Instructions For Use
Acc. to IEC 82304-1 Health software – Part 1: General requirements for product safety

Manufacturer
Image Instruments GmbH
Niederwaldstr. 3
09123 Chemnitz
Germany
Phone +49 371 9093140
Fax +49 371 9093149
Email info@image-instruments.de
Reg.No.: HRB 16678
Registration: Amtsgericht Chemnitz
VAT-ID: DE 812699756
Tax-No.: 214 111 03320

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, prosthetics, implantology, and oral-maxillofacial surgery as well.

Medical Purpose
Standalone software OnyxCeph³™, developed, placed on the marked 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.

Accuracy
The functions provided by the software according to its medical purpose are based on the measurement of image data sets. 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.

Installation
The installation of the software OnyxCeph³™ is performed by the user or by its IT partners. To install the software correctly, the setup instructions enclosed in each installation package must carefully followed. For installation, administrator privileges are required and an up to date Windows™ operating system has to be used. Detailed information on installation and configuration is available at www.onyxwiki.net.

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

Start, Application, Exit
After proper installation of the latest program version the main program can be launched on a client computer from the program group OnyxCeph3 or from the related desktop link by double-clicking. Notes and instructions for using the software are provided via the main menu entry [Help] and the context-sensitive help. The program is terminated via the main menu entry [Exit].

Uninstallation
The workstations are uninstalled using the uninstallation program in the OnyxCeph3 program group. The database server is uninstalled via the Windows ™ control panel in the [Programs and Features] category.

Date
February 10th, 2021