Specification

OnyxCeph³™

Product Description

The standalone Windows™ software OnyxCeph³™ provides software tools to digitally perform analog image-based in-house workflows in orthodontic facilities. To the extent that these workflows output measurement information, their accuracy shall at least match the accuracy of the corresponding analog workflows.
The tools developed for this purpose shall be flexibly configurable and combinable in order to digitally map a wide variety of orthodontic in-house workflows and thus generate a general benefit in the form of savings, facilitation and improvement.
In addition to this general benefit, the application of the software enables a clinical benefit exclusively in the form of deriving metric information from case-relevant 2D and 3D image data and is therefore classified as a medical device.
The OnyxCeph³™ software does not make treatment decisions or provide treatment recommendations. The software itself and its outputs cannot be used directly on patients or for their treatment. According to the intended purpose, the measured values provided within the scope of clinical use can only be used to back up independently made treatment decisions.

Indications for Use

OnyxCeph³™ software is intended to be used for the medical purpose of managing and evaluating two-dimensional and three-dimensional images in the framework of digital orthodontics by qualified staff only.
The use of OnyxCeph³™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.
The software can be used to digitally perform certain image-based orthodontic workflows, such as metric and angular evaluation of image data.

Medical Purpose

OnyxCeph³™ is a software only device and is intended to be used for the medical purpose of managing and evaluating two-dimensional and three-dimensional images in the framework of digital orthodontics by qualified staff only who have received dedicated training for use of the software.
Clinical decisions cannot be motivated exclusively or even mainly on evaluation results provided by the software.
The classification as a medical device cannot be transferred to treatment measures or the manufacture of orthodontic appliances, even if these take into account the calculation results of 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 on a regular base.

The intended use of the software requires the proper registration and productive activation of the software by the user. Non-productively activated versions of the software only serve to familiarise the user with its use or for testing purposes.

Program Versions | Modules

Topic	Content
Program Versions	Available program versions
Version Featurelist	Program version comparison
Module List	Module List
Module Windows	Module Windows

Release Information

[Release history](#)

Prerequisites

All measurement, simulation, and image processing tools provided by OnyxCeph³™ merely serve to assist you in finding a diagnosis. All diagnosis and possible treatments must be based on clinical knowledge and experience. OnyxCeph³™ does not lay claim to replace the diagnosis of the physician.
Additionally, it is pointed out that the results obtained by the measuring functions of OnyxCeph³™ can only be correctly calculated on condition of the object to be evaluated being digitally imaged in the focal plane without distortion. This has to be secured by means of appropriate calibration of the image acquisition process or suitable correction of the digitally recorded images.
The propriety of the used algorithms for 2D and 3D measurements on data sets can be verified by both test images which can be loaded from the root directory of the installation medium and download installation zip file. Both test images have to be classified as image type NoType (2D) resp. NoType (3D) and analyzed by the Calibration analysis. The error of each such measurement should be within the standard deviation displayed in column norm value.

Image and Tracing Types

Topic	Content
Image Types 2D	Pre-defined 2D image types
Tracing Types 2D	Available tracing types
Image Types 3D	Pre-defined 3D image types 3D

Topic	Content
Tracing Types 3D	Available tracing types 3D

Getting Started

↗ Getting Started

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