Yunus Faziloglu /USA/VERITAS
11/27/2007 09:32 AM

To twhite@lsr.com
cc
bcc
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.

2. External and internal photos are needed.

3. Licensed devices require a parts list exhibit.

4. Does the device have any controls accessible to the user that may violate 95.645(a)? Please clarify.

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 0.005623Watts 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.

6. For SAR report,
i. Are there any possible connections to the device other than the cable seen in SAR setup photos?
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.

Best Regards,

Yunus Faziloglu
Curtis-Straus LLC
Bureau Veritas

"Teresa White "
<twhite@lsr.com>
11/30/2007 02:20 PM

To Yunus Faziloglu/USA/VERITAS@VERITAS
cc
bcc
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

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.

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

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

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.

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 0.005623Watts 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.

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.
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.

Best Regards,

Yunus Faziloglu
Curtis-Straus LLC
Bureau Veritas


GE Carescape Telemetry T14 SAR Report (5).pdf


2001989-301A-d1 (3).pdf


GE CARESCAPE T14 Telemetry Parts List Exhibit.pdf

Yunus Faziloglu /USA/VERITAS
12/03/2007 03:34 PM

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

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 0.005623Watts 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