



URGENT: Field Safety Notice (FSN)

Expiry Date misalignment between product labels and Certificates

February 15, 2021

Dear Distributor,

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 <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 Distributors to whom this notice is addressed:

Our records indicate that you have distributed one or more of the affected devices indicated in this notice. We therefore ask you to perform the following activities:

1. First complete the Distributor acknowledgement form supplied without delay and in its entirety **whether or not** you have distributed affected products. The form can be found on page 3 of this

document. Once it is complete, please return to Haemonetics following the instructions on the form. Your response is vital to our monitoring of the effectiveness of this action and may be shared with Competent Authorities.

2. Then communicate with your impacted customers. Haemonetics supply you with an example communication in English under the document RCL-100324-EN(AA)-sample. This communication is based on Haemonetics document used to communicating to our direct customers. This form may be modified and translated according to your local needs and requirements. In particular we ask you to pay attention to updating:
 - a. The headers and footers
 - b. The communication method that your customers should use i.e. your return email address, your telephone number and/or your fax number
 - c. The point of contact, name and job title of who should receive the communication.
3. Lastly and if required by your local regulations, inform the appropriate authorities. Please note that Haemonetics will inform the appropriate European authorities located in the European Union (EEA, EFTA, Turkey and UK).

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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DISTRIBUTOR ACKNOWLEDGEMENT FORM

Please complete this form in its entirety and return to Haemonetics within 7 days:

- ☐ I will inform all affected customers of this Safety Notice.
- ☐ I will inform the Competent Authorities of this Safety Notice if required by national regulations (not applicable for European countries including EEA, Turkey and UK as this is being conducted by Haemonetics).

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