MPBE COVID-19 Rapid Technology Assessment Bulletin

Braun Welch Allyn Thermoscan Pro 6000 Tympanic Near Infrared Thermometer

Dept. of Medical Physics & Bioengineering, St James's Hospital, Dublin.

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About MPBE COVID-19 Rapid Technology Assessment Bulletins

As the COVID-19 emergency evolves, an increasingly wide range of technology is being offered for supply to hospitals and other healthcare providers. This technology extends beyond the standard and familiar medical equipment deployed in clinical settings. These 'new' technologies may be completely new innovations targeted at COVID-19, devices previously regarded as niche that are finding a role in COVID-19 applications, medical equipment or models that have not been routinely used in Ireland, or consumer devices that have been adopted for COVID-19 applications. It is important that healthcare providers can quickly assess the suitability of these technologies for application in their environment.

The Dept. of Medical Physics and Bioengineering (MPBE) at St James's Hospital, Dublin Ireland, has been providing a rapid COVID-19 technology assessment service to the hospital in order to quickly evaluate specific equipment being considered for use in the hospital. These reviews are not presented as exhaustive assessments. Summaries

of the evaluations are provided in short *Bulletin*s highlighting the main findings. The *Bulletins* are intended to assist clinical and other staff assess suitability of the technology, and to highlight any important operational or other issues.

Disclaimer: Bulletins are provided outside St James's Hospital to assist the wider health service and do not in any way amount to a recommendation of any specific provider, technology, machinery, software or otherwise. Furthermore, the Bulletins are providing a *review* of usage and are not suggestive as to suitability, transferability or advice. Assessments are considered with regard to the specific physical and clinical environment in St James's Hospital and not all findings may be transferable. Assessments in these Bulletins focus on technical aspects; clinical efficacy, cost, legal and infection control issues are generally not in the scope of the technical reviews. As such, St James's Hospital accepts no liability whatsoever in relation to the issue and/or usage of any of the product(s) being reviewed in any particular Bulletin.

1. Device: Welch Allyn Braun Pro 6000 Infrared Tympanic Thermometer

The device assessed is a **Welch Allyn Braun Pro 6000 Infrared Tympanic Thermometer** supplied by MDI Medical, Kells, Co. Meath, Ireland.

2. Classification

The device is a CE marked, medical grade Class IIa IR Tympanic Thermometer listed as complying with ASTM Standard E 1965–98.

The device is indicated for the intermittent measurement of human body temperature for patients having ages ranging from newborn (full term and normal weight) to geriatric adults in professional clinical use environments.

3. General Performance & Key Findings

MPBE assessed a sample device and a reference site was also contacted for feedback. The device was found to have good overall technical performance and is therefore considered acceptable for use in St James's Hospital, Dublin.

- **Accuracy:** In lab tests, the device's mean absolute difference was found to be accurate to within +/- 0.2˚C across a temperature range of 36˚C - 41˚C. These values lie within stated specifications and international standard requirements. The device was found to have same-day repeatability within +/-0.2 ˚C.

- **Literature:** A meta-analysis by Niven et al. suggests that generally Braun Thermoscan devices have a mean (LOA) accuracy of 0.02°C (−0.25 to 0.29) when compared to gold standard core temperature measurement. This lies within predefined clinically acceptable ranges (LOA ± 0.5 °C).

- **Reference site:** Feedback from an international reference site recommended use of the Welch Allyn Braun Pro6000 based on their testing, clinical use, and clinical experience.

- **Usability and ease of integration:** The device was found to be easy to use and easy to integrate into existing technical infrastructure within St James's hospital.

4. Other Technical & User Considerations

- **Environment:** The device was also checked in an environment with fluctuating environmental temperatures, and was found to provide stable readings +/-0.3 ˚C. However as per instructions for use, measurements should be taken in stable environmental conditions, i.e. the patient and the device should remain in an environment for 30 minutes, where the temperature is maintained at a constant temperature between 10 ºC to 40 ºC, prior to taking a measurement.

- **Stated Clinical accuracy:** The device has a stated bias of 0.09˚C and limits of agreement of 0.58˚C with a clinical repeatability of 0.19˚C.

- **Maintenance**
    - Periodic readjustment of the device is stated as not required.
    - The manufacturer recommends [2] checking calibration on an annual basis or whenever clinical accuracy of the thermometer is in question.
    - Device calibration can be checked using the Welch Allyn (9600 Plus Calibration Tester).

- **Usability**
    - Local SJH testing in clinical environment have found the devices to be suitable for use.
    - The device is generally quick and easy to use, taking approximately 10-15 seconds per measurement. The device requires a new probe to be fitted per patient.
    - As per all in-ear based temperature measurement systems, this device must be properly positioned within the ear, and the device and patient should remain stable. This device applies novel sensing methodologies to overcome and reduce these and other sources of measurement variability.
    - The device is compatible for integration with existing Welch Allyn devices used in St James's hospital with device mounting (wall or integration with WA VSM models) and data connectivity supported.
    - Usual caveats apply in terms of patient preparation and external temperature fluctuations (see above).

- **Infection Control**
    - The device uses a single-use disposable ear probe cover and therefore reduces the risk of cross-contamination. The device has a comparable risk profile to other contact temperature measurement devices on the market.

- While the device warns users to replace the disposable ear probe cover between use, it is still possible to re-use an already used ear probe. Users should be therefore trained to avoid this practice.
- Used probe covers should be disposed of following use (and not stored back in the docking station).
- The device must be cleaned between patient use as per manufacturer's guidelines, for example:
  - Gently wipe the surface of the probe lens window and metal contacts with a cotton swab or cloth slightly moistened with isopropyl or ethyl alcohol only.
  - The body of the device can be cleaned with an approved set of cleaning agents as per manufacturer's recommendations.

- **Consumables**
  - The device requires a probe cover for each patient incurring a cost dependent on frequency of measurements.
  - Spare replacement probes can be stored with the device docking station – these will need to be replaced regularly.
  - A local centralised storage solution is likely required for each ward for these consumables.
  - These plastic consumables will contribute to total plastic waste generation of the hospital.

5. References

[1] Niven DJ, Gaudet JE, Laupland KB, Mrklas KJ, Roberts DJ, Stelfox HT. Accuracy of peripheral thermometers for estimating temperature: a systematic review and meta-analysis. Ann Intern Med. 2015 Nov 17;163(10):768-77. doi: 10.7326/M15-1150. PMID: 26571241.

[2] Braun Thermoscan Pro6000 Manuals and Documents. Retrieved from: https://www.welchallyn.com/en/products/categories/thermometry/ear-thermometers/braun-thermoscan-pro-6000/documents.html. Last Assessed 12-02-2021.

APPENDIX 1:

Document Log			
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