

# TrendView Recorders - Installation Instruction

## IQOQ Protocol Tool

### IQOQ Protocol Document

IQOQ stands for Installation Qualification & Operation Qualification. This is a custom built report based on the configuration of a recorder. The configuration can be validated as a process of confirming that a piece of equipment or process meets the stated requirements to produce a regulated product.

The IQOQ protocol product is for the Trendview recorders. The manufacturer is obligated to execute a "Validation Protocol" for every piece of equipment that is associated with a "critical process". The IQOQ feature aids in doing this and comes with the Trend Server software when ordering the IQ/OQ part number (50032291-501). When ordering your IQOQ Protocol Tool there are two codes that will be supplied; one for the Trend Server software and one to register IQOQ during the setup.

The CD based application generates customized IQOQ documentation for the specific recorder model and its associated options. The IQOQ report is documented evidence that the process will produce a consistent product that meets specification. The IQOQ report that is generated is a documentation package that provides verification that all aspects of the recorder installation adhere to our recommendations, appropriate safety codes, and approved company specifications and design intentions. The output is a PDF report containing the full configuration details of the recorder.

This provides the user with the ability to demonstrate that they have standard operating procedures for operator training, written methods for the verification of the calibration of the system elements, and upkeep of the system.

This report can then be used to work through and validate each setup item.

The IQ/OQ Protocol documentation includes guidelines for:

Installation Qualification include

- configuration verification
- operating environment
- backup and storage procedures
- data file archiving, storage, retrieval verification

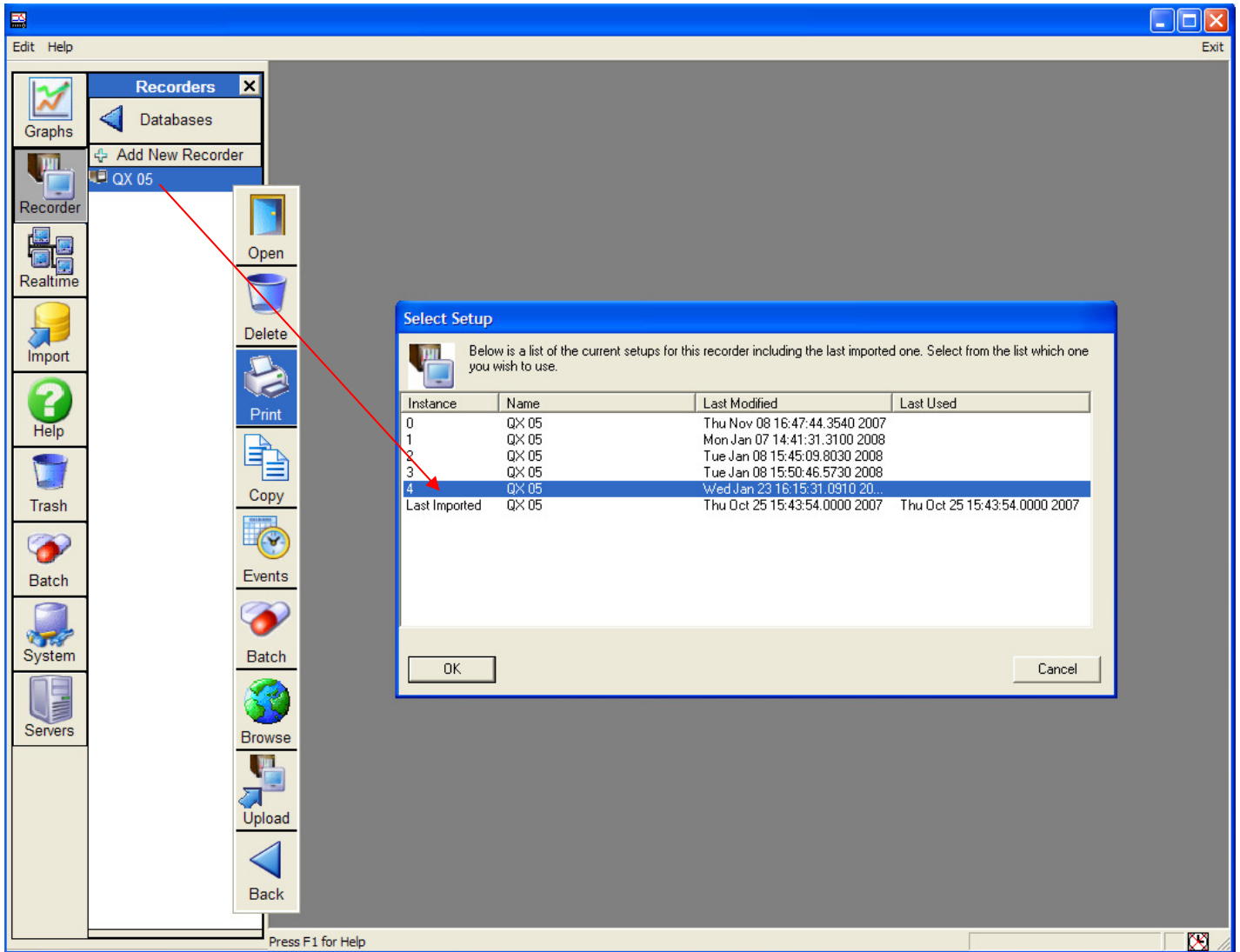
Operational Qualification include

- system device verification
- security verification
- calibration
- input/output verification
- 21 CFR Part 11 compliance

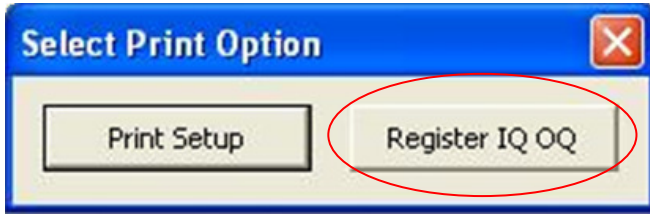
# IQOQ Report Setup

1. In the Trend Server interface select the Recorder icon button from the left side toolbar. This will produce a list of recorders currently residing in a particular database. Right click your mouse on the recorder you wish to run the IQOQ report on and select the Print button from the pop up toolbar

**Figure 1:** Select recorder and setup to generate an IQOQ report

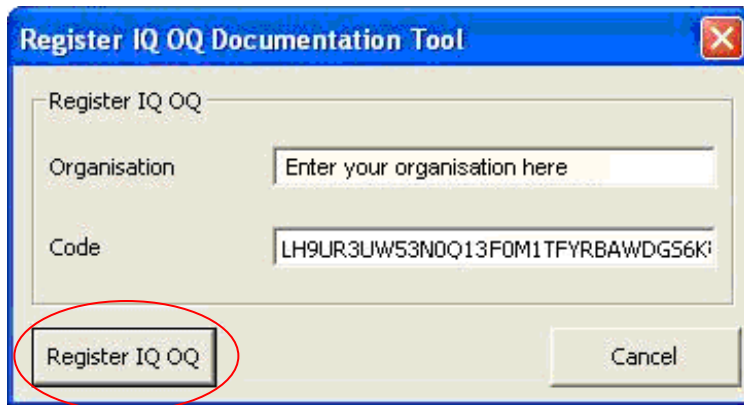


2. Select the desired setup from the Select Setup box. The recorder may have more than one set up saved so be sure to select the correct one.
3. For creating an IQOQ report first you must register your details. Registration is required for each version of Trend Server Pro software.



4. Click on the Register IQOQ button in the Select Print Option box to open the Register IQOQ Documentation Tool. See Figure 2.  
If you simply want to print the setup, without IQOQ, then select Print Setup and the Print Setup box will appear.

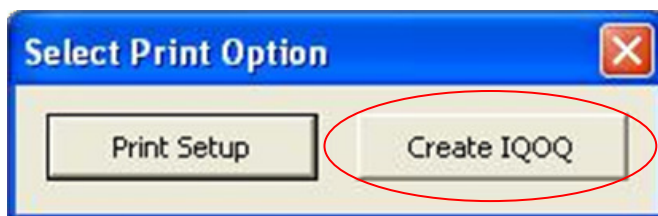
**Figure 2:** Register IQOQ



5. In the Register IQOQ Documentation Tools enter information to register your IQOQ document. Registration is only required once and this process will not be necessary for creating further IQOQ reports.

In the Organisation box enter the company name as stated on the label.

In the Code box enter the code that is supplied with the CD. You will receive two codes one for the Trend Server Pro installation and a second code that enables the generation of the IQ/OQ protocol, enter this code here. Then click on the Register IQOQ button.



6. Once registration is successful the Register IQOQ button, in the Select Print Setup box will change to the Create IQOQ button, select this to enter the document details.

- When the Create IQOQ button is selected the Create IQOQ dialogue will appear. This is where the information about this report is entered.

**Figure 3:** Create IQOQ dialogue box

The screenshot shows a 'Create IQOQ' dialog box with the following fields and controls:

- Document Name:** Recorder 05\_100076.pdf
- Document ID:** Test report #2
- No. Of Computer for TMS Installation (1-10):** 1
- Three Line Footer:**
- Path:** Documents and Settings\My Documents\IQOQ (with a 'Browse' button)
- Company Name:** Your Company Name
- Company Department:** Your Department
- Company Location:** Where your company is located
- Buttons:** 'Create IQOQ PDF Report' (highlighted with a red circle) and 'Cancel'

**Document Name:** Enter the name the PDF document will be saved as. If not changed this will default to the name of the recorder in the recorder list and the serial number.

**Document ID:** Enter ID information that will appear in the header of the PDF document for your own reference.

**No of Computers for TMS installation (1-10):** Number of units where TMS is going to install. This value must be greater than or equal to 1. This value must be an integer value. The report will create a table of inventory of hardware components for each computer where the TMS software is going to be used.

**Three Line Footer:** Three lines of footer information are set as default. Un-Tick this option if only two line are required. The third line footer gives the option to verify with a signature and date.

**Path:** This is the file path where the generated PDF document will be located. A folder is automatically created in this location called IQOQ. The default location is My Documents.

**Company Name:** Enter your company name for which the IQOQ is going to apply.

**Company Department:** Enter details of the department for which the IQOQ is going to apply.

**Company Location:** Enter the Company Location where the IQOQ is going to apply

8. When all the information is entered click on “Create IQOQ PDF Report” and the generation of the document will begin. Once the PDF creation starts, a box will appear saying “Generating IQOQ Report” and progress bar will display the status.
9. The progress bar can be closed during the creation if necessary and the report will not be generated. This may be required if details in the Create IQOQ box need to be changed before the report in run.
10. If the PDF name already exists in the location a warning message will appear. If a file of the same name is already open you will be prompted to close the file first, before clicking, to ensure that the file is replaced with the new PDF being generated.
11. When the IQOQ PDF report is complete it will be saved to the file path specified in the Create IQOQ dialogue.
12. On completion of the report creation, a Yes/No box can be selected to launch the IQOQ PDF report immediately.

The process is complete and any open boxes can now be closed.

**Figure 4:** Sample page from an IQOQ document

Header information: Document description, recorder information and serial number all appear by default.

Header information: Document ID as entered in Print IQOQ Setup dialog

The screenshot displays the following elements:

- Header:** "Installation/Operational Qualification Recorder" and "Serial Number : 100076" (circled in red). Page number "Page: 45 of 136" and "Document ID # Test report #2" (circled in red).
- Menu:** "Menu > Configure > Setup > Edit..."
- Edit Setup Dialog:** A grid of icons for "Field ID", "Pens" (circled in red), "Comms", "Events/Counters", "General", "Screen", "Recording", "Reports", and "Finish".
- Table:** "100076 Configuration Table 9" titled "Pens".
- Footer:** "Compliance Validation Framework" section with fields for "Performed By:", "Date", "Verified By:", and "Date".

The IQOQ document shows how the recorder is currently set up when this report was generated.

Tick marks indicate that the parameter is set or enabled no tick indicates it is not enabled.

Values show the current configuration value.

Footer information: 2 lines by default

Footer information: 3rd line for verification is optional in Print IQOQ Setup dialog