PBX Simple

Version: 1.0 (*Windows 10 compatible*)

Reference Guide – Manual

Version: 1.2

DIMS ID: D99684 (internal reference)

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About PBX Simple

PBX Simple is an effective solutions for self-powered PyroButton-X (PBX) data-logger temperature, humidity, and pressure measurements, including validation, mapping, monitoring, sterilization, and stability studies. This is a file version software, which means there is no database behind the software.

The PyroButton-Xs (PBXs) automatically measure and record temperature, relative humidity, and/or pressure at pre-defined intervals, usually between a few minutes, thereby providing valuable information relative to the requirements. They are typically placed into sterilizators, warehouses, processing facilities, incubators, stability chambers, autoclaves, freezers, refrigerators, cool rooms, delivery vehicles and anywhere else where temperature, relative humidity, and/or pressure dependent goods are processed, stored or shipped. PyroButton data-loggers are extremely robust and made to comply with 21 CFR Part 11 requirements. Their durable - hermetically sealed 305 stainless steel - construction make them the ideal product for "difficult" environments, where other data-loggers could not be used. Water, dirt, corrosive mediums are no match for the design of this product.

PBX Simple is designed to work simply and effectively with the PyroButton-Xs. PBX Simple can be used to:

- Configure (setup) one or more PyroButton-X simultaneously.
- Read/download the measurement data from one or more PyroButton-X(s).
- Display the readings in table and graph modes.
- Save the readings to file for later recall and long-term evaluation
- Reload the readings from file
- Export the results to Microsoft Excel and other programs for further evaluation

PBX Simple has been optimized for the simultaneous operation of large numbers of temperature/humidity/pressure logger devices. That is, one can configure not only one but even 100's (or more) of PyroButton-Xs in the same time, and view on the screen the results of multiple runs simultaneously. Data from the loggers are stored in a file and remain available for later use.

Note: For 21 CFR Part 11 compatible database version software go for PyroButton-SQL v4!

PBX Simple system consists of three integrated units:

- ***PyroButton-X (PBX) data-loggers****. These are calibrated & GMP compliant self-powered data-logging devices integrated with temperature or humidity or pressure sensors, and read/write memory,*
- ***iPBX-Net docking station.*** *It is a multi-logger read/write docking station with integrated software for positional assignment & recognition for 4- or 28- or 60--data-loggers with USB interface; - it is required for programming and data-download.*
- ***PBX Simple application*** *program, which integrates the above hardware and the various functions for temperature or humidity or pressure verification, validation, mapping, monitoring, and management of Facilities, Equipment, or Processes (e.g. EO sterilization).*

The data-loggers can communicate with the software through the USB interface. The devices are self-powered for wireless data logging. The integrated battery has a life expectancy of about 9 years, depending on the usage load. The user can define the data-acquisition parameters, such as resolution, delay, temperature trigger, rate of temperature recording, and the measurement interval.

Devices

Web catalog: http://www.pyrobutton.com/applications/catalog.asp

All PyroButton-X data-loggers are manufactured exclusively for Opulus Ltd., by PyroGroup Technology Kft., Fürj u. 92/B, EKO-Park, Szeged, 6726 Hungary.

PyroButton-Xs (PBXs) (

Figure 1) are the smallest cGMP compliant (calibrated & 21 CFR Part 11 compliant) data-loggers in the world: 17mm in diameter and 6-10mm height.

Figure 1

They are rugged, self-sufficient devices that measure temperature or temperature/humidity or pressure and record the result in a protected memory section. The recording is done at a user-defined rate, both as a direct storage of the measurement values as well as in the form of a histogram.
Every PyroButton-X is factory imprinted utilizing laser technology with a guaranteed unique 64-bit registration number that allows for absolute traceability. The durable stainless-steel package is highly resistant to environmental hazards such as dirt, moisture, and shock. Accessories permit the PyroButton to be mounted on almost any object, including people, equipment, containers, solutions, pallets, and bags.

		PyroButton-X family							
		PyroButton-Xi L (PBXi /L)	**PyroButton-Xi TH (PBXi /TH)**	**PyroButton-Xi THP (PBXi /THP)**	**PyroButton-XL (PBX/L)**	**PyroButton-XE (PBX/E)**	**PyroButton-XTH (PBX/TH)**	**PyroButton-XTHP (PBX/THP)**	**PyroButton-XPE (PBX/PE)**
		Intrinsically-safe Temperature Advanced Data-logger	**Intrinsically-safe** Temperature-Humidity Advanced Data-logger	**Intrinsically-safe** Temperature-Humidity-Pressure Advanced Data-logger	Temperature Advanced Data-logger		Temperature-Humidity Advanced Data-logger	Temperature-Humidity-Pressure Advanced Data-logger	Pressure-Temperature Advanced Data-logger
House Material		304 Stainless Steel							
Dimensions (diameter x height) [mm]		17 x 7.5							17 x 10.2
Weight with Battery		6.01 g	5.64 g	5.89 g	6.01 g	6.01 g	5.64 g	5.89 g	6.56 g
Ingress Protection (IP) rating		IP68							
Operational and functional temperature range [°C]		-20 … 85			-40 ... +85	0 ... +150	-40 ... +85		0 ... +150
Operational relative humidity range [%RH]		0 … 100							
Functional relative humidity range [%RH]		n/a	0 … 100	0 … 100	n/a		0 … 100		n/a
Operational pressure range [kPa]		1 ... 700							
Functional pressure range [kPa]		n/a		30 … 110	n/a			30 ... 110	1 … 700
Calibration/Verification memory size [kbytes]		16							
Data acquisition capacity [recorded data points]/property		119700	59800	29900	119700		59800	29900	59800
Sampling time		1s ... 24hours							
Mission start delay after elapsed time		Available							
Mission start upon temperature alarm point		Available							
Sensor resolution		Temperature: 0.0078 °C	Temperature: 0.025 °C Humidity: 0.04 %RH	Temperature: 0.005 °C Humidity: 0.008 %RH Pressure: 0.18 Pa	Temperature: 0.0078 °C		Temperature: 0.025 °C Humidity: 0.04 %RH	Temperature: 0.005 °C Humidity: 0.008 %RH Pressure: 0.18 Pa	Temperature: 0.015 °C Pressure: 120 Pa
Compatibility with ...	**SPB-Net** docking stations	**No**							
	iPBX-Net docking stations	**Yes**							
	PBC-TH18 calibrator	**via iPBX docking station**							
	PBC-TH28 calibrator	**Yes**							**No**
	PBC-THP28 calibrator	**Yes**							

Table 1 PyroButton-X Family Specification

Information expressed on intrinsically safe PyroButton-X data-logger's label:

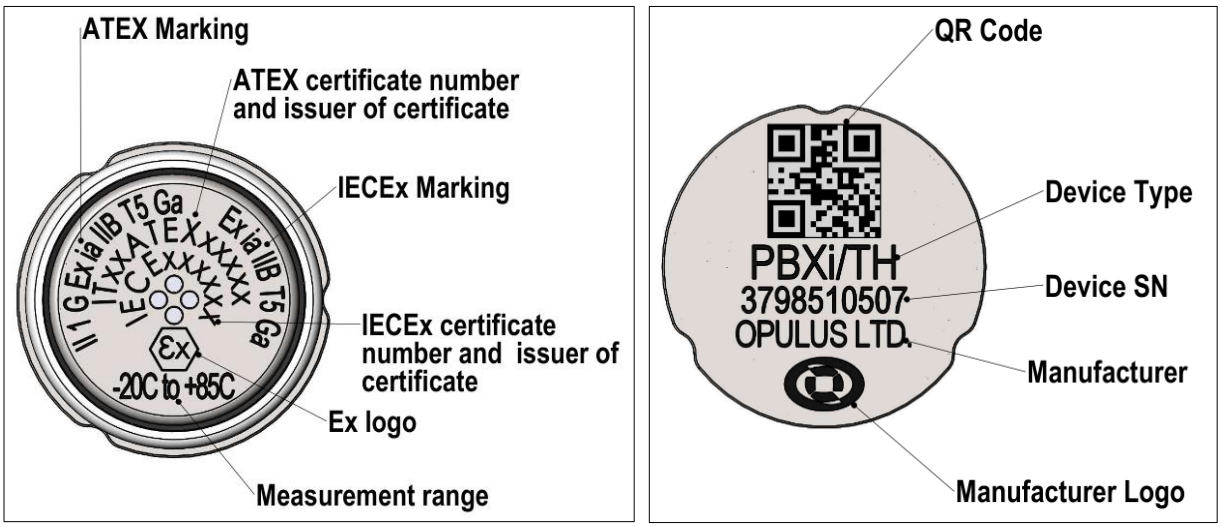


Figure 2

i*PBX-Net** is an intelligent and multi-function docking station for the synchronized parallel programming or data-download of 4- or 28- or 60- PyroButtons (Figure 3***).

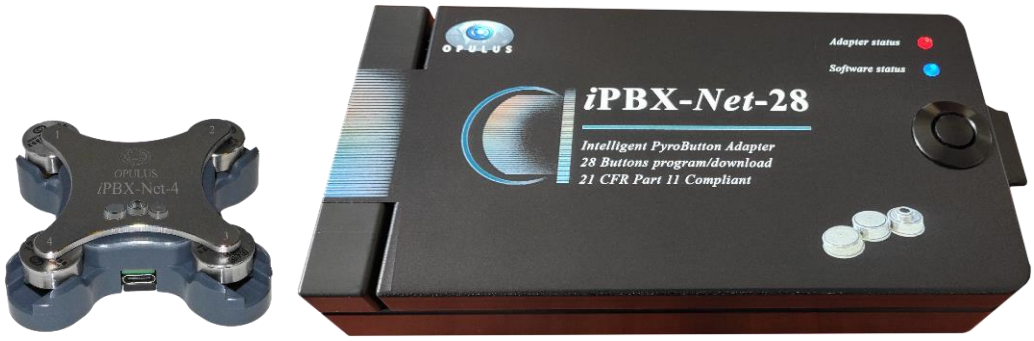


Figure 3

***i*PBX-Net-4** led statuses:

- Green – Default state, ready for software command
- Blue – A communication is in progress
- Red – An error occurred during the PyroButton reading
- Yellow – General warning

***i*PBX-Net-28** Adapter led statuses:

- Red - The docking station is open
- Blue - The docking station is in stand-by mode
- Yellow – A command is running (e.g. when reading a measurement, the blue and yellow colors flash alternately)

***i*PBX-Net-28** Software led statuses:

- Green – Default state, ready for software command
- Blue – A communication is in progress
- Red – An error occurred during the PyroButton reading
- Yellow – General warning

About this manual

This manual contains all of the information needed to achieve competence in the operation of the system.
The chapters contain step-by-step visual guide and user interface controls for the major functions.

Responsibility of the User Relative to Proper Use of the Product

By Proper Use of the Product we shall mean:

1. PyroButton data-loggers shall be used only in compliance with their corresponding specification.
    a. PyroButton data-loggers shall not be used beyond their corresponding specification range.
2. PyroButton data-loggers shall not be immersed into fluid without the necessary protective capsules:
    a. Use PyroPad for steam sterilization or liquid bath.
3. PyroButton data-loggers shall be used only with OPULUS certified software:
    a. An OPULUS software is certified if and only if it is identified by an OPULUS given serial number and registered within the required period.

Responsibility of the User Relative to Product Return for Corrective Action

Opulus will accept Hardware & Software return for Corrective Action from the end user provided the following conditions are met:

1. The return request for corrective action must occur within 60 days of the original Ship Date.
2. The product is directly supplied by OPULUS.
3. The product is eligible for return (see, exclusion below).
4. The return authorization is valid for a period of 30 days.
5. User shall comply with the request of OPULUS to provide support information for the meaningful inspection or examination of the returned product, such as database data.
6. OPULUS reserves the right to reject any return upon inspection.

Products NOT Eligible for Corrective Action Return

For Product return due to customer error, the following are NOT eligible for returns:

- Non-defective, Make-to-Order custom products.
- Parts flagged as non-returnable when ordered.
- Any product damaged or defective due to improper use or maintenance.

Dictionary

21 CFR Part 11 shall mean the US Food & Drug Administration regulation, which defines the requirements for the use of Electronic Records; Electronic Signatures relative to authentication, access, processing, and storage of electronic data. The regulatory rule for electronic records and electronic signatures are intended to make them equivalent of paper-based data sources and evidence systems. Key components include:

- Access control
- Data Security
- Audit trail of events and objects
- Archive & restore of data
- Machine & human readable format of data (e.g., XML).

Ambient Temperature shall mean the temperature of the surrounding environment.

Calibration is the process of measurement of a well defined property such as temperature or humidity by a validated methodology and validated procedure of a test object against an officially recognized reference object (e.g., NIST) to determine the conversion factors for the test object to ensure that the measurements by the test object are within the required specification.

Calibration Verification is the process of measurement of a well defined property such as temperature or humidity by a validated methodology and validated procedure of a test object against an officially recognized reference object (e.g., NIST) to determine that the measurements of the test object are within the required specification.

Data-acquisition shall mean the definition of the rate of measurement over time. High data-acquisition rate means frequent time intervals between measurements (e.g., PyroButton-L & T can be sampled at each second), whereas low data-acquisition rate means infrequent time intervals between measurements (e.g., PyroButton-L, -T, -E, or -TH can be sampled once every 1 sec. to 273 hr.). Sampling rate and data-acquisition rate can be used interchangeably.

Data-logger shall mean an electronic instrument (or specialized computing device in some cases) that records digital, analogue frequency or smart protocol based measurements over time.

Self-powered data-loggers are battery powered data-loggers equipped with microcontrollers, real-time clock, memory, Input/Output interface, and stored program.

Sensor based data-loggers include one or more embedded sensors within the data-logger for the recording of properties, such as temperature, humidity, light, gases, radiation, etc. over time.

21 CFR Part 11 compliant data-logger is a data-logger that supports the requirements for 21 CFR Part 11, including access control, audit trail, protection & verification of data, and output in XML data format to meet the requirements for machine & human readable format.

CGMP compliant data-logger is a 21 CFR Part 11 compliant data-logger, which also calibrated.

Default shall mean a default value or parameter. For example, default calibration factor(s) is set by the manufacturer.

Desktop Shortcut is a link created on a Windows desktop, which when selected by a pointer, will open the program that has been assigned to it.

Docking Station refer to ***i*PBX-Net.**

Dragging is a process of selecting an item on your desktop with your pointer and then while holding your pointer button, pulling said item to another location.

Exporting Data is to convert data from its resident file format into a generic form in order to make it readable by another program.

Icon is a link created on a Windows desktop from the EXE program install, that when selected by a pointer, will open the program that it has been assigned to.

A PyroButton may be **interfered** with if its reading interval is 15 seconds or less, and the measurement is running. The measurement of a PyroButton that has been interfered with must be stopped first before performing any other action, for example reading the measurement data.

***i*PBX-Net** (iPBX-Net-4, iPBX-Net-28 or iPBX-Net-60) is an intelligent and multi-function programmer and controller for the PyroButtons. It has been developed and it is manufactured by Opulus.

IQ or Installation Qualification shall mean establishing documentary evidence that installation of the PyroButton SQL system including, software, data-loggers, docking stations, adapters, and accessories were verified relative to the installation specification requirements of the manufacturer.

Mean, or Arithmetic Mean, or commonly called the Average is the sum of all scores divided by the number of scores.

Measurement Template sets of user defined measurement parameters. Templates can be quickly loaded during PyroButton measurement configuration. When it is loaded, sampling time, and other settings are used. It is practical to save the most commonly used configuration as Templates. (It can be done at the end of the Measurement Configuration Wizard.)

NIST shall mean the National Institute of Standards and Technology of the USA.

OQ or Operational Qualification shall mean establishing documentary evidence that operation of the PyroButton SQL system including, software, data-loggers, docking stations, adapters, and accessories were verified relative to the operational specification requirements of the manufacturer, if the IQ pre-requisite has been satisfied.

OOS or out of specification shall mean all suspect results that fall outside the specification or acceptance criteria established in new drug applications, official compendia, or by the manufacturer.

OOT or out of trend shall mean all suspect results that full outside the trend specification or acceptance criteria established in new drug applications, official compendia, or by the manufacturer

PQ or Performance Qualification shall mean establishing documentary evidence that performance of the PyroButton SQL system including, software, data-loggers, docking stations, adapters, and accessories are in a state of statistical control of the required OQ, if the OQ pre-requisite has been satisfied.

Protocol or Standard Operating Procedure shall mean a well defined set of requirements to be executed by a well defined procedure.

PyroButton is a self-powered CGMP compliant calibrated data-logger.

PyroButton SQL System is a 21 CFR Part 11 & CGMP compliant product, which includes PyroButton data-logger(s), docking station, and PyroButton application program for single workstation application

Raw Data shall mean the data, which has not been corrected relative to the calibration curve.

Resolution is the number of changes that can be determined in a given interval. In the case of data-loggers, it is the number of bits used to record the value of a sample in a digitized signal.

Sampling Time is the increment in which the data PyroButton will take a reading.

Sensor is the device that detects and measures a specific property (e.g., temperature, humidity, pressure etc.)

SOP or Standard Operating Procedure shall mean a well-defined set of requirements to be executed by a well-defined procedure.

Standard Deviation of a probability distribution is defined as the square root of the variance.

Start Delay is a feature that allows a PyroButton to have it started at a future time/date.

Templates: refer to Measurement Templates.

Traceability: Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

Uncertainty of Measurement of a result of the measured property consists of several components, which may be grouped into 2 categories:

- Uncertainty arising from random effect, and
- Uncertainty arising from a systematic effect.

Basic to the approach is representing each component of uncertainty that contributes to the uncertainty of a measurement result by an estimated standard deviation, termed standard uncertainty.

Universal Serial Bus (USB) is a serial bus standard adapter to interface devices, such as the docking station to a computer.

Variance shall mean the statistical dispersion of data of an expected value of a given probability distribution.

NOTE: The variance is computed as the average squared deviation of each number from its mean.

Zooming/ Unzooming data: By holding the Shift key and the left mouse button down on your pointing device over an opened graph, one can select portions of graphed data to expand. Zooming is done by pulling your pointer over the area you wish to expand and then releasing the mouse pointer. To return to the original status hold Shift and double click with the left mouse button.

Before you start

Before commencing to install PBX Simple, you should ensure the following,

a) That installation of PBX Simple will conform to your prevailing Standard Operating Procedure(s) concerning the installation of new software packages.

b) To install PBX Simple you must have administrative or equivalent privileges on the target computer.

If for any reason you have trouble or are in doubt concerning any aspect of the installation procedures described in this manual, contact your Computer System Administrator for assistance.

System requirements

To successfully install PBX Simple onto your computer, ensure that your system meets the following recommended requirements:

- Intel(R) Core i3 CPU
- 2 GB RAM
- 1 GB free hard disk space
- Windows 10 operating system
- 1680x1050 display resolution, High Color

What is in the PBX Simple package?

Usually, the package includes PyroButton-X data-loggers, *i*PBX-Net docking station, PBX Simple Installation CD with Certificate(s) of Calibration (CoC) or the CoC received in e-mail. The PBX Simple Installation CD or Downloaded package also include the User Manual and an eTutorial.

Preparing Your Hardware To Use

1. Connect an appropriate adapter (*i*PBX-Net docking station) to a free USB communication port of the computer (***Figure 4***).

Figure 4

2. Verify that the cable is securely fastened, then place the PyroButton(s) into the receptor(s) (***Figure 5***).

Note: Always hold the PyroButton horizontally (don't tilt in either direction) while inserting it into the iPBX-Net-4 adapter. Press the PyroButton until it stops.

Figure 5

The system is now ready for data down load (read) and/or programming upload (write) operation(s).

PBX Simple Short Tutorial

Setup

1. Install the **PBX Simple** program.
2. Connect the ***i*PBX-Net docking station** to a spare USB communication port.
3. Place the licensed **PyroButton-X(s)** into its place into the receptor(s) of the adapter.

Starting PBX-Simple

1. Double click **PBX Simple** icon. The Login screen appears.
2. Select the **Adm (Administrator)** user, enter the password (by default: 123456), and click the OK button. The Main screen appears.

Manage Users

1. Click the **Add-ins/Manage users** icon to modify the Administrator password (make a note on a secure place).
2. Add a **New user** if more than one person is using the software (it needs Administrator login)
3. **Change** New user password (each user can only change their own password).
4. Click **OK** button.

Configuring a Measurement

1. Click the **Read Docking Station** button on the Home screen.
2. **Select the PBX Logger(s)** to be programmed.
3. Click the **Start Measurement** button. The PBX mission Configuration Wizard appears.
4. Set PBX Mission Parameters
5. On the **Start Mission** page, save the configuration as a template (**Save as Template** button) (optional) and/or click **Start Mission**. The PyroButton-Xs are configured now and the measurement is started according to the above definition (follow the instructions on the screen).

Download Measurement Data from a PyroButton-X

1. Reconnect the PyroButton to the computer via iPBX-Net adapter.
2. Click **Read Docking Station** button
3. In the **PBX in Docking Station table**, select the PyroButton-X(s) to be stopped or downloaded from the list
4. If the measurement is still running, but you want to terminate it, click **Stop PBXs** button and confirm the stop.
5. If the measurement has been finished, click the **Download PBX Data** button. The PBX Measurement Data page appears (the measurement file will be saved to **c:\Users\Public\Documents\PBS MeasData** folder)
6. Evaluate the measurement result data on the **PBX Measurement Data** page.

PBX Simple Installation

The install wizard will guide you through PBX Simple installation. It is recommended, that a competent system administrator executes the procedure.

Insert the PBX Simple install CD in the CD drive of the PC. The installer will auto-start (***Figure 6***). If the auto start option is disabled on the PC, then start the OpAutoStart.exe program manually from Windows Explorer. If the installer has been downloaded from the Opulus website, click on the OpAutoStart.exe manually. The Opulus PBX Simple Installer starts.

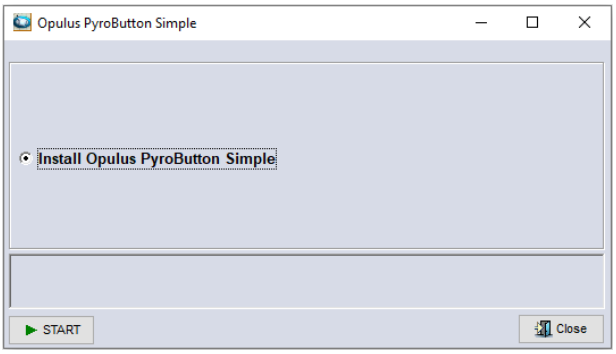


Figure 6

Click **Start**.

Figure 7

Click **Next**.

Figure 8

The information displayed should be printed.
Accept the terms of the license agreement and click **Next**.

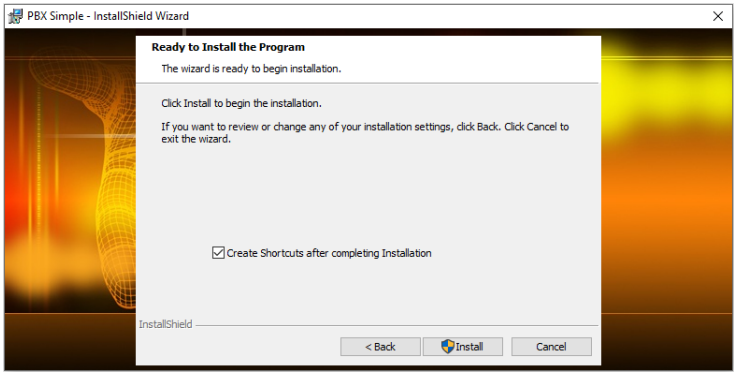


Figure 9

Check Create Shortcuts checkbox and click **Install**.

Figure 10

Click **Finish**.

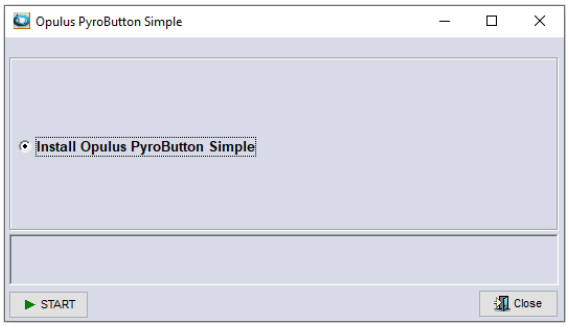


Figure 11

Click **Close**.

PBX Simple Uninstallation

Click on **Start/Settings/Apps**, then find and select **Opulus PBX Simple** from the list of programs and click on it and click **uninstall**. This will start the uninstallation of PBX Simple.

Starting the Software

To launch the program, double click **PBX Simple icon** on the desktop or click on the 'Start' > 'OPULUS' > 'PBX Simple' in the Start menu.

Upon starting the software the Login screen will be displayed (***Figure 12***).

Figure 12

The default user (Adm) will be loaded into the User field and the appropriate password must be entered (by default it is 123456). Click **OK.**

First Time Use – User Manager

Modify Administrator password

NOTE: After first login the Administrator password should be modified.

1. Click the **Add-ins/Manage users** icon to modify the Administrator password (make a note on a secure place).

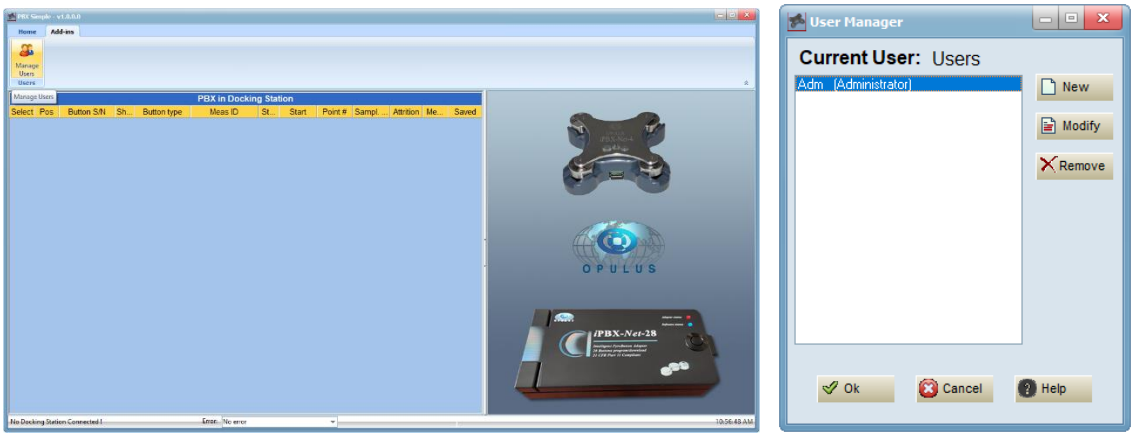


Figure 13

2. Click **Modify** button to modify a user data. The **User Data/Modify user data** page appears with entry fields.

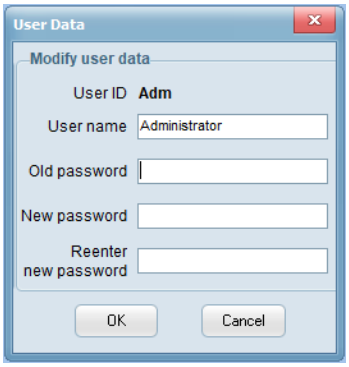


Figure 14

3. Change Administrator password. Both the old password and the two instances of the new password must be supplied.

   NOTE: Make a note and keep it secured.

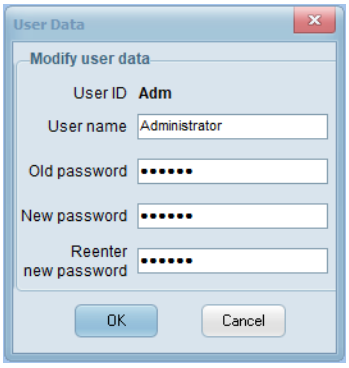


Figure 15

4. Click **OK** button.

Add new user

Add a **New user** if more than one person is using the software.

NOTE: You must be an Administrator (it needs Administrator login) to create a new account!

1. Click **New** button to add a new user. The User data page appears with entry fields.

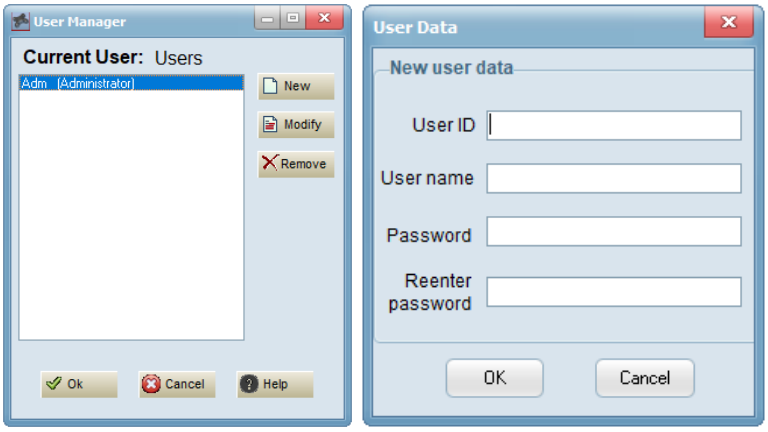


Figure 16

2. Specify user data in the appropriate fields, as follows:
   - **User ID**: unique identifier of the user.
   - **User name**: the name of the user. It will be displayed in the 'User name' drop-down list at program login.

- **Password and Reenter password**: enter the two instances of the new password in both the appropriate fields. After login the new user can change their own password!

3. Click **OK**.

Main Toolbar and Status Bar

The main screen appears (***Figure 17***) when the user successfully logged in.

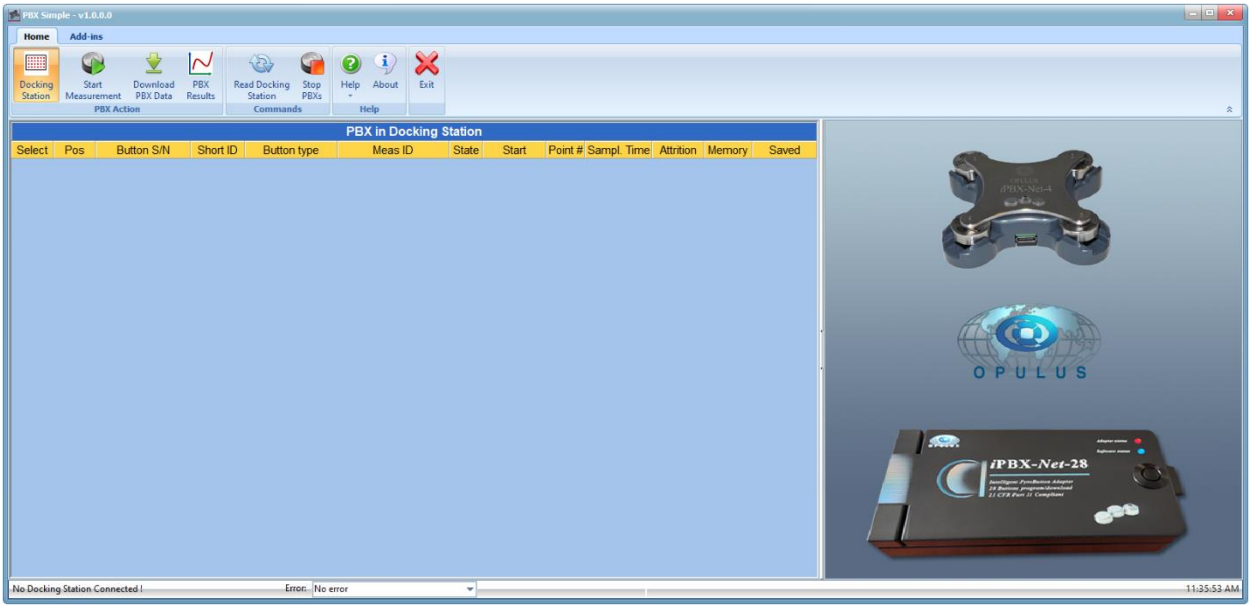


Figure 17

Header caption

At the very top of the screen, the name and version of the application is displayed.

The Main Toolbar

The Main Toolbar is below the caption, with the following elements:

Home

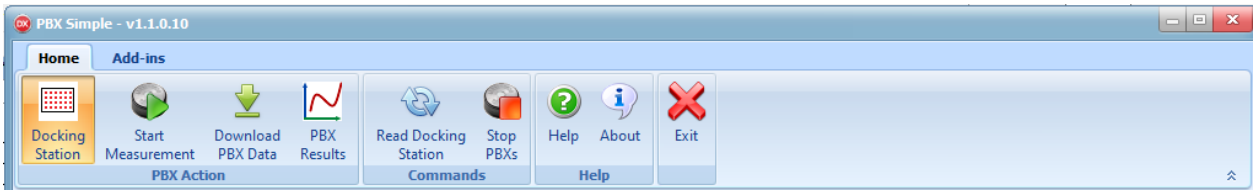


Figure 18

Docking Station: Checks connected Loggers, and lists relevant information needs for programming and downloading measurement data.
Start Measurement: Starts the Measurement Configuration Wizard. PyroButtons can be configured for a new measurement mission with this wizard.
Download PBX Data: Click this button if you want to download the measurement data from PyroButton(s). This feature will read the memory of all the selected PyroButtons, and saves into file automatically (file location: **c:\Users\Public\Documents\PBS MeasData** folder).
PBX Results: View measurement results and perform actions.
NOTE: When you press the PBX Results button, a graph appears only if there was a download in that session, and only the most recent download is displayed, regardless of which button is checked in the docking station field.
Read Docking Station: Re-checks all connected PyroButtons. Click this button, any time, to update the list.
Stop PBXs: Stops the running measurements.

Help: Displays help.
About: Displays the About screen, which provides software version and copyright information.

Exit: closes the application.

Add-ins

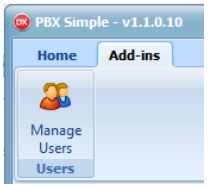


Figure 19

Manage Users: Starts the User Manager module. New user can be added, an existing user can be removed or passwords can be modified.

Status bar

Figure 20

Docking Station information: It can be connected and not connected. if a docking station is connected, the serial number will also be displayed.

Error: If an error occurs during communication, the nature of the error is displayed. if more than one error has occurred since the program started, all errors can be viewed using the Error drop-down window.

Operations with PyroButtons

Docking Station

NOTE: Only connected PyroButtons can be listed here!

*i*PBX-Net docking station is a special device, capable of identify the inserted PyroButtons' serial number and short ID. To correctly use the *i*PBX-Net docking station, the PyroButtons must be inserted or removed with the use of any *i*PBX-Net docking station compatible Opulus software. The software manages the information provided by the docking station.

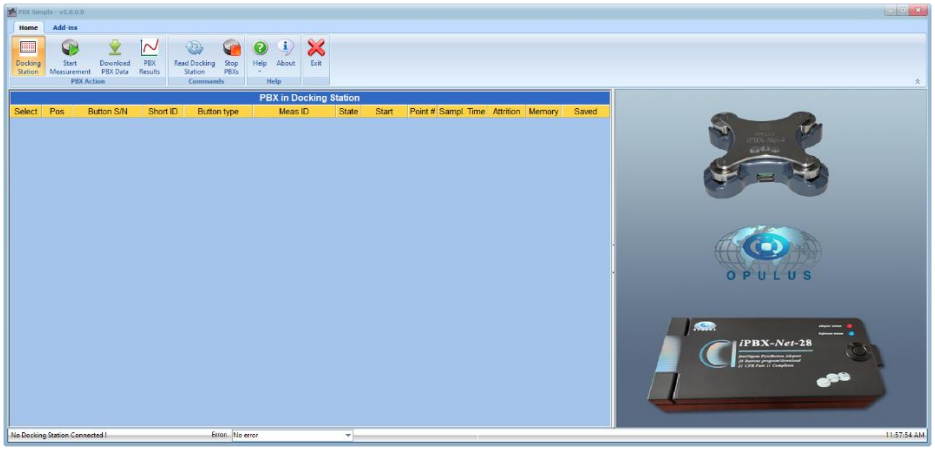


Figure 21

1. Connect the PyroButtons to the PC via the *i*PBX-Net docking station.
2. Click the **Read Docking Station** button on the Home screen. The software communicates with the connected docking station and retrieve the data of the inserted PyroButtons.

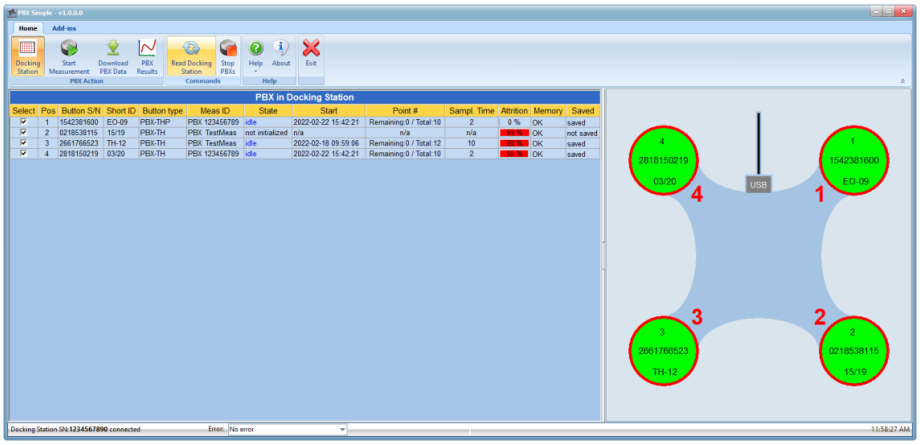


Figure 22

PBX in Docking Station Table

PBX in Docking Station												
Select	Pos	Button S/N	Short ID	Button type	Meas ID	State	Start	Point #	Sampl. Time	Attrition	Memory	Saved
☑	1	1329562079	05/20	PBX-TH	Test meas 20220215	idle	2022-02-16 08:23:46	Remaining:0 / Total:10	1	97 %	OK	saved
☑	2	0218538115	15/19	PBX-TH	PBX TestMeas	not initialized	n/a	n/a	n/a	99 %	OK	not saved
☑	3	2661766523	TH-12	PBX-TH	PBX TestMeas	idle	2022-02-18 09:59:06	Remaining:0 / Total:12	10	98 %	OK	saved
☑	4	2818150219	03/20	PBX-TH	PBX 123456789	idle	2022-02-22 15:42:21	Remaining:0 / Total:10	2	95 %	OK	saved

Figure 23

The list contains all PyroButtons that are connected.

Available columns:

Select: the selected state of the PyroButton. (The PyroButtons to be Configure, Stop, and Read & Save can be selected by selecting the checkbox in the leftmost column.)
Pos.: the PyroButtons' position in the docking station.
Button S/N: the serial number of the PyroButton.
Short ID: the short ID of the PyroButton.
Button Type: the type of the PyroButton.
Meas ID: a unique identifier of the measurement. The measurement ID is entered in the **PBX Mission Configuration - Set PBX Mission Parameters** step.
State: the measurement state of the PyroButton.

Statuses:

- 'Idle' (The PyroButton is not being used. It is a passive state, waiting for action.)
- 'running' (The measurement is in progress.)
- 'ended' (The measurement ended according to the programming.)
- 'stopped by user' (The measurement was aborted by the user.)
- 'stopped due to low battery voltage' (The measurement process was interrupted because the battery charge had reached a critically low level.)

Start: the latest start time of the PyroButton.
Point #: the number of Remaining points / Total points are visible.
Sampl. Time: the latest sampling time of the PyroButton.
Attrition: the attrition of the PyroButton. (It is an estimation of the current attrition of the battery, based on the number of readings.)
Memory: memory state of the PyroButton. The program reads the memory of all connected PyroButtons, and checks their consistency.

Statuses:

- 'OK' (The PyroButton memory is filled with the data needed to operate it.)
- 'Error' (The PyroButton memory is not filled with the data needed to operate it.)
- 'No memory' (The PyroButton has no memory or the memory is corrupted)

NOTE: Move the mouse cursor over a memory cell. The calibration states in a hint are displayed

- 'Valid Calibrations:' (Which parameter has a valid calibration is displayed. It can be Temperature, Humidity, Pressure, Concentration, Permeability)
- 'No Valid Calibration' (There is no valid calibration.)

Saved: the measurement state of the PyroButton.

Statuses:

- 'saved' (The measurements in the PyroButton have already been read out and saved into a file.)
- 'not saved' (Measurements in the PyroButton have not yet been saved to the database.)

NOTE: Double-click on a row to display its data (for detailed information, see **PBX Info** topic).

Table - Popup menu items (right mouse click)

Select all: selects all selectable PyroButtons in the list.
Unselect all: clears all the selection.
Toggle selection: Inverse the current selection.
Edit Short ID: The PyroButton's short ID can be changed.

NOTE: Before clicking with the right mouse button, first click on the row of the button whose short ID you want to change.

Graphical representation of the Docking Station

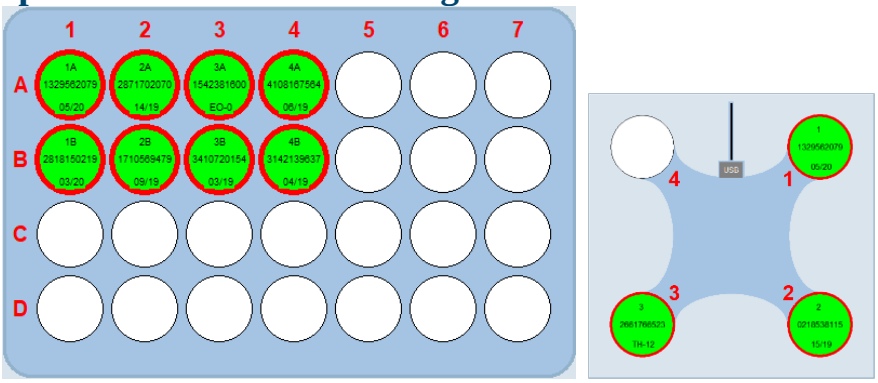


Figure 24

The image represents the docking station with the 4, 28 or 60 positions. The positions with white circles are empty, unoccupied positions. The loaded PyroButton data-loggers are shown by colored circles.

Operation:

- Move the mouse over to a non-empty well position to get SN and/or short ID information.

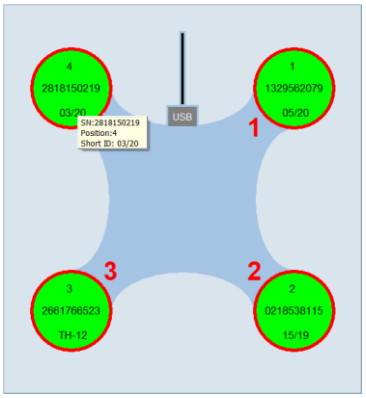


Figure 25

- Single click to select or unselect the PyroButton. This selection also affects the selection that can be made in the PBX in Docking Station table (and vice versa).
- The selected PyroButtons are circled with red.
- Double click to the well position for PyroButton properties and calibration information (for detailed information, see PBX Info topic).

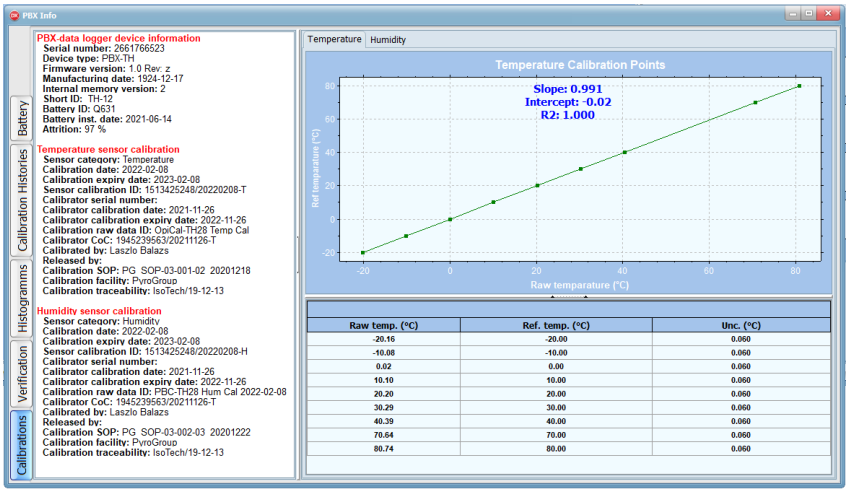


Figure 26

Start Measurement

PBX Mission Configuration

PyroButtons can be configured for a new measurement mission with this wizard. Connect the PyroButtons and select the ones, which are to be programmed, then follow the on-screen instructions to set up the configuration parameters.

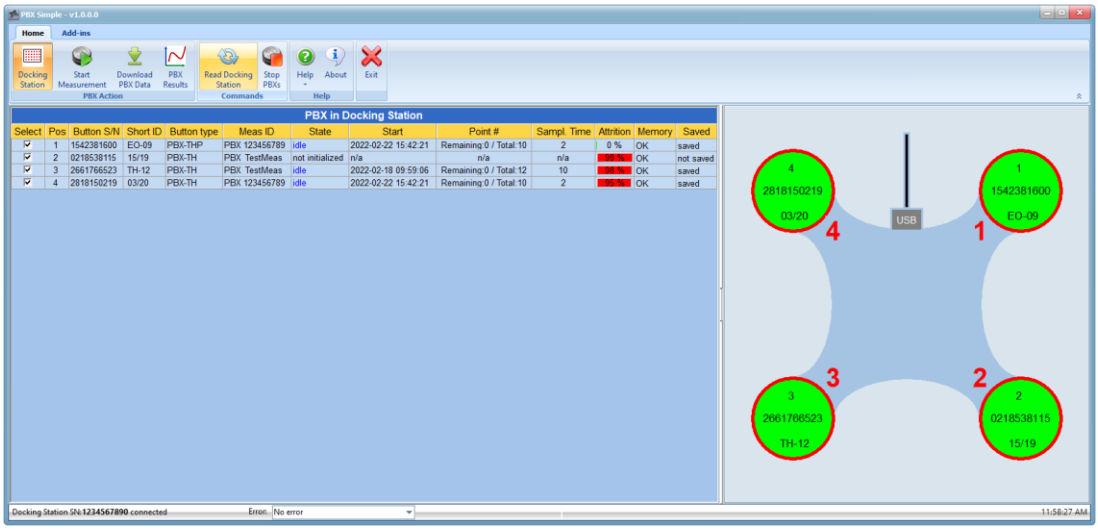


Figure 27

Click **Start Measurement** button.

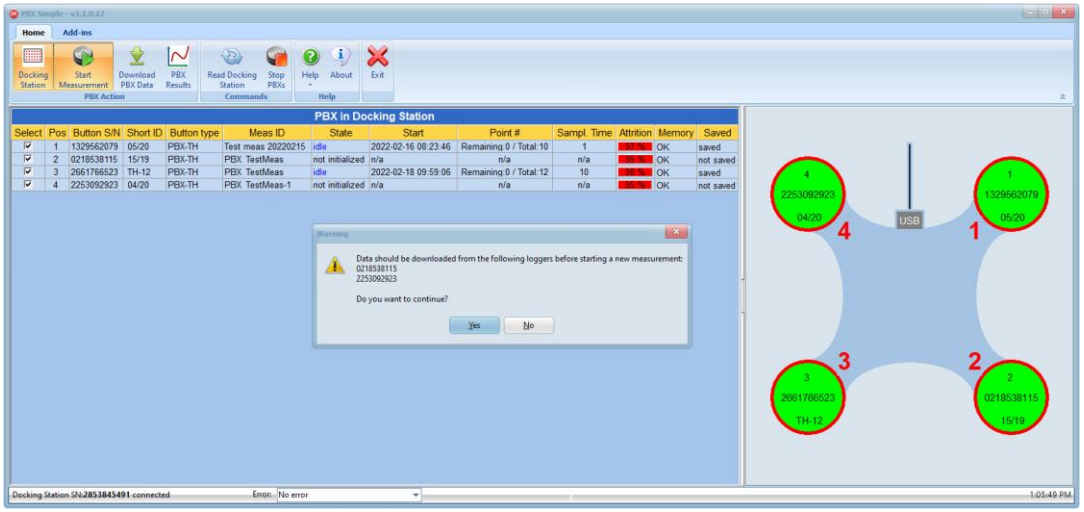


Figure 28

Before PyroButton programming begins, the program checks to see if any of the data loggers you want to program have any previous measurements that have not been saved (the status of the Saved column is '**not saved**') (***Figure 28***).

- If you want to save measurement data, click **No** button. To download data, select the PyroButton(s) for which you want to download the measurement data and click **Download PBX Data** button (the measurement data download starts automatically).
  NOTE: The download folder is **c:\Users\Public\Documents\PBS MeasData\.**

- If you do not want to download the indicated measurement data, click **Yes** button. In this case the programming starts. The PBX mission configuration page appears.

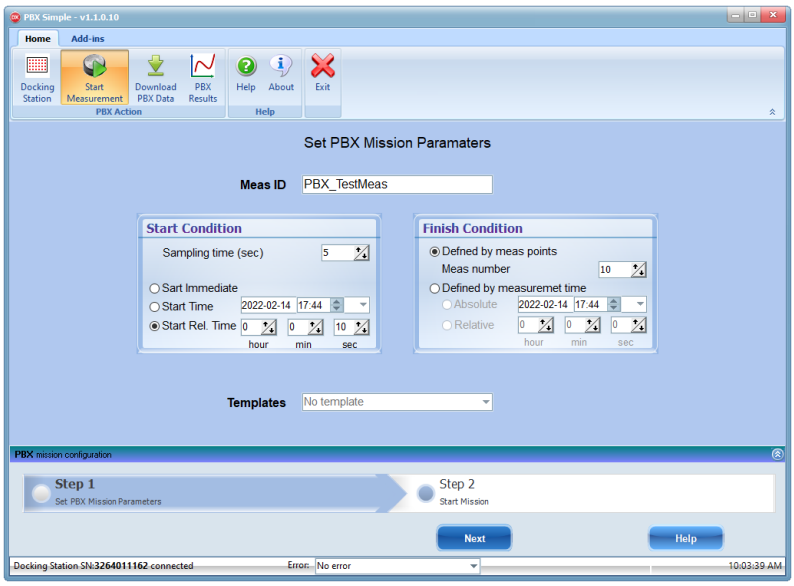


Figure 29

Set PBX Mission Parameters

Meas ID: a unique identifier of the measurement. This is a free text field where any text can be entered, but it is a good idea to enter a text that makes it easier to identify measurements later (e.g. Cold_Room_Temperature_Mapping-20220215). Maximum length is 40 characters.

Templates: parameter values can be downloaded from a previously saved Template (via the template Selection dialog). The loaded parameters can be changed!

Start Condition

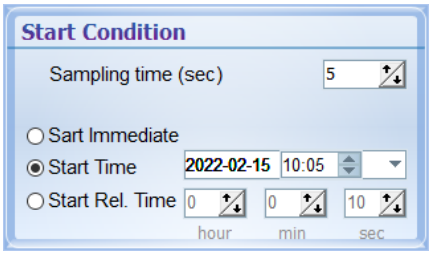


Figure 30

Sampling Time (sec): set the time interval between two readings.

Tip: a too long of Sampling Time may result in missed measurement data. It can also mean that critical changes will not be accurately measured because the preceding and succeeding readings were too far apart. Too short Sampling Time decreases the lifetime of the PyroButton.

Start Immediate: measurement will start immediately when the configuration is uploaded to the PyroButton.

WARNING: It is NOT recommended to configure more than 1 PyroButton with Immediate start, as the readings will not be synchronized. When the Immediate option is selected, every PyroButtons will start its measurement immediately when its configuration is completed. As the configuration process takes some time, e.g. 1-2 seconds, the overall effect will be, that the readings of the PyroButtons will be shifted with the same seconds. For example, 2 PyroButtons are configured at 10:00:00 with 1 minute reading intervals. If the Immediate start is selected, then the first PyroButton will read the temperature at 10:00:00, 10:01:00, 10:02:00 etc. The configuration of the second PyroButton is completed 2 seconds after the first one, therefore it will read the temperature at 10:00:02, 10:01:02, 10:02:02 etc. However if the Relative or the Absolute start is selected (with 2 minutes start delay), then both PyroButtons will read at 10:02:00, 10:03:00, 10:04:00 (i.e., at the same time).

Start Time: select this option if you want the measurement to be started on a pre-defined date and time. Enter the specific measurement start date & time. Use the calendar to select the date.

Start Rel. Time: select this option if you want to specify the amount of time for the delay before starting a Measurement. Set the number of Hours, Minutes, and

Seconds for the delay. The PyroButton will wait the specified time before recording data.

Absolute and Relative features make it possible to preprogram the PyroButton without impacting on the results. For example, the PyroButton could be setup in the office and then taken to a site during the day. In this case, for example, a 12 hours delay would provide sufficient time for the PyroButton to be installed. After 12 hours of the time of programming, the measurement would start.

Finish Condition

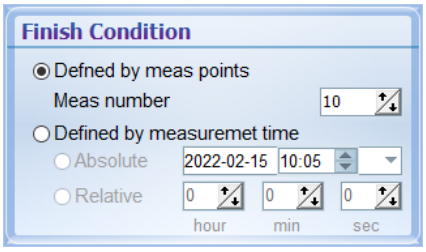


Figure 31

Defined by meas points: add the number of measurement points. If this option is selected, then the length of the measurement will be determined by the product of the sampling time and the measurement points (e.g. if the reading interval is 10 sec., and the number of measurement points are 10, then the measurement will last for 100 sec.).

Defined by measurement time
Absolute: add the exact length of the measurement in absolute time (date and time). The last measurement will be made at the specified hour and minute of the specified day. If the PyroButton max. capacity is less than the defined length of the measurement, then the measurement will determined by the max. capacity.
Relative: add the exact length of the measurement in relative time (hour, min. and sec.). The last measurement will be made at the specified relative time.

Menu buttons

Next: turns the page forward.

NOTE: if you want to abort configuration and close the wizard click any menu button.

Start Mission

The PyroButton measurement configuration (i.e., sampling time and start and stop time set-up) is complete.

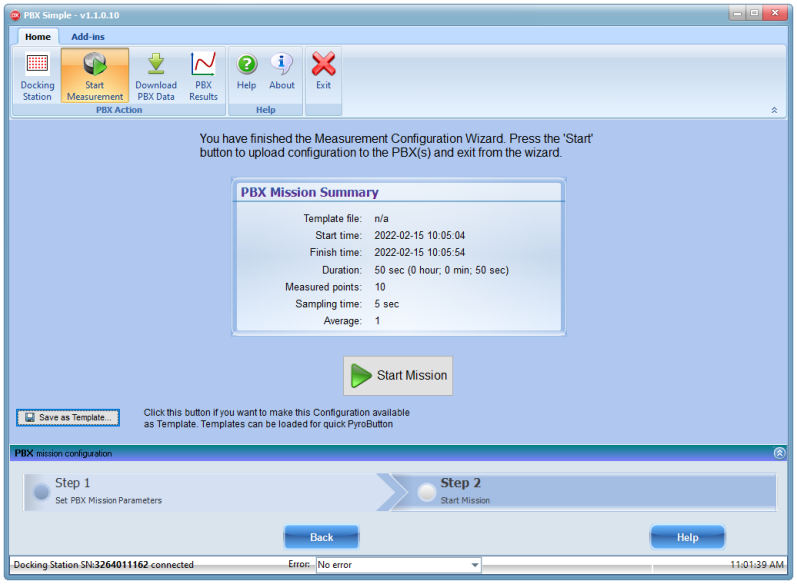


Figure 32

PBX Mission Summary: displays a report of the measurement configuration settings.

Save as Template: click this button to save the measurement configuration in the c:\Users\Public\Documents\PBS MeasData folder as a new Template. Templates can be loaded for quick PyroButton configuration.

Start: click this button to write the settings into the PyroButton, and start the measurement mission.

Menu buttons

Back: turns the page backward.
Exit: click this button to leave the Configuration Wizard without programming the PyroButtons.

NOTE: The PyroButton time is set to the PC time (UTC) each time a mission is started.
After programming, click **Start Mission** button.

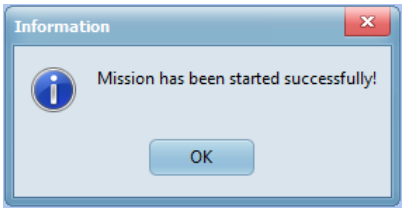


Figure 33

Click **OK**.

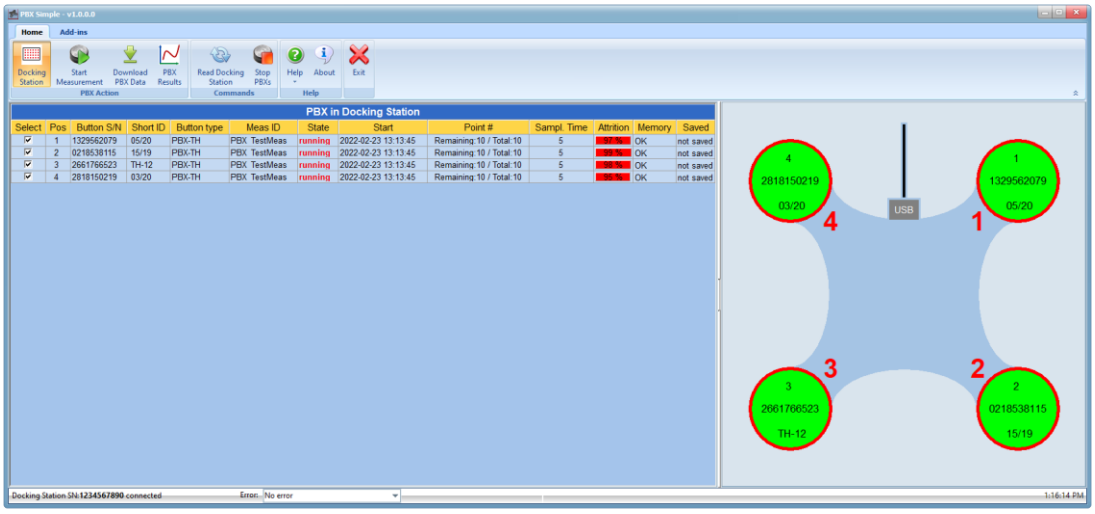


Figure 34

After starting the PyroButton missions, the Measurement **State** changes to running. The **Start** time shows the programmed one. The Points column displays the remaining and total points.

After programming, you can take out the PyroButtons from the docking station and place it at the measurement site. At the end of the measurement insert the PyroButtons to the docking station and click **Read Docking Station** button.

When you click the **Read Docking Station** button, the values change according to the current state of the measurements (if the PyroButton is connected!).

Stop Measurement

If the measurement is still running, but you want to terminate it, click **Stop PBXs** and confirm the stop.

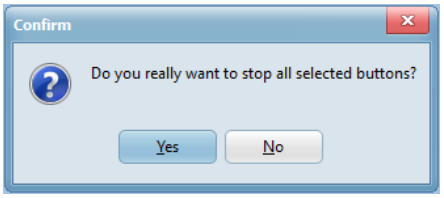


Figure 35

The Measurement **State** changes from running to 'stopped by user'.

PBX in Docking Station

Select	Pos	Button S/N	Short ID	Button type	Meas ID	State	Start	Point #	Sampl. Time	Attrition	Memory	Saved
☑	1	1329562079	05/20	PBX-TH	PBX TestMeas	stopped by user	2022-02-23 13:27:09	Remaining:0 / Total:4	5	97 %	OK	not saved
☑	2	0218538115	15/19	PBX-TH	PBX TestMeas	stopped by user	2022-02-23 13:27:09	Remaining:0 / Total:4	5	99 %	OK	not saved
☑	3	2661766523	TH-12	PBX-TH	PBX TestMeas	stopped by user	2022-02-23 13:27:09	Remaining:0 / Total:4	5	98 %	OK	not saved
☑	4	2818150219	03/20	PBX-TH	PBX TestMeas	stopped by user	2022-02-23 13:27:09	Remaining:0 / Total:4	5	95 %	OK	not saved

Figure 36

Download Measurement Data

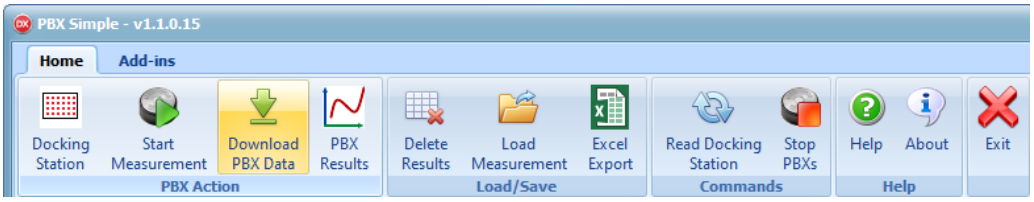


Figure 37

- When the measurement mission has been ended, place the **PyroButton-X(s)** into the docking station.
- Click **Read Docking Station** button. Check the data in the PBX in Docking Station table (e.g. State and Point columns).
- If the measurement is still running, but you want to terminate it, click **Stop PBXs** and confirm the stop.
- Select the data loggers whose measurements you want to save.
- Click **Download PBX Data** button to download the measurement results.

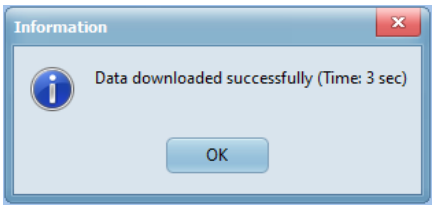


Figure 38

- The PBX Measurement Data page appears (the measurement file will be saved to c:\Users\Public\Documents\PBS MeasData\ folder).

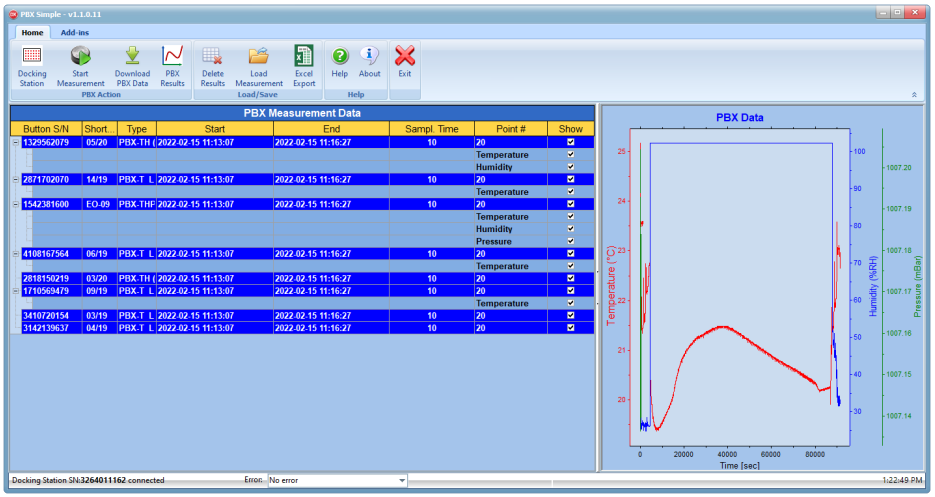


Figure 39

Result Evaluation - PBX Measurement Data

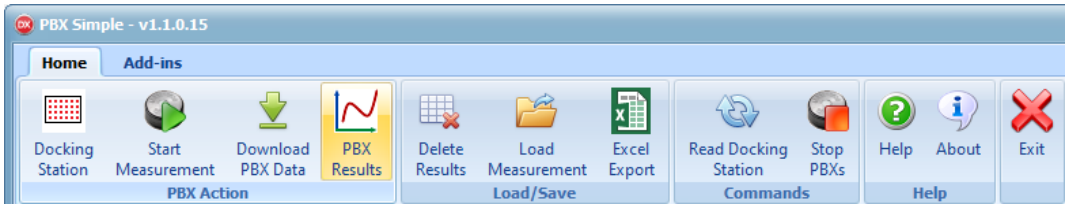


Figure 40

Click **PBX Results** button any time to display the measurement result.

NOTE: When you press the PBX Results button, a graph appears only if there was a download in that session, and only the most recent download is displayed, regardless of which button is checked in the docking station field.

NOTE: When the measurement results have been downloaded from the PyroButton(s) (with the use of **Download PBX Data** button), this window will open automatically.

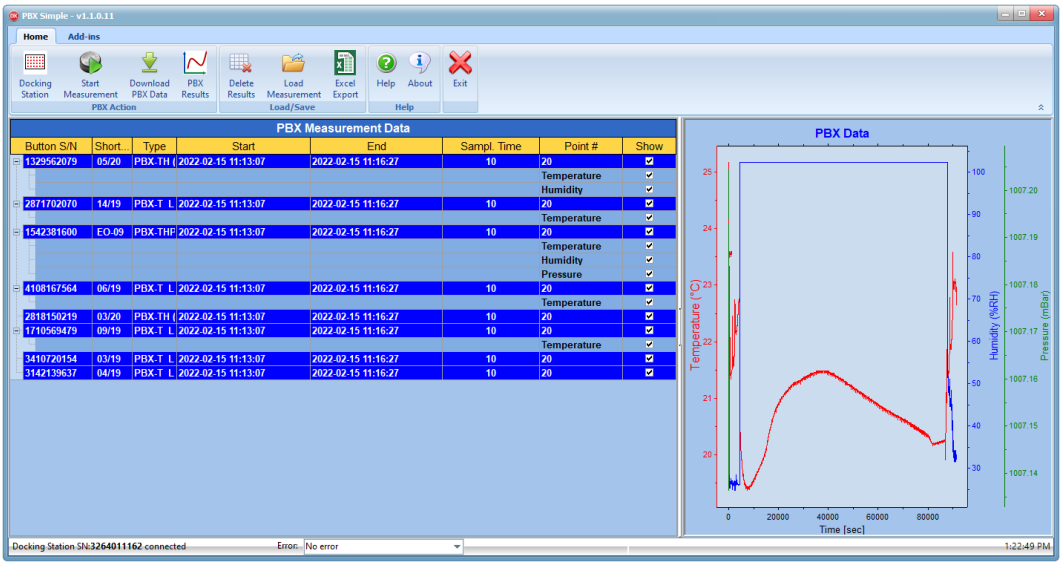


Figure 41

PBX Measurement Data table

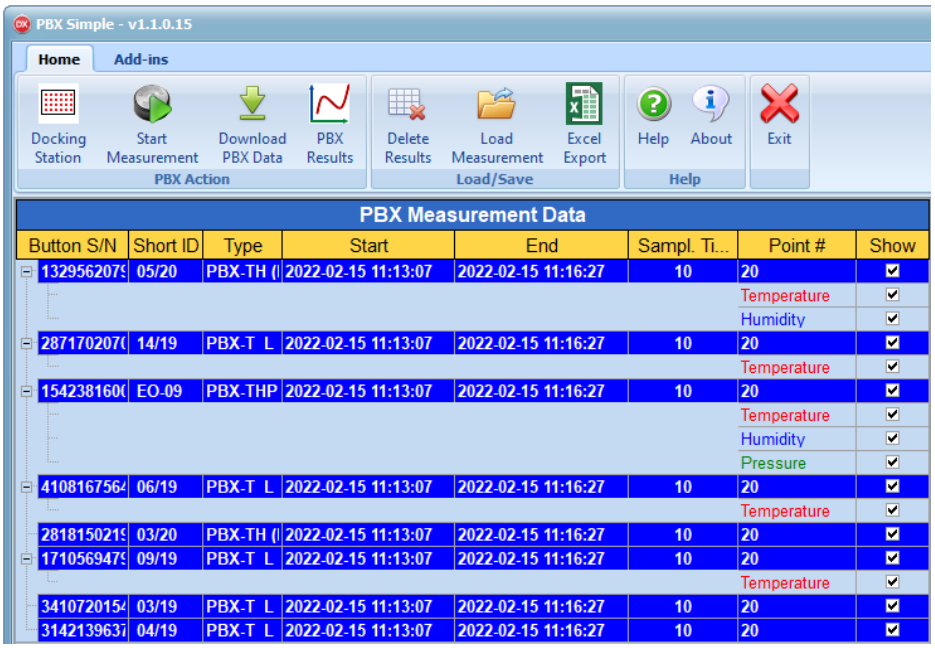


Figure 42

The table contains those measurements you work with.
Select the measurement(s) by clicking the checkbox in the **Show** column. The selected measurements will be graphed. The measurement types are marked with different colors. This marking is consistent with the colors on the graph.

Table - Popup menu items (right mouse click)

Show All: selects all of the measurements (all checkboxes are selected in the Show column).
Hide All: unselects all of the measurements (all checkboxes are empty in the Show column).
Show Temperature: selects all temperature measurements.
Show Humidity: selects all humidity measurements.
Show Pressure: selects all pressure measurements.

PBX Data Graph

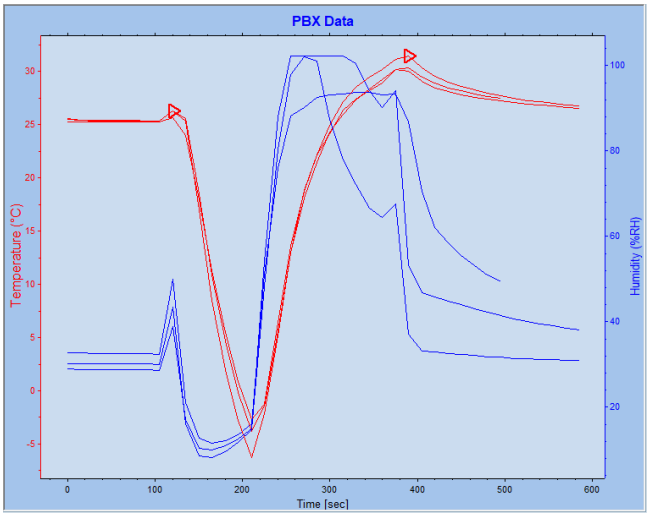


Figure 43

The graph displays the temperature, and/or humidity, and/or pressure versus time. By moving the cursor over the graph (over a measurement point), the PyroButtons' SN, the measurement time and the reading is displayed in a popup hint.

Tip: to zoom in on a desired portion of a graph, move the mouse pointer to the start (or end) of the region of interest. Press and hold the Shift key and the left mouse button, and drag the mouse to the other end of the region of

interest. Release the mouse button and the graph display redraws the selected region. Repeat the process for closer zooms.
To restore the Zoom factor hold the Shift key and double click with the left mouse button.

Tip: to scroll the graph, press and hold the Ctrl key and the left mouse button, then drag the mouse towards the desired direction. Release the mouse button when the graph position is correct. Repeat the process for more scrolling. To restore the scroll factor hold the Shift key and double click with the left mouse button.

Graph - Popup menu items (right click on the graph)

Date and time display

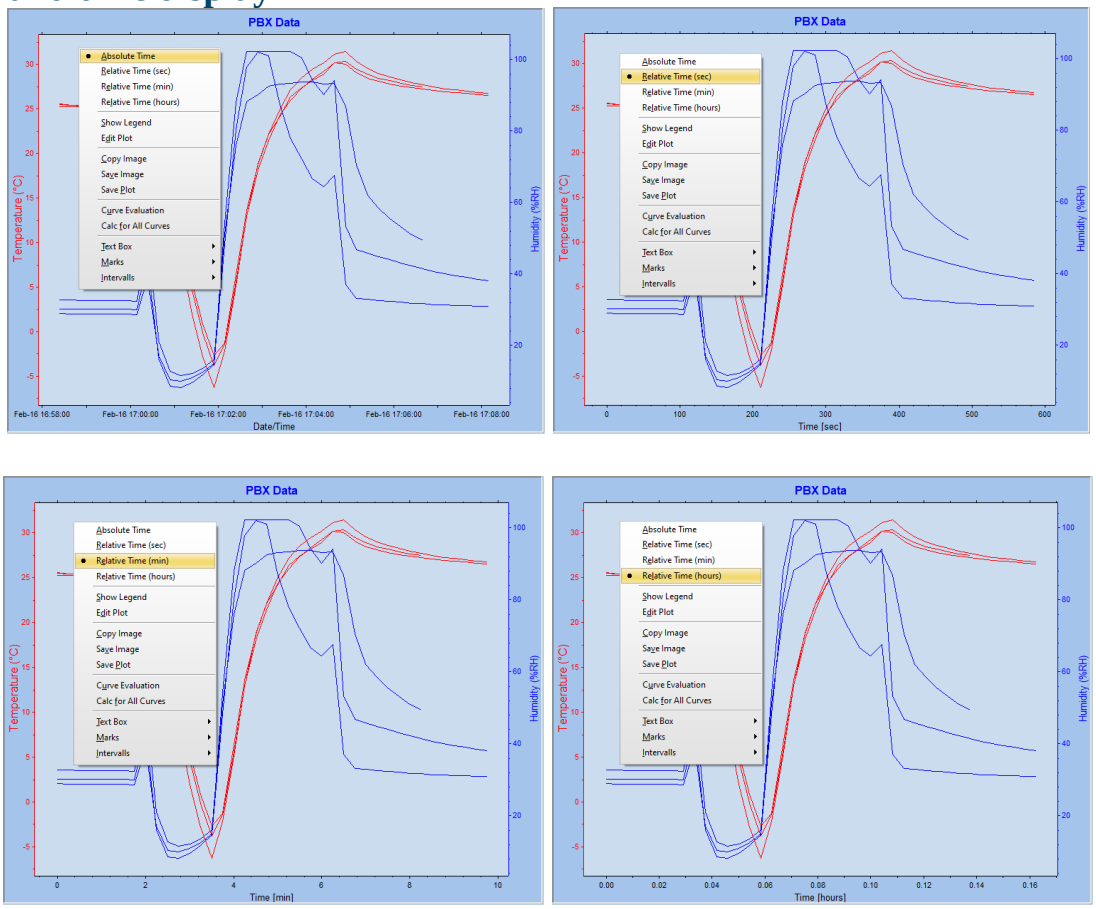


Figure 44

Absolute Time: the date (month-day) and time (hours:minutes:seconds in local time.) are displayed.

Relative time (sec): the time of the first reading is 0 (zero) second. All following readings are related to the first one, and the time difference is displayed in seconds.
Relative time (min): same as above, but it is displayed in minutes.
Relative time (hours): same as above, but it is displayed in hours.

Show Legend

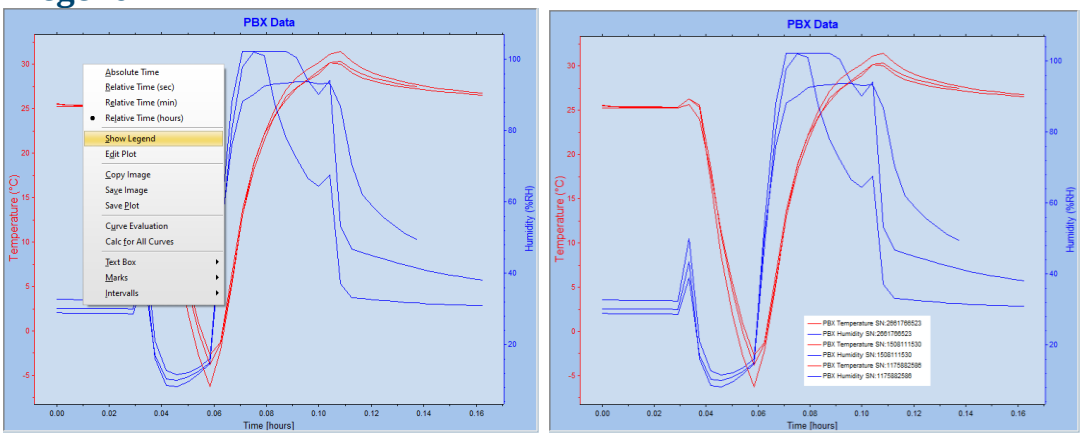


Figure 45

Displays the graph legend. The legend can be moved by grab and move mouse action. Move the mouse pointer over a legend. The curve that is associated with that legend will be highlighted with a thick line.

Edit Plot

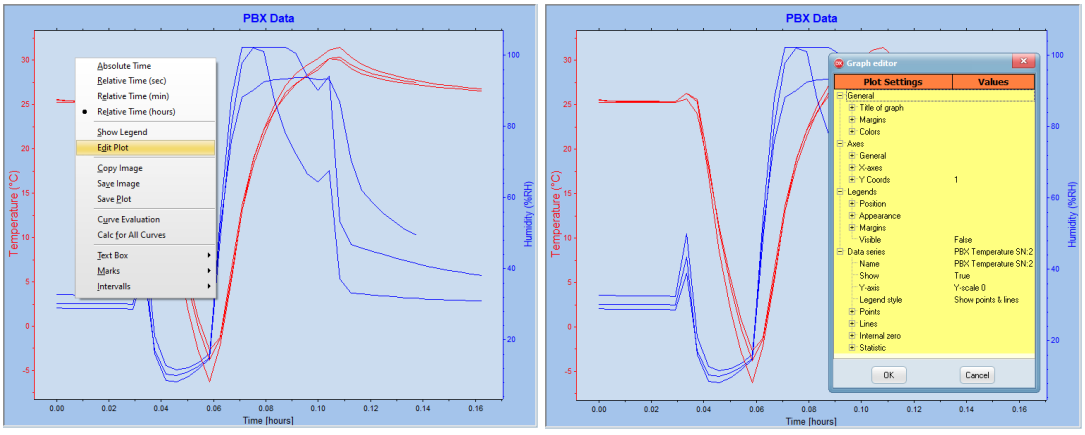


Figure 46

The Graph editor helps to customize the graph. The Graph editor is very easy to use. As soon as we change a parameter, it is immediately visible on the graph.

Copy Image

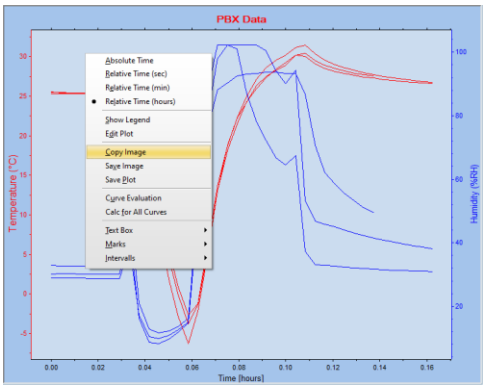


Figure 47

Right click on the graph and select **Copy Image** from the popup menu. The graph will be copied to the clipboard. The graph is stored in a standard graphical format, which means it can be easily pasted into most applications that support graphics including Microsoft Word and Microsoft Excel.

Save Image

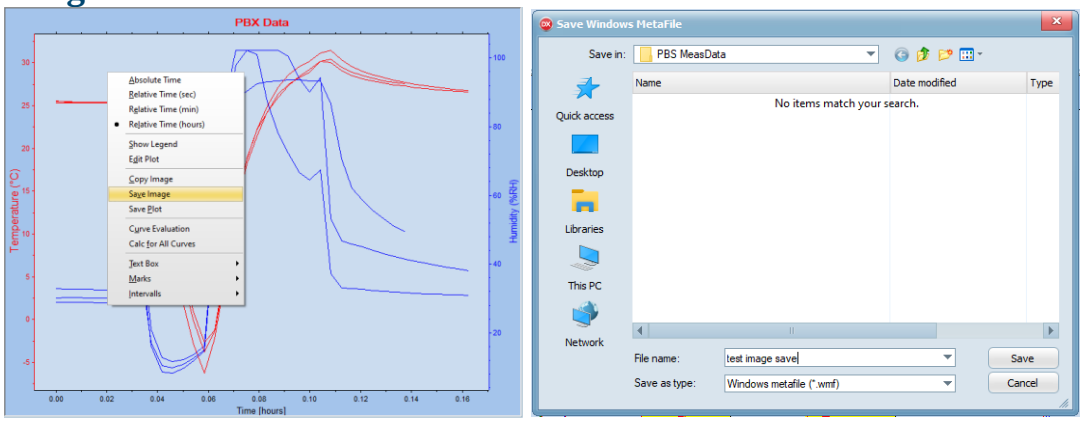


Figure 48

Right click on the graph and select **Save Image** from the popup menu. Type the file name, select the file location and click **Save** button. The saved Windows MetaFile contains all measurement curves, text boxes, mark and intervals.

Save Plot

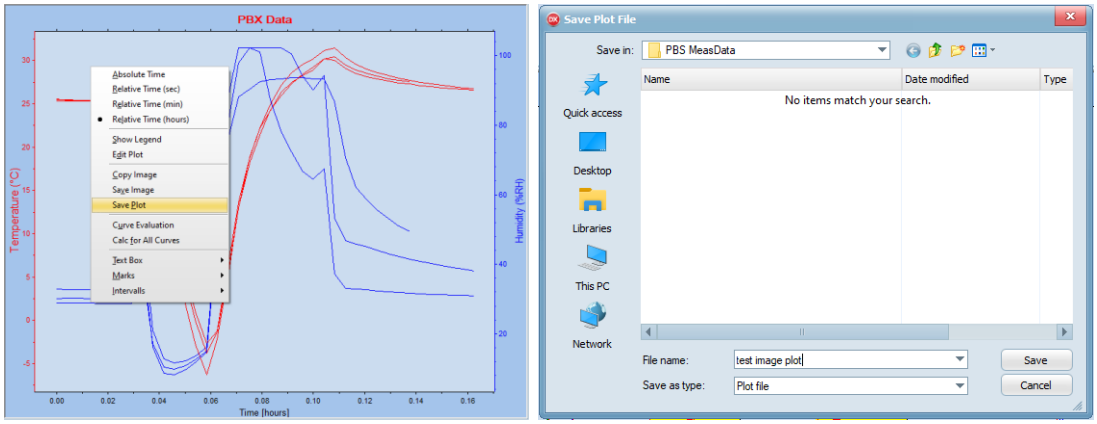


Figure 49

The graph can be saved as a plot file. This file preserves several settings of the graph (e.g. custom properties of the graph, textboxes, marks, intervals).
The plot can be loaded to the program any time for further evaluation (click **Load Measurement** button, select Plot file as a file type and select the previously save plot file).

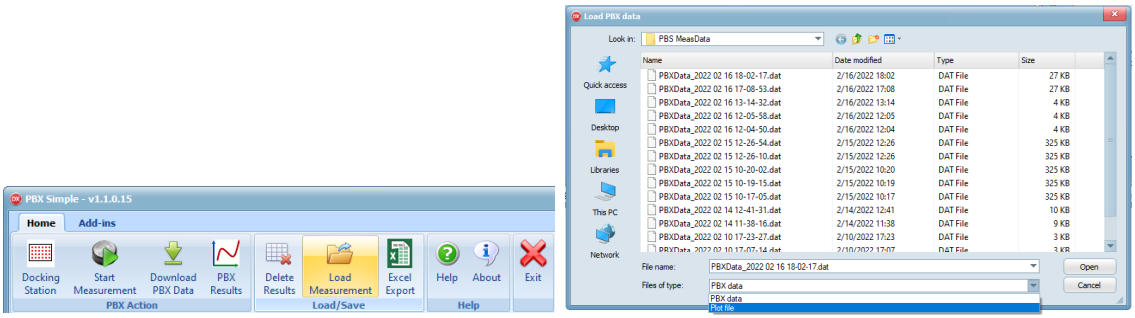


Figure 50

Curve Evaluation

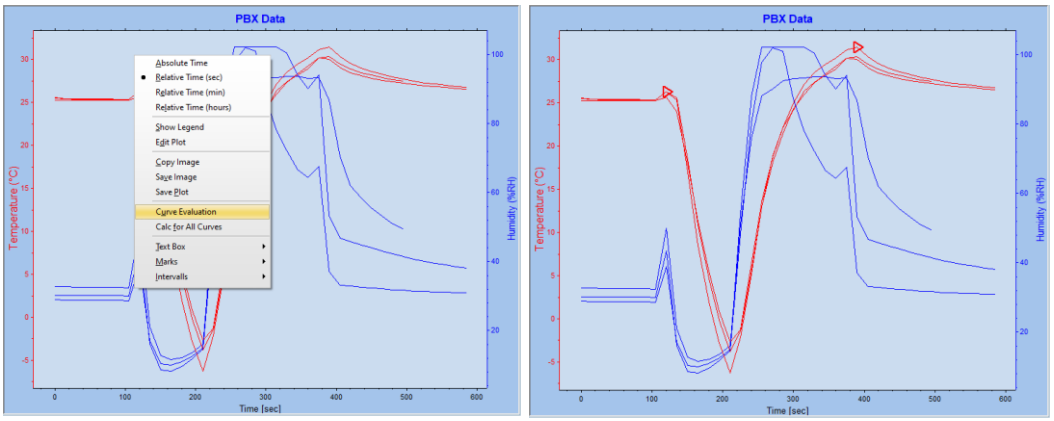


Figure 51

Calculates the parameters of the selected curve. Right click on the graph and select **Curve Evaluation** from the popup menu. Move the mouse pointer to the beginning of the evaluation and left click on a measurement point. Move the mouse pointer to the end of the evaluation and left click on a measurement. The selected evaluation interval marked with red triangles .

After selecting the start and the end point, open an Excel worksheet. select a cell and hit CTR+V (or select the paste function from the right click popup menu).

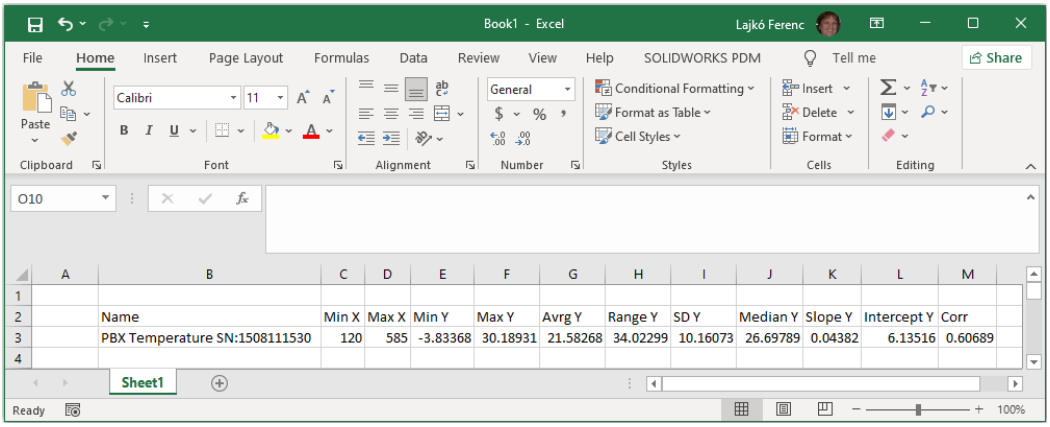


Figure 52

The calculated parameters are:

- Name: the measured parameter and the serial number of the PyroButton.
- Min X: the start time of the evaluation.
- Max X: the finish time of the evaluation
- Min Y: the minimum value of the measured parameter in the evaluated interval.

- Max Y: the maximum value of the measured parameter in the evaluated interval.
- Avg Y: the average value of the measured parameter in the evaluated interval.
- Range Y: the range (Max Y - Min Y) of the measured parameter in the evaluated interval.
- SD Y: the standard deviation of the measured parameter in the evaluated interval.
- Median Y: the median value (this number separates the higher half from the lower half) of the measured parameter in the evaluated interval.
- Slope Y: the slope (this is a number that describes both the *direction* and the *steepness* of the line) of the curve in the evaluated interval.
- Intercept Y: the intercept value (the point where a line crosses the y-axis) of the curve in the evaluated interval.
- Corr: correlation coefficients (r^2) of the fitted curve in the evaluated interval.

Calc for All Curves (evaluates the results of all curves at once)

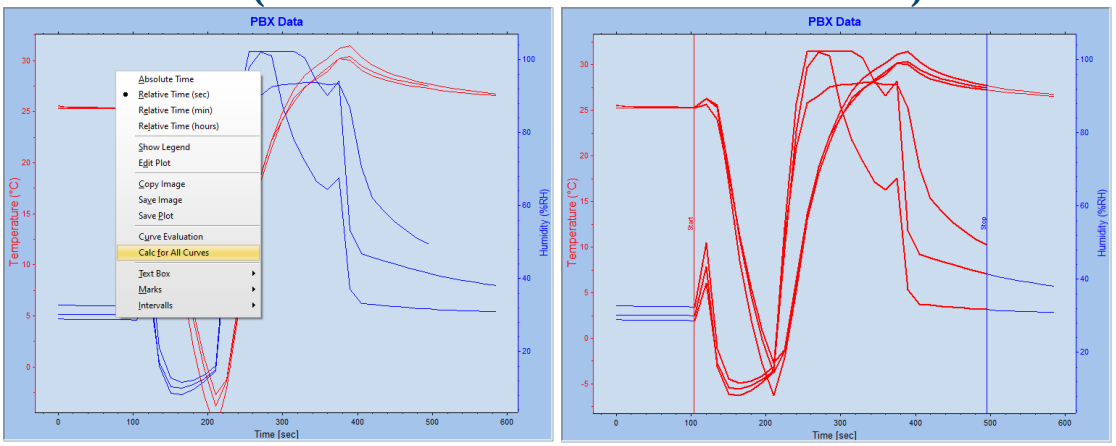
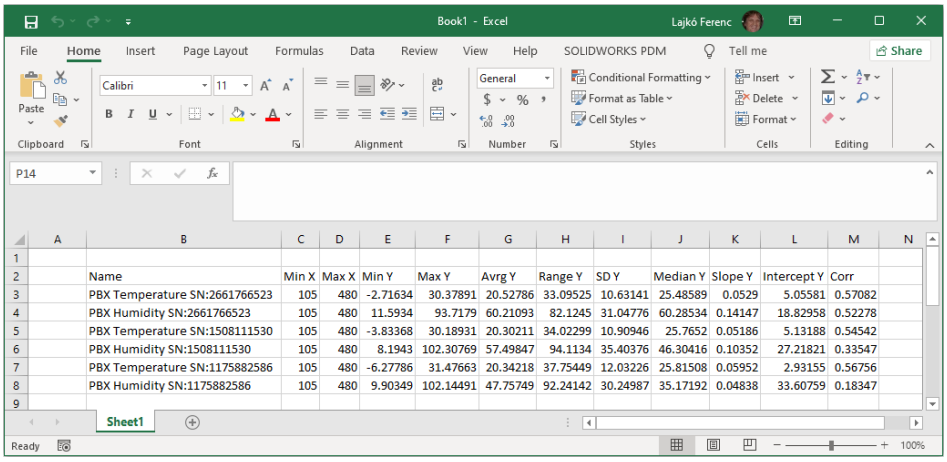


Figure 53

Calculates the parameters of all curves. Right click on the graph and select **Calc for All Curves** from the popup menu. Move the mouse pointer to the beginning of the evaluation and left click on a measurement point. Move the mouse pointer to the end of the evaluation and left click on a measurement point. The selected evaluation interval will be marked with vertical lines. The curves will be highlighted with red color. The lines can be moved by grab and move mouse action.

After selecting the start and the end point, open an Excel worksheet. select a cell and hit CTR+V (or select the paste function from the right click popup menu).



	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1														
2		Name	Min X	Max X	Min Y	Max Y	Avrg Y	Range Y	SD Y	Median Y	Slope Y	Intercept Y	Corr	
3		PBX Temperature SN:2661766523	105	480	-2.71634	30.37891	20.52786	33.09525	10.63141	25.48589	0.0529	5.05581	0.57082	
4		PBX Humidity SN:2661766523	105	480	11.5934	93.7179	60.21093	82.1245	31.04776	60.28534	0.14147	18.82958	0.52278	
5		PBX Temperature SN:1508111530	105	480	-3.83368	30.18931	20.30211	34.02299	10.90946	25.7652	0.05186	5.13188	0.54542	
6		PBX Humidity SN:1508111530	105	480	8.1943	102.30769	57.49847	94.1134	35.40376	46.30416	0.10352	27.21821	0.33547	
7		PBX Temperature SN:1175882586	105	480	-6.27786	31.47663	20.34218	37.75449	12.03226	25.81508	0.05952	2.93155	0.56756	
8		PBX Humidity SN:1175882586	105	480	9.90349	102.14491	47.75749	92.24142	30.24987	35.17192	0.04838	33.60759	0.18347	
9														

Figure 54

The parameters are for all curves:

- Name: the measured parameter and the serial number of the PyroButton.
- Min X: the start time of the evaluation.
- Max X: the finish time of the evaluation
- Min Y: the minimum value of the measured parameter in the evaluated interval.
- Max Y: the maximum value of the measured parameter in the evaluated interval.
- Avg Y: the average value of the measured parameter in the evaluated interval.
- Range Y: the range (Max Y - Min Y) of the measured parameter in the evaluated interval.
- SD Y: the standard deviation of the measured parameter in the evaluated interval.
- Median Y: the median value (this number separates the higher half from the lower half) of the measured parameter in the evaluated interval.
- Slope Y: the slope (this is a number that describes both the *direction* and the *steepness* of the line) of the curve in the evaluated interval.
- Intercept Y: the intercept value (the point where a line crosses the y-axis) of the curve in the evaluated interval.
- Corr: correlation coefficients (r^2) of the fitted curve in the evaluated interval.

Text Box

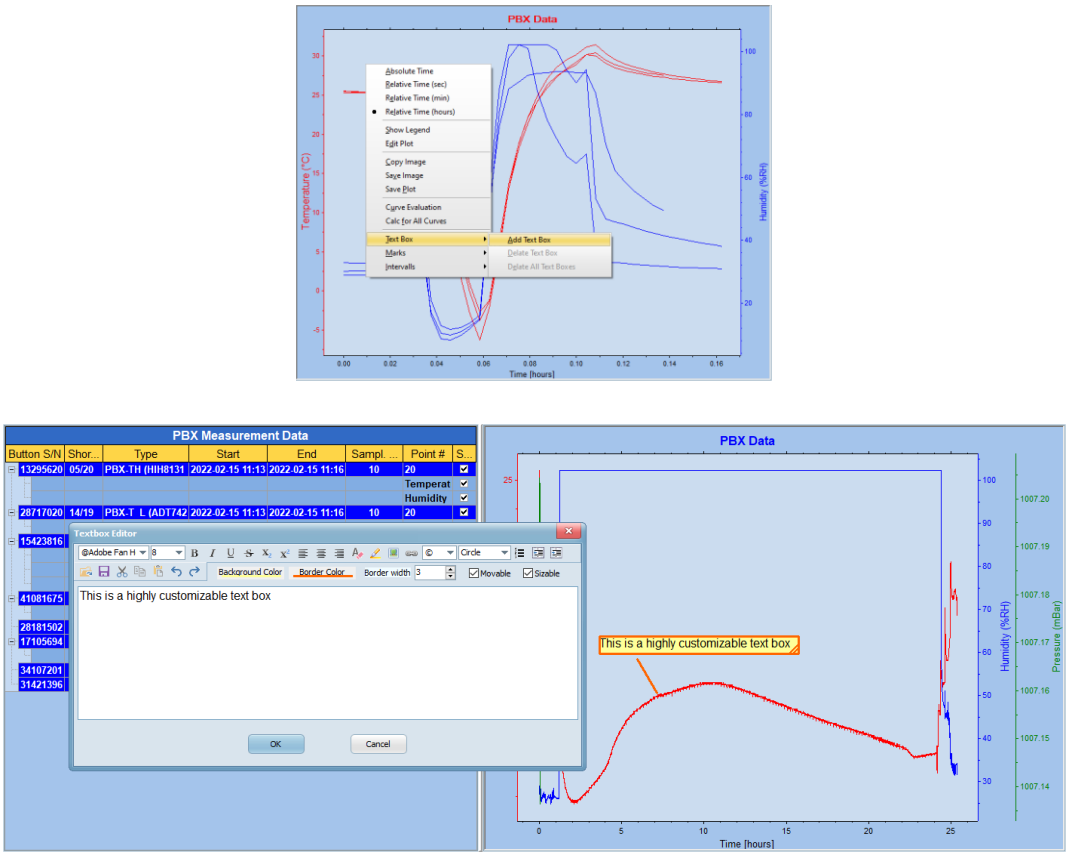


Figure 55

Add Text Box: inserts a text box to the graph. The text box will be anchored to the point where the mouse pointer stood at the moment of clicking. The text box can be moved freely, but the anchor point is fixed. The Textbox editor (double click on the text box) helps to customize the text and the text box too.

Delete Text Box: deletes the text box that the mouse pointer stood at the moment of clicking.

Delete all Text Boxes: deletes all text boxes.

Marks

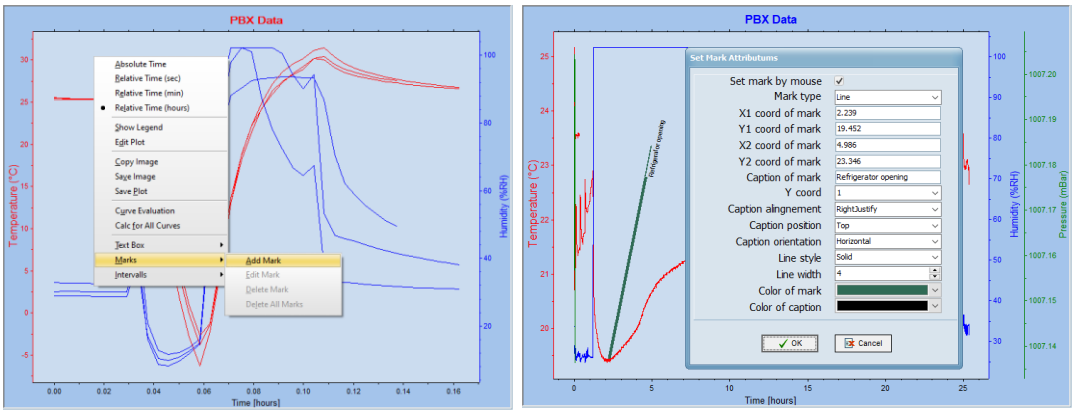


Figure 56

Add Mark: inserts a mark to the graph. Click **Marks**/**Add Mark**. The **Set Mark Attributes** page appears. Set the attributes and click **OK** button. The mouse pointer changes shape. Move the pointer to the start or to the end of the mark and click. Move the pointer to the other end of the mark and click again. The mark can be moved or reshaped. To do this, move the mouse pointer to the end of the mark. The shape changes to move indicator. If you see the move indicator, left click and drag the mark to a new location. Repeat this on the other end of the mark, if it is necessary.

Edit Mark: the mark can be edited. Move the mouse pointer to one end of the mark or the other. The shape of the pointer changes to move indicator. If you see the move indicator, left click. The **Set Mark Attributes** window appears. Many parameters of the mark can be changed here. Press **OK** button to apply the changes.

Delete Mark: deletes the selected mark. Move the mouse pointer to one end of the mark or the other. The shape of the pointer changes to move indicator. If you see the move indicator, right click and select **Marks/Delete Mark** from the popup menu.

Delete all Marks: deletes all marks. Move the mouse pointer to one end of the mark or the other. The shape of the pointer changes to move indicator. If you see the move indicator, right click and select **Marks/Delete all Marks** from the popup menu.

Intervals

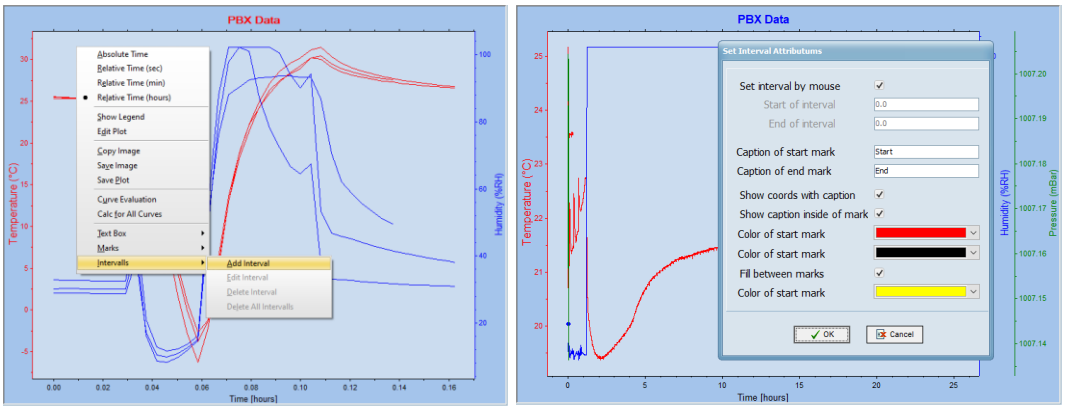


Figure 57

Add Interval: intervals can be added to the measurement. A process can be visualized with this function. Click **Intervals**/**Add Interval**. The **Set Interval Attributes** page appears. Set the attributes and click **OK** button. The mouse pointer changes to green arrow (right). Move the pointer to the start of the interval and left click. A vertical line appears. The mouse pointer changes to green arrow (left). Move the pointer to the other end of the interval and click again. The interval lines can be freely moved by grabbing and moving the line with the mouse. The process step will be visualized by color and text. Repeat the procedure for the other process steps.

Edit Interval: the interval can be edited. Right click on an interval and select **Intervals/Edit Interval** from the popup menu. The **Set Interval Attributes** window appears. Many parameters of the interval can be changed here. Press **OK** button to apply the changes.

Delete Interval: deletes an interval. Move the mouse pointer over an interval. Right click and select **Intervals/Delete Interval** from the popup menu.

Delete all Intervals: deletes all intervals. Right click on the graph and select **Intervals/Delete All Intervals** from the popup menu.

Load and Save

Delete Results

Figure 58

Delete Results: deletes all results which are in the PBX Measurement Data (clears the table and the graph).

Load Measurement

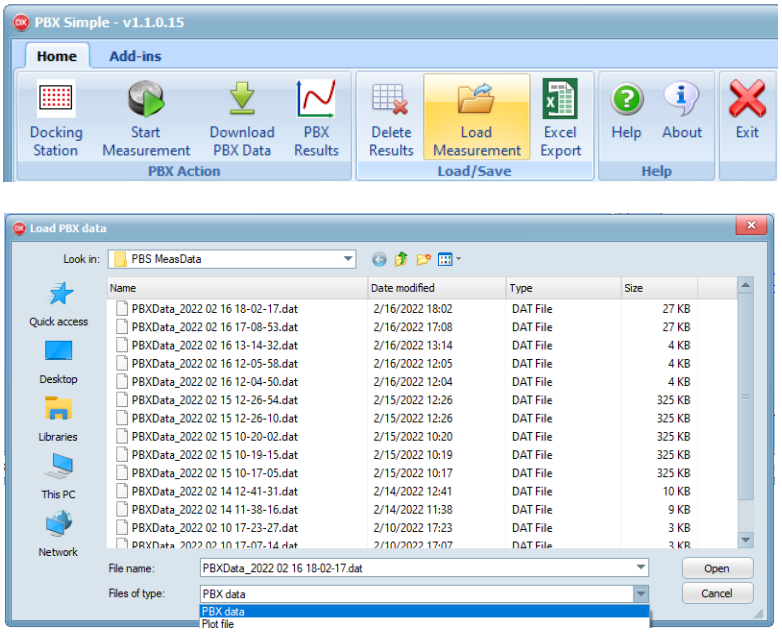
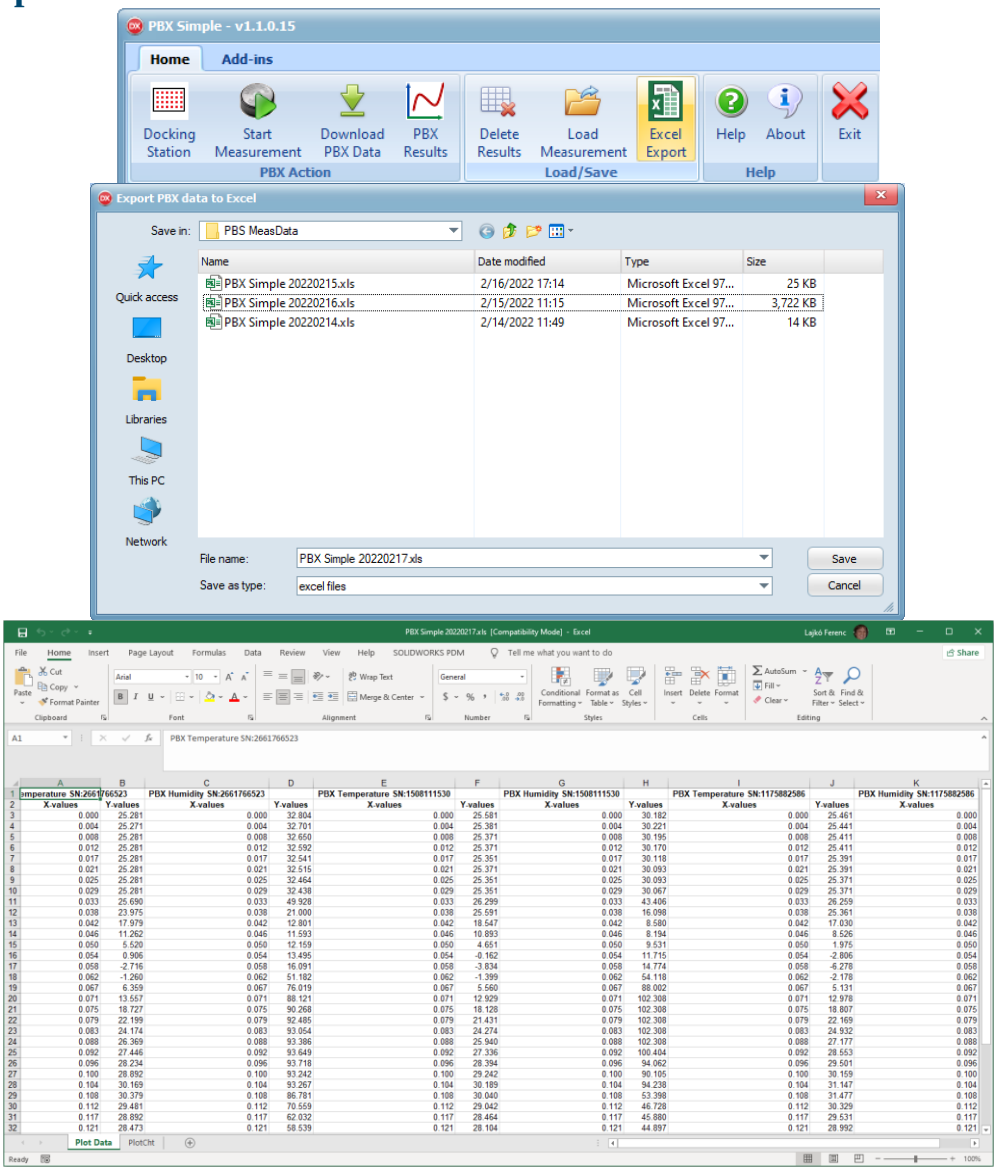


Figure 59

Load Measurement: loads previously saved measurement and plot files.

NOTE: If there are already measurement results in the table, you can use the Load Measurement button to load additional measurements.

Excel Export



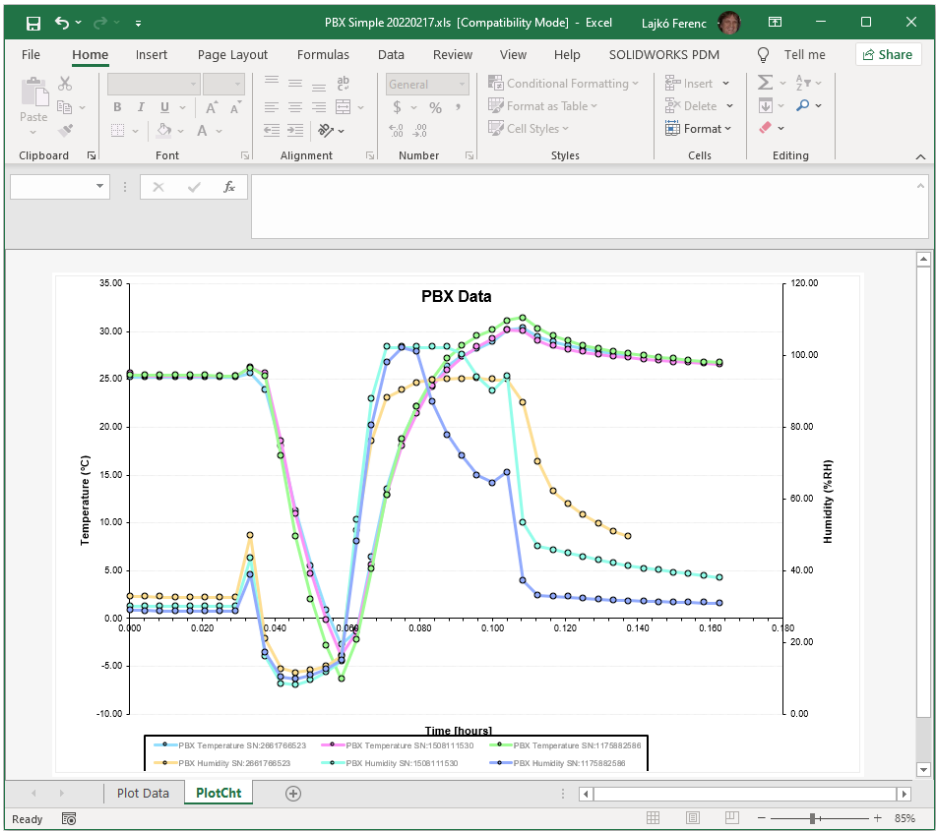


Figure 60

Excel Export: the measurement data can be exported to Microsoft Excel for additional analysis and consolidated presentation.

PyroButton Properties

On the **Docking Station** page double click on a PyroButton row or double click to the well position for PBX information.

Calibrations page

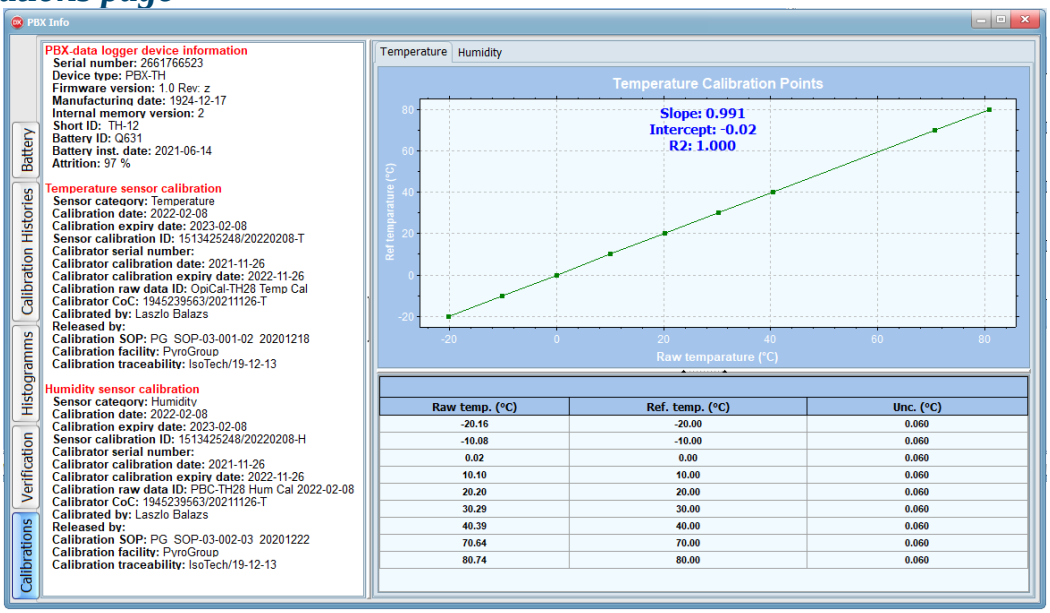


Figure 61

Calibration Information (left panel): the serial number and some other PyroButton property are displayed, as well as who and when calibrated the PyroButton, when will the calibration expire, and the identifier of the calibration Protocol and the certificate.

Calibration Curve (upper right panel): the curve displays the values of the currently selected calibration table (lower right panel). There is a line fitted on every two neighboring calibration points, the slope, the intercept and the R2 value of all lines are displayed.

Calibration Table (lower right panel): these are the raw (As Found) and the Reference values, and the uncertainty of the calibration.

NOTE: Above the Calibration Points graph the sensor type can be selected. It can be temperature, humidity or pressure (depends on the selected logger type)

Verification page

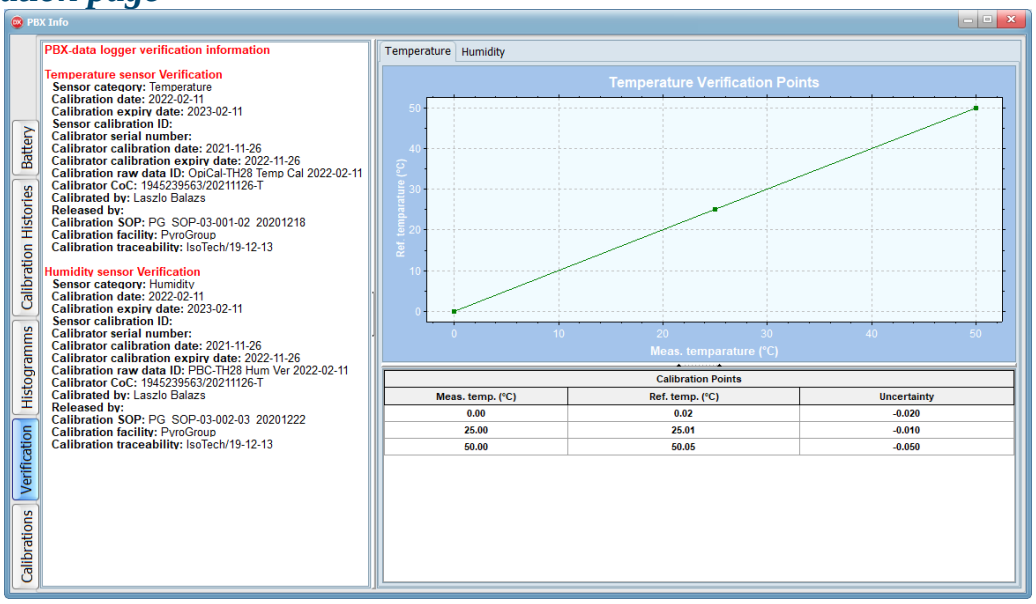


Figure 62

Verification Information (left panel): the serial number and some other PyroButton property are displayed, as well as who and when calibrated and verified the PyroButton, when will the calibration expire, and the identifier of the calibration Protocol and the certificate.

Verification Curve (upper right panel): the curve displays the values of the currently selected verification table (lower right panel).

Verification Table (lower right panel): these are the measurement and the Reference values, and the uncertainty of the measurement.

NOTE: Above the Verification Points graph the sensor type can be selected. It can be temperature, humidity or pressure (depends on the selected logger type)

Histograms page

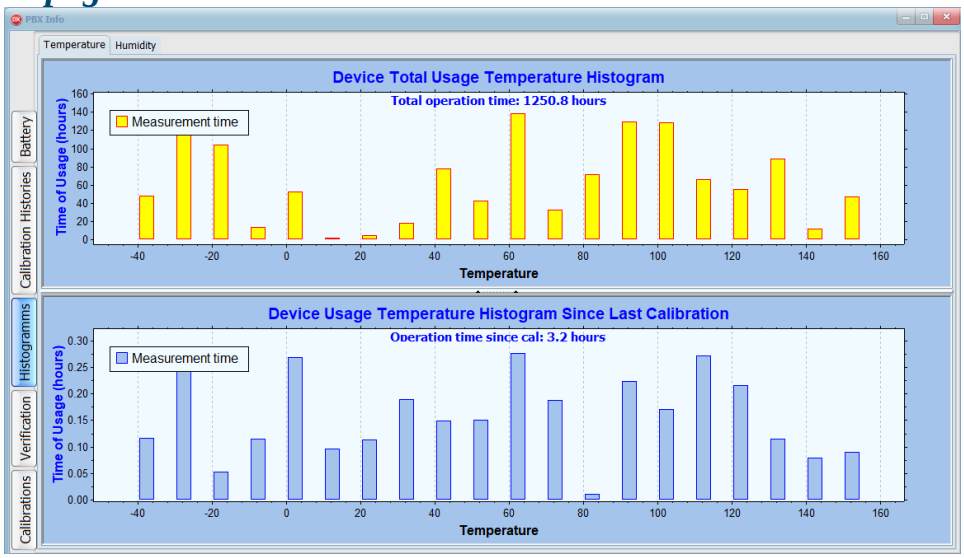


Figure 63

This is a graphical representation (histogram) of the PyroButtons' operation time vs. temperature, humidity, and pressure (it depends on the type of the PyroButton).

Device Total Usage Histogram: This histogram displays the measurement time (operation time) of the PyroButton at different temperature, humidity, and pressure, since the first use.

Device Total Usage Histogram Since Last Calibration: This histogram displays the measurement time (operation time) of the PyroButton at different temperature, humidity, and pressure, since last calibration.

Calibration Histories page

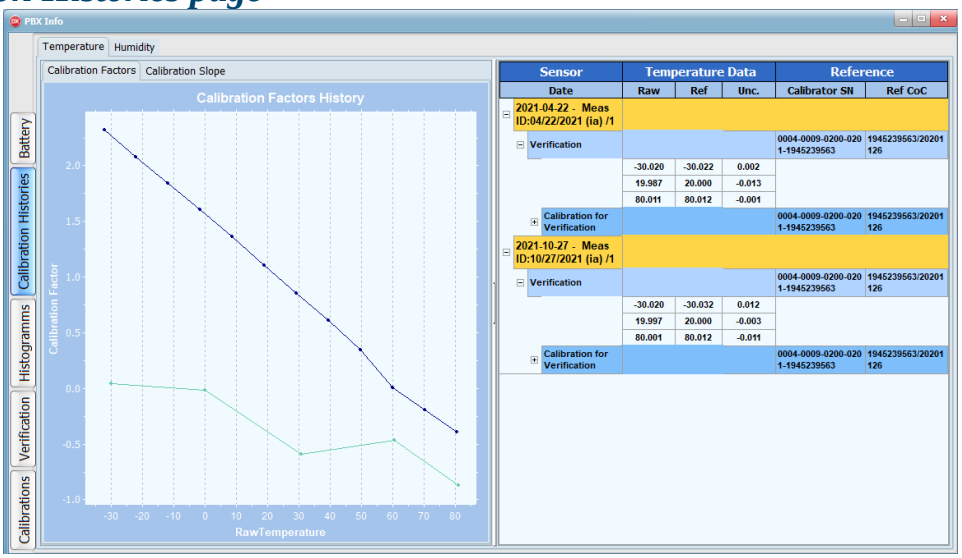


Figure 64

Calibration table: contains all of the calibrations and verifications of the PyroButton.

Calibration Factors History: plots the calibration factors obtained during all calibrations on a graph. The frequency of calibration can be estimated by analyzing the change in calibration factors. An outstanding result may also warn of a deviation from the normal operation of the PyroButton.

Calibration Slope and Intercept History: plots the calibration slope and intercept obtained during all calibrations on a histogram. The frequency of calibration can be estimated by analyzing the change in calibration slope and intercept. An outstanding result may also warn of a deviation from the normal operation of the PyroButton.

NOTE: Above the Calibration Factors History graph the sensor type can be selected. It can be temperature, humidity or pressure (depends on the selected logger type).

Battery page

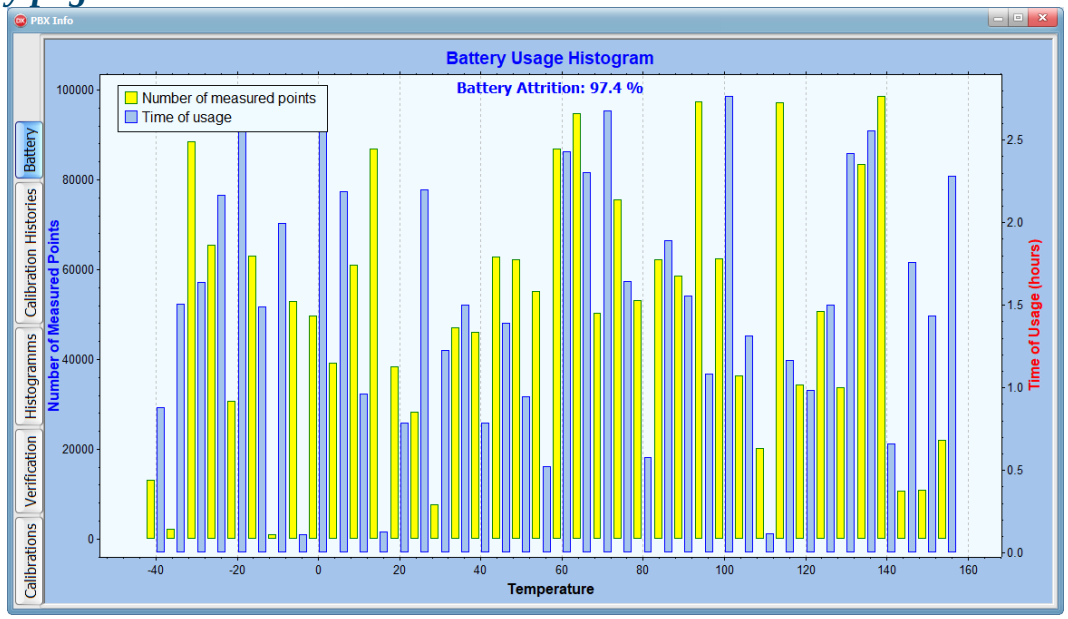


Figure 65

The PyroButtons have an internal battery, which cannot be accessed from the outside, therefore cannot be reloaded. The energy of the battery slowly decreases in time, as it runs more and more measurements. This page is to estimate the current attrition of the battery, based on the number of readings.

The PyroButtons' battery-life decreases more rapidly at higher temperatures. This histogram displays the time spent by the PyroButton on different temperature ranges, the number of the measurement points, and gives an estimation of the current attrition of the battery, based on these data.

▪ REGULATORY COMPLIANCE

1. The data-loggers' memory include all of the calibration data required by CGMP in a protected memory and secured via encrypting
2. Raw data & calibrated data are accessible by the user
3. The data-loggers must be calibrated prior to use
   3.1. OPULUS offers high efficient calibrators, which combines both temperature & humidity calibration within a single unit.
   3.2. The calibration results are stored in the data-loggers & automatically uploaded to the database
   3.3. Each measurement is automatically corrected according to the calibration curve

▪ EFFICIENT & EFFECTIVE MEASUREMENT PROCESS

1. Multiple – 4-, 28-, 60-, PyroButtons can be programmed at the same time by selecting the appropriate docking stations
   1.1. Select all of the data-loggers within the docking station for the programming or downloading of the data
2. Templates can be created for repeated measurements
   2.1. Save an initial measurement process as a template
      2.1.1. The next time you want to configure a measurement just select the template to load the previously defined parameters, including the positions of the data-loggers
3. Store the data-loggers in the docking station for smart asset management
   3.1. Assign meaningful Short IDs for the data-loggers for effective search & retrieval

▪ BEST CALIBRATION PRACTICES

For Best calibration practices use PyroButton Calibration ("PBC") system.

PBC is real-time calibration & calibration verification system for PyroButton data-loggers. For example**,** PBC-TH28 is able to perform both temperature and humidity calibrations or calibrations and verifications of 28 data-loggers in parallel. The hardware/software combination of PBC-TH28 automates several critical functions, including:

- The calibration and calibration verification protocols are generated automatically
- The instrument parameters are controlled dynamically via feedback evaluation
- The monitored values are displayed both digitally and graphically
- Certificate of Calibration reports are generated automatically
- The results are automatically saved and can be retrieved at a later time
- The calibration curves and the correction factors are automatically integrated to the application programs
- Rapid temperature stabilization & high accuracy are ensured by multiple thermoelectric (Peltier) elements
- Rapid humidity stabilization is ensured by computer controlled internal fan and optimized geometry
    - 3-point of 28 PyroButton humidity calibration can be completed in less than 2 hours

PyroButton Calibration ("PBC") Products

- *PBC consists of 2 units: a thermoelectrically controlled digital instrument and the integrating software. PBC is available in 2 models:*
    - *PBC-TH18 is a combined temperature/humidity calibration & calibration verification system. It can execute in parallel the calibration and calibration verification of 18 x PyroButtons.*
    - *PBC-TH28 stands for the calibration & verification instrument & software system for both humidity & temperature calibration of 28 PyroButton or 28 OpButton data-loggers in parallel. It is integrated to PyroButton-TQM to comply with 21 CFR Part 11. PBC-TH28 has been developed by Opulus.*

The calibrators communicate with the software through USB adapter interface. The user can define the data-acquisition parameters, resolution, delay, stabilization time, temperature or humidity calibration points.

Images of PBC-TH18 and PBC-TH28 can be seen below.

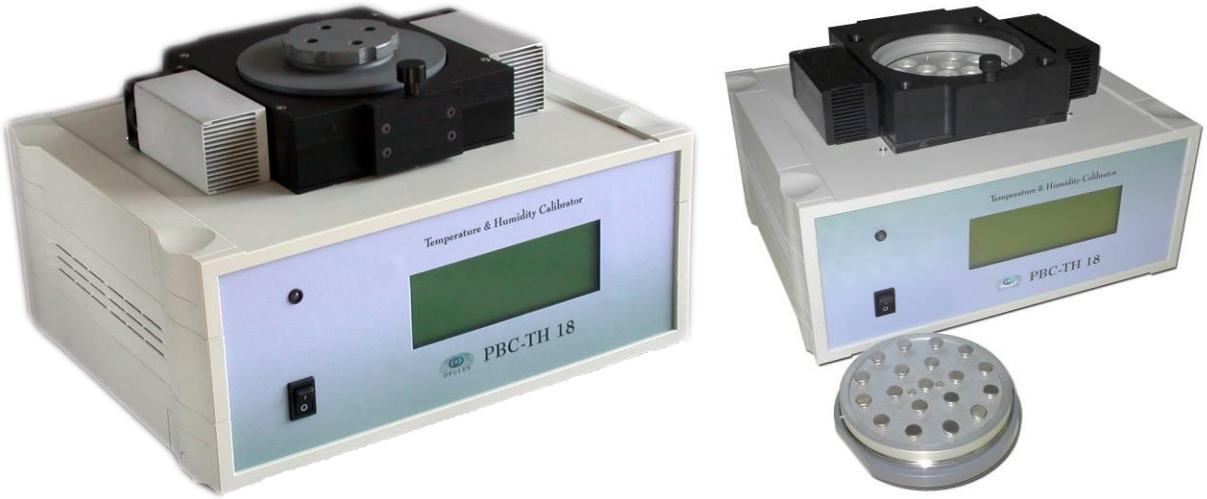


Figure 66

Images of PBC-TH28 can be seen below.

Figure 67

Real-time Graphical Display of the calibration data

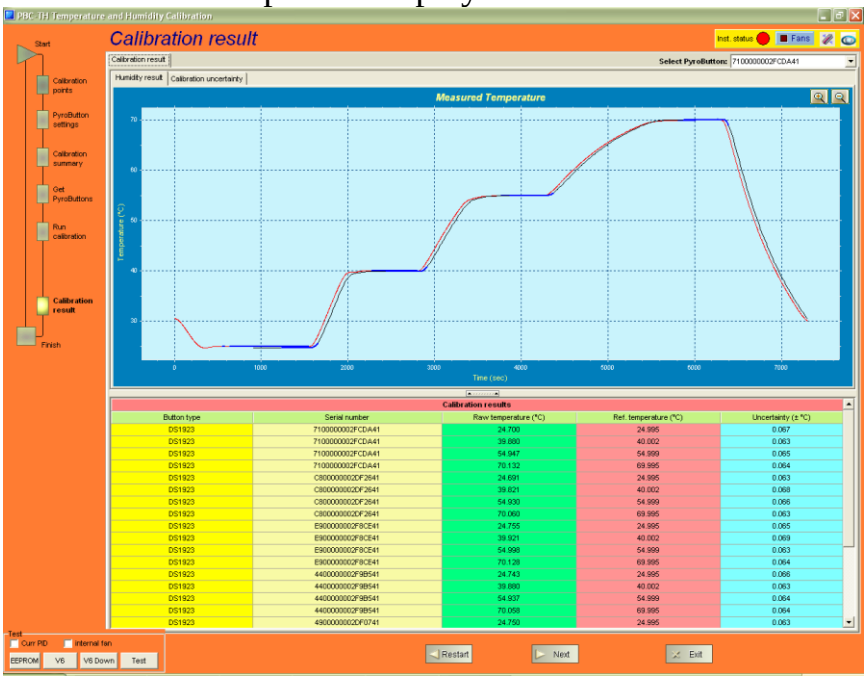


Figure 68

The Calibration Curve with Uncertainty of Measurements

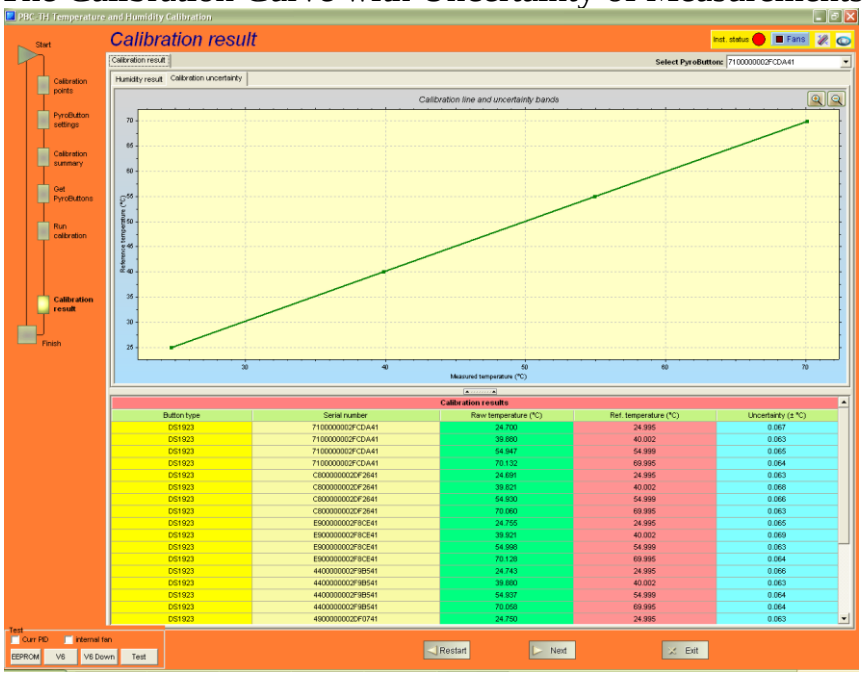


Figure 69

Exhibit A1 – PyroButton Life Cycle of Events

(parameters in red can be defined by the user)

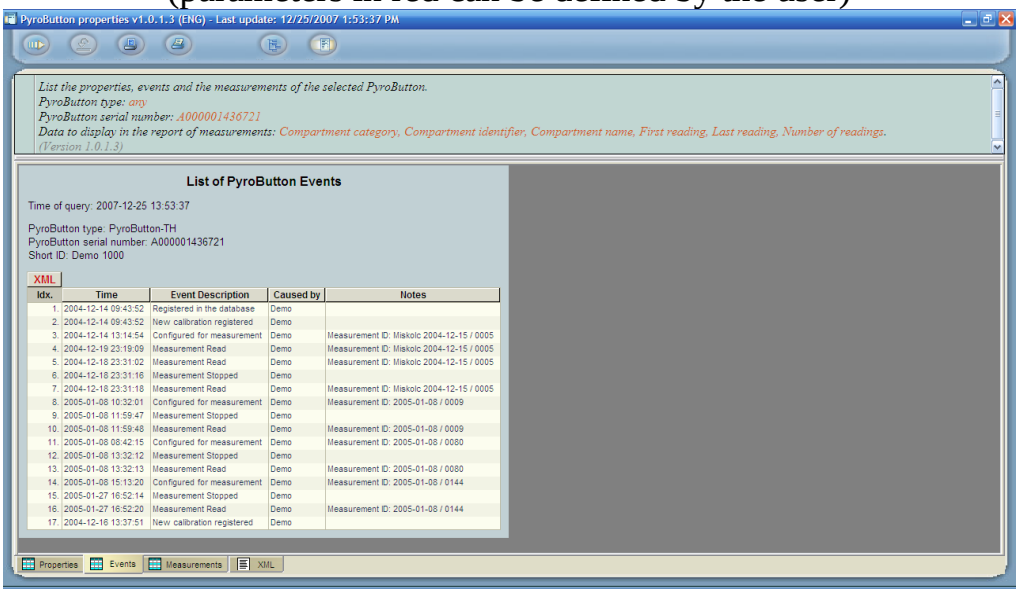


Figure 70

Exhibit A2 – PyroButton Measurement Life Cycle
(parameters in red can be defined by the user)

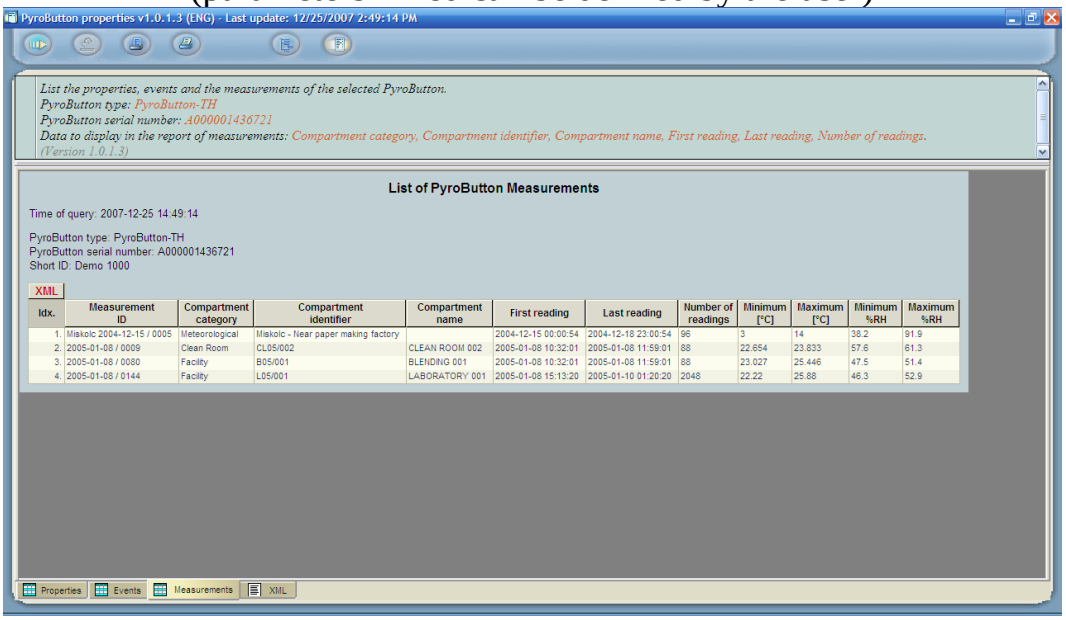


Figure 71

Exhibit B1 – Temperature Calibration with Statistical Summary

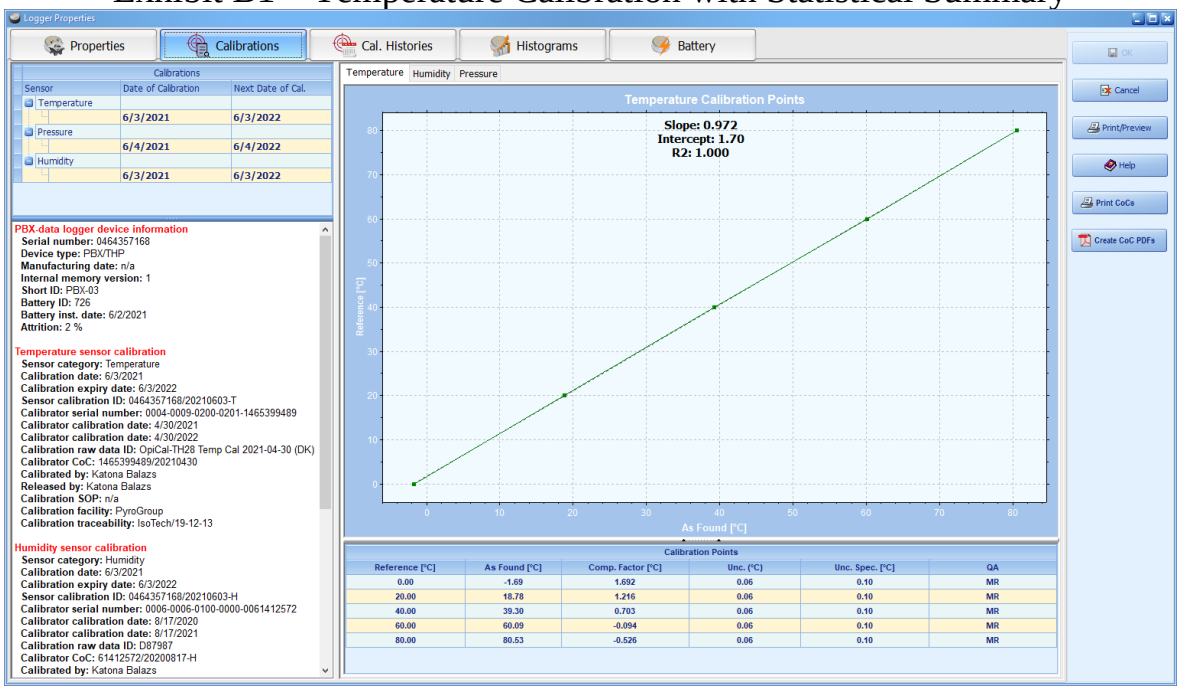


Figure 72

Exhibit B2 – Humidity Calibration with Statistical Summary

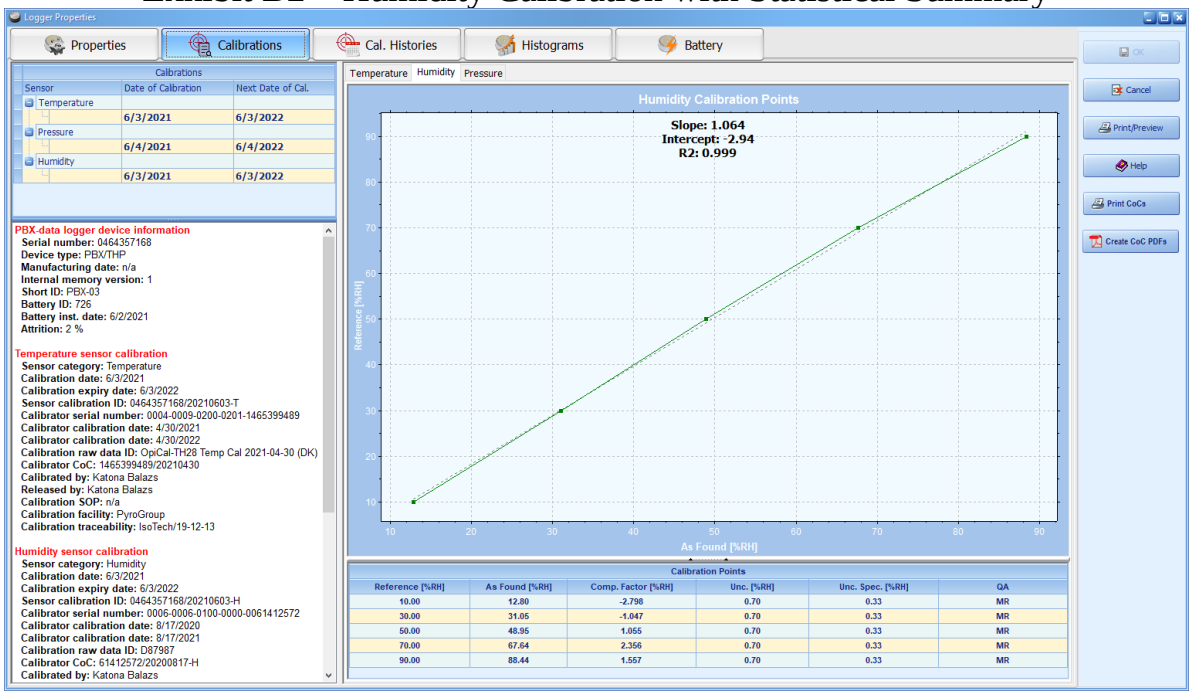


Figure 73

Exhibit C – PyroButton Data-Logger Performance Qualification with Statistical Summary Based on Three (3) Calibrations at Different Times (parameters in red can be defined by the user)

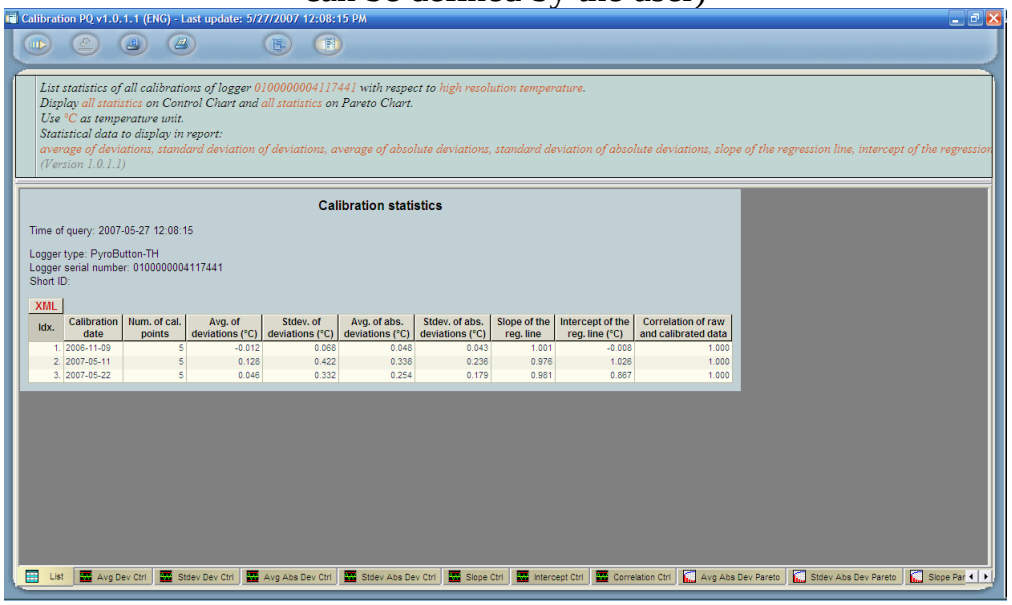


Figure 74

Exhibit D – PyroButton Data-Logger Performance Qualification with Control Chart Representation Based on Three (3) Calibrations at Different Times (parameters in red can be defined by the user)

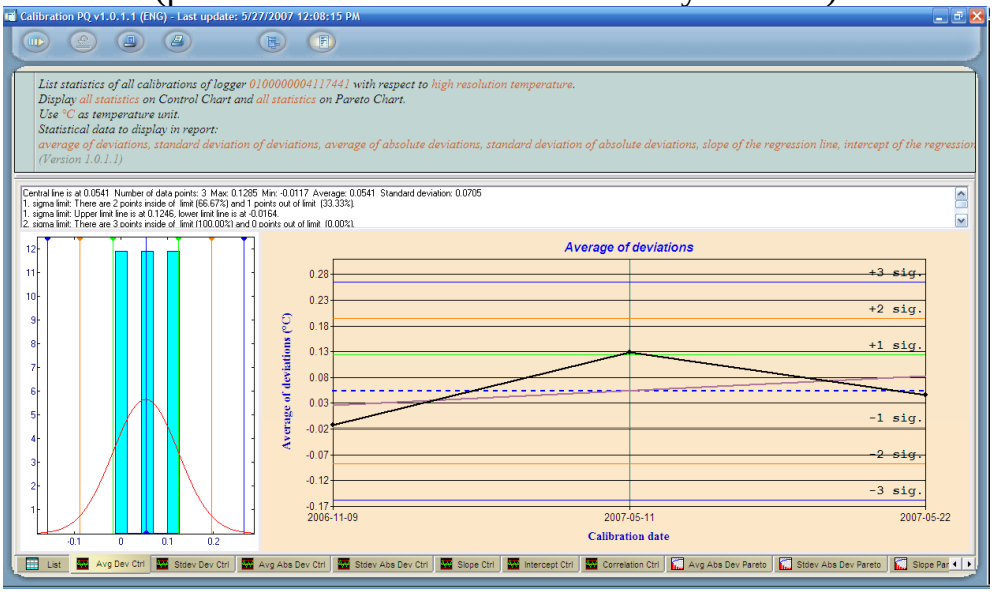


Figure 75

Exhibit E – PyroButton Data-Logger Performance Qualification with Pareto Diagram Representation Based on Three (3) Calibrations at Different Times (parameters in red can be defined by the user)

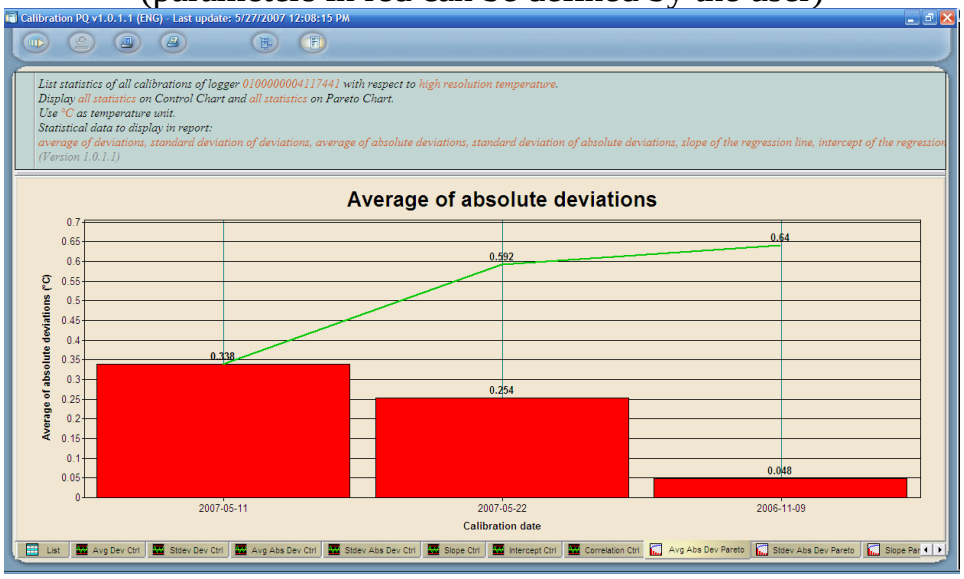


Figure 76

Exhibit I – SPC Evaluation for a Selected Sub-Process & Measurement Property (e.g., Temperature) of a Multiple Connected Sub-Processes (parameters in red can be defined by the user)

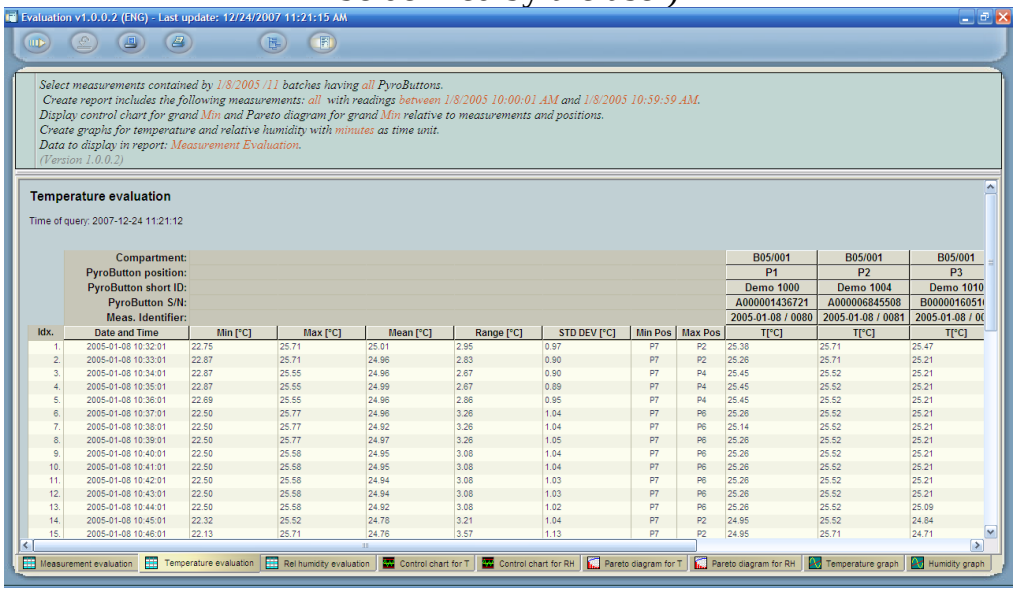


Figure 77

Exhibit J – SPC Evaluation for a Selected Sub-Process & Measurement Property (e.g., Temperature) of a Multiple Connected Sub-Processes (parameters in red can be defined by the user)

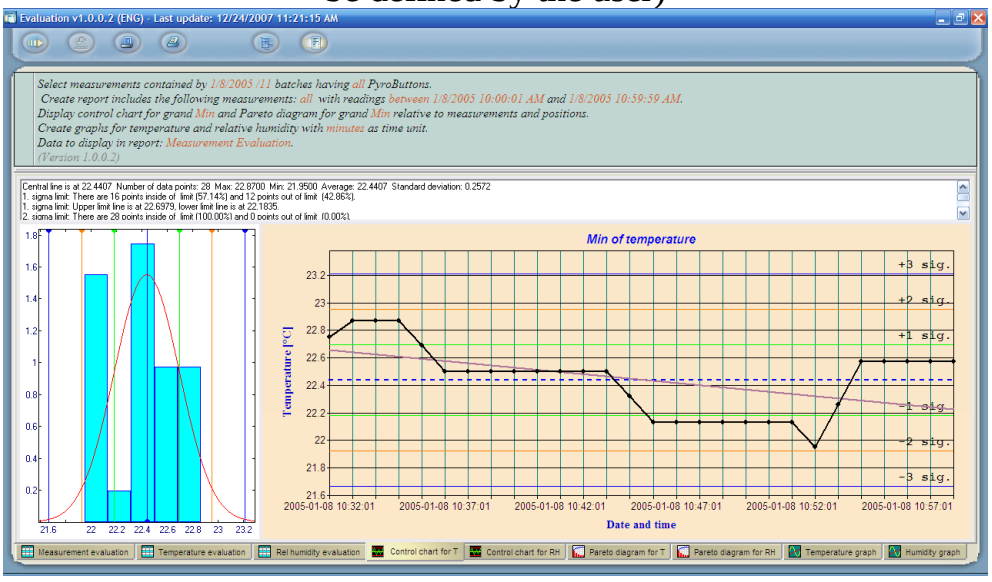


Figure 78

Exhibit K – SPC Evaluation for a Selected Sub-Process & Measurement Property (e.g., Temperature) of a Multiple Connected Sub-Processes (parameters in red can be defined by the user)

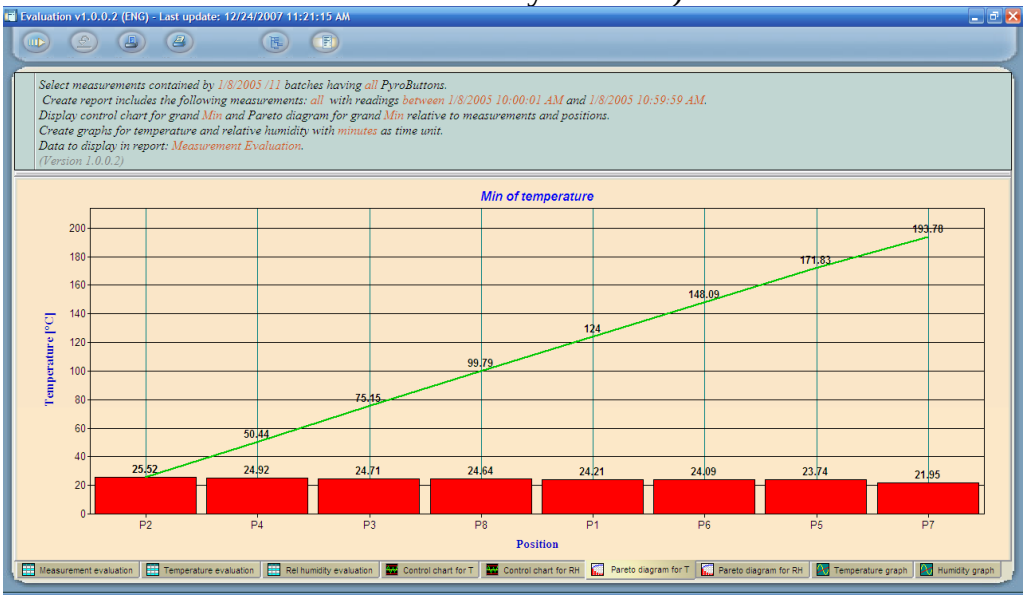


Figure 79

Exhibit L – SPC Evaluation for a Selected Sub-Process & Measurement Property (e.g., Humidity) of a Multiple Connected Sub-Processes (parameters in red can be defined by the user)

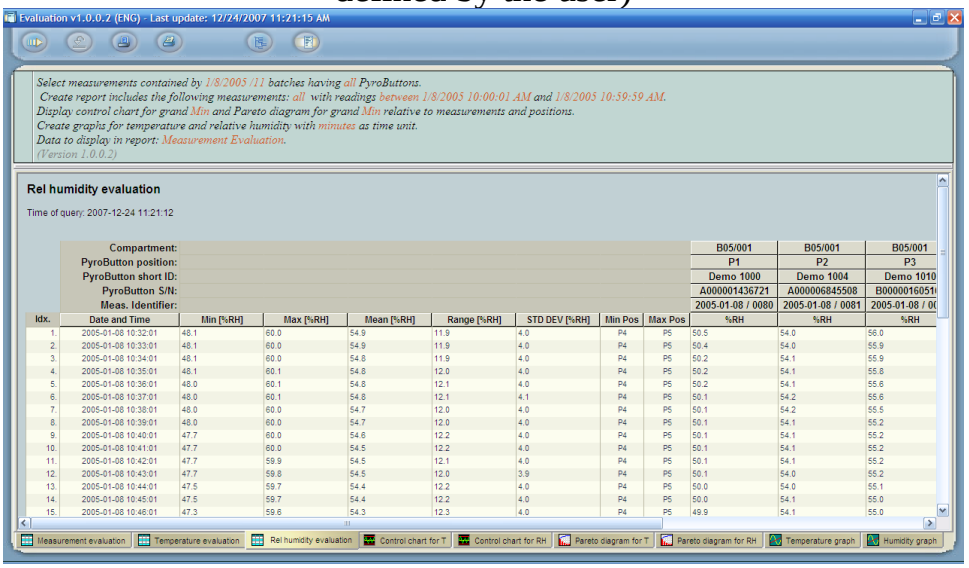


Figure 80

Exhibit M – SPC Evaluation for a Selected Sub-Process & Measurement Property (e.g., Humidity) of a Multiple Connected Sub-Processes (parameters in red can be defined by the user)

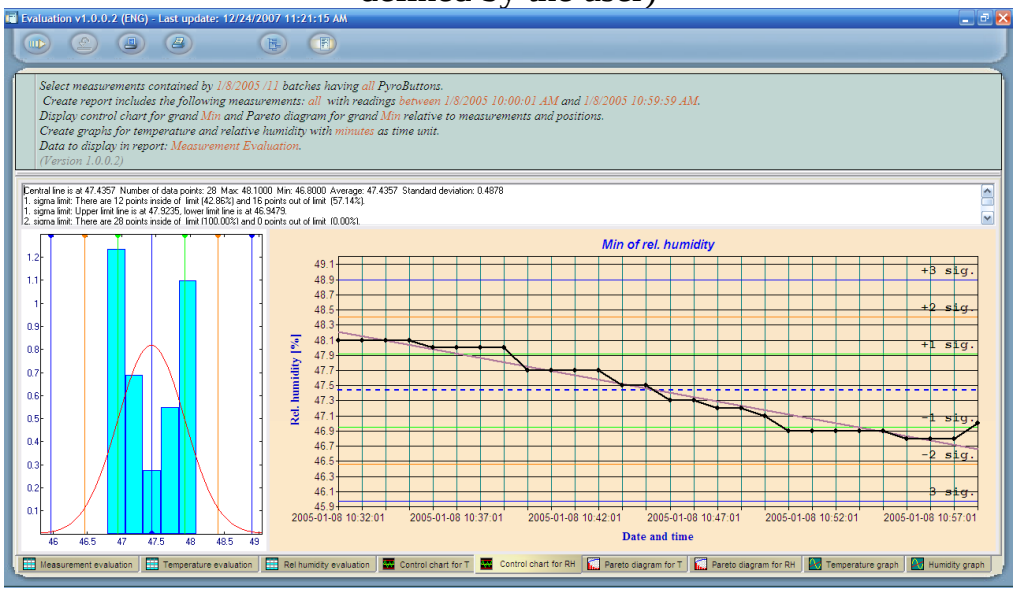


Figure 81

Exhibit N – SPC Evaluation for a Selected Sub-Process & Measurement Property (e.g., Humidity) of a Multiple Connected Sub-Processes (parameters in red can be defined by the user)

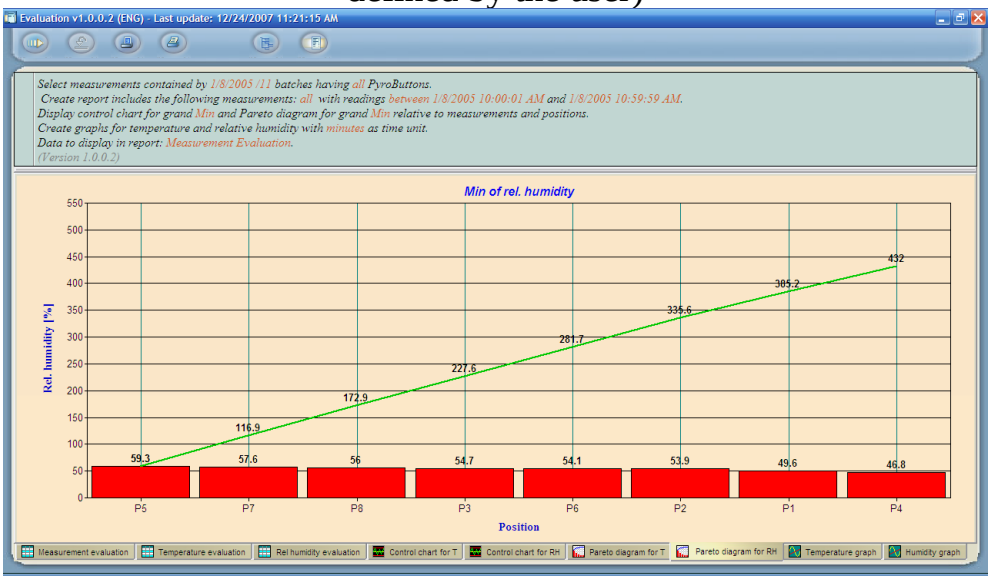


Figure 82

▪ Good Data-Logger Practices

Knowledgeable use of the data-loggers will help you to optimize the benefits, meet quality & regulatory requirements, and at the same time extend the life expectancy of the battery.

Good Data-Acquisition Practices

For a particular measurement process, you should evaluate the data-acquisition requirements and create a data-acquisition plan. It should include:

- Definition of the minimum & maximum warning & critical limits
- Estimation of the maximum rate of change of the monitored values (i.e., frequency)
- Establishment of the Critical Control Points (CCP) relative to the object being monitored, such as load, insulation, traffic, etc.
- Establishment of quality, PROTOCOL, and regulatory requirements
- Selection of a CGMP compliant data-logger relative to physical properties, the dynamic range, resolution, accuracy (uncertainty of measurement), reproducibility, and memory size

- Predict life time expectancy & optimize the battery life span
- Based on the above create a meaningful data-acquisition plan.

Good Calibration Practices

- The goal of calibration is to quantitatively convert measurements made on one of two measurement scales to the other measurement scale. The two scales are generally not of equal importance, so the conversion occurs in only one direction. The primary measurement scale is usually the scientifically relevant or reference scale of an accepted reference material (i.e., NIST). A process model describing the relationship between the two measurement scales provides the means for conversion. A process model that is constructed primarily for the purpose of calibration is often referred to as a "calibration curve".

Statistical Controls: Statistical controls are used in the calibration process to guarantee the 'goodness' of calibration results within predictable limits and to validate the statement of uncertainty of the result. Two types of control can be imposed on a calibration process that makes use of statistical designs:

- Control of instrument precision or short-term variability, and
- Control of bias or long-term variability, utilizing control charts

Short-term variability: standard deviation from each design is the basis for controlling instrument precision. Because the measurements for a single design are completed in a short time span, this standard deviation estimates the basic precision of the instrument. Designs should be chosen to have enough measurements so that the standard deviation from the design has at least 3 degrees of freedom where the degrees of freedom are $(n - m + 1)$ with

- n = number of difference measurements
- m = number of properties (e.g., if only temperature is measured, then m = 1)

Long-term variability: Measurements on a check standard provide the mechanism for controlling the bias and long-term variability of the calibration process. The check standard is treated as one of the test items in the calibration design, and its value as computed from each calibration run is the basis for accepting or rejecting the calibration. The check standard should be of the same type as items that are measured in the designs. The relevant properties must be stable and available to the calibration process on a continuing basis. There should be a check standard at each critical level of measurement. For example, for temperature, if the dynamic range

is between 0 °C and 100 °C, then there should be check standards at the 0 °C; 20 °C, 40 °C, 60 °C, 80 °C, 100 °C levels.
A check standard can also be a mathematical construction, such as the computed difference between the calibrated values of two reference standards in a design.

The creation and maintenance of the database of check standard values is an important aspect of the control process. The results from each calibration run are recorded in the database and evaluated utilizing SQC & SPC.

Intercomparison: Calibration designs are redundant schemes for intercomparing reference standards and test items in such a way that the values can be assigned to the test items based on known values of reference standards. The assumptions that are necessary for working with calibration designs are that:

- Random errors associated with the measurements are independent.
- All measurements come from a distribution with the same standard deviation.
- Reference standards and test items respond to the measuring environment in the same manner.
- Handling procedures are consistent from item to item.
- Reference standards and test items are stable during the time of measurement.
- Bias is canceled by taking the difference between measurements on the test item and the reference standard.

Establishment of Monitoring Points

- The selection of positions for the data-loggers to be placed is a very important part of any validation or monitoring program. The location of the data-logger is directly related to the area it represents. Spatial scales of representative segments to be monitored are determined by the physical dimensions of the overall dimension of the closed environment (e.g., warehouse, processing area, stability compartment, sterility chamber, etc.) and its OQ characteristics. The size of the segment should be validated to ensure that throughout the “local” environment the measured artifact is homogenous (i.e., PQ). The size and geometry of the physical segments can vary depending on the local factors, such as load, traffic, process, etc.

Maintenance of Data-Loggers

- In general, proper data-logger maintenance & inspection are crucial for obtaining accurate and reliable results. PyroButton data-loggers are enclosed in stainless steel housing to ensure long term operation. The durable stainless-steel package is highly resistant to environmental hazards such as dirt, moisture, and shock. Accessories permit PyroButton to be mounted on almost any object, including people, equipment, containers, solutions, pallets, and bags. They can be chemically cleaned or even depyrogenated.
- PyroButton SQL software includes models for time prediction of the battery, warning relative to attrition limits and need for calibration.

Data Analysis & Statistics

Validation & monitoring can produce a great deal of data and information. Different audiences will be interested in different levels of detail. For example, process engineers, validation engineers, quality control, and quality assurance wish to study patterns and therefore want detailed graph, data, and modeling capabilities. On the other hand, management may just want to know trend biases or how often guidelines or specifications are exceeded, whether quality issues are needed to be investigated relative to CAPA, OOS, and OOT.

Regulatory Considerations – Guideline Values

When selecting temperature or humidity to monitor, it is also important to consider whether there is guideline value or standard against which to compare the results.

Storage – USP	Temperature
Refrigerator - Cold	2 to 8 °C
Freezer – Cold	-20 to -10 °C
Cool	8 to 15 °C
Room Temperature	15 to 30 °C
Warm	30 to 40 °C
Excessive Heat	> 40 °C

Table 2

Stability – FDA	Temperature	Humidity	Time
Long Term*	25 °C ± 2 °C or 30 °C ± 2 °C	60% RH ± 5%RH or 65% RH ± 5%RH	12 mo
Intermediate**	30 °C ± 2 °C	65% RH ± 5%RH	6 mo
Accelerated	40 °C ± 2 °C	75% RH ± 5%RH	6 mo
Refrigerator Long Term	5 °C ± 3 °C		12 mo
Refrigerator Accelerated	25 °C ± 2 °C	60% RH ± 5%RH	6 mo
Freezer Long Term	-20 °C ± 5 °C		

Table 3

*It is up to the applicant to decide which condition is to be used
** If 30 °C ± 2 °C and 65% RH ± 5%RH is the long-term condition, there is no intermediate condition

Permeability – USP <671>	Temperature	Humidity	Time
Containers – Permeation	20 °C ± 2 °C	75% RH ± 3%RH	14 days ± 1hr

Table 4

Competency Training

Scheduled competency training for both core & SOP competencies should be performed.

Physical & Electronic Integrity – PyroPad

PyroButtons in their native packaging have stainless steel housing and polypropylene grommet seal. For steam sterilization and similar extreme conditions and in general if immersed in liquid, it is recommended, that additional protection is to be applied. PyroPad provides the needed protection; - PyroPad-OS is a slightly larger stainless steel capsule into which a PyroButton can be placed. It can protect the physical integrity of PyroButton up to 140 psi (10 bar) and 150 °C (see, Appendix B).

Calibration of PyroButtons

PyroButtons are calibrated data-loggers relative to NIST reference & methodology. The calibration curve is based on the correction factors, which is utilized for the correction of each measurement. The details of the calibration are stored within the PyroButton SQL database (see, below). If a measurement point is outside of the calibrated interval, than it will be uncorrected and it will equal to the value of the raw data.

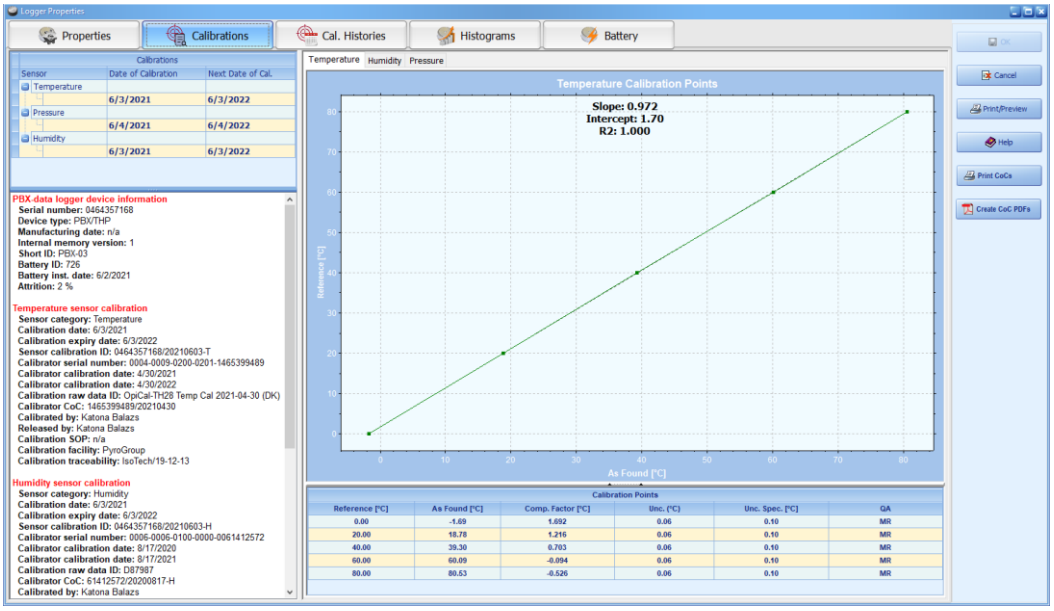


Figure 83

Calibration Performance Qualification model of the SQC/SPC provides support for the determination of recalibration intervals. Click Intelligent Query icon on the

Home toolbar and select Loggers/Calibration PQ model. Click once to view the detailed information on the use of the model. Double click Calibration PQ to access the actual model & result sheet.

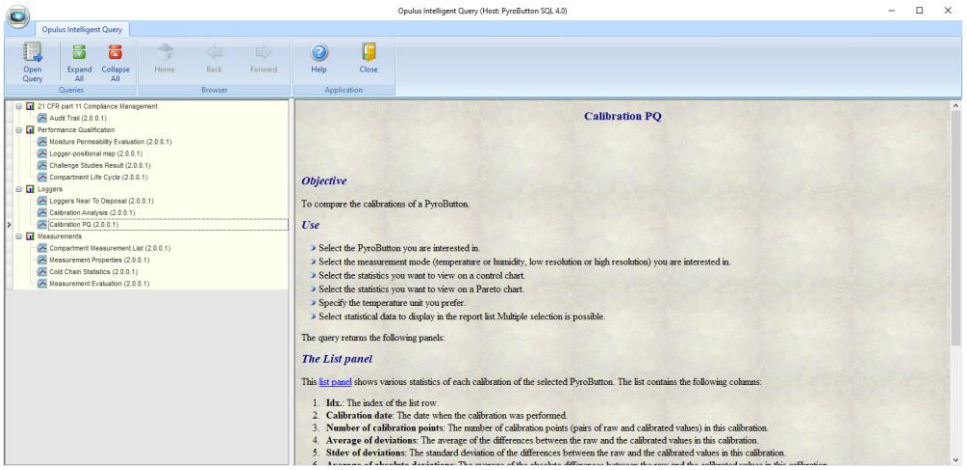


Figure 84

- Temperature recalibration. Temperature recalibration is usually sufficient once a year. If high performance specification requirements must be met, such as the monitoring of tight tolerance incubators, recalibration may be scheduled at every six (6) months. Once sufficient data are documented in the database, then the Control Charts of the Logger Calibration History can predict the appropriate scheduling. The temperature calibration depends on the resolution. For example, if the PyroButtons are used at high temperature resolution, then such calibration should be performed accordingly, as low resolution calibration shall not be compatible.
- Humidity recalibration. Humidity recalibration of the data-loggers is largely dependent on the environment they are being used in. For example, in the case of Ethylene Oxide sterilization, more frequent recalibration will be needed, than for temperatures. Once sufficient data are documented in the database, then the Control Charts of the Logger Calibration History can predict the appropriate scheduling. The humidity calibrations are valid for both low and high humidity resolutions.

Appendix A – Accessories

Mounting Devices

PyroButton FOB holders provide a practical mean for the mounting of the data-loggers to various physical objects. They are available in yellow, blue, green, red, and black colors.

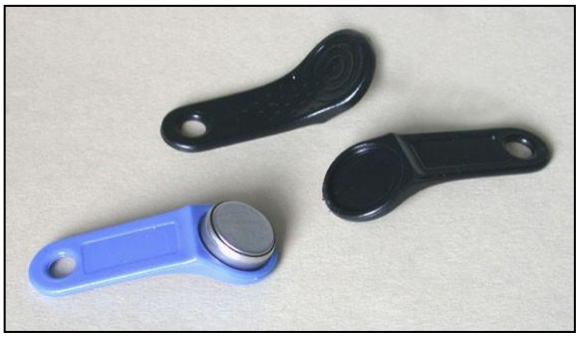


Figure 85

PyroPad-OS – Stainless Steel Capsule

PyroPad-OS ensures protection of PyroButtons up to 10 bar (140 psi) and 150 °C.

Figure 86

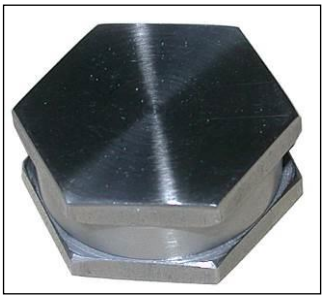


Figure 87

Appendix B – PyroSentry

PyroSentry is an SQL database client/server architecture network driven real-time 21 CFR Part 11 compliant monitoring & emergency facility management system for warehouse & manufacturing facilities, including clean rooms. Up to 8 different sensors can be integrated. Temperature, humidity, differential pressure, and virtual sensors are current available. Additional sensors can be easily embedded.

Figure 88

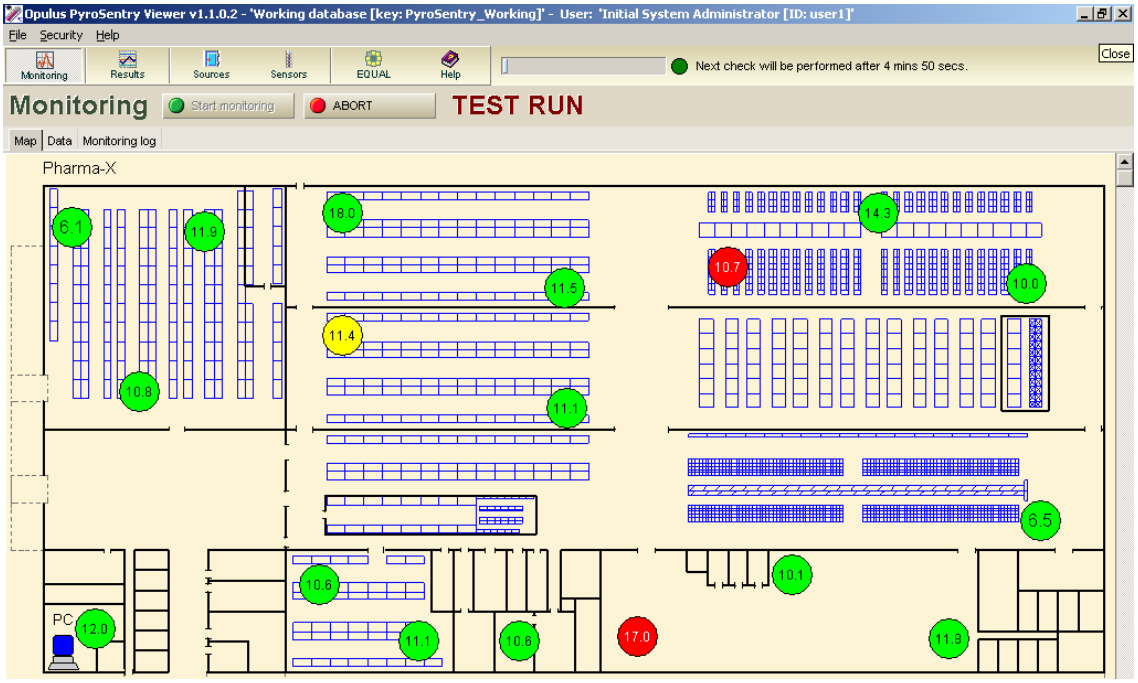


Figure 89

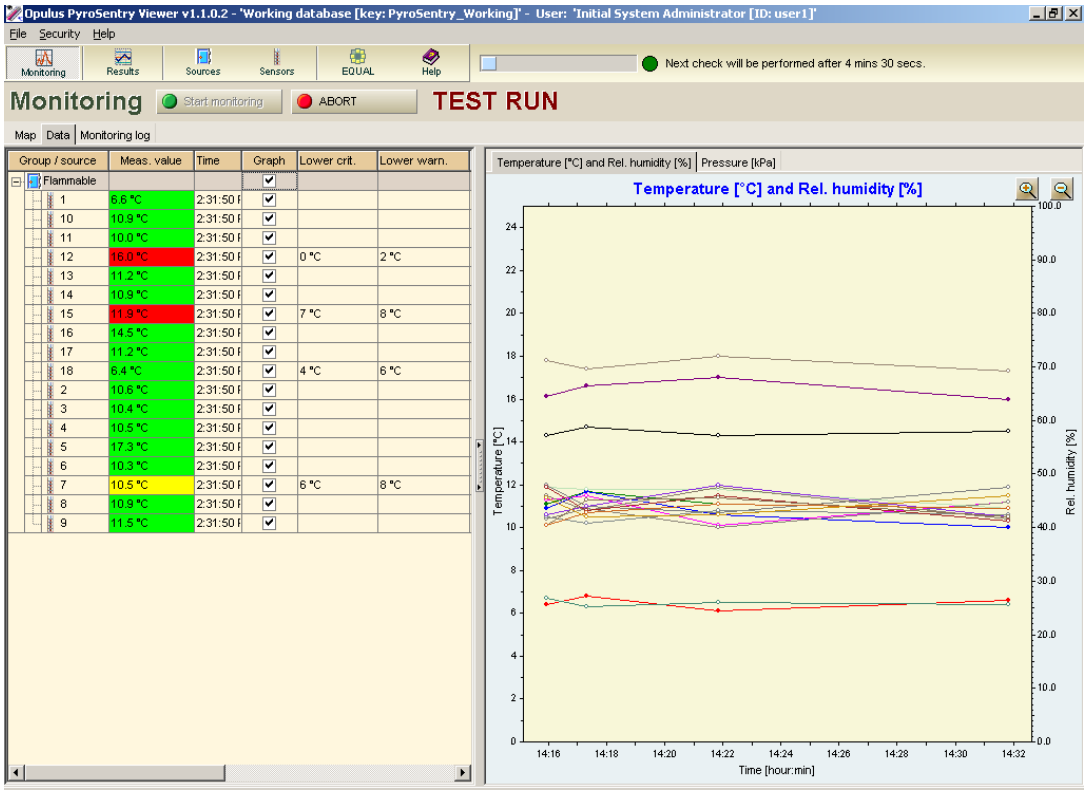


Figure 90