

Thank you very much for your support!

Notice: Please send the completed questionnaire back to info@noras.de or by fax (0931 / 299 27-20)

Evaluation Data Procedure

Sponsor: Noras MRI products GmbH, Leibnizstraße 4, 97204 Höchberg, Germany

Information about you

Name of institution / hospital	Click or type here to enter text.
Date of editing	Click or type here to enter text.
Name of related department	Click or type here to enter text.
Your position in the institution	Click or type here to enter text.
Privacy Notice	We will only use your personal data for internal documentation purposes, namely for clinical evaluation of our products and services and post-market clinical follow-up. Please review our Privacy Policy which provides information how we use and process your data. It's available at https://www.noras.de/en/datenschutzerklaerung/
Adverse events	We are required to pass on to our Quality Management department details of adverse events/product complaints pertaining to our products that are mentioned during the interview. This will have no impact on the confidentiality and anonymity associated with the interview itself.

Product and application details

Name of NORAS product in use (one product per questionnaire)	Click or type here to enter text.
For which concrete applications do you use our product?	Click or type here to enter text.
Used MR Scanner*	Click or type here to enter text.
Used MR Software*	Click or type here to enter text.
How long has our product been in use?	Click or type here to enter text.
How often is our product in use? (please specify, e.g. once a day, 3 times a week or month or year)	Click or type here to enter text.

*optional

Incidents and side effects

Nr.	Question	Evaluation score	Remarks
1	Was there a serious incident that had to be reported when using our product?*	<input type="checkbox"/> Yes <input type="checkbox"/> No	Click or type here to enter text.
2	Did a non-serious incident occur during the use of our product?*	<input type="checkbox"/> Yes <input type="checkbox"/> No	Click or type here to enter text.

3	Did undesirable side effects occur during use of our product?*	<input type="checkbox"/> Yes <input type="checkbox"/> No	Click or type here to enter text.
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*according to the Regulation (EU) 2017/745 (MDR)

Product safety (the higher the value, the safer the product)

Nr.	Question	Evaluation score	Remarks
4	Patient safety <i>How well does our product contribute to patient safety?</i>	Not at all 1 2 3 4 5 Very well <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Click or type here to enter text.
5	User safety <i>How well does our product contribute to user (e.g. doctors, nurses, etc.) safety?</i>	Not at all 1 2 3 4 5 Very well <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Click or type here to enter text.
6	Contamination safety <i>How well does our product contribute to safety of cleaning-personnel (e.g. risk of contamination, etc.)?</i>	Not at all 1 2 3 4 5 Very well <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Click or type here to enter text.
7	Safety risks - What concrete safety risks could arise when using our product? Click or type here to enter text.		

Usability and Functionality

Nr.	Question	Evaluation score	Remarks
8	Functionality <i>How satisfied are you with the products functionality? Does it meet the description according to the marketing and instructions for use?</i>	Not satisfied at all 1 2 3 4 5 Very satisfied <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Click or type here to enter text.
9	Usability <i>How satisfied are you with products ergonomics, handling and workflow?</i>	Not satisfied at all 1 2 3 4 5 Very satisfied <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Click or type here to enter text.
10	Product quality <i>How satisfied are you with the products quality e.g. image quality for coils?</i>	Not satisfied at all 1 2 3 4 5 Very satisfied <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Click or type here to enter text.

Others (the higher the value, the more satisfied you are)

Nr.	Question	Evaluation score	Remarks
11	Delivery reliability	Not at all 1 2 3 4 5 Very well <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Click or type here to enter text.
12	Communication <i>(e.g., reaction times, quality of provided information, etc.)</i>	Not at all 1 2 3 4 5 Very well <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Click or type here to enter text.

In a nutshell – What we do good:

Click or type here to enter text.

In a nutshell – What we can do better:




Click or type here to enter text.

REC	Dokumenten-Nr. N-8.2.1-R03	Revision 04	Erstellt am: 23.01.2025	Bereich VM	NORAS MRI PRODUCTS
	Titel: Rückmeldungen Kundenzufriedenheit				

Änderungsnachweis und Freigabe

Revision	Änderung gegenüber Vorgänger	Datum
N-7.3.6-R06 Marktbeobachtung Fachkreisbewertung_Rev01	Erstausgabe	25.07.2013
N-8.2.1-R03_Rückmeldungen_Kundenzufriedenheit_Rev01	Erstausgabe Durch Freigabe dieses Dokumentes wird N-7.3.6-R06 Marktbeobachtung_Fachkreisbewertung_Rev01 aus dem QM genommen.	23.06.2015
N-8.2.1-R03_Rueckmeldungen_Kundenzufriedenheit_Rev02	Wiedereinsetzung aufgrund von CAPA 2019-04-01-07, neues QM-Format und Überarbeitung hinsichtlich MDR (EU) 2017/745, Übersetzen ins Englische	24.10.2019
N-8.2.1-R03_Rueckmeldungen_Kundenzufriedenheit_Rev03	Firmenlogo neu	13.07.2023
N-8.2.1-R03_Rueckmeldungen_Kundenzufriedenheit_Rev04	<p>Im Rahmen des DECO0319:</p> <ul style="list-style-type: none"> • Überschrift auf Seite 1 ergänzt: „Evaluation Data Procedure“ • Erläuterung auf Seite 1 ergänzt: „Sponsor: Noras MRI GmbH Höchberg“ • Zu Punkt „Information about you“: <ul style="list-style-type: none"> ○ Entfernt: „Years of working experience“ ○ Hinzugefügt: „Data Processing Agreement“ • Zu Punkt „Product and application details“ <ul style="list-style-type: none"> ○ Entfernt: <ul style="list-style-type: none"> ▪ Punkt „How many people (approx.) do use our product within your institution?“ ▪ „Patient population“ (Wegen möglichen Mehraufwand für Ausfüllenden -> Formular wird ggfs. nicht ausgefüllt) • Zu Punkt „Product safety“: <ul style="list-style-type: none"> ○ „Evaluation Score“ ergänzt • Zu Punkt „Product performance“ <ul style="list-style-type: none"> ○ „Evaluation Score“ ergänzt ○ Neue Überschrift: „Usability and Functionality“ ○ Entfernt: <ul style="list-style-type: none"> ▪ „Workflow“ ▪ „Price / Performance“ ▪ „Flexibility“ • Firmenadresse um Land ergänzt 	23.01.2025

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Änderung durchgeführt	Geprüft	Freigabe
<p>Signiert von Sebastian Scheuplein</p>  <p>Sebastian Scheuplein Ich habe dieses Dokument verfasst 2025-01-23 9:21:18 AM MEZ F4FC4484908F42BA948A53EF9AF16880</p>	<p>Signiert von Klaus Sadowski</p>  <p>Klaus Sadowski Ich habe dieses Dokument geprüft 2025-01-26 6:52:44 PM MEZ AD4E03D35DA0411D8CC062A882B7CF01</p>	<p>Signiert von Melanie Roth</p>  <p>Melanie Roth Ich genehmige dieses Dokument 2025-01-27 7:58:19 AM MEZ 864EE11034EB4F59AD757D4507FD604C</p>
Datum: 2025-01-23	Datum: 2025-01-26	Datum: 2025-01-27
S. Scheuplein, TDE	S. Sadowski, EQM	Melanie Roth QM