ElioDX^{TM} Reader R22.1

Instrument and Software Manual

Cat. No. <mark>xxx</mark>

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1. General Information

Warranty Information

ELIONOVA AG warrants to the customer that each Instrument is completely tested and that it meets all performance specifications. This warranty covers all parts and labor, and it is guaranteed for period of 12 months from the date of shipment.

The operation of the device must be performed in accordance with the instructions provided in this manual. The performance guarantee of the device shall be void in all cases where the device is improperly maintained, repaired, or modified by unauthorized service personnel, or if the device is handled in a manner inconsistent with its intended use. The warranty does not include any responsibility for direct or indirect personal and material damages, caused by improper use or maintenance of the instrument.

If the instrument must be returned to the factory for repair under warranty, the instrument must be packed for return in original packaging. Service under this warranty shall be requested by contacting the ELIONOVA office.

IMPORTANT: Do not open the instrument housing.

Warnings

Operation of the instrument in an improper working environment can lead to measurement errors and may damage the device or cause a reduction in service life.

To avoid measurement errors, it is essential to ensure that the instrument is connected properly and that the experiments are carried out correctly.

Incorrect cleaning of the instrument can reduce its service life and can cause damage to the instrument.

To avoid the risk of electric shock, do not expose the instrument or the power adapter to rain or excessive moisture.

Only insert a cuvette when prompted to do so and when the cuvette holder has completed its movement to the frond of the device.

Gently insert the cuvette into the device until it reaches the stop. For effective measurement, it is important that the cuvette stays in contact with the stop when the measurement starts.

Regulatory Notice

Electro Magnetic Compatibility

This instrument is designed to meet the Class-A emissions and immunity levels of the EN61326 product family standard for the CE mark. This rating requires that it is only to be used in a laboratory environment.

Note

This instrument 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 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/her own expense.

Safety

This instrument is designed to meet EN61010-1 requirements for the CE mark, which are internationally accepted safety standards for electrical equipment for measurement, control, and laboratory use. EN61010-1 applies to equipment which is used under the following conditions:

> Indoor use
> Altitude up to 2`000 m

Only use the supplied power adapter
MAINS supply voltage 80 – 264V$_{AC}$

The reader is categorized as a Class 1 laser product based on the international standard IEC 60825-1, which indicates that it is safe to use under expected operating conditions, provided that the manufacturer's instructions are followed.

If the instrument is used in a manner not specified in this manual, the protection provided by the instrument may be impaired. This instrument should not be modified or altered in any way. Alteration of this instrument will result in the following:

Void the manufacturer's warranty.
Void regulatory compliance.
Create a potential safety hazard.

Disposal Instructions

In case of removal or disposal of the instrument, following instructions need to be followed:

Do not dispose in municipal waste; follow local regulations for instrument disposal.

Plastic and metal parts, Electronic PCBs and components can be recycled, so return back the instrument to the manufacturer.

Technical Service & Maintenance

ELIONOVA AG is always accessible to the customers for any kind of information about installation, use, maintenance and others. When asking for service, please refer to this manual and report the data on the identification label (serial number).

Only technicians qualified by ELIONOVA AG are entitled to repair instruments. The user should carry out ordinary maintenance. how? refer to calibration? in which intervals to be repeated?

2. Introduction

Measurement Principle

EVA technology by ELIONOVA comprises two elements: (1) an 8-well cuvette produced by injection molding of polystyrene; and (2) the ElioDX™ reader equipped with a laser to detect evanescence excitation of fluorophores bound to the ElioDX™ cuvette surface. Each well of the ElioDX™ cuvette can be biofunctionalized for the detection of a specific analyte (Figure 1). EVA technology works by generating an evanescent field of exciting light at the bottom of the well. The exciting laser light beam (635nm) is totally reflected at the liquid - solid interface. A 200 nm bottom layer of the adjacent liquid is selectively illuminated: only fluorophores localized in this evanescent field absorb the laser beam photons and subsequently emit light of longer wavelength. The liquid above the 200nm range is not illuminated. An analyte captured at the bottom of the well is detected by an antibody labelled with a fluorophore, which now can absorb light and then emit light of a longer wavelength. The emitted light leaving the device through the bottom is recorded in real time. Fluorophores not being bound to the bottom within the evanescent field (as the specific analyte of interest is not present) do not create a signal (Figure 2).
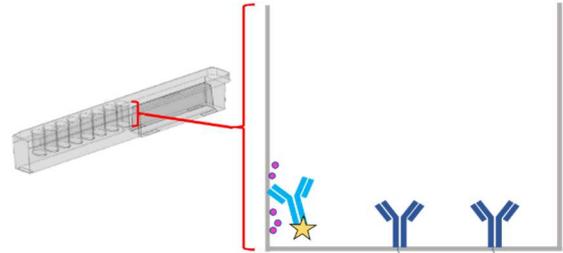

Figure 1. Ready-to-use ElioDX™ EVA Cuvette, biofunctionalized by coating with a capture antibody ⅄ and containing dried detection reagents including a fluorophore-bound detection antibody.
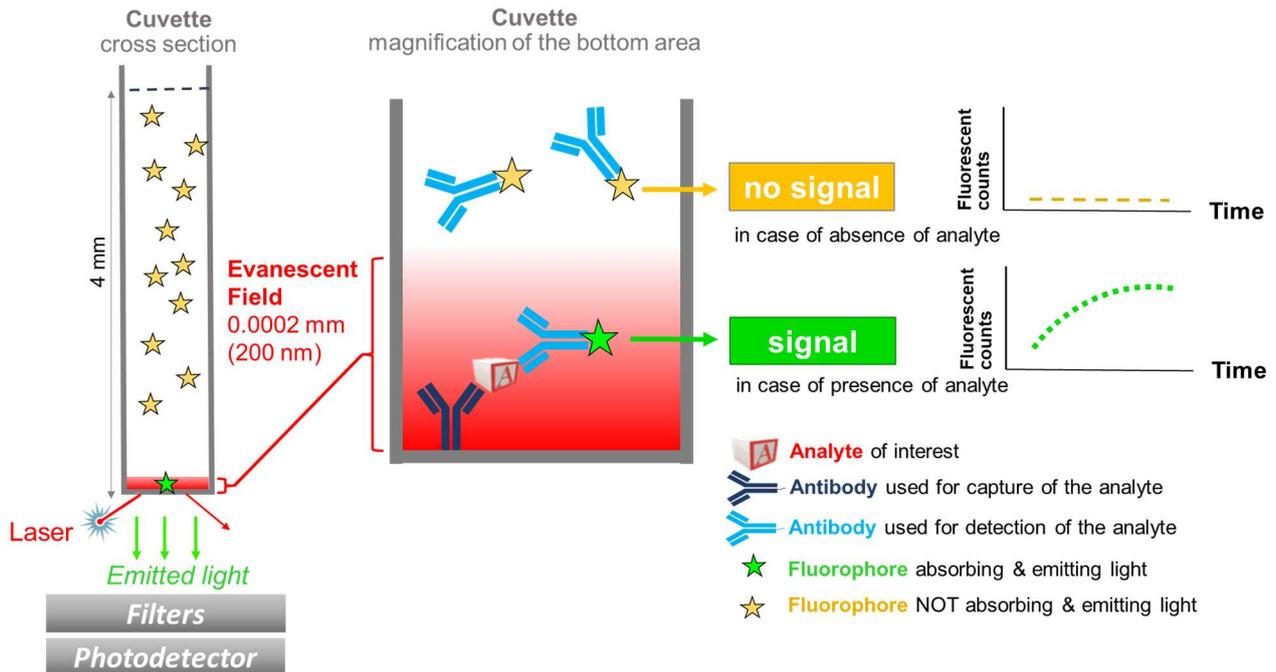

Figure 2. Assay Principle. Fluorophores bound at the bottom of the well within the evanescent field absorb, emit light and thus induce a signal. In the absence of the specific analyte, fluorescence labelled antibodies are not bound to the bottom of the well, and no signal is induced.
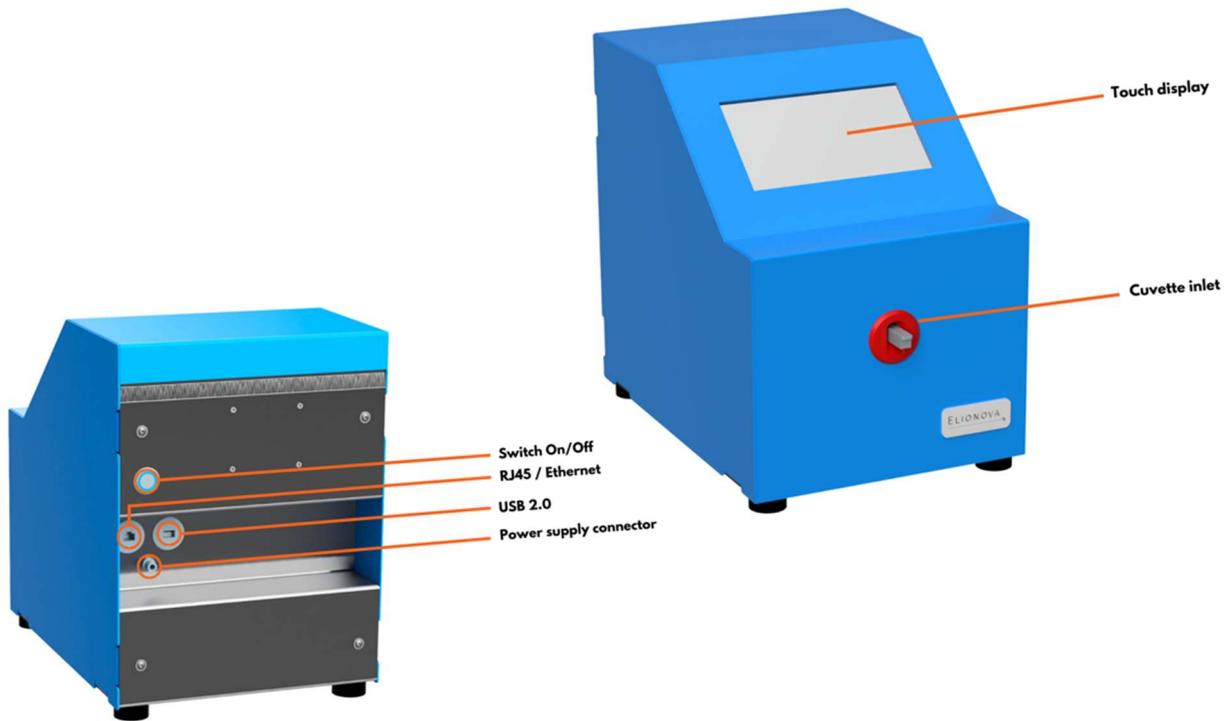
Figure 3. ElioDX ™ Reader 22.1.

Instrument Description

Hardware

The device is composed of the following major subsystems:

- **Linear drive unit,** X-axis driving and positioning the ElioDX™ cuvette within the instrument.
- **Optical unit,** performs the optical measurement. It is composed of a laser diode, laser alignement system, filters and a photomultiplier detector.
- **Minicomputer with touch screen** containing.the software and controlling the instrument components and the Graphical User Interface.
- **Wide angle camera,** to read unique QR Code / Data matrix positioned on top of the ElioDX™ cuvette.
- **External barcode unit.**

Software

to be completed

The software components … Access to ElioCloud System to prepare experiences and harvest results.

Operating modes

The instrument may be operated by in two modes: (1) dynamic measurement, (2) end point measurement. ………..

Technical Specifications

Human Machine Interface	TOUCH PANEL / KEYPAD
Operating Conditions	Temperature: From + 18°C to 30°C
	Relative Humidity: Up to 80%
Size	

Weight	

3.   Preparation of the Instrument for Use

Unpacking

Remove the packaging material and carefully place the unit on a firm and level surface. Make sure the rubber feet are completely attached to the underside of the device.

The device is packed in a specially designed cardboard box. Keep this packaging material, as it will be required should you need to return the device for repair.

Checking the Supplied Parts

When unpacking the device, please check that the following components are present:

- ElioDX™ reader
- Calibration cuvette
- External barcode reader
- AC desktop adapter 12V/2.5 A

Storing

The instrument has to be placed on a level bench. Store the device at temperatures between 10-35 °C with a relative humidity below 85%. Protect the device from moisture and dust during prolonged storage. Do not store the device next to heat sources. Protect it from direct sunlight.

Transport

Before transporting the device, make sure that it is turned off and disconnected. Make sure that there is no cuvette in the instrument.

Power Supply

This instrument is powered by an AC desktop adapter, 12V DC, 2.5A.
The AC adapter meets the following requirements:

Class II
Approval IEC/EN/UL 60601-1 2 MOP
Approval EN60601-1-11
Approved EN55011, FCC CFR47 Part15 Class B
Meets IEC/EN 60335-1
Over voltage protection
Continuous short circuit protection
Meets CoC Tier 2 & DoE Level VI
Universal Input Range 80 - 264Vac

Connect the AC adapter to an outlet 115-230V AC, 50-60Hz using the supplied cable.
Plug the round DC plug of the AC adapter into the socket on the back of the device labeled '9-18V DC input'.

Internet connection

please check and complete.

The ElioDX™ does have a RJ45 « Ethernet» connection port to allow a quick and easy network connection. The ElioDX™ can also be connected to your network through WLAN.

Start Up Instructions

please check and complete.

Once the connection to the network is done, please follow the instructions on the screen to run the first autotest with the calibration Cuvette. The ElioDX™ Reader will tell when it is over. After that, the ElioDX™ Reader is ready to be used.

ElioDX™ Cloud

1. Log in **ElioDX™ Cloud** with your provided credentials.

2. Click on "Prepare an experiment".
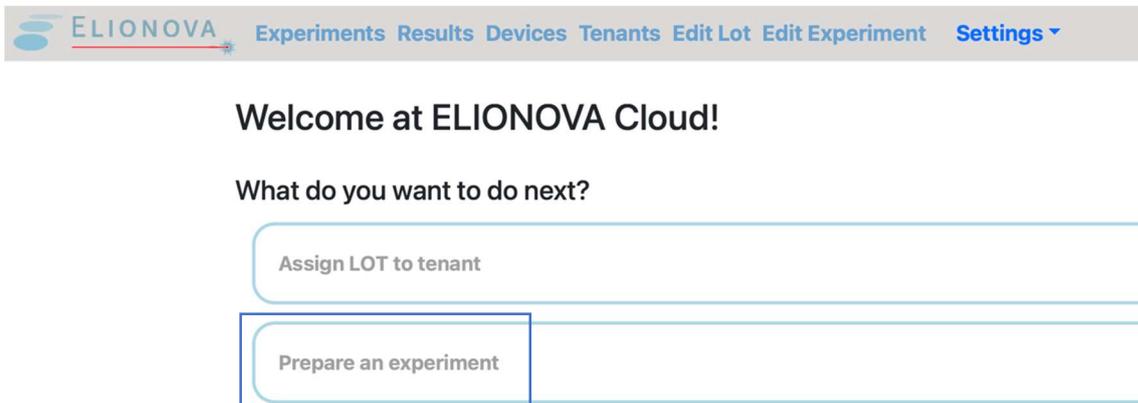
3. Scan your cuvette in the designated box
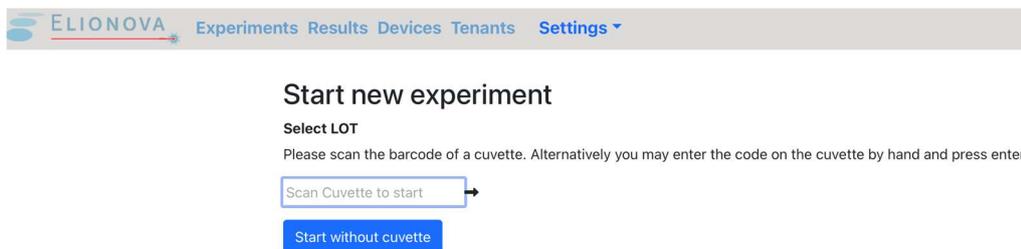
4. After scanning the cuvette, the experiment window will be open. Here you can:

- Change your experimental title.
- Add information for samples to the wells.
- Click on the oval box to turn it in green if you want to designate control wells.
- Fill in the rest of the required information.

5. At the bottom of the experiment window, there are 3 buttons: **Add Cuvette**, **Back** and **Save**. You can add more cuvettes to the experiment and click **Save** when you are finished.

6. After the experiment is saved, you can start the measurement of the registered cuvettes in the reader.

Important note: Only cuvettes that are added to saved experiments with their QR codes can be read in the reader.

7. Once a cuvette is measured, you can find the **Results** button at the end of the cuvette. Click on it to access the link to the result page for that cuvette.

8. At the bottom of the saved experiment, you can click on "**Download**" button to download the results of all measured cuvettes in an Excel file.

Experiment

ID	f162fec4-2c96-4d99-9dee-383531347555
Title	Biolytix EXP8 Try new G12 2024-09-20
Product	Empty Cuvette
Lot	10010 B0920
Cuvette(s)	1, 2, 3, 4, 5

Cuvette 1 (10010 B0920 00001)

	Sample Name	Analyte	Sample Matrix	Concentration	Unit	Extra Info
⬭	G12new-G12APC		Buffer	0	ng/ml	
⬭	G12new-G12APC		Buffer	0	ng/ml	
⬭	G12new-G12APC		Buffer	1	ng/ml	
⬭	G12new-G12APC		Buffer	1	ng/ml	
⬭	G12new-G12APC		Buffer	10	ng/ml	
⬭	G12new-G12APC		Buffer	10	ng/ml	
⬭	G12new-G12APC		Buffer	100	ng/ml	
⬭	G12new-G12APC		Buffer	100	ng/ml	

Results ∨

Date / Time	Assay Name	Device	Type
2024-09-20 15:01:16	Biolytix EXP8 Try new G12 2024-09-20	P6	EXPERIMENT

Cuvette 2 (10010 B0920 00002)

	Sample Name	Analyte	Sample Matrix	Concentration	Unit	Extra Info

[Add Cuvette] [Save] [Download] [Show Statistics]

ElioDX™ Reader

1. Open the Eliodriver software on the screen of the reader or tablet connected to the reader***.

2. Click on "**Processing**" mode and click "**Start**."
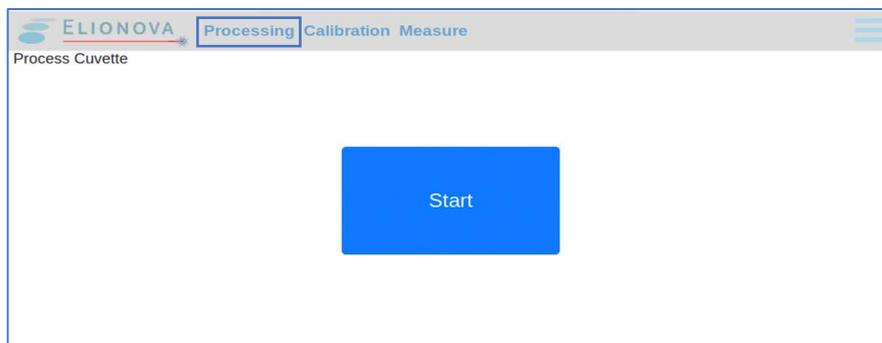
3. Wait until you see the message "**Insert Cuvette**" on the screen.
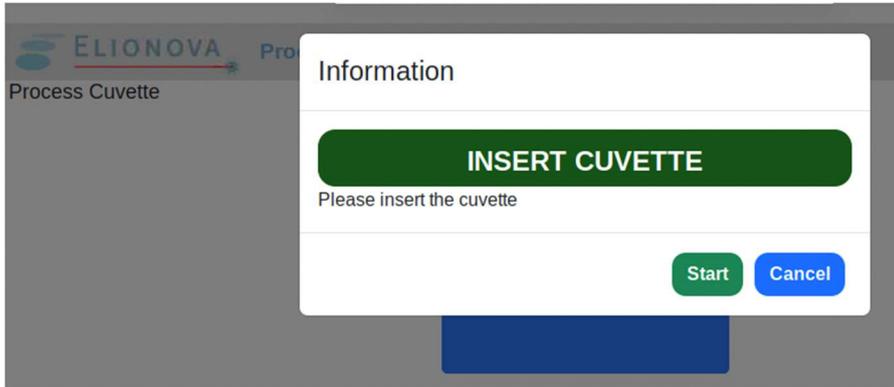
4. Insert your cuvette into the reader.

5. Click on "**Start**" to begin the measurement.

6. The measurement is in progress when you see the screen shown in figure below:
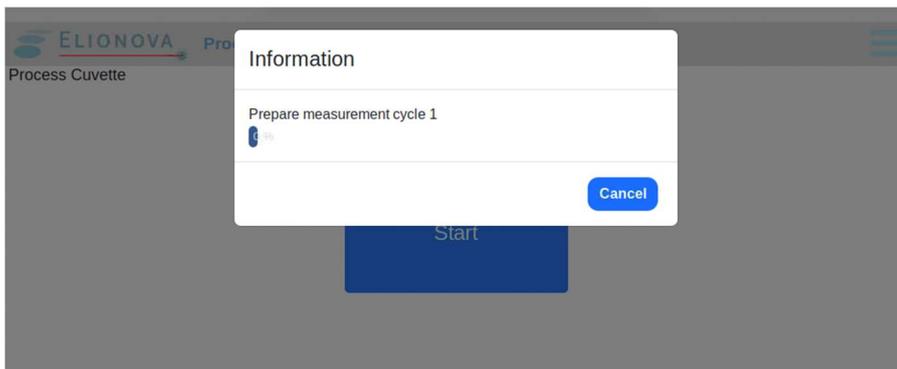
7. When a measurement is finished, you will see the screen as below. Click on ok, you will see the result of your cuvette. To start a new test, close the result page and the screen will be as at step 2.
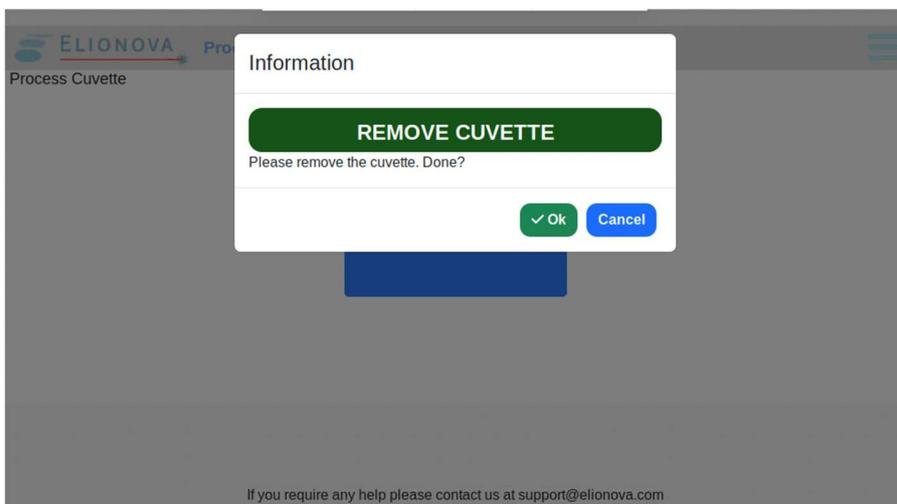
***Note: To make daily warmup of the reader, run the provided color cuvette in the reader for 10 min before running your tests. The reader can be power on overnight.

4. Calibration

The instrument was fully calibrated by the manufacturer. Calibration should be repeated…..(I think yes, First to give a free try to the customer and familiarize him with the machine and also to be sure nothing happened during the transport. See above the text in start up instructions)?

We should discuss with Bruno / Manfred if the operator need to run the calibrator at a fixed frequency I e. 1x per month to be sure everythings is fine (bad part from that means we are not confident as a problem could appear), from the other side, the client detects when something is wrong…

5. Operation

Process

Hanh, Manfred, please complete.

Process	Function

Running the Assay

Hanh, please complete.

The following instructions show how to run an assay developed by ELIONOVA.

standard curve

dynamic measurement

further explanations

Preparations / Cloud conncection

Hanh, please complete.

how to insert data into mask on cloud Hanh / Natalianne are the best candidates to fullfill this category in order to prepare the experiment. Note that the software is not at the endversion and "too early" print screen would be needed to be replaced.

Perform the measurements

1. Switch on the machine.

2. Select the desired program already installed on the device:

- On the start screen "Manual Measurement", click on the "Load Form…" down left on the screen and select the desired file.

- Click then on the green field called "Upload".

3. Wait for the message "INSERT CUVETTE". At this stage, the machine is bringing to the front the ElioDX™ Cuvette holder.

4. Prepare the cuvette (on the Warming plate? Samples need also to be there ?) : put your samples or/and standard into it by pipetting 20ul into each well. *CAUTION: Do not put your fingers on the bottom of the wells.*
We should give some advice within which time pipetting and insertion of the cuvette should be completed.

5. Insert the cuvette until the stop and click on "START".
CAUTION: Do not put your fingers into the red aperture and do not put /remove the cuvette into/from it without being informed by the reader.

6. During measurement, the reader display informs you of the progress and completion of the measurement. The message "perform measurement" and the cycle number of read is displayed on the upper part of the screen.

7. Once the measurement is finished, the machine informs you: "Job Complete", following by the message "WAIT" in a red box. The cuvette will be then moved out of the orifice of the reader.

8. As soon as the information "remove cuvette" is display, you can remove the cuvette, and click on OK when it is done.

9. During the retrieval of the guiding cuvette system, the message "WAIT" in a red box will appear again.

10. The reader will automatically go back to the screen displaying the results, with the notification on the left upper edge that the "Measurement ended".

11. If you click on the right bottom "Close", you will reach the start screen. If you want to perform another measurement, start again from point 1.

Do we need some more detailed descriptions?

Data

Raw data

Export to excel….

Running a Do-it-Yourself Assay

Hanh, please check and complete.

[I think, this part should be fulfilled at the very end to be sure we don't modify it x-times.). The following instructions show how to run a self-made assay. Guidelines how to prepare an ElioDXTM Do-it-Yourself Assay can be found…….(will be a separate document).

Genreral information: standard curve, dynamic / end point measurement, further explanations….

Preparations / Cloud connection

how to insert data into mask on cloud

how to insert your own test program

how to recall a stored test program (saving & recalling of stored test programs).

Perform the measurements

1. Switch on the machine.
2. please describe

Data

Raw data

Export to excel….

Results

Hanh, please check and complete.

[Bitte ergänzen] Wie sehen die Resultate aus, wie speichert man, wie ist die Auswertung (Standardkurve), Beispiele

View Stored Data

Georg, Hanh, please check and complete.

[Bitte ergänzen]

6.   Utilities

Settings

Not needed for Reader 22.1. Will be needen for the 24.1

Date & Time	
User ID	
Password	

Maintenance & Cleaning

Maintenance

The ElioDX™ Reader is maintenance-free.

There are no parts within the instrument that can be serviced by the user. It is only necessary for users to ensure that the device is kept clean.

Cleaning

<mark>**Manfred, please check and complete.**</mark>

Warnings for Cleaning

When cleaning, pay attention to the following warnings. The non-observance of these warnings may result in damage to the user or to the instrument. This can lead to a reduction of the instrument's service life or in measurement errors.

Always avoid spraying liquid directly onto the screen surface of the ElioDX™ reader. This is especially important for the inside of the slot, where there are optical elements that are very sensitive and essential for the functioning of the instrument. Never clean the inside of the slot with sharp, abrasive, solvent-containing agents.

Always wear gloves during cleaning operations that may be associated with contact with biological or generally hazardous materials or liquids.

Ensure that there is no cuvette in the instrument prior to any cleaning.

Remove the USB cable from the instrument before cleaning.

Cleaning the Housing

The housing surfaces should be cleaned regularly. For this purpose, you can use a cloth, or a sponge lightly wetted in water. For heavier soiling, clean the surface of the housing with a mild soap solution diluted with water or glass cleaner and then wipe with a lightly moistened cloth or sponge to remove any residue. Do not use scouring agents.

Cleaning the Slot

<mark>I you mean cleaning the red aperture, the cleaning restrictions should be the same as the one above for the enclosure, it's the same painting process. However it should really be clean only when the door is closed.</mark>

Decontamination

....

7.   Precautions

<mark>**Urs, Hanh, Manfred, Christoohe please check and complete**</mark>

1. Do not use any sharp objects on the Touch Screen.
2. Do not attempt to open the instrument. Do not allow unauthorized persons to operate.
3. Check the cuvette wells before use. They should be scratch-free / dust free.
4. Keep the place dry and clean.
5. Be sure to operate the analyzer under the situation specified in this manual. Otherwise, the analyzer will not work normally, and the analysis results will be unreliable.
6. Personal protective equipments such as lab coats and gloves are necessary while running ElioDX™ assays for safety reasons.
7. In case of problems not specified in this manual, contact ELIONOVA technical service.
8. All biological materials should be handled and discarded as potentially hazardous by following local laws and regulations.