The Ophtascan™ System

Instructions for Use

User Manual

Table of Contents

Introduction

Product Description

The Ophtascan™ system is a medical screening technology designed to screen for cancer and/or type-2 diabetes in human patients. The Ophtascan™ system consists of proprietary hardware named OncoLenz™ and an artificial intelligence enabled software also named Ophtascan application. The hardware, OncoLenz™ enables obtaining stable, accurate and clear photo of the patient's eyes using a specific mobile device. The software analyzes the eyes for deviations in the iris', pupil's and sclera's patterns and colors compared to the average healthy eyes' structure. The identified specific deviated patterns indicate abnormalities in the cell structures and blood vessels and thereby evidencing the risk of cancer and/or type-2 diabetes in the body.

Intended Use

The Ophtascan™ system is intended to screen for cancer and/or type 2 diabetes in human patients by analyzing the patients' iris, pupil and sclera for specific abnormal patters that are indicative of changes in the cell structures and blood vessels, which results from cancer or type-2 diabetes in the body.

Medical Purpose:

The Ophtascan™ system is an innovative technology using the advancements in modern artificial intelligence; specifically advancements in computer vision and machine learning combined with empirical processing and analysis of large datasets of the iris, pupil, sclera and other parts of the eyes and then assess the possible health risks of a person based on established medical research.

Application:

A. Environment (home/ professional use; indoor/outdoor; ambient temperature and humidity)

   The Ophtascan™ system is designed to be used in healthcare institutions by professional medical staff. It is designed so that it can be operated by trained medical professionals, both in indoor and outdoor conditions. Ambient temperature and humidity do not affect the performance of the system.

B. Frequency of use (how often product is intended to be used)

   No restrictions on frequency of use. The Ophtascan™ system can be used as necessary when a doctor sees the need for a patient to be screened or when a person (patient) requests a comprehensive health checkup including periodic general health checkups.

C. Mobility (mobile or stationary use)

The Ophtascan™ systems is a mobile technology.

Warnings

- The Ophtascan™ system cannot be used for other purposes than described in this Instruction for Use.
- Patients undergoing any treatment for cancer are not compatible for screening with the Ophtascan™ system.

Contraindications

- Not intended for paediatric use.
- Not intended for cancer patients who have undergone any anti-cancer treatment or who are undergoing cancer treatment of any type.
- Not intended for patients with epilepsy or pregnant women.
- Cannot be used on patients with serious eye diseases, eye injuries or missing eye.

Limitations

- The Ophtascan™ system is a screening and not a diagnostic tool.
- The Ophtascan™ system requires a computer or tablet, a smartphone and stable highspeed Internet.

Hardware and Software Requirements of End-Point Devices

	Ophtascan™ Software	**OncoLenz™ Hardware**
Device	Microsoft Windows 10 PC or later; Apple MacOS 12 MAC PC or later;	Samsung A33 or Samsung A34 mobile smartphone
Operating system	Microsoft Windows 10 PC or later; an Apple MacOS 12 PC or later;	Android 13 with One UI 5.1 or later; Recommended: Android 14 with One UI 6.1
Internet Browser	Google Chrome 116 or later; the recommended release version is 118	Google Chrome
CPU	Ophtascan is a software-as-a-service and does not do processing on the local device; however, the Microsoft or Apple recommended minimum CPU capacity is recommended.	Octa-core (2x2.6 GHz Cortex-A78 & 6x2.0 GHz Cortex-A55)
Memory (min. requirement)	Minimum recommended memory capacity over and above the Operating System's requirement is 1GB.	8 GB RAM
Storage	Minimum recommended storage capacity over and above the Operating	256 GB

	System's requirement is 1GB.	
Operating temperature	Standard computing temperature range for a personal computer (PC).	
Camera	Standard computing temperature range for a mobile smartphones.	48 MP, f/1.8, 26mm (wide), 1/2.0", 0.8µm, PDAF, OIS 8 MP, f/2.2, 123˚, (ultrawide), 1/4.0", 1.12µm 5 MP, f/2.4, (macro) LED flash, panorama, HDR 4K@30fps, 1080p@30/60fps 720p@480fps

Product Features (Functional Description)

Functionality/Module:

The primary operation analyses and identifies predetermined patterns of deviation in the eyes' shapes of the iris, pupil, and blood vessels in the sclera, and colors compared to average (healthy) eyes. System requires the users to take pictures of both eyes specifically focusing on the iris, pupil and blood vessels of the sclera of the left and right eyes, using the OncoLenz ™ and a specific smartphone and the Ophtascan™ mobile application. The image is then uploaded to the Ophtascan™ cloud (remote server). The results of the analysis have a 95% sensitivity or higher in people who never got anti-cancer treatment of any kind; and type-2 diabetes mellitus with at least 95% sensitivity in people treated and not treated by an endocrinologist.

Patient population

The Ophtascan™ system is intended for use on general population to screen for pre-cancerous, cancer and/or type-2 diabetes. It can be used on human males and females over the age of 18.

Target Users

Medical professionals.

General Safety Instructions

This Instruction for Use (IFU) deals with the specifications, operation and maintenance of the Ophtascan™ system. Oncotech™ Ltd. and/or any of its subsidiaries are by no means responsible for any malfunction or accident arising from a user ignoring the instructions for use and maintenance described in this IFU.

This IFU contains a description of all the functions available; please read this IFU carefully and familiarize yourself thoroughly with its contents before operating the unit. If any technical problem should arise, please contact Oncotech™ technical support.

Ophtascan™ system has no known side effects.

Residual Risks

After the risk management measures have been applied, the residual risks were assessed according to criteria set by risk management planning. Such assessment results were recorded in a risk analysis.

The residual risk assessment was done for each risk. All risks were reduced to an acceptable level and no risks remained as residual.

If you are experiencing abnormal medial conditions please contact your healthcare professional regardless of the results.

Please be aware of security vulnerabilities on the internet. Protect your devices against malware and ransomware.

Please carefully read the full contents of this Instructions for use before using.

Product Installation

Product installation on the user's side is performed using the following steps:

Medical institution, as a client, will get access to Ophtascan™ system, which includes the OncoLenz™ headset as well as the Ophtascan™ application after signing contract with Oncotech™'s regional distributors.

Product Setup and Operations

Operation Principle:

The system consists of a proprietary hardware headset and a specific smartphone that enables the user to take photos of the patient in a particular way with specific settings; as well as software located in the cloud (remote server) and communicating with the user through a web application via an internet browser installed on a computer and a mobile application installed on a smartphone, which determines the probability of a disease selected by the user from the available diseases list, using the images of both of the patients' eyes.

The user uploads photos to the system and receives the results in the web-based application via a web page. The photographing device must be one of the OncoTech™ specified smartphone in combination with the proprietary OncoLenz™ headset.

The user can find on the Ophtascan™ web-site (www.ophtascan.ai) the necessary written and video instructions on the quality of photos and recommendations on how to take them.

The Ophtascan™ system gives a result only if the photos meet all the requirements as specified by OncoTech™.

The results are the estimated risk of the probability of the selected disease and are not a diagnosis for treatment.

Having received a positive result for a disease selected from the list, the user of the system can at his/her own request, contact a doctor for advice and laboratory for functional diagnostics.

The user can periodically monitor changes in the risk of a selected disease of a patient and the Ophtascan™ calculates a forecast of changes in this risk for the user.

Error Codes

The Ophtascan™ system will prompt the user if or when an error occurs including when the photo image uploaded is not of the Ophtascan™'s required quality, format or clarity.

Maintenance

Ophtascan™ software is provided as a Software-as-a-Service (SaaS), hence, it is continually updated. The mobile app will also be periodically updated as necessary to meet functional, security and regulatory

compliance requirements, including compatibility with OncoTech specified mobile device's latest stable release of the operating system.

Troubleshooting

For all issues with The Ophtascan™ system please contact Oncotech's technical support.

Symbols

Symbol	Description
	**Title/Meaning:** Operator's manual; operating instructions **Function/description:** To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.
	Mark of conformity according to the European Medical Device Regulation 2017/745.
	**Title/Meaning**: Manufacturer **Function/description**: To identify the manufacturer of a product. This symbol shall be used filled in all applications to differentiate it from ISO 7000-2497
	**Title/Meaning**: Medical device **Function/description**: To indicate that the software is a medical device according to the European Medical Device Regulation 2017/745.
	**Title/Meaning**: Unique Device Identifier **Function/description**: To indicate a carrier that contains unique device identifier information according to the European Medical Device Regulation 2017/745.
	**Title/Meaning**: Company logo **Function/description**: To indicate the company.

Ophtascan™	**Title/Meaning**: Product logo **Function/description**: To indicate the software product.

Regulations and standards

Ophtascan™ system is classified according to MDR (EU) 2017/745, Annex VIII: Class I, Rule 11. Ophtascan™ system is classified as Class A according to IEC 62304:2006/A1:2015 - Medical device software — Software life cycle processes. The device complies with the following product standards:

- IEC 62304:2006/A1:2015 - Medical device software – Software life cycle processes
- ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes
- IEC 82304-1:2016 - Health Software - Part 1: General requirements for product safety
- Medical Device Regulation MDR (EU) 2017/745
- EN ISO 14971:2019 - Medical devices -- Application of risk management to medical devices
- IEC 62366-1:2015 - Medical devices - Part 1: Application of usability engineering to medical devices.

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