Coroner Service
West Sussex, Brighton & Hove

Regulation 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT DEATHS **THIS REPORT IS BEING SENT TO:** **1 LivaNova UK Limited**
1	**CORONER** I am Joanne ANDREWS, Area Coroner for the coroner area of West Sussex, Brighton and Hove
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.
3	**INVESTIGATION and INQUEST** On 27 April 2023 I commenced an investigation into the death of June LIDDELL aged 68. The investigation concluded at the end of the inquest on 07 January 2025. The conclusion of the inquest was that: June Liddell died on 1 April 2023 at Eastbourne General Hospital, Kings Drive, Eastbourne, East Sussex from a hypoxic brain injury which she sustained during surgery on her aorta at the Royal Sussex County Hospital, Eastern Road, Brighton on 21 March 2023. During surgery the heart lung bypass machine's automated electronic remote clamp had a rare malfunction which caused it to close unexpectedly ceasing circulation of oxygenated blood to Mrs Liddell. The cause of the cessation was not identified before the injury had been sustained.
4	**CIRCUMSTANCES OF THE DEATH** Mrs Liddell underwent cardiac surgery on 21 March 2023 which required her to be placed on a heart lung bypass machine. The machine used was an SP5 sold in the UK by LivaNova UK Limited. At the point in the procedure where preparations were being undertaken to take Mrs Liddell off bypass by warming her blood and increasing the flow back to Mrs Liddell the SP5 did not generate any forward flow. The Perfusionist noted that the touchscreen control panel stopped showing the icons for the opening and closure of the automated Electronic Remote Clamp "ERC". The Perfusionist considered that the failure could be caused by occlusion of one of the lines in the circuit for bypass but did not manually check the ERC.

	The SP5 system generated an error message but then also generated a number of other error messages which forced the message to be moved down the list so that it may not have been visible on the screen as there is only room for 4 error messages at any one time. The error message which the SP5 log shows as being generated at that time was "Arterial clamp is defective". The SP5 machine and ERC in this case had been maintained in accordance with the Manufacturer's recommended maintenance schedule. I heard that this maintenance does not include an inspection of the ERC itself beyond a check that it is functioning at the time of the inspection. I heard that the likely cause of the malfunction of the ERC in this case was water ingress and wear and tear. The machine which was within its service life.
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: I heard that the error message "Arterial clamp is defective" is not one which is included in the Instructions for Use for the SP5 or ERC machine whilst others are explained. As such this message was not one which the Perfusionist community were aware of prior to this incident. The SP5 and ERC instructions for Use documentation does not specify that the disappearance of the icons for the control of the ERC is indicative of a defect with the ERC. The evidence was that this alarm functions in an entirely different way to other alarms on the SP5 system and this was not within the knowledge of any of the Perfusion witnesses that the Court heard from. The Manufacturers maintenance of the machine does not include a process to identify when an ERC is experiencing wear and tear which may indicate that action should be taken.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe 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 10 March 2025. I, the coroner, may extend the period. 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 Mrs Liddell** **MRHA (Medicines and Healthcare Products Regulatory Agency)** **University Hospitals Sussex NHS Foundation Trust** I have also sent it to the **Society of Clinical Perfusion Scientists of Great Britain & Ireland** who may find it useful or of interest. I am also under a duty to send a copy of your response to the Chief Coroner and all interested persons who in my opinion should receive it. I may also send a copy of your response to any person who I believe may find it useful or of interest. 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: 13/01/2025 J. Andrews Joanne ANDREWS Area Coroner for West Sussex, Brighton and Hove