Testing wirelessly-monitored thermometers for improved patient safety

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Abstract. We describe the metrological characterisation of temperature measurements performed by a wireless patient surveillance system developed by Isansys, which allows healthcare providers to remotely monitor a patient's vital signs even after they have left the hospital. The system collects and analyses patient data, such as temperature, heart rate and respiration rate, alerting healthcare providers if it detects the early signs of sepsis - a condition which kills 37,000 patients in the UK annually.

1 Introduction

The National Physical Laboratory (NPL) has combined its expertise and facilities in temperature and humidity measurement to calibrate and assess the performance of a wirelessly monitored clinical thermometer (Lifetemp) for healthcare company, Isansys Lifecare.[1]

Isansys Lifecare Ltd has created a continuously operating vital sign data acquisition, analysis and prediction platform called "the Patient Status Engine" (PSE). This combines unobtrusive wireless wearable sensors, wireless networks, analytical algorithms and 'big data' to provide monitoring for patients in hospital and at home.

This patient monitoring system performs observations of heartbeat, breathing, and oxygen saturation every second, temperature every minute and blood pressure as required.

Figure 1. Patient Status Engine (PSE)

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Wirelessly-readable thermometers need to perform consistently as the wearer's surroundings change and they require accurate calibration in a range of different environments. The calibrated clinical thermometer is a thermistor connected to an electronic module, which transmits the data wirelessly to a tablet or smartphone.

In accordance with the requirements of the standard BS EN ISO 80601-2-56:2012 [2], the thermometer was calibrated at a series of fixed temperatures over a range of ambient temperatures (from 15 °C to 35 ºC) and humidities (from 20 %rh to 80 %rh). The temporal response of the device to applied heating and cooling was also measured.

2 Experiment

The clinical thermometer consists of a 5 mm long, 3 mm outer diameter thermistor connected to an electronic readout module by a pair of wires 75 mm in length. The module sends a signal to a remotely located tablet every second. Specially designed software converts the signal to temperature which is displayed and saved in the database.

The thermistor was placed in the thermometer well of a dry block calibrator to a depth of 75 mm together with a traceably calibrated reference thermometer. The unit was tested by comparison of the displayed temperatures with those of the reference thermometer. The clinical thermometer was tested at 25.5 °C, 35 °C and 44.5 °C. All three temperatures were realized in different environmental conditions as follows:

- Ambient temperature of 25.5 °C and humidity of 50 %rh;
- Ambient temperature of 15.5 °C and humidities of 20 %rh and 80 %rh;
- Ambient temperature of 35.5 °C and humidities of 20 %rh and 80 %rh.

To create the required environment, the dry block calibrator, including the standard reference thermometer and the clinical thermometer, were placed into an environmental chamber. For each condition, the chamber was set to provide the required humidity and temperature. The measurements were performed once stable environmental conditions were reached. The chamber temperature was stable within ± 0.5 °C and the humidity was stable within ± 5 %rh. Temperature and humidity in the chamber were measured using a calibrated hygrometer. Results of measurements are shown in Table 1. The standard BS EN ISO 80601-2-56:2012 states that during the test the clinical thermometer must show no error greater than 0.3 °C.

To test the temporal response, the thermometer was placed in the water bath controlled at a stable temperature of 35 °C (T1). Once thermal equilibrium was achieved the thermometer was moved immediately to the dry block calibrator. The temperature of the dry block calibrator was controlled at 37 °C and 33 °C (T2) to monitor warming and cooling respectively. The temporal response was defined as a time taken by the unit under test (UUT) to reach 90% of the final temperature. The measurement setup is shown in Figure 2.

Figure 2. Measurement setup for measuring temporal response

3. Results

The results of the test are set out in the following tables, where the corrections which show the difference between the ITS-90 temperature and the displayed temperature are stated to the nearest 0.1 °C and represent the mean of the observations.

The temporal response of the clinical thermometer was measured as the thermometer was subjected to a step change between the two temperatures several times. An average of the measured time is recorded in the Table 2.

The temperature of the dry block calibrator was measured by the reference thermometer with an estimated uncertainty of ± 0.04 °C. The uncertainty of

the temperatures measured by the reference thermometer is ± 0.001 °C.

Table 1. Test results

Ambient Temperature, °C	Relative Humidity, % rh	Reference Temperature, °C	UUT Reading,°C
25	50	25.724	25.50
		34.965	34.86
		44.469	44.32
35.5	20	25.443	25.26
		35.538	35.44
		44.459	44.50
	80	25.440	25.31
		35.897	35.80
		44.458	44.50
15.5	20	25.472	25.34
		34.977	34.86
		44.481	44.40
	80	25.472	25.38
		34.975	34.84
		44.481	44.40

Table 2. Temporal response

	Temperature step change	Temporal response
Heating time	T1 = 35 °C T2 = 37 °C	15 seconds
Cooling time	T1 = 35 °C T2 = 33 °C	11 seconds

The uncertainty at the time of test is calculated as follows:

$$U = \sqrt{U_{ct}^2 + U_{RT}^2 + U_{stab}^2 + U_{hom}^2} \qquad (1)$$

where

U_{ct} is the uncertainty of clinical thermometer;
U_{RT} is the uncertainty of reference thermometer;
U_{stab} is the uncertainty due to the stability of the dry block and
U_{hom} is the uncertainty due to the uniformity of the dry block
The estimated uncertainty at the time of test is ± 0.2 °C and it is based on a standard uncertainty multiplied by a

coverage factor $k = 2$, providing a coverage probability of approximately 95%.

4 Conclusions

Results from the performed test showed that the presented clinical thermometer is suitable for use as a part of Patient Status Engine (PSE). The tested clinical thermometer complies with the requirements of the standard "BS EN ISO 80601-2-56:2012 Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurements".

Acknowledgements

The authors thank the Humidity group at NPL for providing the facilities used for realization of the required environmental conditions

References

1. Isansys Lifecare, www.isansys.com
2. BS EN ISO 80601-2-56:2012 Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurements