ESCO MEDICAL Life has begun

CE 0088

USER MANUAL

Data-logger Software MIRI®

Rev. 2.1
Date of Revised 23.10.2019
Rx only

CERTIFIED INCUBATION

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Copyright Information

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Only to be used by a trained and qualified professional. The device is sold under exemption 21 CFR 801 Subpart D.

"Material in this manual is provided for informational purposes only. The contents and the product described in this manual (including any appendix, addendum, attachment or inclusion), are subject to change without notice. Esco makes no representations or warranties as to the accuracy of the information contained in this manual. In no event shall Esco be held liable for any damages, direct or consequential, arising out of or related to the use of this manual."

Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the freight carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Claims

Our routine method of shipment is via common carrier. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim.

If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact your local sales representative or Esco Medical immediately.

Standard Terms and Conditions

Refunds & Credits

Please note only serialized products (products labelled with a distinct serial number) and accessories are eligible for partial refund and/or credit. Non-serialized parts and accessory items (cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. In order to receive a partial refund/credit, the product must not have been damaged, and must be returned complete (meaning all manuals, cables, accessories, etc.) within 30 days of original purchase, in "as new" and resalable condition. The *Return Procedure* must be followed.

Return Procedure

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from Esco Medical Customer Service. All items being returned must be sent *prepaid* (freight, duty, brokerage and taxes) to our factory location.

Restocking Charges

Products returned within 30 days of original purchase are subject to a minimum restocking fee of 20% of the list price. Additional charges for damage and/or missing parts and accessories will be applied to all returns. Products which are not in "as new" and resalable condition, are not eligible for credit return and will be returned to the customer at their own expense.

Certification

This instrument has been thoroughly tested/inspected and found to meet Esco Medical´s manufacturing specifications when shipped from the factory. Calibration measurements and testing are traceable and done according to Esco Medicals ISO certification.

Warranty and Product Support

Esco Medical warrants this instrument to be free from defects in materials and workmanship under normal use, and service for two (2) years from the date of original purchase, provided the instrument is calibrated and maintained in accordance with this manual. During the warranty period Esco Medical will, at our option, either repair or replace a

product that proves to be defective at no charge, provided you return the product (shipping, duty, brokerage and taxes prepaid) to Esco Medical. Any and all transportation charges incurred are the responsibility of the purchaser and are not included within this warranty. This warranty extends only to the original purchaser and does not cover damage from abuse, neglect, accident or misuse, or as the result of service or modification by parties other than Esco Medical.

IN NO EVENT SHALL ESCO MEDICAL LTD. BE LIABLE FOR CONSEQUENTIAL DAMAGES.

No warranty shall apply when damage is caused by any of the following:

- Power failure, surges, or spikes
- Damage in transit or when moving the instrument
- Improper power supply such as low voltage, incorrect voltage, defective wiring or inadequate fuses
- Accident, alteration, abuse or misuse of the instrument
- Fire, water damage, theft, war, riot, hostility, acts of God such as hurricanes, floods, etc.

Only serialized products (those items bearing a distinct serial number tag) and their accessory items are covered under this warranty.

PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY. Items such as cables and non-serialized modules are not covered under this warranty.

This warranty gives you specific legal rights and you may have other rights, which vary from province to province, state to state, or country to country. This warranty is limited to repairing the instrument per Esco Medical's specifications.

When you return an instrument to Esco Medical for service, repair or calibration, we recommend shipment using the original shipping foam and container. If the original packing materials are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped
- Use heavy paper or cardboard to protect all instrument surfaces. Use non-abrasive material around all projecting parts
- Use at least four inches of tightly packed, industrial-approved, shock-absorbent material all around the instrument

Esco Medical will not be responsible for lost shipments or instruments received in damaged condition due to improper packaging or handling. All warranty claim shipments must be made on a prepaid basis (freight, duty, brokerage, and taxes). No returns will be accepted without a Return Materials Authorization ("RMA") number. Please contact Esco Medical to obtain an RMA number and receive help with shipping/customs documentation.

Re-calibration of instruments, which have a recommended annual calibration frequency, is not covered under the warranty.

Warranty Disclaimer

Should you choose to have your instrument serviced and/or calibrated by someone other than Esco Medical Ltd. and their representatives, please be advised that the original warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization.

In all cases, breaking the tamper-resistant Quality Seal should be avoided at all cost, as this seal is key to your original instrument warranty. In an event where the seal must be broken to gain internal access to the instrument, you must first contact Esco Medical Ltd. You will be required to provide us with the serial number for your instrument, as well as a valid reason for breaking the Quality Seal. You should break this seal only after you have received factory authorization. Do not break the Quality Seal before you have contacted us! Following these steps will help ensure that you will retain the original warranty on your instrument without interruption.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazard or improper operation. Esco Medical will not be responsible for any injury sustained due to unauthorized equipment modifications.

ESCO MEDICAL LTD. DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

THIS PRODUCT CONTAINS NO USER-SERVICEABLE COMPONENTS.

UNAUTHORIZED REMOVAL OF THE INSTRUMENT COVER SHALL VOID THIS AND ALL OTHER EXPRESSED OR IMPLIED WARRANTIES.

Table of contents

1 How to use this manual

The manual is designed to be read by sections, and not ideally cover to cover. This means that if the manual is read, from start to finish, there will be some repetition and overlap. We recommend the following method to go through the manual: first, familiarize yourself with the safety instructions; then proceed to the basic user functions that are needed for operating the equipment on a day to day basis; then review the alarm functions. The menu function of the user interface details information that is needed for the advanced level of users only. All parts must be read before the device is taken into use.

2 Safety warning

• Anyone working with, on or around this equipment should read this manual. Failure to read, understand and follow the instructions given in this documentation may result in damage to the unit, injury to operating personnel, and/or poor equipment performance.
• Any internal adjustment, modification or maintenance to this equipment must be undertaken by qualified service personnel.
• If the equipment must be relocated, make sure it is fixed properly on a support stand or base, and move on a flat surface. When necessary move the equipment and the support stand/base separately.
• The use of any hazardous materials in this equipment must be monitored by an industrial hygienist, safety officer or other suitably qualified individual.
• Before you proceed, you should thoroughly understand the installation procedures and take note of the environmental/electrical requirements.
• In this manual, important safety related points will be marked with the following symbols:

NOTE

Used to direct attention to a specific item.

WARNING

Use caution

• If the equipment is used in a manner not specified by this manual, the protection provided by this equipment may be impaired.

3 Indication for use

The Esco Medical MIRI® Incubator is intended to be used to provide a controlled environment for the development of gametes and embryos during in vitro fertilization (IVF)/ assisted reproduction technology (ART) treatments. This includes controlled temperature (at or near body temperature), controlled gas levels (CO_2, O_2, and N_2), and controlled humidity levels (humidification).

4 About the product

The Esco Medical MIRI® incubator is a new generation of desktop CO_2 and O_2 incubator.

Direct warming of the dishes in the chambers gives superior temperature conditions in comparison to conventional incubators.

The MIRI® incubator has 6 fully independent culture heat chambers, each with its own heated bottom, heated lid and a heating optimization plate. The heating optimization plates are customized to accommodate several types of dishes e.g. Falcon®, Nunc®, Sparmed® or Vitrolife®.

For maximum performance, the system has 12 individual temperature controllers, controlling and regulating the temperature in the culture chambers and the lids.

The Incubator needs 100% CO_2 and 100% N_2 in order to be able to control the CO_2 and O_2 concentrations in the culture chambers.

The incubator has been primarily developed and designed for incubation of gametes and embryos with an overlay of either paraffin or mineral oil.

If an open culture (any type of culture where the culture media is not covered with a layer of oil) is used, the user must switch to open culture mode.

☞ Open culture may lead to evaporation and a change in pH if the correct conditions are not maintained.

The incubator can be connected to a PC running the Esco Medical Data logger software for long term data logging and data storage.

The device is manufactured under a full EU certified ISO quality management system.

This product meets the requirements of EN6060-1 3rd edition standards as a Class I equivalent device suited for continuous operation. It also conforms to the requirements of the EU Council directive 93/42/EEC concerning medical devices and is classified as a Class IIa device under rule II.

5 About the Data-logger Software

The Data-logger software is an information providing tool, that can help the users of the MIRI® incubator, to get a quick status overview of the main running conditions, and to analyze the conditions and to store or print the conditions.

The Software will also show alarm conditions but the user alerting and interaction functions are all contained on the device itself.

6 Installing the Software

The software is provided on a USB stick.

6.1 Requirements for the PC

The software is validated and tested to run under the operating system Windows 8. It may run under previous versions of Windows but the manufacturer cannot guarantee the stability.

Minimum:

- Intel Core 2 Duo or AMD Athlon X2 at 2.4 GHz processor;
- 2 GB RAM;
- 2 GB hard disk space;
- Integrated video card;
- Monitor with resolution of 1024 x 768;
- Windows 8 operating system;
- USB 1.1/2.0 port for each connected device;

Recommended

- Intel i5, i7 or AMD FX at >= 3.0 GHz processor;
- 4 GB RAM;
- 4 GB hard disk space;
- Dedicated DirectX 9.0c or higher compatible video card with at least 256MB of memory;
- Monitor with resolution of 1280 x 800 or higher;
- Windows 8 operating system;
- USB 2.0 port for each connected device;

6.2 Installation procedure

☞ In order for Data Logger to run continuously, configure Windows Update service not to restart the computer automatically.

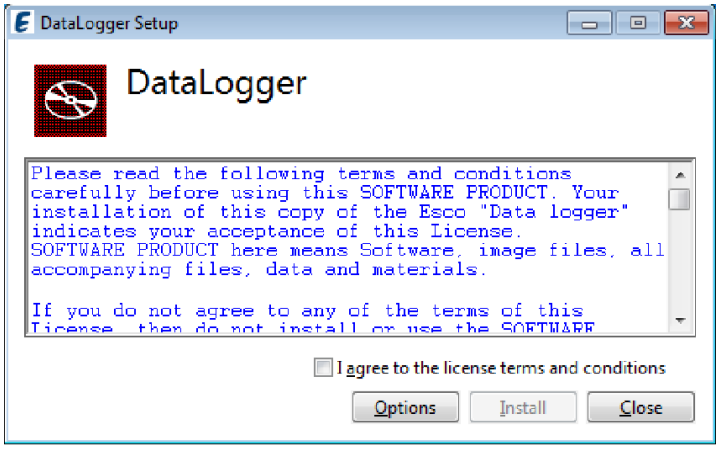
Before the start uninstall any previous version of the Data Logger. Disconnect the incubator from the computer's USB port. Make sure you have an active internet connection.

☞ An Internet connection will be required if the computer does not have. Net Framework 4.0 (client or full version) installed.

1 To install the Data Logger Software, locate on the USB stick the file:

DataLoggerSetup (x.x.x.x).exe. Click on it.

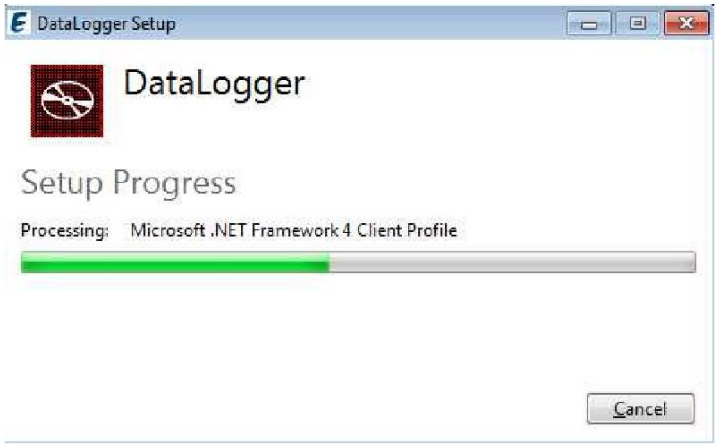
2 Review the license terms and agree.



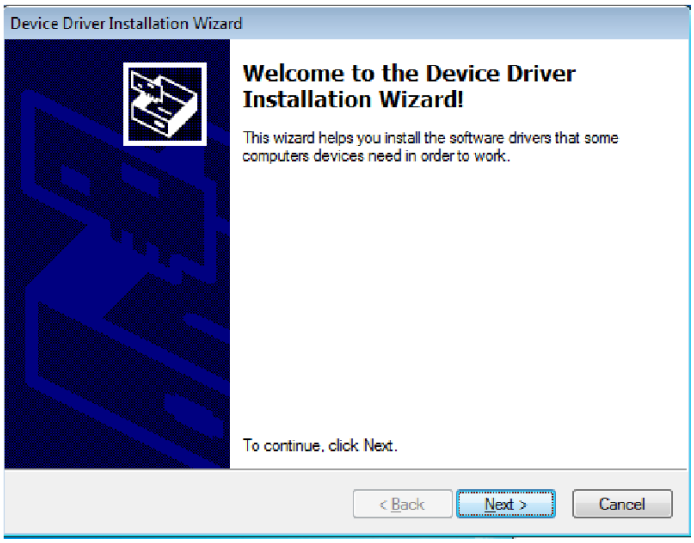
3 Click "**Install**" button.

4 If the User Account Control dialog appears, click "**Yes**".

5 Setup progress will be shown.



6 Before the end a “Device Driver Installation Wizard” window will appear.



7 Click “**Next**” to continue.

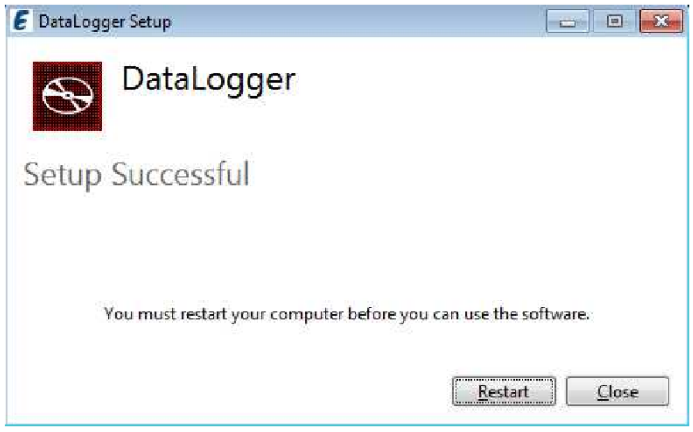
8 A “Windows security” dialog will appear.

9 Mark the checkbox and click “**Install**” to continue.

10 Wait until completion window will appear.

11 Click "**Finish**".

12 The Setup finish window will appear.



13 If the "**Restart**" button is visible, click it. Otherwise click "**Close**".

14 Restart the computer and connect the USB cable from the MIRI® to the PC USB port.

15 Start the data-logger application.

7 Running the data-logger

7.1 Startup

When the application starts the first time the user will be greeted by either the device registration message or the communication error message.

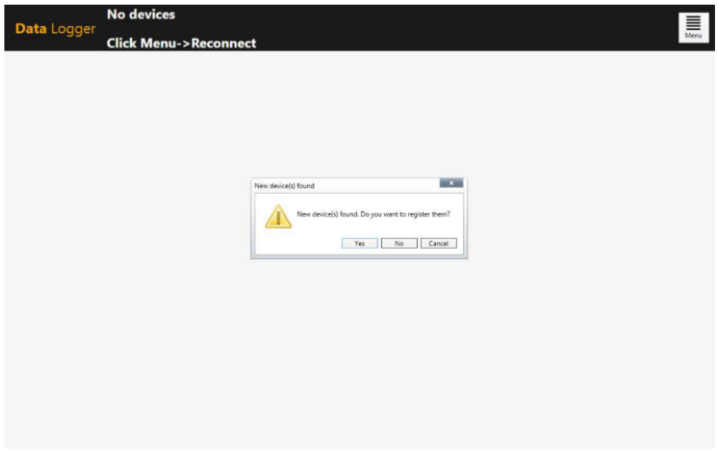


Figure 7.1 Device registration

If device registration message is shown click "**Yes**".

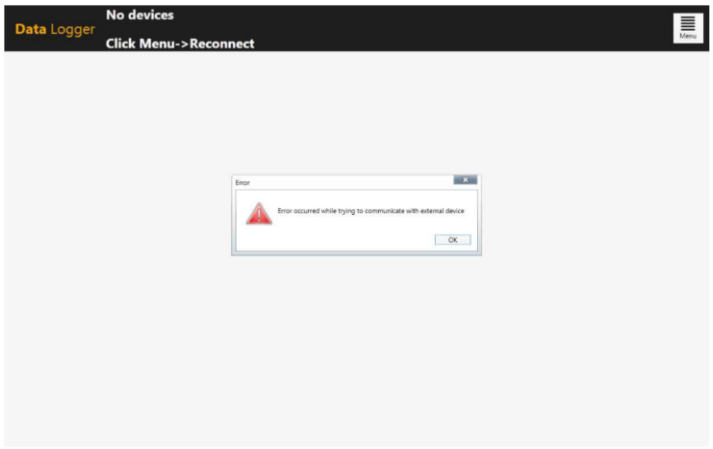


Figure 7.2 Communication error

If Communication error message is shown, check if the MIRI® is connected to the PC with the USB cable (or inspect cable).

To try to establish communication again by choosing "Reconnect" from the "Menu" or restart the data-logger.

☞ The Data logger supports up to three MIRI® devices. If three devices are registered in the data logger and new devices are connected a message: "More than 3 devices" will be shown. To remove unused devices ether the "Menu" and choose "Devices".

7.2 The Main view

The main view shows a figure of the MIRI® incubator. This view will normally be shown when opening the data-logger software subsequent times.

All interaction with the software is simple and intuitive. Navigation between the views are done by pressing the relevant coloured icons in the top line.

Changing back and forth between views can be done by this simple action.

Figure 7.3 Main view

If the compartments temperature, the gas, the pressure and the flow readings show dotted lines like in the Figure 7.1, it means the connection to the incubator is not established and the data-logger is not receiving any data.

Figure 7.4 Main view with menu open

Click the menu if the connection is not established and select “Reconnect”.

The connected devices will be show in the top line. The active device will be bright, the connected but inactive (no data shown) will be dark.

The data-logger can only show the date of one device at a time. It is easy to toggle between the devices, by pressing the icon of the relevant device.

Figure 7.5 Main view with data

In Figure 7.3 the main view with data can be seen. If the MIRI® is running near the PC it is highly recommended to leave the data-logger in this view at all times. It will provide the user with the maximum on the fly information about the running conditions.

On each compartment two temperatures are shown. They are the lid temperature at the top and the bottom temperature below. A sensor name is also indicated (Tx) to make the any calibration adjustments intuitive (i.e. It can be seen where the sensors with what names are located).

7.3 The history View - temperature

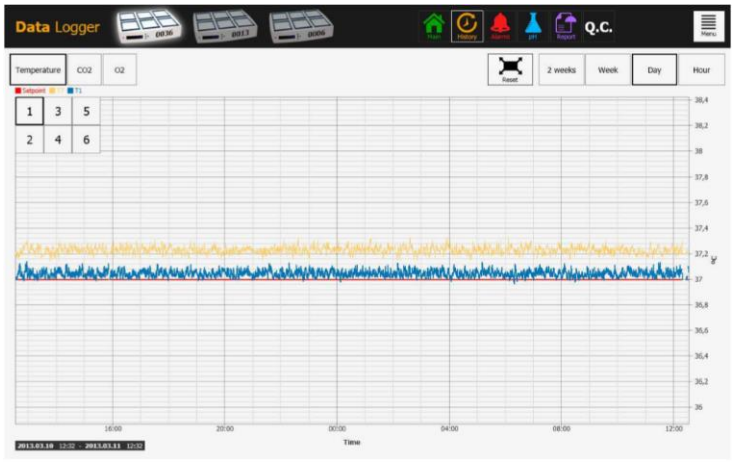


Figure 7.6 Temperature graphs

Pressing the history icon changes the view to the chart view of the temperature.

In the history view it is possible to see the graphs for the temperature data, the CO_2 data and the O_2 data.

In Figure 7.4 the temperature graphs are shown. It is possible to toggle on/off the 1 to 6 of the compartments by pressing the numbered matrix.

With the period buttons, hour, day, week weeks it is possible to change the period viewed.

7.3.1 The zoom functions

By dragging a finger over the area that one wish to enlarge (or by placing the mouse and clicking the left key while holding it and dragging) it is possible to zoom. Zoom can be repeated in steps. To get the back to the original size press the reset button.

7.4 The history View – CO_2

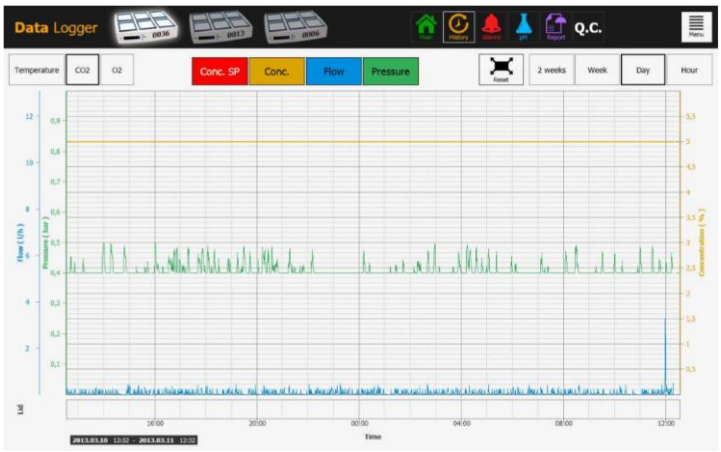


Figure 7.7 CO_2 graphs

By pressing the CO_2 button, the view will shift to the CO_2 graph.

CO_2 set-point Concentration %, Flow and Pressure graphs can be toggled on/off. The period and zoom function follow the functionality of the temperature view.

7.5 The history View – O_2

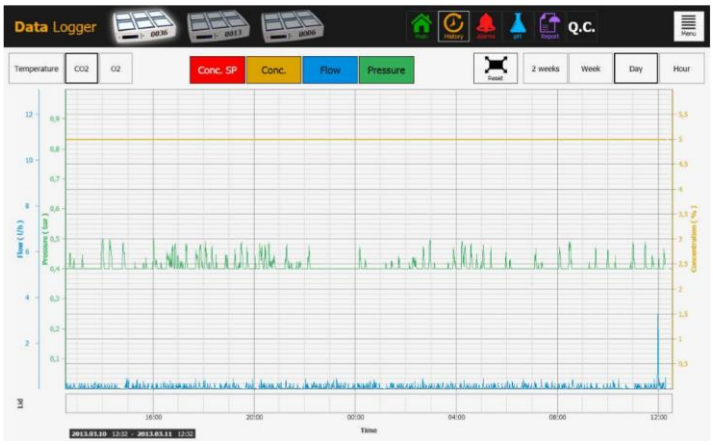


Figure 7.8 O_2 graphs

By pressing the O_2 button the view will shift to the O_2 graph.

O_2 set-point Concentration %, Flow and Pressure graphs can be toggled on/off. The period and zoom function follow the functionality of the temperature view.

7.6 The Alarm views

The alarm view depicts all the parameters and any alarm states in a fast overview graphical format. Each alarm is represented by a red block that increases in the size the, longer the alarm lasts.

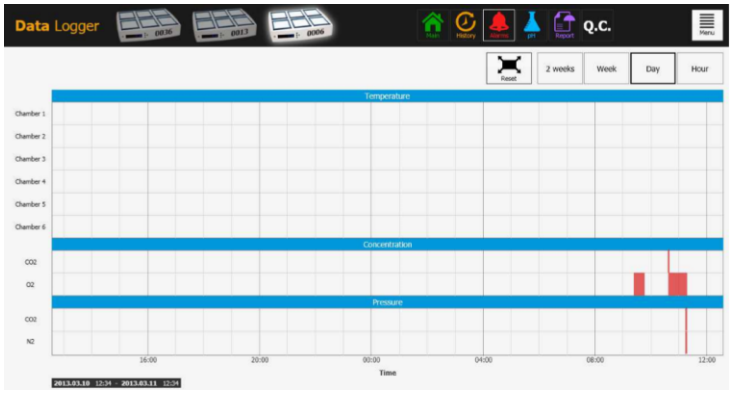


Figure 7.9 Alarm view

Blank or white space indicates that all conditions where OK. In figure 7.7 there has been an O_2 alarm between 9 and 10 and from 10.30 to 11.30. A CO_2 alarm was briefly active at 10:40 and both N_2 and CO_2 pressure alarmed at 11:10.

The period and zoom function follow the functionality of the temperature view.

7.7 The pH measuring view

The MIRI® incubator is equipped with a high-grade pH measuring system. In the back of the unit is located a standard male BNC connector. This can be connected to most standard pH combination probes. Probes that require a separate reference cannot be used. Temperature correction (ATC) is done by the system according to the temperature level set in the calibration dialogue window on the PC Data logger. An external ATC probe cannot be used with the system.

Figure 7.10 pH probe connected to the BNC

All readings from the pH system and the calibration dialogue is shown in the PC data logger software.

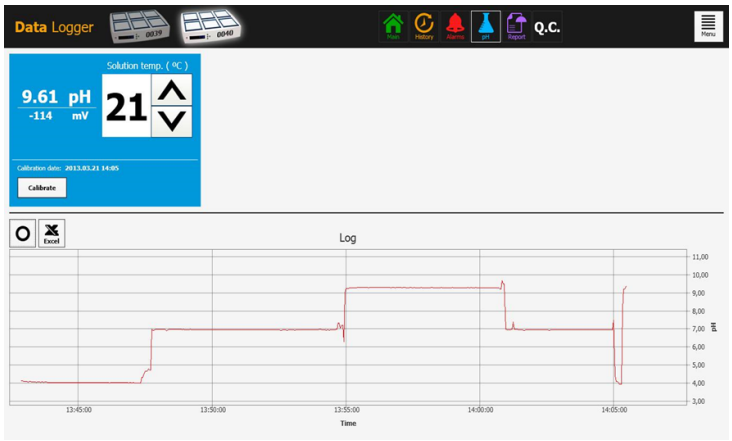


Figure 7.11 pH view

Temperature can be changed in one-degree steps in the arrow up/down buttons. Readings of the pH is in both pH scale and mV.

In the lower portion of the window a graph can be started and the data exported to Excel. By pressing the calibrate button a section for the calibration values and buffers open up.

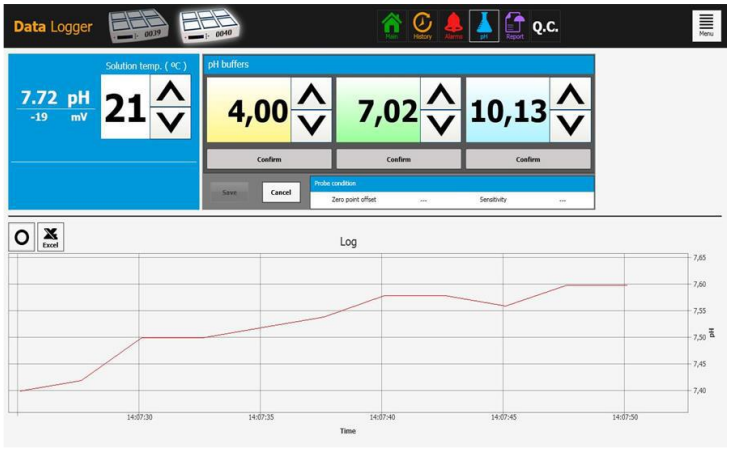


Figure 7.12 pH calibration

The buffer levels can be user set to any desired value with the arrow up/down buttons. When the probe has been placed in the relevant buffer and has stabilized the confirm button can be pressed and the calibration for that buffer is stored. 2 or 3 buffers are required.

For highest accuracy chose 2 or 3 buffers that are close to the area of pH where the measurement should be done.

Any pH buffer can be used as the buffer levels can be user set in the calibration dialogue window.

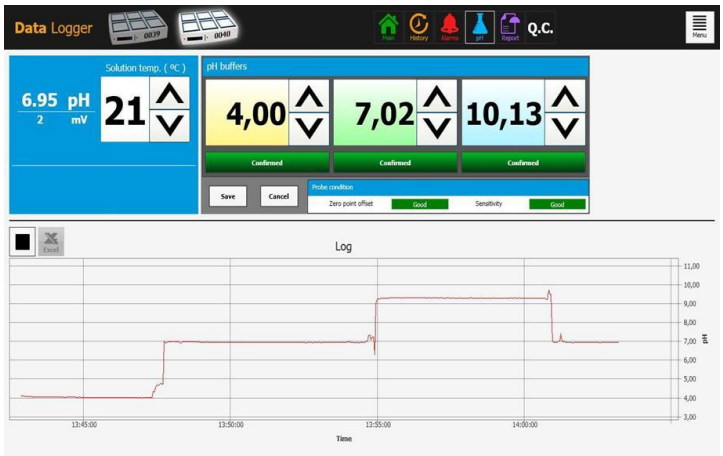


Figure 7.13 Calibration confirmed

7.8 The report views

Pressing the report icon brings the view to the inactive report view.

In the report view a full running report of the incubator parameters can be generated. In this way it possible to document the incubator parameters for quality management or attaching the report to a patient detail when their embryos have been incubated in the device. The function makes it possible to make retrospective analysis of the incubation parameters.

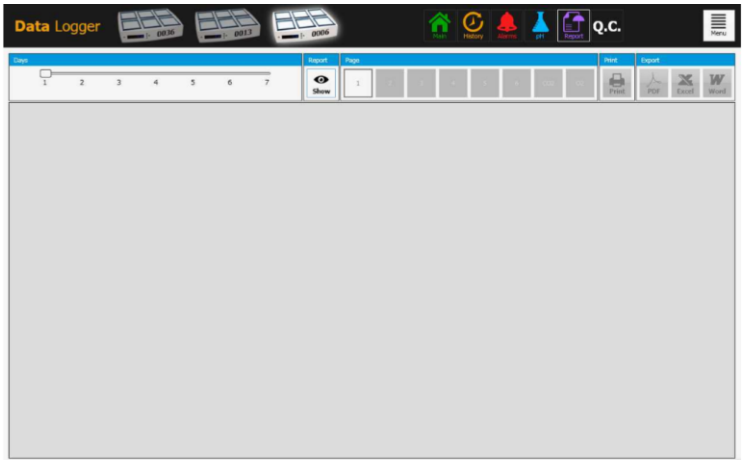


Figure 7.14 Report view

First view is inactive because the parameters needs to be selected. Use the slider for number of days to be included Then press show and the report will be generated.

The report will be several pages with a graph or information about the running conditions as shown in picture 7.13.

The report can be exported as a PDF, doc, excel or printed.

Figure 7.15 Report example

7.9 The QC view

A number of extra sensors is built into the MIRI® incubator. These sensors can be used to track the stability of the device and give early warning of a possible malfunction.

The sensors cannot be read any place on the device or in the data-log.

The readings can be sent as a data block to the manufacturer and analyzed. This requires that the QC function is enabled on the device.

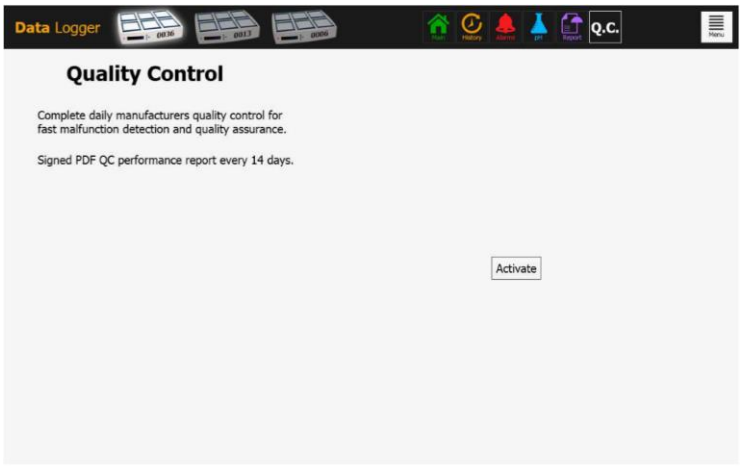


Figure 7.16 QC control view

If that is done the factory will analyze both the additional data but also the regular running parameters and send a signed QC report for the customer.

The service is only available for an extra fee.

7.10 Alarm function

The data logger can be set to send an e mail in case of alarm. Email is sent only when the alarm state changes. The alarm conditions cannot be user set. A cancellation e-mail also be sent.

Activating this type of functionality may mean a large amount of e-mails may be generated if the device is falling in and out of a alarm condition.

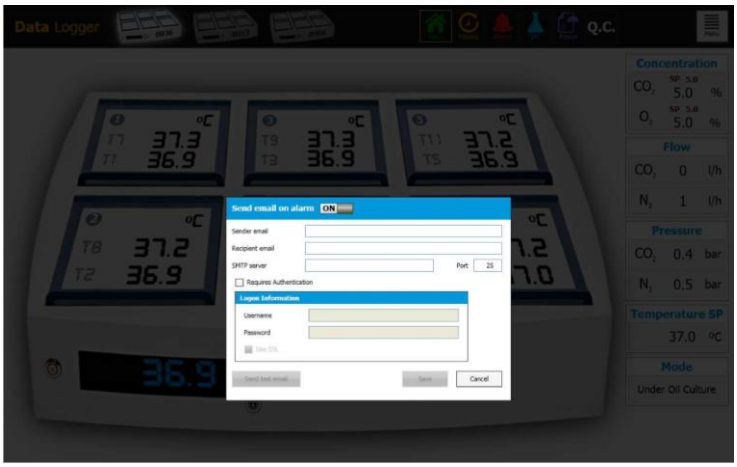


Figure 7.17 Sms alarm setup

Under the menu shown in figure 7.2 select “settings”.

The function can be toggled on/off here. When toggled on the possibility to enter e-mail details are active. A test e-mail can be generated to verify the functionality when set up.