

Instructions For Use

Acc. to directive 93/42/EEG EWG (MDD) Annex I Part 13.6



Manufacturer

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Product Description

OnyxCeph³™ is a powerful Client-/Server Windows Application with a SQL-type Database to work with 2D and 3D image records.

OnyxCeph³™ was primarily developed as an image management and image analysis software for dental units to support the workflow in image-based diagnostics, treatment planning and patient education in general dentistry, orthodontics, prothetics, implantology, and oral-maxillofacial surgery as well.

Medical Purpose

Stand alone software OnyxCeph³™, developed, placed on the market and put into service by Image Instruments is intended to be used for the medical purpose of managing and diagnostically evaluating two-dimensional and three-dimensional images in the framework of dental applications by qualified staff only.

Diagnostic and therapeutic decisions cannot be motivated exclusively or even mainly on evaluation results provided by the software.

The intended medical purpose requires a correct registration and activation of the software by the user.

Unauthorized trial versions can only be used to become familiar with the application acc. to its user interface and functionality but do not represent a medical product so far.

Performance

The correct function of the software requires the use of the most up to date program version (release).

The availability of a new program version is displayed by a release update button top right in the program main window if online connected.

Alternatively, the update information has to be checked on the product website www.onyxceph.com on a regular base.

Installation

To install the software correctly, the setup instructions enclosed in each installation package have to be read carefully. For installation, administrator privileges are required and an up to date Windows™ operating system has to be used.

If properly installed, the main program can be launched on a client computer from the program group OnyxCeph3 or from the related desktop link by double clicking.

IP Ports

To allow communication between server database and client application, IP port 16300 has to be open on both ends inbound and outbound.

Accuracy

All measurements supported by the application are based on digitized landmark coordinates within the coordinate system of the analyzed image data set while a correct calibration of the image data itself is required.

The accuracy of digitized the landmark coordinates is 4 times pixel size for 2D images. The accuracy of digitized landmark coordinates is identically to the accuracy of the vertex coordinates of the source file for 3D image data.

Date

January 15th, 2018