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Rev 2: February 2020

FSN Ref: FSN 00223

FSCA Ref: FSCA 00223

Date: 2023-03-03

Field Safety Notice
croBEE® Real-time PCR System

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages.

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Field Safety Notice (FSN)
croBEE® Real-time PCR System
Bug in older software (version 1.0.02) of croBEE Real Time PCR System

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	In vitro diagnostic medical device
1.	2. Commercial name(s)*
	croBEE® Real-time PCR System
1.	3. Unique Device Identifier(s) (UDI-DI)
	859569630047QT
1.	4. Primary clinical purpose of device(s)*
	The croBEE Real-Time PCR System is an automated instrument used for qualitative and quantitative detection of nucleic acid (DNA/RNA) using polymerase chain reaction (PCR). The instrument is intended for molecular biology applications and for *in vitro* diagnostic use. This product is not intended for the diagnosis, prevention, or treatment of a specific disease. The croBEE Real-Time PCR System is a fluorescent quantitative detection system. The instrument is intended for use in medical and biological laboratories by trained staff of clinical laboratories in molecular biological techniques. The product is intended to be used in combination with real-time PCR kits.
1.	5. Device Model/Catalogue/part number(s)*
	CBRT4/96 *(4 channels)* CBRT5/96 *(5 channels)*
1.	6. Software version
	1.0.02
1.	7. Affected serial or lot number range
	See attachment: croBEE® Real-time PCR System – List of serial Nos.
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Bug in older software (version 1.0.02) of croBEE Real Time PCR System
2.	2. Hazard giving rise to the FSCA*
	A bug in the older software (version 1.0.02) of the croBEE Real Time PCR System was identified based on the post-market surveillance system. This bug may cause the baseline to be incorrectly set to between 1 and 45 for highly positive samples (Ct < 10 approx.) and thus exclude such positive curves from the evaluation. This may result in extremely high positive samples being incorrectly evaluated as negative.
2.	3. Probability of problem arising
	Low
2.	4. Predicted risk to patient/users
	False negative results for extremely positive samples
2.	5. Further information to help characterise the problem
	It is necessary to check the version of the software used in the croBEE Real Time PCR System and if it is different from the latest *version 1.0.13*, upgrade it to *version 1.0.13*. Follow the instructions in the attached file: *SW check and update.docx*

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	Until the software is checked and upgraded to *version 1.0.13*, if necessary, the raw data (amplification plots) of negative samples obtained with the croBEE Real Time PCR System must be checked before the results are released.
2.	6. Background on Issue
	The root cause is now under investigation.
2.	7. Other information relevant to FSCA
	N/A

3. Type of Action to mitigate the risk*		
3.	**1. Action To Be Taken by the User***	
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☒ Other ☐ None It is necessary to check the version of the software used in the croBEE Real Time PCR System and if it is different from the latest *version 1.0.13*, upgrade it to *version 1.0.13*. Until the software is checked and upgraded to *version 1.0.13*, if necessary, the raw data of negative samples obtained with the croBEE Real Time PCR System must be checked before the results are released.	
3.	2. By when should the action be completed?	2023-03-15
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes. If inconsistencies between the clinical diagnosis and test results were observed. In such instances the negative results should be re-examined by reviewing the raw data. False negative results (if any) are expected to have been a rare occurrence.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer***	
	☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None 1) To send instructions to customers and distributors to check the software version in the device and to upgrade it to SW version 1.0.13. 2) To provide customers with expert technical support.	

	3) Investigation of root cause is ongoing, however, as software can be updated to a version that excludes the malfunction, this has no direct effect on patient safety.	
3.	6. By when should the action be completed?	2023-03-30
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	N/A	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**GeneProof a.s.**
	b. Address	**Vídeňská 101/119, Dolní Heršpice, 619 00 Brno, Česká Republika**
	c. Website address	**www.geneproof.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	1) croBEE Real-time PCR System – List of serial Nos.xlsx 2) FSN 00223 – Attachment: *SW check and update.docx*
4.	1. Name/Signature	**Kamil Šplíchal** **QA/RA Director**
		Mgr. Kamil Šplíchal Podepsal Mgr. Kamil Šplíchal DN: cn=Mgr. Kamil Šplíchal, c=CZ, email=kamil.splichal@geneproof.com Datum: 2023.03.03 09:36:42 +01'00'

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

	Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.