

### Temperature Measurement and Control in DigiPol-DP781 Series Automatic Polarimeters

DigiPol-DP781 series Polarimeters have a provision for built in temperature sensors.

- These allow a direct measurement of the temperature of the sample and its recording rather than relying on the temperature of the circulating water.
- They are calibrated with reference to an NIST traceable thermometer and are certified to be accurate to better than  $\pm 0.2^\circ \text{C}$  as required by USP <781>.
- They can be validated as part of the validation/ qualification of DigiPol itself and no separate validation of the circulating controller is required.
- They measure the temperature of the sample in situ, as its rotation is being measured, and the measured temperature is printed right alongside the rotation value measured for a 'no questions asked' record of the temperature of the sample.
- Due to their extremely small size, these sensors measure the temperature of the sample at its tip, which is the actual sample whose temperature is controlled and is probed by the light beam in the polarimeter. This is a vast improvement over other sensors like platinum resistors for example, which can only measure some average temperature of the sample along their entire length contained in the side tube and not the temperature of the sample in the tube itself, pl. see drawing overleaf.

Further, the DP\_WIN software now available for operating the DigiPol-DP781 series in conformity with 21CFR11 regulations:

- Allows continuous monitoring of the sample temperature
- Allows the measurement to proceed only when it is within a defined range, e.g. 24.8 and 25.2C as required by USP<781> and
- Records the measured temperature along with other measurement data in a database secured by electronic signatures.

So, a properly validated DigiPol-DP781 equipped with the built in DP2TC11A, Temperature measurement assembly:

- Is a self contained unit for measuring the optical rotation at the monograph temperature
- Measures the temperature of the actual sample being measured,
- Does not need any other references or validations.

