Federal Communications Commission

Office of Engineering and Technology

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Reply to an OET Inquiry Response

Currently Displaying Inquiry Tracking Number: 516865

Contact Information:

Customer First Name: HABET
Customer Last Name: TER-PETROSYAN
Telephone Number: 6619494048
Extension:
E-mail Address: habet.ter-petrosyan@bsci.com

Address:

Line 1: 25155 Rye Canyon Loop
Line 2:
P.O. Box:
City: Valencia
State: California
Zip Code: 91355
Country: United States

Inquiry Details on 12/20/2022:

First category: RF Exposure *
Second category: General (RF Exposure)
Third category:
Subject: WPT medical device RF Exposure and SAR Compliance Evaluation
Inquiry:

DATE: 19DEC2022

Re: Inquiry for WPT medical device (to be authorized under FCC Part 15) RF Exposure and SAR Compliance Evaluation

Dear Examiner:

This is to request your guidance on compliance evaluation of medical device charger (Charger-3) to FCC RF Exposure and SAR requirements.
The details on Charger-3 are as follows:

· Complete product description, including coil diameters, number of turns and current:

Boston Scientific Stimulator uses a rechargeable battery to provide stimulation, Charger-3 allows to recharge the Stimulator battery as needed. For recharging the Implantable Pulse Generator (IPG) the charger is placed in provided charging belt and placed over stimulator to apply inductively coupled magnetic field. Typically, duration of charging lasts 2.5 to 3 hours if charging from fully depleted IPG battery to fully charged with periodicity of about once a week. The Charger itself is not a source of any type of communication, it is just at receiving end of LSK from IPG (shorting IPG coil at 2 pulses per second) at end of charge. To charge the charger, the provided USB cable is inserted into the wall-plugged AC adapter then the other end of the USB cable is plugged into the charger.

Coil Diameter of the charger: 3.15 inch (80.01mm)

Number of Turns: 27

Coil Current: 2.2A

· Frequency of operation:
79kHz < f < 87kHz

· Power/field-strength:
3.2W maximum conducted power into charger coil (Fast Charge Mode)
54.5dBuA/m at 3m

· Operating configurations:
Battery powered operation at up to 2.5cm charging depth from the stimulator. There are Fast Charge and Normal Modes of operation.

· Conditions for human exposure:
Charger placed in the provided charging belt ensures 5mm separation distance between patients' skin and charger coil.

· Drawings, illustrations:
See Attachment A

· Schematic and assembly drawing of Charger-3, Patient Handbook.
See Attachment_A

Please provide guidance on RF Exposure and SAR compliance evaluation strategy for Charger-3 as a WPT medical device.

Best Regards,

Habet Ter-Petrosyan
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FCC Response on 12/20/2022:

Thank you for yourinquiry. Based on the parameters of yourdevice, especially the relatively low transmit frequency, a combinationapproach of numerical simulation and E and H-field measurements may be used todemonstrate compliance. Please refer tothe "Part 18 and Wireless Power Transfer Updates" presentation from the April2022 TCB Workshop for guidance. Thispresentation can be found online at https://www.fcc.gov/general/equipment-authorization-presentations.

For additionalguidance please refer to the FCC KDB Publications 680106 D01 RF ExposureWireless Charging Apps v03r01 and 865664 D02 RF Exposure Reporting v01r02. These documents can be found online athttps://apps.fcc.gov/oetcf/kdb/reports/GuidedPublicationList.cfm

---Reply from Customer on 01/04/2023---

The following response has been inserted by FCC staff. The inquirer submitted a new KDB Inquiry 177082 in an attempt to respond to this KDB Inquiry 516865. In order to consolidate these inquiries, KDB Inquiry 177082 has been closed and all responses will now take place under this original KDB Inquiry 516865.

This following text was consolidated from KDB Inquiry 177082:

The FCC response to our FCC inquiry (tracking number: 516865) referenced “Part 18 and Wireless Power Transfer Updates” presentation, which has the following relevant statement:

"For all RF devices operating below 100 kHz, the provision in KDB 680106-v03
apply, i.e. field strengths not to exceed 83 V/m and 90 A/m, for E- and H-fields,
respectively"

I would like to inform you that we have already evaluated our WPT medical device for E- and H-fields at 5 mm separation distance (as per the described patient use case in our previous inquiry, tracking number: 516865) and the results show that the 83 V/m and 90 A/m limits are exceeded by 32 V/m and 253 A/m respectively.
Therefore, we would like to get some additional guidance on any other evaluation path forward (e.g. numerical simulation evaluating against internal E-field basic restrictions, etc.) and/or any waiver option that could possibly be available to us.
Additionally, we would like to know if it would be acceptable to FCC if we certify this WPT medical device as per Part 15 instead of Part 18. Please advise.

Thank You.

FCC Response on 01/11/2023:

Unfortunately, with such high fields, you do not meet the limits. There are not many options available besides device redesign or lowering the power. If you seek to file a waiver request, you can submit your request to the Electronic Comment Filing System. This can be found online at https://www.fcc.gov/ecfs/search/search-filings

---Reply from Customer on 02/13/2023---

Hello,

Your response is greatly appreciated. I understand that our WPT device (Charger-3) exceeds the in-air RF field reference levels, however it is also my understanding that the 83V/m and 90A/m limits have some margin built into them as they are based on internal E-field strength basic restrictions. So, we have been able to show through accredited CAD simulations (using human body model) that our WPT (Charger-3) device does not exceed the basic restrictions (internal E-field strength limit) for unintended nerve stimulation and is safe for patients to use. I would really appreciate it if you could review the report we have on that and see whether that would be acceptable for purposes of showing compliance to the unintended nerve-stimulation requirement. Please let me know where to send/upload the report to, because I don't see any file attachment option in this "Reply to Inquiry Response" form.

Thank You.

Best Regards,

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Thank You.

Best Regards,

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---Reply from Customer on 02/14/2023---

Hello,

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FCC Response on 02/24/2023:

Thank you for your response. Unfortunately, there is no provision in our KDB Guidance to allow this for the demonstration of RF Exposure compliance. As stated in FCC KDB Publication 680106 D01 RF Exposure Wireless Charging App v03r01, section 3, a), (2): Evaluation of RF Exposure test data for determining compliance of wireless power transfer (WPT)
systems (both portable and not) operating at frequencies below 100 kHz is provided on a case-by-case basis following a KDB inquiry. In these situations, a WPT device may be considered
acceptable when supporting data from measurements and/or numerical simulations show that, for
all the positions of space relevant for the body exposure, the external (unperturbed) temporal peak field strengths do not exceed the following reference levels:
- 83 V/m for the electric field
and
- 90 A/m for the magnetic field

We hope to address this issue soon in a future TCB Workshop or KDB Publication.

---Reply from Customer on 03/03/2023---

Hello,

It is time sensitive for us (from both business as well as patient benefit perspectives) to be able to release this peripheral medical device (the Charger-3 WPT device) as a product available to our patients in the U.S. Therefore, it is important for us to gain some additional clarity on how to proceed:

1) When should we expect this issue to be addressed in a future TCB workshop or KDB Publication?

2) Before this issue is addressed in a general manner, can we submit a waiver request based on the report we already have (referencing international standards and/or scientific literature on the topic)? In addition, we can also provide historical patient complaints data relating to our existing very similar medical WPT device (FCC ID Q4DSC-5300) showing that historically our patients have not been complaining about unintended nerve-stimulation while charging their IPGs (Implantable Pulse Generators).

3) If needed, we are eager to discuss the details and explain our position in a meeting (either face-to-face or in a conference call) with FCC.

Best Regards,

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---Reply from Customer on 03/15/2023---

Hello,

Would like to know when a response to the questions (submitted on 03MAR2023) should be expected. Please let me know.

Best Regards,

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FCC Response on 03/16/2023:

Thank you for your patience. We were having internal discussions on the matter. Would your team be available for a conference call on Tuesday, March 21, 2023 at 3 pm Eastern Time? Please confirm if this would work for you. If this works for you I will provide you with conference call information.

For the call, please come prepared with a short presentation (maybe just a few slides) providing details and explaining/providing justification for your position. Any supplemental information you have in addition to what has been provided in this KDB Inquiry would be helpful.

---Reply from Customer on 03/16/2023---

Hello,

We would be available for a conference call on Tuesday, March 21, 2023 at 3pm. Please provide us with conference call information.

Thank You.

Best Regards,

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We would be available for a conference call on Tuesday, March 21, 2023 at 3pm Eastern Time. Please provide us with conference call information.

Thank You.

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FCC Response on 03/17/2023:

Excellent. Below is the conference call information:

Microsoft Teams meeting

Join on your computer, mobile app or room device

Click here to join the meeting

Meeting ID: 248 524 430 406
Passcode: efFr4A

Download Teams | Join on the web

Or call in (audio only)

+1360-726-3256,,914231944# United States, Seattle

Phone Conference ID: 914 231 944#

Find a localnumber | Reset PIN

Learn More | Meeting options

---Reply from Customer on 03/22/2023---

Hello,

As discussed in our conference call on 21MAR2023 the PPT slides presented during the meeting (with SAR calculation added) is being uploaded to the FCC portal for your reference.

Best Regards,

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---Reply from Customer on 04/05/2023---

Hello,

I would like to know if there is any update for us as per our discussions in the conference call on 21MAR2023?

Best Regards,

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---Reply from Customer on 04/11/2023---

Hello,

I hope all is well.

Could you please let us know when we can expect further guidance on this matter?

Thanks,

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FCC Response on 04/12/2023:

Dear Inquirer,

we reviewed the issue more in-depth after our conference call. While we do not see a problem in principle with the use of the intrinsic limit, there is currently no procedural path that allows us to leverage those results to provide rule-based compliance easily.

Thus we have to consider this as a special situation where we might find room to support compliance on a case-by-case basis without making any statement that may be construed as precedent.

In order to move in that direction, there are some technical issues that we need to understand better.

The ppt document dated 21 March 2023, slide 12, has an electric field map for the simulated case. We see that EUT is in contact with the simulated tissue surface. We would like to see a simulation with a small gap, e.g., somewhere from 0.5 cm up to. 2.5 cm so we can appreciate how the field changes across the interface.

With this new simulation setup, we may see how well the proper boundary conditions for the parallel and perpendicular components of the E and H vectors are reproduced.

That will also show how rapidly the field strength changes near/on the skin, thus justifying the difference between the field "in the air" and the lower value in the simulated tissue. This, in turn, will provide confidence that the simulation yields a realistic picture. It is also essential to see the behavior of both the E and H vector, as the whole calculation is in the near field.

Finally, we would like to have more information on the level of discretization that was implemented, especially near the separation boundary, to rule out that numerical inaccuracies may affect the results. For instance, as a typical check, one could increase the resolution a couple of times and show that the results are not affected, thus demonstrating (reasonably) that the calculation is converged to a physical solution.

Best regards,

OET Staff

---Reply from Customer on 05/22/2023---

Dear Reviewer,

Attached are two PDF files and a Word file in response to your previous questions. Below is copy of the response from the Word file for your convenience:

"We would like thankOET for their response and provide feedback inline, please see below.

> FCC Response on 04/12/2023:

>Dear Inquirer,

> wereviewed the issue more in-depth after our conference call. While we do not seea problem in
> principle with the use of the intrinsic limit, there is currently noprocedural path that allows us to
> leverage those results to provide rule-based compliance easily.

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> compliance on a case-by-case basis without making any statement that maybe construed as
> precedent.

1. Case-by-caseconsideration

We fully understandthe requirement of case-by-case considerations. On the other hand we try to avoidinquiring OET redundantly for the same type of investigations. Therefore sometime ago IMST aligned with OET (Inquiry Tracking Number: 290781) the generalcourse of action for exposure investigations for low frequency WPT chargers. Wereceived positive feedback regarding our proposed plan back then. We hope thisis still in the sense of OET, and we don't need do hand in a new KDB inquiryfor each investigated WPT charger?

> Inorder to move in that direction, there are some technical issues that we needto understand
> better.

> Theppt document dated 21 March 2023, slide12, has an electric field map for the simulated
> case. We see that EUT is in contact with the simulated tissue surface. Wewould like to see a
> simulation with a small gap, e.g., somewhere from 0.5 cm up to. 2.5 cm sowe can appreciate how
> the field changes across the interface.

2. Phantom to EUTdistance
The influence of the phantom-to-EUT-distance is part of the uncertainty budgetcalculation as per IEC/IEEE 62704-1:2017 (section 7.2.2) and was quantifiedduring our numerical investigation, see report section 3.2.1 Table 5. The particular tolerance simulation showsthat a small shift away from touch position of only 0.25 mm results in adecrease of the internal E-field of about 2%. Stronger decrease of the exposureis to be expected for larger gaps of 0.5 cm or 2.5 cm.
In this context it is worth highlighting that in the sense of a conservativeassessment the maximum expectable coil current (pre-determined by the applicantfor misalignment scenario) was retained continuously throughout the numericalinvestigation, i.e. for touch position assessment. Therefore the investigatedtouch position scenario represents the worst case, see also report section 3.

>With this new simulation setup, we may see how well the proper boundaryconditions for the
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3. Field relations
To our understanding for low frequency inductive WPT application the internalE-field (and also SAR) is dominated by induction, i.e. by eddy currents inducedby the alternating magnetic field. Unlike for classical antenna relatedtraveling wave exposure scenarios at higher frequencies here the internalE-field and SAR is almost unrelated to the primary/external E-field. This topichad been discussed extensively with ISED in the past. A corresponding presentationfrom 2022 including empiric demonstration and a document including analyticalderivation of the previously claimed is attached.

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> of times and show that the results are not affected, thus demonstrating(reasonably) that the
> calculation is converged to a physical solution.

>

>Best regards,
> OET Staff

4. Mesh resolution
Like the phantom-to-EUT-distance (see above) also the impact of the meshresolution is part of the uncertainty budget calculation as per IEC/IEEE62704-1:2017 (section 7.2.3) and was as well quantified during our numericalinvestigation, see report section 3.2.1 Table 6. The number of mesh cells wasmore than doubled in the particular tolerance simulation model, resulting in adeviation of only 0.131 % of the assessed exposure quantity."

Best Regards,

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---Reply from Customer on 06/05/2023---

Hello,

Would like to know when we can expect a response/resolution to this inquiry?

Best Regards,

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---Reply from Customer on 06/14/2023---

Hello,

Is there any update on this inquiry?

Best Regards,

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Boston Scientific

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---Reply from Customer on 06/20/2023---

Hello,

Please feel free to let us know with any questions/comments that there might be regarding our latest responses submitted as part of this inquiry.

Thanks,

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FCC Response on 06/24/2023:

Dear Inquirer,

in regard to your reply of 05/22/2023, the case-by-case option is still available, of course. While the quoted inquiry number 290781 is only partially relevant to issue at hand, our request that was worded as

" The ppt document dated 21 March 2023, slide 12, has an electric field map for the simulated case. We see that EUT is in contact with the simulated tissue surface. We would like to see a simulation with a small gap, e.g., somewhere from 0.5 cm up to. 2.5 cm so we can appreciate how the field changes across the interface.

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does not appear to have been answered in the bullet 2. of your reply, that just mentions previous results and the sensitivity of the simulation. Without clearly addressing that issue we are not able to move forward.

The point at hand is to assess with confidence that a drop in the field strength between the air gap and the region of simulated tissue is indeed occurring due to the change of the dielectric and conductivity parameters. This is critical for demonstrating that the patient will not be exposed to higher-than-allowed fields, from the skin surface to the tissue underneath.

Furthermore, showing that the behavior of the E and H vector on the boundary of the transition between the two media is consistent with the physics predictions will serve as convincing demonstration of the reliability of the simulation model.

We agree that the mesh resolution, as discussed in your bullet 4, seems adequate for the results presented, however, that does not imply that the same resolution will still be adequate for the simulation with the small air gap that we suggested. This is because the field gradient may become quite sharp, and for that reason the resolution, at least locally, may require improvement.

Best regards,

OET Staff

---Reply from Customer on 07/14/2023---

Dear Reviewer,

Attached are two PDF files in response to your previous requests. For your convenience the summary of the responses is copied below:

"Response from IMST 13. July 2023

Wewould like thank OET for their response and provide feedback, please see below.

> FCCresponse on 06/24/2023
>
> Dear Inquirer,
>
> in regard to your reply of 05/22/2023, thecase-by-case option is still available, of course.

1. Case-by-case consideration

Wewould like to clarify that we were not at all trying to question the procedureof case-by-case considerationfor this DUT or in general and are sorry if this false impression was given.

> While the quoted inquiry number 290781 isonly partially relevant to issue at hand, our request
> that was worded as
>
> "The ppt document dated 21 March 2023,slide 12, has an electric field map for the simulated
> case. We see that EUT is in contact withthe simulated tissue surface. We would like to see a
> simulation with a small gap, e.g.,somewhere from 0.5 cm up to. 2.5 cm so we can appreciate
> how the field changes across the interface.
> With this new simulation setup, we may seehow well the proper boundary conditions for the
> parallel and perpendicular components ofthe E and H vectors are reproduced.
> That will also show how rapidly the fieldstrength changes near/on the skin, thus justifying
> the difference between the field "in theair" and the lower value in the simulated tissue.
> This, in turn, will provide confidence thatthe simulation yields a realistic picture. It is
> also essential to see the behavior of boththe E and H vector, as the whole calculation is
> in the near field."
>
> does not appear to have been answered inthe bullet 2. of your reply, that just mentions
> previous results and the sensitivity of thesimulation.
> Without clearly addressing that issue weare not able to move forward.

2. Gap simulations

Withour last reply we actually did provide new simulation results. We carried outthe requested gap-simulationsfor 0.5 cm and 2.5 cm and updated the report accordingly (see "Report_Charger-3_V1.3.pdf",section 3.4). To conclude the results: The larger the gap, the lower theexposure.

> The point at hand is to assess withconfidence that a drop in the field strength between
> the air gap and the region of simulatedtissue is indeed occurring due to the change of
> the dielectric and conductivity parameters.This is critical for demonstrating that the
> patient will not be exposed tohigher-than-allowed fields, from the skin surface to the
> tissue underneath.
>
> Furthermore, showing that the behavior ofthe E and H vector on the boundary of the transition
> between the two media is consistent withthe physics predictions will serve as convincing

> demonstration of the reliability of thesimulation model.

3. Boundary behavior of E- and H-field

Withour last reply we provided rationale that for low-frequency WPT applicationsthe external/incident/primaryE-field is practically unrelated to the exposure (internal E-field, SAR). To ourunderstanding this implies that also the transition between external and internalE-field at the interfaceis not relevant as well. However, please find below a plot of a y-z-plane forthe simulated externaland internal E-field for the phantom being in touch with the DUT:

Fig. 1: Simulated external and internal E-fieldfor the phantom being in touch with the DUT. It isvery important to note that the external E-field distribution shown here only represents onepossible physically correct distribution. Because the external E-Fieldpractically doesn't affect the exposure it was not validated and is hence mostlikely not the actual external (!) E-Field distribution for the DUT.

Interpretationof Fig1: Because the phantom is conductive, the incident/external E-fieldinduces an influencesurface charge distribution at its surface which shields the inside of thephantom (Principleof Faraday cage). This greatly reduces the contribution of the external E-fieldto the internalE-field, and results in a discontinuity of the absolute value of the E-field atthe interface. If thealternating H-field wasn't there, the E-field inside the phantom would benearly zero and the externalE-field would stay nearly orthogonal on the phantoms surface. But because thealternating H-fieldis present, eddy currents and corresponding internal E-fields are generatedinside the conductivephantom. The direction of the internal E-field inside the tissue phantom is aresult of the inducededdy currents from the H-field, which can be clearly seen as a circulatingcurrent in the tissuephantom.

Pleasealso find below a plot of a y-z-plane for the external and internal E-field incase there is a 5mm gap between the phantom and the DUT:

Fig. 2: Simulated external and internal E-fieldin case there is a 5 mm gap between the phantom and the DUT

Interpretationof Fig2: With the increased distance between phantom and DUT the maximum internalE-field clearly decreased. Beside that, the field situation is pricipally thesame as for the situationwhere the phantom is in contact with the DUT, see above.

Tissue medium

Air medium

Tissue medium

Air medium

Pleasealso find below a plot of a y-z-plane for the external and internal H-field thephantom being intouch with the DUT:

Fig. 3: Simulated external and internal H-fieldfor the phantom being in touch with the DUT. The dashed line indicates theinterface between phantom and air.

Interpretationof Fig3: The retroactive effect of the eddy currents (Lenz's law) is quitesmall and the H-field distribution is very similar to the unperturbed casewithout phantom shown in the report in section 2.2.1.

> We agree that the mesh resolution, asdiscussed in your bullet 4, seems adequate for the
> results presented, however, that does notimply that the same resolution will still be
> adequate for the simulation with the smallair gap that we suggested. This is because the

> field gradient may become quite sharp, andfor that reason the resolution, at least locally,

> may require improvement.

4. Mesh resolution

Thankyou for the remark. We revised the previously done gap-simulations (see "Report_Charger-3_V1.3.pdf",section 3.4) whereby we locally refined the mesh at the locations of maximum exposure(phantom bottom side) to match the resolution of the reported model. Thisresulted in a moderateincrease of the maximum internal E-fields from 5.84910 V/m to 6.05818 V/m (0.5cm gap)and V/m 2.20617 to 2.30306 V/m (2.5 cm gap) respectively. However, theconclusion of the investigationof the influence of a small gap between DUT and phantom remains the same: The largerthe gap, the lower the exposure. Please find provided along with this responsethe updated reportincluding the refined gap-simulation results ("Report_Charger-3_V1.4.pdf").

Tissue medium

Air medium

5. Specific absorption rate (SAR)

Pleasefind below a picture of the 1g-averaged SAR for the DUT (Fig4). The maximum1g-SAR valueof 0.0288 W/kg is only about 1.8 % of the 1.6 W/kg BR limit stated in the 47CFR.

Fig. 4: 1g-averaged SAR forthe phantom being in touch with the DUT

> Best regards,

> OET Staff

Bestregards

David (david.schaefer@imst.de)"

---Reply from Customer on 08/01/2023---

Dear Reviewer,

Is there any update on this inquiry?

Thank You.

Best Regards,

Habet Ter-Petrosyan
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---Reply from Customer on 08/15/2023---

Dear Reviewer,

Please let us know when we can expect a resolution to this inquiry.

Thank You.

Best Regards,

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FCC Response on 08/22/2023:

Dear Inquirer,

thank you for your patience, and please rest assured that we are not over-analyzing your application: the fact of the matter is that the issue you are presenting goes well beyond the scope of this inquiry, as it may impact how similar cases will be considered industry-wide from a compliance perspective.

This is probably the first time where we have to consider a scenario for which, despite that test data show noncompliance to the MPE limit, the (simulated) data of the field inside the tissue would show a field strength that is within our limits.

It looks like the critical point that still needs to be clarified is related to the field behavior within the small "air" gap (either 25 or 5 mm), as in the Figure 2, page 2 of 4, of the document "Response from IMST 13. July 2023".

The point of looking at the simulation with a gap was not the to study the sensitivity of the data, but was to see if one could reproduce the noncompliant field near, but outside, the surface of the tissue, and then show the transition to a lower field inside.

This was asked in our earlier reply (06/24/2023) where we wrote:
"…to assess with confidence that a drop in the field strength between the air gap and the region of simulated tissue is indeed occurring due to the change of the dielectric and conductivity parameters. This is critical for demonstrating that the patient will not be exposed to higher-than-allowed fields, from the skin surface to the tissue underneath.
Furthermore, showing that the behavior of the E and H vector on the boundary of the transition between the two media is consistent with the physics predictions will serve as convincing demonstration of the reliability of the simulation model."

Also, the mentioned Figure 2 shows the electric field, but the noncompliance for the test data was for the magnetic field. So we would need a plot that show H as well.

We would expect to see a H field that is above the compliance threshold in the air gap (in accordance to the test data), but then observe some transition to a lesser field inside the tissue. This transition is also not expected to be abrupt, but resolved sufficiently well by using the proper mesh resolution.

Furthermore, the simulation should show the proper continuity of the tangential and perpendicular components of field vectors, or any current flow if a discontinuity occurs know within a small layer.

Without this type of analysis we are in a very difficult position, since we are not able to leverage a more accurate RF exposure evaluation to replace the incident field test data that point to a noncompliance.

Best regards,

OET Staff

---Reply from Customer on 08/23/2023---

Dear Reviewer,

At your earliest convenience, we would like to have a conference call to discuss in detail the attached PDF file in response to your feedback. Please provide conference call date/time option(s) that would work best for you.
For your convenience the summary of our response is copied below:

"Response from IMST 23. August 2023

We would like thank OET for their response and provide feedback, please see below.

> "FCC response on 08/22/2023

> Dear Inquirer,

> thank you for your patience, and please rest assured that we are not over-analyzing your
> application: the fact of the matter is that the issue you are presenting goes well beyond the scope
> of this inquiry, as it may impact how similar cases will be considered industry-wide from a
> compliance perspective.

> This is probably the first time where we have to consider a scenario for which, despite that test
> data show noncompliance to the MPE limit, the (simulated) data of the field inside the tissue
> would show a field strength that is within our limits.

> It looks like the critical point that still needs to be clarified is related to the field behavior within
> the small "air" gap (either 25 or 5 mm), as in the Figure 2, page 2 of 4, of the document
> "Response from IMST 13. July 2023".

> The point of looking at the simulation with a gap was not the to study the sensitivity of the data,
> but was to see if one could reproduce the noncompliant field near, but outside, the surface of the
> tissue, and then show the transition to a lower field inside.

1. Purpose of the requested gap simulations
Okay, so we think we got the point now, if by "noncompliant field near, but outside, the surface of the tissue" you refer to the measurements of the incident fields that BSCE did prior to our numerical investigation.

> This was asked in our earlier reply (06/24/2023) where we wrote:
> "…to assess with confidence that a drop in the field strength between the air gap and the region
> of simulated tissue is indeed occurring due to the change of the dielectric and conductivity
> parameters. This is critical for demonstrating that the patient will not be exposed to higher-than-
> allowed fields, from the skin surface to the tissue underneath.
> Furthermore, showing that the behavior of the E and H vector on the boundary of the transition
> between the two media is consistent with the physics predictions will serve as convincing
> demonstration of the reliability of the simulation model."
> Also, the mentioned Figure 2 shows the electric field, but the noncompliance for the test data was
> for the magnetic field. So, we would need a plot that show H as well.

2. External/internal H-field distribution for gap simulation
Please find below two plots of the y-z-planes for the external and internal H-field, one with the phantom being in touch with the DUT and one with a 5 mm gap between the phantom and the DUT:

Fig. 1: Simulated external and internal H-field for the phantom being in touch with the DUT. The dashed line indicates the interface between phantom
and air. (this is identical to Fig. 3 shown in "Response from IMST 13. July 2023")

Fig. 2: Simulated external and internal H-field with a 5 mm gap between the phantom and the DUT. The dashed line indicates the interface between phantom and air.

Interpretation of Fig1 and Fig2: In both cases – with and without the gap - the retroactive effect of the eddy currents (Lenz's law) is quite small and the H-field distribution is very similar to the unperturbed case without phantom (incident H-field) shown in the report in section 2.2.1. A transition of the H-field to a (notably) lesser H-field inside the tissue is not to be expected, due to the low conductivity of the tissue equivalent medium.

> We would expect to see a H field that is above the compliance threshold in the air gap (in
> accordance to the test data), but then observe some transition to a lesser field inside the tissue.
> This transition is also not expected to be abrupt, but resolved sufficiently well by using the proper
> mesh resolution.

3. MPE limits vs. SAR exposure limits
To our understanding the MPE check (reference level check) of E- and H-field provides an conservative way of demonstrating compliance as an alternative to the more complex demonstration of compliance against the SAR exposure limits (basic restrictions, BR). In CFR 47 § 1.1310 (d)(2) it is stated:
"[...] the limits for maximum permissible exposure (MPE), derived from whole-body SAR limits and listed in Table 1 in paragraph (e)(1) of this section, may be used instead of whole-body SAR limits [...]".
In the introduction of IEEE C95.1-2005 it is stated:
"The safety factors incorporated in the MPEs are generally greater than the safety factors in the BRs. Thus, it is possible to exceed an MPE while still complying with the BRs."
This implies that for a DUT that has failed the MPE check, compliance can still be demonstrated by evaluation of the SAR (BR). In the particular context of our EIAV/SAR exposure assessment this means that to our understanding it is neigther expected nor necessary that the simulated H-fields inside the phantom stay below the MPE limits, because we directly assess the exposure by EIAV/SAR and not by the derived quantity of MPE.

Please note that it is common for small WPT devices that the concept of MPE (reference levels) heavily over-estimates the SAR (basic restrictions) due to the strong gradients of the incident fields. For this reason the upcoming IEC/IEEE 63184 standard "Basic standard for the assessment of the human exposure to electric and magnetic fields from wireless power transfer systems – models, instrumentation, numerical methods and procedures - Frequency range of 1 kHz to 10 MHz" will include a dedicated section 5.2.4 named "Evaluation of incident magnetic fields using coupling factor" for effectively lowering the reference levels for WPT incident fields e.g. depending on their gradients.

> Furthermore, the simulation should show the proper continuity of the tangential and
> perpendicular components of field vectors, or any current flow if a discontinuity occurs know

> within a small layer.

4. Boundary behavior of E- and H-field
To our understanding the H-field plots shown above as well as the E-field plots from our last response show the expectable boundary behavior with respect to the tangential and perpendicular components of field vectors.

> Without this type of analysis, we are in a very difficult position, since we are not able to leverage a
> more accurate RF exposure evaluation to replace the incident field test data that point to a
> noncompliance.

> Best regards,
> OET Staff”

Best regards
David (david.schaefer@imst.de)"

FCC Response on 08/29/2023:

Dear Inquirer,

thank you for providing the additional data. Before we consider a teleconference discussion, we would like to make sure that we have all the important elements lined-up.

Earlier in the inquiry you stated that:
"I would like to inform you that we have already evaluated our WPT medical device for E- and H-fields at 5 mm separation distance (as per the described patient use case in our previous inquiry, tracking number: 516865) and the results show that the 83 V/m and 90 A/m limits are exceeded by 32 V/m and 253 A/m respectively."

Now, the simulation data are supporting compliant values inside and near the patient tissue. As you stated, the reason is that the "retroactive" impact of the induced currents in the tissue are leading to a lower field that we see in the simulation, in accordance to Lenz's law.

This behavior would certainly be capture by a self consistent simulation, like the one you presented.

Thus, to verify the model accuracy, we shall expect that if you change the characteristic parameters of the simulated tissue volume to those of air/vacuum, and leave everything else the same, you would be able to reproduce field values at least somewhat close to the non-compliant levels shown before, from test measurements.

Do you have the data for this basic check? We stress that it is important to leave all the simulation parameter the same, just change the dielectric constant and conductivity (assuming that the magnetic permeability is still the same).

Best regards,

OET Staff

---Reply from Customer on 09/06/2023---

Dear Reviewer,

For your convenience the summary of our response is copied below:

"Response from IMST 06.September 2023

We would like to thank OETfor their response and provide feedback, please see below.

> “FCC response on 08/29/2023

> Dear Inquirer,

> thank you forproviding the additional data. Before we consider a teleconference discussion,we would like to make sure that we have all the important elements lined-up.

> Earlier in theinquiry you stated that:

> "I wouldlike to inform you that we have already evaluated our WPT medical device for E-

> and H-fields at5 mm separation distance (as per the described patient use case in our >previousinquiry, tracking number: 516865) and the results show that the 83 V/m and 90A/m >limits are exceeded by 32 V/m and 253 A/m respectively."

1. MPE estimates vs.validation measurements vs. simulated values

The measurements referencedabove were MPE estimates obtained by BSCI prior to our numerical investigation,using a Narda EHP-200AC field probe. Because this field probe is large comparedto the DUT (see Fig.1 left side below) and because the E-/H-near-field of theDUT is inhomogeneous, those measurements underlie inaccuracies due to spatialaveraging. For this reason, the measurements used in our investigation toquantify the model related uncertainty of the simulation model (see reportsection 2.2.1 and 3.2.2) and for executing the model validation (see reportsection 3.2.3) were done with a much smaller Speag MAGPy-H3D field probe (seeFig.1 right side below, and report section 1.4). As demonstrated in the reportsection 2.2.1, the simulated H-fields are in good agreement with the validationmeasurements obtained with the small MAGPy-H3D probe.

Fig. 1: Geometry ofthe Narda EHP-200AC field probe(left, used for MPE estimates) in relation to the geometry of the DUT and thegeometry of the Speag DAISY8 – MAGPy-H3D field probe (right, used forvalidation measurements).

> Now, thesimulation data are supporting compliant values inside and near the patienttissue. > >As you stated, the reason is that the "retroactive"impact of the induced currents in the tissue >are leading to a lower fieldthat we see in the simulation, in accordance with Lenz's law.

2. Retroactive effect

In both our responses from13. July 2023 and 23. August 2023 we stated the opposite: We claimed that theretroactive effect of the eddy currents (Lenz's law) is quite small andthat the H-field distribution is very similar to the unperturbed casewithout phantom shown in the report in section 2.2.1. To our understandingthe retroactive effect is not the reason for the observed deviation ofthe MPE estimates from the validation measurements and from the simulations. Instead,the deviation is most likely caused by the large dimensions of the NardaEHP-200AC field probe used to obtain the MPE estimates, as explained in section1 above.

> Thus, to verifythe model accuracy, we shall expect that if you change the characteristic

> parameters ofthe simulated tissue volume to those of air/vacuum, and leave everything else >thesame, you would be able to reproduce field values at least somewhat close tothe
>non-compliant levels shown before, from test measurements.

> Do you have thedata for this basic check? We stress that it is important to leave all the

> simulationparameter the same, just change the dielectric constant and conductivity >(assumingthat the magnetic permeability is still the same).

3. E-/H-fielddistribution without phantom

Please find below two plotsof y-z-planes for the E- and H-field without phantom. As requested, the phantomremoval was realized by changing the material properties of the phantom to “air”while everything else was left the same as for the “reported model” presentedin the simulation report.

Fig. 2: Simulated externalE-field for the simulation with the phantom material property set to “air”,whereby all other simulation parameters were kept the same as for the reportedmodel (see report). The phantom geometry is not visualized. It is veryimportant to note that the external E-field distribution shown here onlyrepresents one possible physically correct distribution. Because the externalE-Field practically doesn’t affect the exposure it was not validated and ishence most likely not the actual external (!) E-Field distribution for the DUT.

Interpretation of Fig2:

With the phantoms tissuematerial property changed to air, the external E-field extends to the +z-regionof the simulation domain and is not shielded by the phantom as it can e.g., beobserved in case of the gap-simulations presented in ourresponse from 13. July 2023.

Again, it is very important to note thatthe external E-field distribution shown here only represents one possiblephysically correct distribution. Because the external E-Field practically doesn’taffect the exposure it was not validated and is hence most likely not theactual external (!) E-Field distribution for the DUT.

Fig. 3: Simulated externalH-field for the simulation with the phantom material property set to “air”,whereby all other simulation parameters were kept the same as for the reportedmodel (see report). The phantom geometry is not visualized.

Interpretation of Fig3:

The H-field distribution withthe phantom material property set to “air” is very similar compared to thesimulation results including the phantoms with the material set to tissueequivalent (e.g., compared to Fig.3 from our response from 13. July 2023). Thisdemonstrates again that the retroactive effect of the eddy currents (Lenz'slaw) within the tissue equivalent is quite small.

> Best regards,

> OET Staff

Best regards

David (david.schaefer@imst.de)"

Best Regards,

Habet Ter-Petrosyan
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FCC Response on 09/13/2023:

Dear Inquirer,

OK, we are trying to get a closure on this: we will try to answer you inquiry within a day of your reply, hopefully we’ll get there.

So, we are now learning that you repeated the measurements with a smaller/better probe, the MAGPy. This was not brought up in the discussion of this inquiry until now: we started from your assertion that the test data were showing noncompliance and therefore you provided simulation data for the actual field in the tissue. We then were focused on establishing the reliability of those data.

In your attachment “20230906_FCC_29AUG2023_Feedback_resp-IMST - Sep 6 2023, confidential exhibit” as well as inline in the reply you state

“As demonstrated in the report section 2.2.1, the simulated H-fields are in good agreement with the validation measurements obtained with the small MAGPy-H3D probe.”,

however there is no section 2.2.1, it must be on a different, previously uploaded file. Now there are so many files and it is difficult to keep track of what matters. If you had mentioned in your inquiry that you had got compliant data from MAGPy we would have probably been done for a while.

Please provide the MAGPy test data for the fields from the MAGPy at the various distances from the coil, as required in our guidance.

The field data shall be extrapolated/simulated to 0 cm for the points in which the center of the probe cannot be positioned (due to its finite size). Use at least two points where the probe can collect actual data in the probe center to validated your model/extrapolation, showing up to 30% error.

This is the standard process that we discussed in the April 2022 TCBC Workshop
https://transition.fcc.gov/oet/ea/presentations/files/apr22/41-Part-18-&-Wireless-Power-Transfer.pdf

Best regards,

OET Staff

---Reply from Customer on 09/29/2023---

Responsefrom BSN 29SEP2023

We wouldlike to thank the OET for their response and provide additional clarification,please see below.

DearReviewer,

Thank youfor your further review of our inquiry. We would like to summarize our understatingand approach in evaluating for compliance to basic restrictions as follows:

- · Between 3 kHz and 100 kHz, the universalMaximum Permissible Exposure (MPE) limits of 83 V/m and 90 A/m (fixed for thisfrequency range) are a conservative and more simplistic way of demonstratingcompliance as an alternative to the more complex demonstration of complianceagainst basic restrictions (due to internal Electric field [EIAV]), such asunintended nerve stimulation due to EIAV and/or SAR.

o Thismeans that it is possible to exceed the in-air MPE limits, while still complyingto basic restriction limits.

- · It has never been our intention toclaim that at 80 kHz the external H-field is significantly reduced in tissue. Conversely,we have shown in the report that in the absence of the implant, the H-field is virtuallyunaffected by the presence of the tissue.
- · While the external H-field is notreduced inside the tissue, the external E-field is effectively shielded by the electricallyconductive human skin layer from penetrating into human tissue, and we have presentedample evidence for both claims in the report and in previous responses.
- · It is the internal E-field (as inducedby the H-field) that primarily contributes to unintended nerve stimulationand/or SAR, not directly the H-field value itself.

o Thisis exactly what we presented to the FCC during our first teleconference on21MAR2023 (with Jake Novicky [Jake.Novicky@fcc.gov]) and the FCC Team). Thepresentation slides from that meeting can be found attached to thiscorrespondence.

§ The feedback that we received fromthat meeting was quite positive, where the OET Staff recognized the possibilityof showing compliance (8.564 V/m at 81 kHz) to the basic restriction EIAV limit(10.935 V/m at 81 kHz) via numerical evaluation.

§ As per the FCC request, we also providedcalculated peak SAR value of 0.055 W/kg, which is significantly lower than spatiallyaveraged 1.6 W/kg limit.

For yourreference, the most up-to-date report on the numerical RF exposure evaluation ofour WPT device can be found attached. In addition, we would like to draw yourattention to the fact that for purposes of showing compliance to basicrestrictions the possibility of using internal electric field limits isacknowledged in ET Docket No. 19-226 and Sections 1.1310(a), 1.1310(f) inFCC 19-126, Section 5.2.4 of IEC 63184:2021, aswell as IEC 62311:2019.

We wouldlike to have another teleconference with the FCC, so that we can moreinteractively communicate our approach in demonstrating compliance to the RFExposure requirements.

Best Regards,

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FCC Response on 10/01/2023:

Dear Inquirer,

your reply does not address any of the points we asked in our correspondence of 09/13/2023, resulting from your previous reply where you mentioned the MAGPy results, and based on which we were hoping to get to a conclusion of this long back and forth.

Instead, you proceeded to discuss other items related to the simulation, etc., that were no longer a concern. That seems to be a step back, apparently confusing the issues.

Please address the items in our reply of September 13, 2023.

Best regards,

OET Staff

---Reply from Customer on 10/04/2023---

Responsefrom BSN 04OCT2023

We wouldlike to thank the OET for their response and provide further clarification,please see below.

DearReviewer,

Thank youfor your further review of our inquiry. As an additional step to aid thisreview process we would like to point out the following:

· The in-air H-field measurementresults with the MAGPy-H3D probe are shown in Section 2.2 of the latest reportthat we had submitted and referenced previously in this inquiry. The plot of themeasurement data is shown in Figure 7 of the report, where the H-field exceedsthe 90 A/m in-air reference level even at 7 mm separation distance from thehousing of the DUT. Therefore, that data can not be directly used to provecompliance as per the in-air 90 A/m reference level [from Section 3) a) (2) ofKDB 680106 D01 RF Exposure Wireless Charging App v03r01]. The entire purpose of this inquiryis to get pre-approval from the FCC for an alternate method of showing complianceto the RF Exposure requirements, otherwise there would have been no need to startthis inquiry if our in-air measurement data were to directly support complianceto the in-air reference levels.

§ As described in the report, the in-airH-field measurement data was used for model validation in the subsequentnumerical evaluation that we performed to show compliance to the relevant internationallyrecognized basic restriction limit (instantaneous internal E-field inducedinside human tissue by the incident H-field from the DUT).

· If contrary to the initial feedback rightafter our teleconference on 21MAR2023, the FCC (OET Staff) now insists oncomplying to the 83 V/m E-field and 90 A/m H-field in-air reference levelsas the only option, then could you please kindly describe what these in-airreference levels are based on? And, how the in-air reference levels arederived?

Recognizing the importance of having a contextual discussion on the topic, wewould still like to hold another teleconference meeting with the FCC (OETStaff), so that we can more interactively communicate our fact-based approachin demonstrating compliance to the RF Exposure requirements.

Best Regards,

Habet Ter-Petrosyan
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---Reply from Customer on 10/04/2023---

Responsefrom BSN 04OCT2023

We wouldlike to thank the OET for their response and provide further clarification,please see below.

DearReviewer,

Thank youfor your further review of our inquiry. As an additional step to aid thisreview process we would like to point out the following:

1. The in-air H-field measurementresults with the MAGPy-H3D probe are shown in Section 2.2 of the latest reportthat we had submitted and referenced previously in this inquiry. The plot of themeasurement data is shown in Figure 7 of the report, where the H-field exceedsthe 90 A/m in-air reference level even at 7 mm separation distance from thehousing of the DUT. Therefore, that data can not be directly used to provecompliance as per the in-air 90 A/m reference level [from Section 3) a) (2) ofKDB 680106 D01 RF Exposure Wireless Charging App v03r01]. The entire purpose of this inquiryis to get pre-approval from the FCC for an alternate method of showing complianceto the RF Exposure requirements, otherwise there would have been no need to startthis inquiry if our in-air measurement data were to directly support complianceto the in-air reference levels.

§ As described in the report, the in-airH-field measurement data was used for model validation in the subsequentnumerical evaluation that we performed to show compliance to the relevant internationallyrecognized basic restriction limit (instantaneous internal E-field inducedinside human tissue by the incident H-field from the DUT).

2. If contrary to the initial feedback rightafter our teleconference on 21MAR2023, the FCC (OET Staff) now insists oncomplying to the 83 V/m E-field and 90 A/m H-field in-air reference levelsas the only option, then could

you please kindly describe what these in-airreference levels are based on? And, how the in-air reference levels arederived?

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FCC Response on 10/06/2023:

Dear Inquirer,

thanks for your patience, we understand that this process may appear frustrating from your perspective, at least now looks like we are moving forward in the understanding, despite the detour caused by the discussion on the MAGPy.

So we are taking more direct approach, re-stating the main points to avoid further confusion.

The original point of discussion was related to the request of using the FCC basic restriction RF exposure limits for equipment authorization, while the reference limits are not met.

We maintain, as also previously discussed in our teleconference that we would accept that approach, so long as a convincing demonstration of the results obtained (arguably, via numerical simulation) is provided.

That point has not changed at all, your statement in the Oct 4 reply reflects a misunderstanding, we are not insisting in showing compliance to the limits "in air". Those limits where brought back into the discussion only because in your response of 09/06/2023 you referred to the MAGPy probe showing "the simulated H-fields are in good agreement with the validation measurements obtained with the small MAGPy-H3D probe", seemingly to address our question about exceeding of the limits.

Moving forward, let's suppose we have a simulation showing data consistent to the basic restrictions. We need to validate the simulation, and this can be done as follows

1. Comparing the simulation with measured fields in air (electric and magnetic), as a first basic validation (we assume that this is mostly done)
2. The data in 1. are then expected to show (approximately) the measured data that are not compliant to the FCC equipment authorization limits (otherwise we would be done already, of course!)
3. Perform a simulation in presence of a dielectric layer modeling the tissue, making sure that coil parameters and any other simulation data are unchanged.
4. Provide a discussion clearly illustrating how the data in 3. show that the basic restriction limits (specifying what they are, proper averaging, etc.) are met.
5. As a validation of the simulation in the tissue, examine the electric field in the simulated tissue region as compared to the same location from the simulation in air, i.e. without the tissue, and discuss

5.1 what is the impact of the characteristics of the simulated tissue material on the computed field (e.g. the impact resulting from changing the values from those of air)

5.2 the change in the components of the field vectors on the air-dielectric interface to illustrate that the discretization of the numerical model still captures the proper physics

Following this procedure with the set of steps just outlined, pending a positive review of the results, we would be able to accept the simulation as a demonstration that the basic restrictions are met.

Please provide items of this list in a new file, we recommend to use a short descriptive title with the year-month-day date a s first characters (e.g. 20231005-myfile-rev2), so it will stick out in the (long) list of attachments to this KDB. This file should have all the content required, no referencing to previously uploaded files.

Best regards,

OET Staff

---Reply from Customer on 11/09/2023---

BSN response on 09NOV2023

Dear Reviewer,

Here are the responses to address the specific items requested from us as per the last feedback we received from you on 06OCT2023 (attached is the PDF file "20231109_SUMMARY_OF_THE_RESPONSES_.pdf" containing the illustrations):

Moving forward, let’s suppose we have a simulation showing data consistent to the basic restrictions. We need to validate the simulation, and this can be done as follows

1. Comparing the simulation with measured fields in air (electric and magnetic), as a first basic validation (we assume that this is mostly done)

For low-frequency (less than 1MHz) WPT applications the external/incident/primary E-field is practically unrelated to the exposure (internal E-field, SAR) as stated in Section 3.2 of 680106 D01 Wireless Power Transfer v04. Therefore, to reduce amount of testing there has been no E-field measurement made to compare to simulated E-field.

Measured

Empire (as modeled in simulation software)

Deviation

Coil Inductance

94.50 µH

100.89 µH

6.76 %

Simulated H-field deviation is maximum 5.46% compared to measured H-field as shown in this plot:

It can be concluded, that simulated magnetic field strength and inductance are in good agreement with the measurements, indicating the accurate setup of the numerical simulation model.

2. The data in 1. are then expected to show (approximately) the measured data that are not compliant to the FCC equipment authorization limits (otherwise we would be done already, of course!)

As can be seen from the plot of the measured H-field is more than 500 A/m, which is well over the 90 A/m reference level specified in 680106 D01 Wireless Power Transfer v04.

3. Perform a simulation in presence of a dielectric layer modeling the tissue, making sure that coil parameters and any other simulation data are unchanged.

Figure 9: Cutplane through the maximum of the simulated EIAV inside the flat phantom (relative permittivity of 55 and conductivity of 0.75 S/m). The phantom geometry is not visible.

Position of Maximum

Quantity

Maximum Value

x

y

z

EIAVunaveraged,max

8.56433 V/m

24.8313 mm

−26.7677 mm

5.875 mm

4. Provide a discussion clearly illustrating how the data in 3. show that the basic restriction limits (specifying what they are, proper averaging, etc.) are met.

The basic restriction of peak EIAV at 81 kHz in uncontrolled environment is 10.935 V/m (1.35 · 10−4 · ? [in Hz] V/m), so the simulated maximum value of 8.564 V/m is 21.682 % below the limit. This is acceptable given that Combined Std. Uncertainty (k = 1) is 13.161 % and Expanded Std. Uncertainty (k=2) is 26.321 %.

5. As a validation of the simulation in the tissue, examine the electric field in the simulated tissue region as compared to the same location from the simulation in air, i.e. without the tissue, and discuss

All air medium

2.21867 kV/m

Tissue medium in contact (above) the Charger-3 housing.

0.00854 kV/m

5.1 what is the impact of the characteristics of the simulated tissue material on the computed field (e.g. the impact resulting from changing the values from those of air)

Compared to in-Air medium the incident/external E-field is reduced by factor of 260 in tissue medium at the same location because the phantom is conductive, the incident/external E-field induces an influence surface charge distribution at its surface which shields the inside of the phantom (principal of Faraday cage). This greatly reduces the contribution of the external E-field to the internal E-field, and results in a discontinuity of the absolute value of the E-field at the interface.

5.2 the change in the components of the field vectors on the air-dielectric interface to illustrate that the discretization of the numerical model still captures the proper physics

If the alternating H-field wasn’t there, the external E-field would stay nearly orthogonal on the phantoms surface. But because the alternating H-field is present, eddy currents and corresponding internal E-fields are generated inside the conductive phantom. The direction of the internal E-field inside the tissue phantom is a result of the induced eddy currents from the H-field, which can be clearly seen as a circulating current in the tissue phantom.

---Reply from Customer on 11/28/2023---

Dear Reviewer,

We would like to know if you have had a chance to review our response to the latest feedback from the OET Staff?

Please let us know if you have any further questions on this inquiry, or what the next steps are expected to be.

Best Regards,

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FCC Response on 11/29/2023:

Dear Inquirer,

according to the Table 2 in the ICNIRP 2010 document, the basic restriction electric field limit for 81 kHz is 1.35e-4 f = 1.35e-4 * 81e3 = 10.935 V/m. Thus, the reported field of ~8 V/m appears compliant. The issue is to verify the accuracy of the simulation.

The plot in "516865 - nov 9, 2023 attachment" on page 4 reports a change of the electric field by a factor of 260 within a very small distance across the interface. Perhaps, the picture is not clear enough to show the behavior of the electric field vector very close to the interface: the proper boundary conditions for the electromagnetic vectors across the interface need to be consistent with the change of the dielectric constant by a factor of 55.

As indicated in previous correspondence, one should first verify that the normal components of B and the tangential components of E are continuous (as they always are for the electromagnetic field across an interface). In this case, since the magnetic permeability in air and in the TSL is about the same, it can simply be considered B=mu0 * H.

Verifying this continuity would provide reassurance that the proper field behavior very close to the interface is maintained. Based on that picture, we cannot tell what the resolution is near the interface, and that may affect the accuracy of the calculation for the local field values, even if the general behavior at a larger distance were being captured properly.

Similar checks on boundary conditions shall be done for the normal components. In this case, for the components normal to the interface (e.g., Griffiths, 1999, 3rd ed., eq. 4.26):
D2n – D1n = sfree , where sfree is the surface charge density due to any free charges in the conductor, and D1n and D2n are the normal component of the electric displacement vector.

In the simulation, unless explicitly done, no free charges will be introduced in the TSL conducting layer. Accordingly, the calculation corresponds to a case where the only surface charge is due to the bound charges that are accounted for by the dielectric constant of the TSL. One can then write
D2n – D1n = 0 = eps2 E2n – eps1 E1n => E2n = (eps1 / eps2) E1n ~ E1n / 55 ,
where E1n and E2n are the normal the electric field components and eps1 and eps2 are the dielectric constants (assumed scalar quantities).

If there were no surface charge, the normal component of the field should then be consistent with E2n * 55 = E1n. However, the drop in the electric field is by a factor of 260, that could make quite a difference from the perspective of establishing compliance. Again, it is quite possible that the resolution of the model is not sufficiently accurate to resolve such a large variation near the surface.

Best regards,

OET Staff

---Reply from Customer on 12/05/2023---

Dear Reviewer,

Thank you for the feedback on this matter. We have communicated this feedback to our third-party vendor (IMST GmbH) who performed the simulations being discussed in this inquiry. Here is the feedback we received from the vendor:

"Only e- and h-fields are numerically calculatedby the discrete FDTD update equations, which are derived from the Maxwellequations. All other quantities, e.g. current density, power density, SAR,far-field radiation pattern, scattering parameters and surface chargedistributions are (if of interest) calculated from the e-/h-fields and materialdistribution in post-processing using the corresponding relations.

The distribution of free charges (sfree) on the surface of the conducting phantom is a result of the simulation. It is reflected/included in oursimulation results in particular by the "drop in the electric field"OET is wondering about."

It would be really helpful if we could have a conference call scheduled together with the OET Staff and the representative(s) of IMST GmbH to discuss and clarify any potential misunderstandings that there might be regarding the accuracy of the simulation results. I suggest scheduling a meeting at 8am PST (so that we can have IMST representative[s] from Germany join as well) next week any day from Tuesday to Thursday. Please let me know if any of these dates work for you.

Best Regards,

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FCC Response on 12/06/2023:

Dear Inquirer,

per your request, we can schedule a conference call for Tuesday 12 or Wed. 13 at 8 am PST (11 a.m. EST). Please forward the details when they become available.

Also, please inform your colleagues to provide details about the resolution (seemingly inadequate near the boundary) and the verification of the boundary conditions on the interface.

Also, it is not clear how the claim that the free charge on the boundary is accumulated and accounted for can be supported, since the simulation has given static dielectric parameters. That could only occur in a time-dependent simulation where a flow of charge can be computed, as in a Particle-in-cell model or in a two-fluid simulation with time-dependent space and time distribution.

This seems not to be the case in your simulation. When the simulation begins, there is no free charge on the boundary or anywhere else. Then it seems that it is claimed that as a result of the incident wave, a layer is formed, and there the free charge accounts for the drop in the electric field. That would not be possible unless there was some simulation of charge motion.

It would be useful to add a write-up to address these points before we have a conversation.

Best regards,

OET Staff

---Reply from Customer on 12/11/2023---

Dear Reviewer,

I do apologize for delayed response on this.

Below is the link to the Teams Meeting, starting at 8:00 am PST and ending at 9:00 am PST on 12DEC2023:

Microsoft Teams meeting

Join on your computer, mobile app or room device

Click here to join the meeting

Meeting ID: 281 445 788 340
Passcode: FsEyRV

Download Teams | Join on the web

Join with a video conferencing device

bossci@m.webex.com

Video Conference ID: 118 590 672 5

Alternate VTC instructions

IMPORTANT NOTICE: Please note that this service allowsaudio/video and other information sent during the session to be recorded, whichmay be discoverable in a legal matter. By joining this session, youautomatically

consent to such recordings.

Learn More | Help | Meeting options

Best Regards,

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FCC Response on 12/11/2023:

Dear Inquirer,

we will join the Teams meeting at 8 am PST as requested in your Dec 11 message. The purpose of a teleconference meeting in these cases is to clarify technical issues (we mention some details of the simulation of the boundary layer that were not clear, for instance).

We are unable to provide any verbal approval on the matters related to this inquiry, thus a follow-up through this inquiry system shall be expected.

Please be advised that due to another meeting ending at 8 am PST there may be some delay. For any delay beyond 5 minutes, we will email to Habet.Ter-Petrosyan@bsci.com.

As an alternative, we may suggest setting the start time at 8:15 or 8:30.

Best regards,

OET Staff

---Reply from Customer on 01/17/2024---

Dear Reviewer,

We appreciate your time and consideration in addressing the concerns raised during our discussions on 29NOV2023 and 06DEC2023, as well as in our recent meeting on 12DEC2023.

FCC response on 12/06/2023

>> Also, it is not clear how the claim that the free charge on the boundary is accumulated and >>accounted for can be supported, since the simulation has given static dielectric parameters. That >>could only occur in a time-dependent simulation where a flow of charge can be computed, as in a >>Particle-in-cell model or in a two-fluid simulation with time-dependent space and time distribution.
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In response to your inquiries regarding the observed drop in the electric field within the phantom and the verification of boundary conditions, we have included comprehensive details in the attached PDF report discussing:

1- Theoretical expressions, referencing equations governing boundary conditions for a lossy medium, providing insights into the factors influencing the electric field drop.
2- Highlighting the time-varying magnetic fields as the primary source of the internal electric fields.
3- Conducting additional simulations that utilize reputable electromagnetics tools such as COMSOL and ANSYS. The supplementary results aim to reinforce the validity of the simulations as presented in the IMST exposure report.

We kindly request your review of the attached PDF and PPT files, as the FCC portal only accommodates text submissions. We hope that this additional information addresses your concerns adequately. We are open to scheduling another conference call where we could go over the results and address any questions arising in a more interactive manner.

Thank you for your understanding.

Best regards,

BSN RF Team

---Reply from Customer on 01/17/2024---

Dear Reviewer,

We appreciate your time and consideration in addressing the concerns raised during our discussions on 29NOV2023 and 06DEC2023, as well as in our recent meeting on 12DEC2023.

FCC response on 12/06/2023

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The supplementary results aim to reinforce the validity of the simulations as presented in the IMST exposure report.

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Thank you for your understanding.

Best regards,

BSC RF Team

---Reply from Customer on 01/17/2024---

Dear Reviewer,

Attached is the second file to address the concerns raised during our discussions on 29NOV2023 and 06DEC2023, as well as in our recent meeting on 12DEC2023.

Thank you for your understanding,

Best Regards,

BSC RF Team

---Reply from Customer on 01/17/2024---

Dear Reviewer,

Attached is the second file to address the concerns raised during our discussions on 29NOV2023 and 06DEC2023, as well as in our recent meeting on 12DEC2023.

Thank you for your understanding,

Best Regards,

BSC RF Team

PS: For future communication, please send response to: Paknahad,Javad <Javad.Paknahad@bsci.com>

---Reply from Customer on 01/30/2024---

Dear Reviewer,

We would like to know if you have had a chance to review our response to the latest feedback from the OET Staff? We submitted two attachment in the last response.

Please let us know if you have any further questions on this inquiry, or what the next steps are expected to be.

Best Regards,

BSC RF Team

FCC Response on 02/01/2024:

Dear Inquirer,

in the interest of time, we propose to set up a teleconference and discuss your latest data (or any amended version of that). Please propose a couple of options starting from the next week or later, if preferred. However, before we discuss, please share answers to the points below, so to clarify your latest submitted document(s).

We stress the point that we have no reservations about the simulation tool(s) themselves, as they have been widely used and validated. Here, the focus is solely on your goal of showing compliance for a particular device. The investigations with a high permeability shield could be left as an appendix as a tool validation, but for compliance, we need to clearly see how the "jump" of electric field strength from outside to inside the tissue can be supported based on the physics of the problem.

i. The previously submitted document "20231109_SUMMARY_OF_THE_RESPONSES_ - Nov 9 2023", in Figure 5.1, shows a significant change of the electric field across the surface.

Unfortunately, the image resolution in that document is not sufficient to see the direction of the field vectors. We need to see a better picture of that transition region, so it will be clear what the perpendicular and tangential components of the fields are like near the boundary.

i. Both components of the electric field, normal and tangential, need to be shown, that is because SAR is computed from the magnitude of E, so only one component is not sufficient, of course.

i. In the previous discussion it was claimed that the difference in the normal component of E was due to surface charge accumulated, however the whole process was not explained. Now, in the new document, that surface charge is considered zero (reasonably), thus we want to confirm that the previous claim was deemed incorrect.

i. However, we still need to see a quantitative explanation for why the electric field changes to the level shown. This is critical, because SAR is based on the electric field.

i. The formation of eddy currents was mentioned: eddy currents are supported by the incident magnetic field and cause an opposing magnetic field that reduces the incident component. The overall effect is then to reduce the magnetic field inside the conducting material. A self-consistent, time dependent simulation would show this process in details as the EM enters the material, a transient occurs and then the solution (relatively quickly) settles to a steady state. However, how this process is related to the drastic change of the electric field shown is not discussed.

i. If the simulation is in the frequency domain, or steady-state time domain only, we won't see the transient details (they are not critical) but we shall still have a self-consistent solution. In that case, a difference from the "vacuum" solution could be easily highlighted by showing a situation like in the mentioned Fig. 5.1 (but with sufficient resolution), and then adding one or two "intermediate" cases between the actual tissue

and the vacuum solution. If a sufficient eddy current is established in the tissue, that should reduce the incident magnetic field component. That current (or related electric field) will cause a dissipation in the tissue, that is a measurable SAR value. We need to assess that.

Best regards,

OET Staff

---Reply from Customer on 02/13/2024---

Dear Reviewer,

I do apologize for delayed response on this. We are working internally to prepare the response.
Can we have a Teams meeting this Thursday 15th, Friday 16th or Monday 19th? We are available anytime during these three days. Once we receive the confirmation, we will send the meeting link.

Best regards,

BSN RF Team

FCC Response on 02/13/2024:

Dear Inquirer,

we recommend to wait that the response document is available so we have time to review it. We suggest to send in the responses first (w/o rushing, the more accurate, the better, of course) and then we can set a teleconference shortly thereafter.

Best, regards,

OET Staff

---Reply from Customer on 02/15/2024---

Dear Reviewer,

Thank you for sharing your comments. In response to your queries before our meeting, we have addressed each point. We thoroughly responded to your comments and believe this addresses the concerns. Please kindly review the report, and if further clarification is needed, we would appreciate it if you could arrange a meeting time for early next week.

Best regards,

BSN RF Team

---Reply from Customer on 02/22/2024---

Dear Reviewer,

We would like to know if you have had a chance to review our latest response.

Please let us know whether you have any further questions on this response or when we could arrange a meeting.

Best Regards,

BSC RF Team

---Reply from Customer on 03/04/2024---

Dear Reviewer,

We would like to know if you have had a chance to review our latest response.

For your reference, we have attached the file again.

Please let us know whether you have any further questions on this response or when we could arrange a meeting.

Best Regards,

BSC RF Team

FCC Response on 03/13/2024:

Dear Inquirer,

we believe we have good news; we are now able to close this case and provide support for moving forward with equipment authorization.

In order for us to proceed, we need a minor update to the technical documentation provided in support of this inquiry, as a final document of record. This will be a new document, w/o references to previous communications, and shall include content according to the guidelines discussed here below; this is required because we are not able to accept all the content presented in the attachment of Feb. 15, 2024 and in previous documents.

Will then issue a formal recommendation supporting compliance immediately after receiving the update of the document.

The compliance is here referred to presenting a reliable simulation showing that the basic restrictions are met inside the tissue.

Due to the frequency of the device being less than 100 kHz (thus SAR is not considered for the basic restrictions), for the purpose of equipment authorization and solely for this particular device, we elect to use the basic restriction provided in the ICNIRP, 2010
document https://www.icnirp.org/cms/upload/publications/ICNIRPFactSheetLF.pdf .

For the general population category, the basic restriction for the rms electric field E is expressed as 1.35e-4 f , f being the frequency in Hz. For f=81 kHz then E=10.935 V/m.

The simulation results that we consider in support of this condition are those already contained in the "01FEB2024_FCC_Feedback_BSN-Response_15FEB2024 - Feb 15 2024" document. However, some down-selection is required.

The figure 9 and 10 (there seems to be a typo in the Figure 10 vertical label, it should be relabeled "tangential") show a smooth transition of the electric field. Only the relevant case for conductivity of 0.75 S/m needs to be shown in these figures.

These results indicate that the normal and tangential components of the electric field are about of 6 and 8 V/m rms, respectively. As a worst-case scenario, even if one computes the total electric field strength using the maximum values, that will give ||(6, 8)||=10 V/m, that is already about 10% less than the target basic restriction level of 10.935 V/m. In reality this is an overestimate since the maxima of the tangential and normal component of the field are not located in the same point, and when considering the values at 5 mm (tissue interface) are actually lower than the maxima previously mentioned.

To validate the accuracy of this simulation, additional plots are provided in Figure 5 and 6 of the Appendix at the end of the document for COMSOL and HFSS simulations, confirming the previous result.

Based on these findings, the proposed system could be then considered RF exposure compliant. It is important, however, that the same parameters used in the simulation are implemented in the design. For instance, the coil current shall not be above the 1.65 A rms considered in the simulation (we note that in the initial KDB submission the coil current was 2.2 A).

The content just described would be sufficient to support compliance.

While in general, the responsibility to demonstrate compliance is left to the manufacturer/applicant, in this case we took a more active role in the interest of time and due to the relevance of the issue for the industry in general. Accordingly, to further support the results discussed above, we provided some simple estimates as a "sanity check" for the results presented.

For instance, the magnetic field generated by the coil used in the simulation is computed using a commercial coil calculator program based on the Biot-Savart formula. One can consider the coil data based on the information made available in the KDB submission; for a coil inductance of 94.5 microH and an inner radius of R=35 mm and a 1 mm (guess) wire diameter N=27 turns are required.
The magnetic field on axis for such a coil with current I=1.65 A (rms) is then computed as 0.5*mu0*N*I*/R=0.77 mT, corresponding to 612 A/m. This value is consistent with the simulation data for the magnetic field generated by the coil.

We also observe that due to the skin depth at 81 kHz for a conductivity of 0.75 S/m is 2 m. This value is much larger than the tissue simulation liquid (TSL) layer, thus the reaction due to the TSL current induced by the external magnetic field can be neglected, in other words, the calculation of the magnetic field from the external coil "in air" can be applied inside the TSL domain as well.

This is a well-known result from eddy current analysis: for cases where the skin depth is greater than the TSL layer thickness, the resistance-limited formula for the eddy currents is
a good approximation. This finding agrees to the simulation results that were shown for the magnetic field generated by the coil and penetrating, essentially undisturbed, the TSL layer.

The quasi-static analysis of provides then a good estimate of the induced electric field in the tissue that supports the eddy currents. Again, we already established that the eddy currents do not significantly impact the imposed magnetic field, however we want to obtain the electric field for evaluating the compliance to the basic restrictions. Thus, from Faraday's law, 2 pi r E = pi r^2 dB/dt. Thus, in phasor notation, |E|= pi f B r= pi f mu0 H. For f=81 kHz, r=35 mm, and H=612 A/m then a field of 7 V/m is computed. This is the electric field induced in the TSL that drives the eddy current (especially considering some guessed coil parameters in this calculation) and is remarkably close to the ~8 V/m of the simulation.

Finally, we add a note about some of the 2D field plots in the Feb. 15, 2024 attachment. This was probably one of the first cause of confusion and that led to delays in processing this application.

The Fig. 1 shows the electric field vectors inside the tissue and near the coil. The orientation of is hard to explain, showing the arrows converging on the coil wiring, in both sides, and then diverging for a bit smaller radius.

The vectors at the interface also look quite strange. In short, we are not able to accept that plot. Possibly, some lack of resolution combined with the way the source of 81 kHz- 1.65 A is model could explain that pattern. The electric field plots in Fig. 2, 3 and 4 also seem hard to justify.
They cannot be part of the simulation results supporting compliance.

The discussion of page 5 about the drop by a factor of 6e-6 for E-normal across the interface does not seem to agree with the Fig. 9 (that seems instead reasonable), since the interface at 5 mm shows E-normal of about 5.5 V/m.
Best regards,

OET Staff

---Reply from Customer on 03/15/2024---

Dear Reviewer,

We are thrilled to receive this update and are eager to move forward with equipment authorization. We have prepared a new document as per our understanding of your guidelines, eliminating redundant figures and theoretical expressions. The attached document includes the updated version. We hope this aligns with your expectations for the final document.

We really appreciate the valuable feedback provided, including the "sanity-check" which confirmed the accuracy of our simulation findings. We have incorporated some of the explanations into the final document to enhance understanding of the underlying physics.

Regarding the quality of Figs. 1, 2, 3, 4, we agree with the reviewer's assessment. The potential computational limitations on extremely increasing mesh resolution due to the detailed modeling of the entire external device and the operating frequency posed challenges on clear demonstration of 2D E-field smooth transition at the boundary and led to confusion. Therefore, we have removed these figures and focused solely on the extremely high-resolution line plot showcasing the smooth transition of the tangential electric field at the TSL layer. Sorry for any confusion regarding Fig. 9 and the drop in the electric field. Fig. 9 actually shows the tangential E-field, not the normal E-field.

Thank you for taking the time to thoroughly review our simulation findings. We look forward to your response and the opportunity to move forward with equipment authorization.

Best regards,

BSC RF Team

---Reply from Customer on 03/15/2024---

Dear Reviewer,

We didn't see the document in the attachment list. So, we attach it once again.

Best Regards,

BSC RF Team

FCC Response on 03/15/2024:

Dear Inquirer,

upon review of the document submitted on March 15, 2024, we accept the proposed design as consistent with our RF exposure guidance, that in this particular case are being referred to the basic restrictions per ICNIRP 2010 limits for a frequency of 81 kHz.

You may therefore proceed towards equipment authorization processing.

Best regards,

OET Staff

Attachment List:

01FEB2024_FCC_Feedback_BSN-Response_15FEB2024
01FEB2024_FCC_Feedback_BSN-Response_15FEB2024
06DEC2023_BSC_Charger3_FCCResponse_16JAN2024 PPT
BSN_March15_2024_WPT Charger-3 Compliance Report

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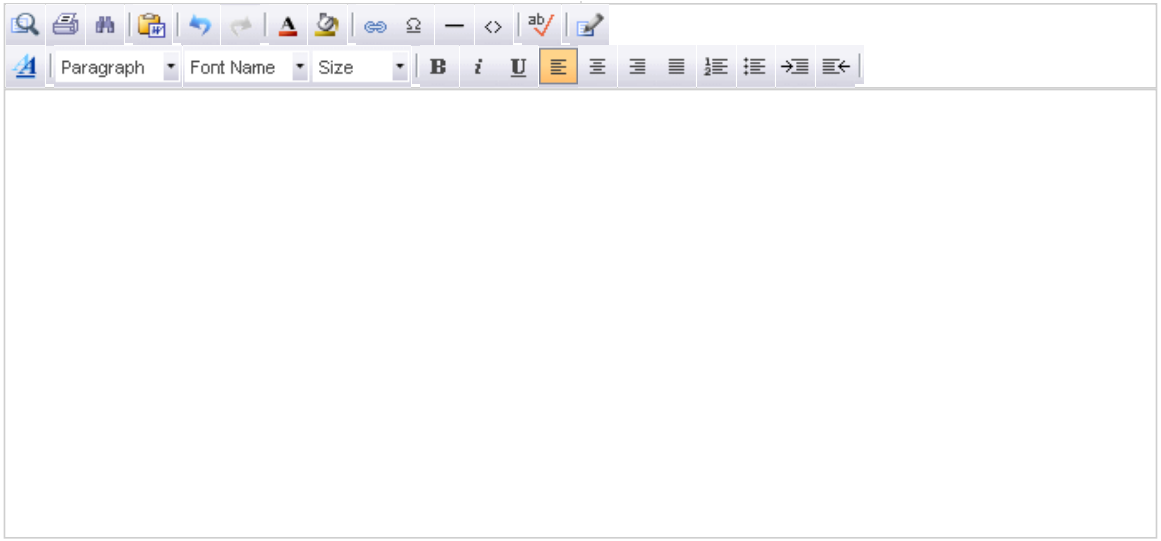

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