

## Instructions For Use

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

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### Warnings

- The user must have sufficient experience in using and handling computers as well as Windows™-based software including the Windows™ operating system used.
- The user may only use the software if he/she is proficient in the language selected for the OnyxCeph<sup>3</sup>™ client.
- Use and configure appropriate security measures such as anti-virus software and firewalls to protect against data loss due to hacker attacks.
- Use non-activated trial versions for learning purposes only but not for clinical cases.
- It is the user's responsibility to install available updates in order to always use the latest version.
- Only use OnyxCeph<sup>3</sup>™ if the 2D and 3D image information to be used for the intended workflow can be clearly and verifiably assigned to the correct patient and has the required quality and resolution.

### Notes

- Use OnyxCeph<sup>3</sup>™ only if you are a dentist, dental assistant or dental technician with professional experience in orthodontics.
- Use OnyxCeph<sup>3</sup>™ for clinical cases only if you have been sufficiently instructed in the use of the software for the intended workflow.
- Note that the use of OnyxCeph<sup>3</sup>™ software for digital orthodontic workflows neither influences nor contradicts conventional clinical treatment concepts and treatment principles.
- Do not give your user access data to third parties.
- Please read the manual carefully.

### Contraindications

There are no known contraindications to the OnyxCeph<sup>3</sup>™ standalone medical software.

### Product Description

OnyxCeph<sup>3</sup>™ is a powerful client/server Windows™ application with SQL database for working with 2D and 3D image datasets.

OnyxCeph<sup>3</sup>™ was developed as an image management and image evaluation software for dental units and primarily supports digital workflows of image-based diagnostics, treatment planning and patient education in general dentistry, orthodontics and orthognathic oral surgery.

## **Medical Purpose | Indication for Use**

OnyxCeph<sup>3</sup>™ software 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.

## **Performance Data**

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](http://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 landmark coordinates in 2D image data at max. one quarter of the pixel size for 2D images. The accuracy of digitized landmark coordinates in 3D image data is identically to the accuracy of the vertex coordinates of the source file for 3D image data.

## **Installation**

The installation of the software OnyxCeph<sup>3</sup>™ 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](http://www.onyxwiki.net).

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.

## **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 1<sup>st</sup>, 2022