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Inquest touching the death of Devon Drew Turner

Medtronic Response to Regulation 28: Report to Prevent Future Deaths dated 18 August 2023

We refer to the Inquest into the tragic death of Drew Turner, Deceased (**"the Deceased"**) on 16 August 2022, subsequent Regulation 28: Report to Prevent Future Deaths dated 18 August 2023 and HM Assistant Coroner's letter dated 9 October 2023 enclosing further documents. We set out below Medtronic's response.

Incident as reported to Medtronic Limited and Immediate Actions Taken

Attendances at Reading University Hospital to download the device memory and perform functional testing of the PM100N Bedside Monitor and Nellcor Saturation probe.

On 11 May 2022, the Adult Nursing Account Manager for Patient Monitoring Solutions at Medtronic Limited ("**the Medtronic Adult Nursing Account Manager**") reported internally that she had been informed by a healthcare professional at Reading University Hospital ("**the Healthcare Professional**") that a patient who had been monitored by a PM100N Bedside Monitor and Nellcor Saturation probe serial number MBH1920704 ("**the PM100N device**") used in a home environment had died on 10 May 2022, and that the police were involved.

By email dated 11 May 2022, the Medtronic Adult Nursing Account Manager asked the Healthcare Professional to isolate the PM100N device and leave it on charge, informing her that if an investigation was underway, the download of data by Medtronic should ideally take place in the presence of the police. The Medtronic Adult Nursing Account Manager also requested that the PM100N device be returned to Medtronic for testing after the download had taken place.

By email dated 14 May 2022 to the Medtronic Adult Nursing Account Manager, the Healthcare Professional suggested that the police did not need to be present for the download and had asked several questions in respect of the PM100N device's functionality.

On 17 May 2022, the Medtronic Adult Nursing Account Manager responded by email to these questions and requested a copy of the data downloaded by the hospital on the date of death. The data provided was a pdf version of the data rather than the more detailed "raw" excel data available from the PM100N device's memory. Both the pdf and Excel file present the same information in a different format.

Arrangements were made on 19 May 2022 for a further download of the "raw" data from the PM100N device memory to take place in the presence of the police on 25 May 2022.

A Business Development Manager at Medtronic Limited (**"the Medtronic Business Development Manager**") and the Medtronic Adult Nursing Account Manager attended Reading University Hospital on 25 May 2022 to download the data from the PM100N device in use by the Deceased at the time of his death. The data obtained was emailed

by the Medtronic Business Development Manager to police officer DC 7712 later that day. DC 7712 subsequently requested a brief summary of the download from the Medtronic Business Development Manager by email dated 25 May 2022, who then provided images of the device screen and an explanation of the PM100N device settings to DC 7712 on 26 May 2022.

On 7 June 2022, DC 7712 contacted the Medtronic Adult Nursing Account Manager to advise that the police were trying to identify a police specialist to carry out a further download of the data to assist "in relation to the alarms and if they did sound", as it was her understanding that the PM100N device would need to be returned to Medtronic in the United States for this testing to be done.

In the absence of the Medtronic Adult Nursing Account Manager, a Regional Sales Manager at Medtronic Limited (**"the Medtronic Regional Sales Manager"**) contacted DC 7712 on 7 June 2022 stating that any further download should be carried out by an engineer from Medtronic who would be able to extract the device's memory data. By email dated 9 June 2022, DC 7712 confirmed that a further download was required and that a Medtronic engineer could undertake this in the presence of the police as the PM100N device could not be taken out of the UK.

On 6 July 2022, the Medtronic Business Development Manager re-attended Reading University Hospital with two other personnel from Medtronic, a service technician (**"the Medtronic Service Technician"**) and a Senior Technical Service Supervisor UK and Ireland, Service and Repair (**"the Medtronic Senior Technical Service Supervisor"**). The Medtronic Service Technician is an Italian national based in the Netherlands. He travelled to the UK on 6 July 2022 to carry out technical checks on the PM100N device and to perform the data download. These were done in the presence of DC 7712.

During the physical examination and functional testing of the PM100N device and subsequent data download, the Medtronic Service Technician, whose first language is Italian, explained to DC 7712 to the best of his ability, the nature of the checks he was completing and the findings from the data download. He also emailed to DC 7712 a copy of the downloaded data from the device memory and an Excel spreadsheet of the same data that day.

The software used for the download on 6 July 2022 has passed formal verification and validation processes to ensure the data downloaded was accurate.

Findings from the visual examination and functional testing

Visual examination on 6 July 2022 found no physical damage to the monitor, which was in good condition. The device was powered up and no error messages or failures were displayed on the monitor, and it was ready to use. All alarms were functioning according to the specification and were clearly audible and/or visible. From the downloaded data reviewed, the Medtronic personnel also concluded that the PM100N device was functioning as expected at the time of the death of the Deceased.

Subsequently, between 19 July 2022 and 14 September 2022, Medtronic staff responded via email to certain email questions received from DC 7712 about the device alarm settings.

Information notified to the MHRA.

Medtronic is dedicated to ensuring the safety, suitability and reliability of all its products and takes all concerns potentially associated with its products extremely seriously.

This incident was initially reported to the Medicines and Healthcare products Regulatory Agency (**"MHRA"**) on 20 May 2022 with follow-up on 20 August 2022. Further correspondence in response to MHRA queries was provided on 18 July 2022, 10 October 2023, 27 October 2023 and 17 November 2023. Based on the conclusions following testing of the PM100N device on 6 July 2022, shortly after the Deceased's death, and the review of the

downloaded data, it was concluded that no corrective action was required in respect of the PM100N device.

Additional investigations carried out in order to respond to the Regulation 28 Report

By letter dated 9 October 2023, HM Assistant Coroner granted Medtronic Limited "Proper Person" status, following which selected information and documentation was provided to the company. This has assisted Medtronic in preparing this response. In that letter HM Assistant Coroner informed Medtronic that she found "…*that the [*PM100N device*] did not contribute to the death*" and that the Deceased died of natural causes.

Since receipt of the documentation from HM Assistant Coroner, Medtronic has conducted further investigations into the machine's functionality in order fully to address HM Assistant Coroner's concerns expressed in the Regulation 28: Report to Prevent Future Deaths dated 18 August 2023.

Witness Statements obtained by the police from Medtronic personnel and used in the Inquest.

We understand that witness statements were obtained by the police from the Medtronic Business Development Manager and from the Medtronic Service Technician. It appears, although Medtronic has not had access to a transcript of the inquest, nor all of the evidence relied upon, that these witness statements were subsequently relied upon by the Court for the purpose of assessing: (a) the functionality of the PM100N device; and (b) the significance of the data that had been logged in the PM100N device memory, as downloaded by the Medtronic Service Technician.

We note from the Regulation 28 Report that HM Assistant Coroner found anomalies in the evidence relating to the PM100N device, namely that "the data revealed that the machine was not used until 3 May 2022" whereas it had been in use by the family since 25 April 2022, and secondly that "from 1.44 to 2.00am the [PM100N device] would have been sounding an alarm that…was set on maximum" and that a "second alarm would have been sounding at 2.00am due to a loss of pulse". For the reasons set out below, the evidence relied on in reaching these conclusions was incomplete.

The witness statements in question were obtained from a business development manager and from a service technician who is not resident in the UK. While these personnel were appropriately qualified to perform the requested tasks of download and functional testing, they were not, nor did they purport to be, technical experts on the PM100N device nor able to give expert evidence on the significance of the logged data from the memory. At the time the request was made to Medtronic to download the data from the PM100N device memory, and prior to the attendance of the Medtronic personnel at Reading University Hospital, Medtronic personnel were under the impression that their role was solely for the purpose of providing access to the data itself. Had the company been made aware that expert witness evidence on the device functionality and the downloaded data would be needed for the purpose of expert evidence to be considered at the Inquest, the company would have arranged for an appropriately qualified and experienced technical expert on the product to have provided such evidence. Such expertise would have had to have been found within the Medtronic design team based in the USA.

Neither of the witnesses had any prior experience of giving evidence in inquest proceedings. Neither of them were informed by the police about the potential relevance of the witness statements they provided after the data downloads nor about the Inquest process. In performing the downloads and testing, and in providing the witness statements, they sought to assist the police to the best of their ability without a full appreciation of the use to which the information they were providing would be put. The process is summarised as follows.

On 31 May 2022, DC 7712 contacted Medtronic Business Development Manager by email advising that she would draft a witness statement for him based on his email. A draft statement was emailed to him for approval later that day. The witness statement was approved by Medtronic Business Development Manager by email dated 7 June 2022

and he was asked to sign, scan and return it to DC 7712 the same day. DC 7712 chased for this on 14 June 2022. The MG11 form attached to her email was marked to indicate the statement was not to be used for "civil or other proceedings". DC7712 printed the statement and provided it to the Medtronic Business Development Manager when he attended Reading Hospital for the further download on 6 July 2022. The Medtronic Business Development Manager signed the statement on the same day. The data download obtained by the Medtronic Business Development Manager on 25 May 2022 was exhibited to this witness statement dated 6 July 2022.

DC 7712 prepared a witness statement for the Medtronic Service Technician whilst he was testing the PM100N device at the Hospital on 6 July 2022. Shortly after the Medtronic Service Technician had completed the testing, and before he left the testing room, DC 7712 presented him with a statement that she had typed on her screen. This represented her notes of the oral comments the Medtronic Service Technician had made as he was downloading the data. DC 7712 asked the Medtronic Service Technician to read and sign the statement then and there, on-screen. He was given only limited opportunity to review the statement. He is not a native English speaker, nor a UK resident. Medtronic are informed that neither the purpose of the statement, nor the meaning of the statement of truth was explained to him. The Medtronic Service Technician has informed Medtronic that he felt obliged to sign the statement as drafted by the police officer, and that he did not appreciate that the statement was intended to stand as his sworn evidence in legal proceedings, nor that it would be liable to be relied upon as formal opinion evidence as to the functionality of the PM100N device or the data downloaded from the device memory. On a more considered reading he has realised that there are certain elements of the statement which may be inaccurate or lost in translation, and which we now wish to correct for the Coroner's record. These are referred to in our response below.

Save for the information referred to above, Medtronic was not asked for any further information or evidence in respect of the PM100N device or the downloaded data, nor was it provided with details of the Inquest nor any of the evidence to be considered at the Inquest. It was not represented at the Inquest, nor designated an Interested Person.

The Medtronic Regional Sales Manager re-attended Reading Hospital on 10 January 2024. In the presence of the Healthcare Professional, he powered on the machine and took three photographs of the settings menu on the machine. These photographs are enclosed within this document as Appendix A.

Concerns Raised in the Regulation 28 Report to Prevent Future Deaths

HM Assistant Coroner's Regulation 28 Report has raised two concerns in respect of the PM100N device as set out below:

1. The PM100N device:
    a. Was either not functioning reliably; or
    b. Was not sufficiently easy to use; and/or
    c. The alarm is either insufficiently loud to wake the parents; or
    d. It cuts out automatically before waking the parents; or
    e. It did not sound at all.
2. The analysis of the PM100N device has not been accurate, or the device has not correctly recorded the data, or the device is not suitable for home use.

We note from HM Assistant Coroner's letter dated 9 October 2023 that she did not conclude that the PM100N device was in fact unreliable, nor that it contributed to the death of Master Turner.

Background Information (the PM100N device) and investigations undertaken

Intended purpose of the PM100N device.

HM Assistant Coroner has been provided with photographs of the PM100N device being used by the Deceased at the date of his death. The machine is designed to measure the patient's pulse rate and the amount of oxygen in the blood (i.e. oxygen saturation levels). When either measurement goes below or above a pre-set limit (in the Deceased's case below 90% (desaturation) or goes above 100%), the monitoring system is designed to warn of this by sounding an audible alarm, showing an indicator, and flashing a number.

The PM100N device is intended for use both in a hospital and (with a slightly adapted range of functionality) a home setting in the UK. This enables patients (and their carers) to have the comfort of living in their own homes whilst receiving care. From the photographs provided to HM Assistant Coroner by the police, the PM100N device was not set to operate in "homecare mode" at the time of death. This is because the photographs of the PM100N device display screen do not show a "house" symbol, which would have been displayed had the home use setting been applied. Activating the "homecare mode" setting is for the healthcare provider to decide along with the appropriate settings for the individual patient in order to meet their medical needs (see below). Setting the device to "homecare mode" means a patient / user cannot modify the pre-set limits that trigger the alarms, nor can they change the patient type selected, e.g. paediatric patient. The "homecare mode" does not prevent a patient/user from adjusting the volume level of the alarm or operating the alarm "snooze" function.

Product information and training provided.

PM100N devices are supplied by Medtronic to healthcare providers (i.e. hospitals) in the UK. They are supplied with an Operator's Manual and also a Home Use Guide.

Medtronic offers training on the use of the device to healthcare professionals. Medtronic does not train individual patients/carers on the use of the devices. We understand that Reading University Hospital provided the device to the Deceased's mother in this case. Training on the use of the device had been provided to healthcare professionals at Reading University Hospital by a Medtronic representative local to the hospital.

The training provided by Medtronic includes details of what is required to set up the device including how the settings for an individual patient can be saved through the service menu as an institutional default setting for the device. The responsible healthcare professionals at the hospital are then expected to set up the device in accordance

with the individual patient's requirements, exercising their clinical judgment as to the appropriate settings, and following the Operator's Manual.

The healthcare provider is responsible for adjusting the settings on the device before it is provided to a patient or carer, so the settings are bespoke to the individual patient's needs and intended location of use.

Settings and adjustments

On 10 January 2024, a photograph was taken for the first time of the "service" settings on the PM100N device (see Appendix 1, Photograph 1). These are settings which can only be accessed using an access code. Such codes are provided by Medtronic to institutional users only, but not to patients or their carers. Photograph 1 shows that the service settings in the PM100N device had been changed from the original factory settings. It is not known by Medtronic whether or not the service settings have been altered since the death of the Deceased, or whether this adjustment took place before the date of death. Medtronic considers it likely that these settings would have been altered at the hospital. In any event, they do not accord with the factory settings.

The treatment of the service settings can only be confirmed by those at the hospital responsible for the custody of the PM100N device at all material times, in particular the healthcare provider who set up the PM100N device for use by the Deceased. The PM100N device memory data does not include information as to what the settings were at any given time. This can only be established by looking at the service settings menu itself. As noted above, the status of the settings applied via the service menu was not ascertained prior to the inquest and did not form part of the body of evidence considered by HM Assistant Coroner.

Service Menu Permission to Alter Alarm "priority" and "Power On Settings"

As indicated above, an institutional user, like a hospital, can change several of the settings for the device's operation for an individual patient from the factory default settings to settings of the hospital's choice via the settings menu. In order to do this, they must have the requisite access code. This code is provided by Medtronic to institutional users only, not to patients and/or carers.

The product requirement document for the device states that it must meet a minimum volume of 45dB and a maximum volume of 85dB +/-3dB. The maximum volume setting for the audio alarm is shown on the PM100N device display as 8 bars and the minimum of 45dB is shown on the device as 1 bar. When the devices are supplied from the factory by Medtronic to healthcare providers, the audio alarms are set at factory default settings. The audio level for any given alarm (whether "low priority", "medium priority" or "high priority") in factory settings is "level 5" (i.e. 5 bars) which is the equivalent of 74.9dB for a high priority alarm, 69.8dB for a medium priority alarm and 67.1dB for a low priority alarm, according to laboratory tests conducted on the device for the purpose of required product standard testing.

The IEC 60601-1-8 standard governs alarm behaviors of the PM100N device. The devices are tested to this standard by specialized labs to ensure that the devices meet the requirements of the standard.

The findings of the Medtronic Service Technician, when undertaking functional testing on 6 July 2022 in the presence of the police, suggest that at least some changes had been made to the settings, after the PM100N device had been supplied to the Hospital. As stated above, the factory default volume setting for the audio alarm is set at a level of 5 bars (on a scale of 1-8 bars) by the factory, whereas the Medtronic Service Technician noted on 6 July 2022 an audio alarm volume setting of 8 bars (i.e. full volume) when the PM100N device was switched on.

An institutional user, like a hospital, can also re-set the factory settings as to which priority ("low", "medium" or "high") is allocated to any given audio alarm, provided they have the requisite access code, referred to above.

The alarm conditions set by the factory for the device trigger a medium priority alarm whenever the high or low pulse rate limits set by the healthcare professional for an individual patient are violated or whenever the high or low SpO2 limits set are violated. At default factory settings this would generate an audio alarm at 69.8dB, which could be manually adjusted by a patient/carer (as explained below). The alarm conditions set by the factory result in a high priority alarm being triggered in the event SpO2 loss of pulse occurs. At factory default settings this would sound at level 5 (i.e. 74.9dB). Based on the photographs taken on 10 January 2024, the alarm priorities on the PM100N device align with factory settings, indicating that they may not have been modified in the service menu.

It is also possible for an institutional user, holding the requisite access code, to change the "Power On Settings". If a device is set to "Factory Defaults", it will always default to factory settings after each power cycle (i.e. being switched "off" and then back "on"). This can include the audio alarm volume and also alarm priority. If the "Power On Settings" are set to "Last Settings", the device will always default to the last settings (saved), whatever those may be, whenever the device is switched off/on again. This can include both the audio alarm volume (on a scale of 1-8 bars) and alarm priority settings ("low", "medium" or "high").

If alternatively, the institutional user sets the device to "Institutional Defaults", after a power cycle the setting will go back to whatever the pre-defined institutional default is that has been set by the hospital or device administrator. Once again, this can include both audio alarm volume and alarm priority. In practice, this means it is open to a hospital to set a default audio alarm volume to the maximum 8 bars (this would result in an alarm being triggered at 82.3dB at "medium" priority alarm setting and 87.6dB at "high" priority alarm setting). A hospital could also set a default alarm priority of "high". These defaults could be set for whenever the high or low pulse rate limits set by the healthcare professional for the patient are violated or whenever the high or low SpO2 limits set are violated. In both cases, this could then be subject to manual adjustment by the patient / carer during the relevant power cycle.

Based on the photographs taken on 10 January 2024, the "Power On Settings" on the PM100N device have been changed from the factory settings to "Last Settings". In practice this would mean that prior to the Deceased's date of death, whatever audio alarm volume setting had last been applied (including, for example, through manual adjustment by the user) at the time the PM100N device had last been powered "off", this would have been the alarm volume setting for the PM100N device the last time it was powered "on" for use before the Deceased's death. The same would apply for the alarm priority setting.

Service Menu Permission to Deactivate Alarm

In his witness statement, the Medtronic Service Technician stated that, "the alarm itself cannot be turned off". This is not strictly accurate. When the device is in **factory default** the user is unable to turn the audible alarms off completely. The audio alarm function cannot be <u>disabled</u> (i.e. permanently muted) without a code, which Medtronic would only provide to the healthcare provider, and not to patients/carers. To permanently mute the audio alarm the user would have to access the service menu (using this code) change the power on settings to "Last Settings" or "Institutional Settings" and set "Permission to deactivate audible alarm" to "Yes".

The photographs taken on 10 January 2024 indicate that the PM100N device had been changed from factory default settings as "Power On Settings" is set to "Last Settings" and the "Permission to deactivate audible alarm" setting is set to "Yes". This means that a user of the machine will, at a point in time which Medtronic cannot determine from available data, have changed the settings of the PM100N device from its factory default settings.

When the "Permission to deactivate audible alarm" setting is set to "Yes", this means that the user would be able to turn off the audible alarms completely. In contrast, when set to "No", the user cannot completely turn off audible alarms and they can instead only be manually turned down to 1 bar (i.e. the lowest alarm volume setting on a scale of 1-8 bars).

Both the Operator's Manual and the Home Use Manual expressly warn users not to silence or decrease the volume of the audible alarm if patient safety could be compromised. It is not known by Medtronic whether or not the Home Use Manual was provided for home use in this instance.

Behaviour of the Alarm

The audio alarm is intermittent at the frequency seen in the table below (Normal Inter-Burst interval). The Inter-Burst interval is a standard term used in alarm regulation that describes the initial behaviour of an alarm once it is triggered in terms of the number of beeps generated in a fixed amount of time.

The device has an intelligent alarm system that increases the frequency of the noise bursts after two minutes of the alarm being triggered in Normal Inter-Burst interval without acknowledgement. This is shown in the table below (Escalated Inter-Burst Interval).

Alarm Priority	Normal Inter-burst Interval	Escalated Inter-burst Interval
High	4,000ms	2,500ms
Medium	8,000ms	4,000ms
Low	16,000ms	8,000ms

Table 2.6. Alarm inter-burst interval

Volume adjustment for the audio alarm

Users, including patients and their carers are able to manually adjust the volume of the audio alarm both up and down (i.e. between a level of 1 bar to a level of 8 bars), and this can be done simply without needing any code. The Home Use Manual (see excerpt below with our highlighting) explains how the user can turn down the volume:

To Adjust Volume

You can adjust the volume of alarms and the pulse beep as follows:

1. Press the Home button to view the Options Menu. Volume is highlighted.

2. Press the knob to select Volume. The Volume screen appears.

3. Turn the knob to highlight the volume setting you want to change (Alarm or Pulse).
4. Press the knob. The volume setting is highlighted in yellow on black, indicating it can be changed.

5. Turn the knob to adjust the volume. Bars increasing in size from left to right indicate increasing volumes.
6. Press the knob to save the adjustment. The setting color reverts to white on blue.
7. Press the Home button to go back to the main screen.

There is also a quick reference guide to turning down the alarm volume on the device itself. This can be seen in the photographs provided to HM Assistant Coroner by the police. If the volume level is manually turned down by a user, it will automatically reset to the pre-set default volume if the device is switched off and on again. The pre-set volume will depend upon the "default" setting applied on the individual device for the particular audio alarm in question.

As indicated above, if an individual device is left at factory default settings, this pre-set volume would be level 5,

or a maximum of 69.8dB (when the high/low pulse rate limits were crossed) and 74.9dB (when SpO2 loss of pulse occurred).

As stated above, the photographs taken on 10 January 2024 show that the PM100N device's "Power On Settings" was set to "Last Settings" in the service menu.

Where "Last Settings" is selected, then the volume level of the audio alarm will revert to whatever was the level before the device was switched off and on again (that setting is saved). This would vary according to the level of audio alarm volume selected by the previous user, for example using the manual adjustment knob, as illustrated above in the Home Use Guide.

The findings of the technical testing undertaken by the Medtronic Service Technician on 6 July 2022 showed the PM100N device had an 8-bar volume level when powered on. Consequently, the factory default settings must have been re-set at some point in time prior to that test. The photographs taken on 10 January 2024 confirm that the device was set to "Last Settings" default settings. This would have returned the audio alarm volume to whatever level the last user had manually selected, which could be higher or lower than factory settings. This is consistent with the volume level observed on the machine when examined on 6 July 2022 which was on the maximum level of "8 bars", after the machine had been switched on for examination.

Whilst the photographs taken on 10 January 2024 show that the service menu default setting for alarm volume was set to "Last Settings", the raw data downloaded from the PM100N device memory shows that the PM100N device was turned off and on again eleven times between the date of the Deceased's death and the date of functional testing by the Medtronic Service Technician on 6 July 2022. Consequently, if the default service menu settings for alarm volume had been set to "Last Settings" prior to the Deceased's death, this would mean that any adjustment made to volume, whether intentionally or inadvertently, on any of those eleven occasions, when the PM100N device was powered off/on, could have been the volume setting then observed at the date of functional testing by the Medtronic Service Technician. Medtronic does not therefore know whether or not the volume level of the alarm observed by the Medtronic Service Technician on 6 July 2022 corresponded to the actual volume level set for the default alarm volume at the time of death.

Device memory and data logging

The PM100N device generates its data based on data received from a sensor which is attached to the patient. For a baby, or small child, the sensor will usually be secured around either the wrist or foot. In order to function, the sensor requires a cardiac signal which it picks up from the movement of blood through the body. Once the cardiac signal is detected and transmitted by the sensor, the device logs the patient's pulse and oxygen saturation every four seconds.

The PM100N device's memory logs and stores certain data, but it does not record: (a) whether an alarm has in fact sounded at a specific time; or (b) the volume of any audio alarm that may have sounded. There is therefore no data memory of when, for how long, and how loudly any given alarm sounded. A maximum of 88,000 events can be stored to memory on the machine. Events are logged every four seconds and therefore the log capacity of the device memory is 96 hours in total. There is no reason to believe that the log is incomplete.

Results of examination and analysis of memory data from the PM100N device

As stated above, on 25 May 2022 and 6 July 2022, Medtronic personnel downloaded the memory log data from the PM100N device in use by the Deceased at the time of his death and provided this to the police. Additionally, and as noted above, on 6 July 2022 a Medtronic Service Technician also completed physical functional checks on the machine in the presence of the police. We understand that the data and findings were all provided by the police to

HM Assistant Coroner.

As stated above, visual examination found no cosmetic damage to the monitor, and it was in good condition. The PM100N device was powered up, no error messages or failures were displayed on its monitor, and it was ready to use. A review of the PM100N device settings on 6 July 2022 found that the alarm volume was set at its maximum level of 8 bars (82.3dB) while the pulse and key beep volumes were silenced. This is confirmed in the photographs taken on 10 January 2024.

Alarms were tested and found to be functioning according to the device specification. The device patient mode was in paediatric mode and the 'nurse call' appeared to function normally (albeit this is a function which can only be used with a nurse call infrastructure, usually in a healthcare setting and not in the home). The PM100N device was tested with a SpO2 simulator and passed the tests as per manufacturer service instructions. The PM100N device was also tested with a spotlight SpO2 functional tester at its maximum values BPM 240 and SpO2 100% and passed all tests. The PM100N device monitor was fully checked for functionality and electrical safety and passed all tests successfully as per the manufacturer guideline. The conclusions of the Medtronic technical team who reviewed the findings and the data downloaded from the PM100N device was that it was functioning correctly and in accordance with specification. We also note in this regard HM Assistant Coroner's express statement in her letter of 9 October 2023 that she did not find that the PM100N device was unreliable.

Response to the Concerns

We set out below our response to the areas of concern raised by HM Coroner.

Concern 1: The Medtronic machine was either not functioning reliably or was not sufficiently easy to use and/or the alarm is either insufficiently loud to wake the parents or it cuts out automatically before waking the parents, or it did not sound at all.

When the data was downloaded and the PM100N device examined on 25 May 2022 and 6 July 2022, the Medtronic Service Technician was able to confirm that the PM100N device was not externally damaged and there were no error messages displayed when it was turned on. The PM100N device was installed with the latest software, and the battery was working appropriately. As set out in detail above the PM100N device passed all functional testing performed in accordance with manufacturer specification.

Data "gap" between 25 April 2022 and 3 May 2022

HM Assistant Coroner raised concerns arising from the apparent lack of data from the machine between 25 April 2022 and 3 May 2022 during which period the Deceased's parents stated the PM100N device was in use. The witness statement of the Medtronic Service Technician states that he was told by the Healthcare Professional at Reading University Hospital that the PM100N device was given to the patient on 25 April 2022. The Medtronic Service Technician has informed Medtronic that he has no memory of the Healthcare Professional being present at the download nor of her providing such information to him. He does recall a lady at Reading University Hospital handing over the PM100N device from storage for testing on 6 July 2022, but does not know if this was the Healthcare Professional in question. It is possible that this information was supplied in the draft witness statement prepared for the Medtronic Service Technician, but that in the pressure of time to sign the statement, this part of the statement was overlooked or misunderstood.

Medtronic has no information about when the PM100N device was supplied to the parents of the Deceased or about the date of first use by the parents.

A senior technician at Medtronic has conducted a further desktop review of the data downloaded on 6 July 2022

from the memory of the PM100N device. That downloaded data does not include data logged before 3 May 2022. The reason for this is that a maximum of 88,000 events can be stored to memory on the PM100N device. As stated above, events are logged every four seconds and therefore the total memory log capacity at any one time is 96 hours. Consequently, by 10 May 2022, any data logged in the PM100N device memory from 25 April 2022 would already have been overwritten as oldest data is overwritten first. The absence of logged data in the downloaded date for the earlier period up to 3 May 2022 does not therefore indicate that the PM100N device was not in use, not performing correctly nor that it was unreliable. Rather it indicates that there was insufficient device memory to retain recorded events from before 3 May 2022.

The witness statement of the Medtronic Service Technician refers to downloading the whole log of the device from "15.03.22 to 07.06.22". This is an error in the statement, stemming from: (a) a typographical error applying the number "15" instead of "5"; and (b) the use of United States date convention formatting. Medtronic has since asked the Medtronic Service Technician to confirm the correct dates. He confirms that, using the same United States date convention format, this should read "05.03.22 to 07.06.22" being 3 May 2022 to 6 July 2022, which is consistent with the date range of data obtained from the PM100N device, and the date on which the device data was downloaded in front of DC 7712.

We have again reviewed the data downloaded from the PM100N device from the date of earliest retained recording (3 May 2022) to the date of death (10 May 2022). The data collected shows the PM100N device was monitoring the Deceased's pulse and oxygen consistently during this period.

On the date of death, the downloaded data shows at line 82861 that the Deceased's oxygen levels started to drop below 90% at 01:59:10 and there is reference to desaturation at that point. The oxygen level continued to drop until 02:14:18 (line A83090) when there was a loss of pulse and no oxygen reading.

The data thereafter shows that the PM100N device remained on and connected to the Deceased until 04:50:56 on 10 May 2022 when the PM100N device was turned off. This appears to coincide with the time at which the ambulance was called.

Operation of the PM100N device audio alarm

As the device (and the data logged in the device memory) do not specifically log whether or not the alarm sounded, nor the volume of the alarm, there is no direct evidence available from the PM100N device's memory to suggest the alarm was not working at the time of death or that the volume was not sufficiently loud. The fact that the PM100N device passed all functional testing and that the alarm functionality was fully operational when the machine was switched on again at Reading University Hospital indicates the PM100N device was working in accordance with the manufacturer specification.

As noted above Medtronic does not know at what point the various service menu settings were accessed and changed from the original factory default settings. This includes, but is not limited to, the change of the "Power On Settings" to "Last Settings", in consequence of which the audio alarm volume level at the point the PM100N device was powered "on" would have defaulted to whatever previous audio alarm level had been saved prior to switching "off" the PM100N device. In addition, Medtronic does not know at what point the "Permission to deactivate audible alarm" setting was changed to "Yes". Further, Medtronic does not know whether or not a user deactivated the audio alarm nor, if so, at what time point this occurred. The below analysis is therefore set out on the basis of what would have occurred had the PM100N device remained in factory default settings.

Once the oxygen level fell below 90%, this would have triggered an audio alarm until either: (a) the Deceased's oxygen saturation level went above 90%; (b) the oxygen level could not be detected; or (c) the PM100N device was

turned off.

The outcome of tests conducted to date indicate that had the device been in factory settings the PM100N device would have continued to sound an audio alarm at the volume set on the machine throughout the period from 01:59:10 until 04:50:56. As noted above, the data downloaded does not record the sound level of the alarm, and furthermore the volume which appeared on first testing the machine in July 2022 cannot be conclusively taken to be the volume at which the machine had been set to sound the alarm. This will have depended on the service menu settings, which have been changed from factory settings by a user (with the required access code), as well as any adjustments made manually to the volume level of the machine by a user. The alarm can also be temporarily muted manually but only for a period of 60 seconds at which point it will then sound again, until manually muted once again.

As referred to above, the audio alarm functionality could only have been disabled entirely with a specific code. The code is intended to be provided to, and kept by, the health care provider only. In the absence of complete alarm deactivation, the highest possible volume audio alarm settings for violation of the SpO2 limits and, separately, pulse limits set by the Hospital for the Deceased is 82.3dB based on the "medium" priority factory default setting, which does not appear to have been changed. This would have been 87.6dB at the point the "SpO2 loss of pulse" alarm was triggered.

As noted above, the factory default alarm settings for the audio alarm are set to "5 bars" when the device is supplied to the healthcare providers though healthcare providers are able to alter the default volume settings as described above as appears may have been the case in this instance. The volume of the audio alarm can also be turned down manually by a user as explained above in the Home User Manual, which warns against adjusting the volume of the alarm to below the level of hearing.

Concern 2: The analysis of the machine has not been accurate, or the machine has not correctly recorded the data, or the machine is not suitable for home use.

Based on its review of the retained downloaded data and the functional testing performed on the device on 25 May 2022 and 6 July 2022, Medtronic has not been able to identify any reason for doubting that the data from the PM100N device memory is accurate and that the PM100N device correctly recorded the data.

Other than the PM100N device time setting running 16 minutes late (which is likely to have been due to an initial set up issue by the healthcare provider), there is nothing in the data to indicate that the information is inaccurate or was not correctly recorded.

We set out below examples from the data downloaded where it shows that the PM100N device was recording the relevant information:

Line of Data	Date	Time[1]	Explanation
82057 to 82300	10.5.22	01:05:36 to 01:21:48	Interference registered at various intervals which is consistent with the evidence of the mother of the Deceased that she put him back in his crib (around 00:56) and fed him (around 01:00).

[1] not adjusted for the PM100N device running16 minutes fast

Line of Data	Date	Time[1]	Explanation
85379	10.5.22	04:46:32	Sensor disconnected. Consistent with the evidence of evidence of the mother and father of the Deceased that they disconnected the PM100N device & started CPR.
85575	10.5.22	04:59:56	PM100N device turned off according to evidence of the mother of the Deceased.
85576 to 85592	10.5.22	12:15:20 to 12:16:24	PM100N device switched back on. Please see photographs of PM100N device taken by police, timed at 12:16:11.
85593	10.5.22	13:24:20	PM100N device was taken away by NHS Community Nurse – possibly switched on to test. No further information. Medtronic have not been informed as to whether or not the volume was adjusted on this occasion.
86318	10.5.22	14:56:44 to 14:57:48	New readings for oxygen & pulse – it is assumed the sensor was attached to someone to test. Medtronic have not been informed as to whether or not the volume was adjusted on this occasion.
86348	25.5.22	12:19:08	Switched on for download by Medtronic
87562	6.7.22	10:29:48	Switched on for download by Medtronic

The PM100N device has been used safely in both the hospital and the home environment throughout the UK. Prior incidents concerning this model of device have been investigated and reported to regulators, including the MHRA, as appropriate. An Operator's Manual is provided to healthcare professionals together with the devices. In addition, a Home Use Guide is also made available to healthcare providers which can be provided to patients or their carers by treating healthcare professionals. Medtronic also offers training on the set-up and use of the devices to healthcare professionals for use in both hospital and home environments, so they are equipped to set up and use the machines and to demonstrate their use to patients and/or their carers. For these reasons, Medtronic believes that the PM100N device is suitable for home use.

Conclusion

Based on the investigations carried out by Medtronic both before and following receipt of the Regulation 28: Report to Prevent Future Deaths dated 18 August 2023 and the subsequent documents received on 9 October 2023, it appears to Medtronic that the PM100N device used by the Deceased was functioning appropriately at all material times, that it was accurately recording data and was accordingly suitable for home use. In light of these conclusions, Medtronic does not consider that modification or change is required to the device in question.

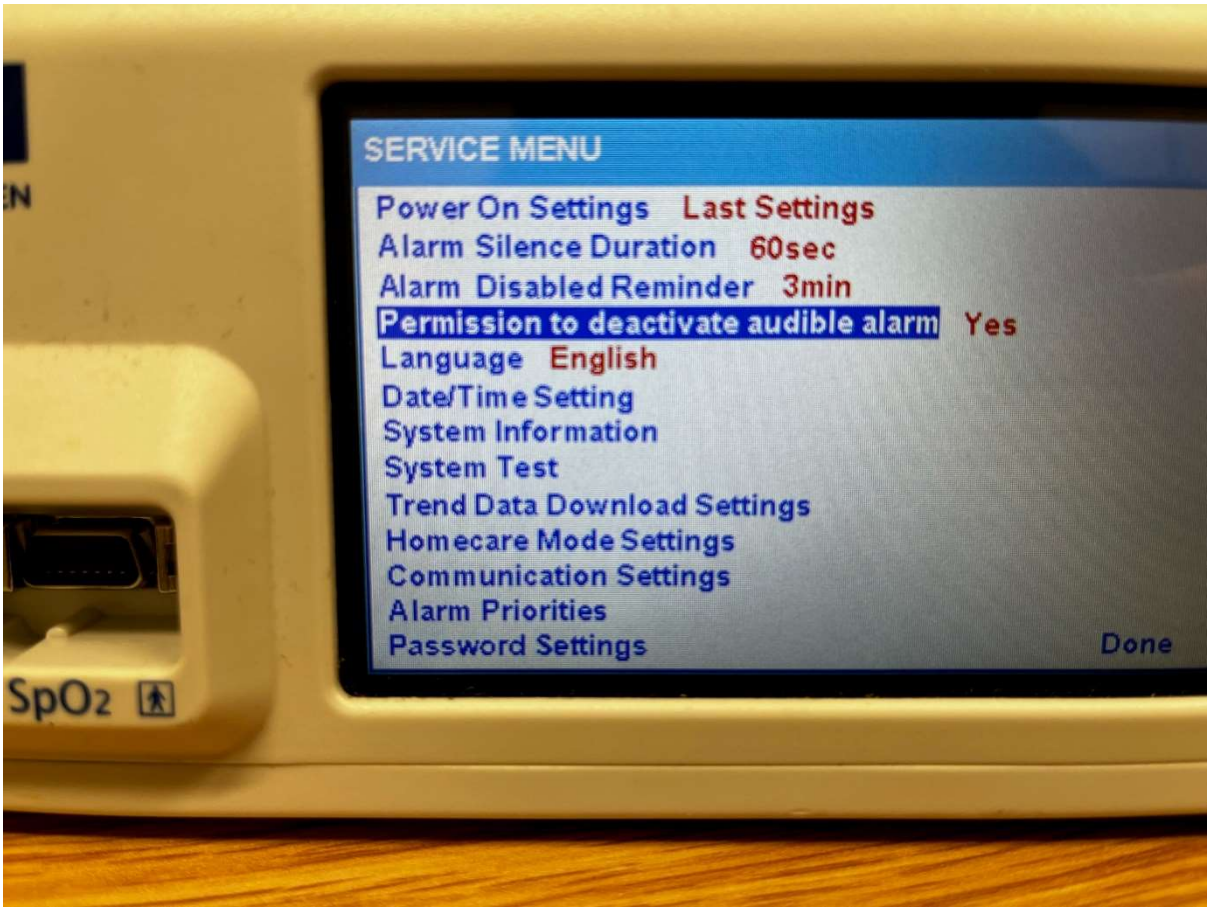
12 January 2024

Appendix A

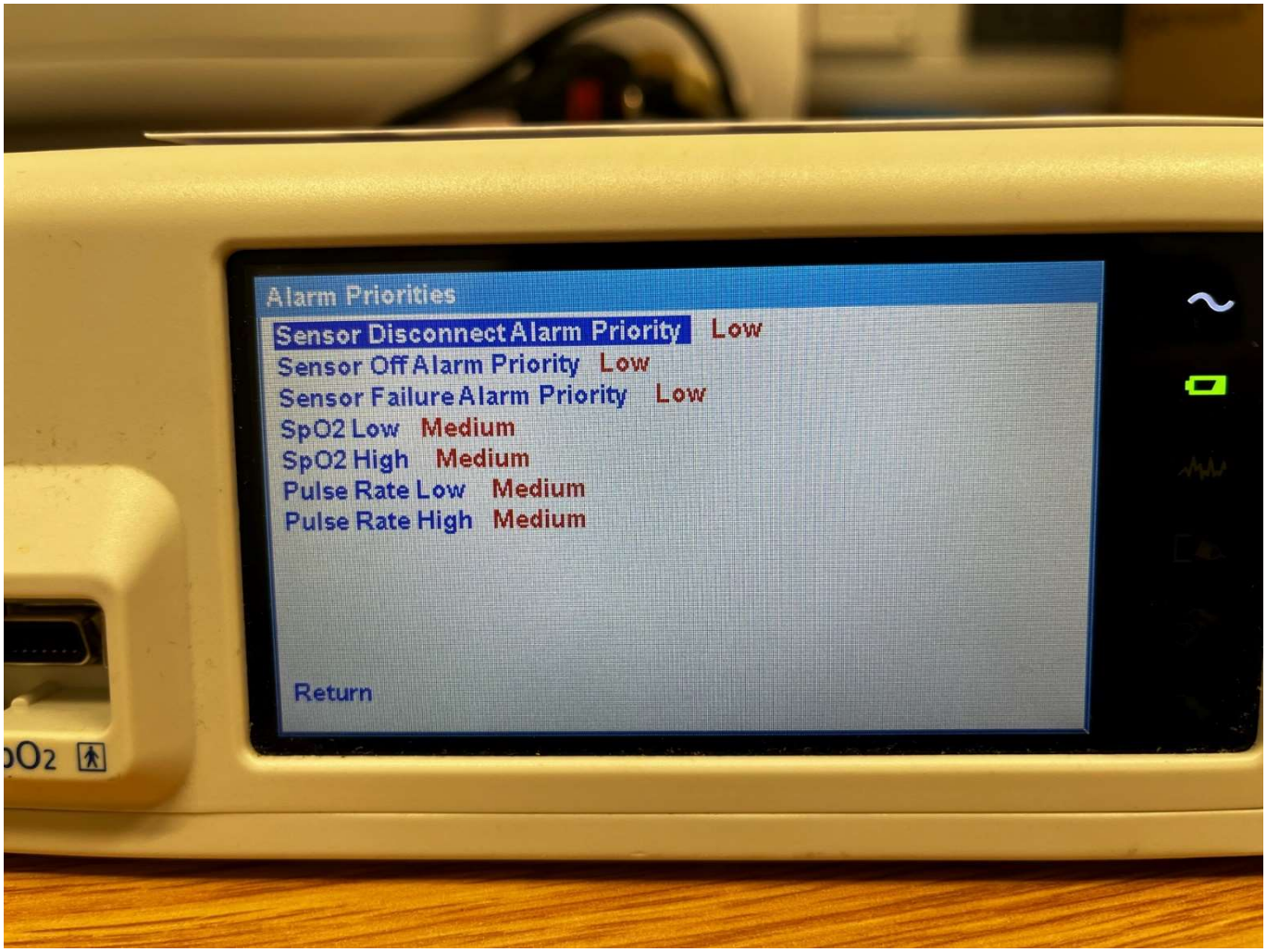
Inquest touching the death of Devon Drew Turner.

Photographs Taken at Reading University Hospital on 10 January 2024

Photograph 1 – Service Menu



Photograph 2 – Alarm Priorities



Photograph 3 – Alarm Volume