

Intended use environment

Device 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.

Indication 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.

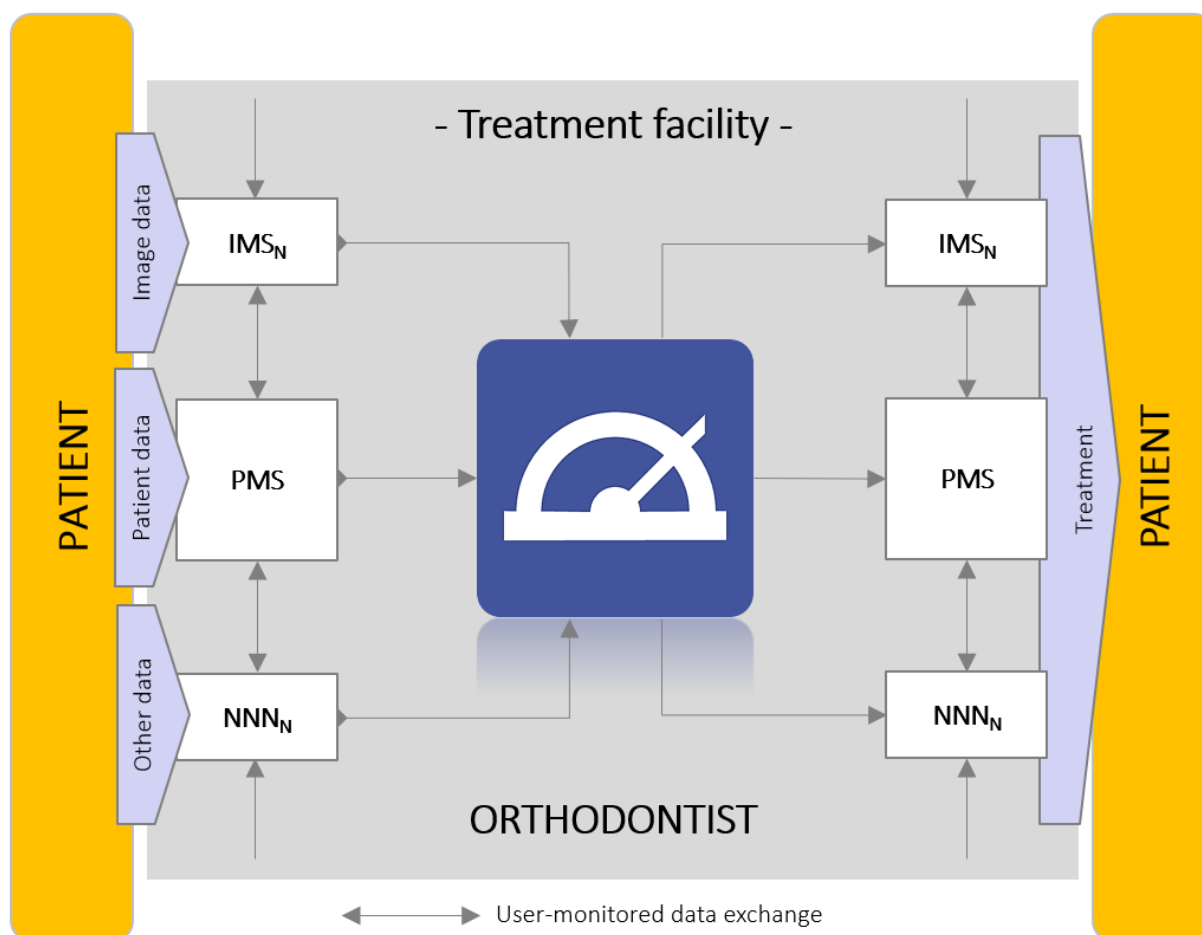
The classification as a medical device cannot be transferred to treatment measures or the manufacture of orthodontic appliances, even if these take into account the calculation results of the software.

Utilisation environment

OnyxCeph³™ is a native Windows™ client/server network application for use within an administered IT infrastructure.

From the inputs (case-related image data and additional information) received via interfaces [VDDS; CLI/HTTP; GUI] under user control, visual and graphical outputs (case-related information) are derived internally according to user specifications using implemented algorithms and displayed or output as a file via interfaces.

This information cannot be used directly for treatment purposes, but must be interpreted together with information from other sources by professionally qualified personnel and processed before further use.



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