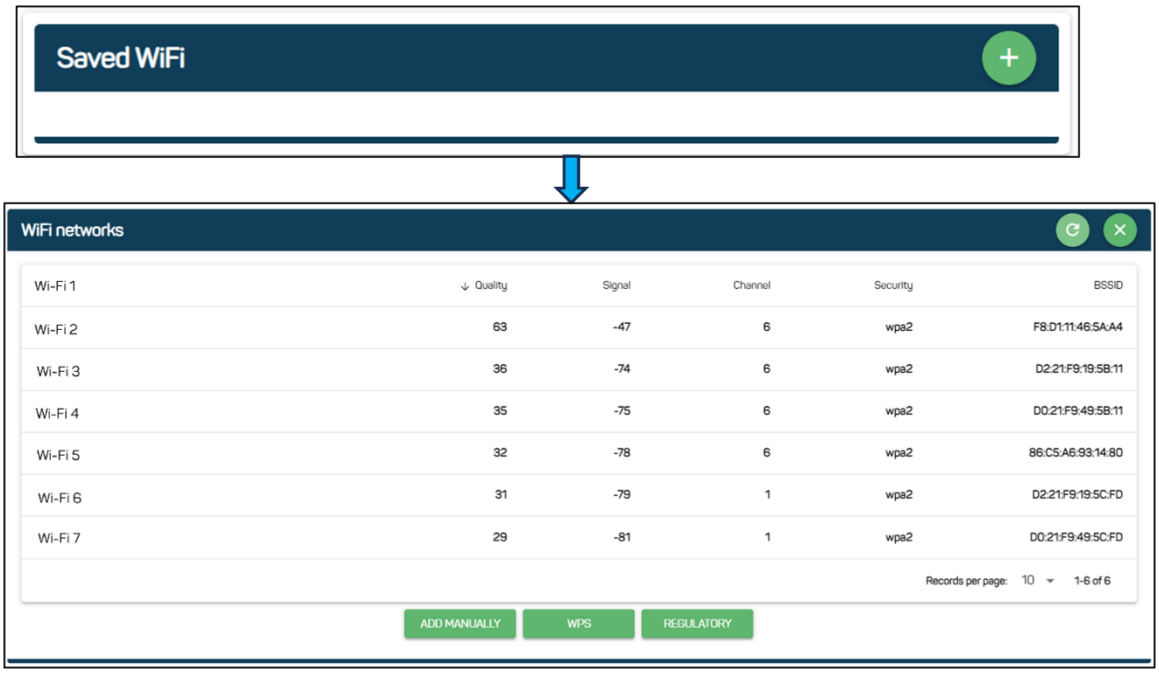
Manage IP Address settings: dynamic VS static IP

In case **DHCP** is selected in relation to a certain interface (Ethernet or WiFi), HYRIS **bCUBEplus** will expect a DHCP to assign a dynamic IP to the device (default).
In case the **Company network** is not provided with DHCP, **static IP** can be manually set by clicking on the **Manual** option and inserting the required information. HYRIS **bCUBEplus** reboot is requested after saving the settings.



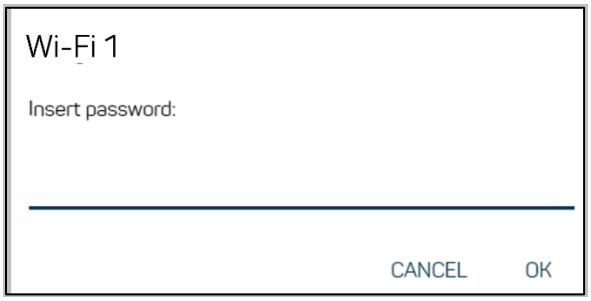
Manage and add Saved WiFi

Click on the  button to search for available Wi-Fi; available Wi-Fi and related signals information are shown in the table



Click on the button to scan the network;

Click on the desired WiFi and add the correspondent password.



When the desired Wi-Fi network is saved, go back to the HYRIS **bAPP™** and unplug the Ethernet cable from the HYRIS **bCUBEplus** . After some seconds, the Status LEDs will show the Ready colors and the HYRIS **bCUBEplus** will be ready to be used.

The **user** can delete the saved Wi-Fi clicking on the button.

WiFi can also be added manually, by clicking on the ADD MANUALLY button. In this case, insert the desired SSID and the related password, then confirm the settings as previously explained.

WPS connection is also possible: click on the WPS button. You now have 120 seconds to allow WPS connection on your router. After connection is performed, the network will be saved automatically on the HYRIS **bCUBEplus** and the network SSID will appear on the saved WiFi list.

Click on the REGULATORY button and select your Country. This could improve the connectivity performances of the device.

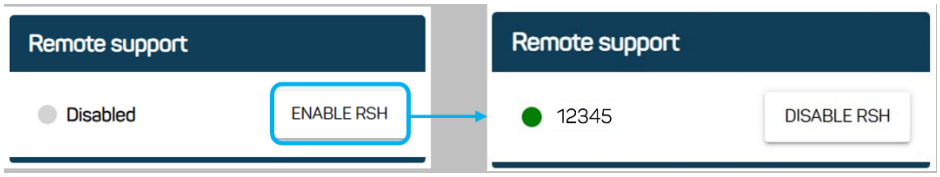
Note: only 2.4GHz, **WPA2** networks are allowed. Make sure no special characters are present in the WiFi SSID.

DNS and Interfaces status

DNS and Interfaces status can be seen by scrolling the page.

Support

This section allows to generate a code for eventual remote support from Hyris support team.



Note: only generate **RSH** code if asked by Hyris support team. This number is randomly and dynamically generated. However, never share this number to unauthorized users.

Controlling HYRIS bCUBEplus via HYRIS bAPP™

HYRIS **bCUBEplus** functioning, operations and settings can be managed and set from HYRIS **bAPP™** when both the PC/Mobile phone and the HYRIS **bCUBEplus** are connected to internet and sharing data to Hyris Services.
HYRIS **bAPP™** functioning, description and procedures can be found in HYRIS bAPP™ – User Manual.

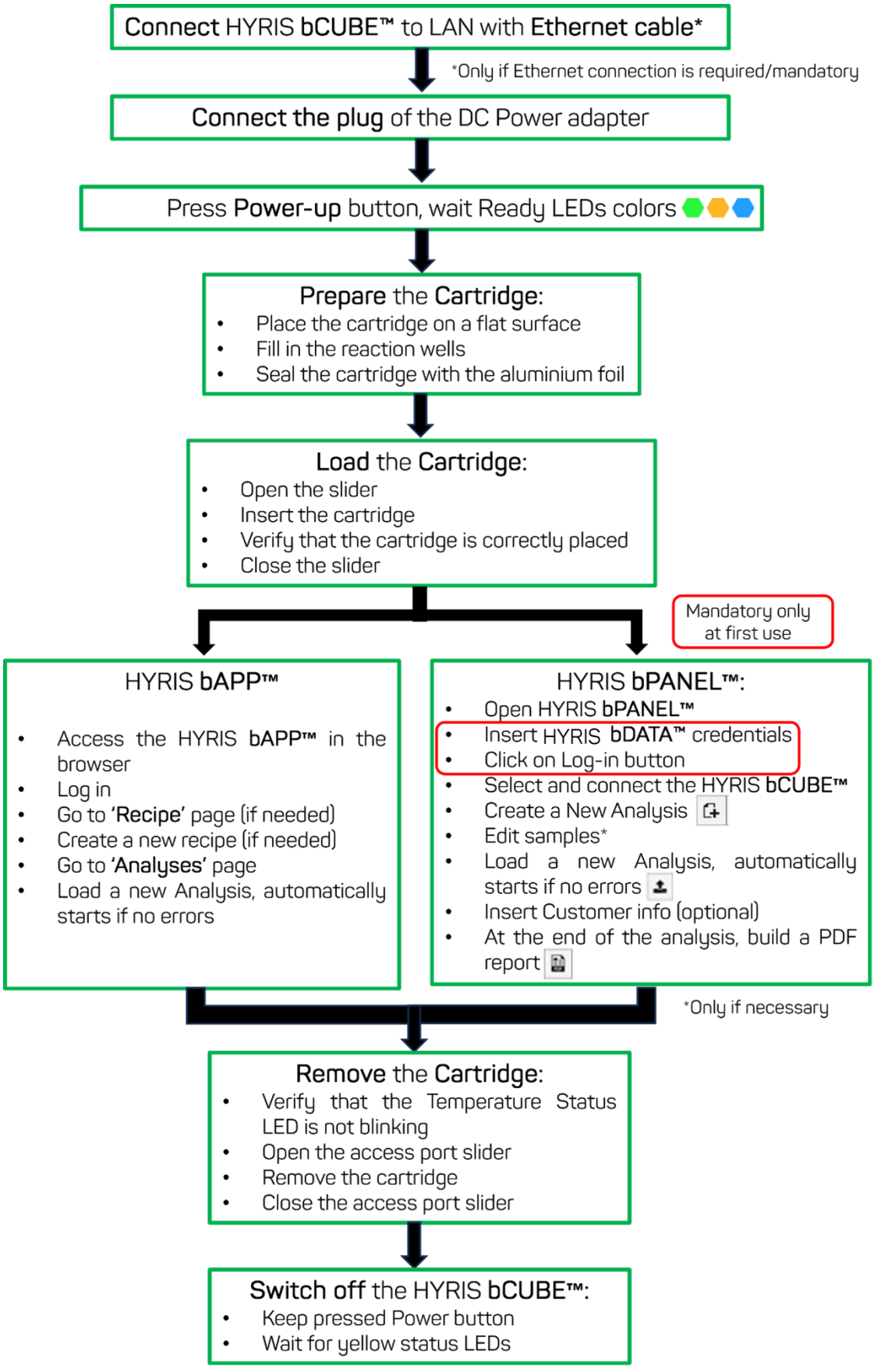
Controlling HYRIS bCUBEplus via HYRIS bPANEL™

HYRIS **bCUBEplus** functioning, operations and settings can be managed and set from HYRIS **bPANEL™** when both the PC/Mobile phone and the HYRIS **bCUBEplus** are connected to the same network.
HYRIS **bPANEL™** functioning, description and procedures can be found in HYRIS bPANEL™ – User Manual.

Note: HYRIS **bCUBE™** must be connected to Hyris Services at least once a week. After this time, new connection must be established in order to use the device. HYRIS **bCUBE™** will automatically sync all the analyses data which had been performed offline

HYRIS bCUBEplus operating procedure

The following chart illustrates the theory of operation of the HYRIS **System™.**


Connect HYRIS bCUBE™ to LAN with Ethernet cable*
*Only if Ethernet connection is required/mandatory
Connect the plug of the DC Power adapter
Press Power-up button, wait Ready LEDs colors
Prepare the Cartridge:
• Place the cartridge on a flat surface
• Fill in the reaction wells
• Seal the cartridge with the aluminium foil
Load the Cartridge:
• Open the slider
• Insert the cartridge
• Verify that the cartridge is correctly placed
• Close the slider
Mandatory only at first use
HYRIS bAPP™
• Access the HYRIS bAPP™ in the browser
• Log in
• Go to 'Recipe' page (if needed)
• Create a new recipe (if needed)
• Go to 'Analyses' page
• Load a new Analysis, automatically starts if no errors
HYRIS bPANEL™:
• Open HYRIS bPANEL™
• Insert HYRIS bDATA™ credentials
• Click on Log-in button
• Select and connect the HYRIS bCUBE™
• Create a New Analysis
• Edit samples*
• Load a new Analysis, automatically starts if no errors
• Insert Customer info (optional)
• At the end of the analysis, build a PDF report
*Only if necessary
Remove the Cartridge:
• Verify that the Temperature Status LED is not blinking
• Open the access port slider
• Remove the cartridge
• Close the access port slider
Switch off the HYRIS bCUBE™:
• Keep pressed Power button
• Wait for yellow status LEDs

Troubleshooting

Status LED error messages

One or more Status LEDs are blinking red/purple

- Power down the machine, disconnect all cables. After one minute repeat the power-up procedure. If the problem persists, contact assistance.

bDATA LED is blinking red

- Connect the HYRIS **bCUBEplus** to internet as soon as possible

bDATA LED is blinking red or yellow

- Connect the HYRIS **bCUBEplus** to internet as soon as possible

bDATA LED is blinking green/yellow

- Make sure the internet connection is available
- If internet connection is available and HYRIS **bCUBEplus** is connected to PC via Ethernet cable and WiFi networks are available, go the Local settings page and add at least one them to the saved WiFi list. Then unplug the Ethernet cable. After some seconds, the bDATA LED should turn steady green.
- If a WiFi is already set and it's reachable, delete it from the Local settings page, refresh the page and check it's shown in the available WiFis list. If so, add it.
- If the problem is not listed or persists after these procedures, please contact the assistance

Connection LED is blinking red/yellow

- Make sure a network connection is available
- If network connection is available and HYRIS **bCUBEplus** should be connected to LAN via WiFi, connect it to PC or directly to your router via Ethernet cable and wait about a minute. If the LED is still blinking red/yellow, reboot the HYRIS **bCUBEplus** . If the problem persists, contact assistance

HYRIS bCUBEplus shutdown and connectivity issues

HYRIS **bCUBEplus** interacts with Hyris System in order to provide real time analysis data.

- In case of sudden HYRIS **bCUBEplus** shutdown (eg. for sudden power cut), HYRIS **bCUBEplus** won't lose any analysis data. Unfortunately, in case analysis was running at the time of the inconvenient, that analysis will be set as **Aborted** on next device connection. In this case, analysis should be repeated.
- In case HYRIS **bCUBEplus** disconnects from our services in the middle of an analysis, the experiment won't stop and will be completed offline. During this time, data won't be shown in real time in HYRIS **bAPP™**. Data will be synchronized on first HYRIS **bCUBEplus** connection. In the meanwhile, the device can be powered off in case the experiment has been completed: data won't be lost.

In case of temporary Hyris Services unavailability, HYRIS **bPANEL™** use is suggested.

In case of doubts, please contact support@hyris.net

Transport shipping and storage

HYRIS **bCUBEplus**

No special conditions of temperature are needed for HYRIS **bCUBEplus** shipping and storage.

HYRIS bCUBEplus - Transport shipping

Transport indications:

- Temperature range: -15°C to 65°C

- Humidity: max 90%

HYRIS bCUBEplus – Storage

Storage indications:

- Temperature range: 10°C to 30°C
- Humidity: max 60%

Hyris bCUBEplus Cartridges

No special conditions of temperature are needed for Cartridges shipping and storage.

Cartridges - Transport shipping

Cartridges transport indications:

- Temperature range: -15°C to 65°C
- Humidity: max 90%

Cartridges – Storage

Cartridges storage indications:

- Temperature range: 10°C to 30°C
- Humidity: max 60%

WARNING

Always refer to indication on shipping and storing packages for correct shipping and storing.

Maintenance

General Maintenance information

In order to keep HYRIS bCUBEplus working for a long time and to ensure the operator's safety, it is necessary that the general checks indicated below are periodically performed:

- All the components and the accessories shall be sight inspected, in order to identify any traces of failure, damage, or disconnection.
- All labels, warnings or instructions printed on the device must be checked to be readable.
- Check that the performances of the device are correct.
- Clean the external surface of the device carefully with the recommended products only.
- Do not replace parts or accessories.
- Discard replaced parts, accessories, and the device at its "end of life" according to the local standards and directives currently in force.

Ordinary maintenance information

Calibration can not be performed by operators/customers but only by Hyris. Maintenance is suggested every 2 years or every 800 analyses.

Please, contact support@hyris.net for more information.

For all ordinary maintenance operations pertaining to the components to which the device is connected, or auxiliary components not produced by Hyris S.r.l., such as computer or Smartphone, please refer to the corresponding user's manual provided with them.

Safety Checks

It is essential to periodically check the equipment and the devices or systems it is connected to and all the connections in order to ensure that the equipment continues working efficiently and safely. It is also necessary to check the equipment to remove any dust deposits. Preventive or corrective maintenance operations must be performed by qualified technical staff expressly authorized by Hyris S.r.l.

A sight inspection can be performed also by the user in order to remark any breaking or disconnection. In case of need, immediately contact a qualified technician to solve the problem detected before continuing to use the equipment or connecting it to other devices.
Always check the connectors of the power supply and of the Ethernet cable for damage. If you find a damaged connector refer to qualified technical support service.

WARNING

Safety Checks must be carefully and continuously performed to guarantee safe operation.

HYRIS bCUBEplus cleaning procedure

Cleaning procedure is suggested at least once a year, depending on the HYRIS **bCUBEplus** usage.

Materials to be prepared

- RNase Decontaminant solution (i.e. RNase AWAY® – REF Thermo Scientific: 7000TS1). Contact support@hyris.net for more info about the RNase decontaminant solution
- 3x disposable non-woven cloth
- Distilled water
- ≥ 70% ethanol

Procedure

Clean the HYRIS **bCUBEplus** following the procedure below:

1. Switch-off the HYRIS **bCUBEplus**
2. Disconnect the electrical cable from the instrument
3. Put the HYRIS **bCUBEplus** on a clean surface (see point 9 on how clean the support surface)
4. Wipe all the external surfaces of the HYRIS **bCUBEplus** with a new non-woven cloth soaked but not dripping with Rnase Decontamination Reagent
5. Wait 20 seconds.
6. Wipe the surfaces of the HYRIS **bCUBEplus** with a new non-woven cloth soaked but not dripping with distilled water.
7. Wipe the surfaces of the HYRIS **bCUBEplus** with a new non-woven cloth soaked but not dripping with ≥70% denatured ethanol.
8. Let dry completely.

Repeat from step 4. to step 8. once.

9. Clean well with the RNase Decontamination reagent, then with ≥70% denatured ethanol the surface on which the HYRIS **bCUBEplus** was installed and re-install the instrument

WARNING

Do not immerse HYRIS **bCUBEplus** in liquids of any kind, do not expose to water or oils to avoid damaging the instrument.

WARNING

Always disconnect the power source and all cables before cleaning the equipment.

WARNING

Check that no liquid is present on or inside the instrument before connecting power and running experiments.

WARNING

For cleaning, use products according to directives and regulations of the country in which the device is used.

Technical support / Service

In case of problems such as failure of the device or anyway in case of partial or incorrect working that cannot be solved through usual maintenance operations, please contact one of the main offices of Hyris S.r.l.

All the support material, as well as user manuals, can also be found at: https://support.hyris.net/hc/en-us

WARNING

In case of failure of the device or if it starts working differently from what expected or what is written in this manual, especially as far as safety is concerned, STOP USING IT IMMEDIATELY and contact the technical service. Do not use the device until the safety conditions have been checked and restored.

Support Contacts

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Mail for technical support: support@hyris.net
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