

IPS CaseDesigner™

Version 2.4

Instructions for Use

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Welcome

Disclaimer of Liability

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Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

Device Description

IPS CaseDesigner is a software solution supporting the diagnostic process and treatment planning of craniomaxillofacial and related treatments.

IPS CaseDesigner has specific functionalities to visualize the diagnostic information, e.g. from CT imaging, to perform specific measurements in the image data and to plan surgical actions in order to support the diagnostic and treatment planning process.

Based on the diagnostic and planning data, the IPS design service can offer individualized surgical aids.

IPS CaseDesigner is a user interface supporting the diagnostic process and treatment planning of craniomaxillofacial and related treatments.

Intended Purpose

Intended purpose of the software is to support the diagnostic process and treatment planning for dental and craniomaxillofacial procedures.

Intended Use

IPS CaseDesigner is software for the transfer and visualization of imaging information from equipment such as a CT scanner to support the diagnostic and treatment planning process in craniomaxillofacial regions.

IPS CaseDesigner facilitates the service offering of individualized surgical aids.

Indications for Use

IPS CaseDesigner is indicated for use as a software and image segmentation system for the transfer of imaging information from a scanner such as a CT scanner. It is also indicated to support the diagnostic and treatment planning process of cranio-maxillofacial procedures.

IPS CaseDesigner facilitates the service offering of individualized surgical aids

Intended User and Intended Patient Target Group

IPS CaseDesigner is used by an interdisciplinary treatment team and is intended to support them in treating patients who are subject to dental, craniomaxillofacial or related treatments.

Intended for patients needing to undergo dental treatment.

Required Compatibility with Other Devices

IPS CaseDesigner is not connected with other medical devices.

This version of IPS CaseDesigner is compatible with previous versions of IPS CaseDesigner.

Devices with Measuring Function

Measurement accuracy depends on the image data, the used scanner hardware, its calibration and acquisition settings. The measurement cannot be more precise than the resolution of the image. IPS CaseDesigner software reports the value, rounded to one digit after the decimal point, based on user-picked points.

Contraindications

None identified for IPS CaseDesigner.

Cautions / Precautions

- Users are advised to obtain training before undertaking a new treatment method or using a new device.
- When using a new device or treatment method for the first time, working with a colleague who is experienced with the new device or treatment method may help avoid possible complications. A global network of mentors is available for this purpose.



Warnings

A number of technical warnings (e.g. inconsistent CT data, corrupt STL data) are visualized in IPS CaseDesigner.

A warning panel may show one or more of the following warnings during the creation of models, diagnostics or osteotomy simulations.

Incorrect alignment of upper jaw detected.

Use the **Manual initialization** action to obtain a correct alignment of the upper jaw to reduce the risk of incorrect surgical planning.

Incorrect alignment of lower jaw detected.

Use the **Manual initialization** action to obtain a correct alignment of the lower jaw to reduce the risk of incorrect surgical planning.

Incorrect alignment of both jaws detected.

Use the **Manual initialization** action to obtain a correct alignment of the jaws to reduce the risk of incorrect surgical planning.

To separate both jaws, hard separation was used.

To reduce the risk of using incomplete (planning) information in the surgery plan, adjust the **Expert settings** for fossa-condyle separation if you do not wish to use hard separation.

Incorrect jaw separation detected.

Adjust the **Expert settings** for fossa-condyle separation to obtain a correct jaw separation and to reduce the risk of incorrect surgical planning.

Upper jaw is manually initialized.

The alignment calculation of the upper jaw is initialized by the corresponding points placed in the **Manual initialization** action. Ensure correct jaw alignment before finalizing the surgical plan to reduce the risk of incorrect surgical planning.

Lower jaw is manually initialized.

The alignment calculation of the lower jaw is initialized by the corresponding points placed in the **Manual initialization** action. Ensure correct jaw alignment before finalizing the surgical plan to reduce the risk of incorrect surgical planning.

Both jaws were manually initialized.

The alignment calculation of both jaws is initialized by the corresponding points placed in the **Manual initialization** action. Ensure correct jaw alignment before finalizing the surgical plan to reduce the risk of incorrect surgical planning.

The DICOM dataset slice thickness is too large

Please turn to the help files for information on how to create valid DICOM files according to the recommended scan protocol.

The DICOM dataset has inconsistent slice increments

Please turn to the help files for information on how to create valid DICOM files according to the recommended scan protocol.

The DICOM dataset slice increment is too large

Please turn to the help files for information on how to create valid DICOM files according to the recommended scan protocol.

Corrupt file

File of [“upper scan”, “lower scan”, “occlusion scan”] could not be opened, please select another file. If the problem persists, contact customer support.

Corrupt files

Both files could not be opened, please select other files. If the problem persists, contact customer support.

The name in the DICOM file differs from the patient name

To reduce the risk of using incorrect data to create the patient model, verify the patient name and check whether patient name and the name in the used DICOM dataset correspond.

Finalize splint for current surgical plan

The generated splint files are only valid for the planned surgery. If you want to change the surgical plan, use the unlock action to remove the splint and make changes.

Intersecting models detected. Increase the autorotation value

Increase the autorotation value to reduce the risk of a surgical misfit.

Intersecting models detected.

Adjust the autorotation to avoid intersecting models. Press Continue if you want to proceed creating the splint.

Fragments might be intersecting

When in the **Virtual Occlusion** wizard upper and lower jaw intersect, grinding will be required to be able to achieve the final occlusal position.

Surgical splint for pre-op position

Be aware that a splint will be created for the pre-op position of the patient.

Verify automatic mandibular nerves

Please verify complete and correct annotation of the automatic nerve canal to avoid injury/damage. If incorrect, please delete the automatic mandibular nerves and indicate them manually.

Automatic dental segmentation is intended to be used only for adult dentition without gemination, crowding and macrodontia.

To reduce the risk of using Automatic dental segmentation on non-suitable patient images.

Cybersecurity

It is recommended that active and up-to-date anti-virus and anti-malware software, together with a correctly configured firewall, are installed on the computer where IPS CaseDesigner is to be used. Furthermore, always lock your computer when it is left unattended.

DICOM Files

DICOM files used in the software must meet the requirements specified in the help file.

Interoperability

N/A since the software is not exchanging data with any other medical device.

Intended Lifetime

For software, the intended lifetime is three years. When used on the supported operating systems it will keep performing according to its intended use.

Performance Requirements and Limitations

IPS CaseDesigner has dependencies on the operating systems it is used with. It is therefore important to make sure IPS CaseDesigner is used only with approved operating systems. More information about which operating systems are approved can be found in the 'IPS CaseDesigner System Requirements'.

Clinical Benefits and Undesirable Side Effects

IPS CaseDesigner is a component of craniomaxillofacial surgery. Clinicians may expect the software to support the diagnostic and treatment planning process.

No side effects known.

Notice Regarding Serious Incidents

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority. The contact information for the manufacturer of this device to report a serious incident is as follows:

Nobel Biocare AB

<https://www.nobelbiocare.com/complaint-form>

Facilities and Training

It is strongly recommended that clinicians, new as well as experienced users of implants, prosthetics and associated software, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience.

For more information please visit

www.nobelbiocare.com.

Professional Use

IPS CaseDesigner is for professional use only.

Handling Instructions

Installation of the Software

Before starting the installation of the software, check the IPS CaseDesigner computer requirements.

Install the software according to the IPS CaseDesigner Installation Guide.

How to Start the Software

To open the application, double-click on the IPS CaseDesigner shortcut icon on the desktop. The software opens, allowing you to start working with patient files.

IPS CaseDesigner Workflow Steps

The patient undergoes a scan according to the scanning protocols defined for IPS CaseDesigner. The models are scanned in final occlusion. Both parts of the dental cast are also scanned, individually but within one DICOM dataset. The resulting DICOM files are used to create the patient model, surgery models, occlusion models and skin.

Diagnostic tools are available for the user to indicate the mandibular nerve or to measure distances, angles or values. A cephalometric framework allows the user to indicate the landmarks to be used in the cephalometric analysis.

With the surgery tools the virtual model can be osteotomized according to different osteotomy types, including Le Fort I, sagittal split, ramus, segmental and chin osteotomies. The movements of the different bone segments can be simulated. A surgical splint file can be created and the list of osteosynthesis plates can be consulted to select the plates to be used in the surgery.

For more detailed information on how to perform specific actions, please refer to the help files that can be accessed via the IPS CaseDesigner software.

If you wish to have a printed hardcopy of the IFU, please contact customer support

System Requirements

Operating Systems

- Windows® 64-bit:
 - Windows 10
- Intel-based Mac (*):
 - macOS® X Catalina (10.15)
 - macOS Big Sur (11)
- Apple Silicon Mac (M1 Chip or Higher):
 - macOS Big Sur (11)

Devices

- Windows desktop
- Windows notebook
- iMac®, Mac® Mini, Mac Pro®
- MacBook Pro®, MacBook Air® (*) All models since 2011 are supported.

* MacBook Air® and Mac® Mini configurations require at least an Intel HD 5000 / Iris graphics.

Other

CPU	Dual-core (3 Ghz)
RAM	8 GB
Graphics card	Dedicated graphics card with optimal 3D support (OpenGL® 3.3) and 2 GB onboard memory or more (such as AMD or NVIDIA). To check the OpenGL® version of your graphics card, go to http://realtech-vr.com/admin/glview . 4 GB or more for 4K displays. When using low-end GPUs, consider selecting planning mode for 3D lighting in the visualization setting if you experience issues. The graphics card of some MacBook Air® and Mac mini® configuration has restrictions with regard to 3D rendering. Consider selecting planning mode for 3D lighting in the visualization setting if you experience issues.
Monitor	Full HD (1920×1080) or higher.
Internet	Broadband Internet connection with 3Mbps upload and 30 Mbps download speed.
Disk space	5 GB of free disk space

**Manufacturer**

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