



URGENT: Field Safety Notice (FSN)

Expiry Date misalignment between product labels and Certificates

February 15, 2021

Dear Customer,

We are writing to advise you that Haemonetics is correcting the expiry date on product certificates for a number of products where the expiry date on the product label is expressed as YYYY-MM.

The current convention for interpreting this expiry date for when only the year and month are printed on the label is to consider the product safe to use until the end of the printed month. During a software update in our production facility, the expiry date that was printed on the certificate was modified to show the YYYY-MM-DD format. This same modification was not carried over to the product labeling thus creating a discrepancy on the date format between the product labeling and the product certificate.

The product certificates available for download have been corrected to reflect the expiry date convention as it has been applied to date (end of the month).

Product & Distribution Information:

The table below lists the product codes manufactured since 2018 that are impacted. Not all codes have been shipped to all customers.

ATSBC1EB	BPF4ARBL	LPS2E	PL1BE	RC1KLE	RN1
ATSBC1EE	BPF4BBS	LPS2KLE	PL2VAE	RC1VAE	RS1VAE
ATSBC1EPSB	BPF4BWL	LRP10BBSL	PL3VAE	RC1VE	WBT434KCE
ATSBC1ESB	BPF4NEOL	LRP10BEL		RC2VAE	
ATSBC1ESE		LRP6SC2F		RC2VE	
		LRP6SCL			

Reason for the Field Notice:

Haemonetics wishes to inform its customers of the possible discrepancy between the expiry date on the product labels and the expiry date stated on the product certificate.

The product certificates have been corrected to match the interpretation conventions of the expiry date when only the year and month are printed on the product labels.

Haemonetics therefore wishes to inform all affected customers that new product certificates are available for download at <http://www.haemonetics.com/en/support/certificates/product-certificates>.

Risk to Health:

There is no risk and no hazard of using products in relation with this field notice. This is due to the fact that the correct expiry date is present on the product labels (end of the printed month) and that this date takes into consideration the shelf life studies that allowed for the current convention of using end of the printed month for the expiry date.

Actions to be taken by all Haemonetics customers to whom this notice is addressed:

We request all customers that have received lots of the product codes listed above to download the updated product certificates for their files. This field notice only concerns the product certificates and not

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the products themselves. All products are conform to specifications and no action is needed on the products.

We require that all recipients of this notice complete the attached acknowledgement form in its entirety. Once complete, please return the form to Haemonetics following the instructions on the form. Your response is vital to our monitoring of the effectiveness of this voluntary correction. This correction is being made with the knowledge of the Competent Authorities.

Follow Up Action by Haemonetics:

Haemonetics corrected and replaced all affected certificates to be downloaded. Current products in the field and products already manufactured and not yet distributed that have the YYYY-MM date format on the label, will have the end of the specified month as expiry date on the certificates. All future production that will have a YYYY-MM-DD format on the product label, will have a matching date on the certificates (not necessarily the end of the month).

We apologize for any disruption this situation may cause your organization. Haemonetics is committed to continually improving its products and services, with safety and quality as the top priority.

Thank you for your business and continued support. Please contact your Haemonetics Account Manager or customer service if you have any questions.

Sincerely,



Andrew Sette
VP, QA & RA, International

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ACKNOWLEDGEMENT FORM

Please complete this form in its entirety and return to Haemonetics:

- I have read the instructions provided in the February 2021 notification regarding the Expiry Date misalignment between product labels and Certificates. I confirm that I understood the notice and have downloaded the corrected certificates wherever necessary.
- I no longer have any of the concerned products in stock.

Name of the person completing this form: _____

Title: _____

Phone Number: _____ Email: _____

Institution Name: _____

Institution Address: _____

City: _____ State: _____ Country: _____

SIGNATURE

DATE

PLEASE RETURN BY EMAIL TO:

QSELA@haemonetics.com