Katy Thorne KC
Assistant Coroner
Berkshire Coroner's Office
Reading Town Hall
Blagrave Street
Reading
RG1 1QH

National Medical Director
NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

[redacted] [redacted]

18 October 2023

Dear Ms Thorne

Re: Regulation 28 Report to Prevent Future Deaths – Devon Drew Turner who died on 10 May 2022.

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 18th August 2023 concerning the death of Devon Drew Turner on 10th May 2022. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to Devon's parents and wider family. NHS England are keen to assure the family and the coroner that the concerns raised have been listened to and reflected upon.

On receipt of your Report, it was shared with colleagues from NHS England's central Patient Safety (including medical device specialists) and Children & Young People teams as well as my regional Quality colleagues in the South East. The Patient Safety Team reviewed the concerns raised and have confirmed that they are not aware of similar incidents and that there are no known patient safety issues relating to SATS machine alarms in general.

From your Report the underlying issue relates to the specification of the SATS machine used, its alarm settings and volume, whether it was suitable for use in a patient's home and whether the machine in this case was working properly. These issues would fall under the remit of the Medicines and Healthcare products Regulatory Agency (MHRA), who are the regulator for all medical devices in the UK, who I note that you have also addressed your concerns to.

We have been in touch with the MHRA regarding the concerns raised in Devon's case. They have advised that they are in receipt of the manufacturer's investigation report into the Medtronic Nellcor PM100N Bedside SpO2 Monitor (serial number MBH1920704) that was being used to monitor Devon's SATS at the time of his death and that Medtronic advised that they found no fault with the device during an examination in the presence of the police. The alarm volume was set at its maximum while the pulse and key beep volumes were silenced. I note your letter to Medtronic, dated 9 October 2023, stating that you are unable to accept some of the evidence in its entirety, and MHRA is continuing to work with the manufacturer to ensure this matter is fully investigated and any identified actions are undertaken.

MHRA advised that the operator's manual for the device indicates it is appropriate for home use when used as an adjunct in patient assessment and is to be used in

conjunction with clinical signs and symptoms. There are several warnings in the operating manual regarding the alarms, including, for example, ensuring the speaker is clear of any obstruction to prevent an inaudible alarm tone. Patients should also be kept under close surveillance when monitoring as it is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the monitoring system can cause inaccurate measurement readings. It is advised not to rely entirely on the monitoring system's readings for patient assessment. NHS England has been asked to be sighted on MHRA's response to you and will review any further considerations from the organisation.

My regional colleagues in the South East have also been engaging with Berkshire Integrated Care Board (ICB) on the circumstances of this case, and NHS England will be seeking assurances that any identified local learnings are acted upon. I understand that they have been in touch with you separately on some of the concerns raised.

I would also like to provide further assurances on national NHS England work taking place around the Reports to Prevent Future Deaths. All reports received are discussed by the Regulation 28 Working Group, comprising Regional Medical Directors, and other clinical and quality colleagues from across the regions. This ensures that key learnings and insights around preventable deaths are shared across the NHS at both a national and regional level and helps us pay close attention to any emerging trends that may require further review and action.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,

National Medical Director