

Urgent Field Safety Notice (FSN 2019.01)

BÜHLMANN IBDoc®

Date: 21.03.2019

Results not uploaded to the Portal IBDoc®

Dear Customer,

Our records indicate that:

- your facility is using the following product:

Product	Product Code	Component	Lot Number
BÜHLMANN IBDoc®	LF-IBDOC8	IBDoc® Portal (Version 3.1.9 and earlier)	Not applicable

Table 1. Affected IBDoc® product

- a failure in the test result upload to the IBDoc® Portal for your patient(s) occurred [n] time(s).

Description of the issue: We have been informed by one of our IBDoc® users of an incident concerning a result that was not uploaded to the IBDoc® Portal although the result had been marked as successfully delivered in the CalApp® smartphone application (check mark symbol in the cloud next to the result in the "results" section of the CalApp® application). BÜHLMANN immediately launched an investigation of the incident and was able to confirm that the missing result was not uploaded correctly to the IBDoc® Portal. With this finding, BÜHLMANN evaluated the raw data of all IBDoc® results since 2018 and identified in total 27 patients' results (less than 0.01% of all results worldwide) that were not uploaded to the IBDoc® Portal, despite having a positive upload symbol within the CalApp® smartphone application. The observed error was identified as an error in the design of the IBDoc® data upload system.

The following result(s) has/have been reported for your specific IBDoc® account:

Patient ID: XXXXXXXX (Individual Patient ID will be inserted for each missing result)

Date: DD.MM.YYYY (Date of missing result)

Patient ID: XXXXXXXX

Date: DD.MM.YYYY

Risk to Health: As Clinical Users did not receive the above mentioned result(s) nor a new result notification via the IBDoc® Portal, they may lack information about the missing patient result(s). According to our risk analysis this may lead to a delay of treatment (Inflammatory bowel disease (IBD monitoring)).

Advice on action to be taken by the Healthcare Practitioner (HCP)/Clinical User:

- Please review the result(s) of the above mentioned Patient ID.
- If no result has been generated since the one missing from the IBDoc® Portal (refer to date outlined above), repeat a calprotectin measurement.
- If result has been generated since the one missing from the IBDoc® Portal (refer to date outlined above), no action is required.

Action ongoing at BÜHLMANN:

- BÜHLMANN will perform a daily scan of all newly generated results by CalApp® application in order to identify any further upload errors until the new Portal update will be released.
- Following the receipt of this FSN, the missing result(s) for your IBDoc® account will be uploaded to the IBDoc® Portal. The clinical users will get a notification via email once the result has been successfully uploaded.
- The new IBDoc® Portal version 3.2.1 update will fix this error.

Transmission of this Field Safety Notice: This notice needs to be passed on to all those who need to be aware of the incident within your organisation or to any other organisation where this software limitation occurred. Please maintain awareness of this notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

BÜHLMANN is committed to offering quality products and superior customer service. If you have any questions or comments arising from this Field Safety Notice, please contact

Ms. Marie-Christine Müller or Ms. Leslie Anchling
Customer Support BÜHLMANN Laboratories AG

Email: support@buhlmannlabs.ch

Telephone: + 41 61 487 12 00

BÜHLMANN offers you our sincere apologies for the inconvenience occurred by the results upload failure.

Best regards,



Fabio Perretta
Head Quality Manager



Laura Zürbrügg
Deputy Head Regulatory Affairs

Field Safety Notice *(FSN 2019.01)*

FAXBACK FORM

Date: 21.03.2019

Please complete and promptly return by email to:

Ms. Marie-Christine Müller, Ms. Leslie Anchling
 Customer Support BÜHLMANN

Email: support@buhlmannlabs.ch

Product	Product Code	Component	Lot Number
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Type of Action:

Further to the enclosed Field Safety Notice, you are requested to complete the following:

- I have received and reviewed the enclosed Field Safety Notice Yes / No
- I have reviewed the above mentioned result(s) Yes / No
- I have observed a deterioration in the state of health of this patient, possibly as a result of the missing result not having been assessed by a clinician on time.
 (If yes, please specify in the comments below.) Yes / No

Company Name: _____ Country: _____

Printed Name: _____ Signed: _____

Title: _____ Date: _____

Email: _____ Phone: _____

Comments:

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