Antec Scientific
Hoorn 131
2404 HH Alphen a/d Rijn
The Netherlands

OQ

for CT 2.1

186.0022, Edition 1, 2025

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CHAPTER 1

Introduction

This document describes the Operation Qualification procedure as advised by the manufacturer. It is a result from our interpretation of many regulations and laboratory practices. In addition, feedback from users and representatives helped us to finalize this procedure.

As regulations and customer requirements may change, manufacturer reserves the right to introduces changes without prior notice. For details on functionality, operation and theory we refer to the instrument user manuals.

In this document, all qualification checks have to be approved, or should be marked “n.a.” if not applicable. Any deviation observed must be documented in the 'non-conformance' record. All relevant documents regarding this qualification must be filed together in one location.

CHAPTER 2

OQ procedure

Introduction

The Operation Qualification (OQ) consist of temperature measurement of the CT 2.1 column compartment. The accuracy of the temperature is measured at 3 different temperatures covering the range from 10 to 60°C.

Required parts, tools and software

Required parts and tools

Part no	Description
250.3056	Calibrated thermometer

Required software

Knauer service tool or any CDS which is compatible with the CT2.1 column thermostat (e.g., Clarity™ or Chromeleon™)

Temperature Test

Using a calibrated thermometer, the column thermostat temperature is measured at 3 different settings to test the accuracy of the temperature.

Preparations

Install the probe of the thermometer in the left top column clamp of the CT 2.1 column compartment. It is important that this is located there were the columns are typically placed. Make sure that the probe does not touch the metal backplate by clamping the wire of the probe in one of the column clamps. During the measurements, the probe should not be (re)moved.

Procedure

1. Set the CT 2.1 temperature to 30°C. Wait for the temperature to be stabilized and read the measured temperature on the external thermometer probe.
2. Set the CT 2.1 temperature to 10°C. Wait for the temperature to be stabilized and read the measured temperature on the external thermometer probe.
3. Set the CT 2.1 temperature to 60°C. Wait for the temperature to be stabilized and read the measured temperature on the external thermometer probe.
4. Remove the thermometer probe and fill the OQ results summary.

C H A P T E R 3

OQ results summary

Test results

	Specified	Measured	Result*1
TEMPERATURE TESTS			
30°C Setting			
Temperature	30.0 ± 1.5 °C	……. °C	……
10°C Setting			
Temperature	10.0 ± 1.5 °C	……. °C	……
60°C Setting			
Temperature	60.0 ± 1.5 °C	……. °C	……

*1 Fill in ‘passed’ or ‘failed’

Final result (passed / failed) _____

Verified by (customer): …….. Deviations (Y/N): ……

Comments:

CHAPTER 4

OQ certification

The undersigned reviewer/customer is authorized to sign and accepts that the engineer is trained and qualified to perform the Qualification procedures on Antec devices.
The undersigned engineer certifies that he/she is trained and qualified to perform the Qualification procedures on Antec devices.
All tests and procedures as described in this document have been completed, and all results are within specifications or clearly indicated if not.

The installation and operation testing has been carried out in accordance to the OQ procedures and to the satisfaction of both parties.

Engineer

Name ……

Initials ……

Company ……

…… ……..……

Date Signature

Reviewer/customer

Name ……

Initials ……

Job title ……

Company & Dept. ……

…… ……..……

Date Signature

Instrument

CT 2.1 p/n: ……. s/n: …….....

OQ test devices

Temperature probe ……. s/n: …….

Other relevant information

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Verified by (customer): …….. Deviations (Y/N): ……

Comments:

Comments

Verified by (customer): …….. Deviations (Y/N): ……

Comments:

CHAPTER 5

Non-conformance record

Any case of non-conformance found during the qualification procedure should be documented and signed for acceptance or corrective action taken.

Table I

Ref.	Non-conformance and action taken	Signature customer	Sign. executing technician
1		……	……
2		……	……
3		……	……
4		……	……
5		……	……
6		……	……

Verified by (customer): …….. Deviations (Y/N): ……

Comments: