LivaNova
Health innovation that matters

06 March 2025

Dear Ms Andrews
Regulation 28 Report, dated 13 January 2025 – Re June LIDDELL (deceased)

We write in response to your Regulation 28 Report, dated 13 January 2025, sent following the conclusion of the inquest into the death of June Liddell on 1 April 2023.
We would like to take the opportunity again to express our condolences to Mrs Liddell's family.
Following careful consideration of the matters raised in the Regulation 28 Report, together with the evidence raised during the course of the inquest including the hearing held on 6 and 7 January 2025, we respectfully provide the following responses to the Matters of Concern.

Background and history of the S5/CP5

The LivaNova S5 has been used by the perfusion community for almost 20 years. Between January 2020 and December 2024, the CP5 (with ERC clamp) was used in more than 6.8 million operations. During that period, there has been only one incident of serious injury or death associated with the ERC clamp. Sadly, that was the unfortunate case of Mrs Liddell to which the Regulation 28 Report relates.
As a global medical device manufacturer, LivaNova develops innovative products that deliver life saving devices for patients, and the approach to quality starts and ends with patient and customer safety. LivaNova's Quality Management System ("**QMS**") is designed to build quality into products at every stage of the lifecycle, starting from the design and development through manufacturing, testing, distribution, and post-market surveillance. As part of the QMS, LivaNova's Corrective and Preventative Actions program embeds a robust process to identify potential issues and to take action to resolve them. The risk management process follows the ISO 14971 international standard for medical devices which ensures the safety and effectiveness of the devices for the intended use.
We monitor the use and performance of our products distributed to the market through the post market surveillance system by gathering data from customer feedback collected through our global complaint handling process and via medical and clinical literature review and post-market clinical data collection activities, with information shared and communicated to customers, patients, and internally via the risk management process. When alerted of potential safety concerns in the market, LivaNova takes immediate actions through the embedded QMS correction and removal process to ensure patient safety.

Matters of concern

The Regulation 28 Report includes three matters of concern, being:

1. the error message "Arterial clamp is defective" is not included in the Instructions for Use ("**IFU**") for the SP5 or ERC clamp;
2. The SP5 and ERC clamp IFUs do not specify that the disappearance of the icons for the control of the ERC clamp is indicative of a defect with the ERC clamp; and
3. Manufacturers maintenance of the machine does not include a process to identify when an ERC clamp is experiencing wear and tear.

Error message

The "*Arterial clamp is defective*" error message is displayed on the CP5 System Panel and is unmistakable and readily understood. It directly describes the issue that is occurring. No additional explanation is necessary or helpful in order to allow a certified perfusionist to understand that there is a functional issue with the ERC clamp which needs to be investigated.
The error message is persistent and remains in place, albeit that in the event of multiple error messages appearing, the messages scroll off the front page but can still be checked by using the scroll button function.
The scroll function is a well-known feature of the CP5 System Panel[1] and is described in the IFU[2].
As such, there is no basis for a certified perfusionist not to see the error message if it is displayed. Once seen, it is obvious that there is an issue with the ERC clamp requiring investigation. No further instructions are needed to describe the error in order to allow any issue to be considered and rectified.

[1] Bundle reference G581 – paragraph 4.20
[2] Bundle reference G125 – section 5.3.1.

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Disappearance of the icons

The clamp icons being displayed on the CP5 Control Panel allows a certified perfusionist to see the status of the ERC clamp, and to operate it manually by pressing the relevant 'open' or 'close' icon.
A lack of icons necessarily indicates that the ERC clamp is not engaged or assigned – it is unavailable for use. If the ERC clamp is installed then the lack of icons indicates to a perfusionist that immediate investigation of the ERC clamp is required since it can no longer be operated from the CP5 Control Panel.
As noted above, during normal operation of the CP5, a perfusionist will open the ERC clamp manually from the Control Panel using the relevant touchscreen icon following resolution of certain alarm situations, e.g. a bubble alarm.
If no icons are showing, it is obvious to certified perfusionists that the ERC clamp is not engaged in the system, cannot be operated from the Control Panel and therefore the ERC clamp requires further investigation. This need to investigate the ERC clamp is reinforced by the clear error message described above being displayed at the same time as the icons disappear from the screen.

Incident in question

LivaNova understands that in the incident case the CP5 acted entirely as intended when an issue was detected with the ERC clamp. It both displayed the relevant error message as described above and removed the icons from the CP5 Control Panel. Each of those independently would have alerted a perfusionist to the need to investigate the ERC clamp immediately. Such an investigation would necessarily have included opening the clamp cover.
LivaNova further understands that the evidence presented at the inquest was that there was a further indication of an ERC clamp issue in that forward flow could not be re-established.
Failure to re-establish forward flow was a clear and independent indication to a perfusionist that there is a blockage requiring investigation. The evidence at the inquest was that such an investigation did take place immediately but crucially – and inexplicably – did not include consideration of the ERC.
LivaNova cannot explain why – in circumstances where there was:

i. a visible alarm message[3];
ii. disappearance of the ERC clamp icons; and
iii. an inability to re-establish forward flow;

the perfusionist failed to consider the ERC clamp, despite undertaking an inspection to identify an obstruction. That inspection should have necessarily included the ERC clamp on the basis it is designed to and operates as a device to prevent flow on the arterial line.
It is of note that the evidence of the perfusionist was that: "*I checked again verbally/visually with Mr [redacted] to rule out any obstruction upward on the arterial line circuit. I then instantly and instinctively released the ERC… with forward systemic flow restored.*"[4]
It is also apparent from his witness statement that the Consultant Cardiothoracic Anaesthetist and Intensivist, on noticing the lack of icons[5], prompted an investigation of the CP5 control panel error messages and the opening of the ERC clamp.
From the above, it is clear that any one of the three indicators alone (alarm, disappearance of the icons and failure to establish forward flow) is sufficient to lead a perfusionist to follow their training to identify a blockage which includes considering, and opening, the ERC clamp within moments.
This conclusion is supported by the expert perfusionist you instructed, who stated "[c]*ritically though, the information that ultimately identified the electronic clamp as the source of the problem was there from the beginning*"[6]. His view accords with that of LivaNova's which is that the perfusionists failed to act on the information that was properly provided by the CP5. The extensive safety record of the CP5 further demonstrates that to be the case with only a single incident of harm recorded across over 6.8 million uses.

IFUs

IFUs are not reference items and are not intended to be referred to in emergency situations. As noted at section 1.1 of the Operating Manual, the operating instructions "*are solely intended for qualified perfusionists".* Indeed, clinical perfusion procedures can only be undertaken by an accredited Clinical Perfusion Scientist and therefore

[3] Machine log evidence suggests that it would not have scrolled off the display for at least 3 minutes from when it was initially displayed. (Bundle reference G35 – paragraph 5.7(d))
[4] Bundle reference G16 – paragraph 23.
[5] Bundle reference G5 – paragraph 5.
[6] Bundle reference G595 - paragraph 6.24

there is a high degree of relevant training and knowledge of a qualified user. The IFU is written for those intended users, being trained perfusionists, for whom the automatic reaction to the error message is to investigate the cardiopulmonary bypass circuit, including the ERC clamp, and to clear any blockage. The error message and lack of ERC clamp icons are two independent identifiers which direct a perfusionist to investigate the arterial clamp specifically. No additional wording in the IFU would or indeed should, change that response.
The fact that this is the only patient death or serious injury that has arisen following a failure of the ERC clamp underlines the view that all perfusionists are trained to automatically check for blockages, including in the ERC clamp, and to clear them and that the operation of the CP5 in the extremely rare event of a failure is clear and appropriate to mitigate the risk of serious injury or death. This is reaffirmed by the statistics which show that in the period from January 2020 to December 2024, during more than 6.8 million uses only one, being the present tragic incident, has involved patient harm (1 in 6.8 million = 0.000015%).
Accordingly, from the evidence in relation to the present incident, it is clear that the tragic incident involving Mrs Liddell should have been avoided.
No additions to the IFUs would have prevented the tragic situation encountered in this incident since the perfusionist for unknown reasons did not follow their training, ignored the clear and obvious warning signs, and failed to immediately resolve the obstruction as they should have done.

Maintenance

The IFU for the ERC is clear that "*Liquids must not enter the housing. Therefore, do not use sprays*" and further states "*Ensure again that no liquids enter the housing*".[7]
In this specific case the device functionality was impacted by infiltration of liquids during the 12 years of previous ERC clamp use. Such liquid infiltration is not addressable by standard maintenance because the ERC clamp is a closed unit intended to operate for its expected service lifetime.
The observed failure rate of the ERC clamp (being 155 in 6.8 million = 0.0023%) is such that a properly maintained ERC clamp in accordance with the IFU does not warrant a specific maintenance schedule to identify instances of wear and tear caused by a failure to follow the IFU in relation to cleaning and disinfection.
Even in the incredibly rare instance of an ERC clamp failure, the device is safe. The CP5 will properly indicate to the trained perfusionist that the ERC clamp has failed (alarm and lack of icons) which together with a failure to re-establish forward flow will necessarily lead to all perfusionists immediately and automatically checking for blockages, including in the ERC clamp, and to clear them as per their training.
Accordingly, there is no proper basis to support a conclusion that the existing standard maintenance procedures in relation to the ERC clamp are of concern such that there is a risk of future deaths.

Conclusion

It is clear to LivaNova that this tragic incident was avoidable and that the CP5 operated as intended in the event of a rare ERC clamp failure.
The perfusionist was notified by way of a clear and unmistakeable alarm message and removal of functional icons. In addition, the inability to reestablish forward flow – even absent the clear indications of a failure - should inevitably have caused the ERC clamp to have been investigated immediately (as ultimately happened) and the issue rectified within moments. Had that been done, no harm would have come to Mrs Liddell. This view is supported by the evidence of the expert appointed to assist the Inquest:
"*What would have taken a competent perfusionist perhaps tens of seconds to a couple of minutes to resolve took more than 12 minutes. This was as a direct consequence of the poor decision making of the perfusionists… they demonstrated a level of competence that was less than Mrs Liddell rightfully should have expected.*"[8]
In light of the above and after careful consideration, LivaNova respectfully does not agree that any drafting changes to the IFU would have led to a different outcome in this case.

Yours sincerely

[redacted]

[redacted]
Senior Director Customer Quality

[7] Bundle reference G546 – section 5.2
[8] Bundle reference G576 – paragraph 3.8.

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