

TrackSense® LyoPro User Manual



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1. Safety Information

Use this equipment only as specified in this manual. Otherwise, the protection provided by the equipment may be impaired.

- “Warning” identifies conditions and actions that may pose hazards to the user
- “Caution” identifies conditions and actions that may damage the equipment being used

1.1. Warnings

Disclaimer: Ellab manufactures equipment intended for use in thermal validation, monitoring and stability studies. Equipment used for applications other than these studies is used at the discretion and sole responsibility of the customer. Ellab cannot accept any responsibility for the use of equipment for any application other than thermal validation, monitoring and stability studies. The customer needs to verify the temperature range of the equipment being used before placing it into an application.

1.2. General

DO NOT use the equipment for any application other than its intended use, e.g. thermal validation, monitoring and stability studies. Any other use of the equipment may cause unknown hazards to the user.

DO NOT use the equipment in environments other than those listed in this user’s guide and follow all safety guidelines. Only trained personnel should use the equipment. Inspect the equipment for damage before each use.

DO NOT use the equipment if it appears damaged or operates abnormally. Before initial use, after transport, or after storage in humid or semi-humid environments, the equipment needs to be dried for a period of at least 2 hours. If the equipment is wet or has been in a wet environment, take necessary measures to remove moisture prior to applying power. The equipment is intended for indoor use only.

1.3. Electrical Hazards

These guidelines must be followed to ensure that the safety mechanisms in the equipment will operate properly. Equipment, when applicable, must be plugged into a 115 VAC ($\pm 10\%$) or 230 VAC ($\pm 10\%$) 50/60 Hz electric outlet as indicated on the label. The power is supplied by an 5V AC/DC adaptor which can be plugged directly into a receptacle. The receptacle must be installed in accordance with local codes and ordinances.

Cautions:

Always operate TrackSense LyoPro Reader Stations at room temperature between 5 °C and 50 °C (41 °F and 122 °F).

DO NOT operate this equipment in an excessively wet, oily, dusty, or dirty environment. The equipment is a precision instrument. Although it has been designed for optimum durability and trouble-free operation, it must be handled with care. The equipment including any probes or loggers are sensitive instruments that can easily be damaged. Always handle these devices with care. Do not allow them to be dropped, struck, stressed or overheated.

TrackSense Clock (Internal)

When using TrackSense LyoPro loggers, ValSuite will start an internal clock in the logger. Beware that the max time deviation at 23 °C will be +/- 5 seconds over 24 hours.

1.4. Directives

1.4.1. EMC

Ellab equipment has been tested to meet the European Electromagnetic Compatibility Directive (**EMC Directive, 2014/30/EU**). The Declaration of Conformity for your instrument lists the specific standards at which the unit was tested.

1.4.2. Low Voltage (Safety)

In order to comply with the European Low Voltage Directive (**LVD 2014/35/EU**), Ellab equipment has been designed to meet the **EN 61010-1** standard.

1.4.3. Waste Electrical and Electronic Equipment



All products supplied after February 1st, 2003 meet the requirements of the Directive 2012/19/EU on the Waste from Electrical and Electronic Equipment (WEEE).

This means that all Ellab products, which must be recycled or handled separately, are marked with the WEEE label in accordance with Directive 2012/19/EU Waste from Electrical and Electronic Equipment.

In addition, Ellab A/S accept scrapped equipment from customers and sort it for waste disposal. Used equipment returned to Ellab A/S for service may also be scrapped in accordance with the Directive. However, it is not legal to ship waste products across country borders for disposal.

Ellab distributors are obliged to register waste in accordance with their national legislation, which may also require them to accept scrapped equipment from end users and dispose of it according to their national laws.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer, pursuant to ISO/IEC 17050. It does not affect the warranty obligations of the supplier.

We reserve the right to exceed the standards as part of our product development program.

1.4.4. Important Notice Regarding Ellab LyoPro Equipment

FCC ID: XUS-LYODL1, FCC ID: XUS-LYORS1 and FCC ID: XUS-LYOAP1.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules.

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.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

ISED CANADA

IC: 8758A-LYODL1, IC: 8758A-LYORS1 and IC: 8758A-LYOAP1.

CAN ICES-3 (B) / NMB-3(B)

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s).

Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage ;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

1.4.4.1. FCC and ISED Applicable to TrackSense LyoPro Access Point

FCC: To comply with FCC RF exposure requirements this device with its antennas must be installed and operated with a min separation distance of 20 cm to any human body.

ISED: To comply with ISED RF exposure requirements this device with its antennas must be installed and operated with a min separation distance of 20 cm to any human body.

This radio transmitter [IC: 8758A-LYOAP1] has been approved by Innovation, Science and Economic Development Canada to operate with the antenna types listed below, with the maximum permissible gain indicated.

Antenna types not included in this list that have a gain greater than the maximum gain indicated for any type listed are strictly prohibited for use with this device. Monopole Antenna / 2144150011 Molex / 5.3 dBi.

1.4.5. ARIB



Ellab LyoPro equipment has been tested to comply with the requirements in the Japanese standard ARIB STD-T66 (Low-Power Data Communication System/Wireless LAN System).

1.5. Ellab Service

Please contact your local Ellab sales representative for the proper service center location. Contact information can be found at www.ellab.com.

When contacting Ellab for support, please have the following information available:

- Model Number
- Serial Number
- Voltage
- Complete description of the problem
- ValSuite Software Version

2. New Order Contents

When a new system is ordered, the equipment is shipped in a custom Ellab suitcase. The suitcase contains the following products:

2.1. TrackSense® LyoPro Orders

- Suitcase
- Reader Station
- Power supply
- Accessories Box
- Screwdriver
- Pen for battery
- O-Ring Sealant
- USB Cable
- Quick Guide
- USB key with Software and other documents
- Access Point for live data **(optional)**



3. TrackSense® LyoPro 10-Slot Reader Station

3.1. Proper Use of Reader Stations

- The Ellab reader station is intended to be used at room temperature. The station should not be exposed to temperatures below 5 °C or above 50 °C
- Do not immerse the reader station in water under any circumstances
- Although the TrackSense LyoPro 10-slot reader station is quite robust, it should be handled with care. Dropping or exposing it to heavy mechanical shock may loosen or damage the electronic connections
- Only use cables (USB) and power supplies provided by Ellab

Operating Temperature	5 to 50 °C
Environmental:	0 – 90% RH, non-condensing
Operating Voltage	External Adapter 100-240V AC, 50-60 Hz or USB
Weight:	1,100 Grams
Dimensions (H x W x D) :	35 x 177 x 148 mm
Material:	Aluminum
Reader/Logger Communication:	Radio Frequency (RF)

3.1.1. LyoPro Reader Station

- Contains 10 logger positions
- Connected to PC via USB or LAN (ethernet)
- Only 1 LyoPro reader station can be used at a time



3.2. Communication Setup – Hardware Settings

All TrackSense LyoPro 10-slot Reader Stations can be connected to PC via USB or LAN (ethernet).

3.2.1. USB connection

- Connect the USB cable to the reader station and PC (USB 3.0 is required)



- Connect the 5V DC power supply to the reader station (option)



- When connecting the 10-slot reader station, the generic driver is automatically detected and installed.

3.2.2. LAN connection

1. Connect the 5V DC **power supply** and **ethernet cable** to the reader station



2. Connect the reader station to the PC using the **USB cable**



3. Read and note the reader station **IP address** located under the station



4. Open the ValSuite user menu, **LyoPro** → **Hardware Settings**

5. Choose "**Ethernet**" and enter the IP address and Alias
6. Select "**Add**" and "**OK**", then remove the USB cable from the reader station



7. Use the "**Test**" function to control the functionality
8. The reader station should now **function remotely**

3.3. LIVE Data Option – Access Point

The TrackSense LyoPro system concept facilitates radio frequency data transmission between data logger and reader station – as well as LIVE data transmissions to a PC, running the ValSuite software package, via the built-in transmitter to the external Access Point.

3.3.1. Specifications

- Temperature Range: +5 to +50 °C
- Anodized aluminum housing
- LED indicators
- Supports up to 100 loggers (requires ValSuite 6.0.16.0 or later)
- Up to 1-12 Access Points per session. Using multiple Access Points requires the use of a separate power supply and a LAN hub
- Connection to PC through either USB or Ethernet (either crossed Ethernet cable or standard Ethernet cable)
- Access Point includes two standard antennas, but remote antennas are available for more difficult transmission environments



Operating Temperature	5 to 50 °C
Environmental:	0 – 90% RH, non-condensing
Operating Voltage	5V DC External Adapter 100-240V AC, 50-60 Hz or USB
Weight:	792 grams
Dimensions (H x W x L) :	34.5 x 160 x 118 mm
Material:	Aluminum

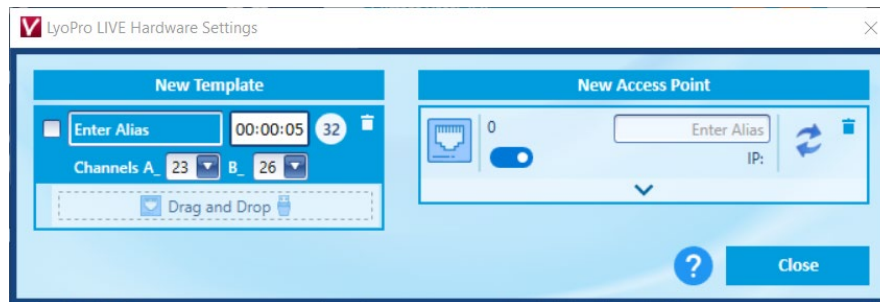
3.3.2. Access Point: Sensitivity to ESD

The Access Point system is sensitive to Electrostatic Discharge (ESD) when the antenna connector is open. The following techniques should be used to help reducing the risk of component damage caused by static electricity.

1. Before handling any antenna / Access Point, immediately drain any electrostatic charge on your body by touching a grounded object. Alternatively, obtain and wear a commercially available wrist strap device, which should be removed for potential shock reasons prior to applying power to the unit
2. The antenna should only be removed/connected when the Access Point is powered off and no other cables are connected to the Access Point
3. **Never** touch the center pin in the open antenna connector
4. Leaving the antenna attached to the Access Point, even during transportation, helps avoiding damage to the connector and is therefore highly recommended

Note: In the event of a failure due to ESD, the Access Point will obtain a permanently reduced sensitivity.

3.3.3. Communication Setup – LIVE Hardware Settings



Alias: insert name of template

Select Transmission Rate:

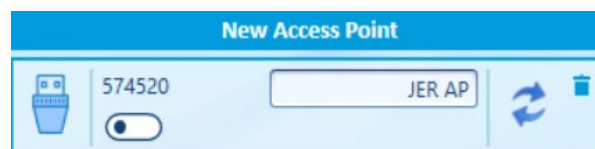
- 5-9 sec for up to 32 loggers
- 10-19 for 32-64 loggers
- 20 or higher for 100 loggers

Important: Please note that due to limitations of the data package size, the ratio between sample rate and transmission rate is automatically set to be less than 1:20.

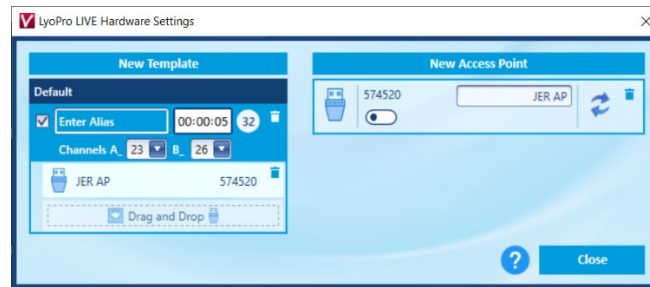
Select channel numbers for antenna A and B – or use suggested default values.

3.3.3.1. USB

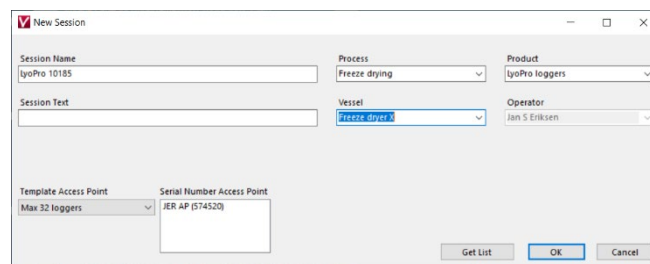
1. Connect the USB cable to the Access Point and PC
2. Verify that the USB is providing power to the Access Point (power light should be green)
3. Once a LIVE data session has been started, verify that the Wireless LED light on the Access Point is blinking green, indicating that communication between the logger and Access Point has been established
4. Insert name and choose connection mode: **USB**



5. Once the access Point has been defined and set up, drag and drop the box into the Template box:



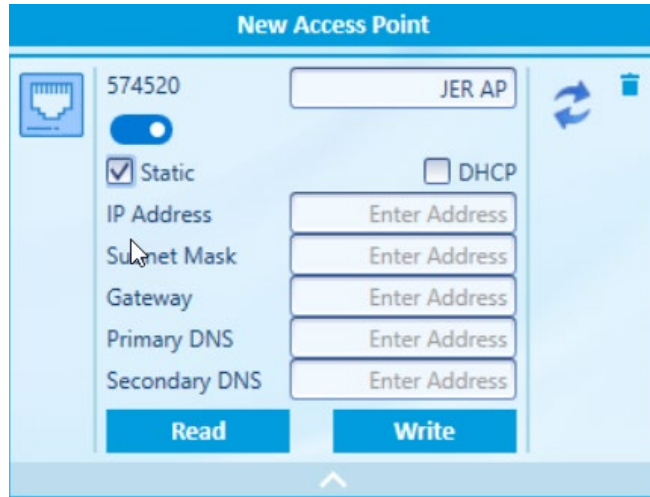
6. The completed template can now be selected and used when starting a session



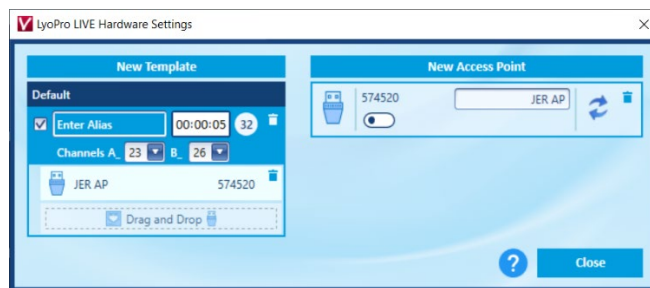
3.3.3.2. LAN

Note: When setting up an IP address on the Access Point, a USB cable must be connected between the Access Point and PC.

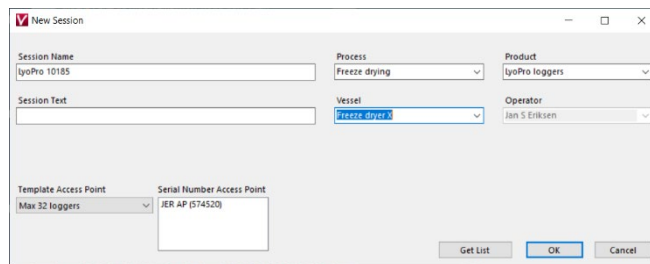
1. Connect the Ethernet cable to the Access Point and LAN network
2. Connect the 5VDC power supply and USB cable to the Access Point. Reference the software manual in order to properly setup the IP address in the ValSuite software
3. Once a LIVE session has started, verify that the Wireless LED light on the Access Point is blinking green, i.e. indicating that communication between the data logger and Access Point has been established
4. Insert name and choose connection mode: **Ethernet** (Static or DHCP)



- Once the access Point has been defined and set up, drag and drop the box into the Template box:



- The completed template can now be selected and used when starting a session



3.4. ValSuite® Software Installation Requirements

ValSuite Pro 6.X System Requirements or higher:

- Multi Core Processor i5/i7 2.0 GHz or higher
- 4GB Ram or higher (Scientific 8GB RAM)
- Resolution 1440 x 900 (with a fix resolution at 96dpi)
- Hard drive with 20GB of free space or more
- Software support 32 Bits on platform: Windows7 SP1, Windows 8.1, Windows10, Windows Server 2008 Service Pack 2, Windows server 2008 R2 and Windows server 2012 R2
- Software support 64 Bits on platform: Windows7 SP1, Windows 8.1, Windows10, Windows Server 2008 Service Pack 2, Windows server 2008 R2, Windows server 2008 SP2, Windows server 2012 R2 and Windows server 2016

The ValSuite software is validated using Windows 10 64 Bits, language version: English operating system. Installing and using this software requires a basic knowledge of software installation and the Windows operating systems.

Note: Windows server 2003, Windows XP, Windows VISTA, Windows 2000, Windows NT 4.00 and Windows ME are not supported.

Note: Do not update the ValSuite software during active sessions. The logger list will be updated and replaced with a new, empty list.

4. Activating ValSuite®

ValSuite Pro is our reputable validation and calibration software ideal for lyophilization. It is fully FDA CFR21 Part 11 compliant and combines all equipment systems including LyoPro into a single platform.

- ValSuite Pro offers features like customized reports with clear pass/fail criteria, test templates, data analysis, monitoring, live data and much more
- ValSuite Pro offers an outstanding Datapoint Process Report Generator (DPRG), which produces fully compliant user reports in accordance with current norms and standards related to validation processes and equipment qualifications
- ValSuite Pro is developed according to GAMP principles and is available in multiple languages for Windows 7, 8 and 10 (32/64-Bit)





For further information please consult the specific ValSuite Software user manual.

Note: The first time you open ValSuite, the software needs to be activated.

4.1. Online Activation - The PC is Connected to the Internet

1. If the PC is connected to the internet, select the **Online activation** option
2. Write the license key (38 digit) from the Ellab e-mail, using the copy and paste function
3. License key example:
B1U10-10R01-GHJ2K-M8N7P-3Q4ST-MG4XM-8GVHT-DU34E-M



Evaluation of a License key format:

Icon	Description
	The License Key is valid and ready to be activated, go to next step.
	The License Key is invalid, try to copy and paste the key again or retype the code.
	The License Key has expired.
	The License Key is a trail and will expire.

4. Select **Activate**

If the activation went well, the License window will close automatically.

The evaluation of the License key can have the following remarks:

Icon	Description
	The License Key is valid and can be activated
	The License Key has already been activated on another PC.

5. The License window will close if the key is valid, and the ValSuite software will be open



4.1.1. Manual Activation – The PC is Not Connected to the Internet

1. Select the Manual activation option if the PC is not connected to the internet
2. Send an e-mail to Ellab with the **computer ID**

Example of computer ID: **F0DEF14E64E41**

3. In the ValSuite activation field, write **the License key** and **receive the Computer key** from Ellab
4. Select **Activate**. If the activation went well, the License window will close automatically.

The evaluation of the License key can have the following marks:

Icon	Description
	The License Key is valid and ready to be activated.
	The License Key has already been activated on another PC.

5. The License window will close automatically if the key is valid and the ValSuite software will open

4.1.2. Releasing the License

Users who wish to release the license so that it may be used on another PC, must follow the procedure below:

1. Select **Help → About ValSuite**
2. Click **License**
3. Click **Clear License**. This will remove the license from this PC. The license will then be released and ready to be used again on another PC

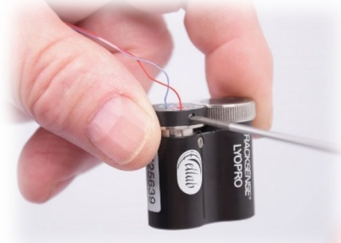
5. How to Start Logging Data with TrackSense LyoPro

Starting TrackSense LyoPro Loggers:

1. Ensure that the battery has enough capacity to cover the expected session length. If the battery is new, activate it separately in the delivered activator for 60 minutes before placing it in the LyoPro data logger with the **+** pole facing downwards



2. If not already mounted, connect the thermocouple sensor to the data logger using the supplied screwdriver. It is important that the **RED** wire goes in the **RED** screw terminal. And that the **BLUE** wire goes in the **BLUE** terminal. Do not tighten too hard in order to avoid possible damage to the thermocouple

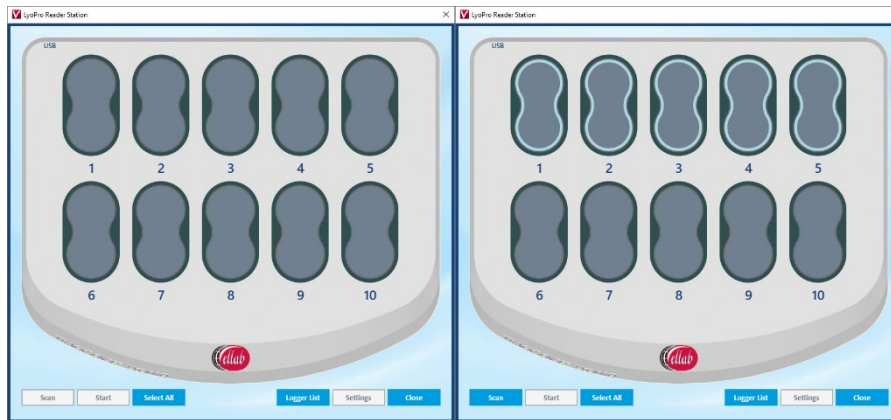


3. Place the data logger(s) in the reader station slot(s)

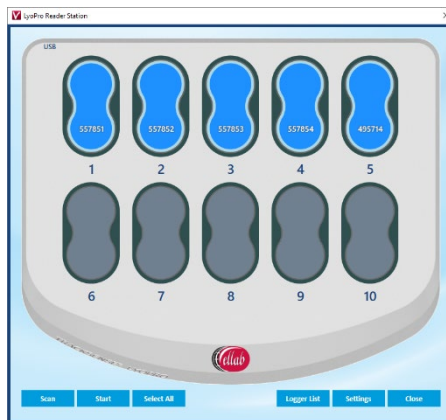


4. Select **LyoPro** → **Hardware Settings** in ValSuite main menu and chose **USB** (default) or **Ethernet connection** and click **OK**

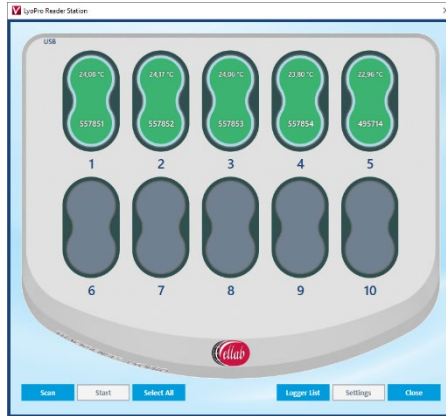
5. Select **LyoPro** → **Start Logger**. A New Session window will then appear. Enter a name for the session (mandatory), session text (optional) and click **OK**. A window will appear displaying a graphic representation of the reader station slots



6. Choose **Select All** and **Scan**. The software will automatically scan for loggers which, when found, turn dark blue and show individual ID numbers. Alternatively mark the data loggers that you want to include in your study



7. If an immediate start (unprogrammed) is required, press **Start**
8. The slots will turn green and begin showing the first live data. The data loggers are now active and can be placed in the process. Press **Close**



9. Alternatively, the data loggers can be programmed: Choose **Settings** at the bottom of the screen. The Logger Settings window will appear. Define **Sample Rate** and optionally Programmed Start/Stop conditions and activate **Primary Control**. Choose **Select All** → **Apply** → **Close**
10. After the settings are setup, select **Start**. When all selected slots turn green the data loggers are programmed and will start logging data. Select **Close**
11. Go to **LyoPro** → **Logger List**. This will showcase all active/programmed data loggers. Review the details to confirm that they were programmed correctly

Reading TrackSense LyoPro Data Loggers and Creating Reports:

12. Place the data loggers into the Reader Station. Go to **LyoPro → Read Logger**, then **Select All** and **Scan**
13. Select **Read**. The software will read all data loggers and display the data in the graph. Select **Close**
14. From the main menu, choose **Session Add** to select the appropriate Reports and Data Analyzes
15. To print a report, click **File → Print**. A Print window will appear with various options. Select the desired modules and click **OK**

Graph Features Review:

Right click the mouse when it is placed on the graph:


- A. Select **Data Viewer** – compare data sets
- B. Select **Interval Data Viewer** – numerically display data
- C. Select **Add Label** – place special information directly in the graph
- D. Select **Copy Graph** – copy graph to the clipboard
- E. Select **Set Axis Min/Max** – scale a graph either automatically or fixed
- F. Select **Properties** – define data series

For more information on the many other ValSuite software features, please consult the separate manual delivered with the system.

6. TrackSense® LyoPro Loggers

6.1. TrackSense® LyoPro

6.1.1. Data Logger Specifications

Ordering codes	Logger type	Temp Range	Operating Pressure	Data Points	Dimensions	Min / Max. Sample rate	Sensor
31201000		Measuring Range: -62 to +62 °C Calibrated Range: -60 to 60 °C	0.001 mBar to 4 Bar abs.	100,000	2x Ø18x32mm	Min. 1 sec. Max. 23:59 (Hours: Min)	Thermocouple mounted by screw terminal

6.1.2. Proper Use

- Never use the data loggers outside their designated temperature range. Damage may occur to the electronics and can cause out-gassing of the battery
- Treat the data loggers as you would any other sensitive electronic equipment. Dropping or exposing them to heavy mechanical shock may loosen or damage the electronic connections
- Check the o-ring and replace it when changing the battery
- Do not remove data loggers from the reader station while they are being read. Doing so may result in loss of data
- Store data loggers in a dry and cool place
- If corrosion is present near the battery contacts, verify that the data logger is not leaking. Lightly clean the area using a cotton swab and alcohol, then change the o-ring
- Any data logger with recurring problems should be returned to Ellab for service
- When data loggers have not been used for an extended period of time, they must be tested every three months by running a short test at room temperature
- When data loggers are not used for a period of two or more weeks, remove the battery from the data logger. If the battery is removed from the logger for more than one week, the activation tool will be needed to re-activate the battery

6.1.3. Data Logger Serial Numbers

All data loggers have a unique serial number. The serial number allows compliance with GMP & GDP regulations. The serial number for the TrackSense LyoPro data logger is located on the side of the black housing.



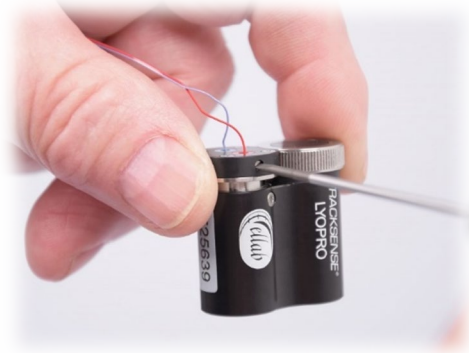
6.1.4. Disassembling / Assembling Data Loggers



Battery:

Disassemble the battery compartment of the data logger by unscrewing the top spanner by hand. Then remove the top lid by turning the spanner around and use it as lift for the lid. Insert the activated* battery according to the indication on the housing (+ pole downwards). Exchange the o-ring and put the lid back before tightening the spanner by hand.

*The battery should be placed in separate activator for 60 minutes before inserted



Thermocouple Sensor:

If not already mounted, connect the thermocouple sensor to the data logger using the included screwdriver. It is important that the **RED** wire goes into the **RED** screw terminal. And that the **BLUE** wire goes into the **BLUE** terminal. Do not tighten the screws too hard in order to avoid possible damage of the thermocouple.

6.1.5. Procedure for Cleaning TrackSense® LyoPro Data Loggers

If any corrosion is present near the battery contacts, verify that no leaking is occurring. Lightly clean the contacts with a cotton swap and alcohol. Change the o-ring if necessary. Let the area dry before placing the battery in the data logger.



Generally, the data logger can be:

- Manually washed/wiped with Water for Injection (WFI)
- Manually wiped with Ethanol
- Decontaminated with vaporized H2O2 – mac. Concentration of 10%
- Autoclaved/sterilized at 121 °C for a max. of 30 mins.

6.1.6. Procedure for Changing the Data Logger O-Ring

The TrackSense LyoPro data logger contains one o-ring, which is located at the battery compartment lid. The o-ring should be replaced with every battery change. Apply a light coat of grease to the o-ring. Be careful and keep the grease away from any battery contacts.

Logger O-Ring:

Ordering code	O-Ring	
66151901	Battery compartment o-ring	
35900053	O-ring grease	

6.1.7. Extended Warranty

Ellab offers an extended warranty on all new TrackSense LyoPro data loggers. The extension is from 2 to 5 years. The warranty needs to be purchased together with the data logger. Please contact your local Ellab sales representative for pricing.

6.1.8. Thermocouple Sensor

6.1.8.1. Proper Use



- Never use the sensor outside the measuring range
- Only use the special screwdriver provided by Ellab to remove sensor from the data logger. Never use any other tools as this can damage the screw terminals
- Any data logger/sensor with recurring problems should be returned to Ellab for service
- To maintain the accuracy of the TrackSense LyoPro data logger, it is recommended that it is re-calibrated by Ellab at least once every 12 months
- Test all new sensors before using them in any application
- Always hold the data logger/sensor by the data logger and not the sensor

7. Battery

7.1. TrackSense® LyoPro Battery

Ellab offers a special battery with a green label, which should exclusively be used for lyophilization applications. This battery is by performance identical to the standard red and blue batteries, but as label is different (shorter) only this battery will work in the LyoPro logger. At the same time, the different color helps identify the correct battery.

Users will have to manually keep track of the number of hours each battery has been used and the date it was inserted into data logger (use Staedtler Pen). In the battery time manager, 100% of the battery power would be equivalent to the default values in ValSuite. For example, the expected lifetime of the LyoPro battery is 27pprox.. 2,400 hours in applications at -60 °C with a 30 second sample rate and 27pprox.. 1,500 hours at -60 °C with a 10 second sample rate.

Ordering code	Type	Temp. Range	Expected lifetime	Battery type	Shelf time	
31200050	TSL-BAT-150 with Activator	-80 to +150 °C*	2,400 hours*	Lithium	10 years	
31200051	TSL-BAT-150 without activator	-80 to +150 °C*	2,400 hours*	Lithium	10 years	

*Measured at -60°C with 30 second sample rate

Note: Do not directly touch the battery poles and ensure that unused batteries are placed at moderate ambient temperatures under +25 °C.

Note: The ValSuite software has a battery time manager feature that provides an estimate of how much battery power is remaining. The feature cannot be utilized if multiple batteries are being used in one data logger.

Note: Even though the batteries have a temperature range of -80 to +150 °C, ensure that the data loggers are not used outside their temperature range.

WARNING: All lithium batteries must **always** be stored separately before and after use.

7.1.1. Proper Use of TrackSense® LyoPro Batteries

- The TrackSense LyoPro data loggers have a standby battery usage that will empty the battery in 28 approx. 12 months, even if the data logger is not used. It is therefore recommended to remove the battery from the data logger when it is not used for several weeks
- If the battery is removed from the data logger for a longer period of time (more than one week), it is necessary to reactivate the battery again
- Only use Ellab batteries. The use of other batteries will void any warranty on the equipment. Other batteries have not been tested in extreme temperatures / environments and they can potentially cause damage to the data logger
- When the voltage of the battery gets to a critically low level, the data logger will perform a controlled shutdown in order to preserve the data stored in the memory
- Ellab recommends that only batteries with more than 3.2V (if the voltage is tested at ambient) are used. The voltage level of the battery can be checked by inserting the battery into the activator unit and then using a voltmeter to measure the voltage over the two poles of the activator
- Stored batteries should not be exposed to temperatures over +25 °C and they should be kept in a dry place prior to use

Note: Always inspect and if needed change o-ring when changing batteries.

7.1.1.1. Proper Storage and Handling

WARNING: It is of utmost importance that batteries are **stored separately** in bags or trays to avoid short circuiting. Leaving batteries in bundles where they come in contact with each other is **highly risky** as it may cause a short circuit and thereby a small-scale explosion or fire hazard.



DO



DO NOT

Note: Please do note, this also includes used batteries. Be sure to dispose of used batteries in a safe and clean manner.

7.1.2. Activating and Testing TrackSense® LyoPro Battery

- TrackSense LyoPro data loggers do not use enough power to activate the battery by itself. Therefore, the activator unit must be used
- New batteries must be activated initially for exactly 1 hour. See the image below. The same procedure applies if the battery has not been installed/used in a data logger for more than 1 week. A new battery has a voltage of approximately 3.6V. Over time, the voltage will drop a little, and towards the end of its lifespan it will increase to around 3.7V before it rapidly drops to zero
- When testing the battery with a voltmeter, it is important to do this while the battery is inserted in the activator/starter. A new battery will show 3.2-3.3V the first time it is inserted into the activator, and during the first 30 minutes in the voltmeter, the voltage will begin to increase to approximately 3.3-3.4V. This means that the battery is ok and ready to be used after 1 hour in the activator
- A weak battery will typically show less than 3.1V when inserted into the activator, at the end of its lifespan, it can also show 3.5-3.7V. In both cases, the initial voltage will begin to drop after a few minutes in the activator.

Note: Leaving the battery in the activator for more than 1 hour will cause the battery to drain at a rate of 2.0 mAh an hour.

8. Calibration

8.1. Ellab Factory Calibration

It is recommended that TrackSense LyoPro data loggers are returned to Ellab at least once a year for factory calibration. Ellab performs the factory calibration, which adjusts and notes a new calibration date in the data logger. A certificate is generated, and the as found / as left data are included by default.

All calibrations performed by Ellab are NIST and NPL traceable. If received, the ETS firmware will also be updated. The software will (by default) automatically warn users 12 months after the last calibration date, which should be considered a recommendation for temperature sensors built on Ellab's experience.

The factory calibration date can only be changed by Ellab, this means that the factory calibration cannot be affected by any of the possible user calibration procedures performed in the ValSuite software. Please note that the calibration certificates express an instant view of the performance, this is why the Ellab factory calibration certificates does not include a recalibration due date.

Note: When shipping equipment back to Ellab for calibration/inspection, please ensure that the equipment is packaged well. Ellab is not responsible for any equipment damaged in shipments sent from customers.

8.1.1. Calibration Types – TrackSense® LyoPro

8.1.1.1. Standard Calibration



- Calibration Points: -60, -30, 0, 30 and 60 °C

8.2. In-House Calibration Solutions

8.2.1. Ellab Temperature Standard (ETS)

The ETS can be operated as an integrated part of the ValSuite software. It is a temperature standard that can be started, stopped and used in report analysis and calibrations.

8.2.1.1. ETS Versions and Measuring Ranges

Ordering code	Type	Temp. Range	Accuracy	
20000190	ETS10	-80 to +250 °C	±0.025 °C ±0.015 °C*	
20000191	ETS20	-50 to +150 °C	±0.020	
20000192	ETS25	-196 to +420 °C	±0.025	
20000193	ETS-A182	-45 to + 150 °C	± 0.025 °C	
20000194	ETS-A213	-95 to +150 °C	± 0.025 °C	

*Accuracy between -50 and +150 °C

8.2.1.2. Proper Use

- Although the ETS is quite robust, it should be handled with care. Dropping or causing mechanical shock will loosen or damage the electronic connections. The platinum resistor is extremely sensitive, drift can therefore occur if not handled properly
- Only use cables (USB) provided by Ellab
- The ETS system must be properly grounded
- Never use the ETS outside the measuring range
- Any ETS with recurring problems should be returned to Ellab for service
- In order to maintain the accuracy of the ETS, it is recommended that they are recalibrated by Ellab at least once every 12 months

WARNING: When returning an ETS to Ellab for service or recalibration, please use the suitcase delivered with the product in order to avoid damage. If the product does not arrive at Ellab in a case, all warranty is lost and Ellab reserves the right to include a suitcase at the user's expense upon returning the product.

8.2.1.3. Setting up the ETS

The ETS can be setup in 3 different ways. It can be used as a standalone unit with a display, in connection with the ETS Suite software or it can be setup in connection with the ValSuite software.

Setup – Stand Alone Unit w/ Display:

1. Connect the ETS using a USB cable to the ETS display
2. Connect the display to the power supply

Setup – ETS using ETS Suite:

Note: USB drivers must be installed first for firmware versions older than 2.0.

1. Connect the ETS to the PC via USB cable
2. Verify that the ETS Suite is detecting the connected ETS

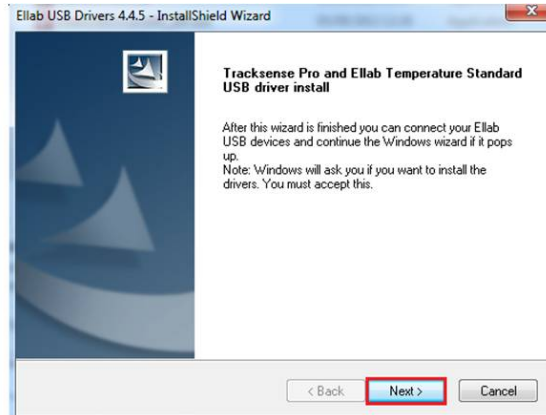
Setup – ETS using ValSuite:

1. If using the USB connection, install the Ellab USB driver first
2. Disconnect all the equipment
3. The driver can be found on the ValSuite USB Key

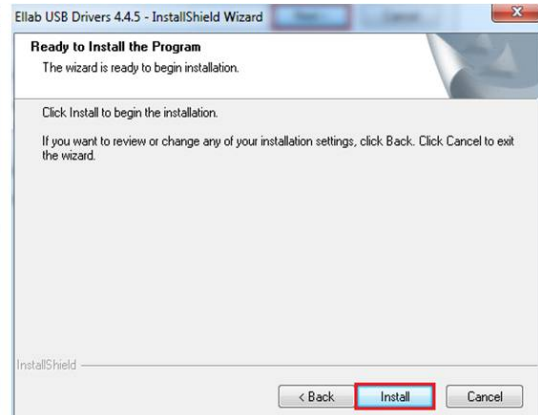
4. Run the file **Ellab USBDrivers_XXX.exe**

8.2.2. Installation for Windows 7, 8 and Windows 10

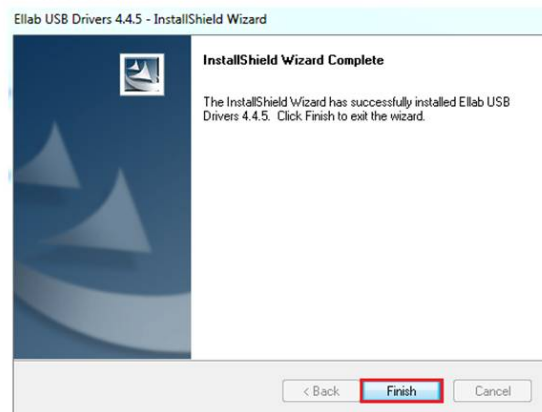
Note: This section is only relevant for users with ETS firmware versions older than 2.0.



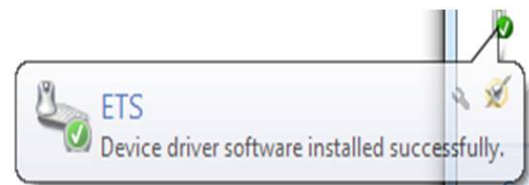
1. Click **Next**



2. Click **Install**



3. Driver is installed, Select **Finish**. Restart computer.



4. The first time the equipment is connected through the USB port, the message above will appear. The equipment is now ready to be used.

8.2.3. Ellab Dry Blocks

Ordering code	Model	Power	Measuring Range
20000155	PTC 155A	115 to 230 VAC / 50-60Hz	-25 to +155 °C
20000425	PTC 425A	115 to 230 VAC / 50-60Hz	+33 to +425 °C
20000156	RTC 156A	115 to 230VAC / 50-60HZ	-30 to 155 °C



20000159	RTC 159A	115 to 230 VAC / 50-60 HZ	-100 to 155 °C	
20000158	RTC 158A	115 to 230 VAC/50-60 Hz	-22 to 155 °C-	

8.2.3.1. Proper Use and Setup

1. Reference the user manual before unpacking and setup
2. Before the dry blocks can be used in conjunction with the ValSuite software, JofraCal needs to be installed
3. Connect the USB cable from the USB port on the computer, to the USB port on the dry block
4. Connect the power cable to an appropriate outlet and turn the bath on

Note: Ensure that the power supply is grounded and connected to the bath USB port and PC before connecting the power.

5. Using the software manual, verify that ValSuite is detecting the dry block

8.3. ValSuite® Calibration Options

ValSuite software includes three different methods for calibrating data loggers: Manual Calibration, Semi-Automatic (only for temperature) and Full Automatic (only for temperature).

8.3.1. Manual Calibration

First enter the reference value (temperature), then select the time of the reference reading, and the software will calculate the offsets.

Note: Please reference the software manual for setting up and running a semiautomatic or full automatic calibration in the ValSuite software.

9. Accessories

Ellab manufactures a wide range of accessories allowing the LyoPro data logger to be adapted to every standard vial from 2R to 100R. Meaning nominal volumes between 4 and 123 ml, as well as a height between 35 and 100 mm according to norm ISO 8362-1:2019.

The unique design allows for the handling of ANY size of vial, simply by introducing a combination of the appropriate LoggerNest, StopperClip, LyoStopper and/or LoggerClip.

9.1. StopperClip

The StopperClip provides an effortless connection between the LyoPro data logger and the vial – ensuring that they are safely steered together. The clip comes with an integrated stopper system, while simultaneously fixing the position of the sensor at the predefined measuring point. The StopperClip is easy to handle within aseptic procedures, making it the ideal choice when using fully automatic robotic systems.

The PEEK StopperClip is also designed to offer room for an additional buffer vial that can be placed between the data logger and vial – and can be manufactured according to any vial dimension.

9.2. LyoStopper


The LyoStopper is made of Silicone rubber and a PEEK tube that covers the two internal neck diameters, namely $\varnothing 7$ mm for 2R and 4R vials, $\varnothing 12.6$ mm for 6R-100R vials.

As all vials have different heights, the PEEK tube part of the LyoStopper is made in lengths that fit exactly according to the actual size of vial to steer the thermocouple into right position repeatedly. That being in the geometric center and in the most critical (warm) ice phase spot, which is usually defined as either 1 mm above vial bottom or directly touching the glass surface.



9.2.1. Standard Versions & Reference Numbers


Ordering code	Description	
---------------	-------------	--

31203023	LyoStopper for 2R vials	
31203043	LyoStopper for 4R vials	
31203063	LyoStopper for 6R vials	
31203083	LyoStopper for 8R vials	
31203103	LyoStopper for 10R vials	
31203153	LyoStopper for 15R vials	
31203203	LyoStopper for 20R vials	
31203253	LyoStopper for 25R vials	
31203303	LyoStopper for 30R vials	
31203503	LyoStopper for 50R vials	
31203003	LyoStopper for 100R vials	


9.3. LoggerNest

Realizing that vials have different heights and diameter, it is necessary to mount the data logger onto a LoggerNest. These nests are shaped as the vial in question and will follow the data logger throughout the conveyer band operation – while at the same time bringing the data logger to the exact same height as the vial. This is mainly important when used with automatic loading systems. The LoggerNest has a built-in holder to keep the LyoPro data logger in place, even during rough handling/movements.

9.3.1. Standard Versions & Reference Numbers

Ordering code	Description	
31203021	LoggerNest for 2R vials	
31203041	LoggerNest for 4R vials	
31203061	LoggerNest for 6R vials	
31203081	LoggerNest for 8R vials	
31203101	LoggerNest for 10R vials	
31203151	LoggerNest for 15R vials	
31203201	Logger Nest for 20R vials	
31203251	LoggerNest for 25R vials	
31203301	LoggerNest for 30R vials	
31203501	LoggerNest for 50R vials	
31203001	LoggerNest for 100R vials	

9.3.2. Standard Versions & Reference Numbers – StopperClips

Ordering code	Description	
31208023	StopperClip 2R	
31208043	StopperClip 4R	
31208063	StopperClip 6R	
31208083	StopperClip 8R	
31208103	StopperClip 10R	
31208153	StopperClip 15R	
31208203	StopperClip 20R	
31208253	StopperClip 25R	
31208303	StopperClip 30R	
31208503	StopperClip 50R	
31208003	StopperClip 100R	


9.4. LoggerClip

The LoggerClip is the connection between the LyoPro and the vial that steers them together. It works like a dual clip placed between the vial neck and the LyoPro logger.

This LoggerClip is made of PEEK and designed to keep the vial and data logger together, while keeping it flexible enough to allow the twists and turns of typical conveyer belts. And they can be manufactured according to actual vial dimensions.



9.4.1. Standard Versions & Reference Numbers – LoggerClips

Ordering code	Description	
31203022 31203042 31203062 31203082 31203102 31203152 31203202 31203252 31203302 31203502 31203002	ConnectionClip for 2R vials ConnectionClip for 4R vials ConnectionClip for 6R vials ConnectionClip for 8R vials ConnectionClip for 10R vials ConnectionClip for 15R vials ConnectionClip for 20R vials Connection Clip for 25R vials ConnectionClip for 30R vials Connection Clip for 50R vials Connection Clip for 100R vials	


9.5. BufferClip

As placing the LyoPro data logger between vials may have an impact on the temperature measured in the sample vial, a special BufferClip is available.

This clip consists of PEEK and initial tests have shown that, especially with low volume vials, there could be small deviations on the sample vial. Making the use of a buffer vial placed in between the LyoPro data logger and sample vial worth considering.



9.5.1. Standard Versions & Reference Numbers – BufferClips

Ordering code	Description	
31203024	BufferClip for 2R vials	
31203044	BufferClip for 4R vials	
31203064	BufferClip for 6R vials	
31203084	BufferClip for 8R vials	
31203104	BufferClip for 10R vials	
31203154	BufferClip for 15R vials	
31203204	BufferClip for 20R vials	
31203254	BufferClip for 25R vials	
31203304	BufferClip for 30R vials	
31203504	BufferClip for 50R vials	
31203004	BufferClip for 100R vials	

10. Examples on how to Configure LyoPro Using LyoStopper or Various LoggerClips

This is required for a complete 2R system setup using buffer vial:



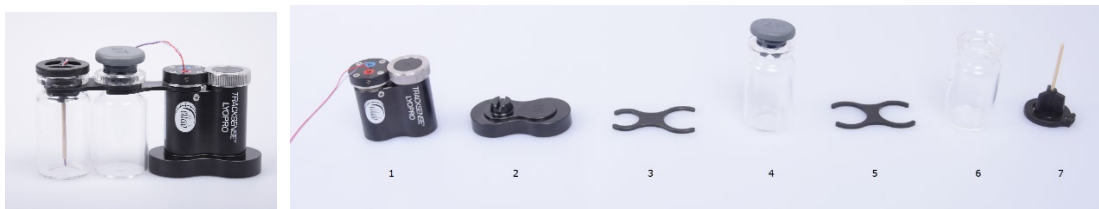
1. **31201000:** LyoPro data logger with thermocouple sensor
2. **31203021:** 2R LoggerNest
3. **31203022:** 2R LoggerClip
4. Buffer Vial 2R w. rubber stopper
5. **31203024:** 2R BufferClip
6. Vial 2R w/o rubber stopper
7. **31203023:** 2R LyoStopper

This is required for a complete 4R system setup using buffer vial:



1. **31201000** – LyoPro data logger with thermocouple sensor
2. **31203041** – 4R LoggerNest
3. **31203042** – 4R Logger Clip
4. Buffer Vial 4R w. rubber stopper
5. **31203044** – 4R Buffer Clip
6. Vial 4R w/o rubber stopper
7. **31203023** – 4R LyoStopper

This is required for a complete 6R system setup using buffer vial:



1. **31201000** – LyoPro data logger with thermocouple sensor
2. **31203061** – 6R LoggerNest
3. **31203062** – 6R LoggerClip
4. Buffer Vial 6R w. rubber stopper
5. **31203064** – 6R BufferClip
6. Vial 6R w/o rubber stopper
7. **31203063** – 6R LyoStopper

This is required for a complete 100R system setup using buffer vial:



1. **31201000** – LyoPro data logger with thermocouple sensor
2. **31203001** – 100R LoggerNest
3. **31203062** – 100R LoggerClip
4. Buffer Vial 100R w. rubber stopper
5. **31203004** – 100R BufferClip
6. Vial 100R w/o rubber stopper
7. **31203003** – 100R LyoStopper

11. Firmware Update

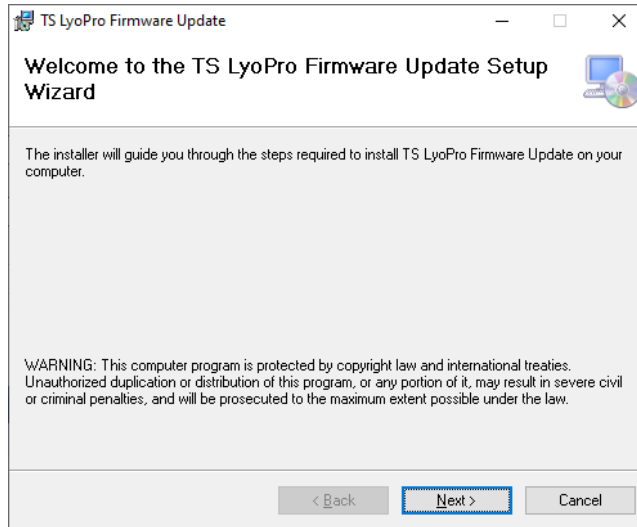
11.1. Reader Station and LyoPro Loggers

Purpose:

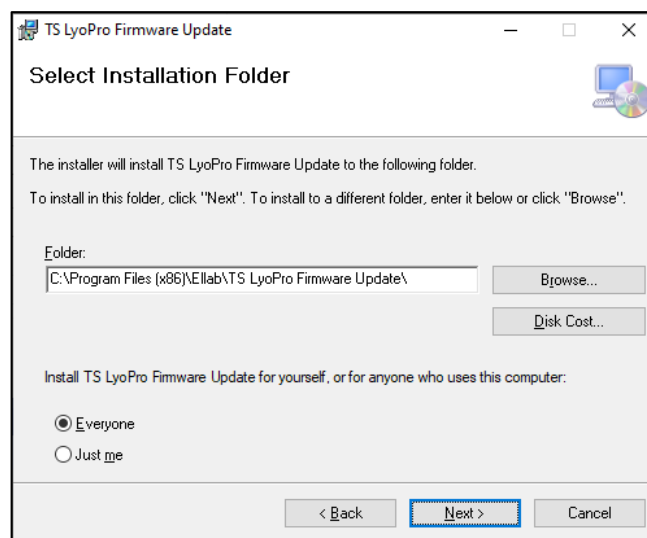
Firmware updater for reader station and logger. Install the TS LyoPro firmware updater located on the provided USB key.

Procedure for installing the firmware upgrading tools for LyoPro Reader Station and Loggers:

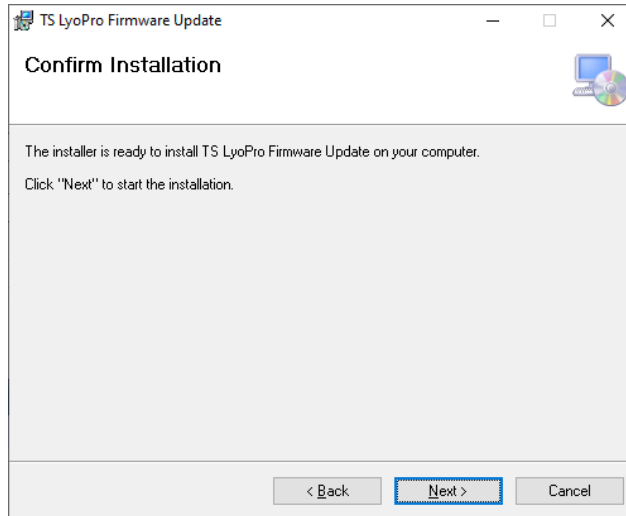
1. Double click the **TSLyoProFirmwareUpdateSetup_XXXXYYZZ.msi** program.



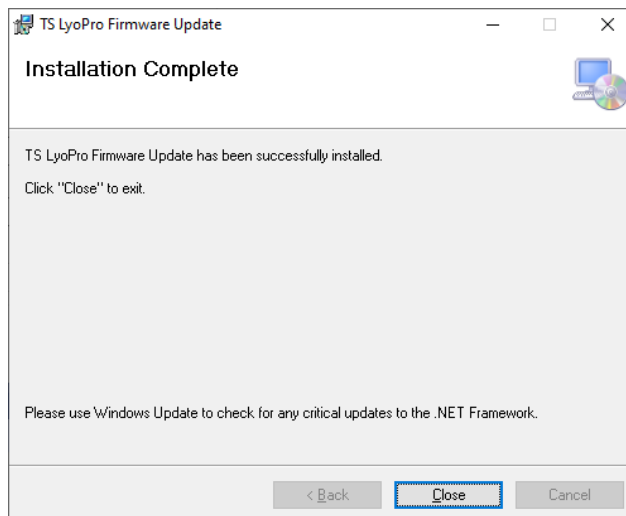
2. Select Next.



3. Select a folder in the Change Directory if necessary and click select Next.



4. Select Next

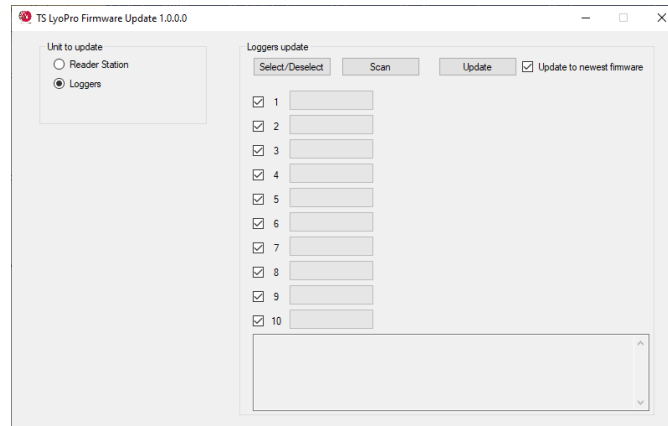


5. Select Close to finish installation.

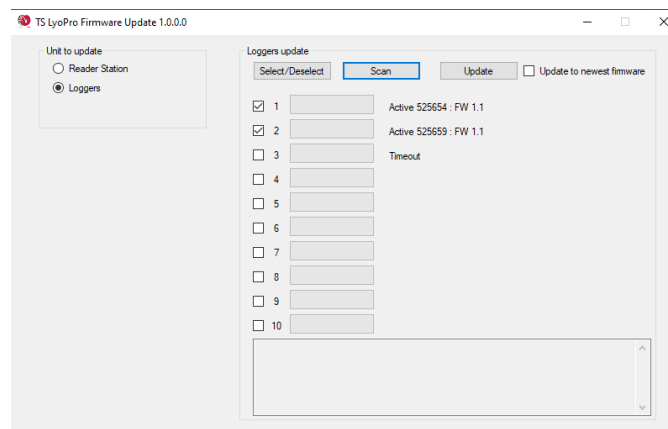
11.1.1. Procedure for Updating the LyoPro Logger and Reader Station Firmware

WARNING: Before updating, users must check the current battery power, since updating loggers will use a lot of battery power. If the battery power is depleted in this process, the logger will need to be shipped to Denmark in order to be re-flashed, as it cannot be restarted manually.

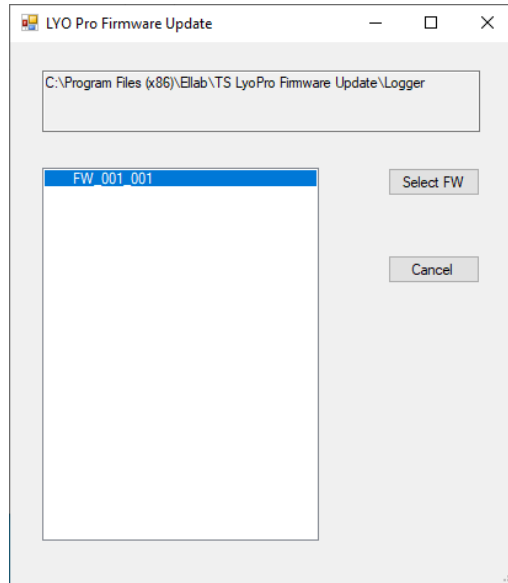
1. Open the firmware updater, which is placed under Programme (x86) by default, and select **Ellab → TS LyoPro Firmware Update**



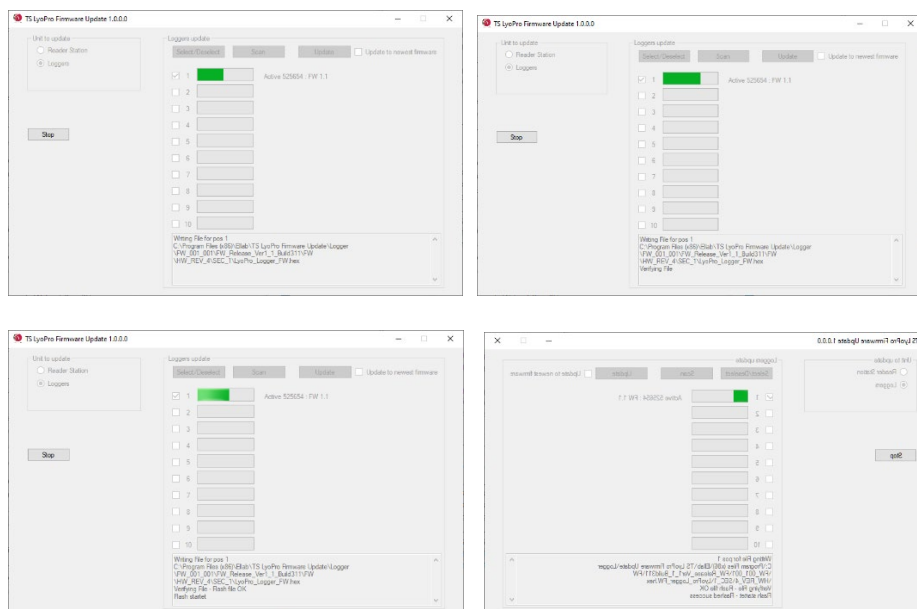
2. Select the **Loggers** button and push **Scan**.



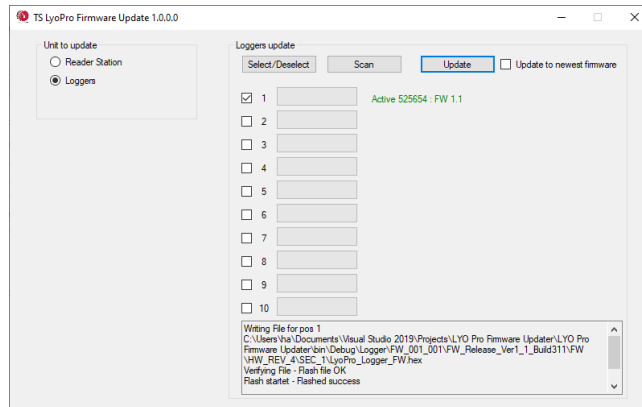
3. Push **Select/Deselect** to toggle all checkmarks – only positions check marked will be considered.
4. Select **Update**



5. Latest FW version will be shown (if **Update to latest firmware** is check marked) or a complete list of available versions.
6. Highlight the requested FW version and push **Select Firmware**
7. The firmware updater program will proceed through 4 stages (write file, verify file, flash and reboot) which will be shown as in window below.

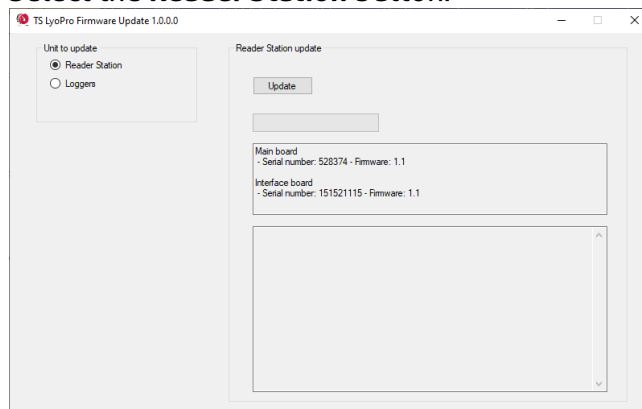


8. Once done, the logger will appear with the new firmware as shown below.

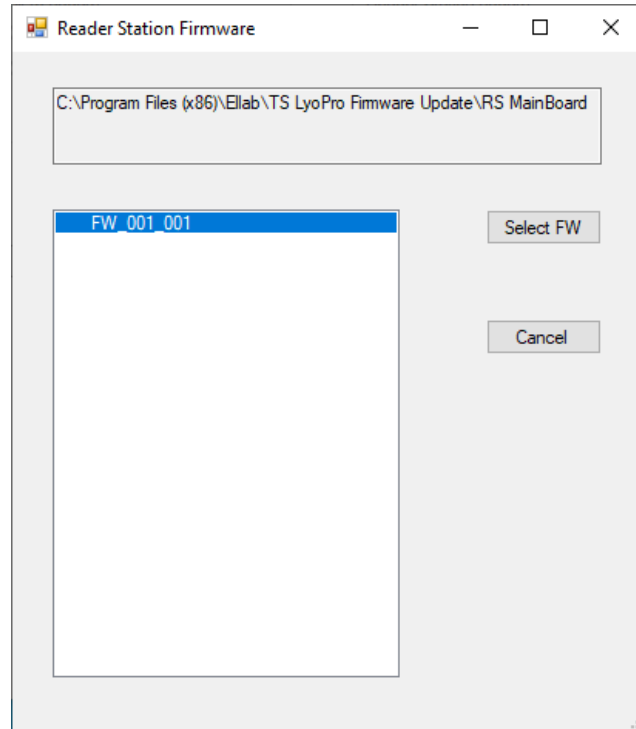


11.1.2. Procedure for Updating the LyoPro Reader Station firmware

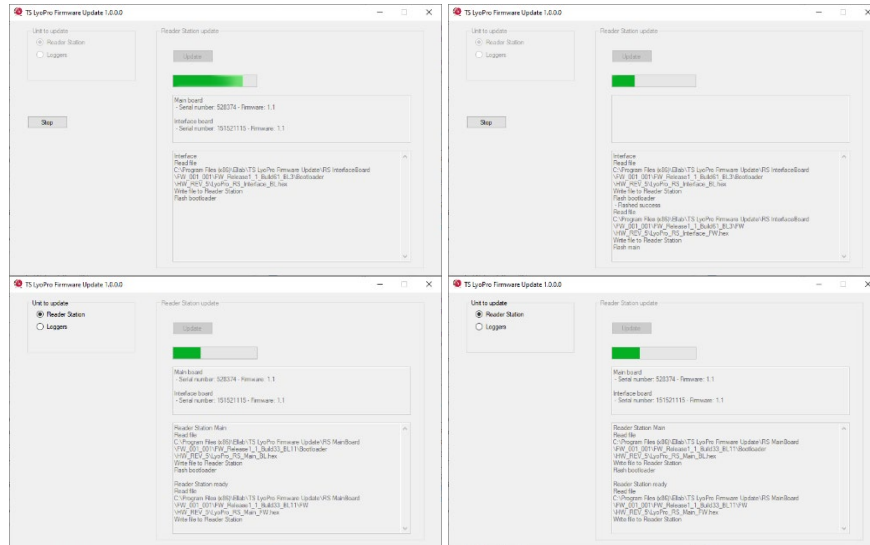
1. Open the firmware updater, which is placed under Programme (x86) by default and select **Ellab** → **TS LyoPro Firmware Update**
2. Select the **Reader Station** button.



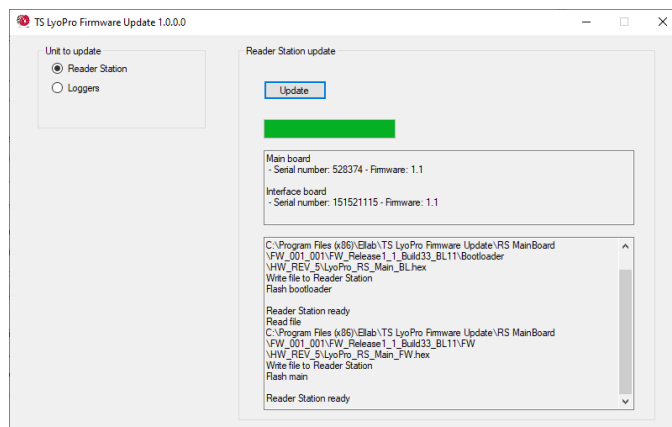
3. Push **Update**.



4. A list will show available firmware versions to choose from.
5. Highlight and push **Select FW**
6. The firmware update program will go through multiple cycles updating the interface and main board inside the Reader Station (writing, verifying and flash bootloader and firmware). Progress will be shown as in window below.



Once done, the reader station will appear with the new firmware as shown below.



12. Ellab Service Contract

Ellab offers annual service agreements. Contact your local Ellab sales representative for pricing and details.

12.1. TrackSense® LyoPro Equipment Warranty

Ellab offers an industry leading 2-year warranty on the LyoPro logger. The thermocouple sensor is not covered, neither is physical damage.

12.2. Extended Warranty

Ellab also offers an extended warranty on all new TrackSense LyoPro data loggers. The extension is from 2 to 5 years. The extended warranty needs to be purchased together with the data loggers. Contact your local Ellab sales representative for pricing.

13. Technical Specifications

LyoPro Data Logger	Specification
Temperature Measuring Range:	-62 to +62 °C
Calibrated Temperature Range:	-60 to +60 °C
Sensor Element Type:	Thermocouple type T
Temperature Accuracy:	+/- 0.3 °C
Sensor Dimensions:	0.55 x 0.95 x 300 mm
Ambient Temperature Range:	-65 to + 140 °C
Ambient Pressure Range:	0.001 mBar to 4 Bar ABS
Housing Material:	PEEK
Diameter:	18 mm (each compartment)
Height:	32 mm
Weight:	27 Grams
Memory Capacity:	100.000 Samples
Minimum Sample Rate:	1 Second
Maximum Sample Rate:	24 Hours
Time Accuracy:	+/- 5 Seconds Per 24 Hours
Battery Type:	TSL-150
Expected Battery Lifetime at a -60 °C/30 sec. sample rate:	2,400 hours
Reader Station	Specification
Ambient Temperature Range:	5-50 °C
Environmental:	0-90% RH, non-condensing
Operating Voltage:	External adapter 100-240V AC, 50-60 Hz or USB
Power Supply:	Power Supply 5V DC or USB
Weight:	1,100 Grams
Dimensions (H x W x D) :	35 x 177 x 148 mm
Interface Connection:	USB or Ethernet (LAN)
Cabinet Material:	Anodized Aluminum
Communication:	RF (Radio Frequency) 2.4 GHz
Logger Capacity:	1-10 pcs.

14. FAQ

For additional questions and answers (FAQ), visit Ellab's FAQ page at: www.ellab.com/contact/faq.

What could be the cause of a spike in a temperature channel in ValSuite while all other channels remain constant?

A battery failure and a disconnected sensor have similar results in ValSuite. The temperature will spike just before the data logger shuts down. One way to differentiate between the two is to check the temperature just before the spike. It is a good indication that the battery is dead, if the temperature drops just before the spike. If the temperature immediately spikes, a disconnected sensor may be the issue. This pertains to all loggers and sensors. Before sending a sensor / logger in for service, verify the results in ValSuite first and, if necessary, run a voltage test on the battery.

What temperatures should the data loggers be at before being returned to the reader station?

If the loggers are too hot or too cold to be held by hand, they are not to be placed in the reader station.

When I read my logger, it gave me no data. What can cause this?

Option 1 – Broken Sensor:

If the reader station slot turned green and the data appears in graph, the logger read ok. Check the data and see if there is 1 sample around -62°C or +62°C. If this is the case the sensor must be exchanged to a new.

Option 2 – Dead battery:

It is possible for a battery to have enough power to be recognized, but not enough power measure and store samples. Test the battery in the activator and replace it if necessary.

Option 3 – The data logger was refreshed:

If the data logger was started and had turned green, but was refreshed while still in the station, it will stop before being placed in the process. Therefore, any data logger that turns green should not be refreshed.

I replaced the battery in my LyoPro data logger, but I still get a low/critically low battery warning when I try to start it?

The error messages are collected on the data loggers last read. If the battery was replaced, start the data logger for a few minutes and then read it. If the error goes away the unit is ready to be used.

Can I use my computer for other jobs while running a TrackSense LyoPro session?

Yes , you can completely close your computer down if necessary. Upon reopening the ValSuite software, the software will automatically allocate the data loggers to the session that they were started in.

15. Changelog

Edition	Section	Change	Date	Author
1.0	New	New	2020-10-27	JER/TWF
1.1	14.3	Updated with text from Ellab's WEEE Declaration of Conformity	2020-12-21	TWF
2.0	6.1.6 9 9.3 & 9.3.1 9.5.1 10	Text updated to further encourage the changing of o-ring with every battery change Updated to relevant standard and added mention of StopperClips New section on StopperClips Updated BufferClip names Updated name of section to include StopperClip	2021-01-21	TWF
3.0	2.1 3.3 + 3.3.1 + 3.3.2 + 3.3.3 + 3.3.3.1 + 3.3.3.2 3.4 7.1 8.2.1.1 9.3.2	Added Access Point option New sections on live data and access point Former section 3.3 Updated the estimated lifetime in battery example Updated ETS models and added new ETS devices Corrected ordering code 31208043	2021-07-01	TWF
3.1	1.4.4 13	Added mention of FCC ID: XUS-LYOAP1 and IC: 8758A-LYOAP1 Expanded technical specifications for reader station	2021-08-19	TWF
3.2	3.2 3.3.3 3.3.3.1 + 3.3.3.2	Updated section title Added New Template option and description Updated section title Added additional steps to the guide	2021-08-31	TWF
3.3	1.4.4.1	New section	2021-11-30	TWF