

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

Urgent Field Safety Notice

Commercial name of the affected product: DBLG1 and DBL-hu

FSCA-identifier: FSCA 2022-0001

Type of action: Recommendations of use of DBLG1 and DBL-hu medical devices manufactured by DIABELOOP

Date: September 26, 2022

To the attention of:

- DBLG1 and DBL-hu Distributors

Details on affected devices:

- DBLG1 associated with Accu-Chek Insight, Roche
 - DBLG1-INS-DEXG6-mg/dl-DE-de
 - DBLG1-INS-DEXG6-mmol/l-DE-de
 - DBLG1-INS-DEXG6-mg/dl-IT-it
 - DBLG1-INS-DEXG6-mmol/l-NL-nl
 - DBLG1-INS-DEXG6-mg/dl-ES-es
 - DBLG1-INS-DEXG6-mmol/l-CH-de
 - DBLG1-INS-DEXG6-mmol/l-CH-fr
 - DBLG1-INS-DEXG6-mmol/l-CH-it
 - DBLG1-INS-DEXG6-mg/dl-BE-fr
 - DBLG1-INS-DEXG6-mg/dl-BE-nl
 - DBLG1-INS-DEXG6-mg/dl-FR-fr
- DBLG1 associated with Kaleido, ViCentra
 - DBLG1-KAL-DEXG6-mg/dL-FR-fr
- DBL-hu associated with Kaleido, ViCentra
 - DBLHU-KAL-DEXG6-mg/dL-FR-fr

Description of the problem:

On 2022-09-21, we executed a remote update to version 1.12.4. One of the main features of this update was the ability to enter a “power saving mode”, which had been requested by a high number of patients. This power saving mode means the handset will not try to connect to the mobile network constantly. Previously the fact that the handset was trying to connect constantly was causing disturbances for patients that happened to be living in poorly-covered GSM zones, or in between 2 different GSM antennas.

Since this update, and most likely linked to this power saving mode feature, some patients might be experiencing issues with the stability of CGM data and sometimes Supervisor alarm. The issue with the CGM data is due to Bluetooth connection instability. In case the handset is not able to receive CGM Data for too long, an alarm (21000) is raised. The supervisor alarm indicates that the handset should be restarted in order to return the handset to a stable state.

The risk for the patient is to go back in open loop but the user is informed before and at the moment of the switch to open loop: all the mechanisms of alarms and alerts work correctly to warn the patient..

Advice on action to be taken by the user:

After our first investigations, we recommend activating **either the Power Saving mode or preferably the Confidential Mode with a 3-days setting** until we come back to you with a solution.

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The confidential mode is located in "Settings>Application>Confidential mode".
Note that the confidential mode will have to be activated again after 3 days.

If the supervisor alarm occurs, we suggest you restart your DBLG1 or your DBL-hu and activate the Confidential mode immediately.

If the problems still persist, we recommend you the following :

- if your device is associated with an Accu-Chek Insight (ROCHE's insulin pump): use your pump in standalone mode and use the DEXCOM app* or receiver to follow your glucose data.
- if your device is connected with a Kaleido (Vicentra's insulin pump): use you back-up insulin plan - you can use the Dexcom app or receiver to follow your glucose data

It's also necessary that you call your local support to raise your situation to our knowledge.

*: available in the Google Play store and Apple store

Transmission of this Field Safety Notice:

This Field Safety Notice must be communicated to all your patients equipped with the systems concerned by this safety notification within 48 hours of receipt of this letter.

This Field Safety Notice needs to be communicated to those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.


Contact reference person:

Frédérique BOIZET
DIABELOOP,
155-157 cours Berriat,
QARA@diabeloop.fr

The undersigned confirms that this Field Safety Notice has been communicated to all the impacted National Health Authorities and Regulatory Agencies.

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.

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Urgent Field Safety Notice - Acknowledgement letter

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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 QARA@diabeloop.fr

A paper copy may be sent to:

Diabeloop
155-157 cours Berriat
38000 Grenoble
France.