

Regulatory References	
ISO 13485:2016	4.2.3
ISO 20417:2021	All

User Manual Oncoprevia

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Oncoprevia is a class 1 medical device in accordance with Regulation (EU) 2017/745 (for MDR).

Product Description

Intended Use

The software is intended for home usage giving an individualized prediction of the user's cancer risk based on a validated statistical algorithm like the Harvard Cancer Risk Score. The user inputs health data including risk factors like lifestyle (e.g. smoking habit) or a family history of cancer. From these inputs one of the three risk groups is determined: standard risk, elevated risk, high risk. Medical screening guidelines from national and international associations of oncology are used to select screenings for individuals based on their risk group. The final personalized prevention screening plan is presented and recommended to the user. It is up to the user to follow up on his recommended personalized prevention screening plan by presenting the software evaluation results to a healthcare professional. The software has no diagnostic nor therapeutic purpose.

Intended Medical Indication

This tool provides personalized prevention screening plans by applying medical screening guidelines from national and international oncology associations, tailored to the user's determined risk category. The final output is a customized recommendation for cancer screenings appropriate for managing the risks associated with potential cancers such as breast, cervical, colorectal, prostate, lung, and skin cancer.

Oncoprevia is designed for proactive health management by non-professional users without prior medical training. It encourages users to engage with healthcare professionals by sharing their personalized prevention screening plans, aiding in informed discussions and decisions about their health screening

schedules. However, it is important to note that Oncoprevia does not serve diagnostic or therapeutic purposes and is intended to complement—not replace—professional medical advice and screening programs.

Characterization of User Profile

Oncoprevia is designed for individual users who are proactive about their health and interested in understanding their personal cancer risks. The ideal user profile includes adults who are comfortable using digital health tools and can competently input accurate health data into the software. Users are expected to have basic technological proficiency, such as the ability to navigate simple software interfaces on mobile devices or computers.

While no prior medical knowledge is required to use Oncoprevia, users should be able to read and comprehend the health-related questions and guidance provided by the software. This includes understanding basic health terms related to lifestyle and familial health history. Users are also expected to be able to follow instructions for entering their health data and interpreting the risk assessments and recommendations provided by the software.

Oncoprevia users are typically health-conscious individuals seeking to make informed decisions about their screening and preventative care strategies. They are motivated by a desire to take proactive steps towards their health, using the insights provided by Oncoprevia to discuss and plan appropriate cancer screening schedules with healthcare professionals. The software is particularly suited for users who value privacy and convenience, offering a user-friendly platform to assess cancer risk from the privacy of their home.

Exclusions

Oncoprevia is not suitable for:

- **Individuals with a prior or current diagnosis of any cancer type:** The software's risk models are not suitable for individuals who have previously been diagnosed with cancer, including carcinoma in situ.
- **Individuals currently undergoing cancer treatment:** Changes in health status and treatments may affect risk profiles, making the software's predictions unreliable.
- **Pregnant women:** The physiological and hormonal changes during pregnancy can impact the validity of risk assessments provided by the software.

Safety Information

Contraindications

Oncoprevia is not designed to automate medical diagnoses or serve as a substitute for professional medical advice. The software provides risk assessments based on user-provided data and established statistical models. It is crucial that all results generated by Oncoprevia be reviewed and interpreted in consultation with a qualified healthcare professional.

Warning and Remaining Risks

While Oncoprevia utilizes robust algorithms to predict cancer risk, users must ensure the accuracy and completeness of the information they input. Inaccurate or incomplete data can lead to incorrect risk assessments, potentially affecting health decisions. Users are strongly advised to:

- **Verify Input Data:** Ensure that all health information and personal data entered into the software are accurate and up-to-date.
- **Follow Safety Instructions:** Adhere to the guidelines and instructions provided within the software to ensure its proper use.
- **Read Information Carefully:** Carefully review all the information provided by the software, including guidelines on how to input data and interpret results, to ensure a comprehensive understanding of the risk assessment process and its implications.

In the event of a serious incident which occurred in relation to this software it is mandatory that the user (you) reports the incident to us (manufacturer) and the competent authority of the Member State in which you are established.

Language

Oncoprevia is available in German and English.

System Requirements

Software

The Oncoprevia software is a web-based application accessible via modern web browsers . Users should ensure they are using the latest version of their browser to guarantee optimal functionality and security.

IT-security Measures

To ensure the security and integrity of user data, Oncoprevia employs advanced IT security measures. These include SSL/TLS encryption for data transmission, firewall protections to guard against unauthorized access, and regular security audits. Users are encouraged to protect their accounts with strong, unique passwords and to enable two-factor authentication where available. Regular updates and security patches are applied to maintain the highest level of data protection and to prevent data loss.

Safety and Maintenance

Oncoprevia is committed to maintaining the highest standards of software reliability and user safety. Software updates, including security patches and enhancements, are deployed regularly to ensure ongoing compliance with medical regulatory standards and cybersecurity best practices.

- **Software Updates:** Updates are automatically pushed to the user interface without disrupting the user experience, ensuring that the latest features and security measures are always in use.
- **Reporting Issues:** Users can report any malfunctions, clinical incidents, or security concerns through a dedicated support channel on the Oncoprevia website or directly via customer support email. Instructions for recovering or resetting lost passwords are provided on the login page and support channels.