Gmail **Steve Nixon <steve.nixon.viamed@googlemail.com>**

# Re: Validation of temperature probe cleaning temperature / IFU draft

1 message

**Steve Nixon** <steve.nixon@viamed.co.uk> 23 February 2022 at 08:36
Reply-To: steve.nixon@viamed.co.uk
To: "Boetcher, Uwe" <u.boetcher@bluepoint-medical.com>
Cc: "Dettweiler, Ralf" <r.dettweiler@bluepoint-medical.com>

Thanks for the update Uwe.

Do we need to clarify the last paragraph where it states '**in accordance with the manufacturer's specifications**', should it be

'in accordance with bluepoint medical's specifications'

or

'in accordance with the temperature probe specifications'

or

'in accordance with our specifications'

Steve

On Wed, 23 Feb 2022 at 08:24, Boetcher, Uwe <u.boetcher@bluepoint-medical.com> wrote:

> Dear Steve,
>
> please find our updated Statement about Reprocessing of Temperature Sensors here.
>
> Again, we will have a discussion on open questions, planned for tomorrow.
>
> Kind regards
>
> Dr. Uwe Boetcher
>
> Quality Management Representative
>
> _____
>
> **bluepoint MEDICAL GmbH & Co. KG**
>
> **An der Trave 15**
>
> **23923 Selmsdorf, Germany**
>
> _____
>
> tel: +49 (0) 38823 - 548 8-26
> fax: +49 (0) 38823 - 548 8-29
> email: u.boetcher@bluepoint-medical.com
>
> web: www.bluepoint-medical.com
>
> Trade register: Schwerin, Reg.-No.: HRA 2600
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**Von:** Main Account <viamedinbox@gmail.com> **Im Auftrag von** Steve Nixon
**Gesendet:** Montag, 21. Februar 2022 17:39
**An:** Boetcher, Uwe <u.boetcher@bluepoint-medical.com>
**Cc:** Dettweiler, Ralf <r.dettweiler@bluepoint-medical.com>
**Betreff:** Re: Validation of temperature probe cleaning temperature / IFU draft

Hi Uwe

In principle the declaration letter is good. Can we change '**und**' to '**and**' paragraph c).

Is there a way that we can say that the sensors are OK when exposed up to 137 degrees C. Or do we just assume that there could be up to 3 degrees difference from set temperature to maximum, therefore if we set at 132 degrees C, the maximum would then be 135 degrees C.

You do test at 134 degrees C for durability, would this allow for 3 degrees margin extra?

Section 1.9 page 2

**High temperature steam**

Sterilization temperature [C]a 121 - 134
Maximum temperature [C] 124 - **137**
Minimum holding time [min] 15 3
The temperature setting on the automatic controller will
not generally be the sterilization temperature, but a higher
temperature within the sterilization temperature band

Can we state the standards on marketing materials?

Will you update the Declaration of Conformity with the applied standards?

Steve

On Fri, 18 Feb 2022 at 09:19, Boetcher, Uwe <u.boetcher@bluepoint-medical.com> wrote:

> Dear Steve,
>
> as mentioned by Ralf in the Email below, we attach the Statement about Reprocessing of Temperature Sensors here.
>
> Additionally, we are looking forward for your feedback on our IFU-draft.
>
> Have a nice weekend!
>
> Kind regards
>
> Dr. Uwe Boetcher
>
> Quality Management Representative
>
> ---
>
> **bluepoint MEDICAL GmbH & Co. KG**
>
> **An der Trave 15**
>
> **23923 Selmsdorf, Germany**
>
> ---
>
> tel: +49 (0) 38823 - 548 8-26
> fax: +49 (0) 38823 - 548 8-29
> email: u.boetcher@bluepoint-medical.com
>
> web: www.bluepoint-medical.com
>
> Trade register: Schwerin, Reg.-No.: HRA 2600

**Von:** Dettweiler, Ralf
**Gesendet:** Montag, 14. Februar 2022 12:30
**An:** steve.nixon@viamed.co.uk
**Cc:** Wigger, D. <d.wigger@bluepoint-medical.com>; Jens Schwarz <j.schwarz@sensatronic.com>; Boetcher, Uwe <u.boetcher@bluepoint-medical.com>; Lindner, Bernd <b.lindner@bluepoint-medical.com>
**Betreff:** AW: Validation of temperature probe cleaning temperature / IFU draft

Hi Steve,

I hope you are doing well!

For a long time we have a discussion with Jens about temperature sensor compliance with updated standard requirements, especially regarding ISO 80601-2-56:2017 and reprocessing. Actually the current IFU and sensor labeling of bluepoint sensors is not up to date. In order to meet the current regulatory requirements regarding reusable medical temperature sensors, Sensatronic has carried out extensive validation tests and updated the labelling of the temperature sensors in this context. In particular, the reprocessing information updated in the IFU has been clarified. Based on it, Sensatronic was able to achieve the US FDA registration of the temperature sensors.

Now we are working on the update of IFU and labels for bluepoint temperature sensors. We have planned to redesign a uniform IFU and labels that will be used for the reusable standard sensors in the future. It means that specific customer content and artwork elements will not be included. Unfortunately this is unavoidable because of the effort balance.

The wording of the new IFU essentially corresponds to that of the Sensatronic IFU. Please find attached draft for check.

The information provided in the product labelling must also meet special country-specific requirements, so that the IFU may also have to include the language of the respective sales territory. Could you please transmit a country list that covers your sales countries? According to your specifications, we would include the necessary translations in the updated version of the IFU.

Could you please think about these news and our plan? We are also preparing a statement that refers to the regulatory requirements of ISO 80601-2-56 and the corresponding Sensatronic test report, which can be used by you as evidence of the successful performance of the cleaning validation.

This is it for now. Your feedback is much appreciated. Please also let me know your questions.

Thanks, Steve!

Best regards,

Ralf

**Von:** Main Account <viamedinbox@gmail.com> **Im Auftrag von** Steve Nixon
**Gesendet:** Donnerstag, 10. Februar 2022 10:38
**An:** Boetcher, Uwe <u.boetcher@bluepoint-medical.com>
**Cc:** Wigger, D. <d.wigger@bluepoint-medical.com>; Jens Schwarz <j.schwarz@sensatronic.com>; Dettweiler, Ralf <r.dettweiler@bluepoint-medical.com>
**Betreff:** Re: Validation of temperature probe cleaning temperature

Thank you Uwe

Steve

On Thu, 10 Feb 2022 at 09:23, Main Account <viamedinbox@gmail.com> wrote:

> ---------- Forwarded message ---------
> From: **Boetcher, Uwe** <u.boetcher@bluepoint-medical.com>
> Date: Thu, 10 Feb 2022 at 09:19
> Subject: AW: Validation of temperature probe cleaning temperature
> To: viamedinbox@gmail.com <viamedinbox@gmail.com>
> Cc: Wigger, D. <d.wigger@bluepoint-medical.com>, j.schwarz@sensatronic.com <j.schwarz@sensatronic.com>, Dettweiler, Ralf <r.dettweiler@bluepoint-medical.com>
>
> Dear Steve,
>
> we will discuss this and come back to you beginning of next week.
>
> Kind regards
>
> Dr. Uwe Boetcher
>
> Quality Management Representative
>
> **bluepoint MEDICAL GmbH & Co. KG**
>
> **An der Trave 15**
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> **23923 Selmsdorf, Germany**

tel: +49 (0) 38823 - 548 8-26
fax: +49 (0) 38823 - 548 8-29
email: u.boetcher@bluepoint-medical.com

web: www.bluepoint-medical.com

Trade register: Schwerin, Reg.-No.: HRA 2600



**Von:** Main Account <viamedinbox@gmail.com> **Im Auftrag von** Steve Nixon
**Gesendet:** Mittwoch, 9. Februar 2022 13:59
**An:** Wigger, D. <d.wigger@bluepoint-medical.com>
**Betreff:** Validation of temperature probe cleaning temperature

Hi Dennver

**Can we provide a validation declaration that the probes are clean after steam sterilization: 3 minutes (134 degrees C to 137 degrees C). This can be a separate statement, an addendum to the IFU or part of the IFU**

Customers are query the cleaning of the temperature probes, will Jens be able to assist with this?

They state that the sterilisation profile sits outside of the standard UK's HTM 01-01 Part C (see attached).

Section 1.9 page 2

**High temperature steam**

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https://www.england.nhs.uk/publication/decontamination-of-surgical-instruments-htm-01-01/

Has Bluepoint quoted 134C/5 min to evidence the durability of the probe, and not as a minimum requirement to ensure effective sterilisation?

Customers say that they can`t ignore the (HTM 01-01) guidelines. There is familiarity with decontamination standards outside of the UK and an appreciation that these meet the EU profile, but in order to supply to the NHS, companies must either fully re-validate products to the UK profile (which means changing the instructions), or provide a written declaration as an addendum to the instructions to state that they have been validated to the UK standards. This is a common problem and many other companies take this latter approach.

Their preferred method of cleaning is through an automated washer disinfector as this achieves validated and repeatable results. Ref. the statement in (HTM 01-01):
"Traditionally, cleaning validation has been about removing visible soiling. Now the emphasis is on removing highly adherent proteins to very low levels. To be able have a greater chance of removing these sticky proteins, there needs to be as efficient a cleaning process as possible, therefore SSDs need to both optimise the cleaning performance of washer-disinfectors and remain within the validation parameters."

Currently, customers do not allow anything into the autoclave unless it can be processed through the washer-disinfector. It can be done in exceptional circumstances but it demands much more thorough manual cleaning procedures with a costly and time-consuming validation process.

With regards to sterilisation cycles, it is possible to re-program the steam sterilizers with a new cycle, but this costs them £5k per year per profile and it has to be validated quarterly.

If they are doing things correctly NHS hospitals should not be buying the temperature probes without the validation declaration.

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Steve

Steve Nixon

Director - Viamed Ltd.

Office: +44 (0)1535 634542

Mobile: +44 (0)7850 252267



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Steve

Steve Nixon
Director - Viamed Ltd.

Office: +44 (0)1535 634542

Mobile: +44 (0)7850 252267



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