Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00527**

21 May 2026

Dear [redacted]

Thank you for your correspondence received on 25 April and your subject access request under Article 15 UK GDPR, relating to the Phonak Naida M70 SP hearing aid and the AutoSense OS algorithm. Although you made a Subject Access Request we believe that this falls into the definition of a Freedom of Information (FoI) Request due to the non-personal nature of the information you have requested. You wrote:

> *I am writing to raise a medical device safety concern regarding Phonak's AutoSense OS algorithm as implemented in the Phonak Naída M70-SP hearing aid.*
>
> *I am [redacted]*
> *Email is my sole contact method as a reasonable adjustment under the Equality Act 2010 (ss.20 and 29). I ask that all responses are made by email and that this adjustment is noted on any file opened in connection with this correspondence.*
>
> *---*
> *MY AUDIOLOGICAL PROFILE*
>
> *My hearing loss is bilateral, severe-to-profound, and markedly asymmetric with a steep high-frequency drop (ski-slope configuration) in both ears. My audiogram — produced by County Durham and Darlington NHS Foundation Trust, ENT Audiology — shows:*
>
> *- Right ear: moderate-to-severe loss across mid frequencies, dropping to profound loss at 4–8 kHz (approximately 110–130 dB HL).*
>
> *- Left ear: moderate loss at low frequencies, deteriorating to severe-to-profound at high frequencies (approximately 100–130 dB HL at 2–8 kHz).*
>
> *This profile is clinically significant. A ski-slope severe-to-profound loss of this asymmetry is not adequately represented by population-average audiological models. Fitting decisions — including gain curves, noise reduction, directionality, and environment classification — that are derived from or calibrated against population averages carry material clinical risk when applied to an individual with this profile without individual human clinician review.*
> *---*
> *THE DEVICE AND THE SAFETY CONCERN*

I was fitted with Phonak Naída M70-SP hearing aids by County Durham and Darlington NHS Foundation Trust. The devices operate Phonak's AutoSense OS algorithm, which makes continuous automated adjustments to processing including environment classification, gain changes, noise reduction parameters, and directional microphone behaviour — all derived from algorithmic analysis of my individual audiogram data.

I submitted a Subject Access Request to Phonak / Sonova UK Ltd requesting:

1. Confirmation of whether automated decision-making or profiling under UK GDPR Articles 4 and 22 had been applied to my personal data in connection with AutoSense OS; 2. The specific algorithmic parameters applied to my audiogram; and 3. The name and role of any clinician who individually reviewed those parameters before or after fitting.

Phonak's response asserted that "the algorithm does not process personal data" and that audiogram-derived AutoSense OS parameters fall outside the scope of UK GDPR.

This position is, in my submission, legally and clinically unsustainable. Audiogram data is biometric data processed to produce health-affecting, individualised outputs for a specific identified patient. The assertion that algorithmic processing of a patient's audiogram to produce individualised gain curves, environment classification outputs, and noise reduction profiles does not constitute processing of personal data would — if accepted — mean that no medical device manufacturer bears individual accountability for the automated clinical decisions their devices make about specific patients on an ongoing basis.

The safety concern I am raising is this: if Phonak's position is correct — that AutoSense OS does not process personal data and no individual human clinical review of its outputs is required — then there is no named clinician accountable for the automated decisions being made, continuously, about my hearing, by a Class IIa medical device fitted to a patient with a severe-to-profound asymmetric ski-slope loss.

I apply the Burgess Principle binary test (UK Certification Mark UK00004343685) to this situation:

"Was a named human being able to personally review the specific facts of my specific situation before the algorithmic fitting decisions applied to my device were made and implemented?"

Based on Phonak's own response: NO.

SPECIFIC QUESTIONS FOR THE MHRA

I ask the MHRA to consider and respond to the following:

1. Does the AutoSense OS algorithm, as implemented in the Phonak Naída M70-SP, constitute a medical device function subject to the Medical Devices Regulations 2002 (as amended), and if so, what individual clinical accountability obligations apply to its automated outputs?

2. Is Phonak's assertion — that audiogram-derived algorithmic processing outputs fall outside the scope of personal data — consistent with the MHRA's understanding of the applicable regulatory framework for software functions in medical devices (MDSW)?

3. Does the MHRA consider that a hearing aid operating an adaptive AI algorithm, fitted

to a patient with a documented severe-to-profound asymmetric audiological profile, requires individual human clinician review of the algorithm's ongoing decisions about that patient — and if not, what safeguard exists in place of that review?

4. Has the MHRA received any adverse event reports or post-market surveillance data in connection with AutoSense OS or equivalent adaptive algorithms in hearing aids where population-average calibration was applied to patients with atypical audiological profiles?

I am also making a formal Subject Access Request under Article 15 UK GDPR for any records held by the MHRA concerning Phonak Naída M70 / AutoSense OS, including any adverse event reports, post-market surveillance submissions, or regulatory correspondence.

MHRA Response

We have treated your correspondence as a FOIA request in its entirety because the information you have requested concerns regulatory matters, policies, oversight activities, any recorded information held regarding medical device regulation and adverse event reporting, rather than seeking access to your own personal data held by us.
Although you reference your personal circumstances within your correspondence, this alone does not make the request a SAR. A request is only treated as a SAR where the requester is specifically seeking access to their own personal data held by the organisation.
As your request does not ask for copies of your personal data or records held about you personally, it falls within the scope of FOIA.

1. Does the AutoSense OS algorithm, as implemented in the Phonak Naída M70-SP, constitute a medical device function subject to the Medical Devices Regulations 2002 (as amended), and if so, what individual clinical accountability obligations apply to its automated outputs?

AutoSense OS is embedded software operating within the Phonak Naida M70 SP and forms part of a Class IIa medical device registered with the MHRA under the Medical Devices Regulations 2002 (as amended).

We can confirm that the Agency holds this information. However, the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

To be helpful you can find the information you seek at our Public Access Registration Database (PARD). Software, including artificial intelligence, is regulated as a medical device where it has a medical purpose: Software and artificial intelligence (AI) as a medical device - GOV.UK. Regulatory responsibility for the safety and performance of the device rests with the manufacturer.

2. Is Phonak's assertion — that audiogram-derived algorithmic processing outputs fall outside the scope of personal data — consistent with the MHRA's understanding of the applicable regulatory framework for software functions in medical devices (MDSW)?

The Agency doesn't hold this information. The applicability of the UK General Data Protection Regulations (UK GDPR) is outside our regulatory scope. We suggest that the manufacturer of the product be approached.

For CE marked devices (like Phonak Naida), under the EU Medical Devices Regulation (EU) 2017/745 and corresponding General Safety and Performance Requirements (GSPRs), manufacturers are obligated to ensure that any data processed by a medical device, especially health and biometric data derived from audiograms, is handled securely and appropriately. This includes requirements for data integrity, confidentiality, and traceability. Devices must be designed and manufactured in a way that minimises risks associated with data processing, such as unauthorised access or misuse. Furthermore, the GSPRs stipulate that the intended use of the software, including the processing of patient-specific data, must be clearly defined and validated to ensure safety and performance. Manufacturers are expected to implement technical and organisational measures to protect data, and to ensure that any algorithmic decision-making is both transparent and subject to appropriate clinical oversight.

3. Does the MHRA consider that a hearing aid operating an adaptive AI algorithm, fitted to a patient with a documented severe-to-profound asymmetric audiological profile, requires individual human clinician review of the algorithm's ongoing decisions about that patient — and if not, what safeguard exists in place of that review?

The Agency doesn't hold this information. However, the UK Medical Devices Regulations 2002 (as amended) and the applicable safety standard (BS EN IEC 60601-2-66:2020) provide safeguards through the manufacturer's obligations to identify and control foreseeable risks through a documented risk management process, validate the embedded software in accordance with standards, and maintain post-market surveillance, including reporting serious incidents to the MHRA where criteria are met. The clinical suitability of your individual fitting remains a responsibility for your audiology provider.

4. Has the MHRA received any adverse event reports or post-market surveillance data in connection with AutoSense OS or equivalent adaptive algorithms in hearing aids where population-average calibration was applied to patients with atypical audiological profiles?

Following a search of our electronic records, we have established that the information you requested is not held by this Agency.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
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