

Introduction

In a regulated laboratory the purchase price of an instrument is only relatively small part of the total cost. For some instruments there are expensive consumables and the manufacturer will provide the original instrument very inexpensively in order to lock the laboratory into these. For other instruments the manufacturer will design it in such a way that yearly validation requires special tools only available to their affiliates and locking the laboratory into expensive yearly visits. When making purchases it is of course important to look at the total cost of ownership which will include all or some of the following; initial cost, consumables, maintenance, validation/calibration, and expected life span.

Reducing the cost of Refractometer Validation

Rudolph avoids expensive annual validation costs by offering a refractometer IQOQPQ kit for purchase by the customer along with full documentation on how to use the kit to perform a refractometer validation. Thus the instrument owner can perform their own refractometer validation. The kit consists of a range of fluid standards traceable to NIST (US National Institutes of Standards and Technology.) These fluids have selected refractive indices at different specified temperatures. Different fluids have different temperature coefficients.



Test protocols

Calibration and Linearity

The five fluids in the kit enable a laboratory to check the performance of the instrument across the whole range of interest

Temperature reference point

The enables a method based on differential temperature coefficients to provide that the temperature reference point of 20C is correct.

Temperature span

The kit enables a method to check that the temperature span from the 20C reference point is correct.

Useable life

The kit contains enough fluid for at least 7 validations. The fluids will expire 2.5 years from opening. There are no parts to send back to Rudolph or extra costs during that time. Additional kits may be purchased as needed.

Applicability

The Rudolph kit will enable the validation of any temperature controlled laboratory refractometer. The kit will not work with non-temperature controlled refractometers. However the US, European, British, Chinese, Indian and Japanese pharmacopeias all require temperature control so any refractometer meeting these standards can be validated with Rudolph's Refractometer Validation IQOQPQ kit.

Versions

Standard version validates water and higher refractive index materials

Special version adds the ability to validate materials with refractive indices much lower than water such as Isoflurane and Sevoflurane.

More technical details

Request a copy of the validation protocol from Rudolph Research (info@rudolphresearch.com)