Eckert & Ziegler

Urgent Field Safety Notice

(Singapore version)

Eckert & Ziegler
BEBIG GmbH

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Contact: Bernd Schumacher
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Subject:	Offset of Depth Dose Curve
Commercial Name of Affected Product:	Ru-106 Eye Applicator
Types:	Ru6.A03, Ru6.A04, Ru6.A05, Ru6.A06, Ru6.A07, Ru6.A09, Ru6.A13, Ru6.A14
Reference:	UFSN-2019Ru-106
Date of Notification:	15 Aug. 2019
Type of Action:	Information / Recall

Description of Problem:

- This notice refers to the Ru-106 Eye Applicators sent by Eckert & Ziegler BEBIG from 1 April 2019 to 7 August 2019.
- Because of a systematic offset in axial positioning, the data of the Depth Dose Curve referring to z-coordinate = 1, 2, 3 …10 mm have been measured with a shift of +0.35 mm.
  This results in a deviation of the certified dose rate against the correct value.
  For most applicator models the relevant range for the treatment planning is z = 0-6 mm. For these models the actual depth dose rates of the applicators are 7-18% higher than certified.
  For the small models CCX and CIA the relevant range for the treatment planning is z = 0-4 mm. For these models the actual depth dose rates of the applicators are 9-18% higher than certified.
- The deviation can lead to an overdosage of 7–18% at the prescription point and to organs at risk, depending on the clinical practice.
- The user is advised to use the corrected data provided for each individual applicator as an attachment to this notice.

Note: For several decades the certified total uncertainty of the Ru-106 Eye Applicators dose rate was 20%. Since April 2019 it was reduced to 11% by various improvements. Due to the quadratic calculation of uncertainties and for a confidence level of 95%, the current failure leads to a maximum total deviation of 21%. This is close to the former uncertainty which had been the basis for the current clinical practice.

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This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation, including the Chairman Medical Board and/or relevant Head-of-Departments, where the devices have been transferred to.

Please reply to this email confirming that you have received and understood this information and that you have forwarded it to the people which already have received the named products or will receive them.

The undersign representative from Eckert & Ziegler BEBIG GmbH confirms that this notice has been notified to the appropriate Regulatory Agency.

We sincerely apologise for any inconvenience and thank you in advance for your cooperation. For further information please feel free to contact us.

Kind regards,

[redacted]

Bernd Schumacher
Head of Quality Management

P06D002e Rev.6

CONFIRMATION

Urgent Field Safety Notice from Eckert & Ziegler BEBIG GmbH, Reference UFSN-2019Ru106

This is to confirm that we have received and understood the Field Safety Notice. It was forwarded inside our clinic to the respective personnel.

Name of clinic: .....

Country, City: .....

Name: .....

Signature, date: .....

Urgent Field Safety Notice
Attachment

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Subject: Offset of Depth Dose Curve

Reference: **UFSN-2019Ru106**

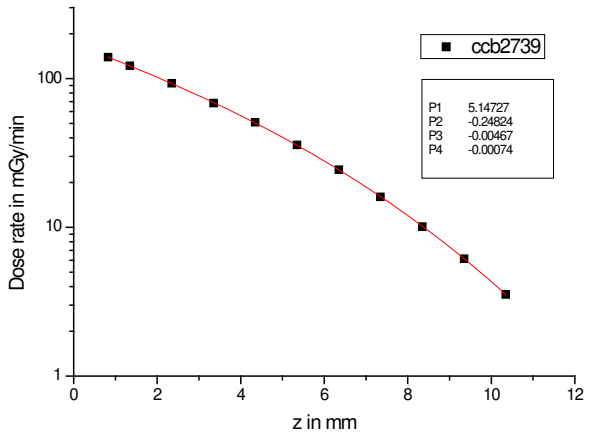
Date of notification: 15 Aug 2019

With this attachment, we provide to you the corrected dose rate curve $\dot{D}(z)$ along the central axis of each individual Ru-106 Eye Applicator concerned by the offset. The correction has been performed by interpolation to the dose rate at the respective distances to the surface z_{new}.

The graph replaces that one given on the appendix of the certificate. In the table, the measured dose rates $\dot{D}_{meas}$ at the corrected distances (z_{corr} =1.35, 2.35, …, 10.35 mm) are stated together with the interpolated data $\dot{D}_{int}$ (z_{new} =1.00, 2.00, …, 10.00 mm).

Serial number of applicator	CCB 2739
Certficate no.	53819
Reference date	13.06.2019

z_{corr} [mm]	$\dot{D}_{meas}(z)$ [mGy/min]	z_{new} [mm]	$\dot{D}_{int}(z)$ [mGy/min]	$\dot{D}_{rel}(z)$ [%]	$\Delta(z)^{***}$ [%]
0.0	183.4**	0.0	172.0**	168**	
0.5	151.9**	0.5	151.7**	149**	
0.83*	139.4	0.83*	139.6	137	
1.35	122.0	1.00	133.4	131	9
2.35	92.8	2.00	102.1	100	10
3.35	68.3	3.00	76.7	75.2	12
4.35	50.8	4.00	56.4	55.2	11
5.35	35.8	5.00	40.3	39.5	13
6.35	24.4	6.00	27.9	27.4	15
7.35	16.0	7.00	18.7	18.3	
8.35	10.1	8.00	12.0	11.7	
9.35	6.14	9.00	7.35	7.20	
10.35	3.53	10.00	4.30	4.21	



* Due to technical reasons the value at 0.83 mm was measured correctly and therefore does not change.
** Extrapolated data according the previous and new fit function.
*** Relative deviation between previous and corrected dose rates

Please note: Since we have not carried out a new measurement, we are unfortunately unable to issue a new certificate for you. Hence please use this information as a substitute for the corresponding appendix of the certificate.