

	Form	RA-F-012
	Field safety notice report (FSN)	Revision 2

Urgent Field Safety Notice

Commercial name of the affected product: YourLoops

UDI-DI : 3760364780082

FSCA-identifier: FSCA 2024-0001

Type of action: FSN - #FSN 2024-0001

Date: 2024-10-22

Attention: Healthcare professionals using YourLoops with DBLG1 system

Details on affected devices: YourLoops, version 3.4.0 UDI-DI : 3760364780082

Description of the problem:

Following the deployment of version 3.4.0 of YourLoops, we noticed a problem with the display of the patient's TDD (Total Daily Dose), which was incorrect.

The detectability of this incorrect information was considered as very high (as it was doubled) and the probability of patient consequence estimated to be low. On the other hand, the TDD displayed on the DBLG1 handset was not affected by this bug and is correct. On the TDD modification screen, the history of the actual TDD is indicated as well, and therefore the patient necessarily sees this history when they want to modify this TDD following a HCP request.

A display banner was then put in place from October 02nd to 10th in order to inform the user of the display error. Correction by bugfix implementation for Yourlops was performed very rapidly.

However, because of this issue, if the incorrect TDD was taken into account by the Healthcare Professional (HCP) to determine a treatment, the insulin amount determined to be injected can be too high and potentially generate upcoming hypoglycemia alerts and rescue carbs requests.

Post market follow up, shows that this TDD has been taken into account by some doctor in an erroneous way.

Therefore, if you have seen patients and considered their TDD displayed in YourLoops during the period from September 12th to 26th 2024 in order to determine a treatment, please verify the treatment values assigned to them.

The current TDD value displayed in YourLoops is correct now.

Advice on action to be taken by the user:

The affected version of YourLoops was corrected on September 26th by the release of YourLoops 3.4.1, further we noticed the event.

From September 12th to 26th 2024, if you have considered the TDD displayed in order to determine a treatment, we recommend you to verify the treatment values assigned to the patient.

From September 26th the TDD displayed is correct and no action is necessary from your end.

Transmission of this Field Safety Notice:

This information was transmitted to competent authorities.

This notification must be communicated to all your patients for whom treatment has been adjusted from September 12th to 26th, within 48 hours of receipt of this letter.

The acknowledgement of receipt enclosed with this notification must be returned to us as soon as all your patients concerned by this safety notice have been informed of the notification.

We sincerely regret the inconvenience caused and thank you in advance for your support and cooperation. Remaining at your disposal, please accept, Madam, Sir, our best regards.

Contact reference person:

Viviane PAYROU

DIABELOOP Quality, Regulatory and Clinical Director


vigilance@diabeloop.fr

Signature: 

Company confidential

Please verify latest revision before each use

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Urgent Field Safety Notice - Acknowledgement letter

Commercial name of the affected product: YourLoops

UDI-DI : 3760364780082

FSCA-identifier: FSCA 2024-0001

Type of action: FSN - #FSN 2024-0001

If during this time range (from September 12th to 26th 2024) you have considered the TDD displayed in order to determine a treatment, we recommend you to verify the treatment values assigned to the patient.

Date:

By sending back this document to Diabeloop, the signatory confirms that the Field Safety Notice mentioned above has been received, understood and communicated within his/her organization as applicable.

Name of the person:

Organization:

Address:

Email address:

Phone number:

Signature

The document must be sent to vigilance@diabeloop.fr

A paper copy may be sent to:

Diabeloop

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38000 Grenoble

France