psyomics™

7 Quy Court Colliers Lane,
Stow-Cum-Quy,
Cambridge,
England,
CB25 9AU

Date: 22 January 2025
Our Reference: VIG-FSN-2025-01

Field Safety Notice - Censeo Digital

For attention of: Medical Device Safety Officers, Medical Device Leads, Chief Clinical Information Officers of Customers using Censeo Digital, Clinical Safety Officers, and Healthcare Professionals using Censeo Digital

Affected Medical Device	Censeo Digital
Affected Software Version(s)	Version 3

Dear Healthcare Provider,

Description of the problem

As part of its responsibility as a medical device manufacturer, Psyomics conducts continuous and rigorous surveillance to ensure the ongoing safety, performance and reliability of our products.

Following recent discussions with the Medicines and Healthcare products Regulatory Agency (MHRA), the MHRA has determined that:

1. Censeo Digital has been incorrectly registered as a Class I medical device; and
2. The current Clinical Evaluation Report (CER) does not demonstrate adequate evidence of safety and effectiveness as required by UK MDR 2002 (as amended).

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Company No. 09470381, Registered Office Address: C/O Chater Allan, 7 Quy Court Colliers Lane, Stow-Cum-Quy, Cambridge, England, CB25 9AU

As a result of this assessment, we are contacting you to advise you to stop using Censeo Digital until it has been assessed by an Approved Body / Notified Body and determined to be compliant.

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication. Please retain a copy of this letter and confirm the receipt of this notice via the Customer Acknowledgement Form (see below).

Actions Required by Healthcare Providers

To minimise disruption caused by the temporary unavailability of Censeo Digital, we recommend the following actions:

Item	Action
Acknowledge receipt of this Field Safety Notice:	• Please confirm receipt of this Field Safety Notice by completing the Customer Acknowledgement Form (page 4) as soon as possible.
Implement alternative triage and diagnostic tools:	• We recommend that customers utilise validated non-digital methods or alternative software solutions that align with your clinical pathways to maintain continuity in patient care.
Revisit internal processes:	• Review and, if necessary, update internal processes to ensure patients presenting with mental health concerns are directed to appropriate care pathways.
Maintain communication:	• Psyomics will keep in close contact to provide updates on the progress of regulatory review and product redevelopment. • For specific support or clarification, please reach out to chloe.dowson@psyomics.com

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Next Steps

We sincerely apologise for any inconvenience this development may cause and thank you for your understanding and cooperation. We are committed to supporting our customers to minimise disruption where possible.

This Field Safety Notice has been notified appropriately to the MHRA.

Kind regards,

Dr Melinda Rees

Dr Melinda Rees
CEO
Psyomics Ltd.

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