

Ref: FOIA Reference 2019/20-685

Royal Stoke University Hospital  
Quality, Safety and Compliance Department  
Newcastle Road  
Stoke-on-Trent  
Staffordshire  
ST4 6QG

Date: 2<sup>nd</sup> March 2020

Email [foi@uhnm.nhs.uk](mailto:foi@uhnm.nhs.uk)

Dear

I am writing in response to your email dated 24<sup>th</sup> February 2020 requesting information under the Freedom of Information Act (2000) regarding Haemonetics devices for plasma procedures.

On the same day we contacted you via email as we required clarification on the specific device you were referring to.

You replied via email with the following:

*"I'd like to know about any Haemonetics plasma device the Trust has used, but if you need specific model names then please can you tell me if you've used the PCS2 or MC+ models".*

As of 1<sup>st</sup> November 2014 University Hospitals of North Midlands NHS Trust (UHNM) manages two hospital sites – Royal Stoke University Hospital, and County Hospital (Stafford). Therefore the response below is for the two sites combined from that date where appropriate.

**Q1 Please can you tell me if the Trust has used any Haemonetics devices for plasma procedures over the last 10 years and how many of these devices are currently in operation?**

A1 As per your above clarification the Trust has already answered a request made by you regarding PCS2 therefore this information is exempt under section 21: *information reasonably accessible by other means*. This is because the information is available via the Trust's public website at the following link: FOI ref: 361-1920 September 2019

<http://www.uhnm.nhs.uk/aboutus/Regulatory-information/Statutory-Policies-and-Procedures/FOIdisclosurelog/Pages/default.aspx>

Information for the MC+ model is not applicable, as we do not have this device at UHNM

**Q2 Please provide a figure for each year over the last 10 years. If possible, please also state how many patients have had this device used on them?**

A2 As answer 1

**Q3 If the Trust has used any of these devices please can you tell me?**

- If there have been malfunction incidents with the device where particles have been found in plasma. Please provide details of the incident, the date it occurred and if the patient who was connected to the machine was affected in any way as a result of the malfunction
- If there have been malfunction incidents with the device where a loud noise came from the machine whilst it was in use. Please provide details of the incident, the date it occurred and if the patient who was connected to the machine was affected in any way as a result of the malfunction
- If there has been any type of malfunction with the device. Please provide details of the incident, the date it occurred and if the patient who was connected to the machine was affected in any way as a result of the malfunction
- Please can you tell me if the machine continued to be used after any of the malfunction incidents?
- How many of these incidents have been reported to the MHRA or another regulatory agency. For each incident reported please include all detail given to MHRA if possible

A3 As answer 1

\*Please note that any individuals identified do not give consent for their personal data to be processed for the purposes of direct marketing.

***UHNM NHS Trust is a public sector body and governed by EU law. FOI requestors should note that any new Trust requirements over the EU threshold will be subject to these regulations and will be advertised for open competition accordingly.***

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An anonymised copy of this request can be found on the Trust's disclosure log, please note that all requests can be found at the following link: <http://www.uhnm.nhs.uk/aboutus/Statutory-Policies-and-Procedures/Pages/Freedom-of-Information-Disclosure-Log.aspx>

This letter confirms the completion of this request. A log of this request and a copy of this letter will be held by the Trust.

If you have any queries related to the response provided please in the first instance contact my office.

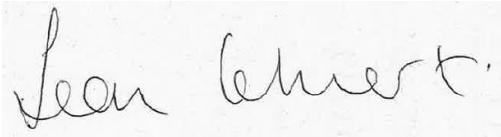
Should you have a complaint about the response or the handling of your request, please also contact my office to request a review of this. If having exhausted the Trust's FOIA complaints process you are still not satisfied, you are entitled to approach the Information Commissioner's Office (ICO) and request an assessment of the manner in which the Trust has managed your request.

The Information Commissioner may be contacted at:

Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF or via [www.ico.org.uk](http://www.ico.org.uk).

If following review of the responses I can be of any further assistance please contact my secretary on 01782 676474.

Yours,

A handwritten signature in black ink on a light-colored background. The signature reads "Jean Lehnert" in a cursive script.

Jean Lehnert  
**Information Governance Manager**