User Manual

Data-Logger Software

ESCO MEDICAL MRI-6A10/XQ-1

Version 1.1

Rx only

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Users of ESCO MEDICAL products should not hesitate to contact us if there are any unclear points or ambiguities in this manual.

CAUTION:
If the equipment is used in a manner not specified in this manual, the safety of the user may be at risk and the equipment may be damaged. Always use the equipment as outlined in this instruction manual.

Table of Contents

1 Welcome

Congratulations with the acquisition of your MRI-6A10/MRI-6A10/XQ-1 incubator.

We at ESCO MEDICAL are proud that you have chosen our product to serve your needs. We hope to hear from you with feedback on this product that can benefit future product developments.

We will strive to serve you well.

Thank you.

2 Reading Instructions for the Manual

The manual is meant to be read chronologically.

3 Explanation of Symbols Used in Manual

NOTE

Used to direct attention to a specific item.

DANGER

Used when caution is needed.

4 Indications for Use

The AT MEDICAL MRI-6A10/XQ-1 Incubator is intended to be used to provide an environment with controlled temperature at or near body temperature and CO_2, O_2, and N2 gases and humidification for the development of gametes and embryos during in vitro fertilization (IVF)/ assisted reproduction technology (ART) treatments.

5 About the Product

The ESCO MEDICAL MRI-6A10/XQ-1 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 MRI-6A10/XQ-1 incubator has 6 completely separate culture heat chambers each having its own heated bottom, heated lid and a heating optimization plate. The heating optimization plates are customized to accommodate several types of dishes for either Falcon® or Nunc®.

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

The Incubator needs 100% CO_2 and 100% N2 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 open culture (any type of culture where the culture media is not covered with a layer of oil) is used the reservoir in each compartment must be filled with sterile water.

☛ **Open culture may lead to evaporation and a change in pH. If the correct conditions are not maintained**.

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

This product fulfils the requirements of EN60601-1 3rd edition standards as a Class I type B equivalent device suited for continuous operation. It also conform 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.

6 About the Data-Logger Software

The Data-logger software is an information providing tool that can help the users of the MRI-6A10/XQ-1 incubator, to get a quick status overview of the main running conditions, and to analyse 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.

7 Installing the Software

The software is provided on a USB stick.

7.1 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
- 2GB RAM
- 2GB 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 >= 3.0GHz processor
- 4GB RAM
- 4GB 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

7.2 Installation Procedure

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

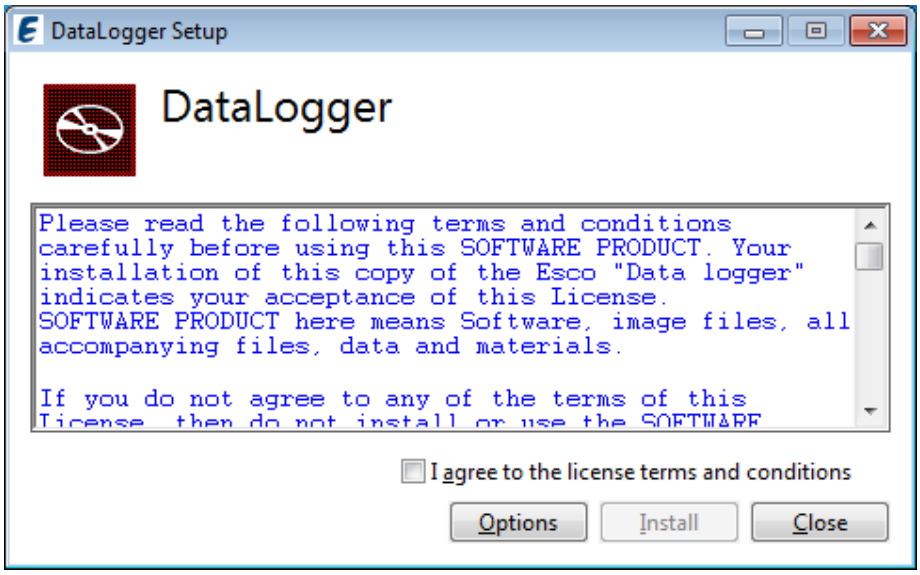
Before the start, uninstall any previous version of the Data Logger.
Disconnect the incubator from the computer's USB port.
Make sure you have an active internet connection.

☛ **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:

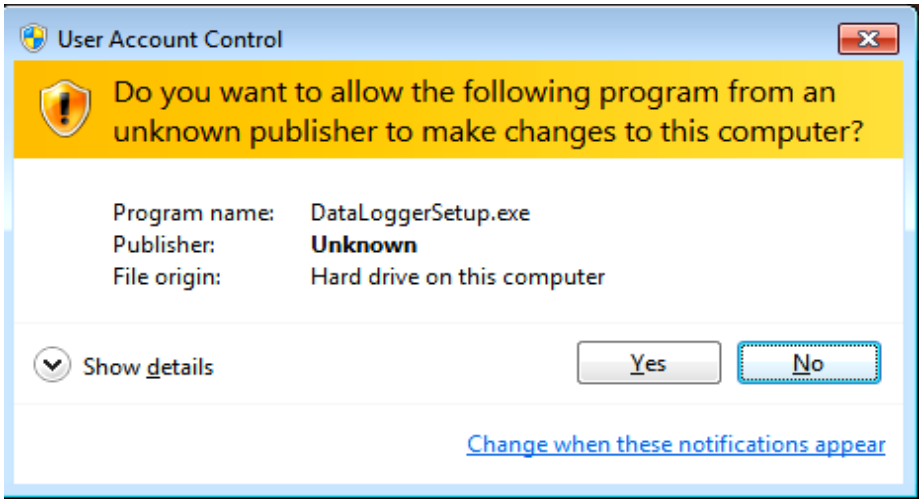
DataLoggerSetup (x.x.x.x).exe. Click on it.

2. Review the license terms and agree.

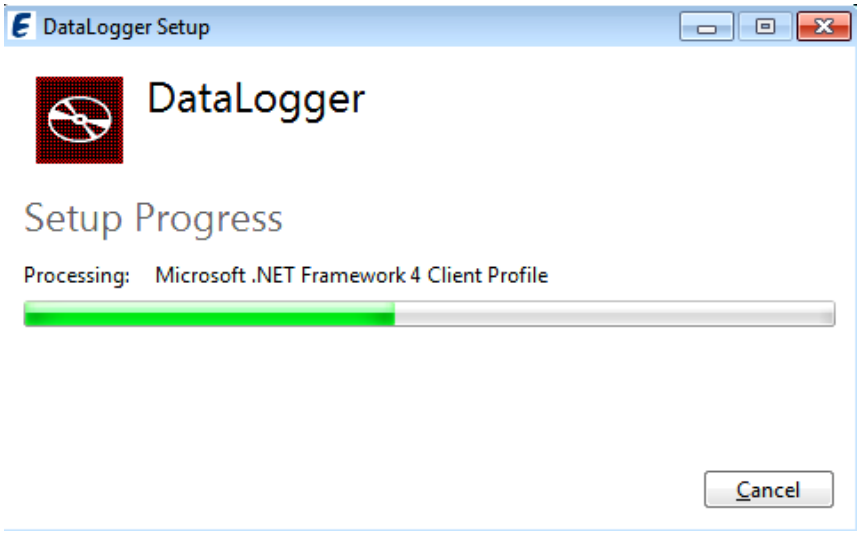


3. Click “**Install**” button.

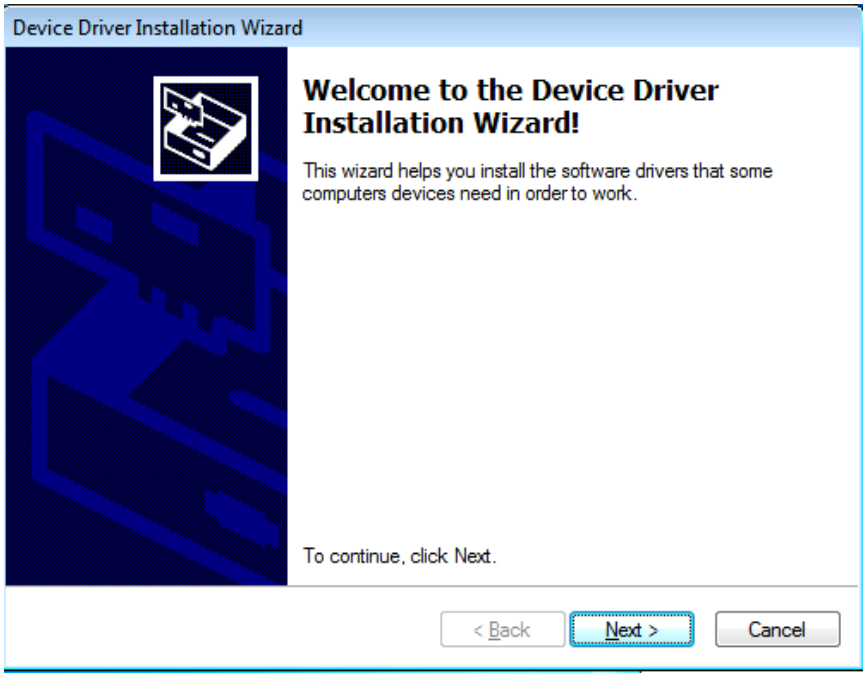
4. If the User Account Control dialog appears, click “**Yes**”.



5. Setup progress will be shown.

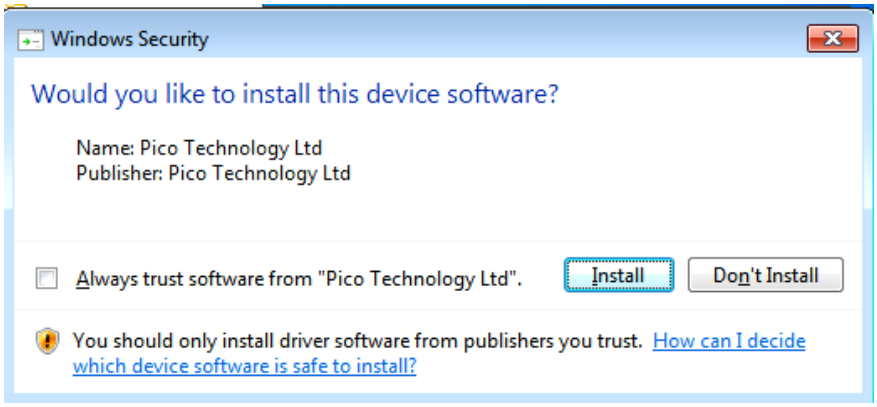


6. Before the end a “Device Driver Installation Wizard” window will appear.



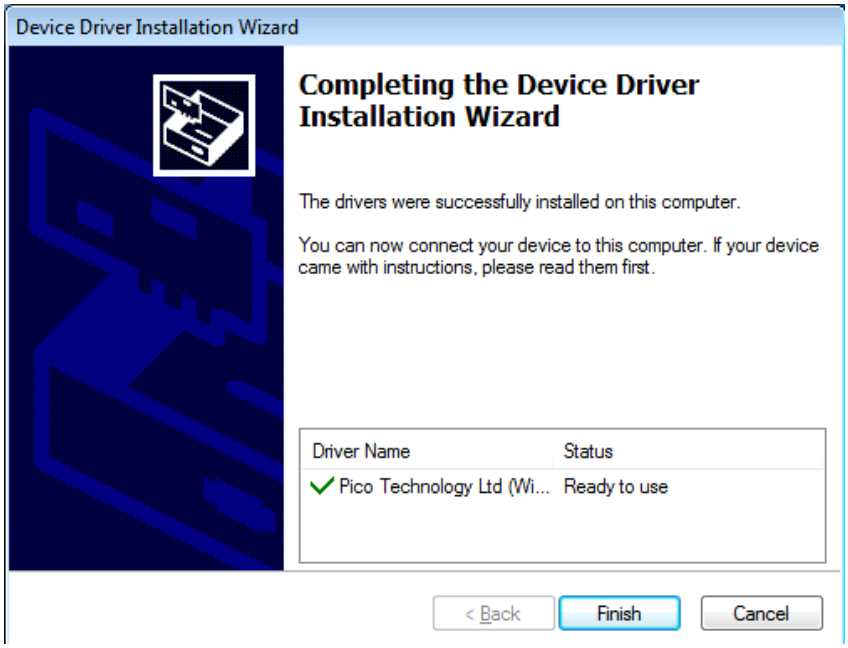
7. Click “**Next**” to continue.

8. A “Windows security” dialog will appear.



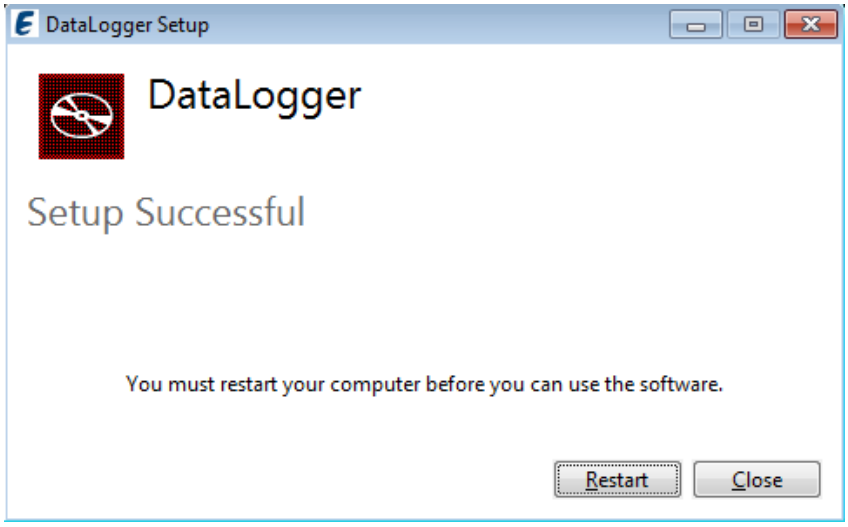
9. Mark the checkbox and click “**Install**” to continue.

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 MRI-6A10/XQ-1 to the PC USB port.
15. Start the data-logger application.

8 Running the Data-Logger

8.1 Start Up

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

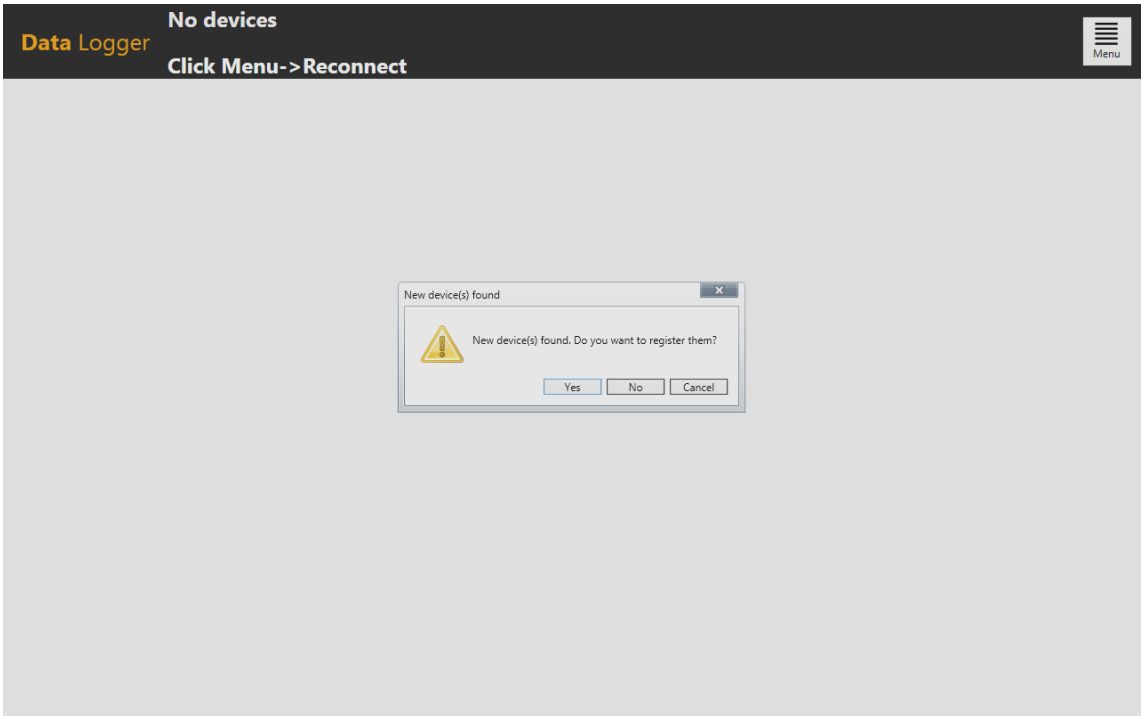


Figure 1. Device Registration

If device registration message is shown click “yes”.

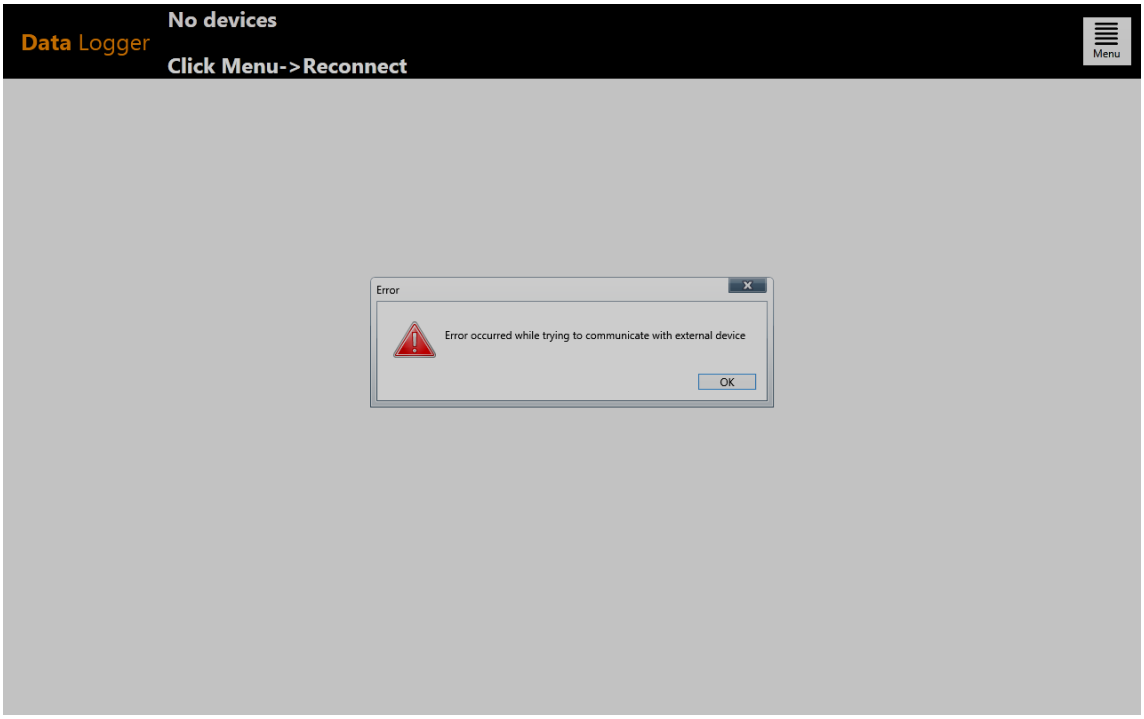


Figure 2. Communication Error

If Communication error message is shown, check if the MRI-6A10/XQ-1 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 MRI-6A10/XQ-1 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”.**

8.2 The Main View

The main view shows a picture of the MRI-6A10/XQ-1 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 3. Main View

If the compartments temperature, the gas, the pressure and the flow readings show dotted lines like in Picture 1, it means the connection to the incubator is not established and the data-logger is not receiving any data.

Figure 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 5. Main View with Data

In Picture 3 the main view with data can be seen. If the MRI-6A10/XQ-1 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).

8.3 The History View - Temperature

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

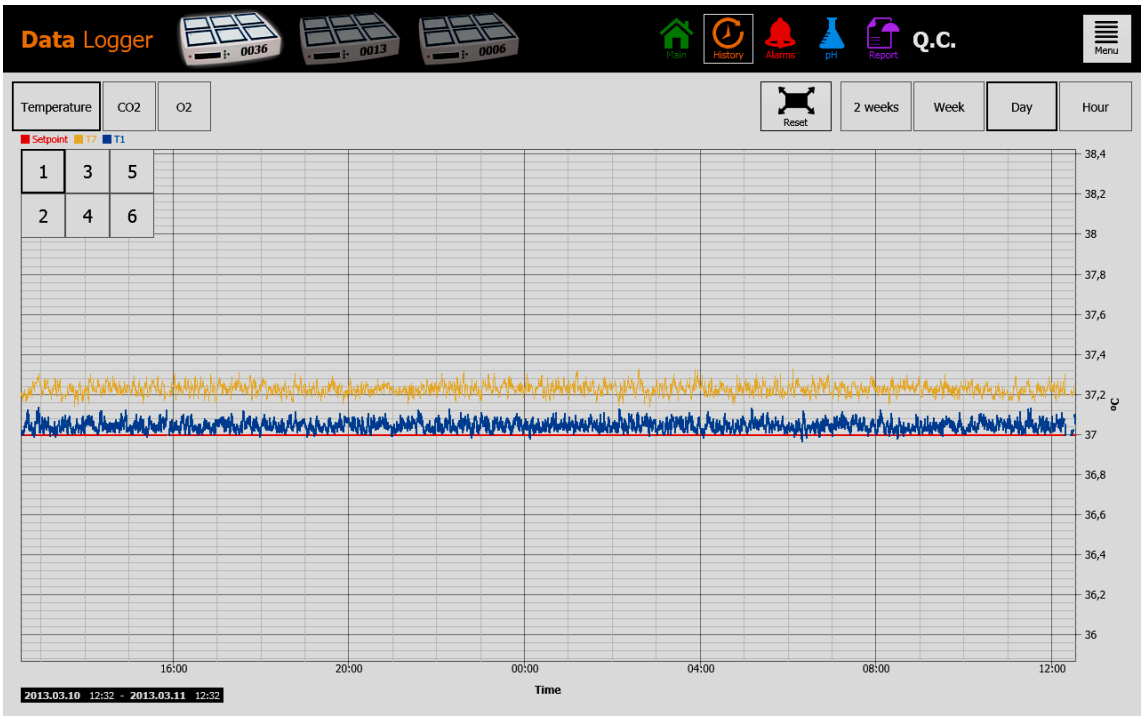


Figure 6. Temperature Graphs

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 picture 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, 2 weeks it is possible to change the period viewed.

8.3.1 The Zoom Function

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.

8.4 The History View – CO_2

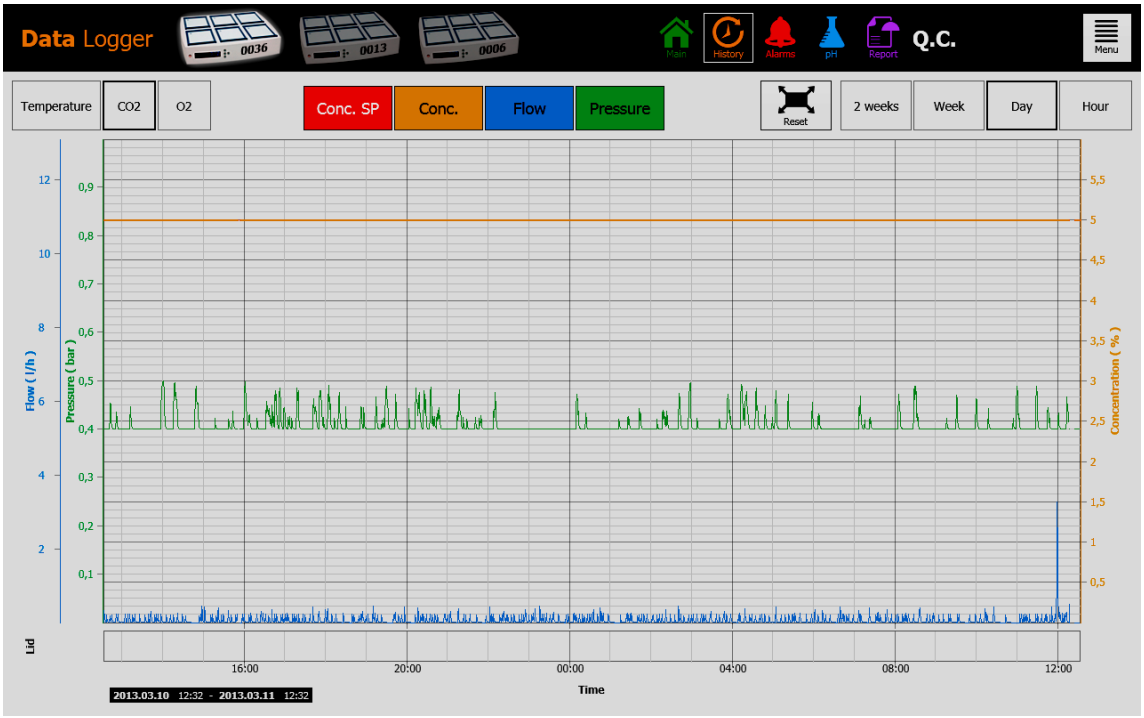


Figure 7. CO_2 Graphs

By pressing the CO2 button the view will shift to the CO2 graph.

CO2 set-point, Concentration %, Flow and Pressure graphs can be toggled on/off. The period and zoom function follows the functionality of the temperature view.

8.5 The History View – O_2

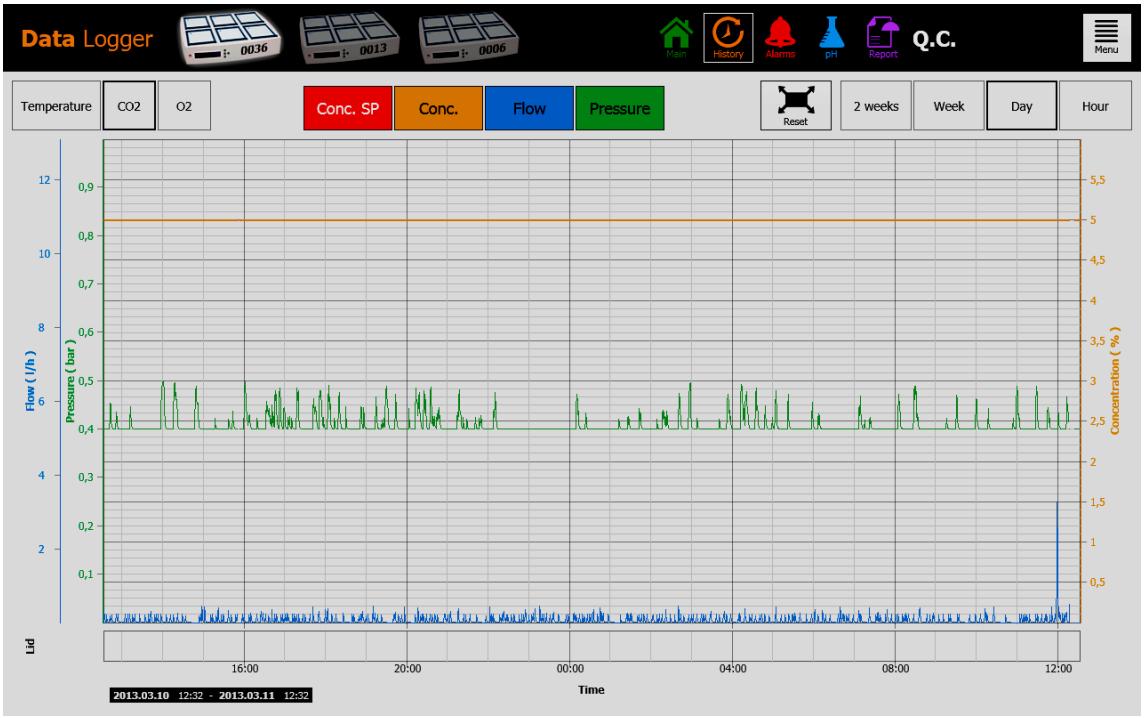


Figure 8. O2 Graphs

By pressing the O2 button the view will shift to the O2 graph.

O2 set-point, Concentration %, Flow and Pressure graphs can be toggled on/off. The period and zoom function follows the functionality of the temperature view.

8.6 The Alarm View

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 size the longer the alarm lasts.

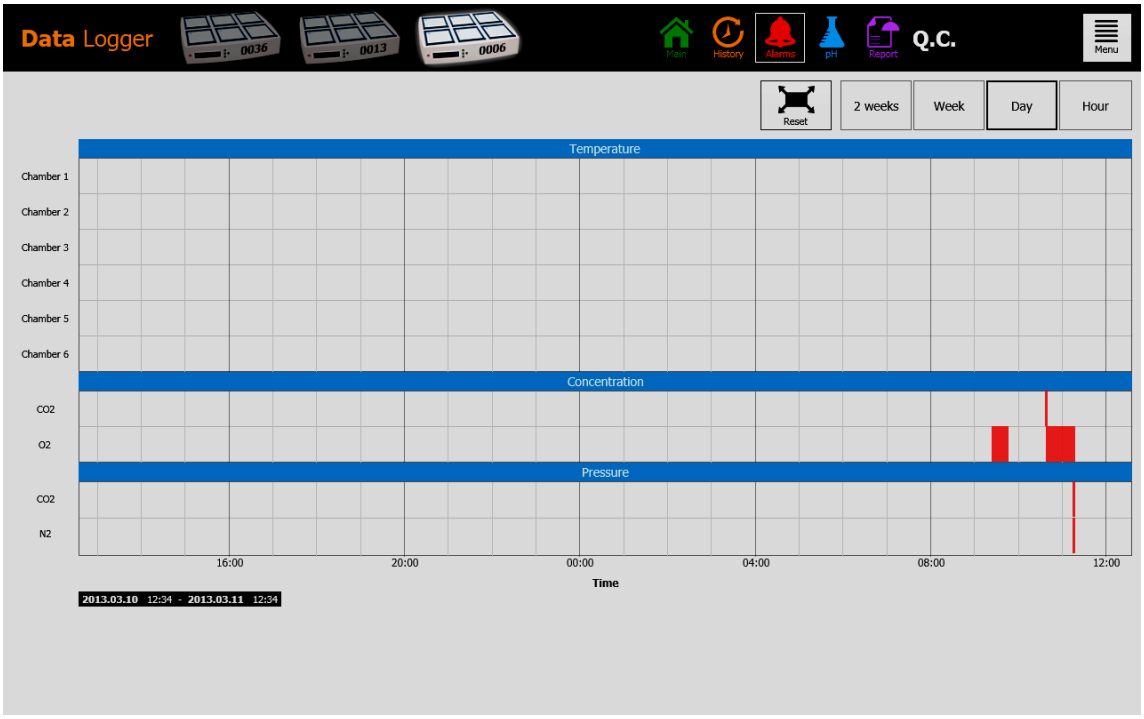


Figure 9. Alarm View

Blank or white space indicates that all conditions where OK.
In picture 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 follows the functionality of the temperature view.

8.7 The pH Measuring View (The functionality is not available in the US)

The MRI-6A10/XQ-1 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.

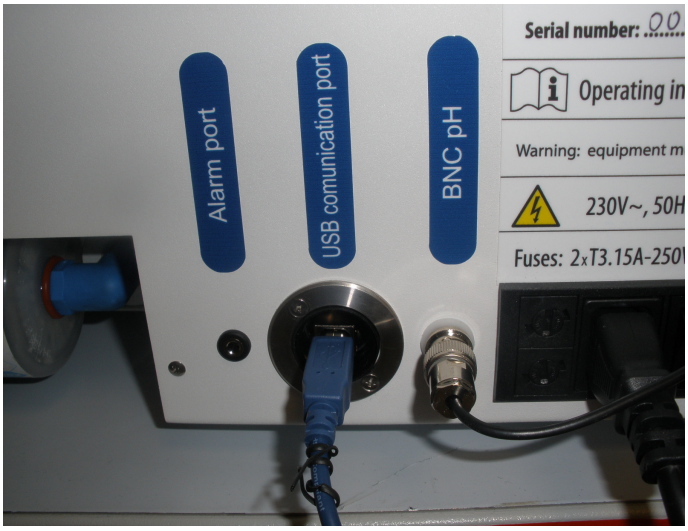


Figure 10. pH Probe Connected To the BNC

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

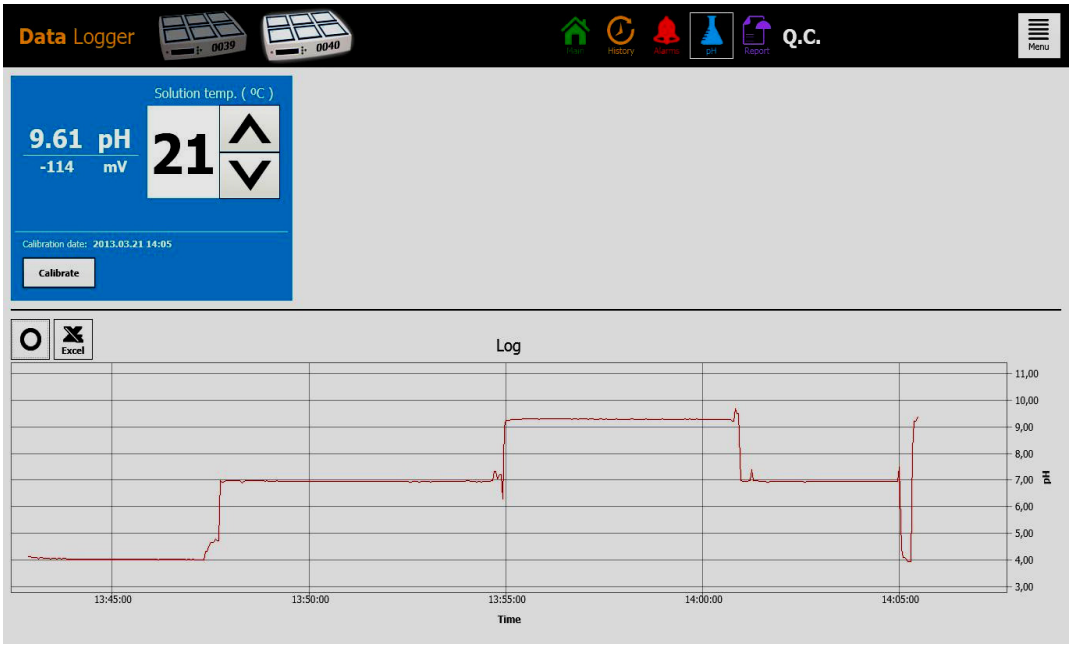


Figure 11. pH View

Temperature can be changed in one degree steps on 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.

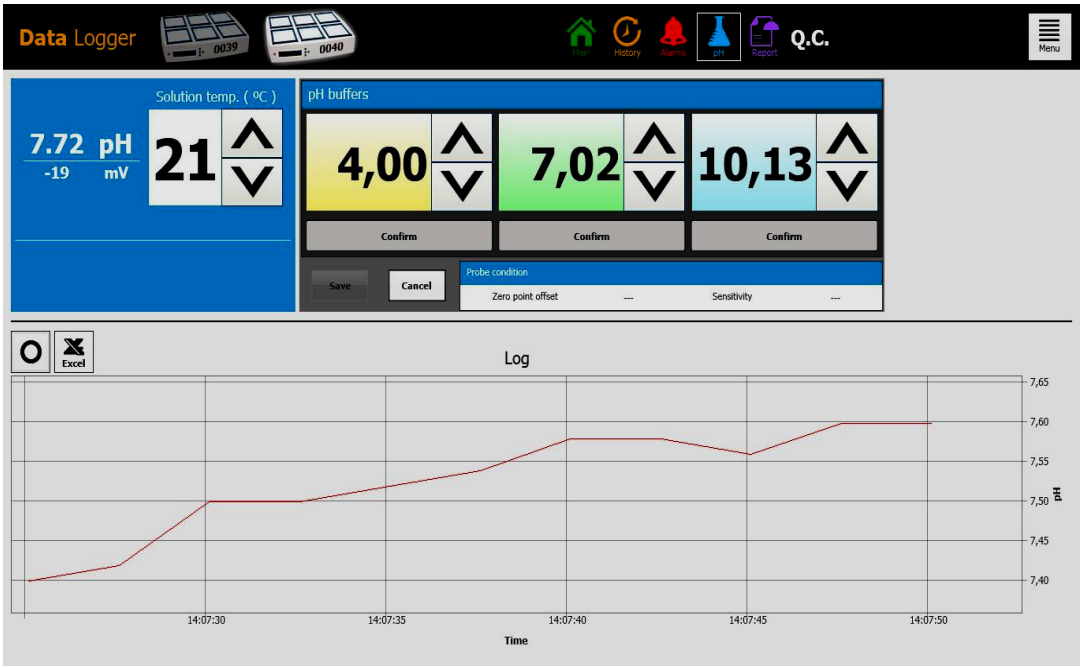


Figure 12. pH Calibration

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.**

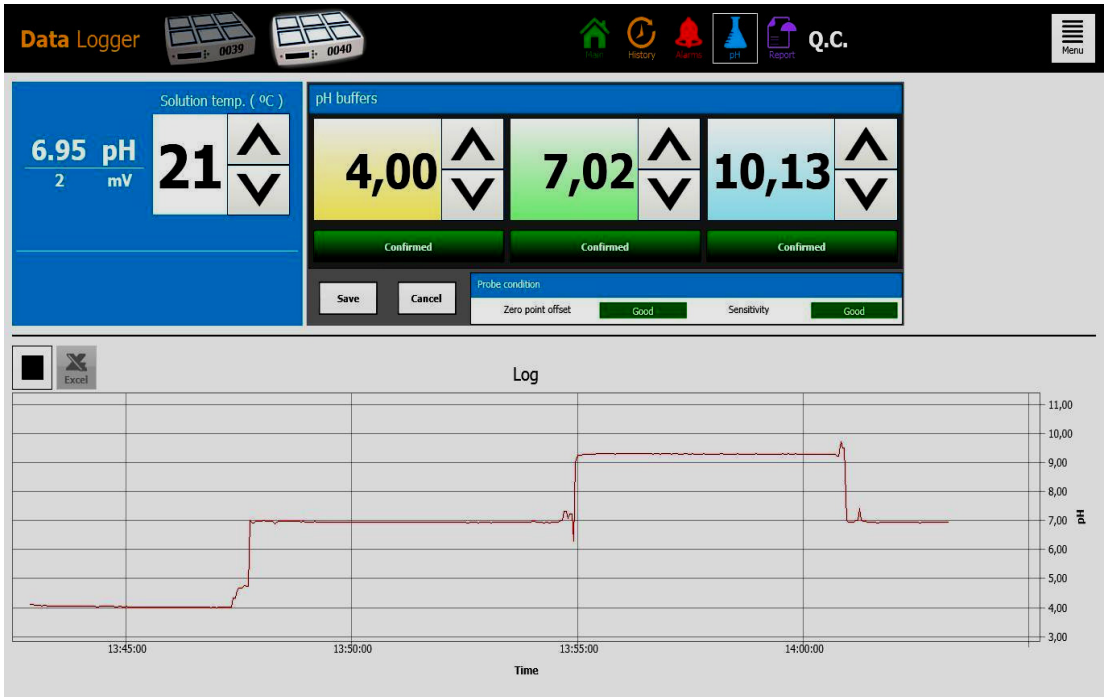


Figure 13. Calibration Confirmed

8.8 The Report View

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 patients details when their embryos have been incubated in the device. The function makes it possible to make retrospective analysis of the incubation parameters.

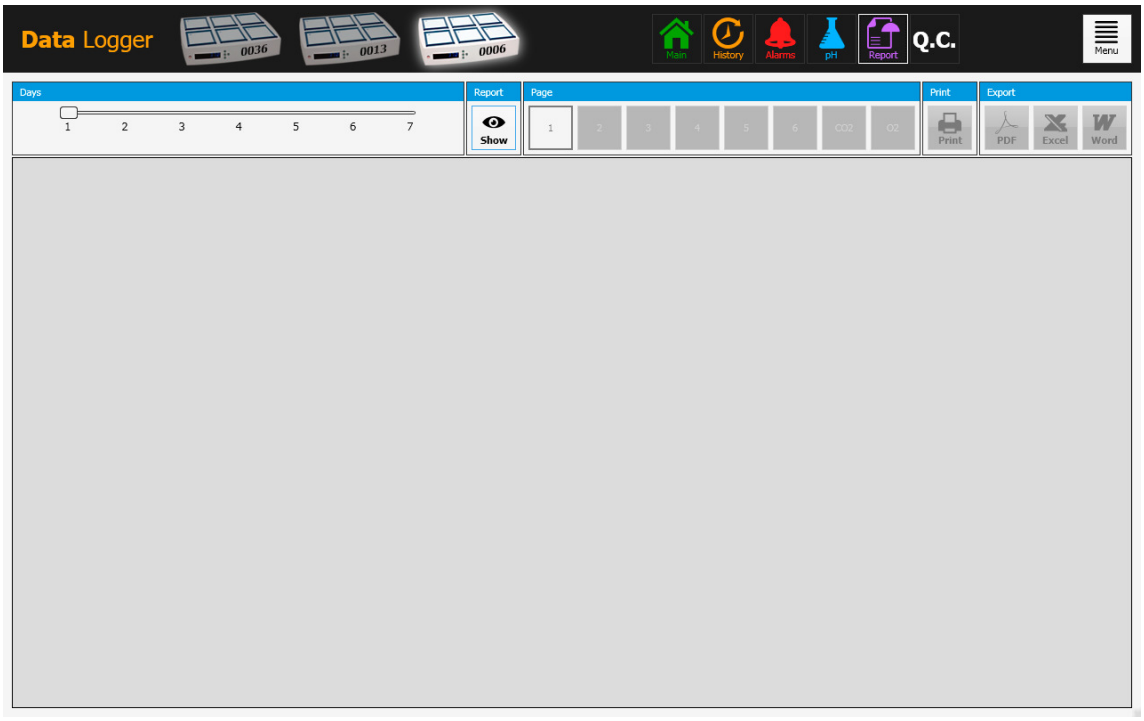


Figure 14. Report View

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 13.

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

Figure 15. Report Example

8.9 The QC View

A number of extra sensors is built into the MRI-6A10/XQ-1 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 analysed. This requires that the QC function is enabled on the device.

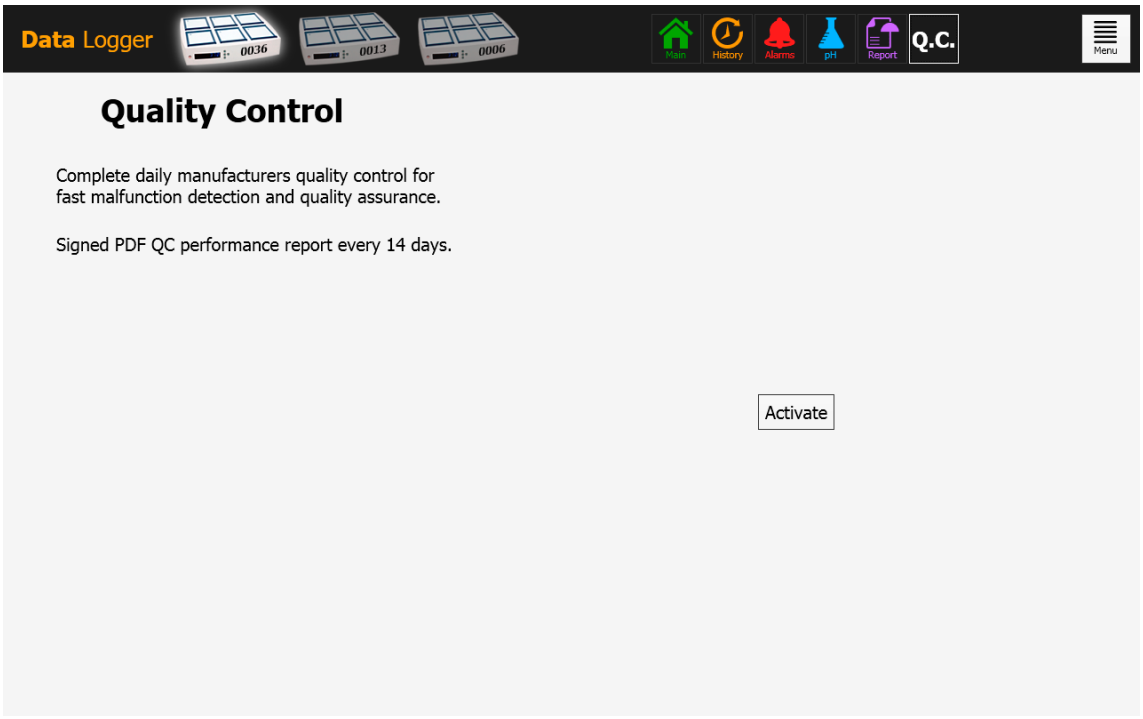


Figure 16. QC Control View

If that is done the factory will analyse 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.

8.10 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 will 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 an alarm condition.**

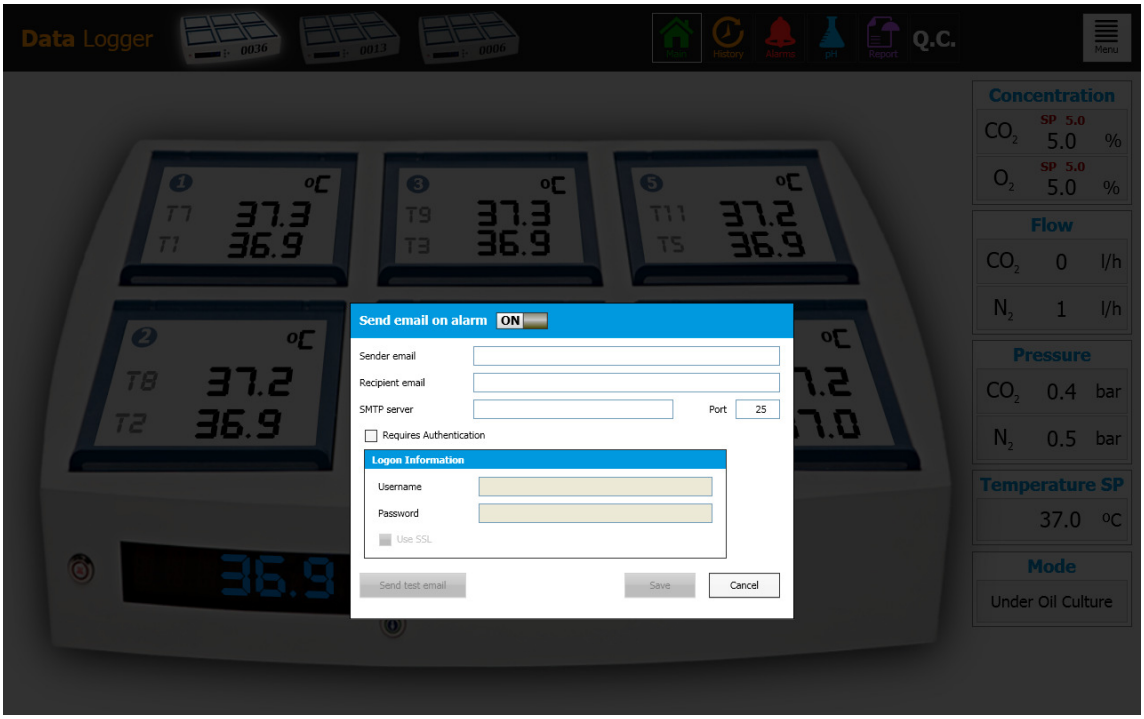


Figure 17. SMS Alarm Setup

Under the menu (shown in picture 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.

9 Technical Assistance

For more information, contact the ESCO MEDICAL– representative in your Country.

All goods and services are sold subject to the terms and conditions of sale of the company within ESCO MEDICAL which supplies them.

A copy of these terms and conditions is available only on request.

Contact your local ESCO MEDICAL representative for the most current information.

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