

Re: Cell Saver[®] 5/5+ serial number(s):

Dear Customer:

During our qualification testing in accordance with regulatory requirements, we determined that some recently produced Haemonetics devices have experienced a radio frequency level output from our Liquid Crystal Display (LCD) above the specifications of the electrical standard. This emission is not dangerous and does not present any risk to operator or donor health.

We have also determined that these emissions will not affect any other CE marked, Underwriters Laboratories (UL) and/or ETL mark medical devices within the vicinity of the CS5/5+.

We will be executing a field correction to upgrade your device(s). The only devices affected are those with the serial numbers listed below:
(insert SN info)

You will be contacted by a Haemonetics Service Representative within the next 30-days to schedule the upgrade during routine Preventive Maintenance. Your local regulatory authorities and bodies are aware of this field correction.

Please note that only the devices with the serial numbers listed above are affected by the field correction. All other Haemonetics devices you may have with different serial numbers are not affected.

In the interim, we recommend that you continue using the CS5/5+ device. If you have any questions about this field correction please contact *(insert contact info)*

Thank you for your attention and we apologize for any inconvenience.

Sincerely,

CL100154 Rev. A

Re: MCS[®]+ serial number(s):

Dear Customer:

During our qualification testing in accordance with regulatory requirements, we determined that some recently produced Haemonetics devices have experienced a radio frequency level output from our Liquid Crystal Display (LCD) above the specifications of the electrical standard. This emission is not dangerous and does not present any risk to operator or donor health.

We have also determined that these emissions will not affect any other CE marked, Underwriters Laboratories (UL) and/or ETL mark medical devices within the vicinity of the MCS+.

We will be executing a field correction to upgrade your device(s). The only devices affected are those with the serial numbers listed below:
(insert SN info)

You will be contacted by a Haemonetics Service Representative within the next 30-days to schedule the upgrade during routine Preventive Maintenance. Your local regulatory authorities and bodies are aware of this field correction.

Please note that only the devices with the serial numbers listed above are affected by the field correction. All other Haemonetics devices you may have with different serial numbers are not affected.

In the interim, we recommend that you continue using the MCS+ device. If you have any questions about this field correction please contact *(insert contact info)*

Thank you for your attention and we apologize for any inconvenience.

Sincerely,

CL100148 Rev. B