



X-TRACKER[®]

User manual

V02

CE

FC



*Read and familiarize yourself with this manual before using this instrument.
To ensure the safety of the operator, technician,
use only the information specified in this manual.*

**X-TRACKER® is intended for
Research Use Only (RUO).**

**X-TRACKER® is NOT an In Vitro Diagnostic instrument and is
therefore NOT INTENDED for diagnostic use.**

Instrument Manufacturer Informations



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1 About this manual

This manual contains the instructions needed to use the X-TRACKER® instrument safely and in accordance with its functions and the field of application listed in section 3.2 of this manual.

1.1 Target audience




This manual is intended to be used by staff performing experiments in research laboratories.

Users are expected to have a working knowledge of the procedures and practices required by their research activities.



To use this equipment safely, it is essential to follow all the instructions listed.

1.2 Agreement

	Warning	Instructions and/or warning of dangerous conditions for the user
	Attention	Instructions to prevent damage to X-TRACKER® or loss of data.
	Note	Instructions on how to use X-TRACKER® when steps to follow are not self-evident.

2 List of acronyms

Acronym	Definition
CMR	Carcinogenic, Mutagenic and Reprotoxic
CTC	Circulating Tumor Cells
DI	Distilled
GUI	Graphic User interface
EDTA	EthyleneDiamineTetraAcetic acid
EMC	ElectroMagnetic Compatibility
PBS	Phosphate Buffered Saline
PPE	Personal Protective Equipment
PFA	ParaFormAldehyde
RUO	Research Use Only
Seefter®	Micro-filter(s) for research analysis of cells

3 Safety notes

The operator must comply with the following warnings, cautions and notes to ensure safe operation of the X-TRACKER® instrument. Additional warnings, cautions and notes, which apply to specific parameters, are listed in the sections relating to each parameter.

3.1 User qualifications

This manual describes the recommended inspection and preparation procedures before using the instrument, as well as cleaning and maintenance after use.

It cannot be used as the sole support for training purposes.



X-TRACKER® operates under pressure and should only be used by trained operators in a laboratory environment, under a chemical hood depending on the type of protocol chosen.

All the biological fluids (blood samples or other matrices) are considered as potentially infectious and manipulated with gloves. All the biological fluids and associated tubes have to be eliminated with appropriated procedures and material has to be cleaned

3.2 Field of application

X-TRACKER® is an automated benchtop instrument that captures cells and particularly CTCs from a biological fluid sample on one or several Seefter® micro-filter(s) for research analysis of cells.

X-TRACKER® is intended for deployment in university research centers, laboratories and clinical research institutes. X-TRACKER® is a RUO instrument: its use is limited to research purposes only.

3.3 Known risks

Known hazards and/or potential injuries associated with the use of the X-TRACKER® are mainly: splashing, spillage and/or exposure to hazardous liquids.

3.4 Installation and configuration

- Do not place the X-TRACKER® instrument or accessories on an unstable surface.
- Do not use the X-TRACKER® instrument for purposes other than those specified in this manual. Doing so will void the instrument warranty.
- Use the X-TRACKER® instrument only with the power adapter supplied by SmartCatch®.
- The X-TRACKER® instrument must be connected to the power supply line only via an earthed socket.
- Do not expose the X-TRACKER® system to excessive humidity , such as direct exposure to rain. Excessive humidity can cause the X-TRACKER® system to fail.
- Spilled liquids on the instrument may cause operating errors or instrument failure.
- **Risk of explosion** - Do not use X-TRACKER® in an explosive atmosphere or in the presence of anesthetics or flammable gases.
- **User safety**- If a power cable is damaged in any way, stop using X-TRACKER® immediately.

- **Leakage current test** - Interconnecting auxiliary equipment, including a PC monitor or accessory not listed in this manual, with this instrument may increase the total leakage current. When interfacing with other equipment, qualified personnel must perform a leakage current test before use. Serious injury or death could result if leakage current exceeds the applicable standards.
- **Electromagnetic compatibility (EMC)** - The X-TRACKER® should not be placed in the vicinity of a powerful transmitter such as a television, AM/FM radio or cell phone, as this may interfere with the instrument's performance or prevent the proper operation of the level sensors included in the instrument.
- Follow exactly the protective measures specified above.
- Use only the equipment and accessories listed in section 4.3.
- The pollution level of the instrument is level 2 (IEC 61010-1:2010)

3.5 Handling

- To avoid the risk of electric shock or malfunction of the unit, no liquids may enter the unit. If liquids have entered an instrument, take it out of service and have it checked by a service technician before using it again.
- Do not use caustic or abrasive cleaning products.
- Pressing the tablet's touchscreen with a sharp or pointed instrument may cause irreversible damage. Press on the integrated PC touchscreen using only your finger, with gloves or with a standard stylus.
- If the X-TRACKER® instrument inadvertently gets wet, take it out of service. It must be carefully dried and checked by qualified technical professionals.

3.6 Safety checks

- Under no circumstances perform any unscheduled testing or maintenance on the X-TRACKER® instrument or the power cord while the instrument is in operation. Before cleaning or performing maintenance of the X-TRACKER® system, unplug the power cord, the connecting cable and the pressurized air supply. The operator must not perform any maintenance operations other than those specified in this manual.
- The use of accessory equipment that does not comply with the equivalent safety requirements of this equipment may reduce the safety level of the resulting system.
- Always inspect the instrument before use.

3.7 Installation and inspection

X-TRACKER® installation is carried out by the trained technician, who will check the integrity of the packaging contents.

4 System

4.1 Product name

- Product name : X-TRACKER®
- Model: S2

4.2 Product Description





Instrument system contains 2 parts:

- a) The instrument : X-TRACKER®
- b) The consumable : CTC-POD® (sold separately) or CTC-INSITU (sold separately)






Figure 4.2: *Instrument in process configuration with CTC-POD® which contains Seefer®*



4.3 Material Provided

Item	Description	Quantity
X-TRACKER®		1
Dummy-POD		1
Power supply + cord adapted to country		1
Pressurized air connection kit		1

4.4 Material For First Use

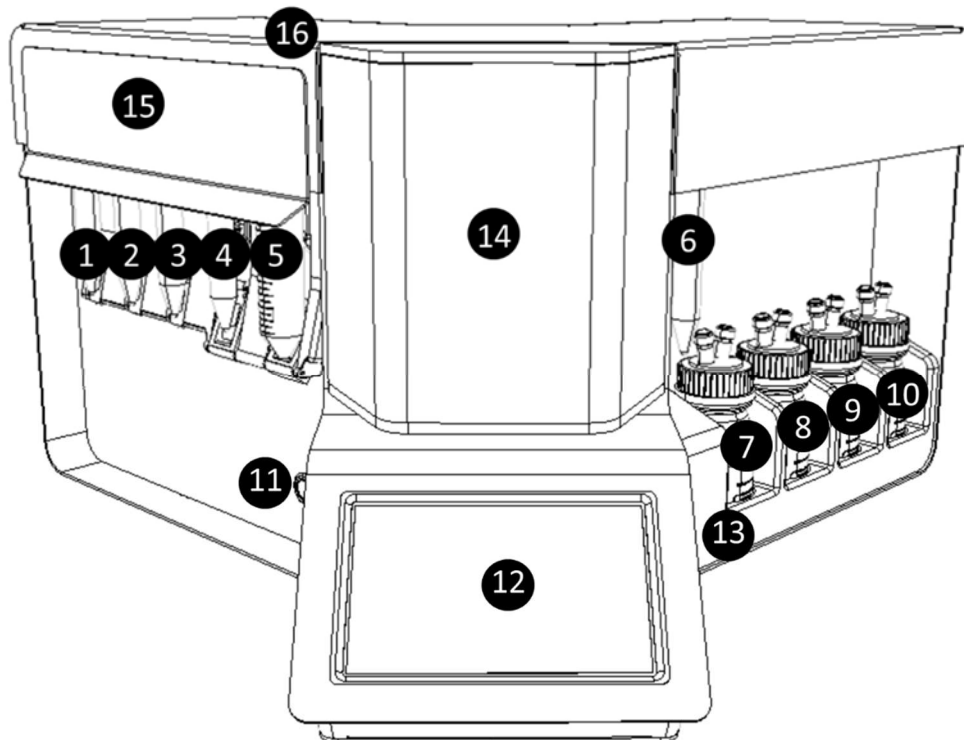
Item	Description	Quantity
Falcon Test tube 15 mL		6
Reservoir 100mL Duran™ Pressure Plus laboratory glass vials		4
Reservoir 1000mL Duran™ Original GL		1

4.5 Material Not Provided

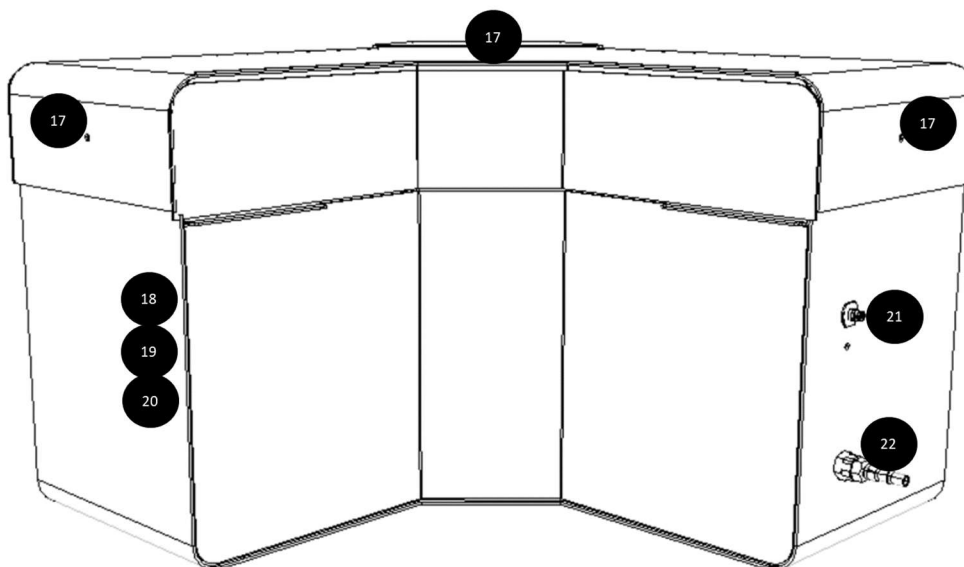
Item	Description	Quantity
CTC-POD®	 X-Tracker® consumable	Sold Separately
CTC-INSITU	 X-Tracker® consumable	Sold Separately
Kit High Volume + Reservoir	Kit composition : <ul style="list-style-type: none"> - Falcon Test Tube 50mL - Reservoir 100mL Duran Pressure Plus laboratory glass vials 	Sold separately
Kit Standard Volume + Reservoir	Kit composition : <ul style="list-style-type: none"> - Falcon Test Tube 15mL - Reservoir 100mL Duran Pressure Plus laboratory glass vials 	Sold separately
Kit Maintenance Fluidic	Kit composition : <ul style="list-style-type: none"> - Fluidic tube - Fluidic ferrules 	Sold separately
External compressor	Portable air pressure supplier	Sold separately
Reservoir	Kit composition : <ul style="list-style-type: none"> - Reservoir 100mL Duran Pressure Plus laboratory glass vials - Reservoir 1000mL Duran 	Sold separately

4.6 Instrument main elements

4.6.1 Location of main components



Front Panel



Rear Panel

4.6.2 Description of main components

N°	Components	Technical description	Material used
1	Elution buffer <i>Elution buffer</i>	Buffer in which the cells will be collected. For the protocol with cell detachment, 5 mL are required, otherwise the tube will remain empty.	15 mL plastic tubes from Falcon brands
2	Ethanol	Prepares the system to start each protocol. Ethanol must be > 95% - 12 mL are required at the start of each protocol	15 mL plastic tubes from Falcon brands
3	Fixative <i>Fixative</i>	The protocol with fixation involves placing the X-TRACKER® in a fume cupboard: Paraformaldehyde 4% - 5 mL are required otherwise the tube will remain empty.	15 mL plastic tubes from Falcon brands
4	Biofluid	Blood sample tube, or other biofluid.	15 mL plastic tubes from Falcon brands If the volume of biofluid to be passed through the machine is < 12 mL place a Falcon 15 mL, otherwise place a Falcon 50 mL .
5	Empty load <i>Tube à vide</i>	Tube used for sample recirculation.	15 mL plastic tubes from Falcon brands If volume to be passed through the machine is < 12 mL place a 15 mL test tube, otherwise place a 50 mL test tube from Falcon brands.
6	Eluate <i>Eluat</i>	Tube receiving the capture product in the elution buffer (1) at the end of the detachment protocol, otherwise this tube remains empty at the start of the process. It must be changed for each new process.	15 mL plastic tubes from Falcon brands
7	Buffer <i>Buffer</i>	PBS 1X (Phosphate Buffered Saline) - a minimum of 40 mL is required at the start of each protocol. The user may choose another type of buffer if it behaves like PBS in terms of viscosity (aqueous).	100mL Duran Pressure Plus laboratory glass vials
8	DI water	A minimum of 40 mL is required at the start of each protocol	100mL Duran Pressure Plus laboratory glass vials

N°	Components	Technical description	Material used
9	Detergent	A minimum of 40 mL is required at the start of each protocol. We recommend Detojet® concentrate at 10ml/L.	100mL Duran Pressure Plus laboratory glass vials
10	Bleach	A minimum of 40 mL of 1% concentrate is required at the start of each protocol.	100mL Duran Pressure Plus laboratory glass vials
11	Button ON/OFF	Press for 2 seconds to switch on the machine. The LED ring on this button communicates the system status X-TRACKER®	/
12	Touch screen	The touch screen projects the graphic user interface (GUI). It is used to select protocols, enter sample data and monitor ongoing processes. The touch screen can be used with laboratory gloves (Nitrile, Latex, Neoprene).	/
13	Bottle holder	The bottle holder ensures contact between the bottles and their level sensors. It can be removed for cleaning.	/
14	POD cover	The cover protects both the device and the user. It must remain closed except when the CTC-POD® or CTC-INSITU is being fitted or removed.	/
15	Drawer	The drawer must be opened to replace tubes Falcons 1 to 5 at the start of the protocol. The drawer must be completely closed while X-TRACKER® is running for detection purposes.	/
16	Lid	The lid provides access to the fluidic system. The lid must only be opened for maintenance purposes.	/
17	Screws	The 3 manual screws open and seals the X-TRACKER® lid (16)	/

N°	Components	Technical description	Material used
18	Ethernet socket	The Ethernet socket is there to duplicate the GUI displayed on the screen to another instrument (PC or tablet).	/
19	USB socket	The USB socket is available for extracting data from the X-TRACKER® or for connecting an external keyboard and mouse.	/
20	DC Power In	Power supply connection socket. This socket is fitted with a connector to enable it to be plugged into a single position. It also contains a system to prevent unintentional removal. It must only be used with power supplies supplied by SmartCatch.	/
21	Waste disposal	This fluid connector is used to connect the waste tank.	1000mL Glass bottle provided Transparent and plastic/glass contentant can be used as replacement
22	Air inlet	Connection for pressurized air for the system. Connection is made by simply plugging in the module supplied in the kit. The source of pressurized air can be a compressor or the infrastructure network. Pressurized air must be between 2 and 7 bars and stable at +/- 0.2bars.	/

4.7 Technology

The X-TRACKER® system directs the flow of the various reagents and the biological sample to be analyzed within the consumable. The system enables continuous recirculation of the biological sample during the process.









The consumable CTC-POD® or CTC-INSITU contains the microfilter(s) (Seefter®). They are made up of pores of the right size and geometry to help retain the cells of interest, based on their physical properties of size and deformation.






4.8 Label



4.9 Safety symbols

The following symbols are used on the X-TRACKER® instrument

Symbol	Definition	Symbol	Definition
	Consult operating instructions or electronic operating instructions		CE mark certifying that the product complies with essential safety and electromagnetic compatibility requirements for European Union. (Self-declaration of conformity on request).
	Research Use Only, Instrument For Research Use Only		Instruments using potentially carcinogenic, mutagenic and reprotoxic (CMR) substances or substances classified as endocrine disruptors
	Catalog number		Indicates the presence of potential biological risks.
	Serial number		Indicates separate collection of waste electrical and electronic equipment (WEEE).

Symbol	Definition	Symbol	Definition
	Manufacturer		Temperature limits
	Date of manufacturing YYYY-MM-DD		Continu Current
	FCC mark certifying that the product complies with essential safety and electromagnetic compatibility requirements for US	FCC ID :	Identifier assigned to a device registered with the FCC.

5 Technical safety warnings

 **It is forbidden to open a test tube or bottle while a process is running, to avoid a drop in pressure or splashes.**

5.1 Reagents

 **Reagents must be refilled unless requested by the system DO NOT refill reagent when a procedure is in progress.**


Reagents must be handled with the appropriate personal protective equipment (PPE).

Please read the safety data sheets from your(s) supplier(s). As a reminder, ethanol is a flammable solvent; fixative such as paraformaldehyde (PFA) is carcinogenic, mutagenic and reprotoxic (CMR).

5.2 Pressure

5.2.1 Inlet air pressure

X-TRACKER® operates on pressure. Liquid flow and control cannot be performed without pressure.

 **The inlet pressure must be between 2 and 7 bars.
The inlet pressure must remain stable at ± 0.2 bars.
If needed, we can provide a pressure source**

During installation, the pressure reducing valve is calibrated to match the inlet air pressure. If the inlet air pressure changes significantly, this calibration must be repeated.

To protect the X-TRACKER® instrument against these air pressure changes, we recommend isolating the instrument between uses by disconnecting the air inlet(22).

5.3 System pressure

Proper sealing of test tubes and reservoirs (1-10) is essential to achieve the desired system pressure throughout the various stages of a protocol.

Make sure test tubes are properly screwed in. Ensure that bottle caps are properly sealed. At the start of any protocol, a pressure test will be carried out to check that the system is properly sealed.



Falcon cylinders and tubes should only be opened when requested by the system

5.4 Fluids Liquid – Biofluids and other liquids

The tightness of the fluidic connections on the CTC-POD® or CTC-INSITU must be ensured for each use. For maintenance, all fluidic connections must also be checked for tightness.



It is forbidden to open any of the fluidic connections or to remove the CTC-POD® or CTC-INSITU Unless requested by the system

5.5 Liquid waste

A waste container **must be connected to the machine via the waste connector (21). The tank must not be made of metal and must have a minimum volume of 250 mL.** The waste contains all the reagents used by the machine, including the biofluid to be treated. The appropriate treatment must be given to the waste in accordance with the location and laboratory where the X-TRACKER® instrument is installed.



The waste container must NOT be hermetically sealed to prevent pressurization and alteration of the system pressure differentials, and NOT metallic to ensure correct reading of the level sensor.

5.5.1 Waste sensor

The liquid level sensor for the waste tank must be placed in contact with the waste tank. The level sensor must be placed so that left 200 mL above it in the container.

200 mL corresponds to the minimum liquid waste produced by the X-TRACKER® during a protocol.

The waste level sensor is present to warn the user of potential liquid spills if the waste container is full.



If you do not choose to use the high level liquid waste sensor, it must remain on the X-TRACKER®, with no obstacle within 4 cm of it (green LED on only).

5.6 Biofluids

The X-TRACKER® instrument can accept biofluids with volumes ranging from 6 to 45 mL.

- For volumes below 12 mL, place your "biofluid" sample (4) in a 15mL Falcon tube. Also place an empty 15mL Falcon tube in "empty load" (5).

- For volumes greater than 12 mL, place your "biofluid" sample (4) in a 50mL Falcon tube. Also place a 50mL Falcon tube in "empty load" (5).



It is essential to have the same tube sizes in positions (4) and (5). If this is not the case, there is a risk of liquid overflowing out of the tubes into the pneumatic parts, and therefore a risk of damage to the equipment.

Factory instrument calibrations are made for whole blood in EDTA. If another fluid is used, contact SmartCatch for the best flow and pressure recommendations for your protocols.



Users are exposed to biological risks associated with the samples they examine. The user must be fully aware of and follow the protocols within their organization for handling them.

6 User qualification

When X-TRACKER® is installed, a referring user is trained in the correct use of the instrument. The user must be able to :

- Ensure that the instrument is properly connected to its power supply;
- Make sure the instrument is pressurized;
- Handle the necessary reagents with the inherent safety precautions;
- Follow procedures in the event of reported errors;
- Carry out user maintenance;
- Manage the waste generated by the instrument;
- Start X-TRACKER® protocols;
- Know all the operating steps of the graphical user interface;

7 Installation instructions

Installation of X-TRACKER® must be carried out in the presence of a trained technician.

7.1 Placement



When using CMR fixatives such as formalin, it is essential to place the X-TRACKER® instrument under a chemical hood. If this is not the case, X-TRACKER® can be installed on a laboratory bench.

7.2 Access to pressurized air

Access to pressurized air close to the machine is required.

In the case of a pressurized air network already present in the host structure, a direct pneumatic connection is possible.

In the case of a compressor connection, it is preferable for the compressor to be close to X-TRACKER® (<5 m).

7.3 Calibration



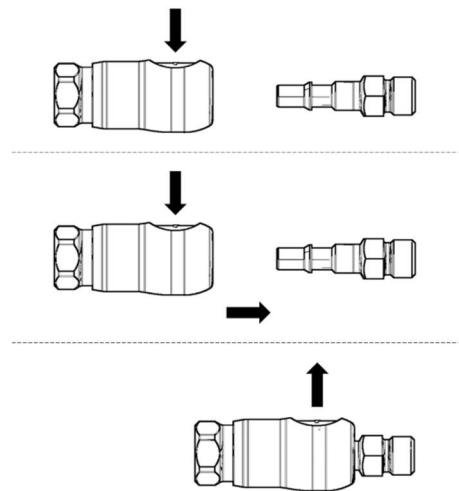
Before connecting X-TRACKER® to the pressurized network, an initial pressure check must be carried out by trained personnel. This is followed by a 2-bar calibration using the instrument's internal pressure reducer. This calibration is necessary to avoid damaging the instrument.

Without this calibration, the X-TRACKER® instrument must not be used. If the pressurized air source changes, this calibration must be repeated.

7.3.1 Pressurized air on/off.

The connection to pressurized air is made via a safety connector. To enable connection :

- Press the connector button
- Press and hold the button to insert the connector
- Release the button



Reverse the procedure to disconnect X-TRACKER® from the pressurized air supply:

- Press the connector button
- Unlock the connector by holding down the button
- Release the button

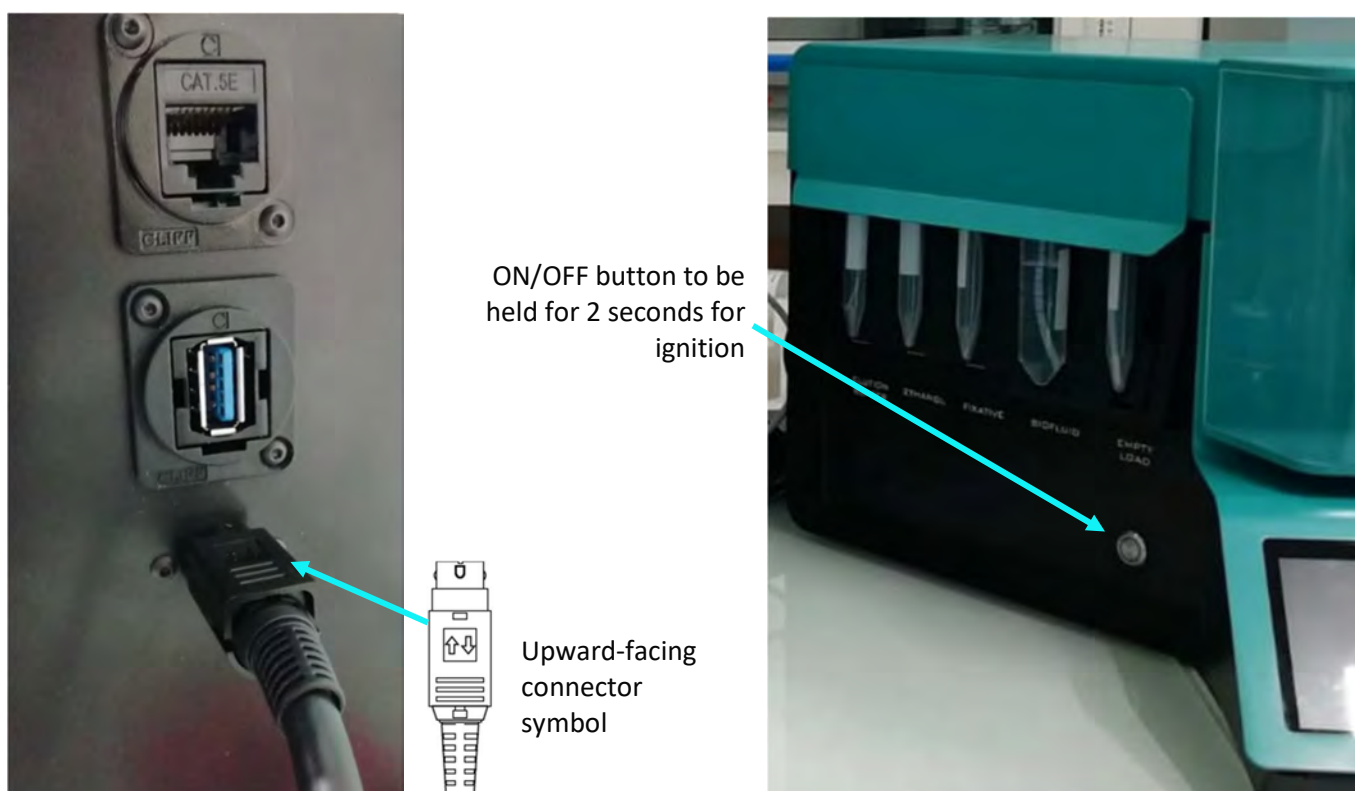
7.4 Power on

Once these steps have been completed, the X-TRACKER® instrument can be connected to its power supply. The input connector is flattened, so that it can only be plugged in one position. It also features a security system to prevent it from being pulled out.



To remove the power connector, it is necessary to release the plastic part of the connector to disconnect it.



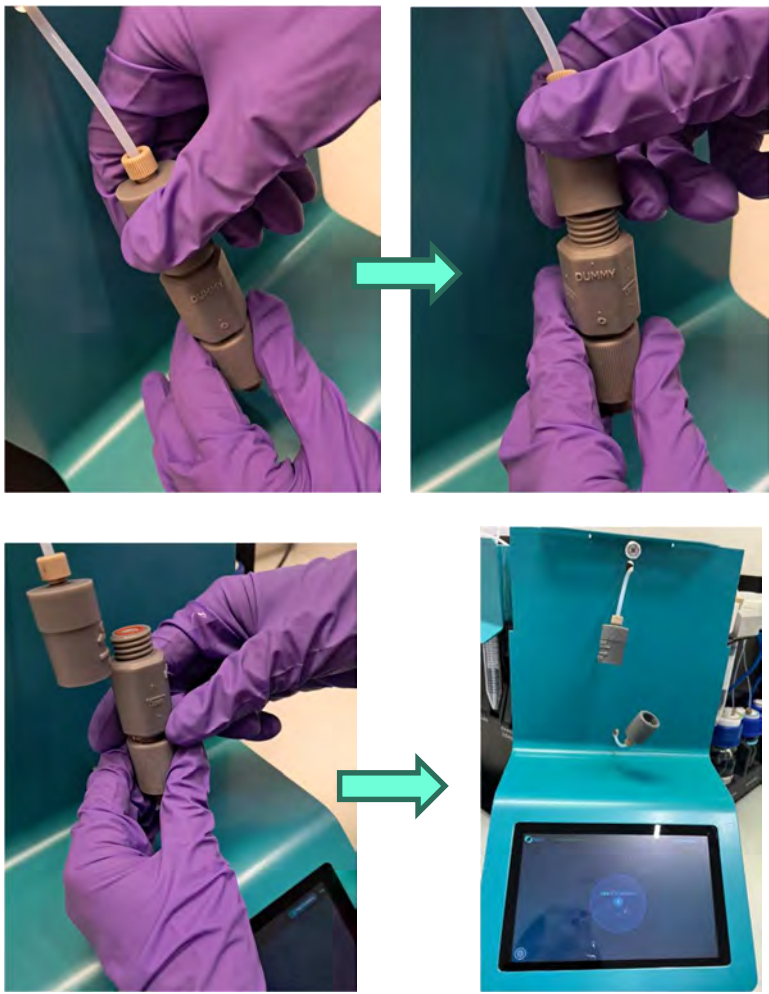
Press the ON/OFF button (11) for 2 seconds to start the X-TRACKER and display the user interface (GUI).

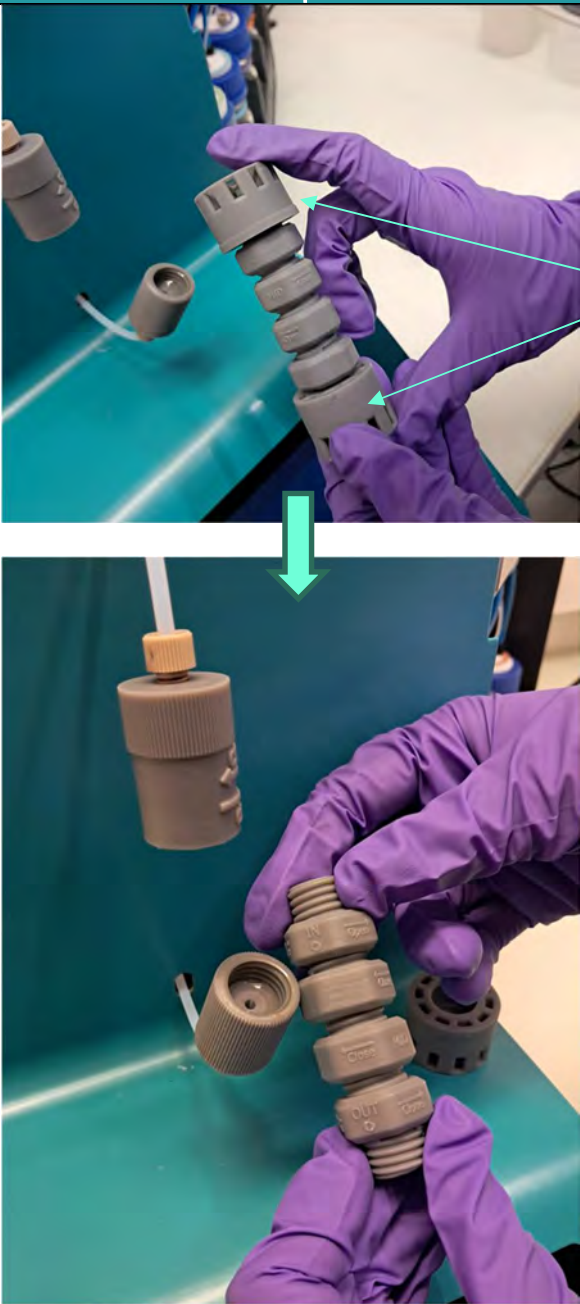


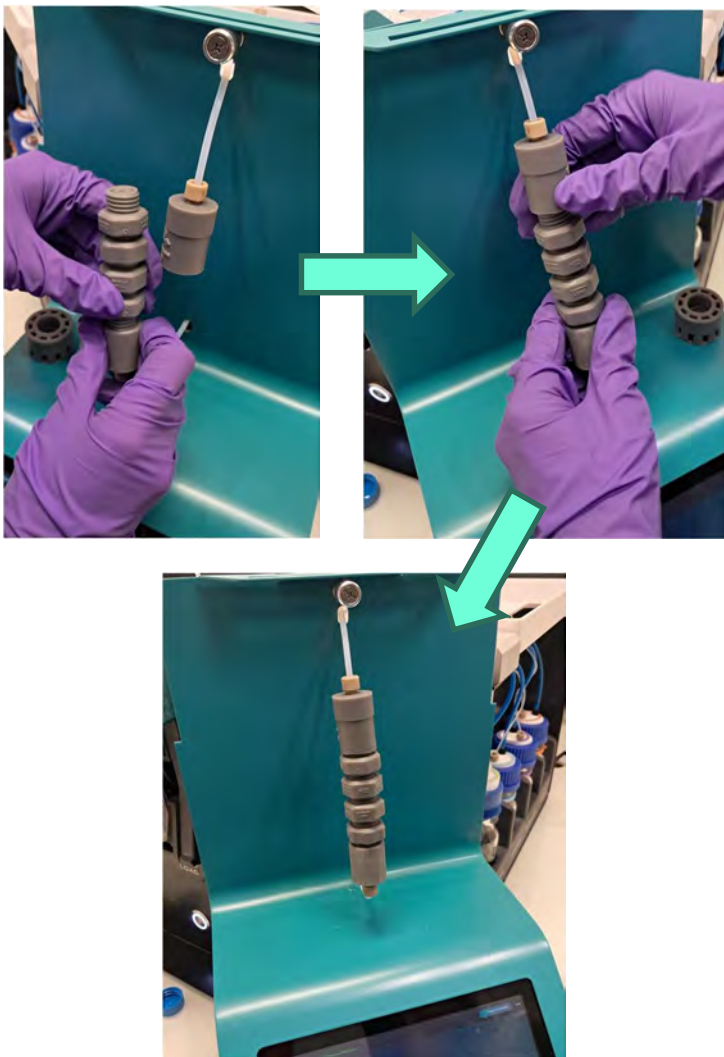



7.5 Start-up

An initial start-up test will be carried out in the presence of the trained technician. The aim of this test is to check that the electronics have not been disturbed during transport, and that there are no air and/or liquid leaks. At the end of the test, a blank protocol will be run before the first use with a sample of interest.

8 CTC-POD® or CTC-INSITU Installation

Step	Description/Illustration
 <p>Only remove the Dummy-POD if requested by the system</p>	
<p>1- Remove the security POD cover (Part 14)</p>	
<p>2- Remove the Dummy by unscrewing them</p>	

Step	Description/Illustration
<p>3- Remove caps of the CTC-POD® or CTC-INSITU by unscrewing them</p>	 <p>CTC-POD® caps</p>

Step	Description/Illustration
<p>4- Screw CTC-POD® or CTC-INSITU on X-TRACKER®</p>	<div data-bbox="651 264 1378 1317">  </div> <div data-bbox="587 1361 667 1440">  </div> <div data-bbox="687 1350 1439 1458"> <p>It is important to ensure that the consumable CTC-POD® is properly connected to the instrument before starting a protocol.</p> </div>
<p>5- Put the security POD cover (Part 14)</p>	<div data-bbox="959 1529 1150 1888">  </div> <div data-bbox="592 1877 671 1944">  </div> <div data-bbox="687 1888 1439 1955"> <p>It is forbidden to start the protocol without the protective cover.</p> </div>

9 Protocol description

X-TRACKER® offers 3 typical protocols:

- Isolation and resuspension of cells (Protocol 1)
- Isolation and fixation of cells on filters (Protocol 2);
- Isolation of cells on filters without fixation (Protocol 3).

9.1 Protocol diagram

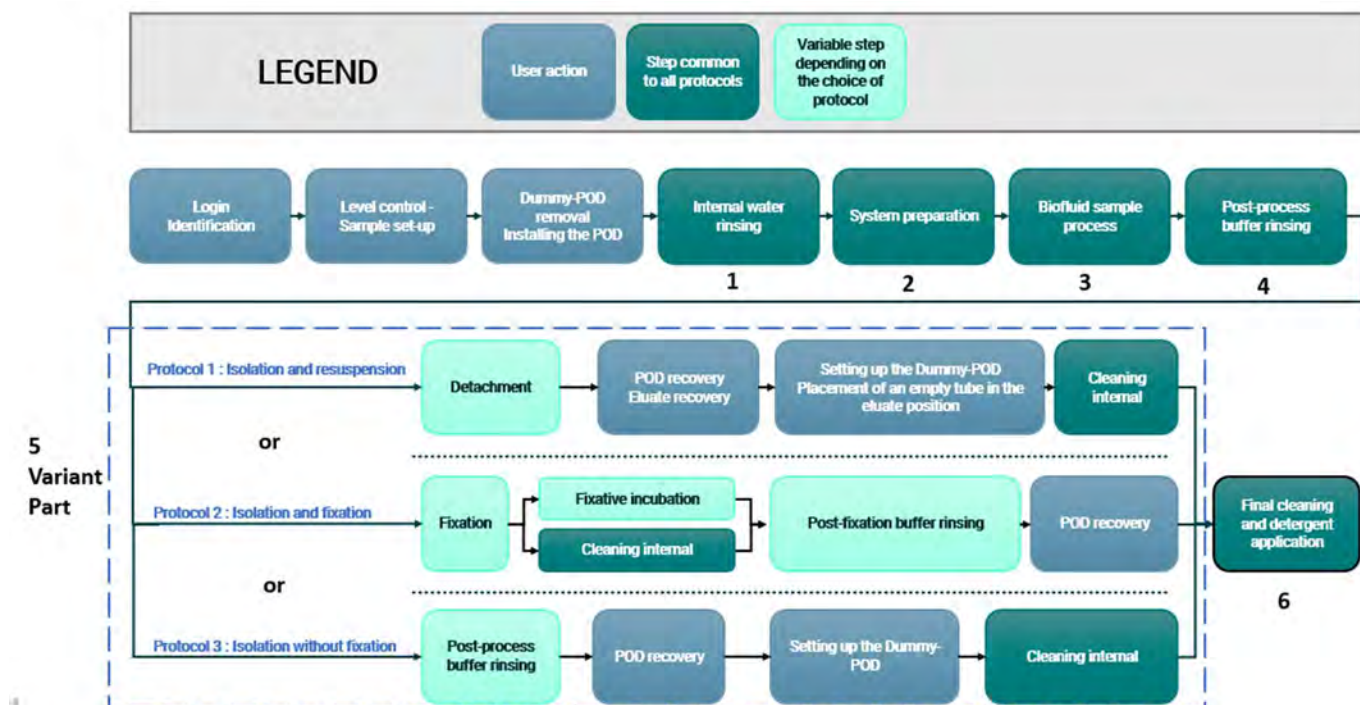


Figure 9.1: Protocol diagram

9.2 Common steps to all protocols

Step	Step description
Step 1: Internal water rinse	Remove detergent from all fluid paths and vent CTC-POD® or CTC-INSITU circuit for replacement.
Step 2: System Preparation	Load all reagents and prepare the system by clearing all fluid paths of bubbles with the 95% ethanol solution. The system is rinsed with the buffer bottle 1 and buffered to accommodate the biofluid sample.
Step 3: Biofluid sample process	The total sample volume recirculates from the "biofluid" tank (4) through the CTC-POD® or

Step	Step description
	CTC-INSITU to the "empty load" tank (5), thereby capturing the CTC. Recirculation time (Processing time) and pressure (Isolation pressure) can be set by the machine administrator (see section 11.4).
Step 4: Post-process rinse	The system is rinsed with the buffer solution, and the CTC-POD® or CTC-INSITU is also rinsed at low flow. The rinse time can be changed by the user (see section 11.4).
Step5: Variant part	Depending on the choice of protocol, described in the following section.
Step6: Cleaning and detergent filling	<u>Final cleaning</u> : The CTC-POD® or CTC-INSITU circuit is cleaned with detergent, water, bleach, then water again <u>General cleaning</u> : circuit cleaning except CTC-POD® or CTC-INSITU with detergent, water, bleach, then water again. <u>Detergent filling</u> : the CTC-POD® or CTC-INSITU circuit is filling with detergent until the next use.

The steps when the user closes the CTC-POD® or CTC-INSITU circuit or place the CTC-POD® or CTC-INSITU are detailed in the GUI.

9.3 Protocol 1 : Isolation and resuspension of cells

9.3.1 Protocol 1: Description

Once the step 4 - post-process rinsing has been completed, the cells of interest are trapped on the microfilters. Rinsing continues with the "Elution buffer" liquid (1) in which the cells will be preserved. After asking the user to change the "Eluate" tube, a reverse flow is applied with the buffer liquid. Cells of interest are detached from the microfilter and directed to the "Eluate" tube (6). The user recovers the "Eluate" tube (6) and recovers the CTC-POD® or CTC-INSITU and closes the connectors.

9.3.2 Protocol 1: Cleaning

Once the CTC-POD® or CTC-INSITU circuit is closed, and validated by the user, a cleaning sequence lasting approximately 15 minutes is started. Per cycle, all circuit tubes are cleaned with detergent, water and a solution of bleach. Step 7 follows this cleaning sequence without validation.

9.4 Protocol 2: Isolation and fixation

9.4.1 Protocol 2:Description

After the step 4 -post-process rinsing with buffer solution (7), the cells of interest are trapped on the microfilter. Rinsing continues with the "fixative" liquid (3) in which the cells are chemically fixed. Once the entire volume of CTC-POD® or CTC-INSITU is filled with fixative, the CTC-POD® or CTC-INSITU is isolated from the rest of the fluidic circuit for the duration of incubation.



This fixation step is the only one in which CMR-sensitive products are used. The following pictogram indicates the location of the CMR substance.

9.4.2 Protocol 2: Cleaning

While the CTC-POD® or CTC-INSITU is incubating, a cleaning sequence lasting around 15 minutes is run through the rest of the circuit. The fluidic circuit is then rinsed with buffer solution (7), and the circuit remains under this solution.

9.4.3 Protocol 2 Fixative rinse

The CTC-POD® or CTC-INSITU is rinsed again to remove the fixative. The CTC-POD® or CTC-INSITU is then returned to air for recovery by the user. The cells of interest are attached to the microfilters. The CTC-POD® or CTC-INSITU is removed, and the circuit is closed, then step 7 for detergent starts after validation.

9.5 Protocol 3 : Isolation without fixation

9.5.1 Protocol 3: Description

Once the step 4 - post-process rinsing has been completed, the cells of interest are trapped on the micro-filters. The CTC-POD® or CTC-INSITU is returned to air, and the user recovers it and closes the circuit.

9.5.2 Protocol 3: Cleaning

The CTC-POD®'s connectors are closed, after validation a cleaning sequence lasting approximately 15 minutes is started. Per cycle, all the circuit tubing is cleaned with detergent, water and bleach. Cleaning is followed by step 7, without validation.

10 Graphic User Interface (GUI)

10.1 Classic workflow

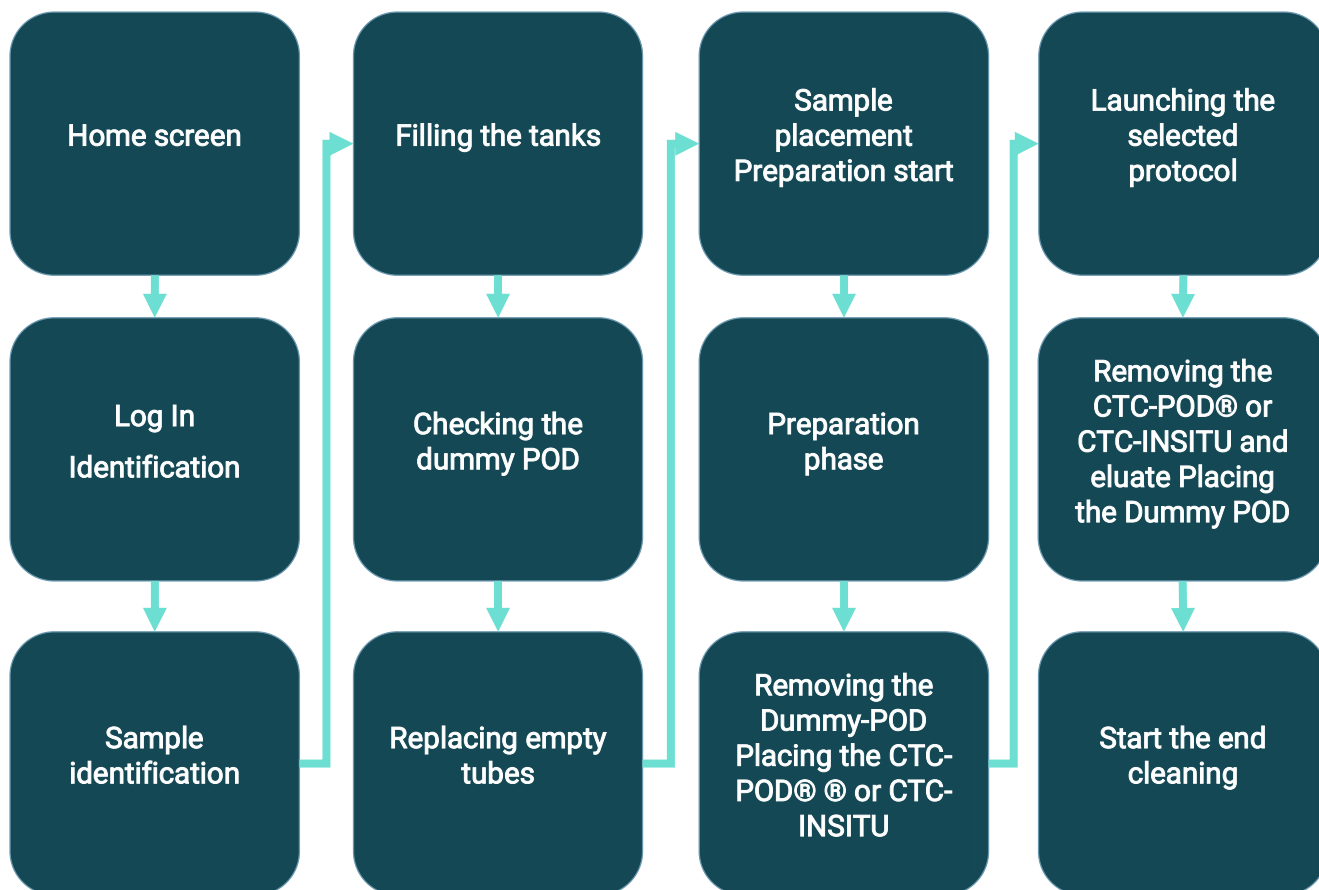


Figure 10.1: Classic workflow

10.2 Initialization

When the instrument is powered up, press the ON/OFF button (11) for 2 seconds, and the screen lights up and the machine initializes. This can take up to 3 minutes.

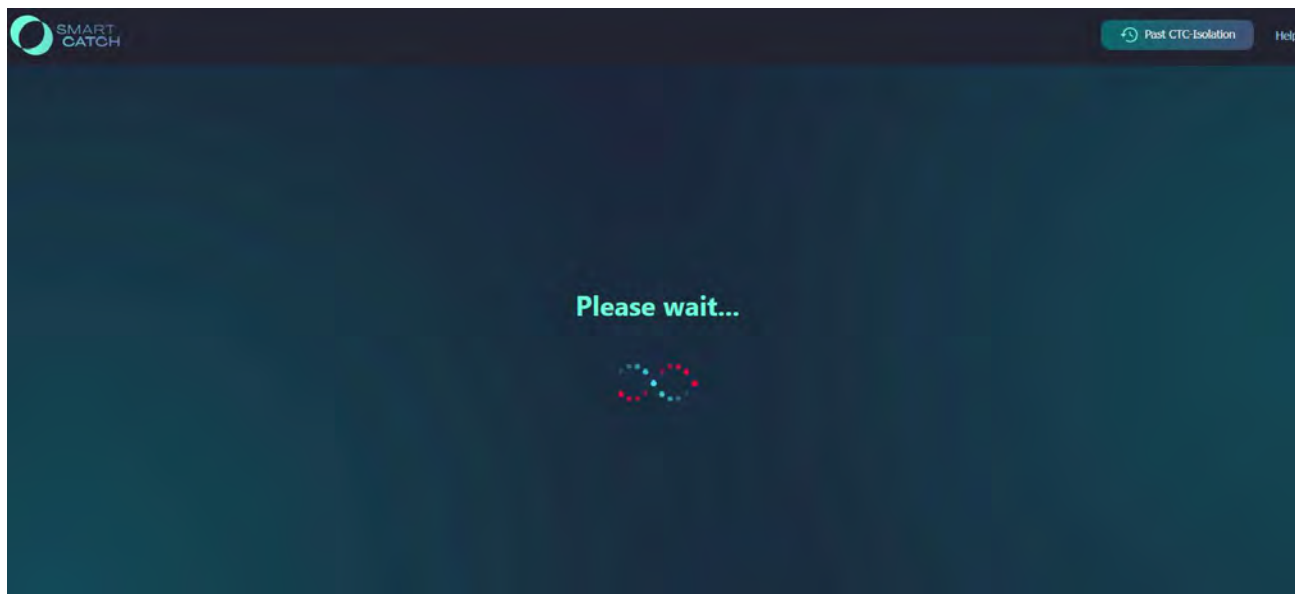


Figure 10.2: Instrument initialization X-TRACKER®

10.3 Home



Figure 10.3 GUI page for welcome screen

10.4 Settings page

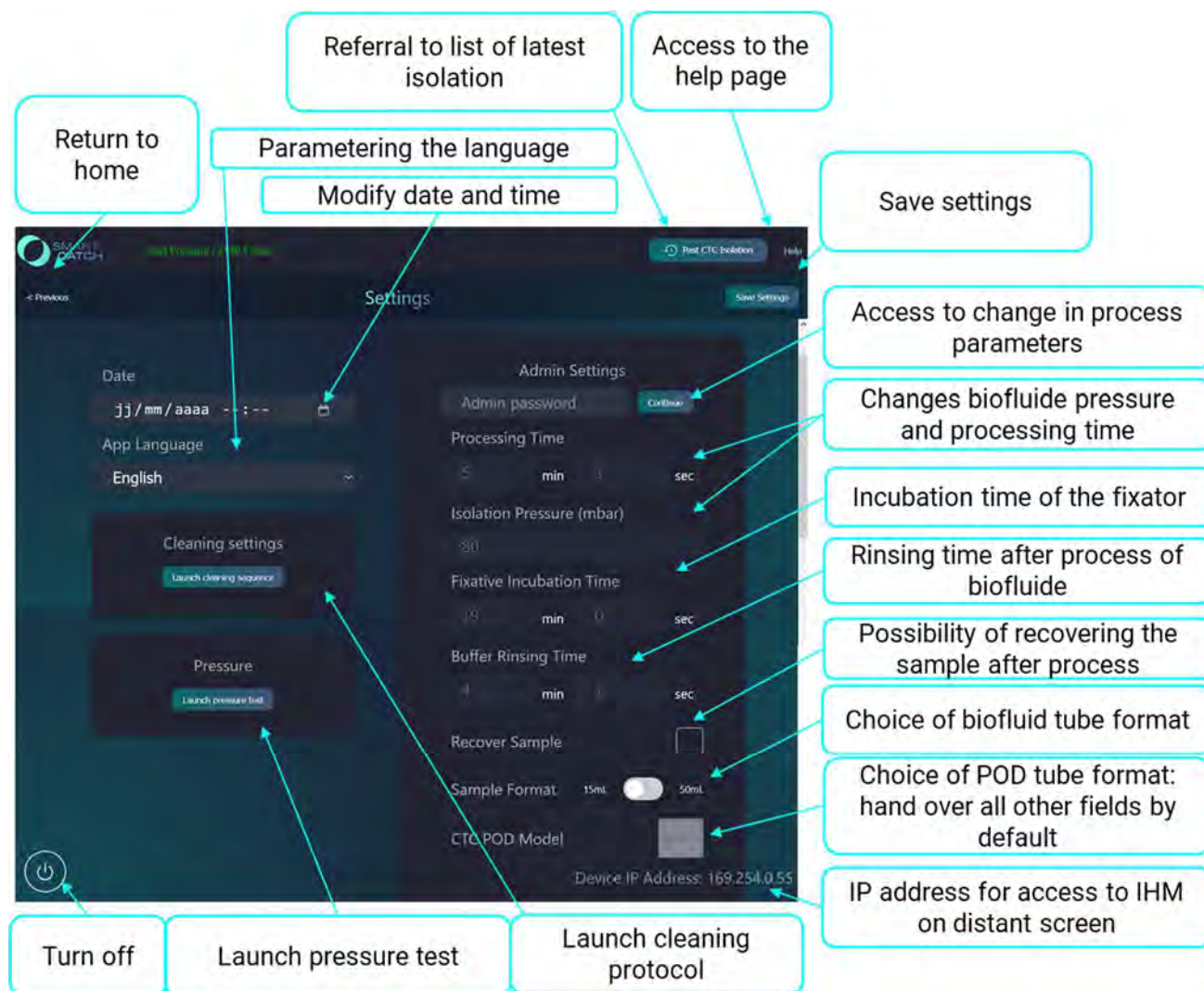


Figure 10.4: Parameterization GUI page

10.5 Log In

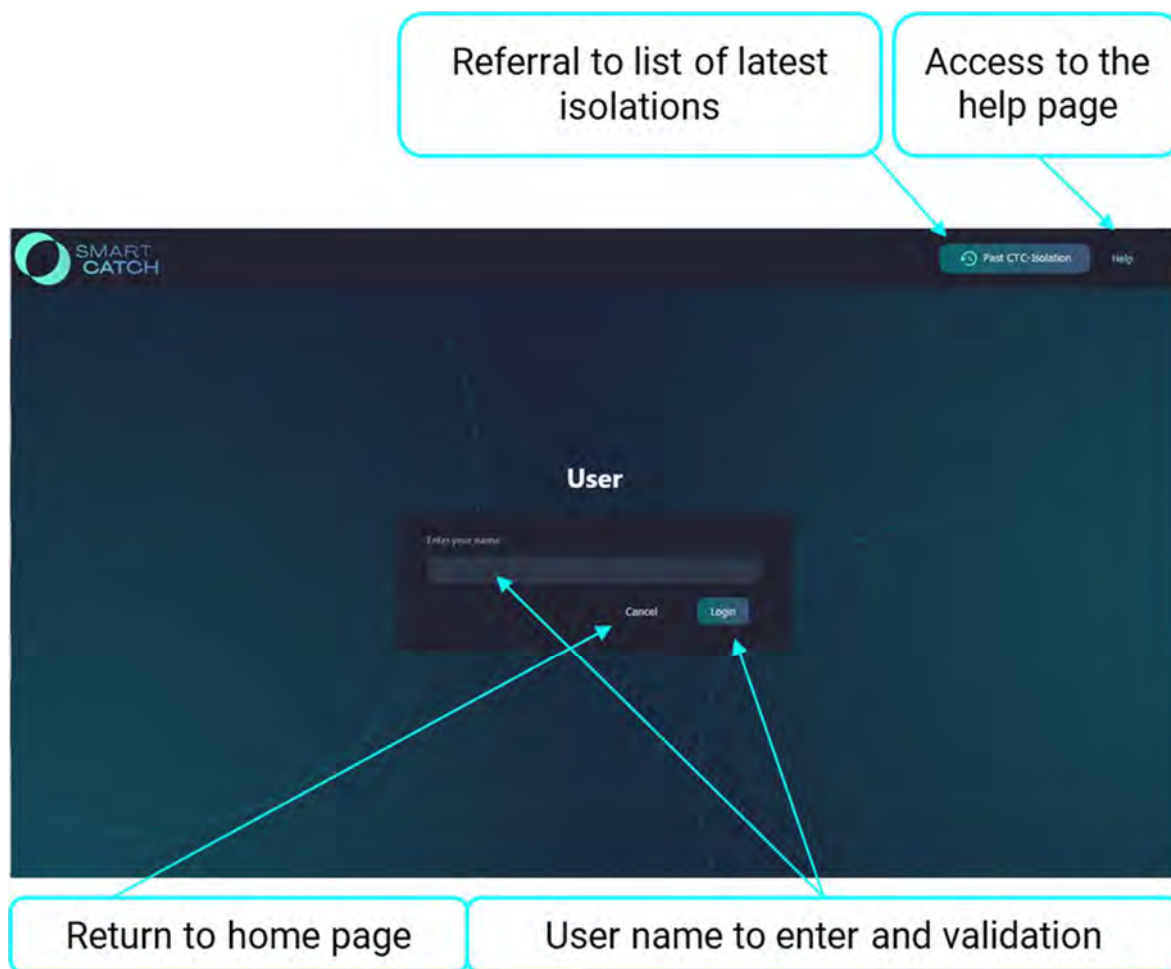


Figure 10.5: GUI page for user login

10.6 Choice of protocol

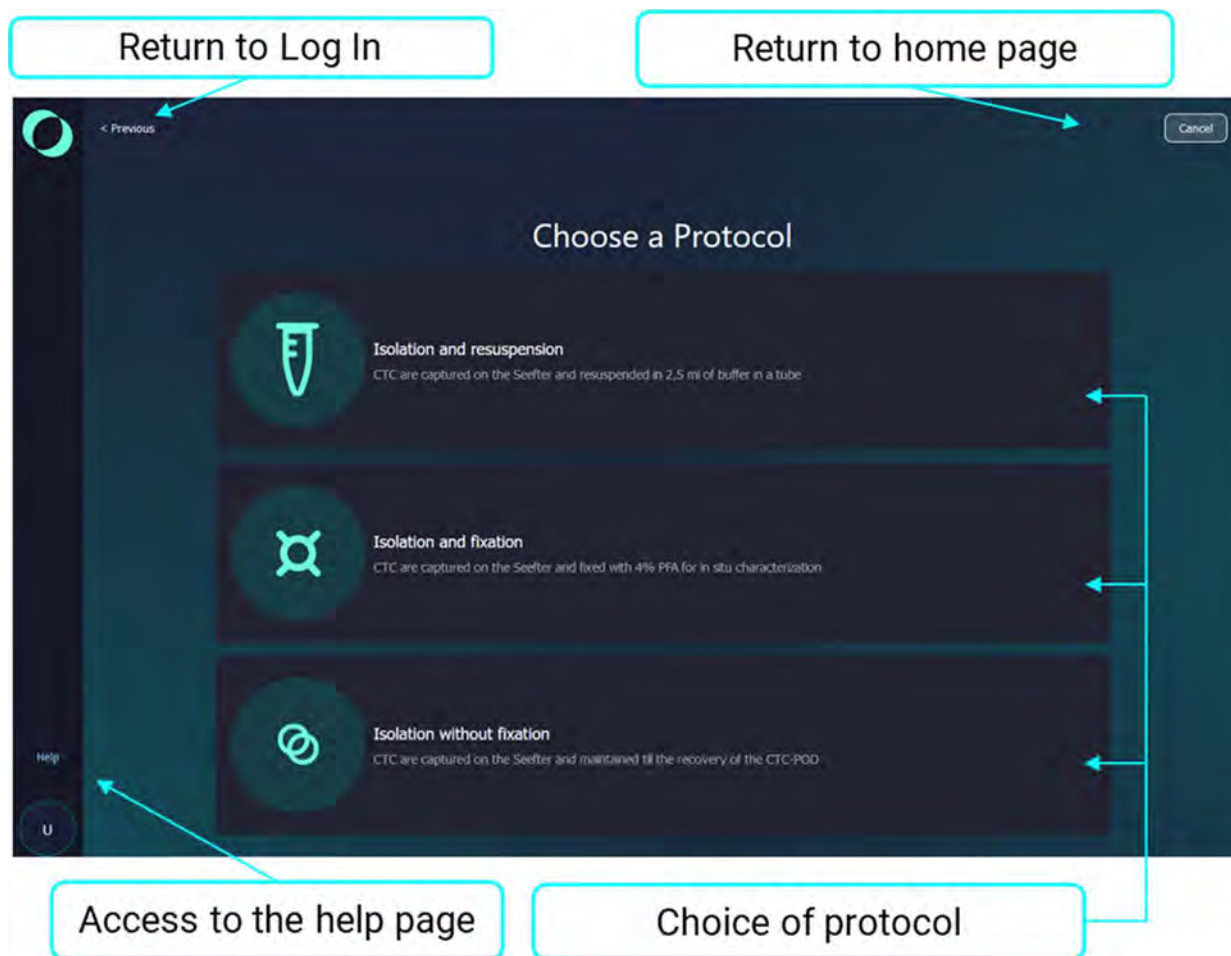
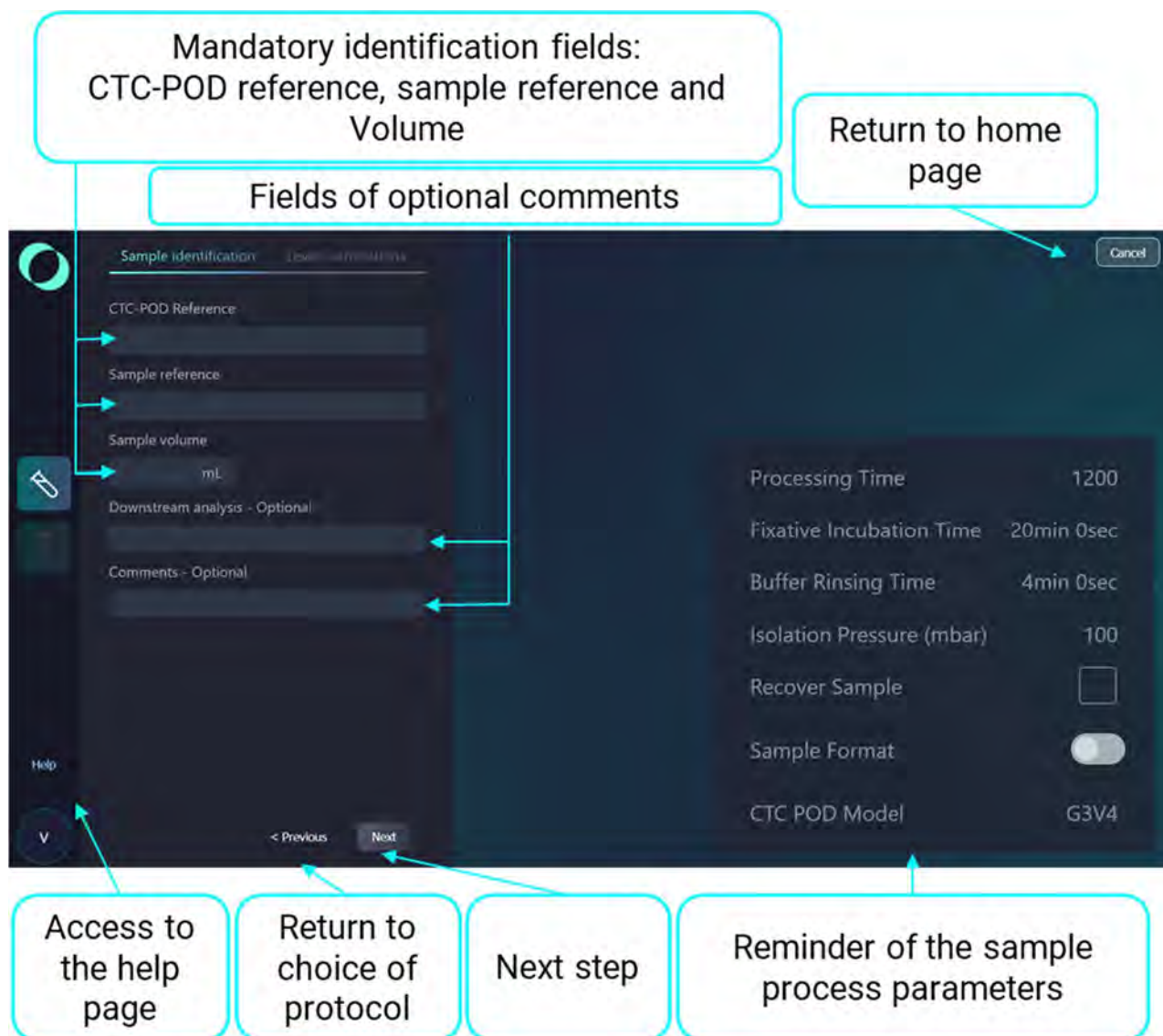


Figure 10.6: GUI page for protocol selection

10.7 Sample identification



The screenshot shows the 'Sample identification' screen. On the left, there are input fields for 'CTC-POD Reference', 'Sample reference', 'Sample volume' (with a unit 'mL' dropdown), 'Downstream analysis - Optional', and 'Comments - Optional'. On the right, there is a list of process parameters: 'Processing Time' (1200), 'Fixative Incubation Time' (20min 0sec), 'Buffer Rinsing Time' (4min 0sec), 'Isolation Pressure (mbar)' (100), 'Recover Sample' (checkbox), 'Sample Format' (toggle), and 'CTC POD Model' (G3V4). At the bottom, there are navigation buttons: '< Previous', 'Next', and a 'Cancel' button in the top right corner. A 'Help' icon is in the bottom left.

Annotations with arrows pointing to specific elements:

- Mandatory identification fields: CTC-POD reference, sample reference and Volume** (points to the first three input fields)
- Fields of optional comments** (points to the 'Downstream analysis - Optional' and 'Comments - Optional' fields)
- Return to home page** (points to the 'Cancel' button)
- Access to the help page** (points to the 'Help' icon)
- Return to choice of protocol** (points to the '< Previous' button)
- Next step** (points to the 'Next' button)
- Reminder of the sample process parameters** (points to the list of parameters on the right)

Nota: The CTC-POD® reference corresponds to the batch number of the CTC-POD®.

Figure 10.7: GUI page for sample identification

10.8 Filling the reservoirs

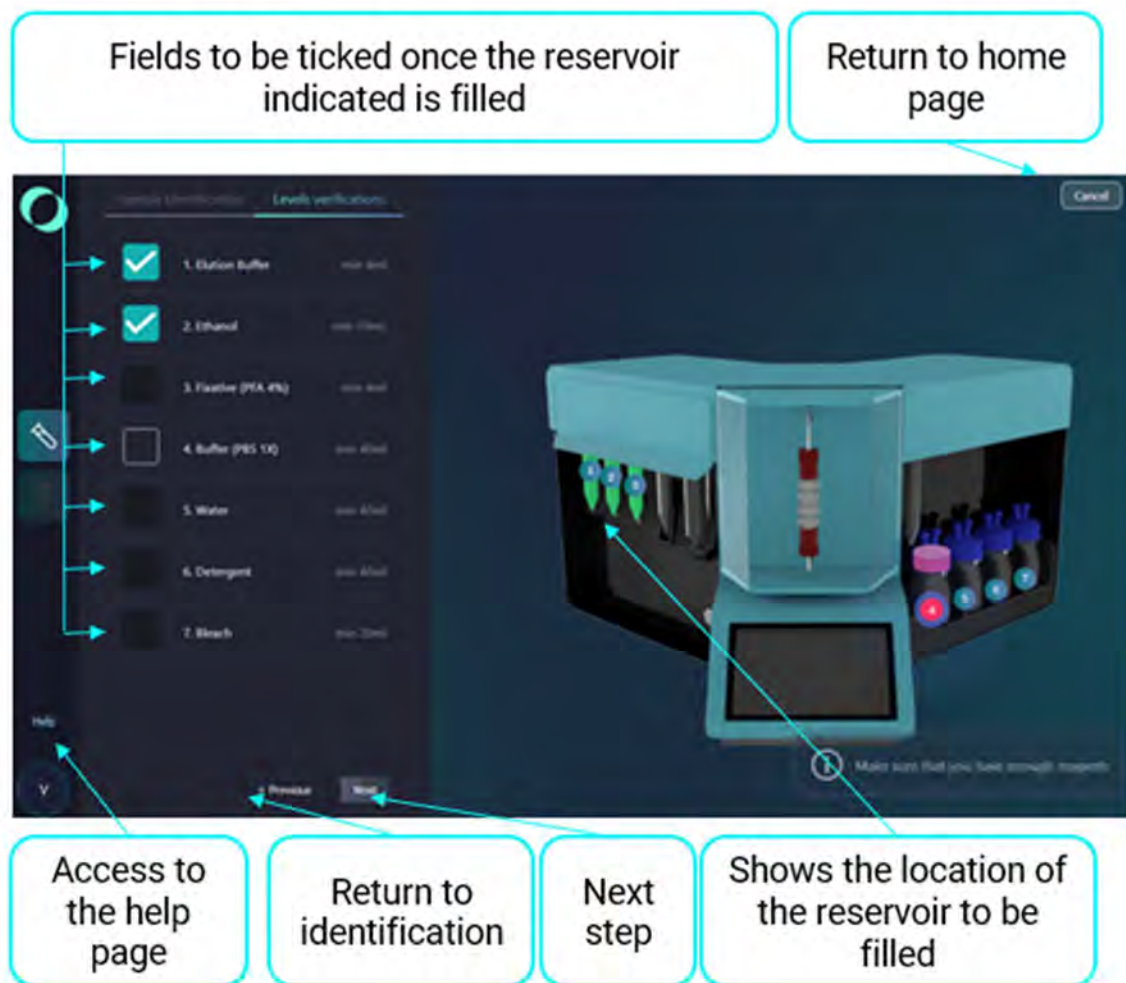


Figure 10.8: Tank filling GUI page

10.9 Closing the Dummy POD connectors

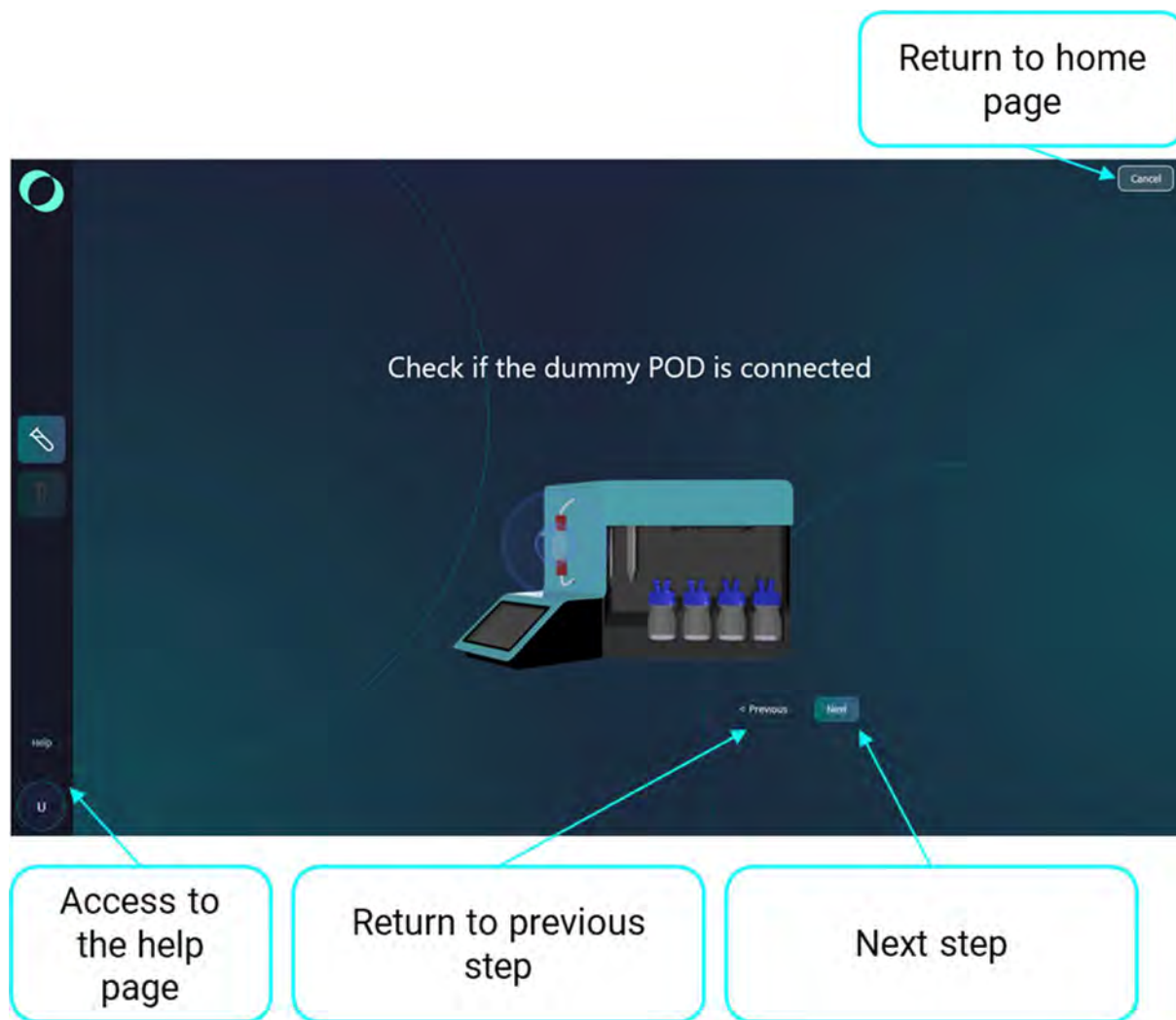


Figure 10.9: GUI page for closing dummy POD connectors

10.10 Placement of empty tubes

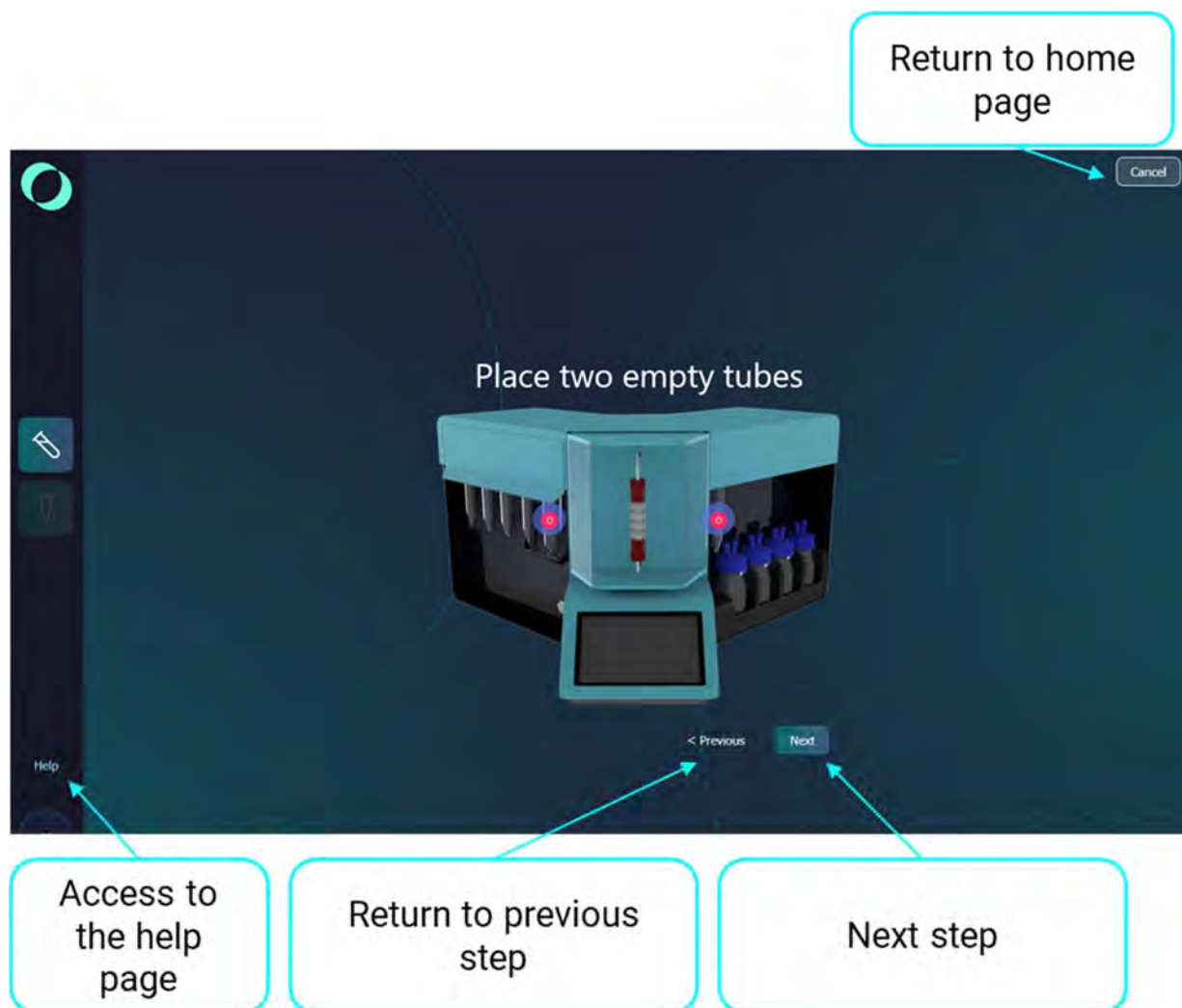


Figure 10.10: GUI page for replacing empty tubes

10.11 Biofluid sample placement

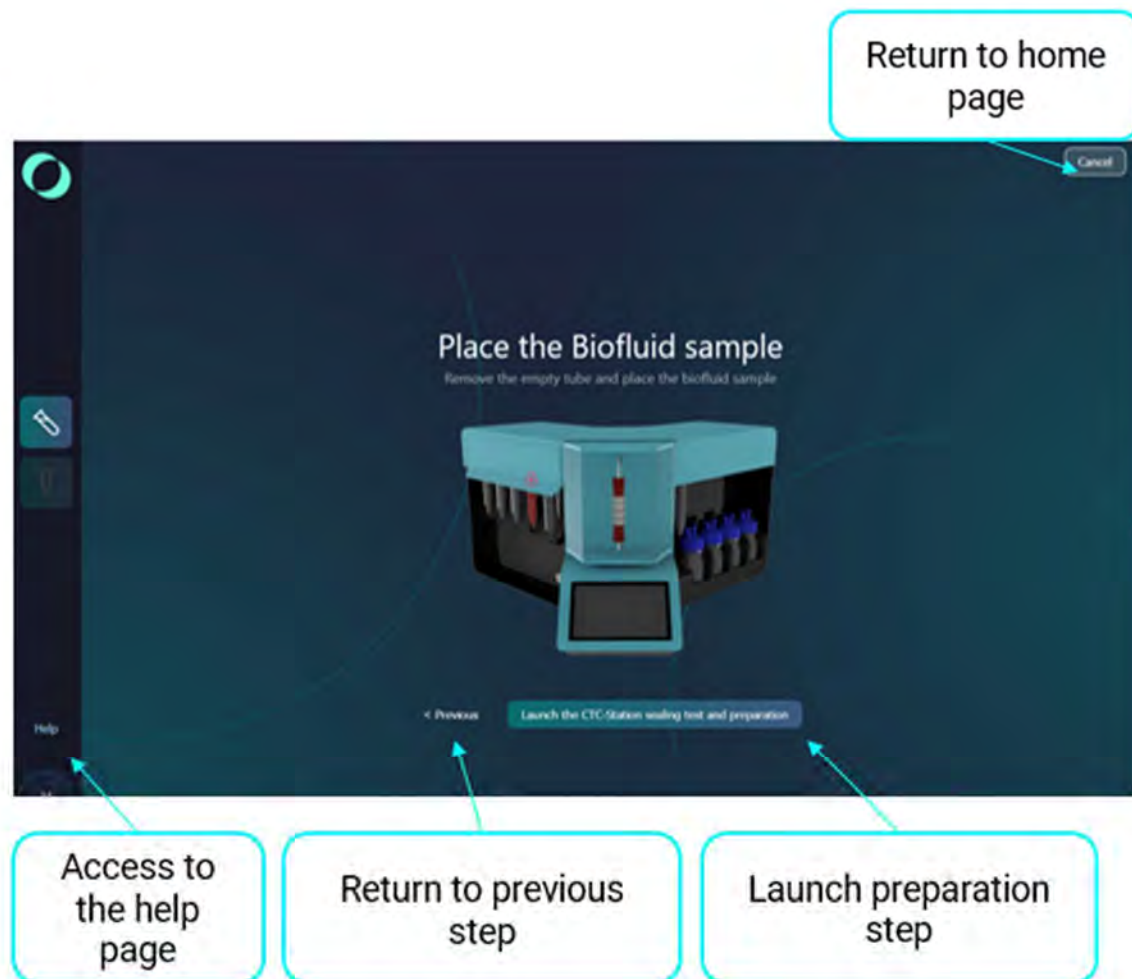


Figure 10.11: GUI page for biofluid sample placement

10.12 Preparation phase

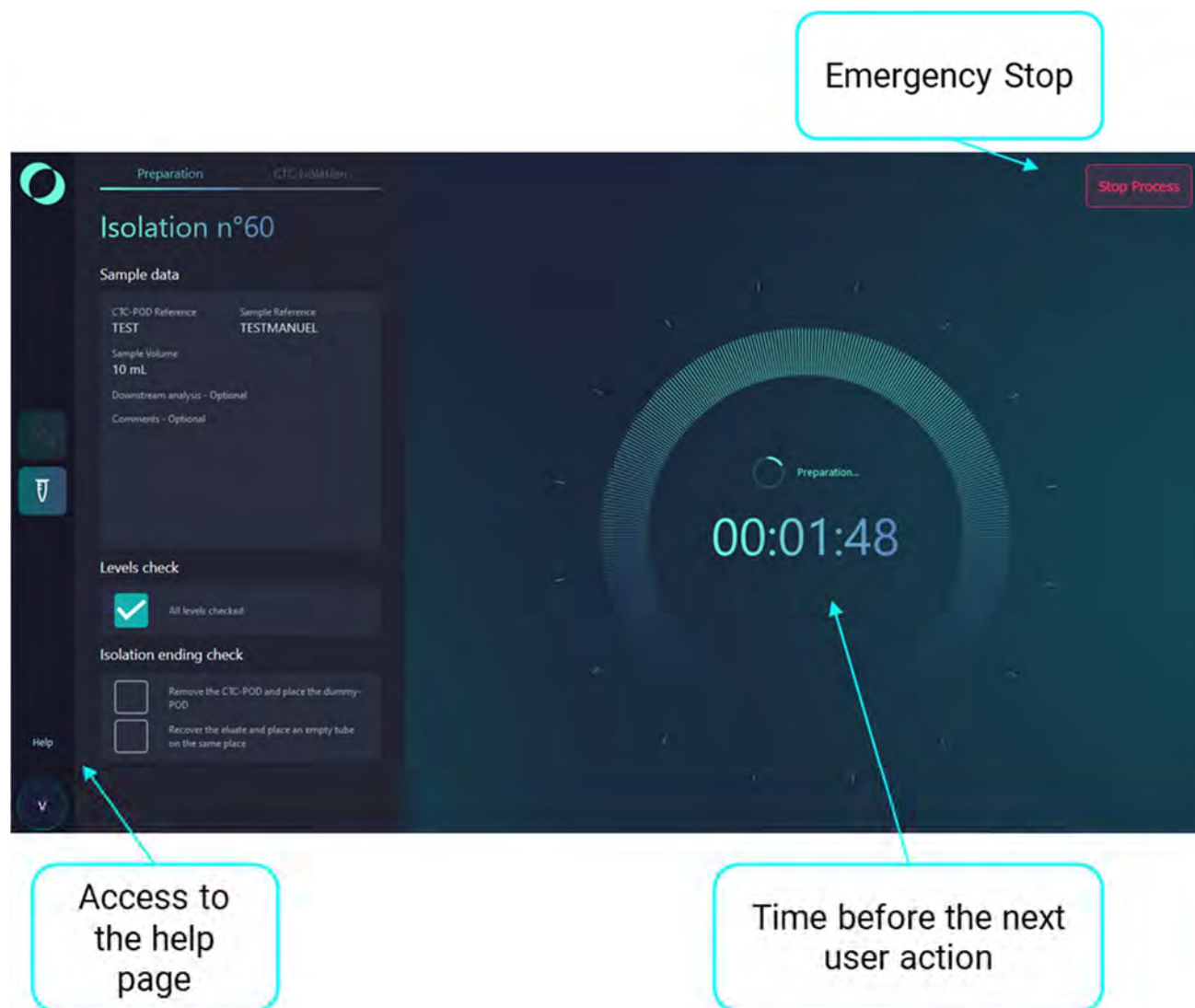


Figure 10.12a: GUI page for the preparation phase

Note: The "stop process" button pauses the process, to be used in an emergency. The pause button allows the process to be resumed or exited by being redirected to cleaning.

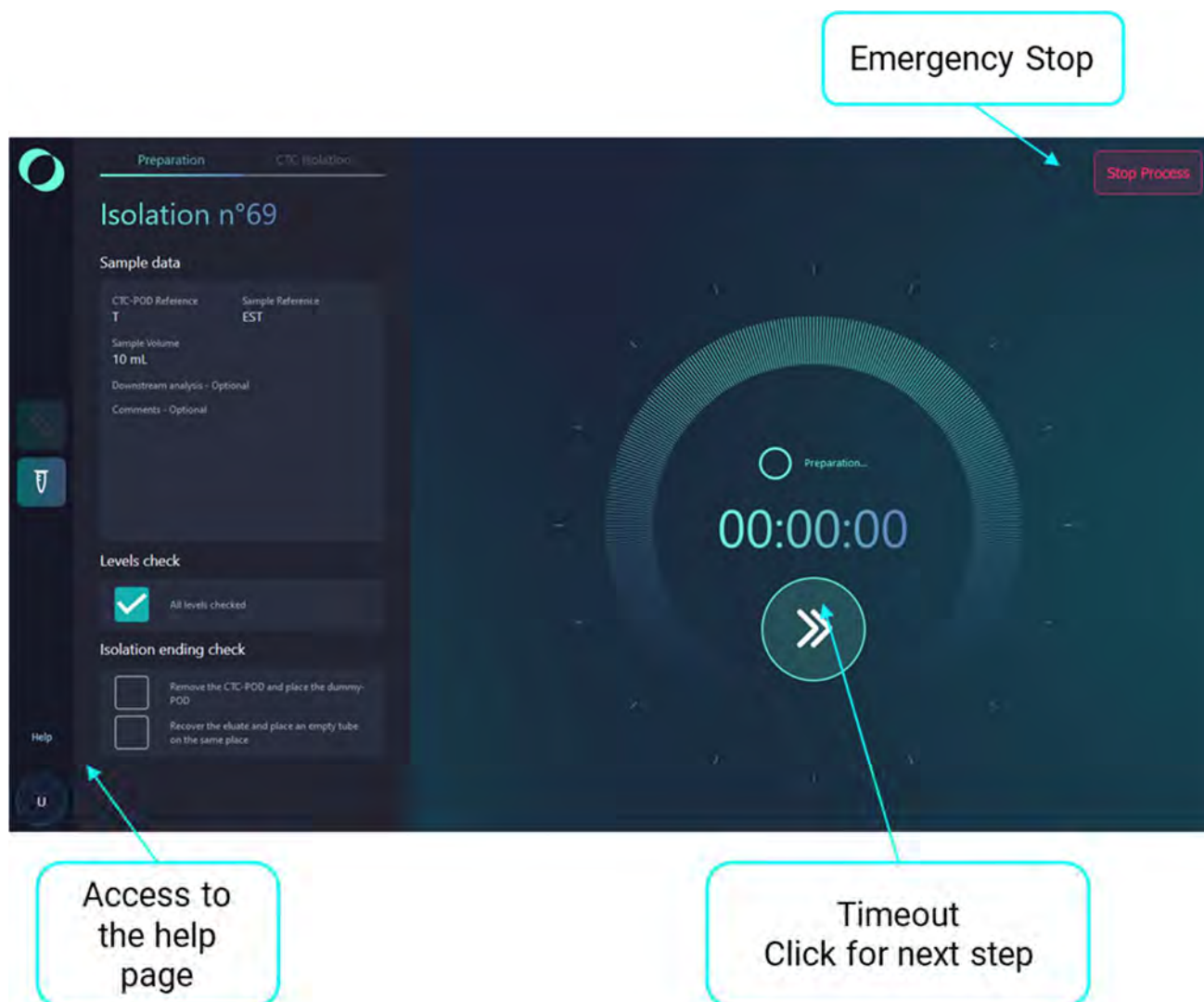


Figure 10.12b: GUI page for end of preparation phase

10.13 Setting up CTC-POD®

See section 8 for more details

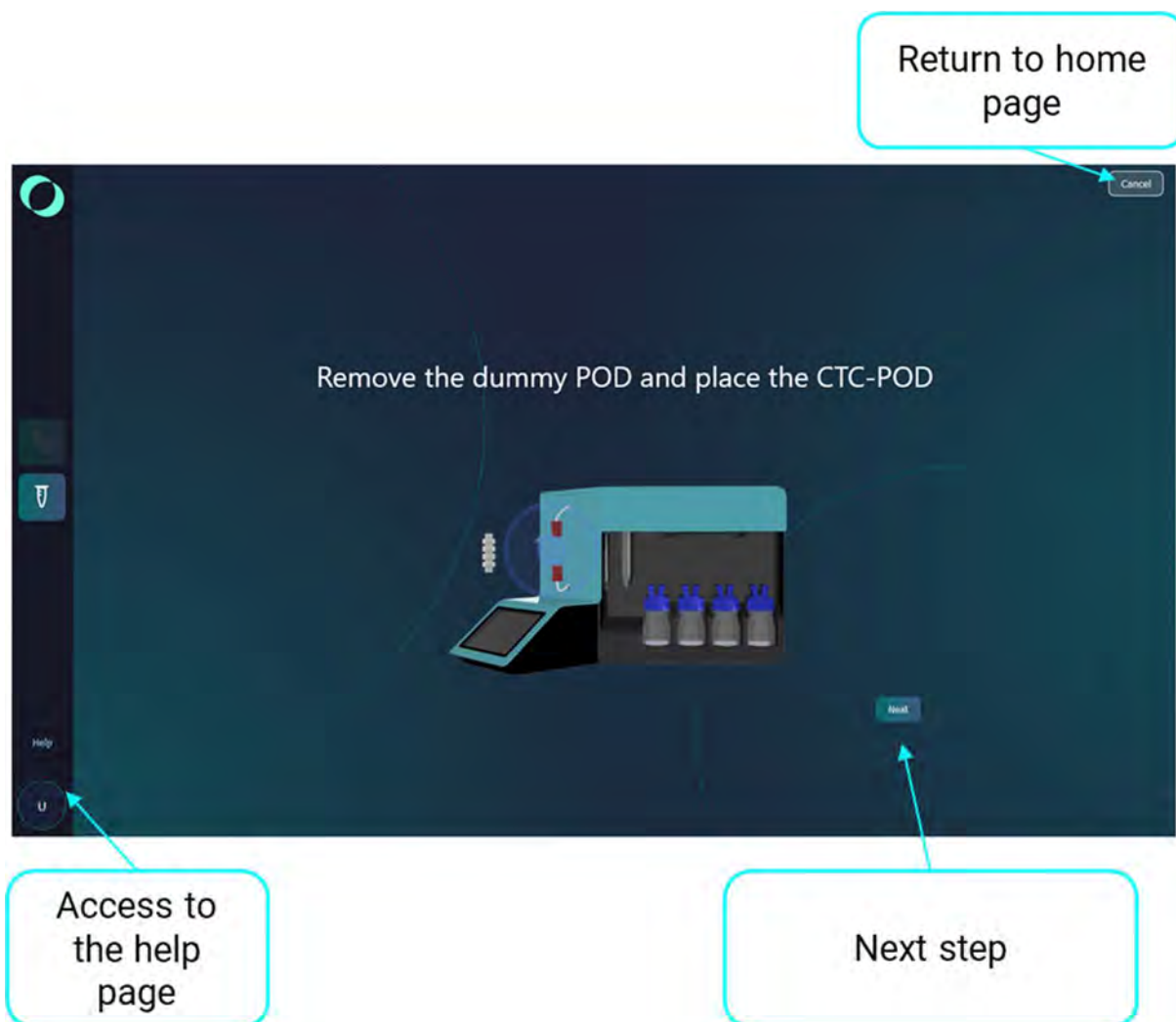


Figure 10.13: GUI page for setting up CTC-POD® or CTC-INSITU

10.14 Launching the selected protocol

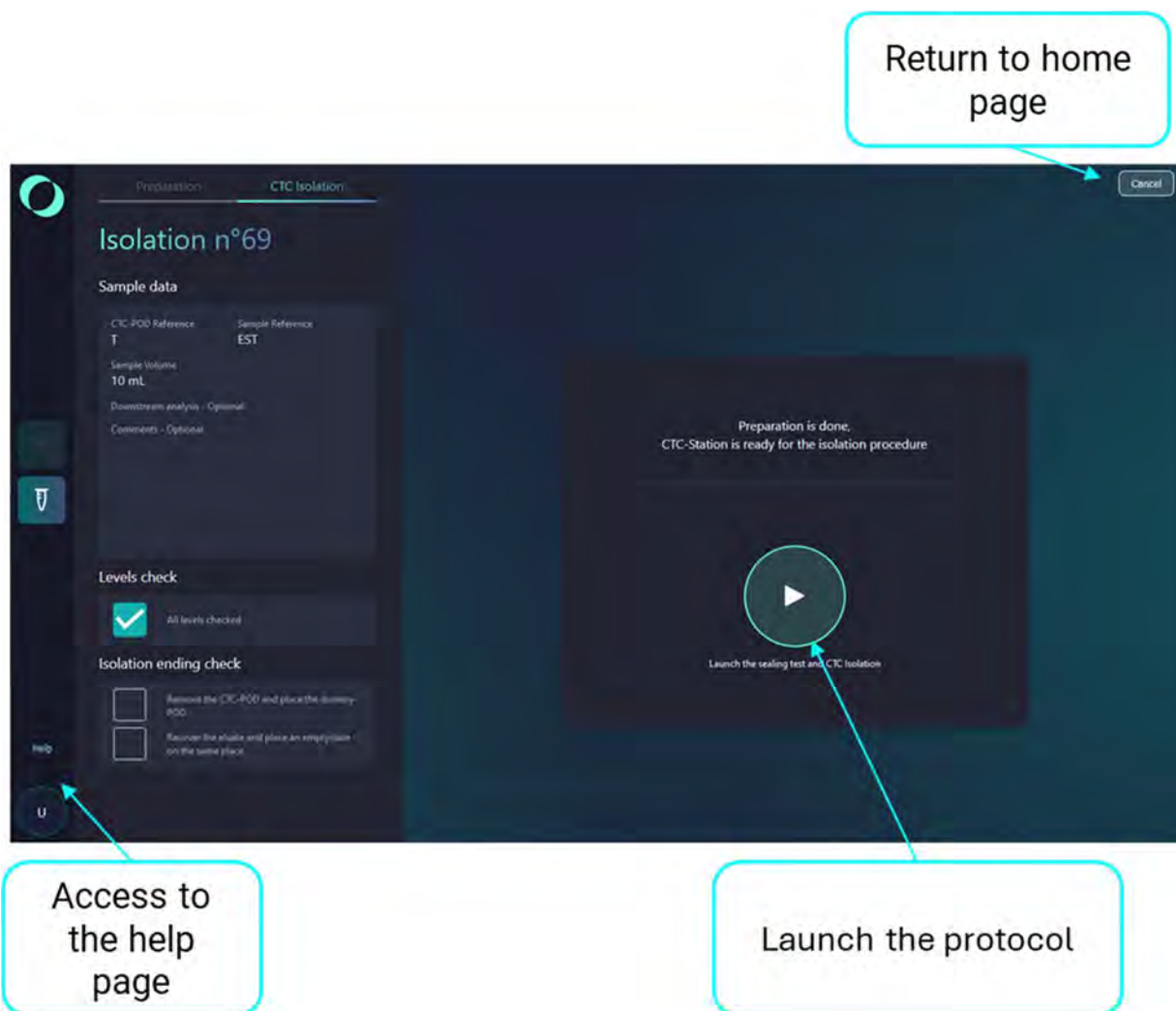


Figure 10.14: GUI page for launching the selected protocol

10.15 Isolation progress

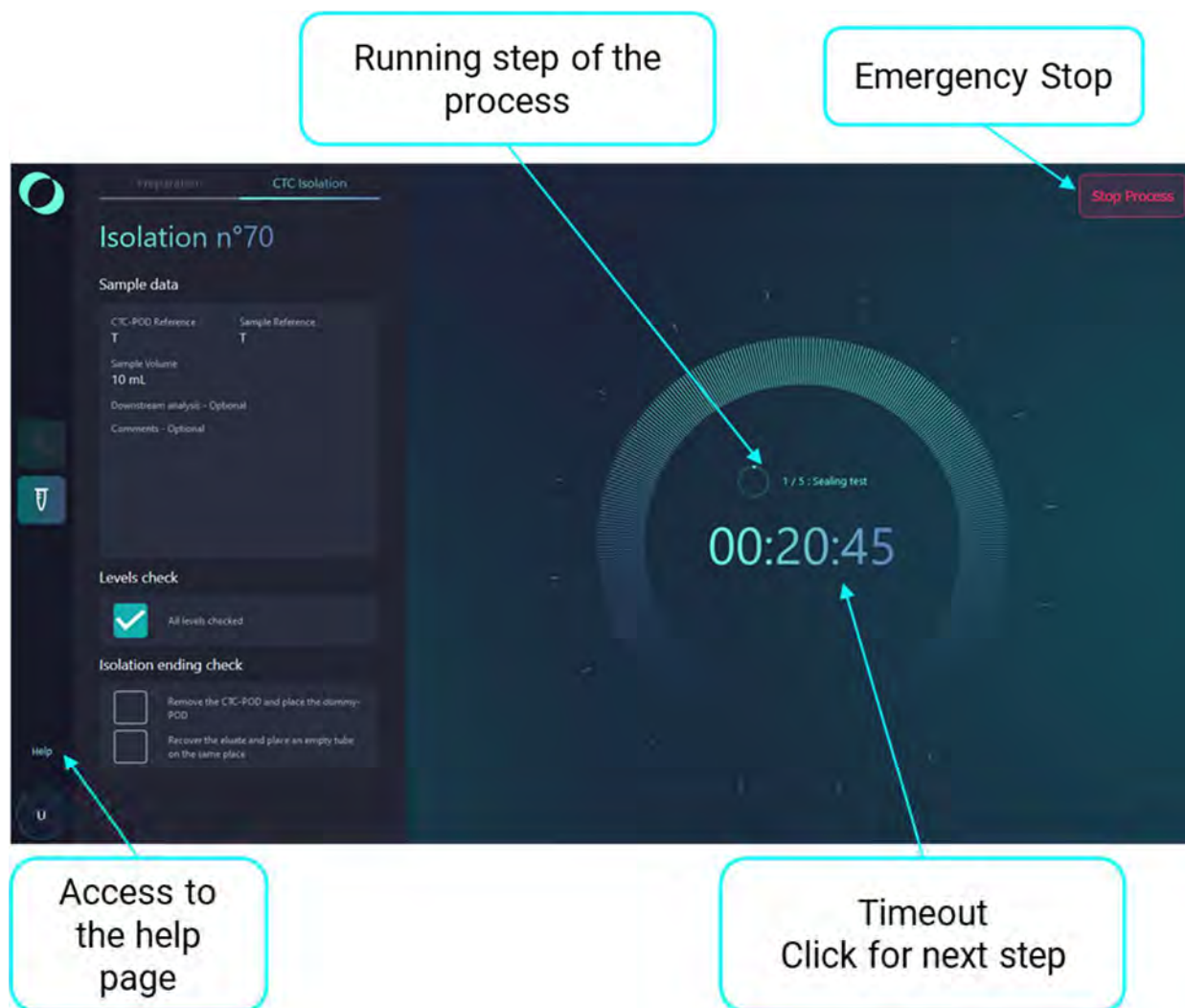


Figure 10.15: GUI page showing progress in isolating cells of interest

10.16 Eluate tube replacement (Process Isolation and resuspension)

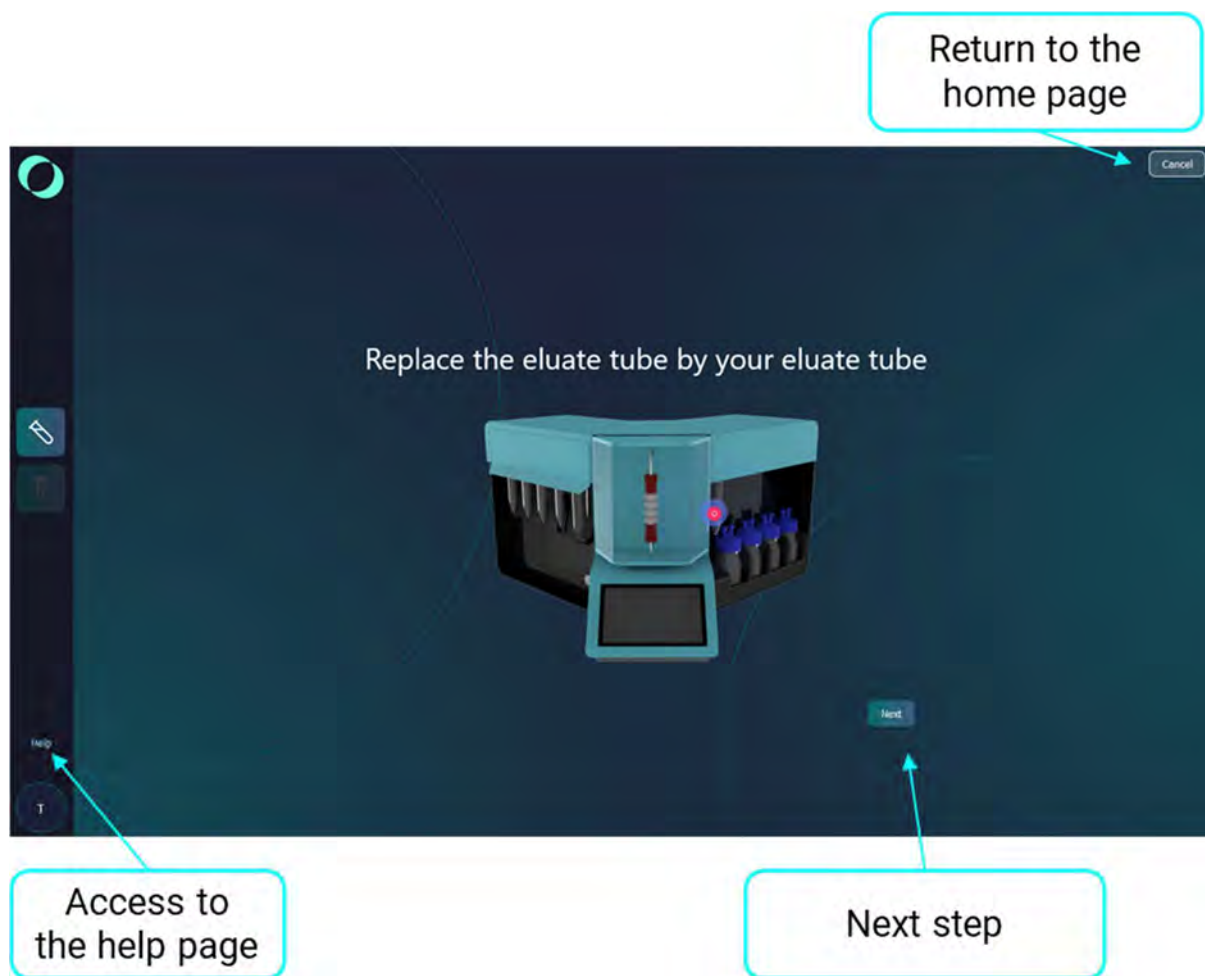


Figure 10.16: GUI page requesting eluate tube replacement

10.17 Press on emergency stop

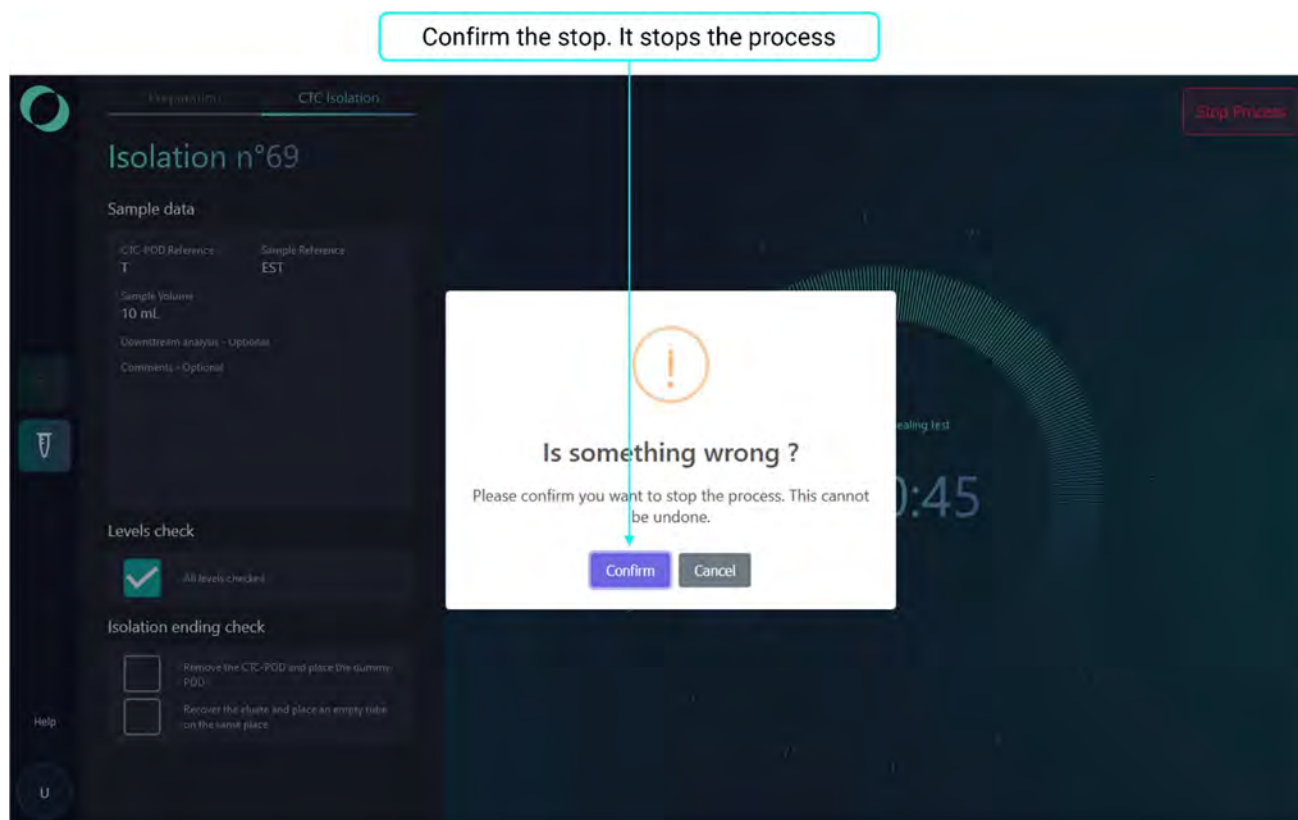


Figure 10.17 GUI page when emergency stop is pressed

10.18 Retrieve CTC-POD® & eluate tube - Close CTC-POD® connectors - Start cleaning process

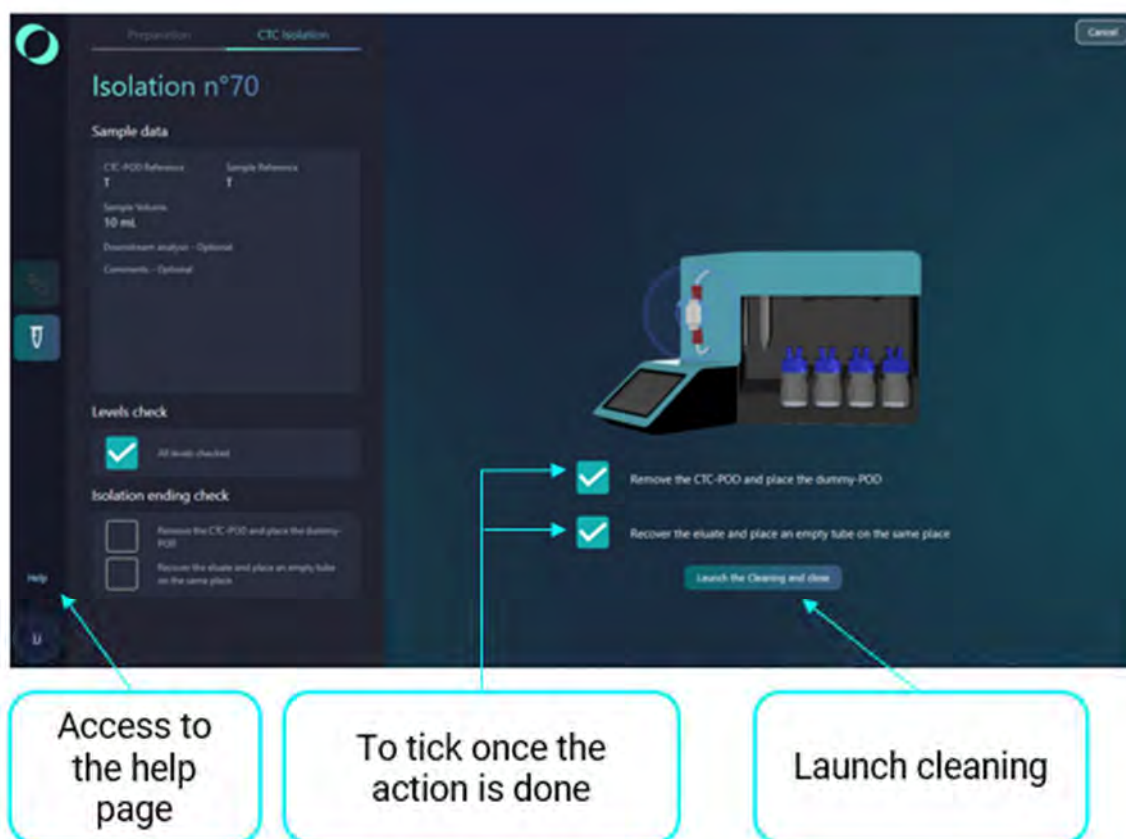


Figure 10.18: GUI page for recovery of CTC-POD® and eluate tube - Closing the CTC-POD® connectors - Starting cleaning

10.19 Report file

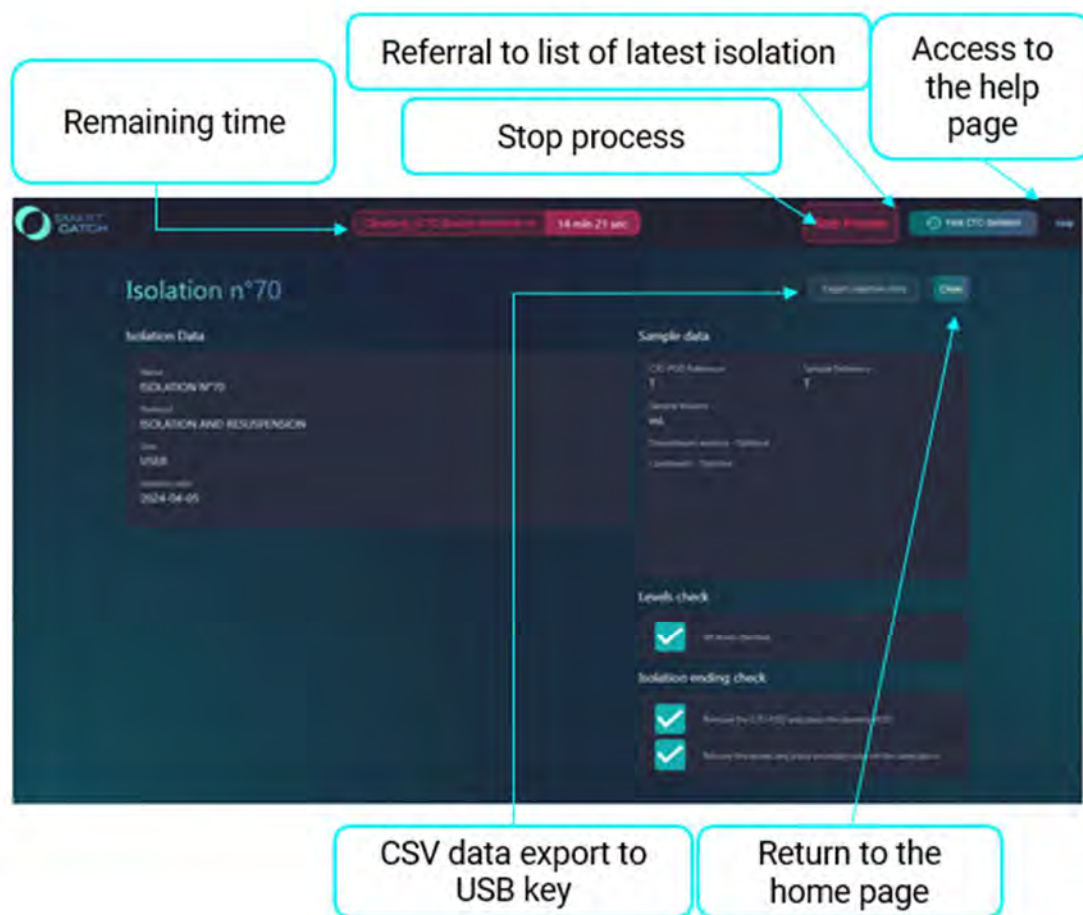


Figure 10.19: GUI page for reporting and exporting data in ".csv" file

10.20 Back to home - X-TRACKER® not available

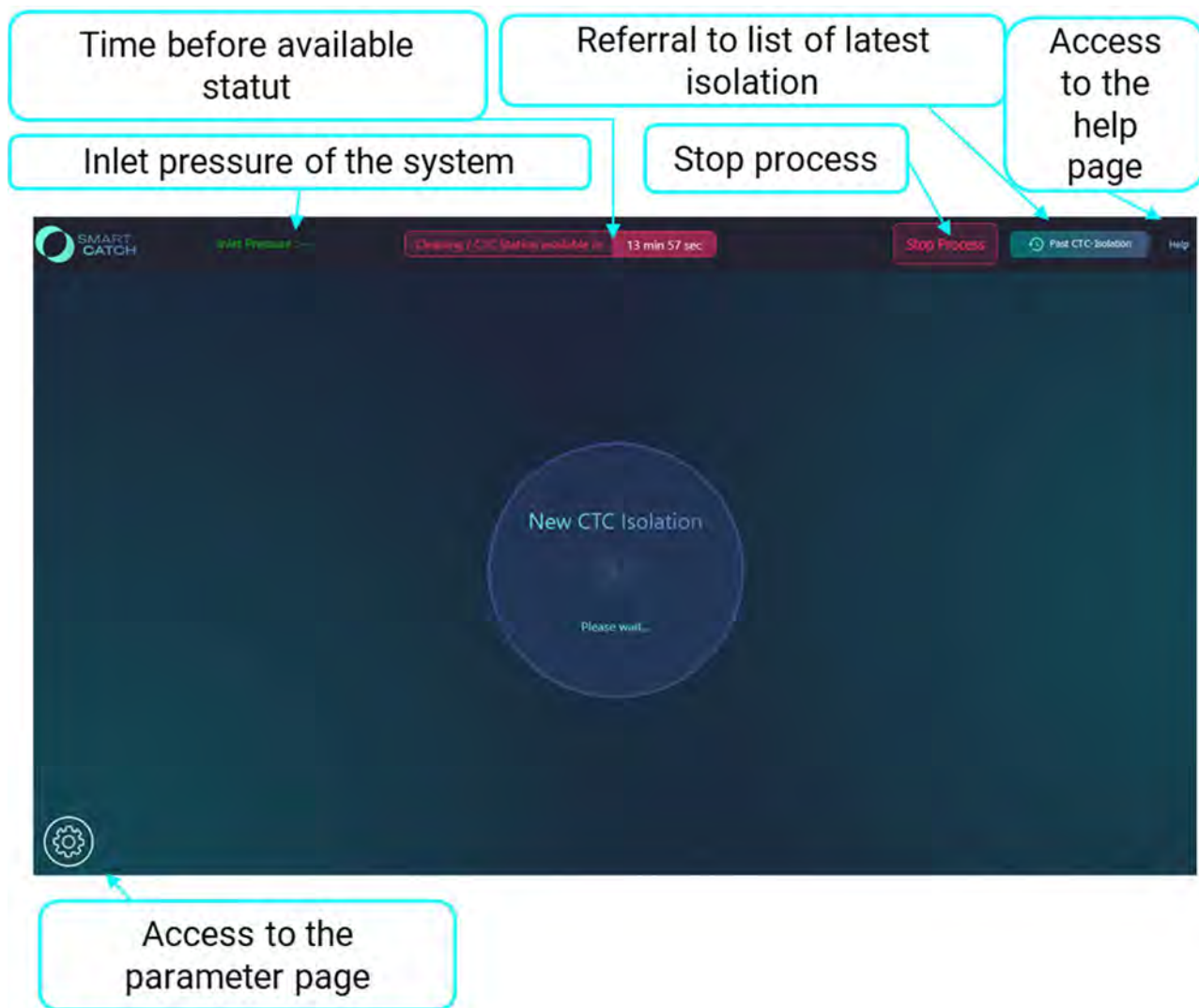
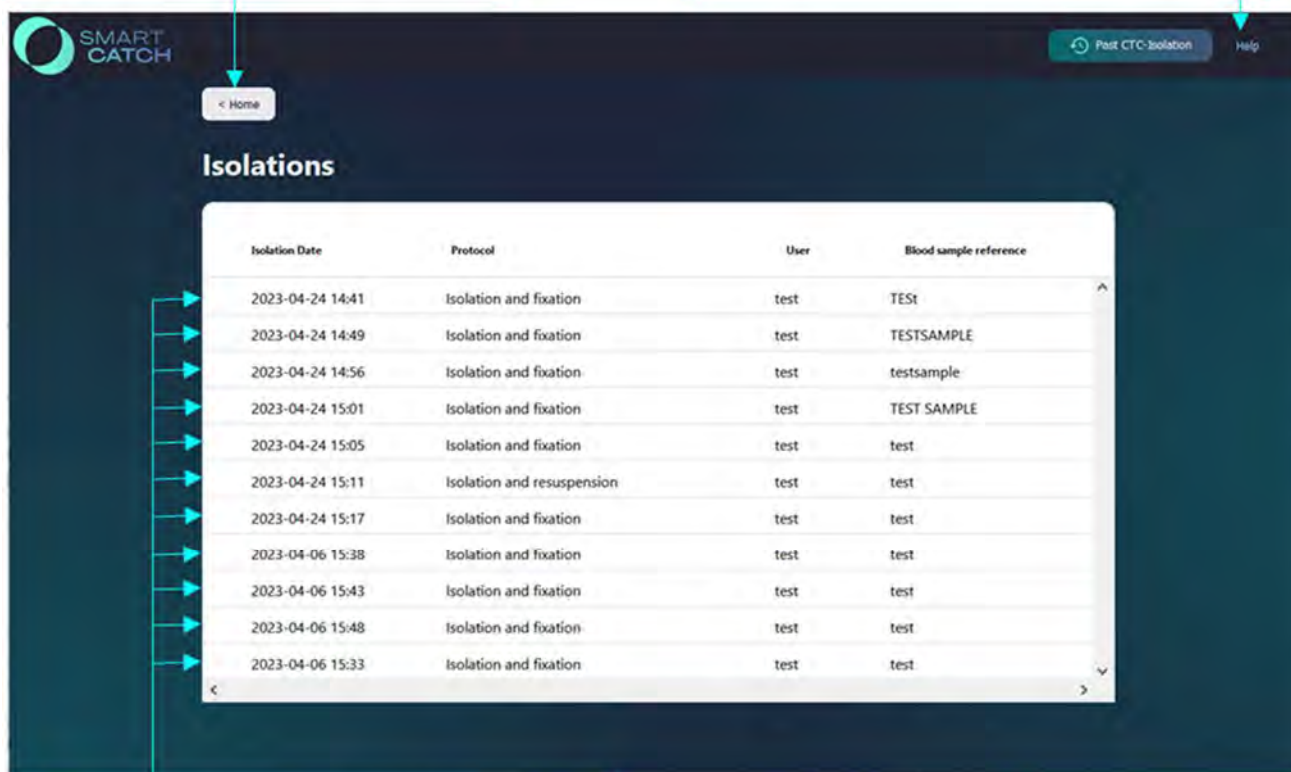


Figure 10.20: GUI page for return to reception and unavailability of X-TRACKER®

10.21 History of instrument protocols

Return to home page

Access to the help page



Isolations

Isolation Date	Protocol	User	Blood sample reference
2023-04-24 14:41	Isolation and fixation	test	TEST
2023-04-24 14:49	Isolation and fixation	test	TESTSAMPLE
2023-04-24 14:56	Isolation and fixation	test	testsample
2023-04-24 15:01	Isolation and fixation	test	TEST SAMPLE
2023-04-24 15:05	Isolation and fixation	test	test
2023-04-24 15:11	Isolation and resuspension	test	test
2023-04-24 15:17	Isolation and fixation	test	test
2023-04-06 15:38	Isolation and fixation	test	test
2023-04-06 15:43	Isolation and fixation	test	test
2023-04-06 15:48	Isolation and fixation	test	test
2023-04-06 15:33	Isolation and fixation	test	test

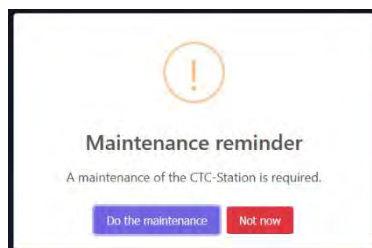
Access to report page and data export

Figure 10.21: GUI page for accessing past isolation data

11 User maintenance

11.1 Maintenance reminder

When the following message appears on the screen, the level 1 maintenance need to be performed see section 11.2.



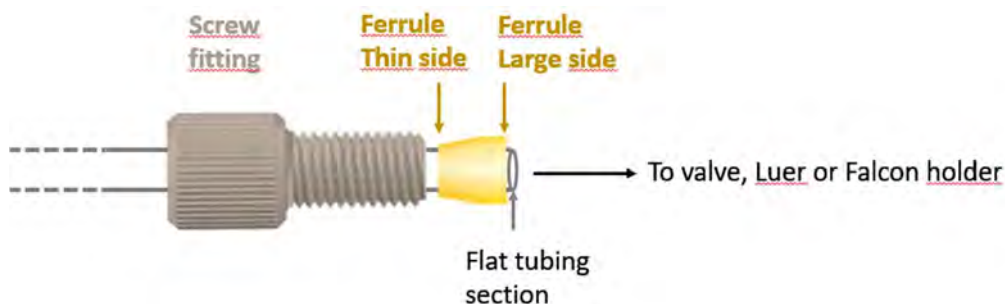
The message will appear each time the instrument is used, until maintenance is carried out.

11.2 Level 1 maintenance

It is important that the user wears laboratory PPE (Personal Protective Equipment) during the level 1 maintenance operation: gown, glasses, and gloves.

- Make sure that the system is disconnected from electrical and pressure sources
- The user removes the screws (17) holding the lid (16) and removes the lid.
- With tubings from the fluidic kit, the user replaces each of the tubings through which biofluid passes during isolation. The procedure to follow is shown on screen.

To ensure a watertight system, the fitting and ferrule assembly must be placed on the manifold as follows:



The fitting is screwed until the ferrule crushes in the bottom of the screw thread.

- Once all the tubing has been changed, the user is prompted via the interface to start a cleaning cycle.



During cleaning, it is important to check that there are no leaks in the new fluid circuit.

- The user closes the lid (16) and secures it with the screws (17).

12 LED communication

The ON/OFF button (11) on the front panel features a luminous ring which communicates different X-TRACKER® statuses according to its color and flashing frequency.

Color	Frequency	Type	Description	Error Number (See §13)
Red	Quick blinking	Error	An air leak is detected, screw the various tanks back on correctly	1.1 or 1.2
Red	Slow flashing	Error	Communication error between display and instrument. Wait 1 minute before restarting the instrument.	3.1 or 3.2 or 3.3 or 3.4
Red	Permanent	Information	Emergency stop button engaged	/
Orange	Quick blinking	Action required	A bottle whose name appears on the screen must be filled.	/
Orange	Slow flashing	Action required	The garbage can must be emptied	/
Orange	Permanent	Action required	A cleaning operation is to be launched	/
Purple	Permanent	Information	Fixer incubation in progress	/
Green	Permanent	Information	Maintenance mode	/
Yellow	Permanent	Information	Manufacturer mode	/
Blue	Slow flashing	Action required	Validation is required to move on to the next step	/
Blue	Permanent	Information	X-TRACKER® is switched on and initializes	/
Blue-green	Fade in(*)	Information	A protocol is underway	/
White	Permanent	Information	X-TRACKER® is on and ready to go	/
No	No	Information	X-TRACKER® is not powered up	/
Pink	Fade in(*)	Information	Cleaning in progress	/

(*) Fade: LED intensity increases slowly then decreases cyclically.

13 Troubleshooting Guide

Some troubleshooting can be carried out by the user without difficulty.



Users are reminded that they must wear the appropriate personal protective equipment for the items they are handling.

When using the fixative, the communication LED lights up purple and fades.

The most common problems that can be encountered:

Category	Error N°	When	Steps to problem solving
Air leak	1.1	To launch a protocol	<ol style="list-style-type: none"> 1. Make sure all tanks are properly closed. 2. Ensure that all fluidic connections exiting from bottles and test tubes are screwed down as far as they will go. 3. Ensure that the inlet pressure is at the same value as on the day of installation. 4. Run a new machine setup to check that the problem has been solved. 5. If the leak persists, contact SmartCatch.
	1.2	During protocol execution	<ol style="list-style-type: none"> 1. Stop the process via emergency stop. 2. Make sure all tanks are properly closed. 3. Ensure that all fluidic connections exiting from bottles and test tubes are screwed down as far as they will go. 4. Ensure that the inlet pressure is at the same value as on the day of installation. 5. Start pressure test. 6. Depending on the process step in progress, the user will be prompted to resume at the point where the stop occurred, or to move on to the next step.
Liquid leak	2.1	CTC-POD® connector leak	<ol style="list-style-type: none"> 1. Stop the process via emergency stop. 2. Reconnect the Luer-Locks to the CTC-POD®, pressing down firmly and screwing the transparent part that locks the CTC-POD in place. 3. Depending on the process step in progress, the user will be prompted to resume at the point where the stop occurred, or to move on to the next step. 4. If the problem persists, change CTC-POD®. 5. If the problem persists, change the CTC-POD® connectors included in the maintenance kit. 6. If the problem persists, contact SmartCatch.

Category	Error N°	When	Steps to problem solving
	2.2	Valve connector leaks	<ol style="list-style-type: none"> 1. Stop the process via emergency stop 2. Screw the corresponding connectors back on 3. Depending on the process step in progress, the user will be asked to resume at the point where the stop occurred, or to move on to the next step. 4. If the problem persists, change the connectors on the tubing concerned, which are included in the maintenance kit. 5. If the problem persists, contact SmartCatch.
Loss of software communication	3.1	The error is signalled via the interface - Outside a running process	<ol style="list-style-type: none"> 1. If the reported communication error occurs outside a running process, wait at least one minute. X-TRACKER® will try to resolve the error on its own before returning to a usable state. 2. If X-TRACKER® is unable to resolve the error. Whenever possible, switch off the machine via the interface. Otherwise, hold down the On/OFF button (11) for 5 seconds to switch off X-TRACKER®. 3. Re-activate X-TRACKER® by holding the ON/OFF button (11) for 2 seconds. 4. Contact SmartCatch if the problem persists.
	3.2	The error is signalled via the interface - during an ongoing process	<ol style="list-style-type: none"> 1. Use the emergency stop button to stop the flow. 2. If emergency stop is not available, disconnect air supply (22) to stop flow. 3. Wait at least one minute. X-TRACKER® will try to resolve the error on its own before returning to a usable state. 4. If X-TRACKER® is unable to resolve the error. If possible, switch off the machine via the interface (see section 10.2). Otherwise, hold down the On/OFF button (11) for 5 seconds to switch off X-TRACKER®. 5. Reconnect air supply (22) 6. Re-activate X-TRACKER® by holding the ON/OFF button (11) for 2 seconds. 7. Start a cleaning process (see section 10.18) 8. Contact SmartCatch if the problem persists
	3.3	Interface no longer responds - Outside a running process	<ol style="list-style-type: none"> 1. Wait at least one minute. THE X-TRACKER® will try to resolve the error on its own before returning to a usable state. 2. If X-TRACKER® fails to resolve the error. Press and hold the On/OFF button (11) for 5 seconds to switch off X-TRACKER®.

Category	Error N°	When	Steps to problem solving
			3. Re-activate X-TRACKER® by holding the ON/OFF button (11) for 2 seconds. 4. Contact SmartCatch if the problem persists.
	3.4	Interface no longer responds - Outside a running process	1. Disconnect air supply (22) to stop air flow. 2. Wait at least one minute. X-TRACKER® will try to resolve the error on its own before returning to a usable state. 3. If X-TRACKER® fails to resolve the error. Press and hold the ON/OFF button (11) for 5 seconds to switch off X-TRACKER®. 4. Reconnect air supply (22) 5. Re-activate X-TRACKER® by holding the ON/OFF button (11) for 2 seconds. 6. Start a cleaning process (section 10.18) 7. Contact SmartCatch if the problem persists

13.1 List of error codes

Error code	Description
FGTSENS_001 FGTPRES_001	<i>OverPressure</i> for pressure control system , triggered when controller input pressure exceeds maximum value (2.1bars)
FGTSENS_002 FGTPRES_002	<i>UnderPressure</i> for pressure control system, triggered when controller input pressure falls below minimum value (1.6bars)
FGTSENS_003 FGTPRES_003	<i>ValueError</i> for the pressure control system, triggered when the Value received is not the one expected

NB:

- **FGTPRES** : FGT Pressure

14 Conditions of transport, storage, use and removal

14.1 Environmental conditions

		Minimum	Maximum
Transport and Storage	Temperature	0°C	40°C
	Relative air humidity	10%	90%
Use	For indoor use only		
	Temperature	10°C	30°C
	Relative air humidity	30%	85%

14.2 Location



During transport and storage, the X-TRACKER® must be protected from foreign objects. The X-TRACKER® must be stored away from liquid splashes.



When in use, the X-TRACKER® must be placed flat on a laboratory bench or in a chemical hood depending on the type of chemical used.

14.3 Lifting and transport instructions

To avoid any risk of damage to the unit, transport it in an upright position.

For a change of location in the same room, it is recommended that 2 operators equipped with their personal protective equipment (PPE) laboratory proceed with the following steps:

1. Disconnect connections: power supply, pneumatic supply, fluid outlet to waste, waste tank overflow sensors;
2. Lift the machine vertically with an operator on either side (Figure 14.3.1);
3. Move the instrument to its new location.

For a change of premises, before moving the instrument, please ensure before to

1. Remove connections: power supply, pneumatic supply, fluid outlet to waste, waste tank overflow sensors;
2. Empty all fluid reservoirs;
3. Use adhesive tape to secure any moving parts: cylinder tanks, CTC-POD® cover, etc;
4. Lift the unit vertically with an operator on either side (Figure 14.3.1);
5. Lift the unit vertically, placing an operator on either side of the packaging (Figure 14.3.2);
6. Use a cart or pallet truck to move the unit to the required location.
7. Inspect the system for damage after transport.

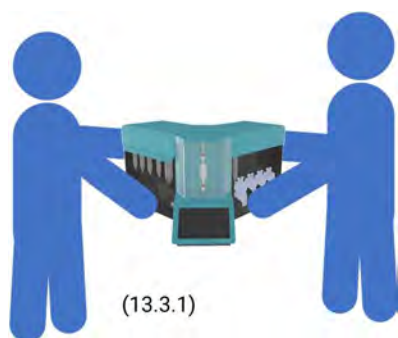


Figure 14.3.1: Transport mode of X-TRACKER® without packaging;

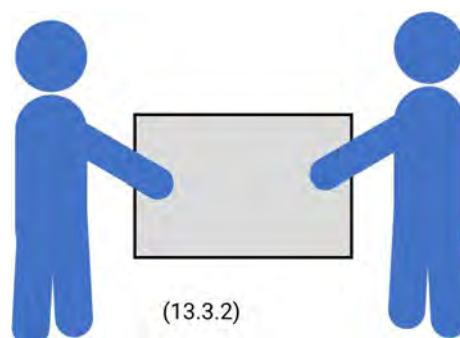


Figure 14.3.2: Transport of X-TRACKER® with packaging

14.4 Cleaning and maintenance



- Under no circumstances should cleaning be carried out when X-TRACKER® is switched on. The instrument must be switched off. Unplug the instrument from the power supply.
- Do not immerse any part of the electrical connector, cable or accessories in the cleaning or disinfecting solution. This could cause internal damage and shorten product life.
- Use wipes or cloths soaked in standard detergent and/or disinfectant solutions.
- Do not use abrasive materials for cleaning.
- Do not spill liquids on X-TRACKER®.
- The bottle holder (13) can be removed for better access to the areas to be cleaned.

14.5 Recycling



It is imperative that you do not dispose of the metal casing, including the touchscreen, and all or part of the electronic cards, with household waste, but rather with waste electrical and electronic equipment for reuse, recycling or any other form of recovery of this electrical and electronic equipment.

For each type of components, please apply the local recycling policy. If you need more information, contact SmartCatch.

It is the responsibility of each research facility to ensure that only theoretical and practical staff members, competent in the use of X-TRACKER® equipment, participate in the reprocessing or non-reprocessing of this system. The X-TRACKER® instrument can be returned to SmartCatch for disposal.

NB : For the consumable, please refer to its specific datasheet

15 Regulatory Information

15.1 CE compliance statement for Europe

The equipment complies with

- Electrical safety requirements for electrical equipment for measurement, control and laboratory use (EN 61010-1: 2010 + A1: 2019)
- Electro-Magnetic Field (EMC) (EN 62311: 2008)
- Low voltage directive (2014/35/UE).

15.2 FCC compliance statement for US

This device complies with part 15 of the FCC Rules (Federal Communications Commission FCC 47 CFR PART 15: 2024)

Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

SmartCatch is not responsible for any changes or modifications not expressly approved by the company. Such modifications could avoid the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. 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. Operation 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."

15.3 Canadian compliance statement for Canada

The class A equipment meets all requirements of the Canadian Interference-Causing Equipment (ICES 001 Ed.5 2020 / NMB 001 Ed.5 2020).

15.4 Other compliance statements (UK, Switzerland)

The equipment meets all requirements of the Electrical safety requirements for electrical equipment for measurement, control and laboratory use for Switzerland (SN EN 61010-1:2010) and United-Kingdom BS EN61010-1:2010 (for United Kingdom).

15.5 Proof of compliance statements

Summaries of electric safety and EMC test reports are available on request

- P02_DEV_SAFETY_RS-EVE-24A097-1A Ed.0.pdf
- P02_DEV_SAFETY_RS-EVE-24A097-2A Ed.0.pdf
- P02_DEV EMC_EU_RCE-EMI ESS24A097SMA-01Av0.pdf
- P02_DEV EMC_US-CA_RC-EVE-24A097-2A Ed.0.pdf

16 DOCUMENT HISTORY

VERSION	DATE	DESCRIPTION OF CHANGES
01	02/01/2025	Creation
02	31/01/2025	Update following registration recommendation and introduction of CTC-INSITU (new POD consommable)