

HAEMONETICS®**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

HAEMONETICS®

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

Sample Customer Letter

URGENT: Field Safety Notice (FSN)

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February 5, 2021

Dear Customer,

The manufacturer Haemonetics makes continuous efforts to supply users of our products with the highest levels of product quality and reliability. In accordance with this principle, 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
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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 customers to whom this notice is addressed:

If required insert distributor footer

On distributor letterhead

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 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 [insert distributor name] 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 [insert distributor contact] if you have any questions.

Sincerely,

Insert distributor contact name

Insert distributor job title

If required insert distributor footer

URGENT: FIELD SAFETY NOTICE (FSN)
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ACKNOWLEDGEMENT FORM

Please complete this form in its entirety and return to **Insert distributor name**:

- 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 **FAX OR EMAIL TO:**

INSERT DISTRIBUTOR FAX/EMAIL INFORMATION

If required insert distributor footer