Regulation 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT DEATHS **THIS REPORT IS BEING SENT TO:** **1** MEDTRONIC **2** ROYAL BERKSHIRE NHS FOUNDATION TRUST **3** BERKSHIRE INTEGRATED CARE BOARD **4** MEDICATION AND HEALTHCARE PRODUCTS REGULATORY AGENCY **5** NHS ENGLAND
1	**CORONER** I am Katy Thorne KC, Assistant Coroner for the coroner area of Berkshire.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and Regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. As set out in the case of R ([redacted]) v Assistant Coroner for East London, the issuing of a Regulation 28 report entails no more than the coroner bringing some information regarding a public safety concern to the attention of the recipient. The report is not punitive in nature.
3	**INVESTIGATION** On 23 November 2020, I commenced an investigation into the death of Devon Drew Turner aged 16 weeks. The investigation concluded at the end of the inquest on 16 August 2023. The conclusion of the inquest was natural causes. The medical cause of death was Sudden Unexpected Death in an Infant with Trisomy 9 Mosaicism (SUDI with Mosaic Trisomy 9)
4	**CIRCUMSTANCES OF THE DEATH** 1. Devon Drew Turner was born on 17 January 2022 at Basingstoke and North Hampshire Hospital. He died on 10 May 2022 at Royal Berkshire Hospital of Sudden Unexpected Death in an Infant with Trisomy 9 Mosaicism. (SUDI with Mosiac Trisomy 9) 2. Devon was born with a number of abnormalities due to a rare chromosomal disorder, Mosaic Trisomy 9 which had caused him serious health vulnerability, and particularly with his respiratory system, throughout his short life. He had been admitted to the Paediatric Intensive Care Unit twice. 3. On 21 April 2022 he was discharged home to live with his parents and needed respiratory support on a CPAP machine throughout the night and for long periods during the day and monitoring on a SATS machine. Throughout Devon's time at home he was visited by the community nurses every 2-3 days and the family were supported by the specialist nurses at UHS. 4. On 30 April 2022 he was admitted to Basingstoke and North Hampshire Hospital with an increasing need for CPAP but was discharged the following day at 12.50pm as he remained stable. 5. On 10 May 2022 Devon was given his 1am feed and the family settled down to sleep. At 4.30am Devon's mother woke to find him unresponsive. An ambulance was called and he was taken to the Royal Berkshire Hospital but despite the best efforts of the medical teams he could not be revived and he died the same morning. Despite extensive post-mortem examination by a number of specialists it was not possible to come to any firm conclusion about what specifically caused his death, and the cause of death was given of SUDI with Trisomy 9 such that it was possible to conclude that it was a natural death and was linked directly to his diagnosis of trisomy 9.

	6. On examination of the CPAP machine that was maintaining his breathing, no faults were identified and it was confirmed that the only interventions by human hand were consistent with the parents' account, namely that he was given his feed at 1pm, the parents had gone to sleep and had woken again at 4.30am to find Devon unresponsive, the CPAP machine continuing to blow. The CPAP machine recorded at 4.30am when they disconnected him from it and turned it off as they called 999. 7. By contrast the SATS machine, which was also examined and confirmed to be functioning, was set to alarm when Devon's oxygen levels fell below 90%, but despite his oxygen being recorded as falling below this level, an alarm was not heard by the parents. There are some anomalies in the evidence relating to the SATs machine. 8. Firstly the SATS machine technician provided evidence that the data revealed that the machine was not used until 3 May 2022. The evidence suggested that it was the same machine that had been used by the family consistently since 25 April 2022. 9. Secondly the SATS machine technician provided evidence that the data showed that from 1.44am to 2.00am the SATS machine would have been sounding an alarm that could be silenced temporarily by pressing a button but that the alarm would restart after 60 seconds, sounding again. The alarm sound on this machine was set on maximum. A second alarm would have been sounding at 2.00am due to a loss of pulse.
5	**CORONER'S CONCERNS** During the course of the investigation my inquiries revealed matters giving rise to concern. In my opinion there is a risk that future deaths could occur unless action is taken. In the circumstances it is my statutory duty to report to you. The MATTERS OF CONCERN are as follows. – According to the evidence heard at the inquest: 1. Devon was discharged home on 21 April 2022 with a SATS machine from University Hospital Southampton (UHS). However, as the family lived in the Royal Berkshire NHS Foundation Trust area, and they used a different brand of SATS machine to that issued from UHS, this first machine was changed to a different second SATS machine the following day on 22 April 2022. 2. The family had been trained to use the UHS issued SATS machine. Matter of Concern 1: 3. On 25 April 2022 this second SATS machine, stopped working. It had some sort of error message on the screen. The parents contacted the community nurse team and Devon's mother had to attend the hospital that night to pick up a new SATS machine. 4. Therefore the first concern is regarding the reliability of such SATS machines sent home with vulnerable patients. 5. If a safety plan is put in place which includes the use of a SATS machine to monitor the wellbeing of the patient, and that machine is less than at least 99% reliable, or has software issues, or is unsuitable for home use, or is complicated to use, this may result in a false sense of security from the family who will rely on the machine to alert them if the oxygen levels drop below a certain figure. 6. Therefore there is a risk that future deaths will occur if hospital trusts do not ensure that the SATS machines are reliable and easy to use and that parents are trained to use the particular brand they are issued with. 7. Action should be taken by Royal Berkshire NHS Foundation Trust to identify what happened in this instance and to ensure that such events are avoided. This may involve the local Integrated Care Board and/or MHRA. Matter of Concern 2: 8. The third machine was issued to the family on 25 April 2022, which remained with them until Devon's death. It was manufactured by Medtronic (Model number MBH1920704). It is not known if this was the same brand as the second SATS machine mentioned above. 9. The concern is that this Medtronic machine was also either not functioning reliably or was not suitable for the home environment.

	10. On 10 May 2022 Devon was given his 1am feed and the family settled down to sleep. At 4.30am Devon's mother woke to find him unresponsive. The CPAP machine log confirms those two times. 11. The SATS machine was seized by the police on 10 May 2022. 12. Medtronic technician, [redacted] made a statement dated 6/7/2022 which I append to this Report, in which he states that: • The testing of the SATS machine revealed that it was functioning properly • The data from the machine shows that from approximately 1.44am Devon's oxygen saturations started to drop and continued to fall until approximately 2.00am when there was no pulse. • The alarm would have been sounding throughout that time and that at the loss of pulse, at 2.00am a further alarm would have sounded. • The machine alarm was at maximum volume • There is a silence button on the machine but that it only silences the alarm for 60 seconds, after which interval the alarm would sound again throughout the whole period that the saturation levels were low. 13. Given the crucial role a SATS machine has in monitoring a vulnerable baby at home, with non-medically trained carers who need to sleep, there should be no doubt but that the alarm sound will sound reliably, that its volume will wake sleeping exhausted parents and should provide an accurate log of events. 14. The conclusions that the data from the SATS machine appear to provide do not accord with the other evidence provided to the inquest about the events in question. That gives cause for concern that either the analysis of the SATS machine has not been accurate or the SATS machine has not correctly recorded the data or that this SATS machine is not a suitable device for use at home. 15. For example, the community nurses would have noticed if the SATS machine was not working in the first weeks of Devon being at home and yet it has recorded that it was not used at all until 3 May 2022. 16. Secondly in order for the SATS machine data to have been correct about events of 10 May 2022, either both the parents would have had to sleep through an alarm sounding for at least 15 minutes at full volume as well as a second alarm after 15 minutes at the loss of pulse, or the parents would have had to have used the silence button on the alarm system every 60 seconds for that 15 minute period. 17. The SATS machine silence button was not within reach of Devon's mother unless she sat up and reached up and over baby Devon in his cot. Devon's father would have had to get out of bed altogether. A copy of the police photographs of the bedroom on 10 May 2022 is attached to this report. It is inconceivable that these concerned and careful parents, who had taken such an active role in Devon's care, would have turned off this alarm in this way several times and failed to notice his respiratory distress, and when he was found unresponsive, would have forgotten that they had silenced the alarm in this way. Therefore either the SATS machine did not function as it should or was not sufficiently loud to wake either of these careful parents. 18. The **potential for future deaths** is that future parents will also rely on the SATS machine to alert them to a vulnerable child stopping breathing and taking action will not be alerted because either the alarm is too quiet, or it cuts out automatically before waking the parents, or it simply does not sound at all. 19. **Action** needs to be taken by the Trust, Integrated Care Board, MHRA, NHS England and Medtronic to investigate these events and establish whether the Medtronic SATS alarm may be insufficiently loud or may be unreliable.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you (and/or your organisation) have the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 13/10/2023.

	Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons • The family of Devon Turner • UHS NHS Trust I have also sent it to • Medtronic • Royal Berkshire NHS Foundation Trust • Berkshire Integrated Care Board • Medication And Healthcare Products Regulatory Agency • NHS England who may find it useful or of interest. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**Dated: 18/08/2023**  **Katy Thorne KC** **Assistant Coroner for** **Berkshire**