



"Teresa White "
<twhite@lsr.com>
12/05/2007 05:07 PM

To Yunus Faziloglu/USA/VERITAS@VERITAS
cc
bcc
Subject RE: CS03079 GE Medical FCC ID: OU52014748-002 TCB Questions 2

Hi Yunus,

Here are the customer's responses. I will be sending you the Confidentiality Letter separately.

1. Please supply a copy of complete user's manual as required in 95.653 to address paragraphs (a) through (b)(3) of that section. Applicant Response: Complete User's Manual attached.

SAR level is incorrect (Pg 28) [Applicant response] It is incorrect in the "full" version of the manual I sent out, but if you see the excerpt I sent initially it is correct. The "full" version is the first draft, and the excerpt is what has been revised so far with the intention of correcting issues as the SAR level. Would it be possible to accept the excerpt as an amended version of that portion of the "full" version?

3. Licensed devices require a parts list exhibit. Applicant Response: Parts Exhibit attached.

OK. If this is confidential document, confidentiality request letter must include Parts List as well. Please confirm with the applicant and let us know. [Applicant response] I missed this as well. LS Compliance can draft a revised version of the original letter for us to sign.

6. For SAR report,

i. Are there any possible connections to the device other than the cable seen in SAR setup photos? Applicant Response: The transmitter has two serial ports used for external SpO2 or NIBP units.

Can these two serial ports mentioned be populated while it is operating on the patient? [Applicant response] The ports can be populated with an external SpO2 or NIBP unit while it is operating on the patient.

ii. On Pg 14, there may be issues with the positions vs frequencies listed. It would make sense if "back" and "front" positions were each tested for low and high channel. Currently there are two "back" position entries with 1399.975MHz. It is possible one of them may actually be 1395.025MHz assuming back position produces higher SAR readings than front. So rows 2 and 3 may have their frequencies switched. Please clarify with the SAR lab. Applicant Response: This issue is due to a typographical mistake. This was brought up to the SAR test lab, and a revised report was issued to correct this mistake. A revised SAR results report is attached.

Still looks inconsistent. At the low frequency channel the "BACK" position seems to produce higher SAR, while in the high channel it is the "FRONT" position that produces higher SAR. Regardless of the channel, it is expected that same positions will produce similar SAR levels and one of them; either front or back, will prevail the other. Please clarify with the SAR lab again. [Applicant response] I re-verified this with the SAR lab, and when the last correction was made these SAR levels were not repositioned in the table (page 14 of the SAR report). A corrected version of the SAR report is attached.

Regards,
Teresa

Teresa White
Quality Manager

LS Research, LLC
Direct: 262.421.4991
Fax: 262.364.2649

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From: yfaziloglu@curtis-straus.com [mailto:yfaziloglu@curtis-straus.com]
Sent: Monday, December 03, 2007 2:34 PM
To: Teresa White
Subject: CS03079 GE MEdical FCC ID: OU52014748-002 TCB Questions 2

Hi Teresa,

Please see additional comments below.

Best Regards,

Yunus Faziloglu
Curtis-Straus LLC
Bureau Veritas

▼ "Teresa White" <twhite@lsr.com>

"Teresa White"
<twhite@lsr.com>

11/30/2007 02:20
PM

To Yunus Faziloglu/USA/VERITAS@VERITAS

cc

Subject RE: CS03079 GE MEdical FCC ID:
OU52014748-002 TCB Questions

Hi Yunus,

Responses to issues 1-4 and 6 are below. Response to issue 5 will be forthcoming.

Thanks.

Regards,
Teresa

Teresa White
Quality Manager

LS Research, LLC
Direct: 262.421.4991
Fax: 262.364.2649

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From: yfaziloglu@curtis-straus.com [<mailto:yfaziloglu@curtis-straus.com>]

Sent: Tuesday, November 27, 2007 8:32 AM

To: Teresa White

Subject: CS03079 GE Medical FCC ID: OU52014748-002 TCB Questions

Hi Teresa,

Please address the following issues for this application,

1. Please supply a copy of complete user's manual as required in 95.653 to address paragraphs (a) through (b)(3) of that section. **Response:** Complete User's Manual attached.

SAR level is incorrect (Pg 28)

2. External and internal photos are needed. **Response:** Photos sent on 11/28/07.

OK

3. Licensed devices require a parts list exhibit. **Response:** Parts Exhibit attached.

OK. If this is confidential document, confidentiality request letter must include Parts List as well. Please confirm with the applicant and let us know.

4. Does the device have any controls accessible to the user that may violate 95.645(a)? Please clarify. **Response:** The controls accessible to the user will not violate 95.645(a). The controls accessible to the user provide the following functions (this is discussed in detail in the User's Manual – Transmitter Setup section): -Check ECG lead connections; -Pause Alarms; -Print ECG graph strips; -Generate a remote event.

OK

5. In EMC report,

- i. Please note, Pg 7 does not refer to body-SAR for RF evaluation which has been performed for this device.
- ii. Limits on Pg 14 that are listed as 47dBuV/m must be 46dBuV/m instead.
- iii. On Pg 28, it is not clear how measured and declared RF power levels were determined as 0.005186 and 0.005623 Watts respectively.
- iv. Frequency stability data is required as explained in 2.1055 for temperature variation (-30 to +50 degrees C) and for specified battery end-points. Exhibit 9 in report does not seem to address this.

This item is open for response.

6. For SAR report,

- i. Are there any possible connections to the device other than the cable seen in SAR setup photos? **Response:** [The transmitter has two serial ports used for external SpO2 or NIBP units.](#)

Can these two serial ports mentioned be populated while it is operating on the patient?

- ii. On Pg 14, there may be issues with the positions vs frequencies listed. It would make sense if "back" and "front" positions were each tested for low and high channel. Currently there are two "back" position entries with 1399.975MHz. It is possible one of them may actually be 1395.025MHz assuming back position produces higher SAR readings than front. So rows 2 and 3 may have their frequencies switched. Please clarify with the SAR lab. **Response:** [This issue is due to a typographical mistake. This was brought up to the SAR test lab, and a revised report was issued to correct this mistake. A revised SAR results report is attached.](#)

Still looks inconsistent. At the low frequency channel the "BACK" position seems to produce higher SAR, while in the high channel it is the "FRONT" position that produces higher SAR. Regardless of the channel, it is expected that same positions will produce similar SAR levels and one of them; either front or back, will prevail the other. Please clarify with the SAR lab again.

Best Regards,

Yunus Faziloglu
Curtis-Straus LLC
Bureau Veritas

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Faziloglu/USA/VERITAS] GE Carescape Telemetry T14 SAR Report (6).pdf

**Yunus
Faziloglu/USA/VERITAS**

12/06/2007 04:23 PM

To "Teresa White" <twhite@lsr.com>

cc

bcc

Subject CS03079 GE Medical FCC ID: OU52014748-002 TCB
Questions 3

Hi Teresa,

Following issues remain with respect to original item numbers .

1. The draft manual and the excerpt can be accepted provided they supply a letter stating what they explained in the response below.

6i. According to the SAR test setup photos (photo #4), these two serial ports mentioned do not seem to be populated. These kinds of terminations may affect the SAR levels . Please clarify the reason with the SAR lab.

Best Regards,

Yunus Faziloglu
Curtis-Straus LLC
Bureau Veritas

"Teresa White" <twhite@lsr.com>



"Teresa White "
<twhite@lsr.com>

12/05/2007 05:07 PM

To Yunus Faziloglu/USA/VERITAS@VERITAS

cc

Subject RE: CS03079 GE Medical FCC ID: OU52014748-002 TCB
Questions 2

Hi Yunus,

Here are the customer's responses. I will be sending you the Confidentiality Letter separately.

1. Please supply a copy of complete user's manual as required in 95.653 to address paragraphs (a) through (b)(3) of that section. [Applicant Response: Complete User's Manual attached.](#)

SAR level is incorrect (Pg 28) [Applicant response] It is incorrect in the "full" version of the manual I sent out, but if you see the excerpt I sent initially it is correct. The "full" version is the first draft, and the excerpt is what has been revised so far with the intention of correcting issues as the SAR level. Would it be possible to accept the excerpt as an amended version of that portion of the "full" version?

3. Licensed devices require a parts list exhibit. [Applicant Response: Parts Exhibit attached.](#)

OK. If this is confidential document, confidentiality request letter must include Parts List as well. Please confirm with the applicant and let us know. [Applicant response] I missed this as well. LS Compliance can draft a revised version of the original letter for us to sign.

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Response: The transmitter has two serial ports used for external SpO2 or NIBP units.

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Applicant Response: This issue is due to a typographical mistake. This was brought up to the SAR test lab, and a revised report was issued to correct this mistake. A revised SAR results report is attached.

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Regards,
Teresa

Teresa White
Quality Manager

LS Research, LLC
Direct: 262.421.4991
Fax: 262.364.2649

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From: yfaziloglu@curtis-strauss.com [mailto:yfaziloglu@curtis-strauss.com]
Sent: Monday, December 03, 2007 2:34 PM
To: Teresa White
Subject: CS03079 GE Medical FCC ID: OU52014748-002 TCB Questions 2

Hi Teresa,

Please see additional comments below.

Best Regards,

Yunus Faziloglu
Curtis-Straus LLC
Bureau Veritas

▼ "Teresa White" <twhite@lsr.com>

"Teresa White"
<twhite@lsr.com>

11/30/2007 02:20
PM

To Yunus Faziloglu/USA/VERITAS@VERITAS

cc

Subject RE: CS03079 GE Medical FCC ID:
OU52014748-002 TCB Questions

Hi Yunus,

Responses to issues 1-4 and 6 are below. Response to issue 5 will be forthcoming.

Thanks.

Regards,
Teresa

Teresa White
Quality Manager

LS Research, LLC
Direct: 262.421.4991
Fax: 262.364.2649

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From: yfaziloglu@curtis-straus.com [<mailto:yfaziloglu@curtis-straus.com>]

Sent: Tuesday, November 27, 2007 8:32 AM

To: Teresa White

Subject: CS03079 GE Medical FCC ID: OU52014748-002 TCB Questions

Hi Teresa,

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1. Please supply a copy of complete user's manual as required in 95.653 to address paragraphs (a) through (b)(3) of that section. [Response: Complete User's Manual attached.](#)

SAR level is incorrect (Pg 28)

2. External and internal photos are needed. [Response: Photos sent on 11/28/07.](#)

OK

3. Licensed devices require a parts list exhibit. [Response: Parts Exhibit attached.](#)

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OK

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Yunus Faziloglu
Curtis-Straus LLC
Bureau Veritas

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"Teresa White "
<twhite@lsr.com>
12/14/2007 09:55 AM

To Yunus Faziloglu/USA/VERITAS@VERITAS
cc
bcc
Subject CS03079 GE MEdical FCC ID: OU52014748-002 TCB
Questions 3

Hi Yunus,

Please see below for responses to issues.

Thanks.

Regards,
Teresa

Teresa White
Quality Manager

LS Research, LLC
Direct: 262.421.4991
Fax: 262.364.2649

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From: Ferrer-Herrera, Manuel J (GE Healthcare) [<mailto:Manuel.Ferrer@med.ge.com>]
Sent: Thursday, December 13, 2007 5:48 PM
To: Teresa White
Cc: Steinike, Michael (GE Healthcare)
Subject: RE: TCB Issues
Importance: High

Teresa,

In response to the TCB comments I am attaching the following documents :

- 1 - A signed letter documenting the correction made in the user's manual excerpt to address the correction of the SAR level.
- 2 - A total of 5 files from the SAR lab. This is a new report in which the SAR lab addressed the concern pointed out by the TCB by repeating the SAR compliance test, including the effect of terminating the serial ports of the transmitter.
- 3 - A copy of the user's manual excerpt updated with the correct SAR level per the attached report.

Note: I will be on vacation from Dic 17 to Jan 3. I will appreciate if you Cc Mike Steinike in any e-mail

exchange during that period. He may be able to help out as well.

Thanks!

-Manuel

From: Teresa White [mailto:twhite@lsr.com]
Sent: Thursday, December 06, 2007 3:35 PM
To: Ferrer-Herrera, Manuel J (GE Healthcare)
Subject: TCB Issues
Hi Manuel,

Here is the final response from the TCB:

1. The draft manual and the excerpt can be accepted provided they supply a letter stating what they explained in the response below. **SAR level is incorrect (Pg 28)** [Applicant response] It is incorrect in the "full" version of the manual I sent out, but if you see the excerpt I sent initially it is correct. The "full" version is the first draft, and the excerpt is what has been revised so far with the intention of correcting issues as the SAR level. Would it be possible to accept the excerpt as an amended version of that portion of the "full" version?

6i. According to the SAR test setup photos (photo #4), these two serial ports mentioned do not seem to be populated. These kinds of terminations may affect the SAR levels. Please clarify the reason with the SAR lab.

Please address.

Thank you!

Regards,
Teresa

Teresa White
Quality Manager

LS Research, LLC
W66 N220 Commerce Court
Cedarburg, WI 53012

Direct: 262.421.4991
Fax: 262.364.2649
www.lsr.com

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SAR Probe Calibration.pdf



CARESCAPE T14 Draft excerpt.pdf



CARESCAPE Telemetry T14 Transmitter User's Manual Clarification.pdf



GE Carescape Telemetry T14 SAR Data Plots.pdf



GE Carescape Telemetry T14 SAR Photos.pdf



GE Carescape Telemetry T14 SAR Report.pdf



SAR Dipole Calibration.pdf