



Ovizio Imaging Systems

ILine F Pro User Manual

#### Document

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08/10/2020	5.3	Compliance upgrade (FCC statements)

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## General Notice

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Every effort has been made to ensure that the contents of this manual are correct and up to date. The devices described in this document are protected by patents and other intellectual property rights. Ovizio and Ovizio Imaging Systems are protected brand names.

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Ovizio does not warrant that the operation of the device, or software, will be uninterrupted or error free.

The foregoing warranty shall not apply to defects resulting from improper or inadequate maintenance, unauthorized modification or misuse, operation outside of the environmental specifications for the product, or improper site preparation.

## Support

The Ovizio support can be contacted by mail to [support@ovizio.com](mailto:support@ovizio.com).

Software updates and online documentation are made available through the support web site at <http://support.ovizio.com>. A login and password are required to access your private support section and has been communicated when the microscope has been delivered. Should you meet any issue with your BioConnect disposable system or with the iLine F Pro, please send an email to [support@ovizio.com](mailto:support@ovizio.com). An Ovizio team member will contact you to fix it.

### **Ovizio Imaging Systems SA/NV**

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## Intended use

The system is designed for the in-line monitoring of morphological cellular parameters via a closed loop disposable probe that can be sterilized.

The system is referred hereafter as the iLine F Pro (cGMP).

The iLine F Pro is not classified as a medical device and as such ISO-13485 requirements do not apply.

The iLine F Pro is intended to be used standalone, with the delivered power supply unit. Except for the power supply port which is used to power the device, the various external ports are reserved for debugging and maintenance purposes only, and shall not be used during nominal use of the system.

The BioConnect cartridge interface and BioConnect pump interface available on the iLine F Pro front are intended to be used with a genuine BioConnect sold exclusively by Ovizio Imaging Systems S.A.

Ovizio assumes no liability for damage caused by, or any risks arising from the use of the device for purposes other than those for which it is intended, or use outside the specifications set forth by Ovizio.

In case of violation of the conditions described above, the Declaration of Conformity shall be invalid.








## Serial Number

The serial number of the device can be found on a sticker on the left side of the microscope when in front of you (eg. 20200313000 on the illustration below)

### iLine F Pro



## Symbols

---	Direct Current
CE	CE Marking
FCC	FCC Mark, stating the equipment is compliant with the regulations of the US Federal Communications Commission regarding electromagnetic interference
	Do not dispose. The equipment must be properly recycled.
	Safety warning. Read the user manual.
	Power symbol printed on the main instrument switch. Use to turn the instrument on or off.
	Protective conductor terminal
	Earth terminal

## Compliance

The iLine F Pro meets the requirements of the following Directives of the European Union:

- Low Voltage Directive (LVD) 2014/35/EU
- Electromagnetic Compatibility (EMC) Directive 2014/30/EU
- FCC ID: 2AXQY-I3TFMICG02A. *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.*

## Safety Warnings



### General

- The manual contains information and warnings, which have to be followed by the user to ensure safe installation, operation and to retain the equipment in safe condition. If the equipment is used in a manner not specified in this manual, the protection provided by the equipment may be impaired.
- This equipment is designed for monitoring bioreactors and must not be used for other purposes
- Wear personal protective equipment adapted to lab use of system
- This equipment must be used by trained personnel only
- If the equipment is integrated in a larger system, the installation in that system and the safety of the overall system is the responsibility of the integrator of the system.
- The power supply unit must be connected to a power socket providing connection to earth.
- The equipment must be installed such that it does not obstruct the way to the power supply connecting cable.



### Risk of electrical shock hazard

- Any interruption of the electrical wiring outside the **iLine F Pro** will make the device hazardous. Intentional interruption is prohibited.
- Capacitors inside the iLine F Pro may still be charged, even if the iLine F Pro has been disconnected from all voltage sources.
- Any adjustment, maintenance and repair of the opened device under voltage must be avoided as far as possible and, if inevitable, the activities must only be carried out by qualified personnel.
- Only use the equipment with the dedicated power supply, as described in the specifications



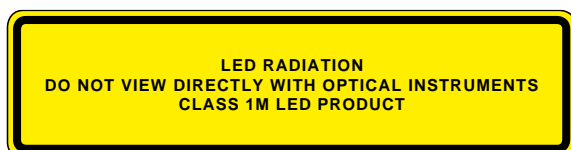
### Risk of damaging the equipment

- In most cases, a pump is installed with the **iLine F Pro**. The membrane part of the pump is disposable and may get damaged after sterilization, resulting in fluid leaking into the pump engine. Make sure that there are no visible damage to the pump membrane ( See part 15 in the *Connect > Get Started > Description* section) such as tears, before connecting to the pump engine.
- Do not use the front pump module for other purposes than connecting the BioConnect disposable
- The equipment needs cooling via the metal housing and the heat sink. Make sure the housing is not covered and the sides and the top have a free air flow passing.



### High power LED

The instrument operates high power LEDs that shall not be viewed with optical instruments, but are otherwise safe for the user.



### Other risks

The equipment housing may become hot during normal operation.

The use of the disposable bioconnect may lead to a higher oxygenation of the liquid due to oxygen diffusing through the tube walls into the liquid.

### Instructions for lifting and carrying



Do not lift or carry the equipment by handling the integrated pump module.

The device shall be held by its bottom plate only when being carried.

### Noise

The system uses pinch valves in its normal operation. A regular clicking sound is normal.

### Operating conditions

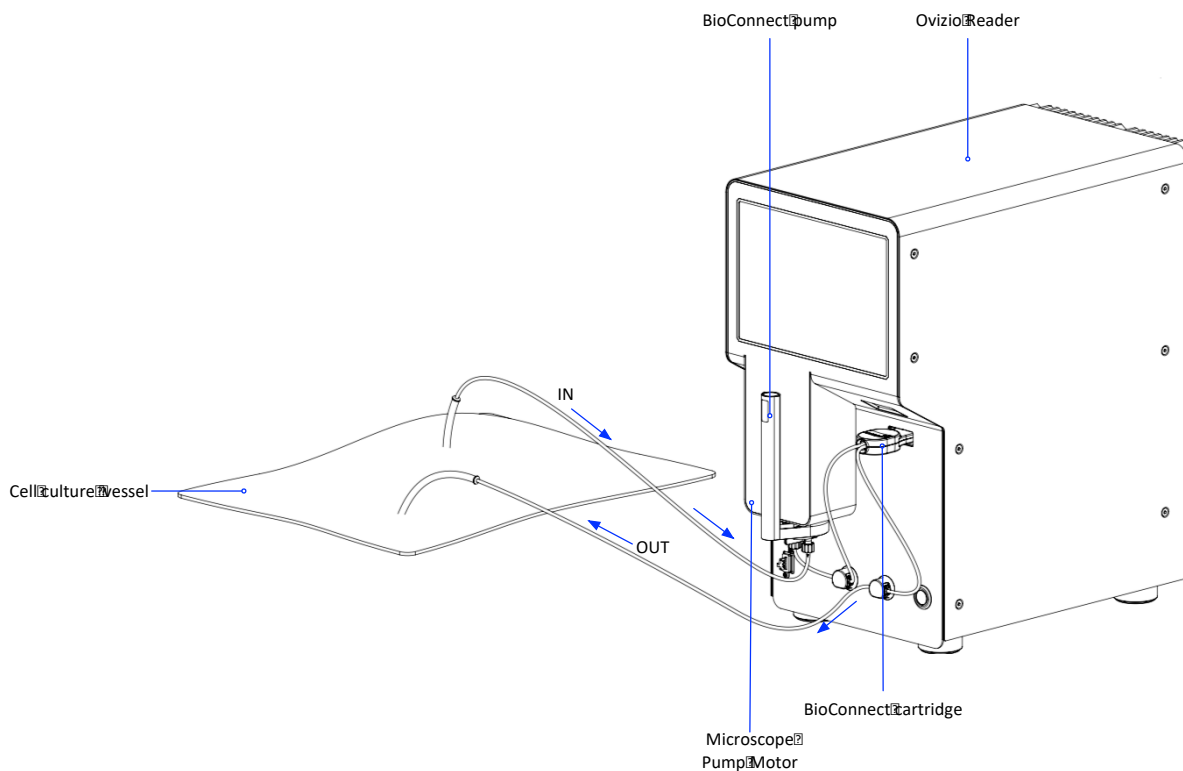
See specifications at the end of this manual

## Introduction

## System overview

Your online cell monitoring device is composed of two parts:

- The iLine F Pro
- The disposable probe called *BioConnect*.



System overview

The *BioConnect* pumps cells in closed loop from the inside of the bioreactor. The pump creates a flow of cells through the fluidic system contained in the cartridge.

The iLine F Pro uses the optical properties of your cells to count them, determine their viability and assess their morphological parameters. The cells are finally injected back into the bioreactor.

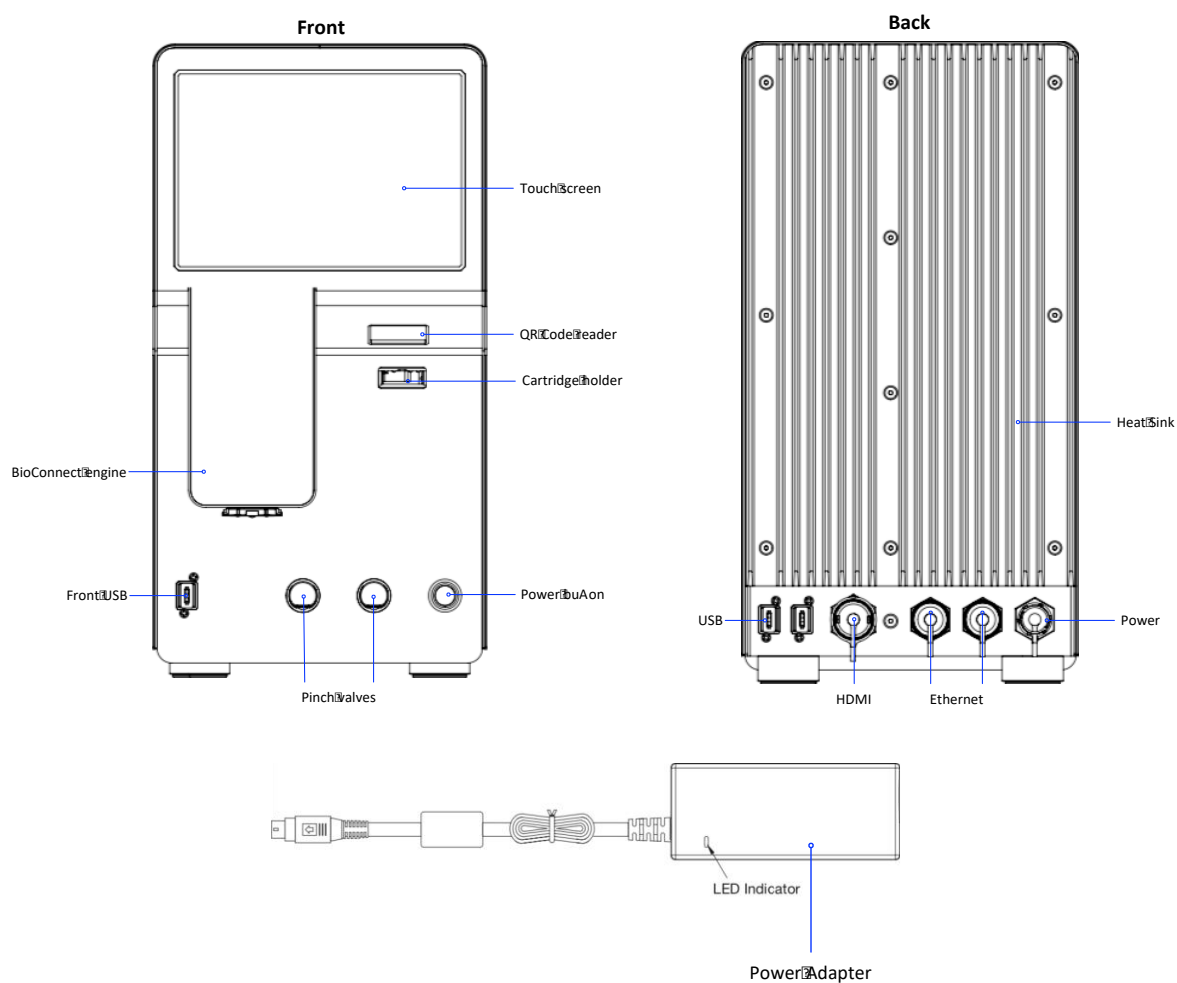
## Anatomy of your iLine F Pro

### Package contents

iLine F Pro

1 Power Adapter with Regional power plug

### Description



### Front

**Power Button:** The power button is used to startup and turn off the device. The power button flashes blue during the boot sequence and turn green when done. Press the button 2 seconds to turn the device off. The button blinks orange during shutdown. After that, it remains steady orange to indicate that the device is connected to the power.

**Cartridge holder:** The cartridge holder is where you insert the BioConnect cartridge.

**Pinch Valves:** Pinch valves are used to stop the flow while acquiring a data point.

**BioConnect engine:** The BioConnect engine couples to the pump and creates the flow

**QR Code Reader:** Reads the QR code label on the cartridge. This lets the system know the BioConnect version and serial number for traceability.

**Front USB plug:** Can be used to copy data or proceed to software update during maintenance operations.

**Touch screen:** Gives access to the user interface.

## Back

**USB plugs:** For maintenance purposes. Used to connect a mouse and a keyboard directly to the device embedded PC

**HDMI:** For maintenance purposes. Used to connect a screen directly to the device embedded PC

**Ethernet plugs:** The ethernet plug is used to connect your device to your local network. This allows remote control and data backup on shared drives.

**Power plug:** The power inlet connects the instrument to an electrical outlet through the supplied power adapter.

**Heat sink:** cools the device without fan.

## Cautions



Never insert anything else than a BioConnect cartridge into the cartridge holder



Never clamp the input or the output of the BioConnect this may cause **leaks** or device malfunction

## Accessories

### BioConnect (disposable tube set) description

The BioConnect has been developed to address all types of benchtop bioreactors, including disposables and rocking motion bioreactors.

It is equipped at both inlet and outlet with PVC tubing for welding, or male Luer locks for connecting to female Luer locks under a LAF hood.

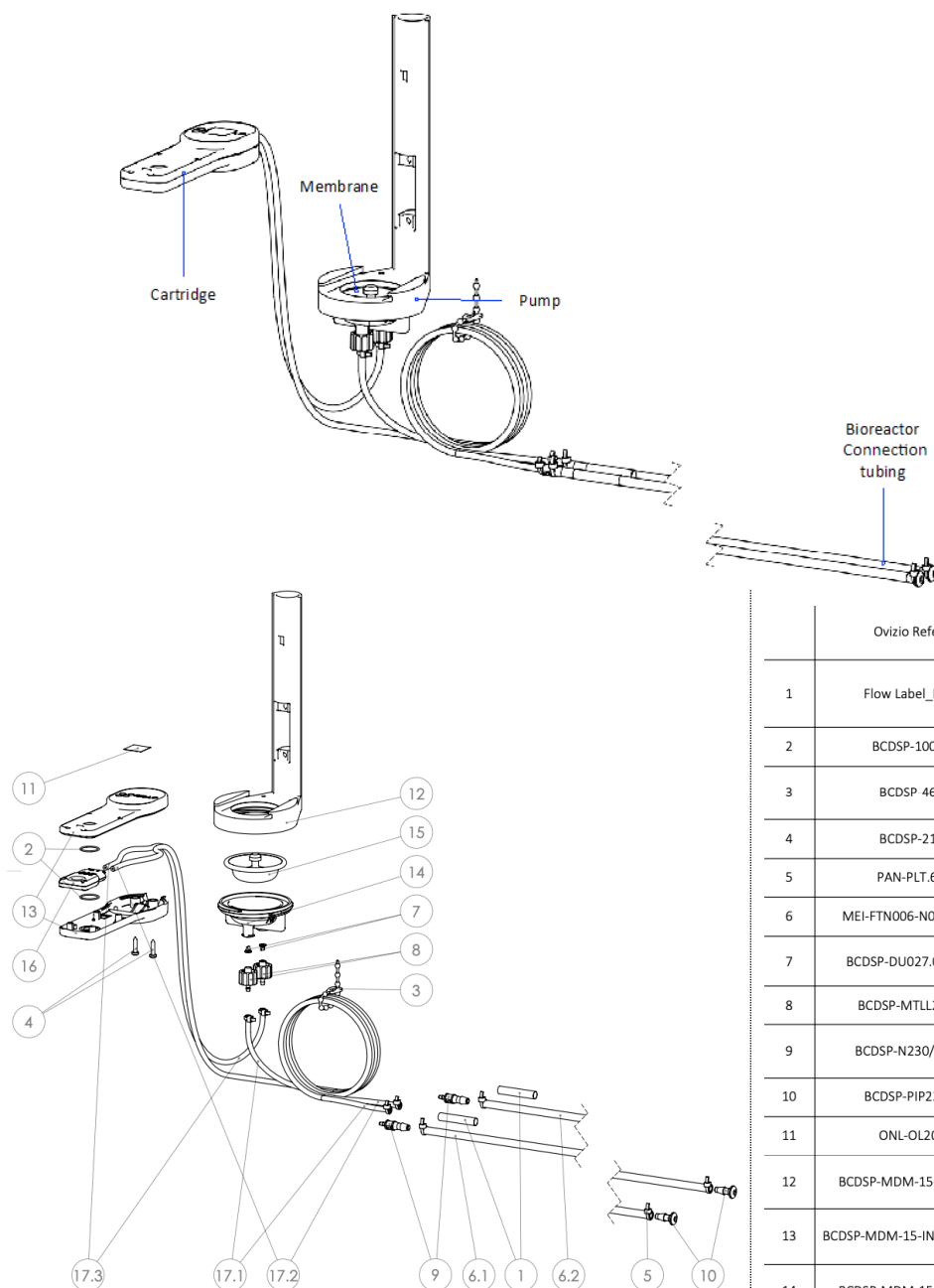
The inlet of the BioConnect must be connected to a dip tubing that dives into the culture. The outlet of the BioConnect can be connected to a surface port, or any available port in case there is no surface port available.

**Connect**



## Get Started

### Description



	Ovizio Reference	Description
1	Flow Label_I3TFBCD	Wrap-around stickers 37x25 mm, polyester
2	BCDSP-10021979	O-ring EPDM 70 - black - 10x1mm I.D.xThick.
3	BCDSP 462677	100.0 mm long
4	BCDSP-212406	Phillips DIN 7981 C-H - ST2,2X9,5MM
5	PAN-PLT.6SM-C	71.0 mm long, 1.8 mm wide
6	MEI-FTN006-N00-B8207-01	.118" ID x 0.178" OD
7	BCDSP-DU027.002-154.01	2,7mm diameter - 50 Shore A - 600 kPa Max Back Pressure
8	BCDSP-MTLL210-6005	1/16" (1.6 mm) ID Tubing Barb Connector
9	BCDSP-N230/210-6005	200 Series Barbs, 1/8" (3.2 mm) and 1/16" (1.6 mm) ID Tubing
10	BCDSP-PIP230-6005	200 Series Barb
11	ONL-OL2050LP	White label - 0.5" x 0.5" Wheaterproof Polyester
12	BCDSP-MDM-15-INJ-OVI-001	Upper Housing - Motor Engine Slider - Electronic slot - Press-Fit
13	BCDSP-MDM-15-INJ-OVI-005&006	Cartridge - 25x8.4mm slot - Press-fit + screw assy
14	BCDSP-MDM-15-INJ-OVI-003	Membrane Chamber - Male Luer Connection (Inlet/Outlet)
15	BCDSP-M202-Membrane V4.5.0	Pt-cured - 37.8mm O.D. - 5mL Volume
16	BCDSP-FC V6.13	200µm channel height
17	RAU-PtSi-tub-1x3	1 x 3 mm (ID x OD)

BioConnect drawing

## How to connect



Make sure to attach the BioConnect correctly to your cell culture vessel, otherwise its sterility may be compromised.

The way you connect the BioConnect to your cell culture vessel depends on your bioreactor type

The BioConnect has been developed to be connected to all types of benchtop bioreactors, including disposables and rocking motion bioreactors.

Bioreactor type	Connection type
Glass and steel benchtop bioreactor	Use the interface part (see below), to be autoclaved with bioreactor (or your own interface) or connect the BioConnect by welding or Luer locks in sterile conditions after sterilization
Disposable benchtop bioreactor	
	If the bioreactor is equipped with a dip tubing + surface tubing, connect using either welding or Luer lock under sterile conditions
	If the bioreactor has a 12mm port available, autoclave the BioConnect connected to the interface piece (see below) and install the whole assembly onto the disposable vessel, under sterile conditions (LAF hood)
Wave-like bioreactor (this bioreactor must have a dip tubing on the inlet line of the BioConnect)	Connect by welding or Luer locks under sterile conditions



Interface part

## Startup



The first time you connect the adapter to the device it will startup automatically

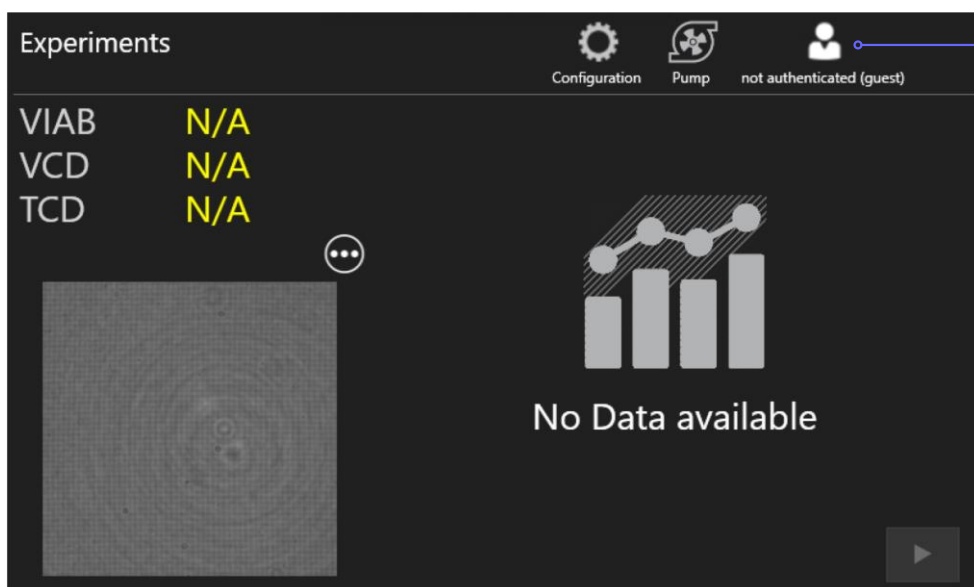


For optimal performance, always turn on the iLine F Pro 1h before starting a run. This allows the instrument to reach a stable internal temperature.

Do not check the device calibration before the device reaches a stable internal temperature.

1. Connect the power adapter to the iLine F Pro
2. Turn ON the iLine F Pro by pressing the power button
3. Wait for the OsOne software to show on screen

- 1 Login to start your first monitoring session. The default guest user has limited rights.

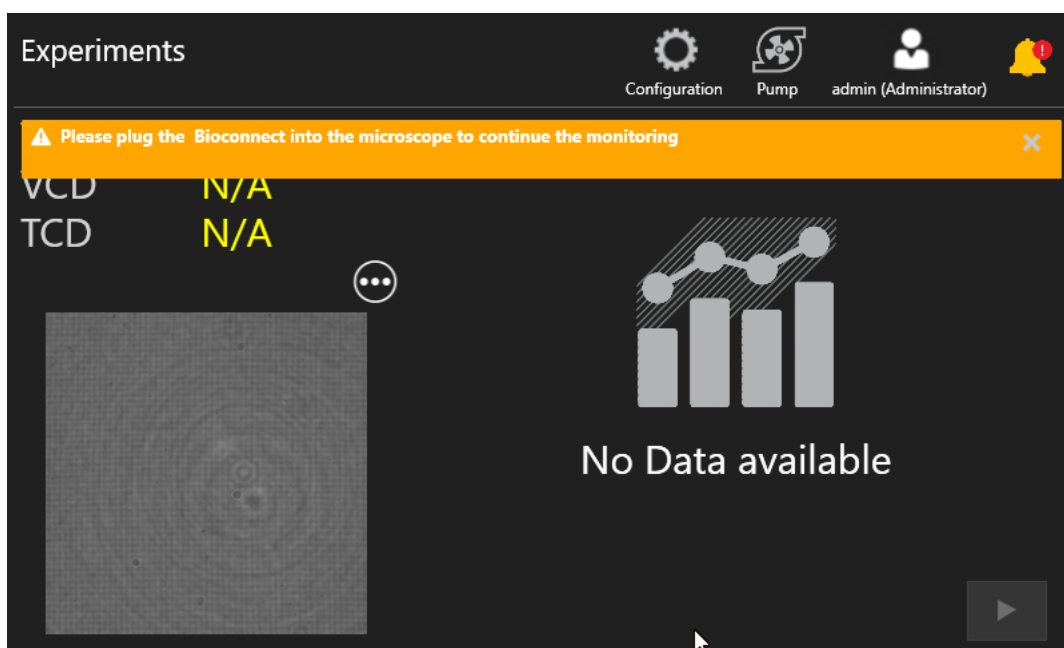


Click here to  
login as  
operator

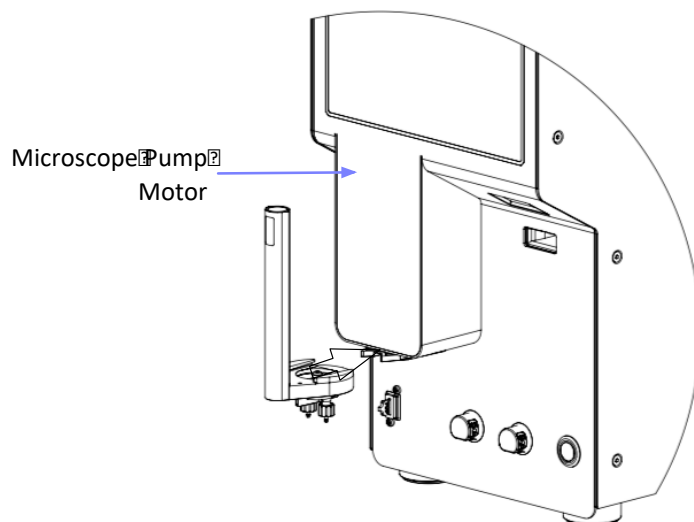
- 2 A window pops up to Sign in as another user.



- 3 You can now connect your BioConnect to the iLine F Pro as indicated by the orange alarm window

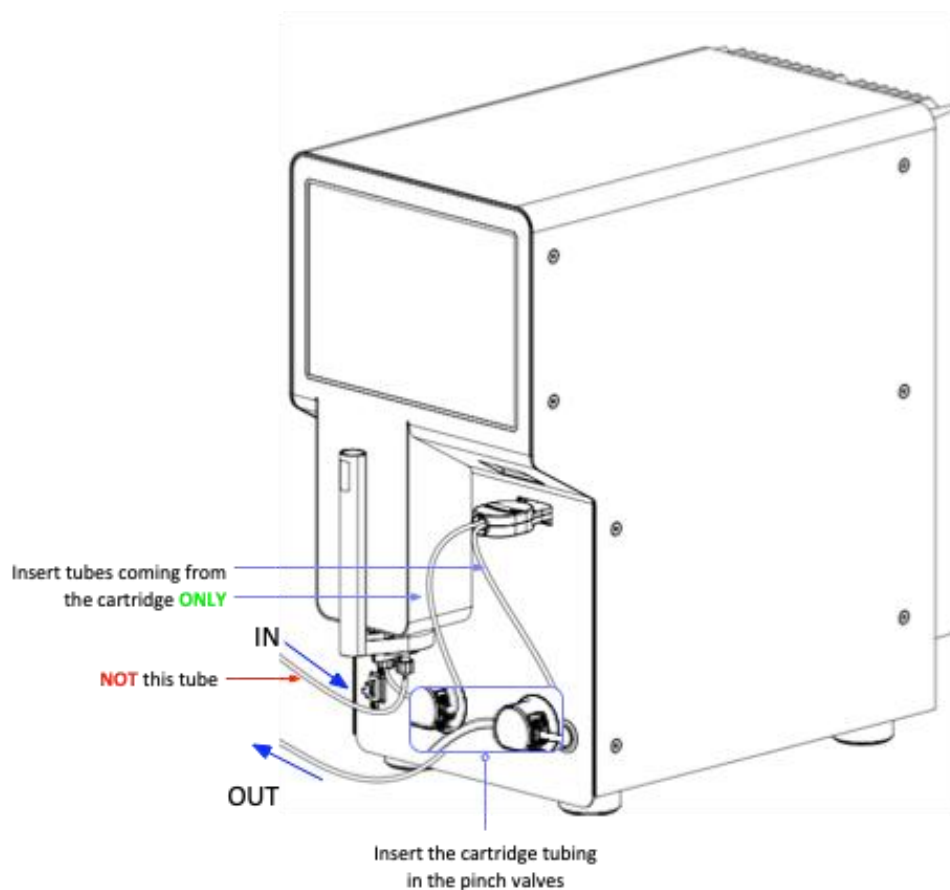


- 4 First connect the BioConnect pump to the iLine F Pro. For that, introduce the white plastic part (Upper Housing) into the microscope pump motor

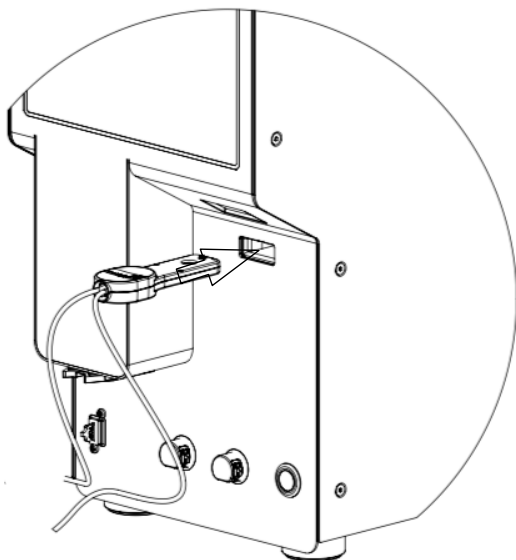


- 5 Insert the cartridge tube into the pinch valves. Any of the cartridge tubes can be inserted into any of the pinch valves.

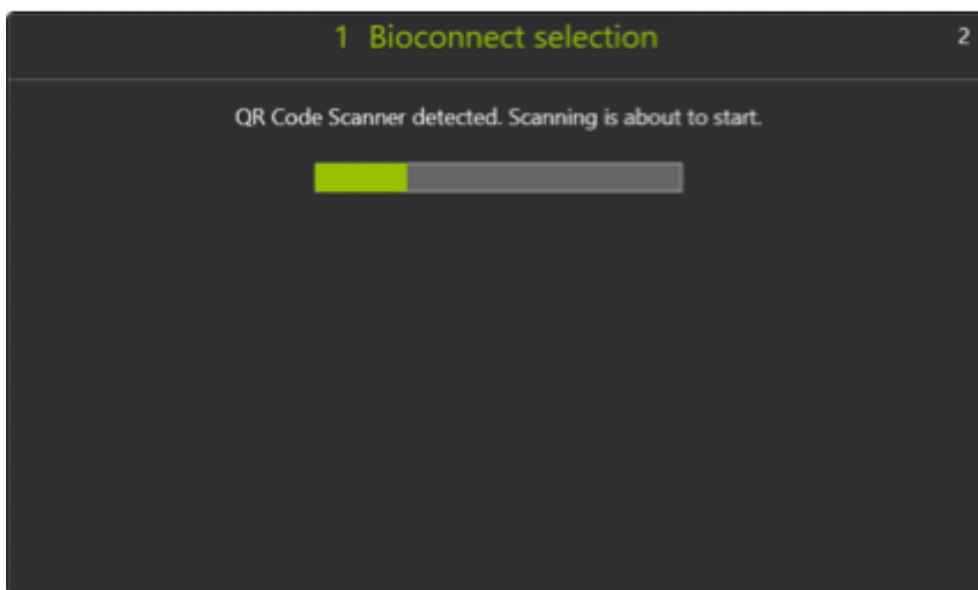
Do **NOT** insert any other tube into the pinch valves than those directly connected to the cartridge.



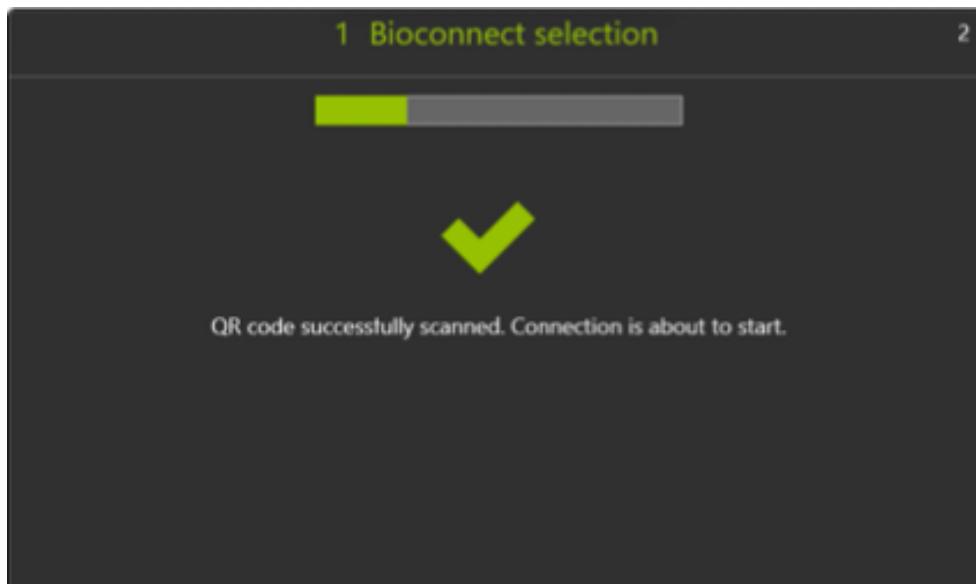
- 6 Then insert the BioConnect cartridge into the iLine F Pro



- 7 The QR code placed on the BioConnect cartridge will be read to identify its serial number for traceability purposes.



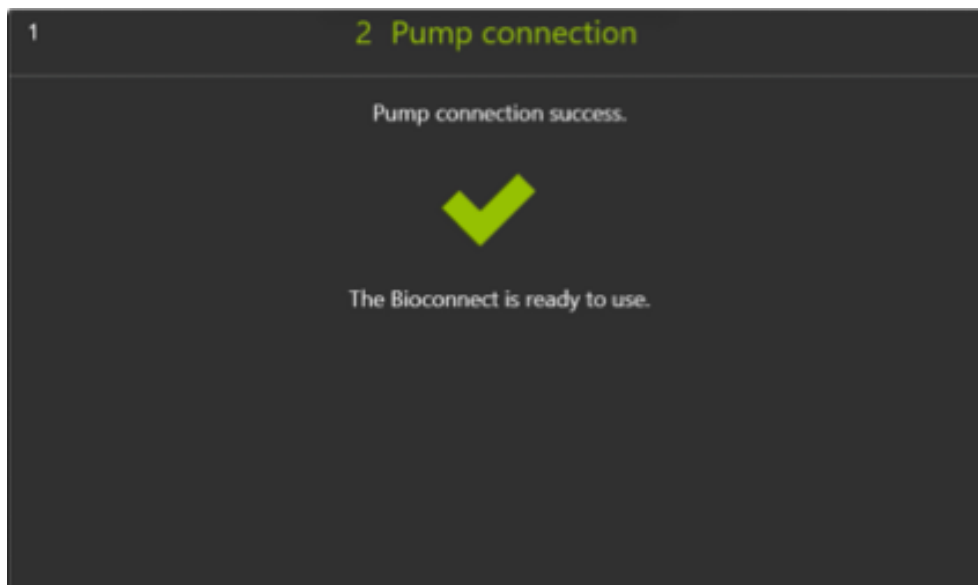
- 8 After successful QR code identification, the iLine F Pro will connect to the BioConnect pump. You may hear a click sound when done.



- 9 During connection do not remove any part of the BioConnect from the iLine F Pro

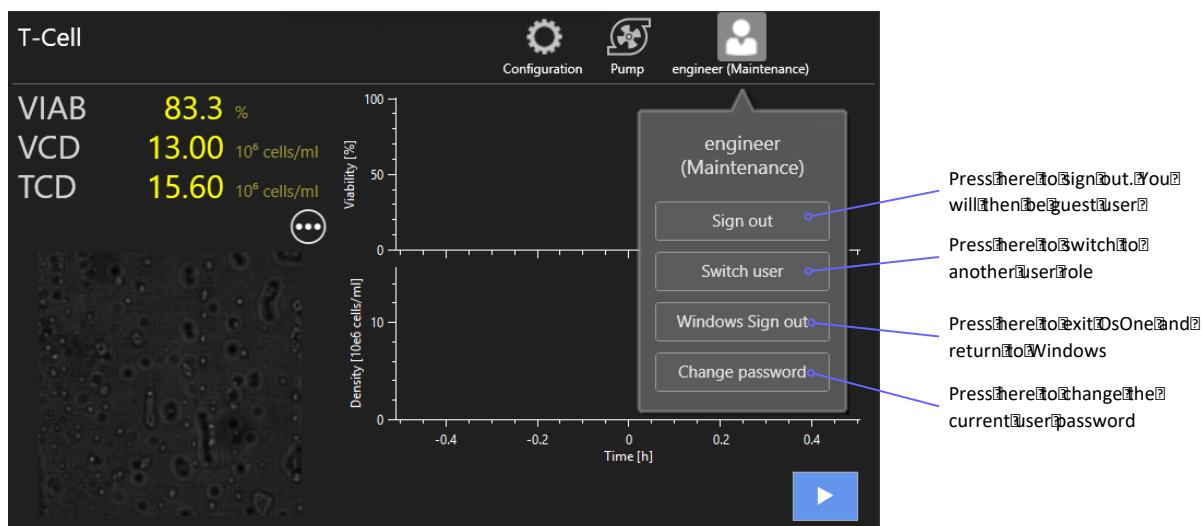


- 10** Now the BioConnect connection is complete and you can startup a bioreactor monitoring session.



## Logout

If you want to switch user that has a different role, quit OsOne or change the current user password, click on the user icon in the top right corner of the screen

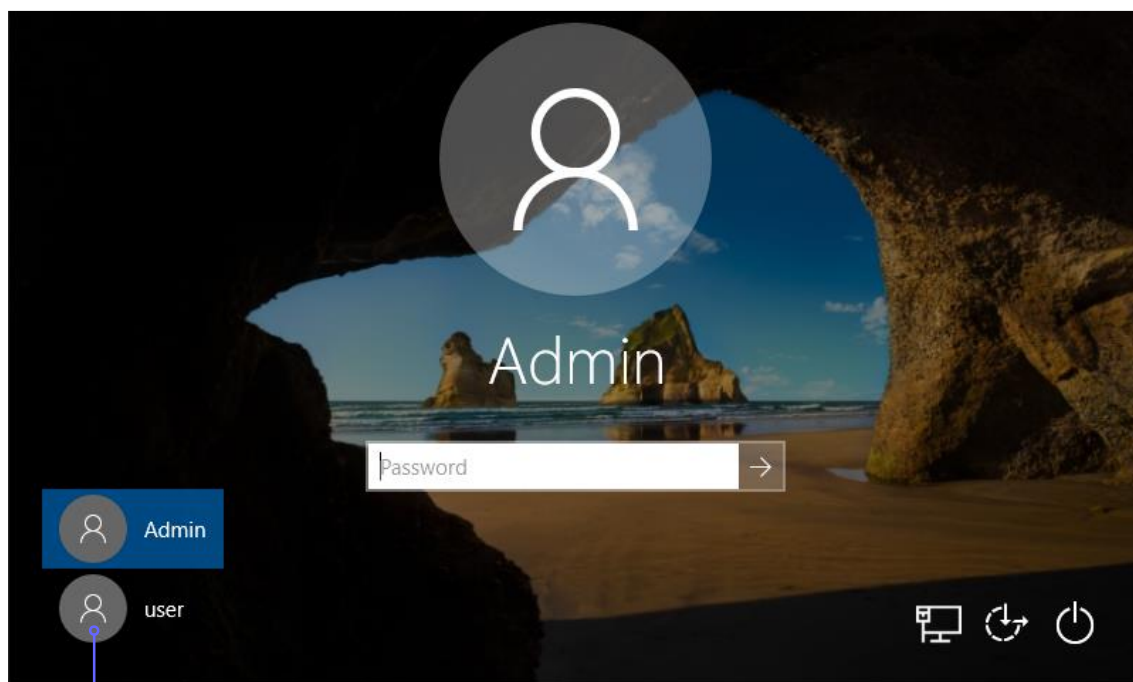


## Windows sign out

When you start the device OsOne is started automatically and the operating system behind is hidden (Windows 10).

If you want to close OsOne, select the *Windows Sign out* menu item. You will then be directed to the Windows login screen. Click on the user *user* to restart OsOne.





Press here to  
restart  
OsOne

## Measure

## Get Started

The online suspension bioreactor monitoring application automates the online measurements of cell viability and cell density of any type of suspension cell culture.



You must login prior to be able to start a monitoring session. Login as *operator* user by default.

Starting your monitoring session is as easy as pressing the blue *Start* button. A wizard will guide you through the required steps to initiate a monitoring session.

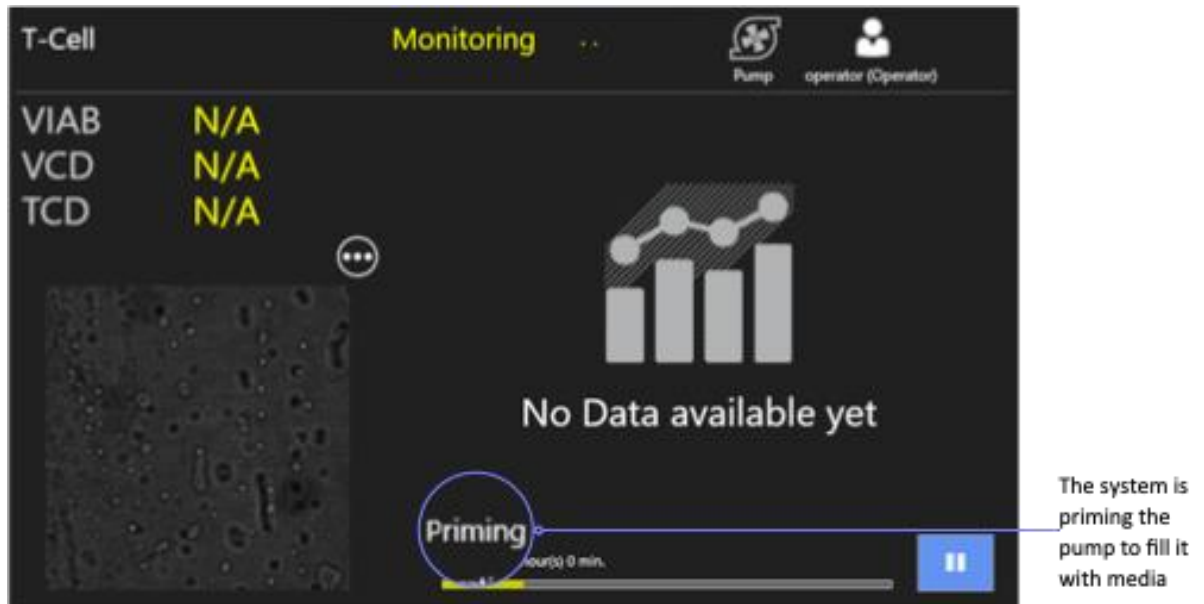


Click here to  
start your  
monitoring  
session

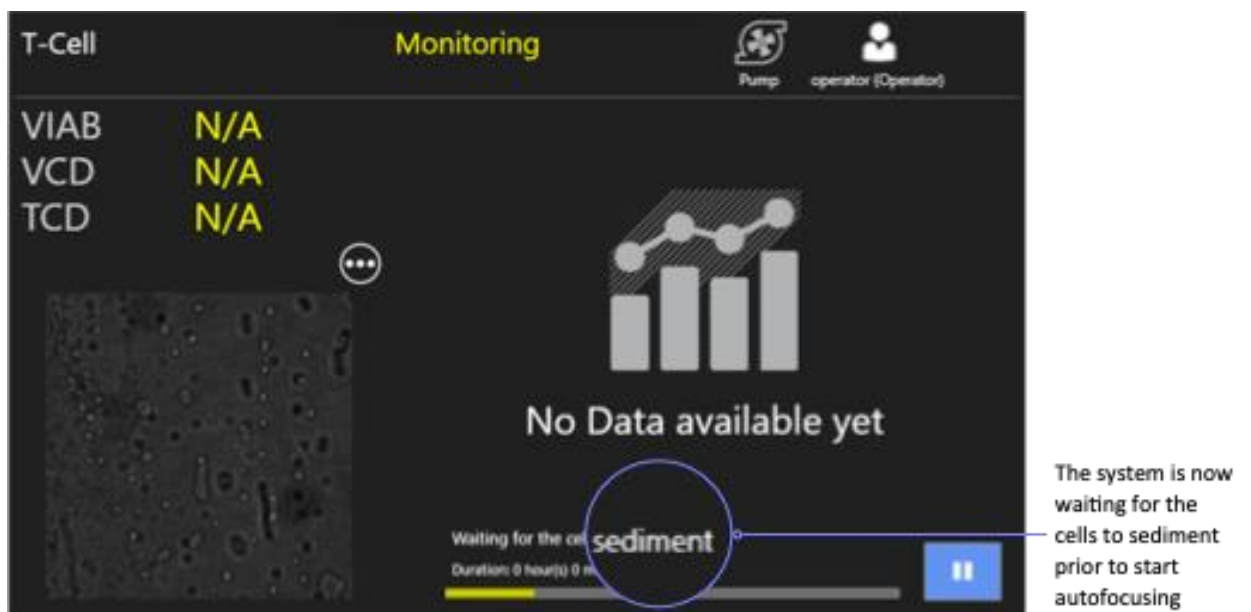
## Start the monitoring wizard

If it is the first time you are starting OsOne, start a new session. Give it a name and press *Next*.

The system will start the priming step by pumping on the BioConnect line.



Then, the system will automatically set the initial focus.



To do so, the system will first stop the flow and wait for the cells to sediment. After cell sedimentation, the system will make the autofocus.



Before the recording of data, the system will also capture a so-called *background image*. This image will be used to compensate for permanent defects in the field of view.

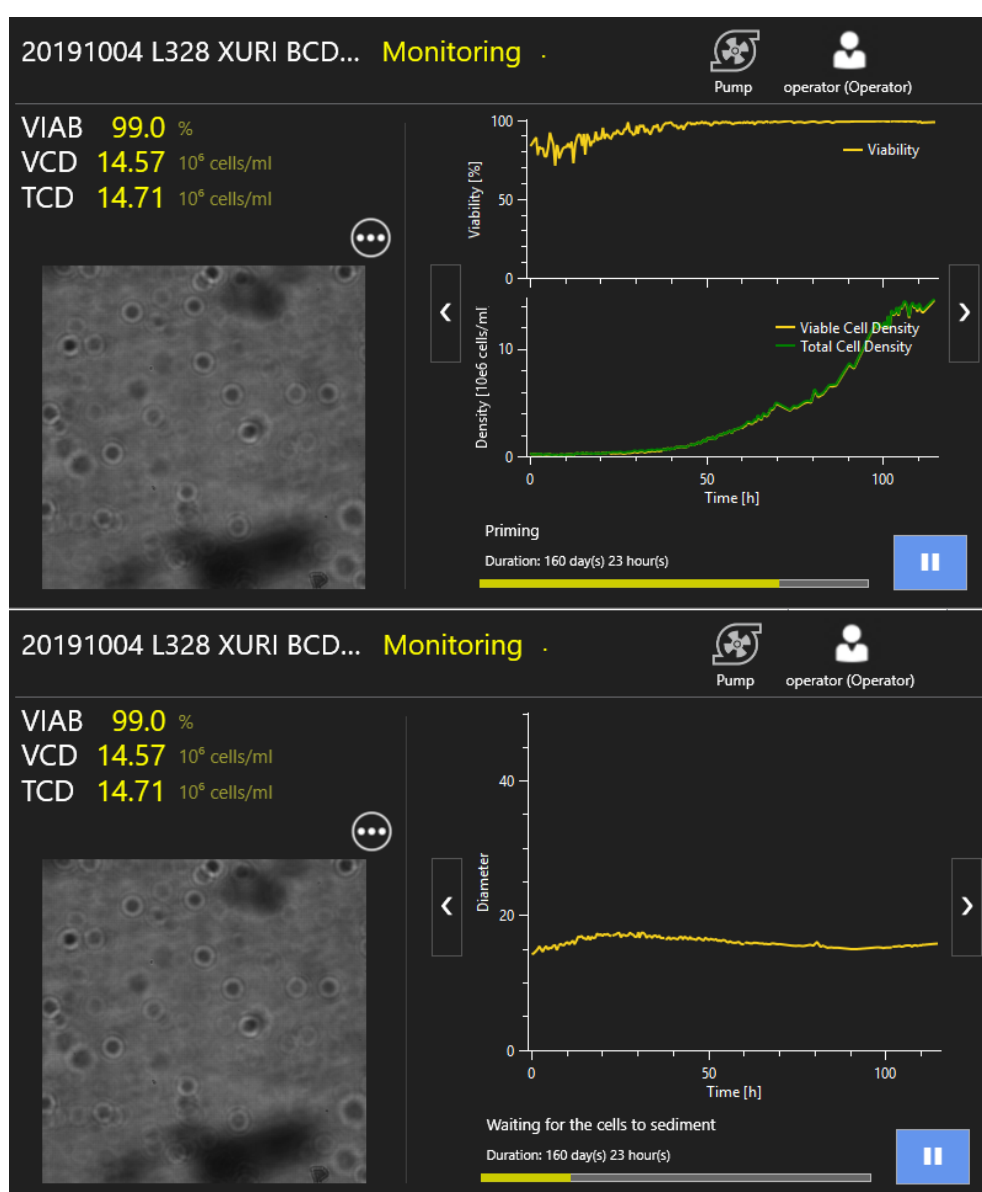


Right after this sequence of operations, the system will finally start monitoring.

## Monitor

### Cell density, Viability and Diameter

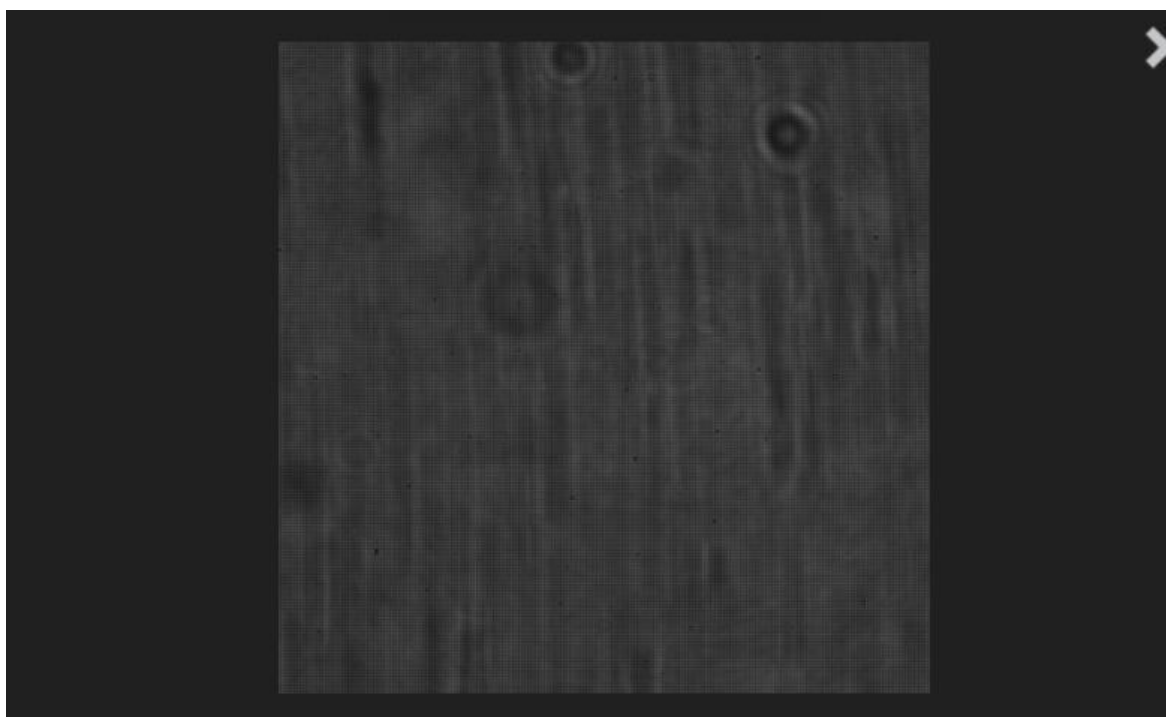
After launching a monitoring session, the Live image and the computed results (values and graphs) related to the investigated cell culture will be displayed on the Live screen. The computed results will be updated based on the cell line configuration (30 minutes - 2 hours). The main calculated parameters are the total cell density (TCD), viable cell density (VCD), cell viability (VIAB) and average cell diameter.



## Detailed views

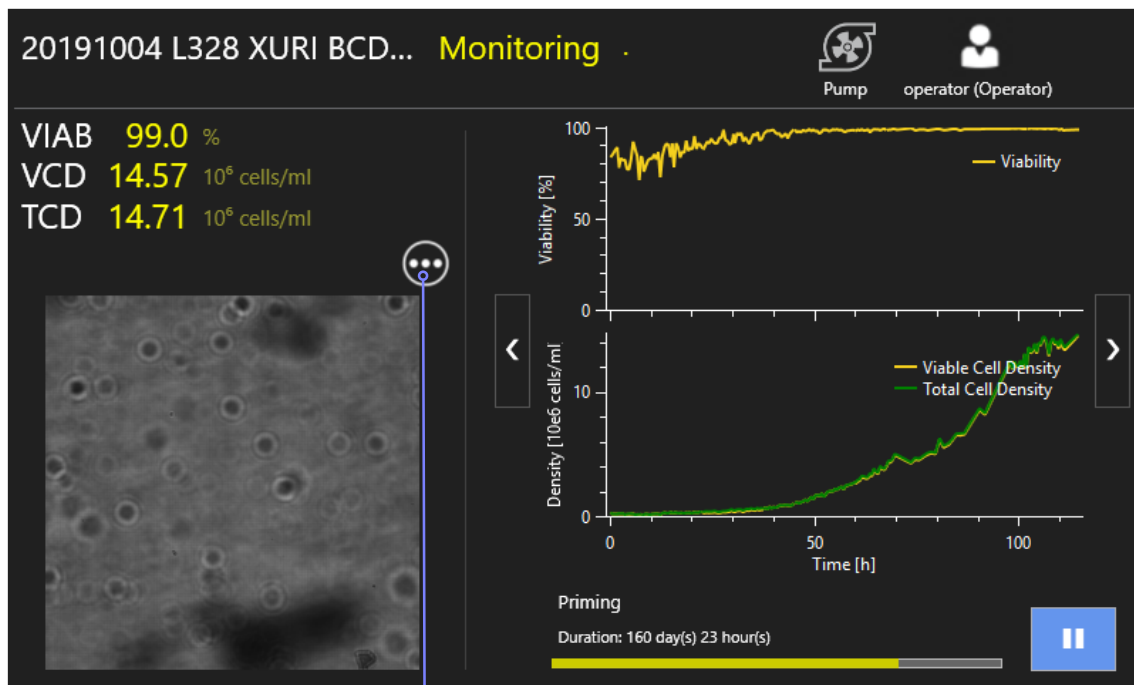
### Live image

Click on the Live image to enlarge it. The following screen will be displayed.



## Advanced results

Click on the three dots next to the measurement figures to access advanced results



Click here to see  
Advanced  
results

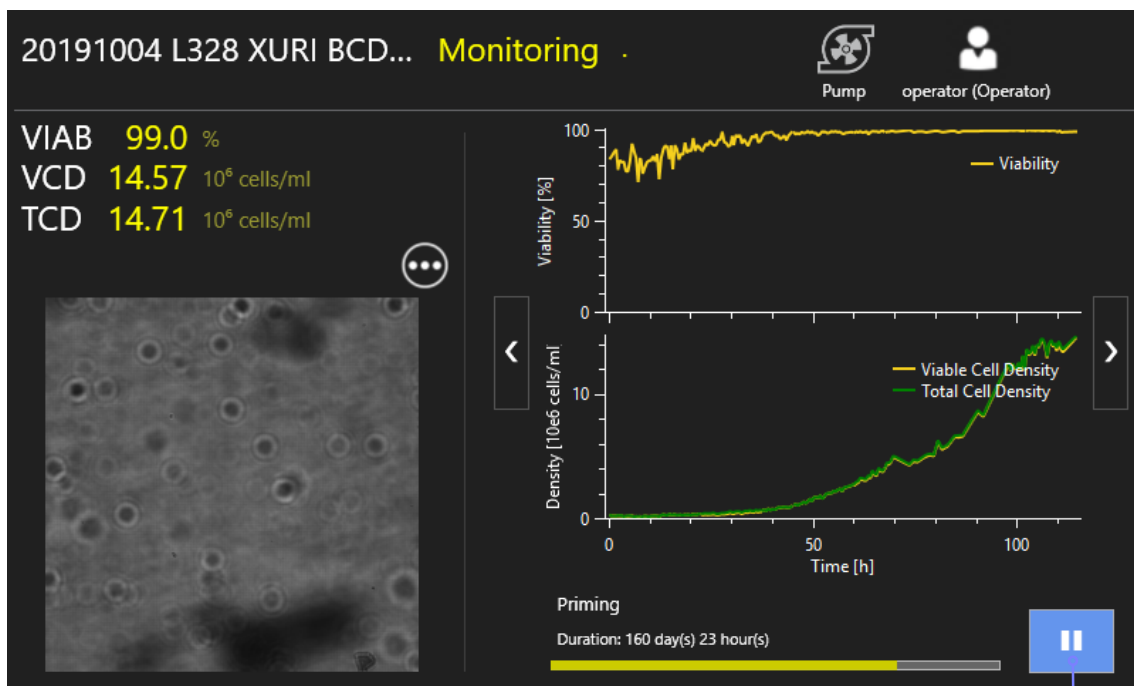
Advanced results					
VIABILITY	15.5	%	Total Cell Density	$5.24 \times 10^6$ cells/ml	
VCD	0.81	$10^6$ cells/ml	Total cell count	1152 cells in 25 images	
TCD	5.24	$10^6$ cells/ml	Viable cells	178 cells	
			Dead cells	974 cells	
			Rejected events	712 events	
			Aggregate Rate	6.5%	
			Average circularity	0.92	
			Average Diameter	13.16	



## Pause

Press the “Pause Monitoring” button in the lower right corner of the Measure tab to stop your monitoring session. The current monitoring session can then be resumed or a new monitoring session can be created.

When a monitoring session is paused, it is also possible for the user to either flush the system, stop pumping or disconnect the BioConnect.



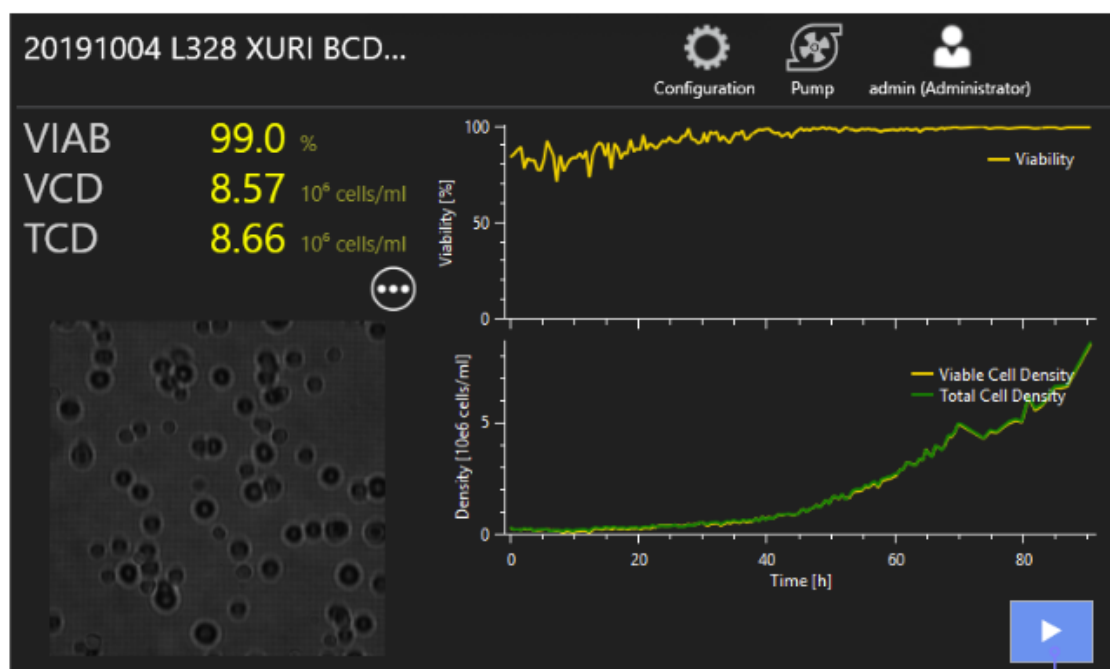
Click here to pause your monitoring session



When you pause your monitoring session the pump will continue pumping cells to avoid clogging of the BioConnect.

## Continue

In the event you paused a monitoring session and want to resume it, press the “Continue monitoring” button to resume your last monitoring session.



Click here to  
continue your  
monitoring  
session

## How a data point is acquired

The pump hooked to the BioConnect has different modes of pumping over time that follow different sequences of operations.

For example, one sequence of operations is used during data point acquisition, another during flushing operations and so on.

A data point is computed by averaging the counts on 25 images (the number of images is set by default for statistical relevance).

The pump follows this sequence of operations:

- Autofocusing
- Acquisition of background image to compensate for permanent defects in the image, if any
- Acquisition of 25 images with a sedimentation time of 30 seconds between images to make sure all the cells are roughly in a layer of 50  $\mu$ m high by default

- Computation of measurement based on the 25 images acquired during the previous step
- Wait sequence if there is enough time before the acquisition of the next data point (depends on data point acquisition frequency)
- Flush sequence to avoid clogging

The following drawing describes a typical sequence of operations:



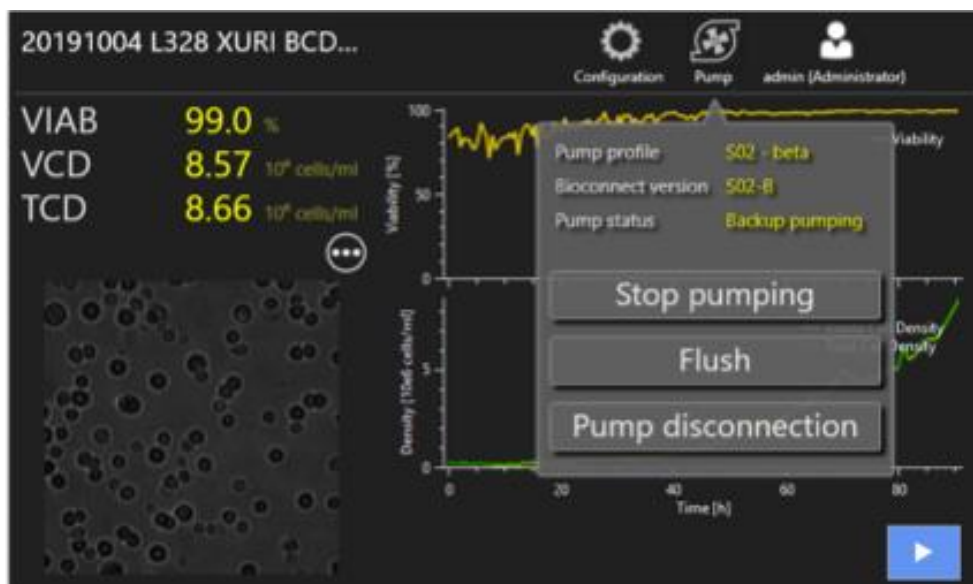
The actual sequence of operations may differ depending on your cell line, for example with different sedimentation times.

## Pump Operations



You must pause your monitoring to get access to the pump menu

*Backup pumping* refers to pumping mode when not in an active monitoring session



### Stop Pumping

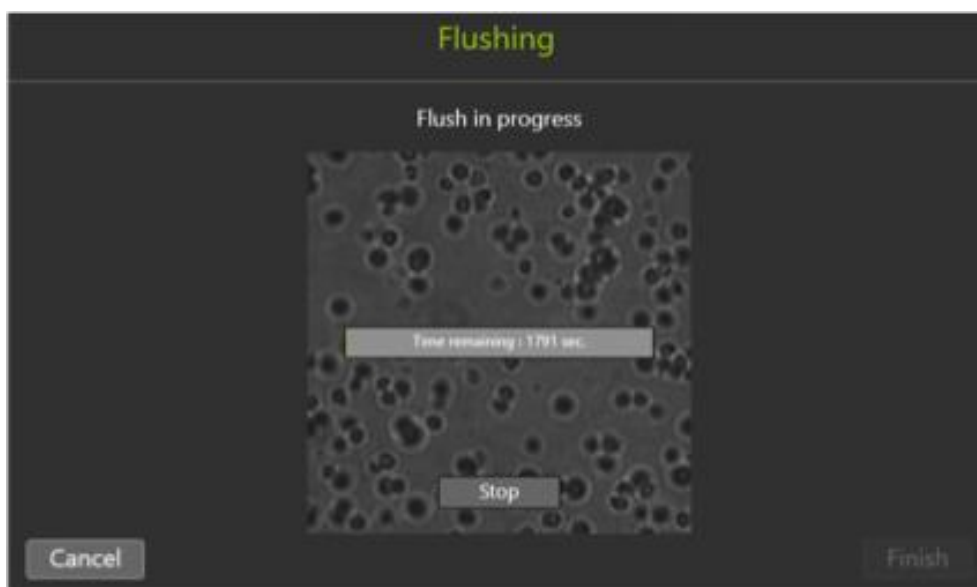
One can stop the pump on purpose by selecting the stop pumping menu item. In that case the system will stop pumping for 10 minutes and automatically resume afterwards.



## Flush

In the event your fluidic circuit is clogged and you get an alarm related to fluidic issues, you may flush the BioConnect by running the pump continuously with higher flow rate. This process will last 30 minutes by default. You can stop it anytime by pressing the *Stop* button.

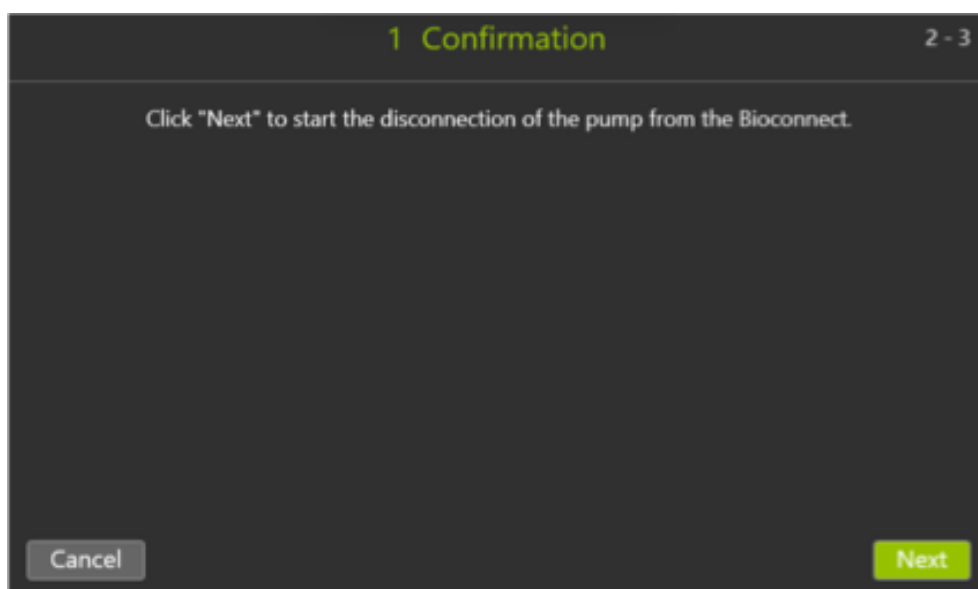
When completed the system displays a Flush success screen and you need to press the *Finish* button to get back to normal operations.





## Pump Disconnection

When your monitoring session has ended you will need to disconnect it from the iLine F Pro. Select the Pump Disconnection menu item to proceed.



The pump engine will now decouple from the BioConnect pump



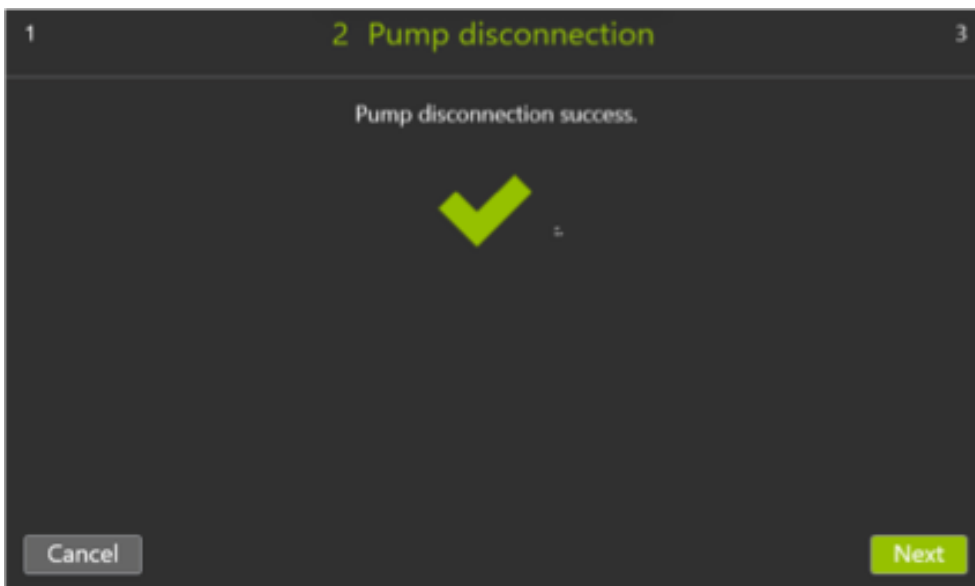
You must wait a minute the time for the membrane to be fully in low position. You will hear a click sound when the engine is actually decoupled.

**Never** try to **remove** the BioConnect pump before this operation has completed.

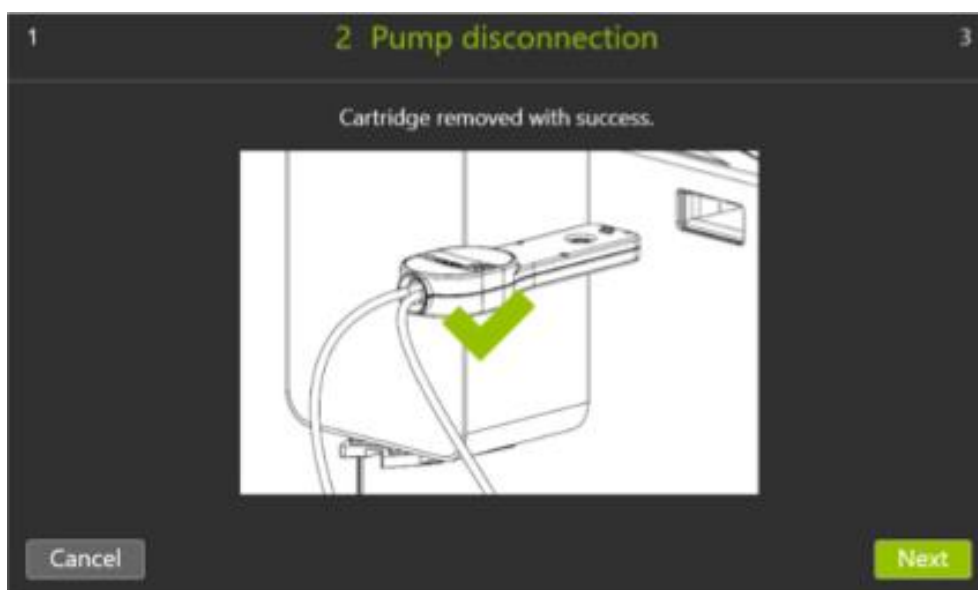
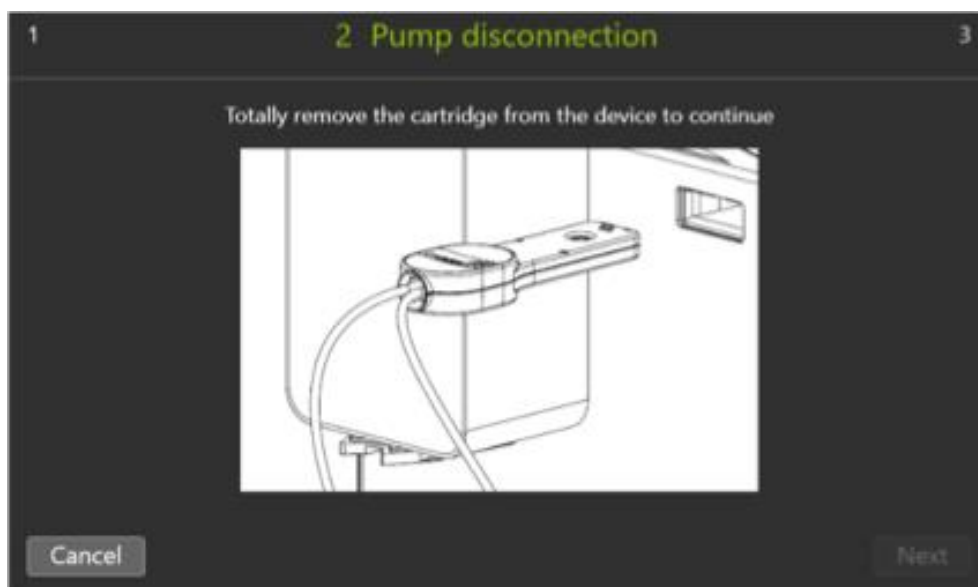


If not complete the engine may still be hooked to the BioConnect.

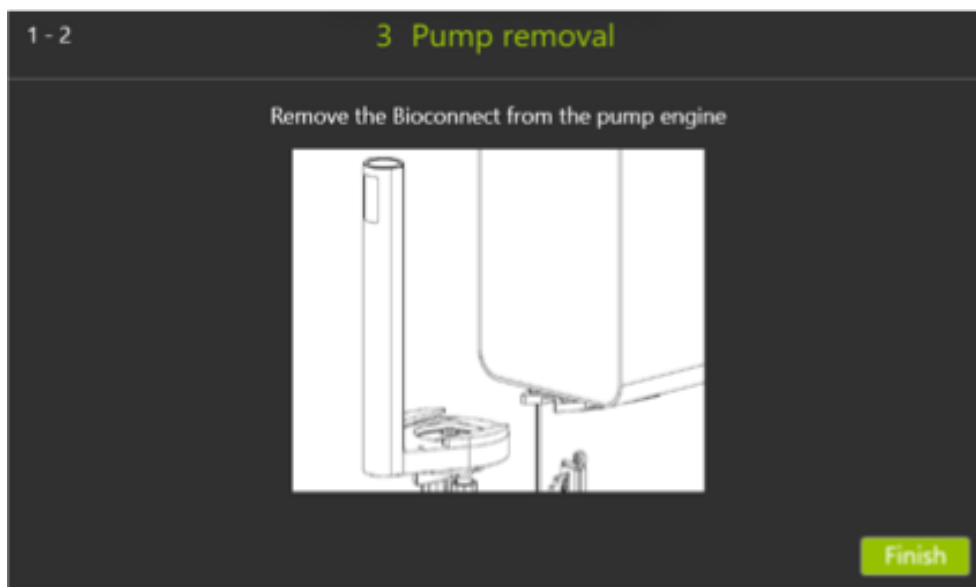
Applying force to remove the BioConnect pump may compromise the integrity of the BioConnect and lead to **biological hazard**.



Now you can remove the BioConnect cartridge from the microscope



Now you can disconnect the BioConnect pump from the Microscope pump motor



The BioConnect pump does not require special force.

Applying abnormal force to remove the BioConnect pump may compromise the integrity of the BioConnect and lead **to biological hazard**.



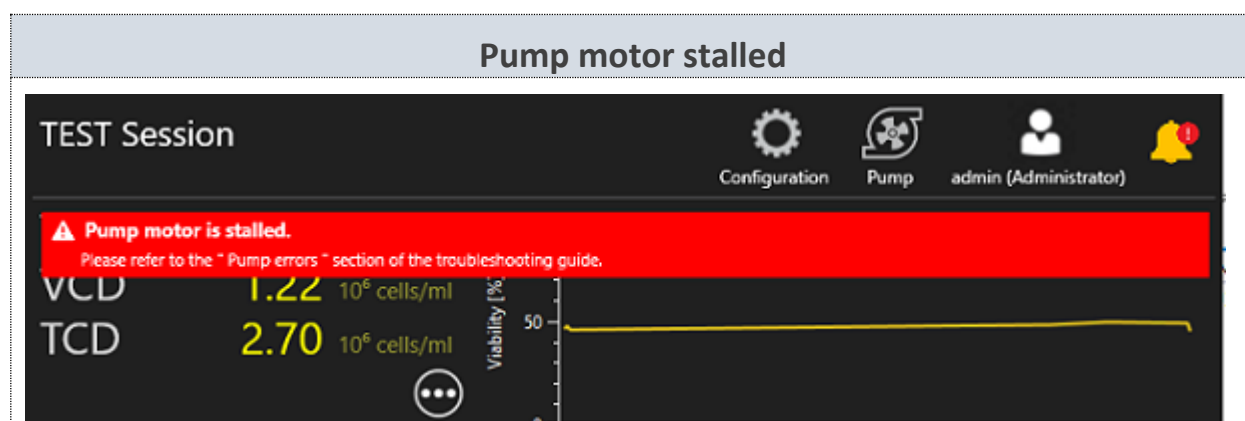
## Troubleshooting

## Introduction

Various events may occur during the setup of a bioreactor run or during the run itself such as bad quality images leading to measurement issues. In all cases the alarms or notifications are displayed with a banner on top of the live screen.

The next sections describe each of them in detail.

### BioConnect Alarms



#### Description:

OsOne informs the user that the pump motor has stalled.

#### Cause(s):

- Pinched tubing during the setup in the lab.
- Tube welding not popped open
- BioConnect assembly defect (internal tubing pinched).
- Aggregates/Clogging present in the cell culture.
- Unexpected pinch valve action (software bug).
- Wrong pump profile setting.
- The pump motor could be too old and not working as expected (not powerful anymore).

#### When?

This alarm can be triggered anytime (before or during a monitoring) when the pump is executing one of the following sequences:

- Priming
- Flushing
- Backup pumping (pumping mode when not in an active monitoring session)

#### Type:

ERROR

#### Does it prevent from starting a monitoring?

YES

### Is it handled by OsOne?

If this error occurs during a monitoring, a software component running in the background – called the “Restart tool” will:

- Close OsOne
- Restart OsOne
- Restart the monitoring

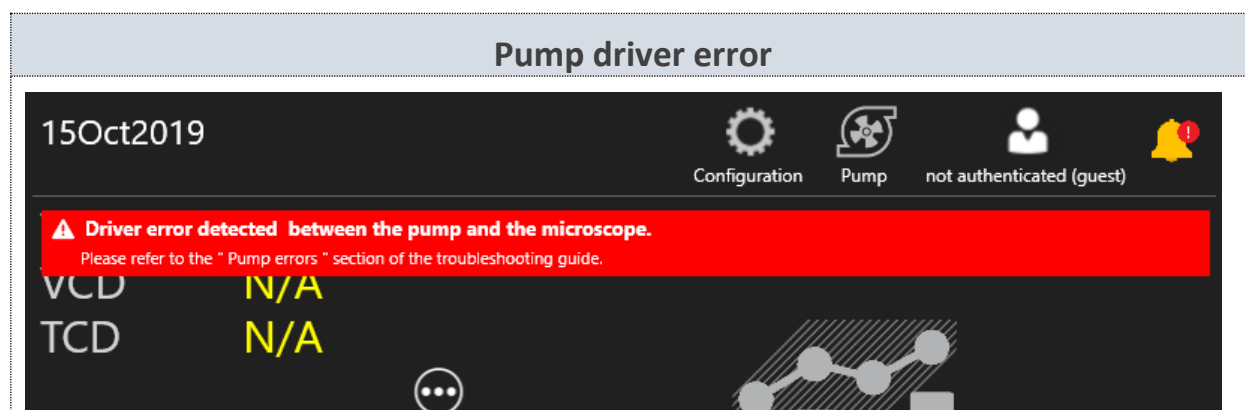
If the error is not automatically resolved after 3 consecutive tries of the “Restart tool”, monitoring is stopped.

### How to fix it?

- Check if any tubing is pinched
- Check in the OsOne “Live” image if no aggregates are present in the field of view and if yes, try to flush the fluidic system
- Replace the BioConnect

### How to prevent it?

- Be careful not to pinch any tubing during the setup
- Have the motor replaced during the maintenance if it appears that it is too old and makes noise during normal operations.



### Description:

A hardware error related to the pump motor has been detected by OsOne

### Cause(s):

There was an unexpected error with the pump:

### When?

This alarm can be triggered anytime when OsOne uses the BioConnect

### Type:

ERROR

**Does it prevent from starting a monitoring?**

YES

**Does it interrupt the monitoring?**

YES

**Is it handled by OsOne?**

YES

If this error occurs during a monitoring, the “Restart tool” will:

- Close OsOne
- Restart OsOne
- Restart the monitoring

If the error is not automatically resolved after 3 consecutive tries of the “Restart tool”, monitoring is stopped.

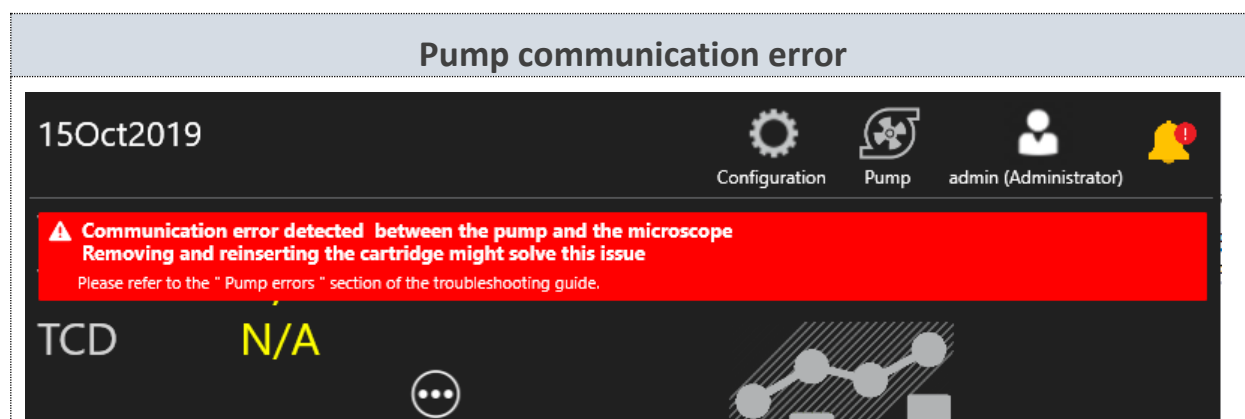
**How to fix it?**

- Restart OsOne
- Remove the BioConnect cartridge from the microscope and insert it again
- Power off the microscope, wait a minute and power the microscope on.

If the above actions do not fix the issue, please contact Ovizio support (support@ovizio.com).

**How to prevent it?**

There is no way to prevent that kind of error



**Description:**

OsOne informs the user that there was a communication error between OsOne and pump motor.

**Cause(s):**

- An external device may have caused electromagnetic perturbation.
- Damage cable or bad connection inside the microscope

**When?**

This alarm can be triggered anytime when OsOne uses the BioConnect

**Type:**

ERROR

**Does it prevent from starting a monitoring?**

YES

**Does it interrupt the monitoring?**

YES

**Is it handled by OsOne?**

YES

If this error occurs during a monitoring, the “Restart tool” will:

- Close OsOne
- Restart OsOne
- Restart the monitoring

If the error is not automatically resolved after 3 consecutive tries of the “Restart tool”, monitoring is stopped.

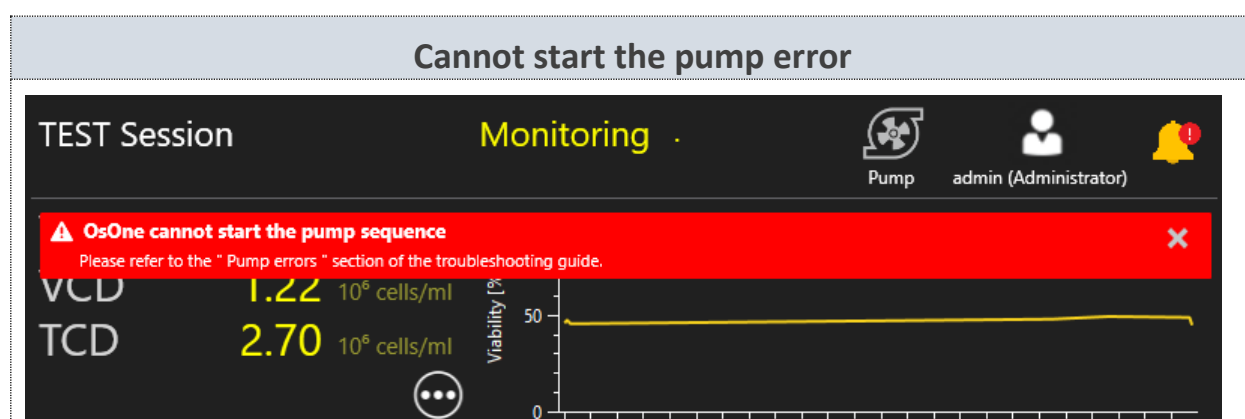
**How to fix it?**

- Restart OsOne
- Remove the BioConnect cartridge from the microscope and insert it again
- Power off the microscope, wait a minute and power the microscope on.

If the above actions do not fix the issue, please contact Ovizio support (support@ovizio.com).

**How to prevent it?**

There is no way to prevent that kind of error.



**Description:**

OsOne informs the user that there was an error when OsOne tried to start a pump sequence.

**Cause(s):**

OsOne tried to start a sequence while the pump was still busy

### When?

This alarm can be triggered anytime when OsOne uses the BioConnect

### Type:

ERROR

### Does it prevent from starting a monitoring?

YES

### Does it interrupt the monitoring?

YES

### Is it handled by OsOne?

YES

If this error occurs during a monitoring, the “Restart tool” will:

- Close OsOne
- Restart OsOne
- Restart the monitoring

If the error is not automatically resolved after 3 consecutive tries of the “Restart tool”, monitoring is stopped.

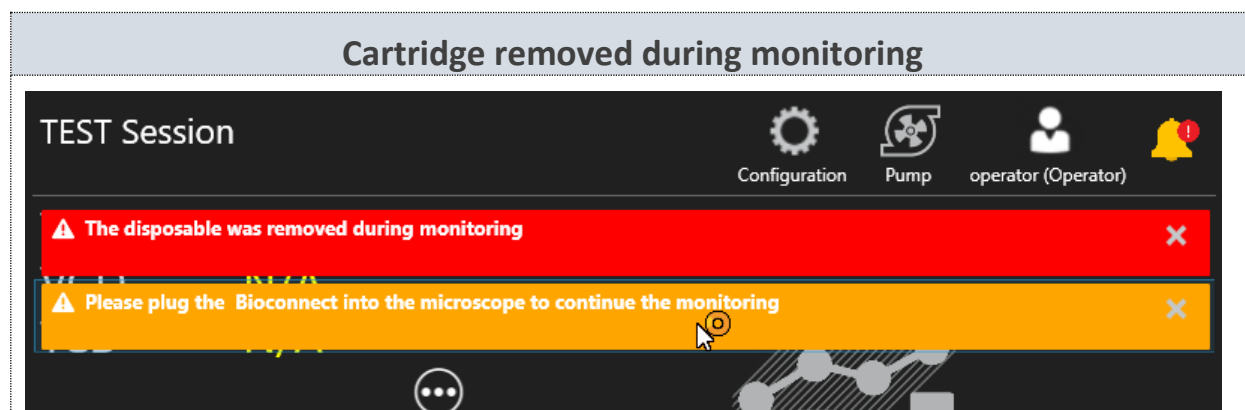
### How to fix it?

- Restart OsOne
- Remove the BioConnect cartridge from the microscope and insert it again
- Power off the microscope, wait a minute and power the microscope on.

If the above actions do not fix the issue, please contact Ovizio support ([support@ovizio.com](mailto:support@ovizio.com)).

### How to prevent it?

There is no way to prevent that kind of error.



### Description:

OsOne informs the user that the BioConnect cartridge has been removed from the microscope during the monitoring.

**Cause(s):**

OsOne lost the connection with the BioConnect cartridge during a monitoring and then stop it.

**When?**

This alarm can be triggered anytime during a monitoring.

**Type:**

ERROR

**Does it prevent from starting a monitoring?**

NO

**Does it interrupt the monitoring?**

YES

**Is it handled by OsOne?**

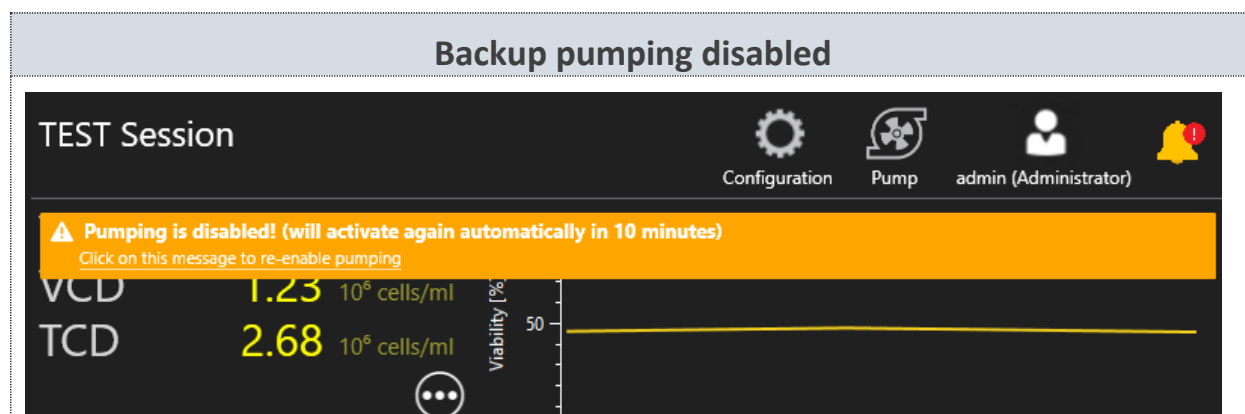
NO

**How to fix it?**

Insert the BioConnect cartridge back into the iLine F Pro and restart the monitoring.

**How to prevent it?**

By educating the OsOne users not to remove a BioConnect cartridge during a monitoring.



**Description:**

OsOne informs the user that the backup pumping has been disabled.

**Cause(s):**

An authenticated user pressed the “Stop pumping” button.

**When?**

- When the monitoring is not running
- When the “Stop pumping” button is enabled

**Type:**

WARNING

**Does it prevent from starting a monitoring?**

NO

**Does it interrupt the monitoring?**

NO

**Is it handled by OsOne?**

YES. OsOne will automatically reactivate the pumping 10 minutes after it has been deactivated.

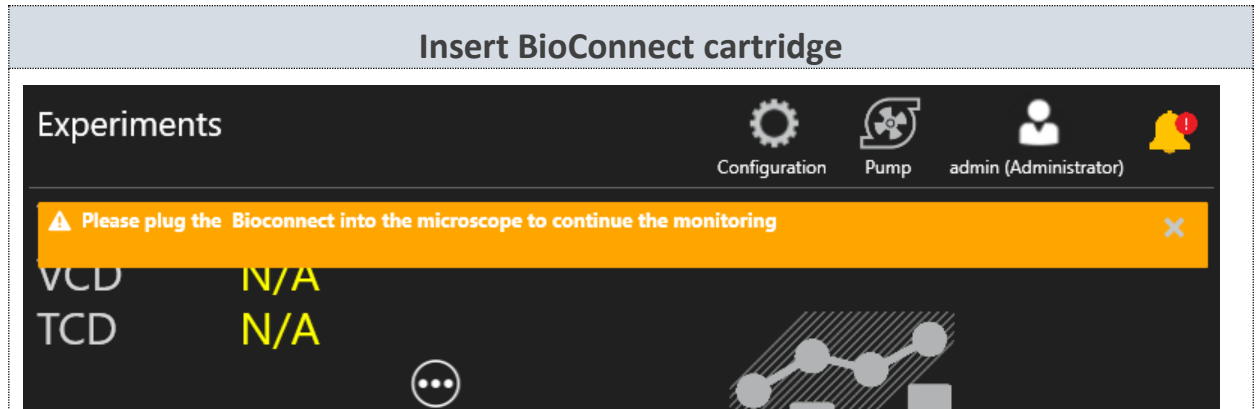
**How to fix it?**

- Click the link in the alarm to reactivate the pumping.
- Let OsOne automatically reactivate the pumping.

**How to prevent it?**

N/A





**Description:**

OsOne informs the user that in order to Start/Continue a monitoring, the BioConnect cartridge should be inserted inside the microscope.

**Cause(s):**

OsOne detected that no BioConnect cartridge is inserted inside the microscope.

**When?**

This alarm can be triggered anytime

**Type:**

WARNING

**Does it prevent from starting a monitoring?**

YES

**Does it interrupt the monitoring?**

NO

**Is it handled by OsOne?**

N/A

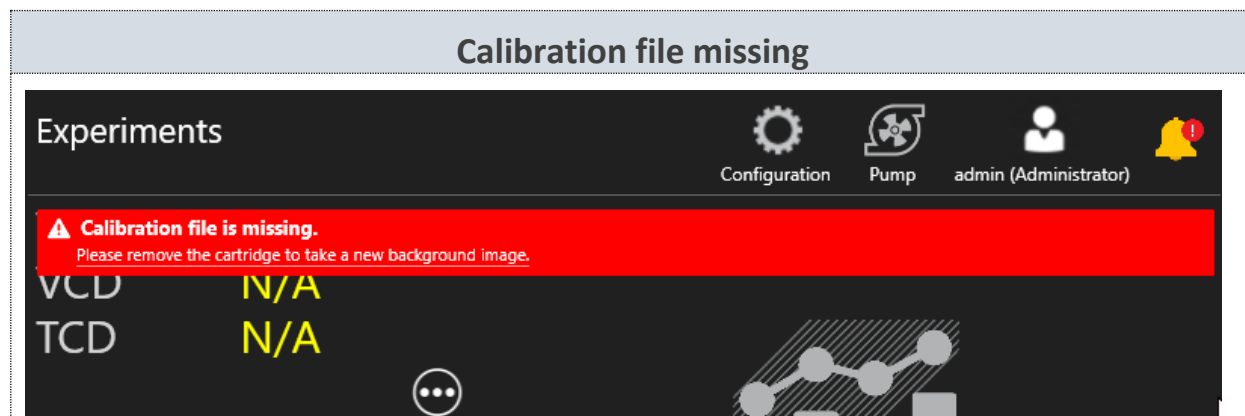
**How to fix it?**

By inserting a BioConnect cartridge inside the microscope.

**How to prevent it?**

N/A

## Calibration Alarms



### Description:

OsOne informs the user that the calibration file is missing.

### Cause(s):

OsOne did not find a file named "CalibrationImage.h5" inside the "C:\Users\<OsOne user>\AppData\Roaming\OsOne\Calibration" folder

### When?

This alarm is triggered at the start of OsOne.

### Type:

ERROR

### Does it prevent from starting a monitoring?

YES

### Does it interrupt the monitoring?

NO

### Is it handled by OsOne?

YES, if the BioConnect cartridge is not inserted at the start of OsOne: in that case, OsOne will automatically take a new background image.

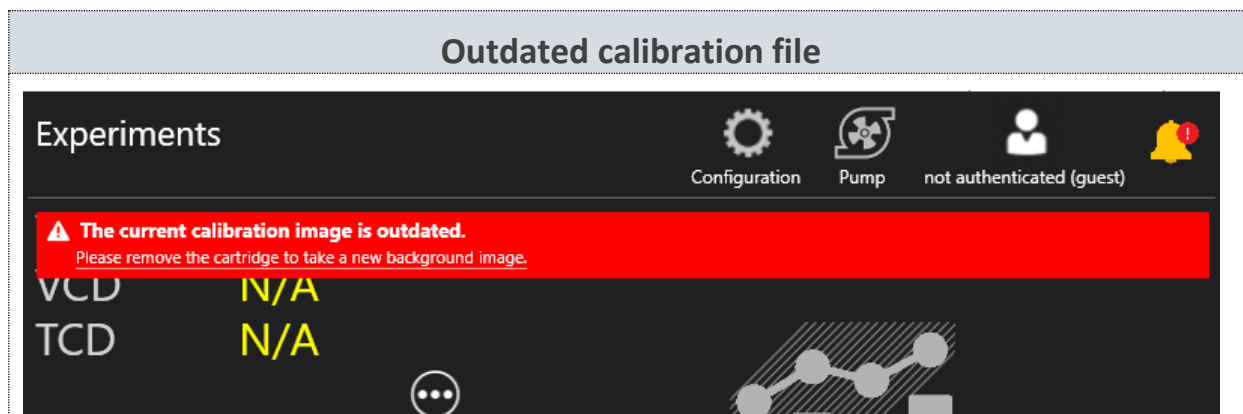
NO, if the BioConnect cartridge is inserted inside the microscope at the start of OsOne.

### How to fix it?

By removing the BioConnect cartridge from the microscope the time that OsOne can take a new background image.

### How to prevent it?

By never deleting the "CalibrationImage.h5" file inside the "C:\Users\<OsOne user>\AppData\Roaming\OsOne\Calibration" folder.



#### Description:

OsOne informs the user that the calibration image is outdated.

#### Cause(s):

The calibration image has been taken more than 30 days ago.

#### When?

This alarm is triggered at the start of OsOne when OsOne checks when the calibration image has been taken.

#### Type:

ERROR

#### Does it prevent from starting a monitoring?

YES

#### Does it interrupt the monitoring?

NO

#### Is it handled by OsOne?

YES, if the BioConnect cartridge is not inserted at the start of OsOne: in that case, OsOne will automatically take a new background image.

YES, if the BioConnect cartridge is inserted and a monitoring session is started. In that case OsOne acquires a background image when cells are flowing and hence blurred, leading to an equivalent background image as above

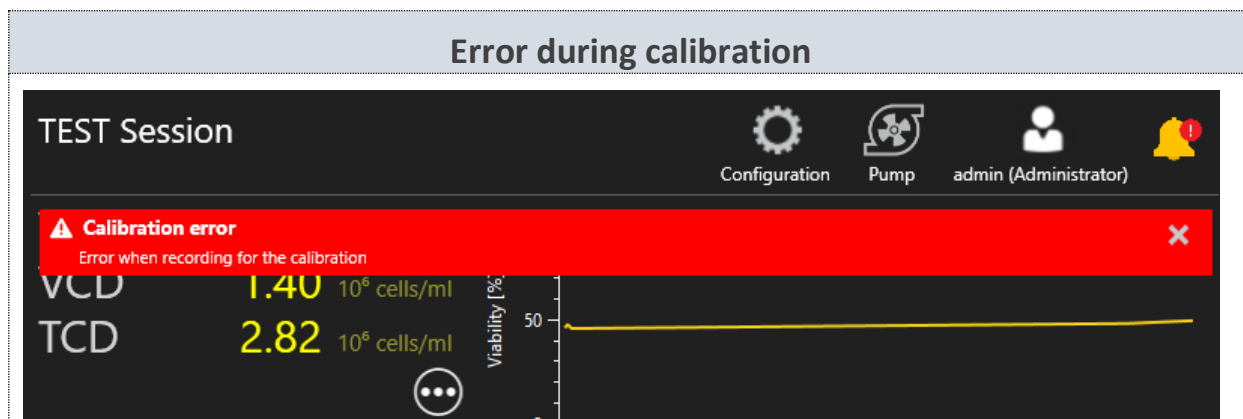
NO, if the BioConnect cartridge is inserted inside the microscope at the start of OsOne and cells are not flowing

#### How to fix it?

By removing the BioConnect cartridge from the microscope the time that OsOne takes a new background image if a monitoring session is not active.

#### How to prevent it?

By occasionally removing the BioConnect cartridge (when OsOne is running) so that OsOne can automatically take a new background image.



#### Description:

OsOne informs the user that an error occurred while taking a new background image.

#### Cause(s):

- A hardware error occurred while OsOne tried to capture a background image.
- The user inserted the BioConnect cartridge while OsOne was capturing a background image and a monitoring session is not active.

#### When?

This alarm is triggered while OsOne is capturing a background image (outside of a monitoring).

#### Type:

ERROR

#### Does it prevent from starting a monitoring?

YES

#### Does it interrupt the monitoring?

NO

#### Is it handled by OsOne?

NO.

#### How to fix it?

By removing the BioConnect cartridge and restarting OsOne.

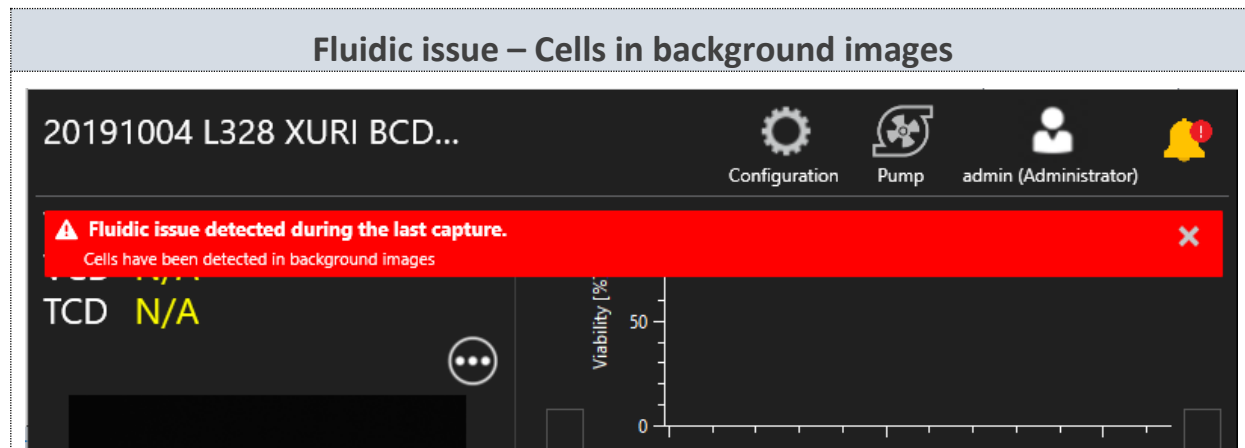
If restarting OsOne does not solve the issue, try to power off the microscope, then power on.

If powering off and on the microscope does not solve the issue, please contact Ovizio support (support@ovizio.com).

#### How to prevent it?

There is no way to prevent that kind of error.

## Measures



### Description:

OsOne informs the user that a potential fluidic issue could have occurred during the monitoring.

### Cause(s):

Objects have been detected in the background images. The presence of objects in the background images indicates that these objects are stuck in the flow cell because normally, the flush performed by OsOne during the acquisition of the background images should have made them disappear.

### When?

This alarm is triggered during the monitoring, when OsOne completed the computation of the last recorded images.

### Type:

ERROR

### Does it prevent from starting a monitoring?

NO

### Does it interrupt the monitoring?

YES

### Is it handled by OsOne?

YES. If a fluidic issue occurs during the monitoring, OsOne will automatically (automatic flush wizard):

- Stop the monitoring
- Start a flush sequence of 5 minutes
- Restart the monitoring.

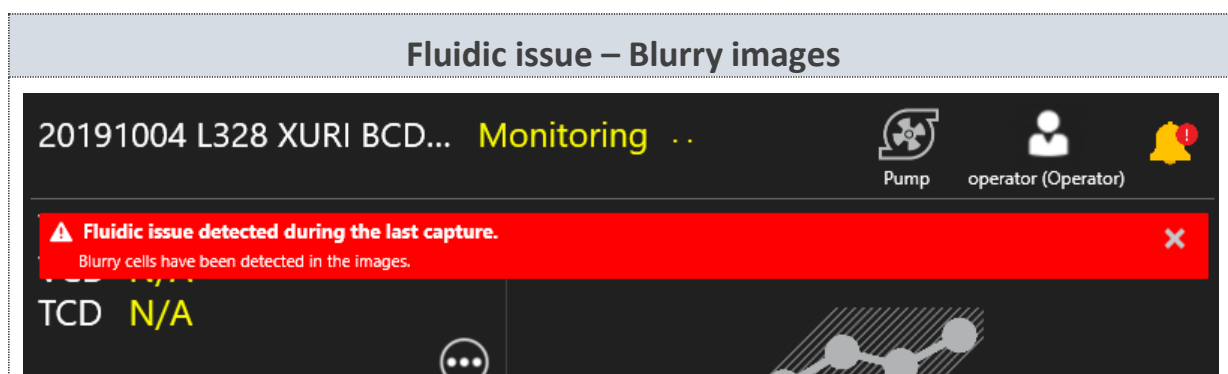
If this error occurs 5 times consecutively without being resolved, the above automatic actions won't be performed anymore.

### How to fix it?

If the automatic flush wizard does not solve the issue, it is recommended to stop the monitoring and start a manual flush (duration = 30 minutes).

### How to prevent it?

There is no way to prevent that kind of error.



### Description:

OsOne informs the user that a potential fluidic issue could have occurred during the monitoring.

### Cause(s):

- If the tubing is not inserted inside the pinch valves during the monitoring, it is possible that the cells moved during the acquisition, making the recorded images blurry.
- Large aggregates in the images.
- Bubbles in the imaging window

### When?

This alarm is triggered during the monitoring, when OsOne completed the computation of the last recorded images.

### Type:

ERROR

### Does it prevent from starting a monitoring?

NO

### Does it interrupt the monitoring?

YES

### Is it handled by OsOne?

YES. If a fluidic issue occurs during the monitoring, OsOne will automatically (automatic flush wizard):

- Stop the monitoring
- Start a flush sequence of 5 minutes
- Restart the monitoring.

If this error occurs 5 times consecutively without being resolved, the above automatic actions won't be performed anymore.

### How to fix it?

- If the cells move during acquisition, please check if the BioConnect tubes are properly inserted inside the pinch valves.
- If large aggregates are visible in the “Live” image, and if the automatic flush wizard does not make them disappear, it is recommended to stop the monitoring and start a manual flush (duration = 30 minutes).

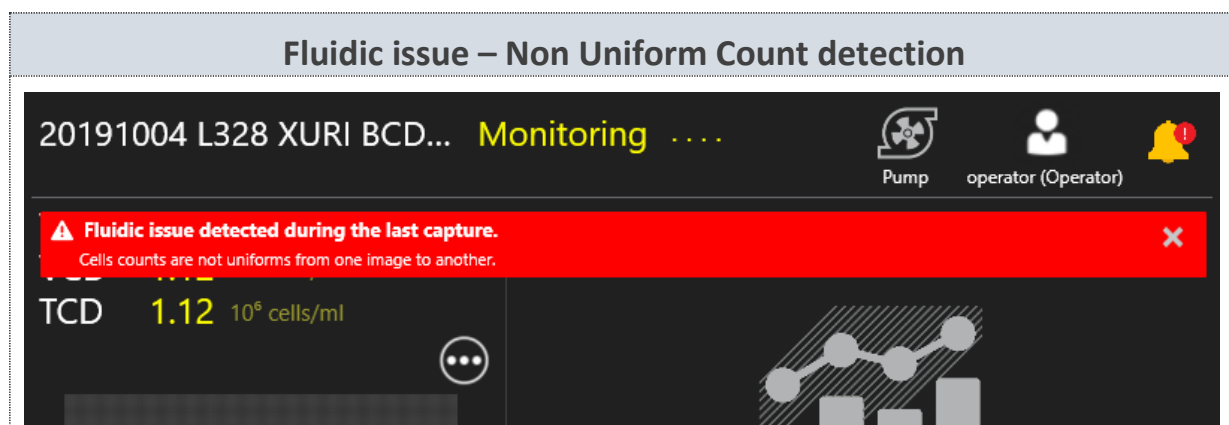
Remark: If the cells move during the acquisition whereas the Bioconnect tubes are properly inserted inside the pinch valves, please contact Ovizio support (support@ovizio.com).

### How to prevent it?

To prevent the “Blurry images” issue, it is recommended to check the installation of the BioConnect tubes before starting a monitoring.

Following items should be checked too :

- Are the tubings correctly welded ?
- Try decreasing the rocking speed or tilt angle of the rocking motion platform.
- Check if the dip tube entry point is remaining submersed into the liquid.



### Description:

OsOne informs the user that a potential fluidic issue could have occurred during the monitoring. This alarm was triggered because the cell count values are not uniform from one recorded image to another.

### Cause(s):

- If the BioConnect tubes are not properly inserted inside the pinch valves during the monitoring, it is possible that the cells move during the acquisition, making the recorded images blurry.
- Large aggregates in the images.

### When?

This alarm is triggered during the monitoring, when OsOne completed the computation of the last recorded images.

### Type:

ERROR

**Does it prevent from starting a monitoring?**

NO

**Does it interrupt the monitoring?**

YES

**Is it handled by OsOne?**

YES. If a fluidic issue occurs during the monitoring, OsOne will automatically (automatic flush wizard):

- Stop the monitoring
- Start a flush sequence of 5 minutes
- Restart the monitoring.

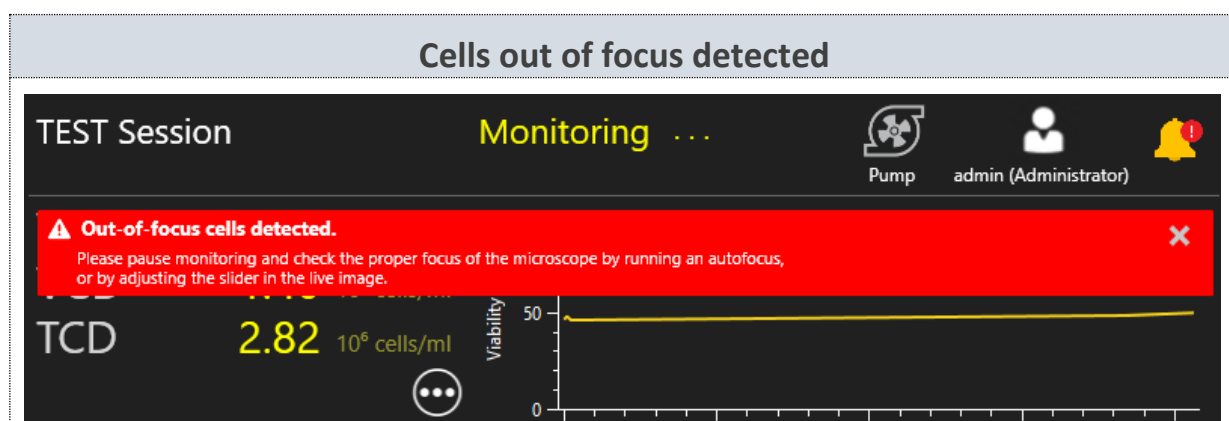
If this error occurs 5 times consecutively without being resolved, the above automatic actions won't be performed anymore.

**How to fix it?**

- If the cells move during acquisition, please check if the Bioconnect tubes are properly inserted inside the pinch valves.
- If large aggregates are visible in the "Live" image, and if the automatic flush wizard does not make them disappear, it is recommended to stop the monitoring and start a manual flush (duration = 30 minutes).

**How to prevent it?**

There is no way to prevent that kind of error.



**Description:**

OsOne informs the user that out of focus cells have been detected during the monitoring.

**Cause(s):**

- At the start of the monitoring, OsOne could have focused on something else (e.g.: a reflection in the image) than cells (because of low cell concentration).

**When?**

This alarm is triggered during the monitoring, when OsOne completed the computation of the last recorded images. This alarm is only triggered if out of focus cells are detected twice consecutively (see below "Is it handled by OsOne?")



**Type:**

ERROR

**Does it prevent from starting a monitoring?**

NO

**Does it interrupt the monitoring?**

NO

**Is it handled by OsOne?**

If OsOne detects out of focus cells in the images, it will try to correct the focus automatically without stopping the monitoring. If cells are still out of focus after this focus correction, OsOne will trigger the “Out of focus cells” alarm.

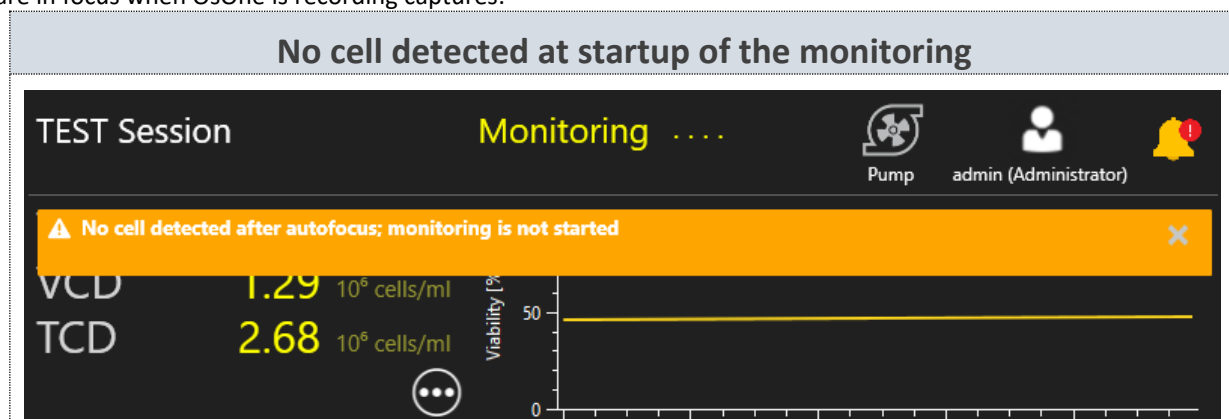
**How to fix it?**

It is recommended to stop the monitoring and restart it so that a long-range auto focus is performed by the monitoring wizard. If the restart of the monitoring does not solve the issue, it is recommended to:

- Stop the monitoring
- Activate the “Start monitoring with manual focus” in the monitoring configuration screen.
- Set the focus manually
- Start the monitoring

**How to prevent it?**

It is recommended to look at the first images (just after having started a monitoring) and to check if the cells are in focus when OsOne is recording captures.



**Description:**

OsOne informs the user that no cells have been detected when starting the monitoring, and that the monitoring has not started

**Cause(s):**

No cells have been detected in the image at the start of the monitoring.

**When?**

This alarm is triggered at the end of the monitoring wizard.

**Type:**

WARNING

**Does it prevent from starting a monitoring?**

YES

**Does it interrupt the monitoring?**

NO

**Is it handled by OsOne?**

YES. OsOne will automatically try to find cells 5 minutes later by performing a long range autofocus. (this operation is repeated until cells are detected)

**How to fix it?**

If cells are clearly visible on the Live image but OsOne keeps making the autofocus in order to find cells:

- Press the "Pause monitoring" button.
- Activate the "Start monitoring with manual focus" in the monitoring configuration screen.
- Set the focus manually
- Start the monitoring

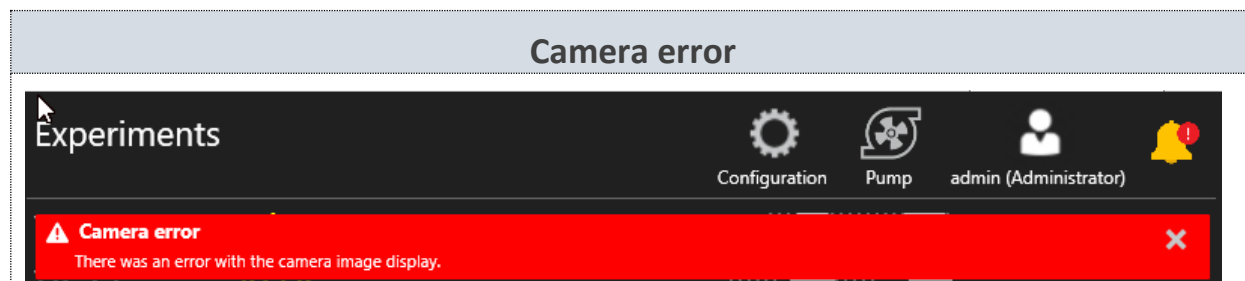
If no cells are visible :

- check if tubing is not clamped
- check if tubing did pop open after welding
- check if tubings are properly welded

**How to prevent it?**

By starting a monitoring session when cells are visible on the Live image.

## Hardware



### Description:

OsOne informs the user that a Camera error has been detected.

### Cause(s):

- OsOne could not connect with the camera
- There was an error during the transfer of the images

### When?

This alarm can be triggered anytime

### Type:

ERROR

### Does it prevent from starting a monitoring?

YES

### Does it interrupt the monitoring?

YES

### Is it handled by OsOne?

YES, if this error occurs during a monitoring. In that case the “Restart tool” will:

- Close OsOne
- Restart OsOne
- Restart the monitoring

If the error is not automatically resolved after 3 consecutive tries of the “Restart tool”, the monitoring could not continue because OsOne could not record any images.

### How to fix it?

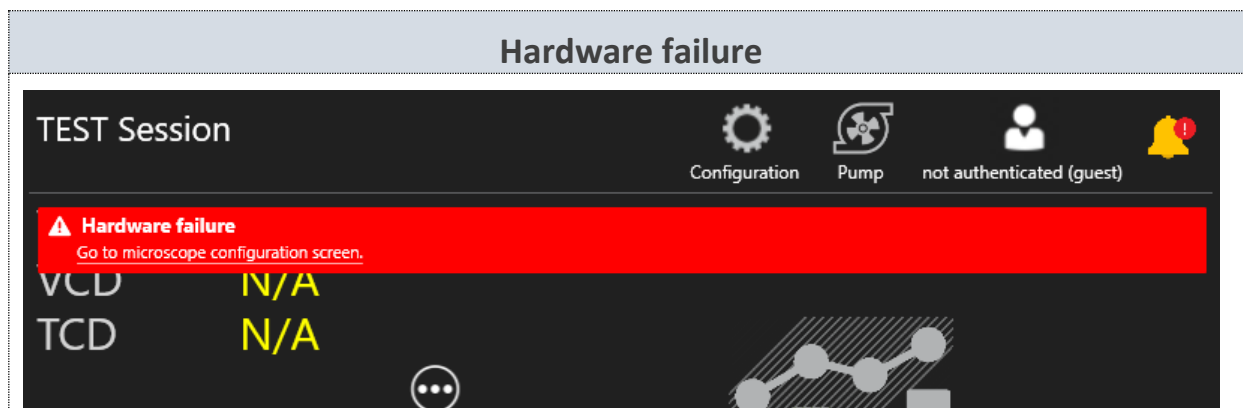
If this error occurs outside of a monitoring, it is recommended to restart OsOne.

If restarting OsOne did not solve the issue, please try to power off the microscope, wait a minute and power the microscope on.

If the issue still occurs after having power off/on the microscope, please contact the Ovizio support (support@ovizio.com).

### How to prevent it?

There is no way to prevent a camera error.



#### Description:

OsOne informs the user that it could not connect with one (or many) of the hardware components at the start of OsOne.

#### Cause(s):

OsOne could not connect with one (or many) of the hardware components at startup.

#### When?

This alarm is triggered at the start of OsOne

#### Type:

ERROR

#### Does it prevent from starting a monitoring?

YES

#### Does it interrupt the monitoring?

YES, if it happens during an automatic restart performed by the "Restart tool".

#### Is it handled by OsOne?

NO

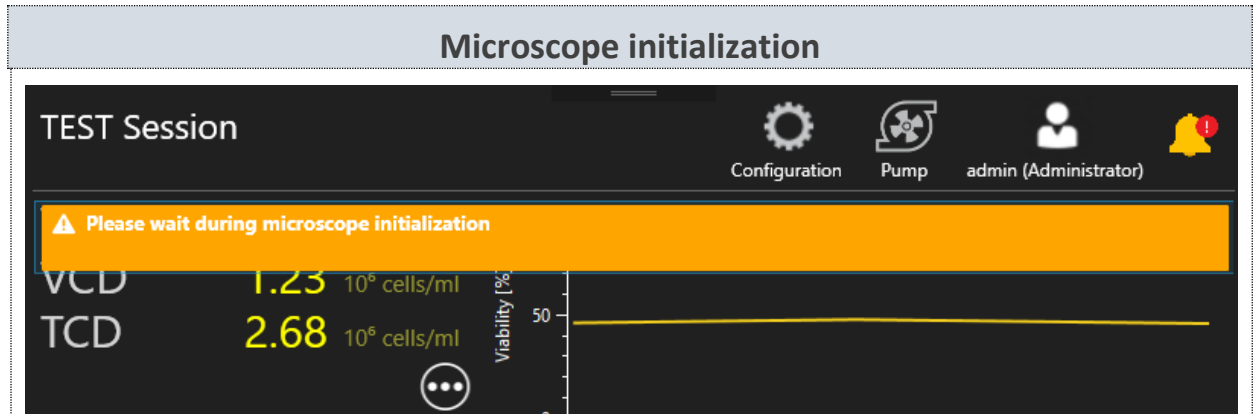
#### How to fix it?

If restarting OsOne does not solve the issue, please try to power off the microscope, wait a minute and power the microscope on.

If the issue still occurs after having power off/on the microscope, please contact the Ovizio support (support@ovizio.com).

#### How to prevent it?

There is no way to prevent a hardware failure at the start of OsOne.



**Description:**

OsOne informs the user that the microscope is being initialized.

**Cause(s):**

The microscope is initializing after powering the microscope on or restarting OsOne.

**When?**

This alarm is triggered after powering the microscope on or when restarting OsOne.

**Type:**

WARNING

**Does it prevent from starting a monitoring?**

YES

**Does it interrupt the monitoring?**

NO

**Is it handled by OsOne?**

N/A

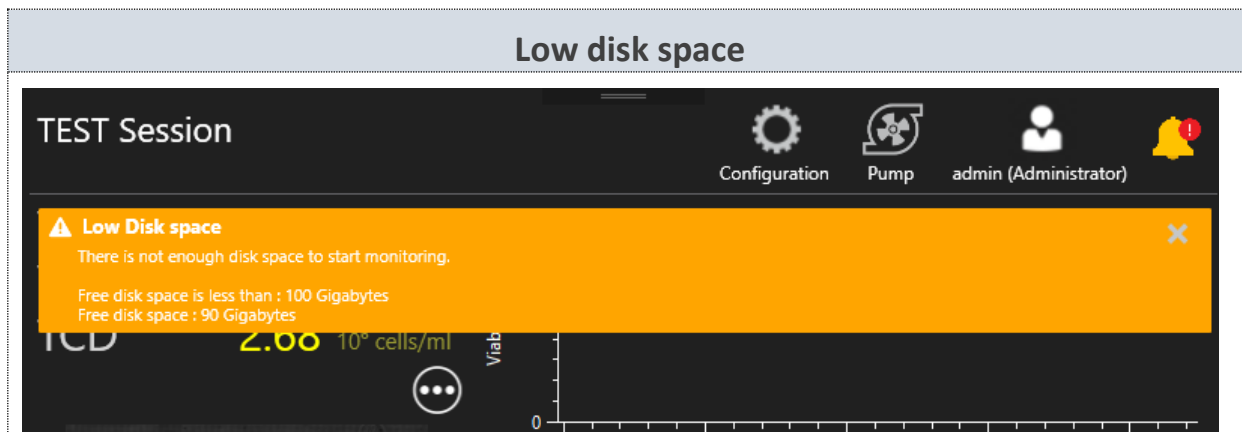
**How to fix it?**

By waiting for the initialization process to be complete.

**How to prevent it?**

N/A

## Storage



### Description:

OsOne informs the user that there is not enough free disk space to start a monitoring session.

### Cause(s):

The free disk space (in Gb.) is lower than the “Notify when free disk space is less than” value set in the “Storage” configuration screen.

### When?

This alarm is triggered when the user presses the “Start” monitoring button.

### Type:

WARNING

### Does it prevent from starting a monitoring?

YES

### Does it interrupt the monitoring?

NO

### Is it handled by OsOne?

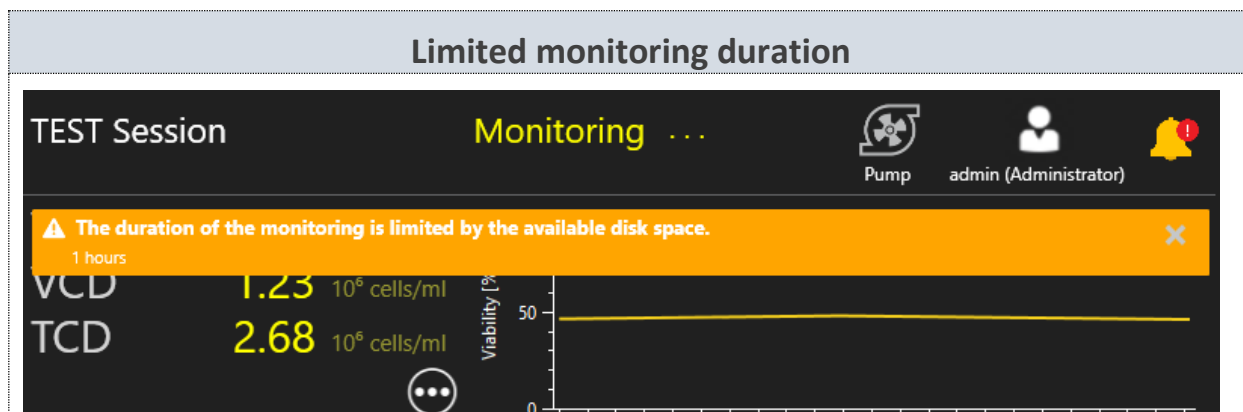
N/A

### How to fix it?

By making some free disk space or by reducing the “Notify when free disk space is less than” value in the “Storage” configuration screen.

### How to prevent it?

- By verifying that the remote copy and the automatic clean up options are enabled. With these 2 options enabled, experiments will be automatically cleaned up from the computer.
- By setting a reasonable value for the “Notify when free disk space is less than” property. Setting this value too high (e.g.: 500 Gb) will automatically increase the risk to have this alarm triggered.
- By verifying that there is no connection error preventing recorded data to be remotely copied.



#### Description:

OsOne informs the user about the day(s)/hour(s) left before the computer will run out of disk space.

#### Cause(s):

The computer is almost out of free disk space.

#### When?

This alarm is triggered during the monitoring.

#### Type:

WARNING

#### Does it prevent from starting a monitoring?

NO

#### Does it interrupt the monitoring?

NO

#### Is it handled by OsOne?

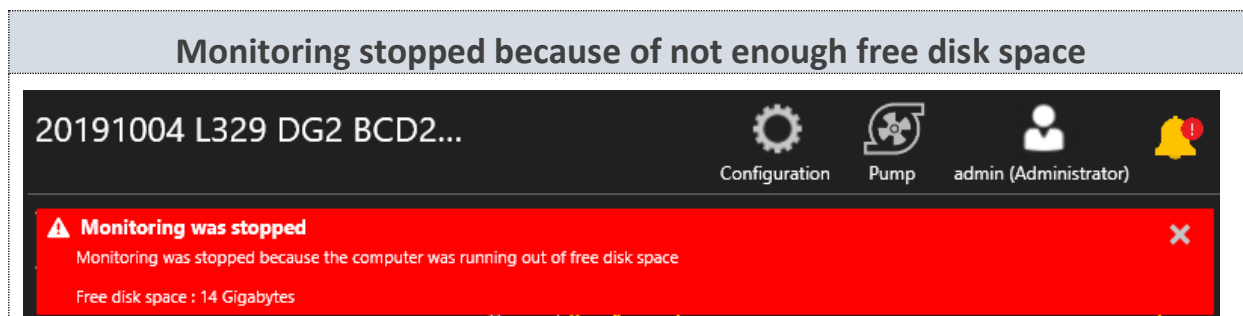
NO

#### How to fix it?

By making some free disk space and/or by reducing the “Notify when free disk space is less than” value in the “Storage” configuration screen.

#### How to prevent it?

- By verifying that the remote copy and the automatic clean up options are enabled. With these 2 options enabled, experiments will be automatically cleaned up from the computer.
- By verifying that there is no connection error preventing recorded data to be remotely copied.



#### Description:

OsOne informs the user that the monitoring was stopped because the computer was running out of free disk space.

#### Cause(s):

The free disk space (in Gb.) during the monitoring is lower than the “Notify when free disk space is less than” value set in the “Storage” configuration screen.

#### When?

This alarm is triggered during the monitoring.

#### Type:

ERROR

#### Does it prevent from starting a monitoring?

NO

#### Does it interrupt the monitoring?

YES

#### Is it handled by OsOne?

NO

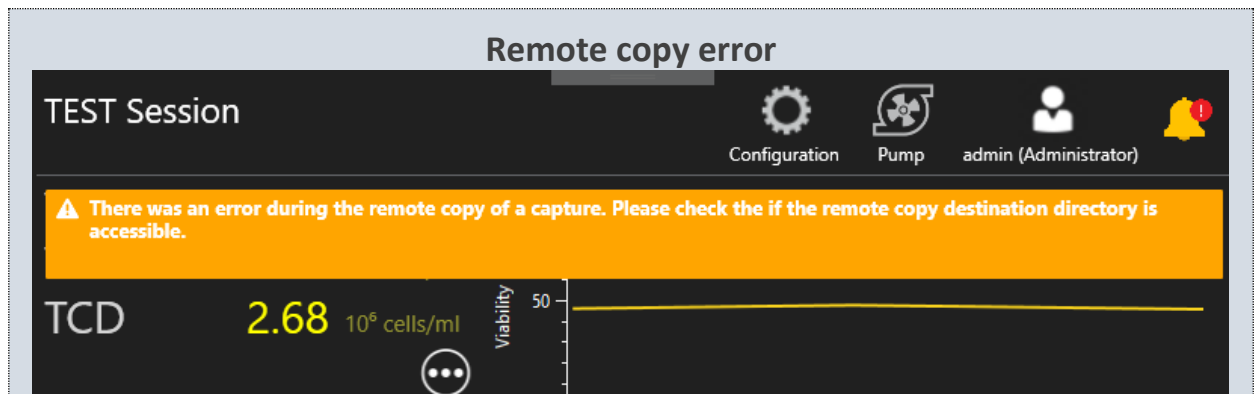
#### How to fix it?

By making some free disk space and/or by reducing the “Notify when free disk space is less than” value in the “Storage” configuration screen.

#### How to prevent it?

- By verifying that the remote copy and the automatic clean up options are enabled. With these 2 options enabled, experiments will be automatically cleaned up from the computer.
- By setting a reasonable value for the “Notify when free disk space is less than” property. Setting this value too high (e.g.: 500 Gb) will automatically increase the risk to have this alarm triggered.
- By verifying that there is no connection error preventing recorded data to be remotely copied.





### Description:

OsOne informs the user that there was an error during the copy of the data (hdf5 files, csv results files) to the remote location.

### Cause(s):

- A connection error between the computer and the remote location
- The remote location access is denied to OsOne
- Wrong remote location path.

### When?

This alarm is triggered during the monitoring.

### Type:

WARNING

### Does it prevent from starting a monitoring?

NO

### Does it interrupt the monitoring?

NO

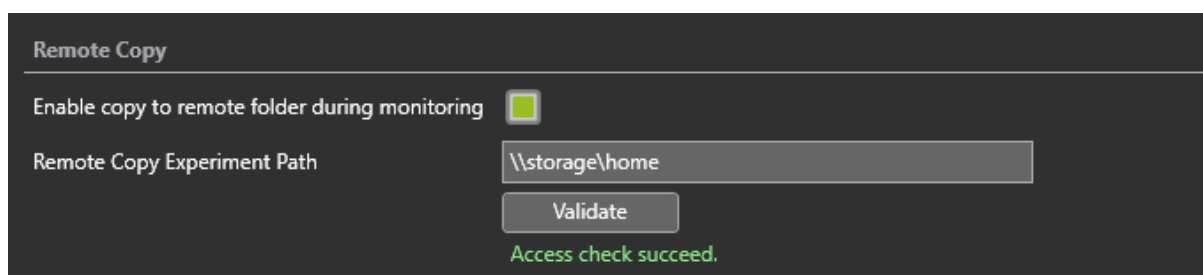
### Is it handled by OsOne?

NO

### How to fix it?

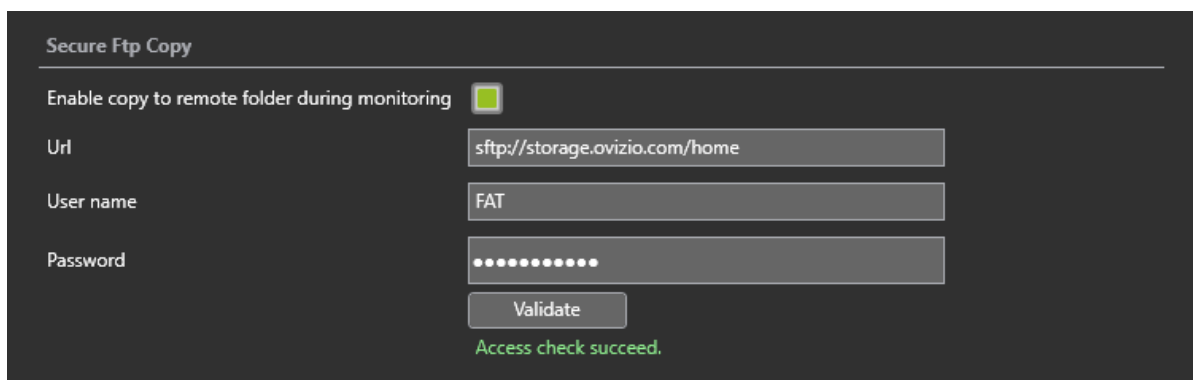
By verifying in the storage configuration under the “Remote Copy” section (if the “Enable copy to remote folder during monitoring” is checked) that:

- A valid remote path has been specified
- OsOne has access to this remote path (by clicking the “Validate” button)



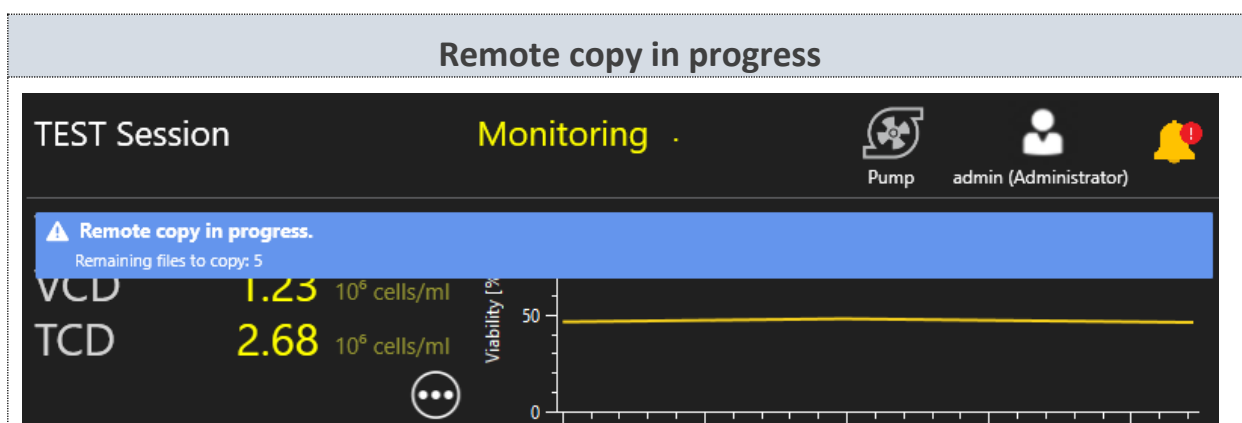
By verifying in the storage configuration under the “Secure Ftp copy” (if the “Enable copy to remote folder during monitoring” is checked)

- A valid SFTP URL has been specified
- OsOne can access this SFTP URL (by clicking the “Validate” button)



#### How to prevent it?

See above the “How to fix it?” section.



#### Description:

OsOne informs the user that monitoring data (hdf5 files, csv results files) are being copied to the remote location.

#### Cause(s):

Remote copy in progress

#### When?

This alarm can be triggered anytime.

#### Type:

INFORMATION

**Does it prevent from starting a monitoring?**

NO

**Does it interrupt the monitoring?**

NO

**Is it handled by OsOne?**

N/A

**How to fix it?**

N/A

**Configure**

## Monitoring session configuration

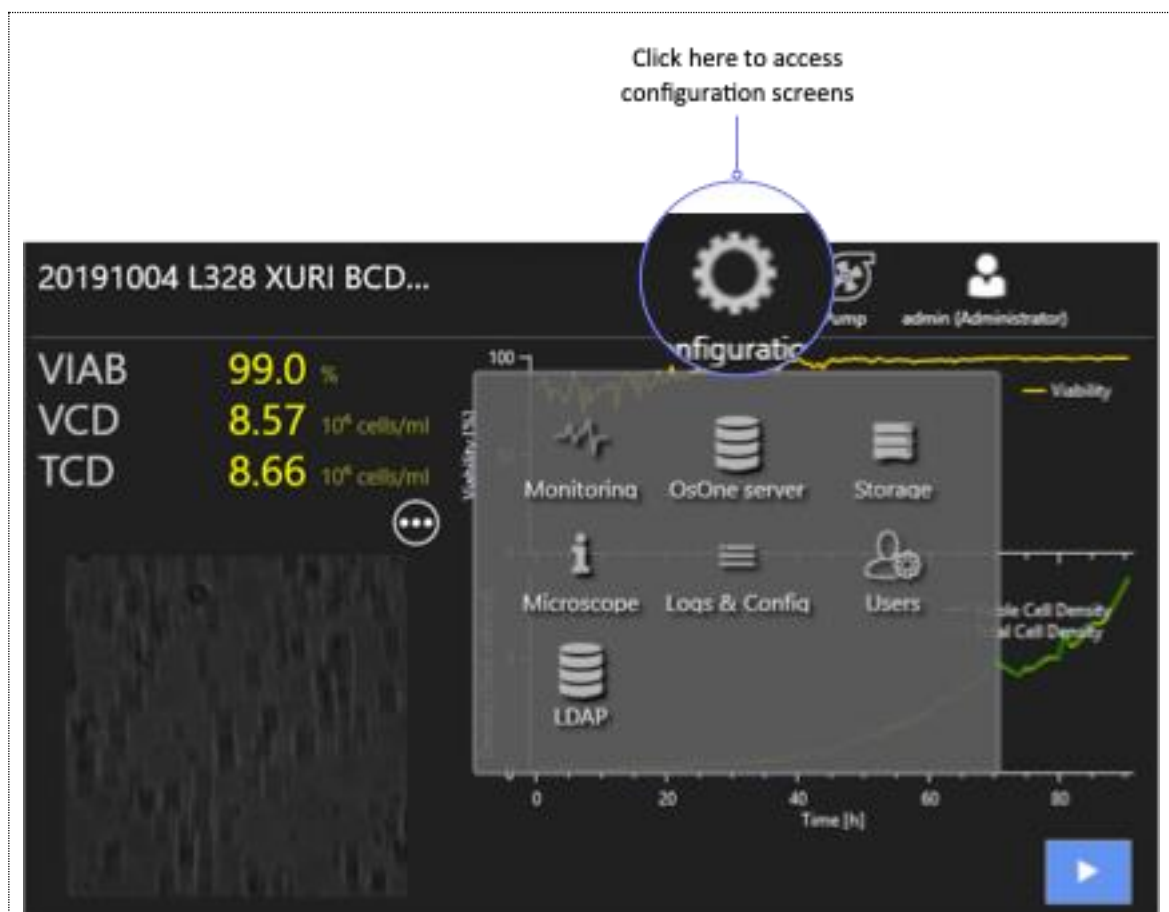
This section gives a description of all the configuration options related to the online monitoring of suspension cells.



You must **pause** your monitoring session to enable the configuration menu

The available configuration options associated with a user depend on the permissions granted to the user role. The following section assumes that the user is logged in with Administrator rights.

To access the configuration screen related to the monitoring, click on the configuration icon on the top of the Live screen and then on the monitoring icon.



## Start the monitoring with manual focus

Monitoring configuration

Start monitoring with manual focus

Wizard priming duration (seconds)

90

Default acquisition settings

Frequency

Every hour

Cell line

T-Cell

v6

Export Only Good Measurements

Sedimentation images recording

Disabled

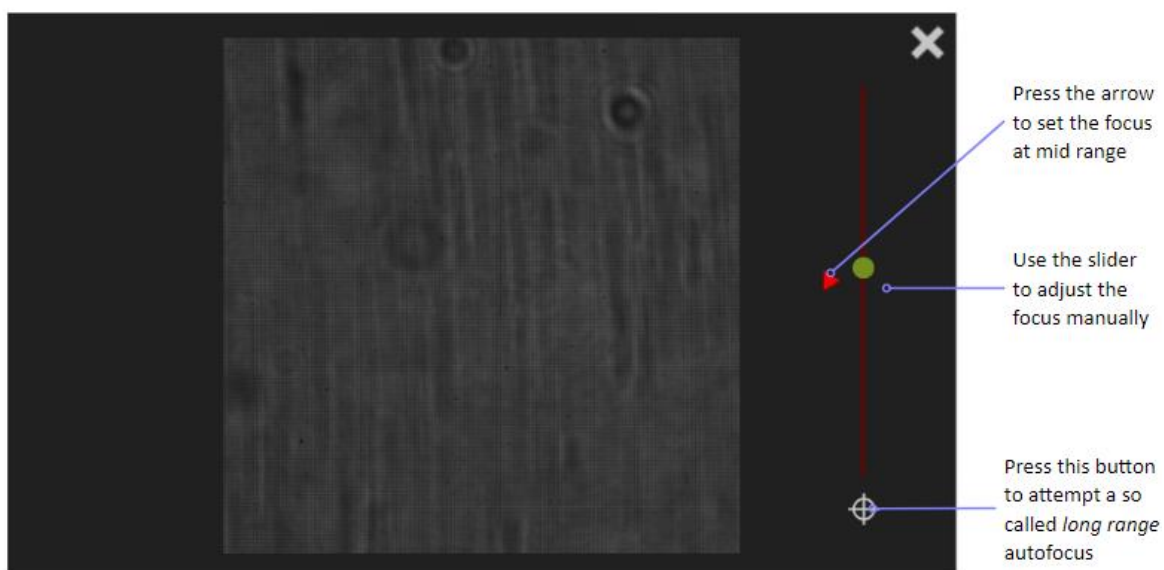
Reset to defaults

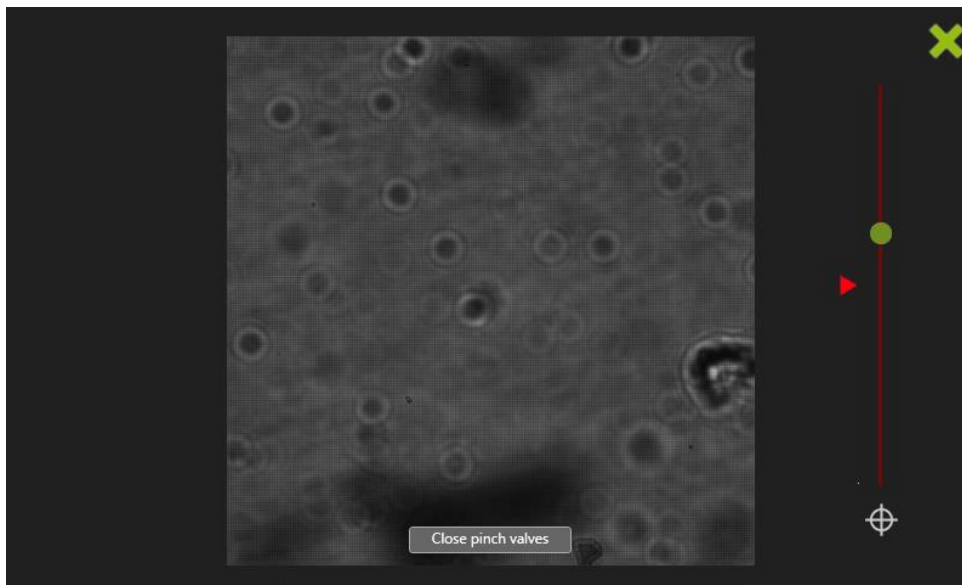
Cancel

Done

The manual focus can be enabled when the system cannot automatically adjust the focus.

Check the related checkbox in the monitoring options. Then, press Done and click on the Live image of the main screen. A focus slider will appear to manually adjust the focus before launching a monitoring session.





## Frequency

The frequency at which data points are acquired.

## Cell line

The default cell line that will be selected when starting a monitoring session.

## Export only good measurements

Property that defines if a measurement resulting from a fluidic issue is:

- Added in the OsOne graphs
- Exported to the remote location (if the remote copy is enabled).

## Sedimentation images recording

Records images during sedimentation to help Ovizio support define the best sedimentation time.

# OsOne Server

Enable OsOne Server if you want to access your iLine F Pro functionalities remotely with your SCADA system without the need to access the user interface.

Many functionalities are available such as reading measurements, starting and stopping a monitoring session. See Annex I for a comprehensive list of functionalities.

By default, the following protocols are available:

- RestFUL http web service
- OPC (UA)

Enter the client's credentials to remotely authenticate to OsOne.

When OsOne server is enabled, you may also want to access it through OPC (UA). For that check the *Enable OsOne OPC UA Bridge* box.

Server configuration

Enable OsOne server

☐

Server port

9000

User name

ovizio

Password

••••••

OPC Configuration

Enable OsOne OPC UA Bridge

☐

OsOne OPC UA Bridge Status

Not Running

Reset to defaults

Cancel

Done

## Testing the web service

You can test the web service by opening a browser on another computer or locally by entering the following URL in the address bar: [http://\[IP\]:9000/swagger](http://[IP]:9000/swagger), where [IP] is the IP address of the iLine F Pro where the Server runs. You should then get a web page that allows you to test the various services.

## OsOne REST API

### Monitoring

Show/Hide | List Operations | Expand Operations

DELETE	/api/monitoring	Stop the monitoring.
GET	/api/monitoring	Gets the monitoring information
POST	/api/monitoring	Start a monitoring session.
GET	/api/pump	
POST	/api/pump	Posts the pump.

### System

Show/Hide | List Operations | Expand Operations

[ BASE URL: , API VERSION: V1 ]

ERROR { }



See *OsOne Server User Manual* for a comprehensive description of all possible commands.

## Testing OPC UA

Open an OPC UA client (for example <https://github.com/FreeOpcUa/opcua-client-gui>) and type in the following command `opc.tcp://[IP]:51210/UA/OvizioServer`

FreeOpcUa Client

Actions

`opc.tcp://localhost:51210/UA/OvizioServer`

DisplayName	BrowseName	NodeId
Root	0:Root	i=84
Objects	0:Objects	i=85
Server	0:Server	i=2253
Microscopes	2:Microscopes	ns=2;i=15011
Microscope #1	3:Microscope #1	ns=3;i=1
BridgeConnected	2:BridgeConnected	ns=3;i=2
Hardware	2:Hardware	ns=3;i=3
Monitoring	2:Monitoring	ns=3;i=6
Alarms	2:Alarms	ns=3;i=16
FluidicIssues	2:FluidicIssues	ns=3;i=17
FrequencyNotAchieved	2:FrequencyNotAchieved	ns=3;i=21
OutOffFocusCells	2:OutOffFocusCells	ns=3;i=18
SaturatedBackgroundImages	2:SaturatedBackgroundImages	ns=3;i=20
SaturatedImages	2:SaturatedImages	ns=3;i=19
AverageCellDiameter	2:AverageCellDiameter	ns=3;i=15
CellLine	2:CellLine	ns=3;i=10
Experiment	2:Experiment	ns=3;i=9
Frequency	2:Frequency	ns=3;i=11
IsReady	2:IsReady	ns=3;i=7
IsRunning	2:IsRunning	ns=3;i=8
TotalCellDensity	2:TotalCellDensity	ns=3;i=12
Viability	2:Viability	ns=3;i=14
ViableCellDensity	2:ViableCellDensity	ns=3;i=13
Storage	2:Storage	ns=3;i=22
Types	0:Types	i=86
Views	0:Views	i=87

## Storage Configuration

### Disk space

Use this setting to get an alarm when the available local storage space is lower than a given size.

Storage configuration

Notify when free disk space is less than
10
Gigabytes

Remote Copy

Enable copy to remote folder during monitoring
Remote Copy Experiment Path
\\storage\home
Validate
Access check succeed.

Secure Ftp Copy

Enable copy to remote folder during monitoring
Url
sftp://storage.ovizio.com/home
User name
FAT
Password
.....
Validate
Access check succeed.

Cleanup

Automatic Clean up
Delay Before Clean Up
60
Days

Reset to defaults
Cancel
Done

## Remote Copy

The remote copy functionality allows you to copy all images captured during your session to a network shared folder.

Enter the path of the remote copy folder and click on *Validate*. This will display a pop-up window asking you to enter your credentials to access that remote folder.

For each data point, the following files will be copied:

1. The hologram hdf5 files
2. <Experiment name>\_<time step>\_ cellcounting\_features.csv: contains one line for each cell in the data point, listing all cell morphological features
3. <Experiment name>\_<time step>\_ cellcounting\_summary.csv: contains a line for each capture acquired for the data point (typically 25) with VCD and Viability, as well as summary data for the data point such as average VCD, TCD, Viability, Diameter etc.
4. <Experiment name>\_<time step>\_ cellcounting\_aggregated\_summary.csv: contains a summary information for all captures. The file is updated each time a new capture is created
5. <Experiment name>\_<time step>\_ records.txt: contains metadata about the experiment and aggregated summary for each data point (one line per data point)
6. export\_logs.zip: contains all OsOne logs and OsOne Configuration information

In case of connection loss, OsOne keeps track of the files that have not been copied to the remote folder. OsOne will continue the remote copy process once the connection restored and a notification banner will display the number of files that still need to be copied.

## Secure FTP Copy

The remote copy functionality allows you to copy all images captured during your session to a SFTP remote folder.

Enter the SFTP URL and your SFTP credentials. Then, click on *Validate* to ensure that the SFTP information are valid.

See above the “Remote Copy” section for a description of the data copied during the SFTP remote copy process.

## Automatic Clean up

Delete all files that have been safely copied to the remote location. Moreover, files are only deleted if they are older than the specified “delay before cleaning up”.

## Information

This screen displays hardware and software information about the iLine F Pro.

Scroll down to see its serial number and the OsOne software version.

The Use Custom Pump Profile checkbox is for maintenance purposes only.

Camera

Name

Point Grey Research - BFS-U3

Connection

Ready

Serial number

19194745

Status

On

Light Source

Name

N/A - N/A

Connection

Ready

Status

Standby

Wavelength

630nm

Partial coherence

On

Objective Actuator

Name

N/A - N/A

Connection

Ready

Done

Pump

Name

N/A - iLine-F D3HM G02-A Rev. 2.1.0

Controller

Ready

Status

Backup pumping

Use custom pump profile

☐

Cartridge

QR code

I3TF-BCD-S02-B 1.0.5 20190404089

Temperature sensor

Name

N/A - N/A

Connection

Ready

Status

On

About

Done

About

Manufacturer	Ovizio Imaging Systems
Mode	Transmission - D3HM
Model	iLine-F D3HM G02-A Rev. 2.1.0
Serial number	I3TFMIC20200124001
Hardware Version	2.1.0
Firmware Version	1.1.1
OsOne version	7.2.0.22497
Computer Name	I3TF20200124001
IP Address	192.168.178.43

Done

Mode	Transmission - D3HM
Model	iLine-F D3HM G02-A Rev. 2.1.1
Serial number	I3TFMIC20200313000
Hardware Version	2.1.1
Firmware Version	1.1.4
OsOne version	7.3.0.0
Computer Name	ComputerName
IP Address	192.168.1.2


Regulatory

FCC ID	2AXQY-I3TFMICG02A
--------	-------------------

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.

Done

## Logs



Logs configuration

Max size (MB) 10

Number of files to keep 10

Logging Level Detailed

Reset to defaults Cancel Done

When the microscope and its software are in use, all the actions taken by the user and the software are stored into files called log files or audit trail. In case of problems with the microscope or its software these files give crucial information about the origin of the issues.

In case of problems, we recommend changing the logging level to **Trace** and to try to reproduce the issue. Detailed information about the microscope behavior will be recorded and can subsequently be sent to [support@ovizio.com](mailto:support@ovizio.com) for further analysis and diagnosis.

The log configuration screen lets the user choose the number of back-up files to keep and their maximum size. We recommend keeping the default values unless the Ovizio support team gives you other instructions.

### Audit trail

OsOne is recording all user actions inside a file named "audittrail.log". The "audittrail.log" log file is part of the OsOne log files.

#### User actions

User actions are actions initiated by a user or involving a user using OsOne:

- from the microscope touch screen on any of the OsOne user interfaces (e.g., starting a monitoring via the touch screen by pressing the "Start" button)
- on disposables connected to the microscope (e.g., inserting the Bioconnect cartridge inside the microscope)
- remotely via OPC or via a Web service (e.g., starting a monitoring remotely via OPC)

### User actions recorded in the audit trail

Users actions recorded in the audit trail are the actions that can:

- modify, create or reset the OsOne configuration (e.g., modifying the password expiration value in the "Users" configuration screen)
- modify, create or delete OsOne records (record a capture)
- control the microscope (e.g., start an autofocus)
- involve an OsOne user (e.g., user logging in OsOne)

Note: The audit trail functionality cannot be disabled in OsOne, meaning that it constantly records user actions.

### Content of the audit trail

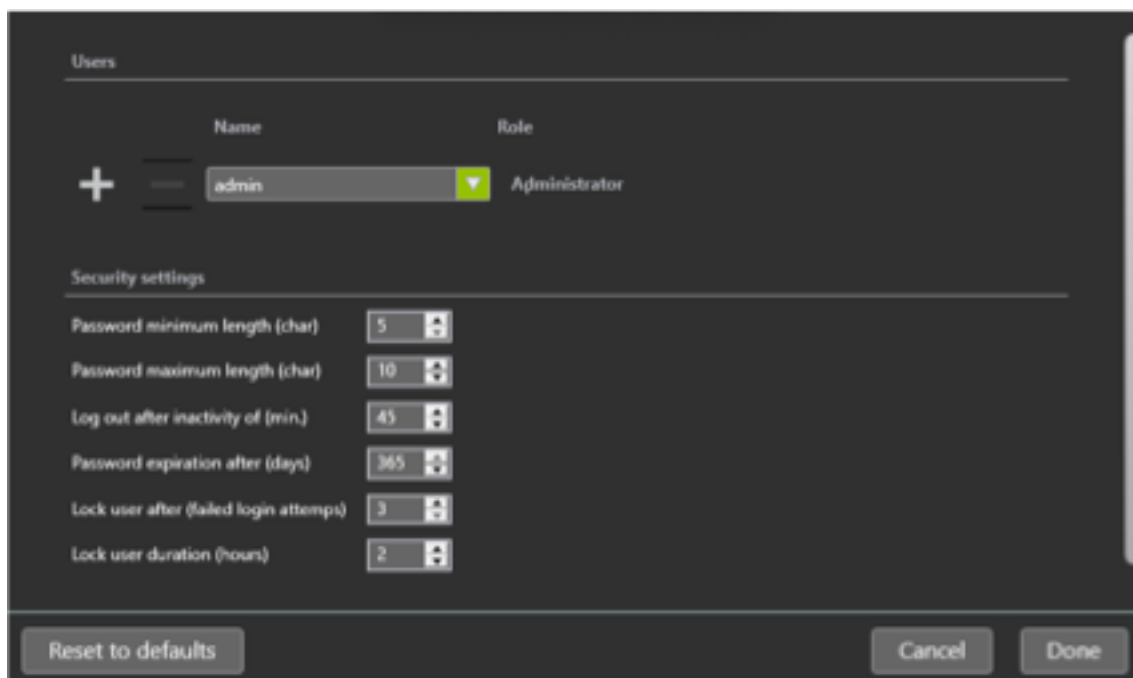
Each action recorded in the audit trail will always contain the following information:

- Date and time of the action
- User name and role of the user logged in OsOne when an action is made
- Name of the executed action
- When the action is related to a modification of the configuration settings, the old and new values will be recorded

### Audit trail location

The audit trail log file is located in the OsOne log folder (...\\AppData\\Roaming\\OsOne\\Logs\\)

## Users



The screenshot shows the 'Users' configuration window in OsOne. It features a table with columns for 'Name' and 'Role'. The first entry is 'admin' with the role 'Administrator'. Below the table is a 'Security settings' section with several input fields: 'Password minimum length (char)' set to 5, 'Password maximum length (char)' set to 10, 'Log out after inactivity of (min.)' set to 45, 'Password expiration after (days)' set to 365, 'Lock user after (failed login attempts)' set to 3, and 'Lock user duration (hours)' set to 2. At the bottom, there are three buttons: 'Reset to defaults', 'Cancel', and 'Done'.

Name	Role
admin	Administrator

**Security settings**

- Password minimum length (char): 5
- Password maximum length (char): 10
- Log out after inactivity of (min.): 45
- Password expiration after (days): 365
- Lock user after (failed login attempts): 3
- Lock user duration (hours): 2

Buttons: Reset to defaults, Cancel, Done

### What

The user management feature is meant to:

- Restrict access to OsOne features only to authorized and authenticated users (created by users with the Administrator role)
- Control what users can do in OsOne
- Trace users, modifications, alteration, addition of data /settings in the audit trail
- Guarantee of data integrity

## Why

- To comply with Title CFR21 part 11 (US Regulation) that regulates Electronic Records and Electronic Signatures

## How

- Users are created by Administrators
- Users must provide valid credentials to access OsOne
- By giving different rights to the users
- By logging all authenticated users' actions (failed login, deletion, modifications of data...,) to an audit trail
- By checking that the data are not corrupted, have not been modified outside the system, and if they are, by informing the user

In order to give different rights to the users, the following concepts are used:

- **Roles:** Rather than assigning individual permissions directly to each user, permissions are grouped into roles. When users are created, they are assigned a role.

## Built-in Roles

- The “Administrator” role: is the only user that can access all functionalities and create other users
- The “Operator” role: can operate the device but cannot access configuration items
- The “Guest” role: cannot do anything, is the default user at startup

## Built-in users

Users that exist by default in OsOne, they cannot be deleted and their passwords cannot be modified.

For each role (except for the “Guest” role), there is a built-in user:

- User “**admin**” for the “Administrator” role
- User “**guest**” the default user with limited rights
- User “**operator**” for the “Operator” role
- User “**engineer**” for the “Maintenance” role. For Ovizio only.

The passwords of these accounts will be communicated when the software will be delivered.

First use

The first time OsOne is opened built-in users only exist. The first thing to do is to create new users.

To do so, the administrator of the system first creates his own Administrator user account using the built-in user “admin” and its password (provided) by Ovizio.

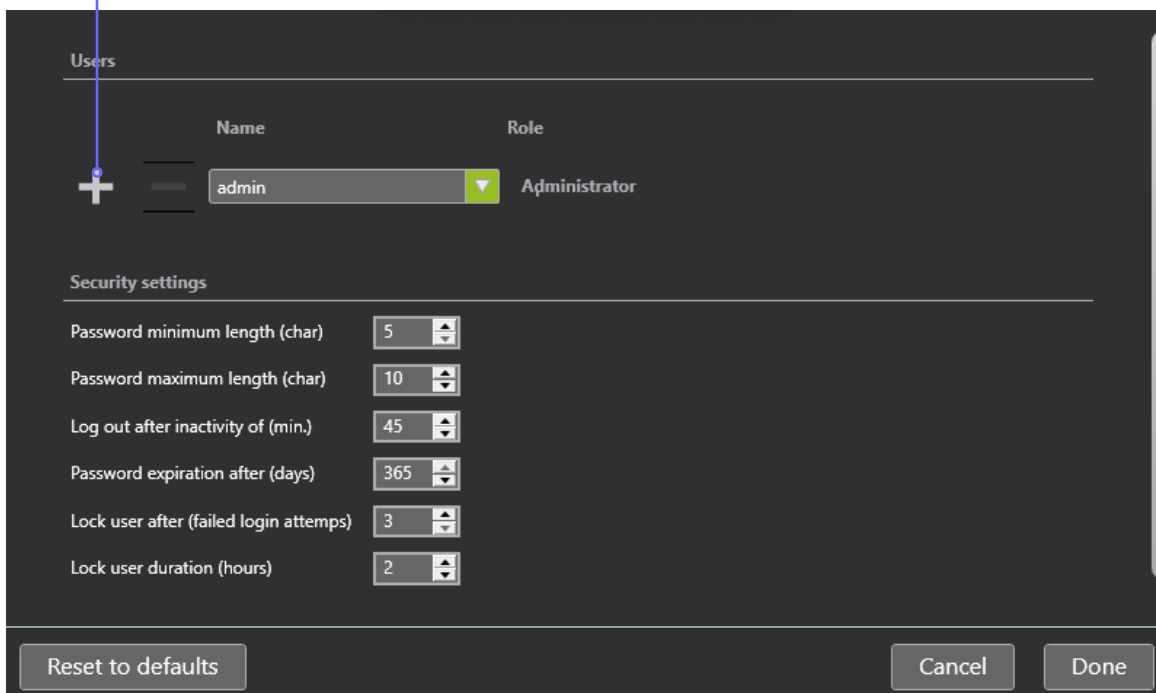


Once his own Administrator account is created, he uses it to create OsOne users and give them different permissions according to the needs (see below the *Login* and the *Users* section for more detailed explanations about how to accomplish these tasks).

**Remark:** It could be possible to use OsOne only with the 3 built-in user accounts. However, in this case, multiple users may use the same account limiting the traceability of actions.

### Create a new user

Click here to add a new user



Name	Role
+	Administrator

**Security settings**

- Password minimum length (char): 5
- Password maximum length (char): 10
- Log out after inactivity of (min.): 45
- Password expiration after (days): 365
- Lock user after (failed login attempts): 3
- Lock user duration (hours): 2

Reset to defaults Cancel Done

Users

	Name	Role
+	admin	Administrator

Name

Enter user name

Role

Operator

Password

Cancel

Validate

Password length : min 5 chars.

Security settings

Password minimum length (char)

5

Password maximum length (char)

10

Reset to defaults

Cancel

Done

### Deleting an existing user

Press the “-” button to delete an existing user.

Users

	Name	Role
+	Jon	Operator

Users

	Name	Role
+	Jon (Disabled)	Operator

Deleted users will still be visible inside the “Name” combo box. They are identified by the word “Disabled” next to their user name.

## Security settings

### Password minimum length

The "Password minimum length" setting defines the minimum length required for the password of an OsOne user.

### Password maximum length

The "Password maximum length" setting defines the maximum length allowed for the password of an OsOne user.

### Log out after inactivity

The "Log out after inactivity of(min.)" setting defines the duration after which an inactive user will be automatically logged out.

### Password expiration

Passwords expire after a defined amount of time (the "Password expiration after (days)" setting) and must be renewed during authentication.

### User locked after failed login attempts

A failed login attempt is defined when OsOne does not recognize the combination of user name and password. A user locked by OsOne won't be allowed to authenticate even if the provided credentials are valid. The "Lock user after (number of failed login attempts)" setting defines after how many failed login attempts the account of an existing user will be locked.

### Lock user duration

The "Lock user duration (hours)" setting defines the time (in hour(s)) during which a user account will be locked.

## LDAP

If your company already owns a user directory such as LDAP or Active Directory, you can leverage its users and groups in OsOne.

Note that it is not possible to see the users associated with such a user directory in the OsOne *Users* configuration section. Moreover, it is not possible to apply security settings to such users.

You will need to contact your user directory manager to correctly configure the settings below.

LDAP Server Configuration

Enable LDAP Authentication

☐

Server Url

ldap.mycompany.com:636

Use SSL

☐

Users Domain Name

CN=Users,DC=ldap,DC=mycompany,DC=com

Account attribute mapping

sAMAccountName

Login Format

%username%

Groups Mapping

Administrator

CN=ovizio-admin,CN=Groups,DC=ldap,DC=mycompany,DC=com

Maintenance

CN=ovizio-maintenance,CN=Groups,DC=ldap,DC=mycompany,DC=com

Operator

CN=ovizio-operator,CN=Groups,DC=ldap,DC=mycompany,DC=com

Reset to defaults

Cancel

Done

The table below describes the settings related to remote user management

Item	Meaning	example
<b>LDAP Server Configuration</b>		
Enable LDAP Authentication	Check the box to allow the use of external user management	
Server Url	The address of the LDAP Server	ldap.mycompany.com:636
Use SSL	Indicate whether the server use Secure SSL or Secure authentication	
Users Domain Name		CN=Users,DC=ldap,DC=mycompany,DC=com
Account attribute mapping	Account attribute mapping	sAMAccountName

Login Format		<ul style="list-style-type: none"> <li>– Active Directory: %username%</li> <li>– OpenLDAP: uid=%username%,cn=users,dc=ldap,dc=mycompany,dc=com</li> </ul>
<b>Group mapping</b>		
Administrator		CN=ovizio-admin,CN=Groups,DC=ldap,DC=mycompany,DC=com
Maintenance		CN=ovizio-maintenance,CN=Groups,DC=ldap,DC=mycompany,DC=com
operator		CN=ovizio-admin,CN=Groups,DC=ldap,DC=mycompany,DC=com

## Remote Access

## OsOne Files

On MacOS in Finder > Go > smb://<device ip address>

On Windows in an explorer window \\<device ip address>\OsOne

You will then get access to all OsOne folders

- Cache
- Calibration
- Config
- Experiments
- Logs

## Remote access with VNC

You can access the user interface remotely by using a VNC client that you can download here

<https://www.realvnc.com/en/connect/download/viewer/>

## Maintenance and Servicing



## Maintenance

### Cleaning

The instrument can be cleaned with a soft cloth, wetted with IPA (iso propyl alcohol), if required

The instrument does not contain user serviceable parts.

Servicing can only be performed by a qualified technician (see chapter “Servicing”). A yearly maintenance is advised.

### Decontamination

The instrument can be cleaned with a soft cloth, wetted with IPA (iso propyl alcohol), Spor-Klenz® (STERIS Life Sciences) or Vesta Syde SQ Disinfectant (STERIS Life Sciences) if required.



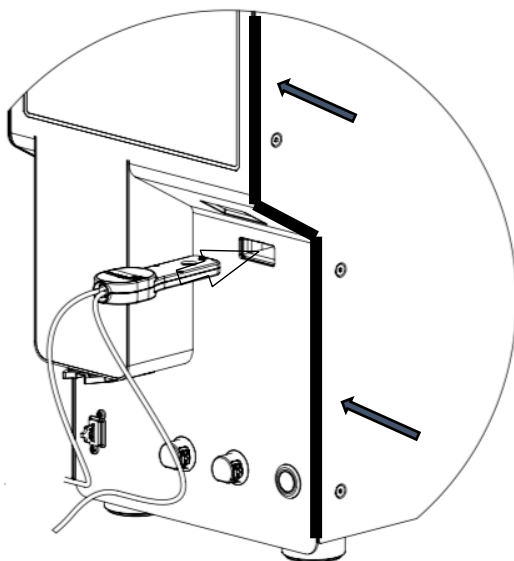
Do not spray Spor-Klenz® (STERIS Life Sciences) or Vesta Syde SQ Disinfectant (STERIS Life Sciences) directly on the black heatsink at the back of the instrument.



Do not use strong acid or base or abrasive cleaning agents.



The black seal in the front housing can leave marks on the cloth you’re using when wiping with cleaning agents. That is a known behavior and not a sign of degradation of the seal.



The disposable is delivered sterile (by gamma irradiation) and should be trashed after used. It is not autoclavable.

## Servicing

### Safety precautions

#### Mains



This instrument can only be used with the dedicated power supply as supplied by Ovizio (see Specifications chapter at the end of this manual). Replacement by other power supply can jeopardize safe operation of the instrument.

### High intensity light source



This instrument includes a high intensity red LED light source. There is no hazard for the operator's eyes when the device housing is closed. Do not stare at the light source or at the light beam during maintenance when the housing is opened.

## Replaceable parts

### Battery



The equipment is supplied with an onboard computer which contains a replaceable battery. The battery is only to be replaced by qualified personnel. Battery type CR2032 (Li-ion 3 V, 225 mA) should be used

## Known issues

Issue	Workaround
USB storage device on front usb port not recognized	Try other usb storage device or one of the usb ports at the back
Unrecoverable OsOne crash due to power loss during critical file writing	Use UPS Restore the software configuration via your Disaster Recovery Procedure
Front seal leaving marks on wipe when cleaning	Accept as is. No degradation of seal.
Black heatsink at the back leaving marks on wipe when cleaning	Accept as is. No degradation of coating. Do not spray cleaning agent on the surface. Use other cleaning agent.

## Specifications

### iLine F Pro

Type	iLine-F Holographic transmission microscope
Light source	Partially coherent monochromatic LED 630nm (Red)
Sensor	CMOS camera – 5MPixels - 8 bits
Microscope objective	Olympus LUCPLFLN20X Microscope Objective 20x
Total Magnification	22.2X
Lateral resolution	1µm
Field of view	318µm x 318µm
Acquisition rate	15fps
Data volume	128Mb per measurement point
Power consumption	45W Typical, 90W Max
Cleaning agents	Cleaning the external surfaces of the device was tested with the following agents : <ul style="list-style-type: none"> <li>• IPA (IsoPropyl Alcohol)</li> <li>• Spor-Klenz® (STERIS Life Sciences)</li> <li>• Vesta Syde SQ Disinfectant (STERIS Life Sciences)</li> </ul>
Operating System	Windows 10 LTBS
Cell monitoring performance	The device, together with the imaging equipment, provides a $\pm 10\%$ cell density variation and Cell counting range of 0.5 to 10 Mcells/mL

### Integration capabilities

Automation via RestFUL web services
OPC ready

### Physical data

Device	400 (15.7" - L) x 223 (9.2" - W) x 423 (16.7" - H) mm – 21kg
Shipment box	515 x 320x 550 mm

### Environmental conditions

General	Indoor and dry use only
Temperature	15 to 25°C
Humidity	Lower than 80%, non condensing
Altitude	Less than 2000m above sea level
Particle level	The system is designed to operate in unclassified areas.

## Power Supply

Brand/Model	CUI Inc. SDI90-24-U
Input Cable	The system is delivered with a power input cable suitable for the country of delivery
Input Voltage	100-240VAC $\pm 10\%$ ~50-60Hz $\pm 5\%$
Input Current	1.2A
Output Voltage	24 V DC
Output Power	90 W

## BioConnect Device

### Features

Feature	Benefits
<b>Closed-loop</b>	In-line monitoring
	No sample consumption
	No sterility risks
<b>Single-use</b>	Ready to use
	No cleaning required
	Optical quality guaranteed
<b>Automated</b>	Continuous cell culture monitoring
	Less time consuming
	Low operational costs

## Specifications

### Material of construction

Fluid-contact parts are made of:

<b>Tubing interface</b>	Polyvinyl chloride
<b>Pump body, Flow cell</b>	Polycarbonate
<b>Connectors</b>	Polypropylene
<b>Membrane, Tubing</b>	Silicone

### Operating parameters

<b>Operating temperature</b>	Min 15°C – Max 25°C
	R.H < 80%
<b>Operating pressure</b>	Min 0 [0] psig [mbarg] – Max 7.25 [500] psig [mbarg]

<b>Monitoring Duration</b>	From 4 to 30 days
<b>Total process volume</b>	From 0.3 to 10.0L total process volume <sup>1</sup>
<b>Typical hold-up volume</b>	From 0.001 to 0.05 L
<b>Liquid hold-up duration</b>	< 5min
<b>Typical flow rate</b>	From 4 to 12 mL/min

#### Shelf-life

6 months at storage temperature from 15 to 30 °C

#### Recipient Interface

To ensure a safe and sterile connection, the device features a PVC tubing (3,1x4,2mm IDxOD) for both inlet and outlet connection. The tubing is suitable for cut welding with most of standard welding equipment.

#### Sterilization

All devices are sterilized by gamma irradiation (25 kGy) and individually packaged

#### Packaging

Double PE bag with Tyvek fast-opening. No tool required

#### Regulatory Compliance

All fluid-contact materials have passed the current USP Biological Test or ISO 10993 certification.

#### Quality Control

Each device is individually assigned a serial number, integrity tested and certified. CoC is provided at shipping. Other documentation available upon request

It complies with cGMP requirements for single-use device manufacturing.

#### Disclaimer

The BioConnect shall not be used in any clinical procedures or for diagnostic purposes unless Ovizio approved  
Specifications subject to change without notice.

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<sup>1</sup> Total volume required for efficient pumping and monitoring