# *CM130 installation qualification (equipment qualification)*

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## Using this document

### Objective of an equipment qualification

Equipment Qualification (EQ) is a formal process that provides documented evidence that an instrument is fit for its intended purpose and kept in a state of maintenance and calibration consistent with its use.
Increasingly, regulatory agencies are acknowledging that EQ is an important prerequisite for obtaining reliable data. In particular, EQ provides an assurance that an instrument functions correctly independently of the applications with which it will be used.

### Who should use this document?

The CM130 Procedures for Equipment Qualification document has been designed for use by qualified and trained persons performing or reviewing the equipment qualification procedures. For the purposes of this document, there are two types of persons:

**The Performer** is a qualified and trained person who will carry out the qualification procedures as defined within the sections of this document.

**The Reviewer** is the owner or nominated trained and qualified person who will review and acknowledge the successful completion of the performer's tasks.

### Equipment qualification procedures document

This document comprises three distinct sections:

- **Section 2: Installation Qualification Procedure (IQ)** ensures that the instrument is received as designed as specified, that it is properly installed in the selected environment, and that this environment is suitable for the operation of the instrument.
- **Section 3: Operational Qualification Procedure (OQ)** is the process of demonstrating that an instrument will function according to the operational specifications in the selected environment.
- **Section 4: Performance Qualification Procedure (PQ)** is the process of demonstrating that an instrument performs according to a specification appropriate for its routine use.

## Other required materials

Ensure that all of the individual instructions for use (IFU) documents are available for use during qualification as the performer will be directed to reference them from time to time whilst carrying out certain qualification procedures.

## Validation form completion

The CM130 Procedures for Equipment Qualification require that the performer(s) and reviewer(s) complete the validation forms throughout this document. These forms are designed to:

- Identify the performer(s) and reviewer(s) who are validating the CM130 system along with their individual credentials.
- Check that the performer(s) and reviewer(s) have read and understood the information in the qualification procedures and on the validation forms found in this document.
- Identify each of the individual parts that make up the CM130 system.
- Record results after the qualification procedures have been performed.
- Check that a procedure has been successfully completed.
- Check that the owner or owner-nominated personnel approves the qualification being carried out.

## Form completion requirements

All entries on a form must be made in permanent blue or black ink.

All items on the forms must be completed (except for the optional comment section).

## Correcting form entries

If it is necessary to correct any entry made to the form, i.e. single word, procedure result, incorrect date entry, etc. proceed as follows:

- Draw a diagonal line through the incorrect entry.
- The performer should write NR (Not Required) along the diagonal line.
- The performer should initial and date along the diagonal line.
- The correct entry should be made to the upper right of the original entry.

# Installation qualification procedure

## Introduction

Installation Qualification (IQ) covers all procedures relating to the installation of the instrument in the selected environment. IQ establishes that the instrument is received as designed and specified, that it is properly installed in the selected environment, and that this environment is suitable for the operation and use of the instrument.

At the time of installation, all of the information pertinent to the proper installation, operation, and maintenance of the instrument is reviewed. Site requirements and the receipt of all components and instructions for use necessary to perform the installation are confirmed. During physical installation, serial numbers are recorded, and all of the fluidity, electrical and communication connections are made for components in the system. Documentation describing how the instrument was installed, who performed the installation, and other miscellaneous details should be archived. For convenience, a checklist is provided.

## System identification

| **Manufactured by** | | |
|---|---|---|
| HACH COMPANY<br>100 Dayton Ave<br>Ames, IA 50010 U.S.A<br>Tel: (800) 227-4224<br>Fax: (970) 669-2932<br><br>Email: orders@hach.com<br><br>www.hach.com | | |
| **Supplier** | | |
| | | |
| **End-user** | | |
| | | |
| **Product** | **Serial/Lot number** | **Installation date** |
| CM130 Analyzer | | |
| Remote Indicator | | |
| Monthly Maintenance Kit | | |
| Tubing Maintenance Assembly Kit | | |
| Performance Check Kit | | |
| **Location Installed** | | |
| | | |

## Completed protocol acceptance

| | | | |
|---|---|---|---|
| **Performer** | Name (print clearly) | Signature | |
| | Title | Initials | Date (dd/mm/yyyy) |
| **Performer** | Name (print clearly) | Signature | |
| | Title | Initials | Date (dd/mm/yyyy) |
| **Reviewer** | Name (print clearly) | Signature | |
| | Must be responsible owner-nominated person | | |
| | Title | Initials | Date (dd/mm/yyyy) |

## Installation requirements

CM130 system:

- ✓ 1 CM130 Analyzer
- ✓ 1 CM130 Installation Kit
- ✓ 1 CM130 Remote Indicator
- ✓ 1 Tubing Maintenance Assembly Kit
- ✓ 1 Performance Check Kit
- ✓ 1 Monthly Maintenance Kit

Install the CM130 analyzer as described in the CM130 User Manual. Before powering the instrument on, ensure that the installation requirements are met and the table below has been completed. All steps below shall be performed per the instructions for use included with the instrument.

| Requirement | Complete (Y/N) | Comments |
|---|---|---|
| **Power requirements** | | |
| • 108 to 132 VAC, 50/60 Hz; 1 A maximum | | |
| **Environmental conditions** | | |
| • Operating temperature: 15 to 30° C (60 to 85° F) | | |
| • Operating humidity: 5 to 90% non-condensing at 30° C (85° F) maximum | | |
| **Sample requirements** | | |
| • Pressure: 276 to 689 kPa (40 to 100 psi nominal) | | |
| • Pressure spikes (120 psi or less) | | |

| | | |
|---|---|---|
| • Flow rate: 250mL/minute minimum at sample inlet | | |
| • Temperature: 15 to 40° C (60 to 104° F) | | |
| • Filtration at sample inlet: 15µm or less | | |
| **Cabling Requirements** | | |
| • Ethernet: 100 m (328 ft) maximum, RJ45 connector | | |
| • Remote Indicator: 762 m (2500 ft) maximum, CAT5e/CAT6 Ethernet cable with four twisted pairs of 24 AWG solid copper wiring<br>• Make sure that the cable shielding includes an inner foil wrap around all of the pairs and an outer braid, also known as SFTP or SF/UTP. Do not use stranded or copperclad aluminum conductors. | | |
| Comments: | | |

## CM130 document identification

| Document name | Document number | Version | Language | Accepted |
|---|---|---|---|---|
| UNPACKING GUIDE, CM130 PERFORMANCE CHECK KIT | DOC273.53.80544 | | | |
| UNPACKING GUIDE, CM130 MONTHLY MAINTENANCE KIT | DOC273.53.80542 | | | |
| INSTRUCTIONS FOR USE, CM130 REMOTE INDICATOR REPLACE-MENT | DOC273.53.80541 | | | |
| INSTRUCTIONS FOR USE, CM130 COLORIM-ETER REPLACEMENT | DOC273.53.80543 | | | |
| CM130 USER MANUAL | DOC023.53.80540 | | | |
| CM130 EQUIPMENT QUALIFICATION | DOC013.53.80555 | | | |
| DVD, CM130 INSTAL-LATION OVERVIEW | DOC083.53.80560 | | | |
| Comments: | | | | |

## Installation procedure

All steps below shall be performed per the instructions for use included with the instrument.

| Installation step | Complete (Y/N) | Comments | |
|---|---|---|---|
| **Mount the analyzer** | | | |
| • Mount fasteners in wall | | | |
| • Deviation from level (mm) | | Value: | Deviation: ≤ 10 mm |
| • Attach analyzer to fasteners | | | |
| • Deviation from vertical (mm) | | Value: | Deviation: ≤ 10 mm |
| • Tighten fasteners | | | |
| **Plumb the analyzer** | | | |
| • Attach drain line and ensure open to atmosphere | | | |
| • Ensure drain line has constant downward slope | | | |
| • Install grab sample assembly to sample inlet fitting | | | |
| • Attach sample tubing to grab sam-ple assembly | | | |

| | | |
|---|---|---|
| • Plumb sample inlet tubing to sample source | | |
| • Open sample source and shutoff valves and check for leaks | | |
| **Install the remote indicator** | | |
| • Install cable in wall/ceiling | | |
| • Mount Remote Indicator backplate | | |
| • Insert cable through backplate and mount to wall/ceiling | | |
| • Strip color-coded wires and connect to green 8-pin connector | | |
| • Install strain relief and ensure cable is secured | | |
| • Connect cable to housing | | |
| • Attach housing to backplate | | |
| • Depress test button next to battery and ensure beeping sound is heard | | |
| • Install Remote Indicator cover | | |
| **Analyzer electrical installation** | | |
| • Strip and connect other end of Remote Indicator color-coded cable to Remote Indicator connector | | |
| • Connect an Ethernet cable to the RJ45 connector | | |
| • Tighten cable gland fitting nuts on Ethernet cable and Remote Indicator cable | | |
| • Connect power cord to wall outlet | | |
| **Configuration** | | |
| • Set the date and time zone | | |
| • Configure the network settings | | |
| **Reagent and colorimeter installation** | | |
| • Install the colorimeter | | |
| • Install the reagents<br>Indicator bottle should be attached to the red cap and the buffer bottle should be attached to the black cap | | |

Comments:

# Operational qualification procedure

## Introduction

Before starting the procedure, ensure that the performer and review have read and understood the Equipment Qualification Overview.

The CM130 Equipment Qualification document is designed for use by a qualified person in order to validate the monitoring system.

The Operational Qualification procedure should only be performed after completion of the Installation Qualification Procedure (Section 2) or after replacement of any components of the CM130 system.

## System identification

| **Manufactured by** | | |
|---|---|---|
| HACH COMPANY<br>100 Dayton Ave<br>Ames, IA 50010 U.S.A<br>Tel: (800) 227-4224<br>Fax: (970) 669-2932<br>Email: orders@hach.com<br>www.hach.com | | |
| **Supplier** | | |
| | | |
| **End-user** | | |
| | | |
| **Product** | **Serial/Lot number** | **Installation date** |
| CM130 Analyzer | | |
| Remote Indicator | | |
| Monthly Maintenance Kit | | |
| Tubing Maintenance Assembly Kit | | |
| Performance Check Kit | | |
| **Location installed** | | |
| | | |

## Completed protocol acceptance

| | | | |
|---|---|---|---|
| **Performer** | Name (print clearly) | Signature | |
| | Title | Initials | Date (dd/mm/yyyy) |
| **Performer** | Name (print clearly) | Signature | |
| | Title | Initials | Date (dd/mm/yyyy) |
| **Reviewer** | Name (print clearly) | Signature | |
| | Must be responsible owner-nominated person | | |
| | Title | Initials | Date (dd/mm/yyyy) |

## Operational procedure

All steps below shall be performed per the instructions for use included with the analyzer.

| Requirement | Complete (Y/N) | Comments |
|---|---|---|
| **Power the analyzer on** | | |
| • Confirm that the analyzer boots | | |
| • Set the analyzer to idle mode if necessary | | |
| **Perform a colorimeter flush** | | |
| • Visually confirm that the stir bar is rotating inside the colorimeter while it is flushing | | |
| **Verify flow rate** | | |
| • Temporarily remove the drain line from the analyzer | | |
| • Place a 250mL or larger beaker under the drain port on the analyzer | | |
| • Perform a second colorimeter flush | | |
| • Confirm that at least 245 mL of sample is captured in the beaker after the flush cycle completes | | Volume: |
| • Reattach the drain line and confirm it has a constant downward slope | | |
| **Set the analyzer to measurement mode** | | |
| • Confirm analyzer speaker emits a “Starting test cycle” notification | | |
| • Confirm no errors are reported on the CM130 in the first 5 minutes | | |
| • Confirm that the RI has a dark water icon and blue analyzer icon in the first 10 minutes after starting measurement mode | | |
| • Confirm that a measurement shows on the display after 20 min | | |
| • Confirm that the RI has a blue or amber water icon and blue analyzer icon after the first measurement is displayed | | Chlorine Value:<br>RI Water Icon Color:<br>RI Analyzer Icon Color: |
| • Shut off flow from the water system by closing the inlet valve and confirm that the analyzer displays an “insufficient sample flow” alarm within 10 minutes | | |
| • Confirm that the analyzer is emitting an audible alarm | | |
| • Navigate to Notifications and confirm that the insufficient sample flow alarm is listed | | |
| • Confirm that the RI has a dark water icon, a red analyzer icon, and that it is emitting an audible alarm | | RI Water Icon Color:<br>RI Analyzer Icon Color:<br>RI Audible Alarm: |

| | | |
|---|---|---|
| • Mute the alarm at the analyzer and confirm that the analyzer and RI stop emitting an audible alarm | | Analyzer Audible Alarm:<br>RI Audible Alarm: |
| • Select the alarm from the notifications list, press Ok and confirm that the description references the sample flow | | |
| • Restore flow from the water system by opening the inlet valve, then set the analyzer to measurement mode | | |
| • Allow the instrument to make one successful measurement before continuing | | Chlorine Value: |
| • Pour 5-10 mL of tap water into the analyzer funnel when the progress scrim is between 60-70% | | |
| • Confirm that the analyzer displays a “High chlorine” alarm at the end of the measurement | | Repeat previous step as necessary to obtain a “High Chlorine” alarm |
| • Confirm that the analyzer is emitting an audible alarm | | |
| • Confirm that the RI has a red water icon, a blue analyzer icon, and that it is emitting an audible alarm | | RI Water Icon Color:<br>RI Analyzer Icon Color:<br>RI Audible Alarm: |
| • Mute the alarm and confirm that the analyzer and RI stop emitting an audible alarm | | Analyzer Audible Alarm:<br>RI Audible Alarm: |
| **Set the analyzer to idle mode** | | |
| • Confirm no errors reported in the first 2 minutes | | |
| • Navigate to Settings, then About and record the software version displayed | | Version: |
| | | |
| Comments: | | |

# Performance qualification procedure

## Introduction

The purpose of the Performance Qualification (PQ) is to ensure that the instrument *consistently* performs according to a specification appropriate for its routine use. The test frequency is higher than for the OQ. PQ should always be performed by the user under conditions that are the same as, or similar to, those for routine use and sample analysis.

During routine use, procedures shall exist which demonstrate that the equipment "will continue to perform without problems". However, testing should not be the only activity to ensure on-going reliable data. Preventative maintenance, on-going training for new operators, and an appropriate error-detection system are equally important. Each clinic should have a comprehensive quality assurance program that is well-understood, accepted and followed by individuals, as well as organization, to prevent, detect, and correct problems. The purpose of this is to ensure that the equipment is running without problems and that the analytical results have the highest probability of being of acceptable quality.

The supplier can provide recommendations on what to check, environmental conditions, recommendations for acceptance criteria and recommended actions if criteria are not met or trouble is encountered. Performance checks are recommended to be carried out more frequently on new instruments. If the instrument continually meets the performance specifications, the time interval can be increased.

## Steps for performance qualification

At a minimum, the instrument should run for 24 hours and the below steps should be taken to ensure the instrument meets the criteria for performance.

| Requirement | Pass/Fail | Corrective action (if required) |
|---|---|---|
| Ensure there are no alarms/errors | | |
| Perform and pass performance check | | |
| Comments: | | |

## Completed performance qualification

| | | | |
|---|---|---|---|
| **Performer** | Name (print clearly) | Signature | |
| | Title | Initials | Date (dd/mm/yyyy) |
| **Performer** | Name (print clearly) | Signature | |
| | Title | Initials | Date (dd/mm/yyyy) |
| **Reviewer** | Name (print clearly) | Signature | |
| | Must be responsible owner-nominated person | | |
| | Title | Initials | Date (dd/mm/yyyy) |

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