

Document Title	Document Description	Version No.
IFU	Clinical Facing Instructions for Use	1.0

psyomics

Quality Management System

Clinical Facing Instructions for Use

Document Title	Document Description	Version No.
IFU	Clinical Facing Instructions for Use	1.0

What is Censeo?

The 'Censeo Digital' medical device is software intended for use as a clinical decision support tool for mental health concerns in patients/service users who have been referred to Censeo by a healthcare service. This software is intended to be used by patients/service users aged 18-65 anywhere in which they have internet access with an internet-enabled device.

This medical device is inappropriate for being used to make a diagnosis or as a risk assessment tool in place of a clinician directly assessing a patient. This medical device should not be used as a crisis support tool.

This medical device software uses service users' answers to produce a mental health report. The report informs clinicians in making triage, assessment or treatment decisions related to mental health, by providing a consistent and comprehensive set of data to assist their decision-making.

Scope and Limitations of Censeo Digital

Censeo Digital is intended solely as a clinical decision support tool and should be used by individuals who have been referred by a mental health service provider. This device is not a diagnostic tool, nor does it replace direct clinical assessments by mental health professionals.

Censeo is not intended for crisis support; if you are in immediate need, please contact emergency services or a crisis support organisation.

The device is designed for adults aged 18-65 with basic proficiency in English and access to an internet-enabled device.

Intended User

The Censeo Digital report is to be used by healthcare professionals with appropriate clinical training in mental health assessment or treatment. This includes, but is not limited to:

- Mental health specialists such as psychiatrists, clinical psychologists, and mental health nurses.
- General practitioners (GPs) and other primary care providers who are involved in the initial assessment, triage, and referral of patients with potential mental health conditions.

Both categories of professionals must be:

1. Trained and competent to make autonomous clinical decisions about a patient's mental health, including triage, referral, and treatment planning.
2. Experienced in interpreting mental health reports that reference DSM-5-TR and ICD-11 diagnosable mental health-related conditions.

Document Title	Document Description	Version No.
IFU	Clinical Facing Instructions for Use	1.0

3. Able to integrate the report's triage prioritisation categories for suicidality risk, self-harm risk, level of distress due to trauma symptoms, and tendency to engage in risky impulsive behaviour into their clinical decision-making.
4. Capable of considering relevant social factors like the patient's housing situation, relationship status, and employment status when determining appropriate next steps.
5. Responsible for making the final professional judgement on triage, referral and treatment recommendations for the patient, using the Censeo Digital report as one component of a comprehensive evaluation.

The required qualifications and training refer to the user's clinical expertise, not to specific training in the use of the Censeo Digital device itself. All users must comply with all relevant information management and security procedures at all times.

Intended Use Environment

The Censeo Digital report is designed for use in clinical environments where triage, assessment, or treatment decisions are made, such as hospitals, mental health clinics, primary care settings and remote environments including professionals working from home. The report is accessed through a secure platform with appropriate authentication and authorisation. Compliance with data protection and security standards is required.

Patients can complete the adaptive questionnaire anywhere with internet access and an internet-enabled device.

Patient indications for use

- Patients with mental health concerns aged 18-65
- Mental health service provider referral to Censeo Digital.

Mental healthcare professional indications for use

- A mental healthcare professional requires a comprehensive summary of patient-reported symptoms to support the decision-making process for clinical triage, assessment or treatment.

Censeo Digital covers the following mental health conditions:

- Bipolar disorder (I and II)
- Major depressive disorder
- Generalised anxiety disorder
- Social anxiety disorder
- Panic disorder
- Obsessive-compulsive disorder
- Insomnia
- Psychosis
- Emotionally unstable personality disorder
- Eating disorders (anorexia nervosa and bulimia nervosa)
- Trauma

Document Title	Document Description	Version No.
IFU	Clinical Facing Instructions for Use	1.0

- Adjustment disorder
- Alcohol abuse
- Substance abuse
- Suicidality
- Self-harm

Contraindications for use:

- Using Censeo Digital by itself to diagnose or perform diagnostic activities – Censeo Digital provides information that a clinician can consider alongside other inputs, and must use their own expertise when performing diagnostic tasks.
- Using the device as a risk assessment tool – triage information is only provided to inform triage prioritisation.
- Patients with any indication of neurological deficit.
- Using the device as a crisis support tool.
- Using Censeo Digital without a basic understanding of the English language.

Warnings:

Censeo Digital must not be used:

- To diagnose
- As a crisis service

How it Works:

1. Referral:

The service user will receive a referral to their phone, they will then use this unique link to sign up for the Censeo platform. This will ask them to enter an email address and password & additional demographic information used for identification purposes.

2. Reminders:

After referral, Censeo will periodically remind them to complete the questionnaire on three occasions if they have not already done so. They can complete the questionnaire or opt out of these reminders which are available on the reminder SMS.

3. Questionnaire:

Document Title	Document Description	Version No.
IFU	Clinical Facing Instructions for Use	1.0

They will answer questions regarding their mental health symptoms and other related factors such as their employment situation & current social context. These questions presented are adaptive based on their previously chosen answers.

4. Report Generation:

Censeo analyses the responses and, once complete, produces a comprehensive mental health report which is delivered to the appropriate mental health service provider.

5. Crisis Support:

Throughout the questionnaire, crisis support information and contact details are prominently displayed for immediate access if needed. This information is in the top left-hand corner of your screen available after clicking on the logo shown for urgent help.

6. Review Process:

Only fully completed assessments are sent to and reviewed by clinicians. Partial or incomplete assessments are not transmitted and therefore not evaluated.

Service User Referral

In the majority of occasions, referrals to Censeo are automatically sent to Censeo via a technical integration, which does not require any manual steps to be completed. On these occasions, you will not be involved in the referral process.

The referral portal feature is a different method of referring service users to Censeo. It allows manual referrals to Censeo via a feature on the Censeo web portal. After logging into your Censeo account, you will see the 'Refer Patients' button. Using this page you will then be able to refer service users to Censeo.

Detailed instructions and training on the standard operation procedure are provided upon implementation of the referral portal

Service-User Facing Report

A report can be made available to service users if the functionality is available and a clinician has judged that it is appropriate. To ensure that the report is both informative and appropriate for service users, the content and language had to be carefully adjusted for a layperson audience. Key adjustments include:

Document Title	Document Description	Version No.
IFU	Clinical Facing Instructions for Use	1.0

- **Simplified Language:** The clinician-facing report’s medical terminology was replaced with non-technical, user-friendly language. We deliberately avoided condition-based terms that could confuse or alarm users unfamiliar with medical jargon.
- **Psycho-Educational Material:** To add value, we included psycho-educational content. This provides service users with easy-to-understand information on their symptom profiles, helping them make sense of the data without needing specialised knowledge in mental health.
- **Sensitive Information Exclusion:** The patient-facing report omits certain sensitive aspects of the clinician's report, such as triage priority, which could be distressing or misunderstood by the patient. Instead, the focus remains on educational content that promotes understanding without venturing into diagnostic or treatment guidance.
- **Visual Adjustments:** The layout and presentation of the report have also been redesigned to be visually intuitive. Charts, graphs, or other data representations are simplified to make the report accessible and easy to navigate for users without a medical background.

Performance Characteristics:

Censeo is properly installed and working if the report and dashboard are available. If there is an unforeseen issue that occurs whilst you are using Censeo, Censep will notify you of this via an error message.

Maintenance and updates are carried out on Censeo to ensure the device is as safe to use as possible. Maintenance occurs on an ad hoc basis. Maintenance updates happen on a new version of the device (which is then updated as the current version which you use) rather than happening on the “live” device on the website. As such any maintenance updates do not impact your ability to use the current version of the device.

Warnings:

Censeo Digital must not be used:

- To diagnose
- As a crisis service

Document Title	Document Description	Version No.
IFU	Clinical Facing Instructions for Use	1.0

Foreseeable Medical Emergency Situations

Censeo is not suitable for anyone in a situation of crisis. However, if you feel immediately at risk of harm from yourself or anyone else please contact one of the services below as Censeo is not an appropriate tool to use in this situation.

- Samaritans - call 116 123, email jo@samaritans.org
- Emergency services - call 999
- NHS 111 - call 111, select option 2 to speak to someone about your mental health needs

Decommissioning/uninstalling

If you wish to discontinue use of Censeo you can deactivate your account by contacting support@censeo.co.uk for further assistance.

Product Specification:

Hardware Requirement	Mobile phone, tablet, or desktop
Internet access required	Yes, Censeo requires access to the internet to view the online version of the mental health report. The PDF in some occasions may be available offline.
Minimum Internet browser version requirements	Censeo is compatible with the following browsers: <ul style="list-style-type: none"> • Chrome • Firefox • Safari • iOS Safari • Opera • Opera mobile • Android - Chrome browser • Android - Firefox browser • Edge • Samsung browser
Support Languages	en-GB

Incident Reporting:

Please contact us at vigilance@psyomics.com if you have discovered a potential issue with Censeo. In case a serious incident has occurred concerning the product, please also report it to

Document Title	Document Description	Version No.
IFU	Clinical Facing Instructions for Use	1.0

the Medicines and Healthcare Products Regulatory Agency (MHRA) through the Yellow Card Reporting Scheme.

Software information:

App name:
Censeo Digital
App version
3.189.14
Date of release
6 Nov 2024

Manufacturer or maintainer:

Psyomics Ltd.
7 Quay Court
Colliers Lane,
Sto-Cum-Quy,
Cambridge,
CB25 9AU
UK