Nobel Biocare™

IPS CaseDesigner®

Version 2.6

Instructions for Use

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Welcome

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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 / Indications for Use

IPS CaseDesigner is software indicated for supporting the diagnostic and treatment planning process of dental and craniomaxillofacial procedures. IPS CaseDesigner is software that is also used as an image segmentation system and for the transfer of imaging information from a scanner such as a CT scanner.

IPS CaseDesigner also facilitates the service offering of individualized surgical aids.

Intended User and Intended Patient Target Group

IPS CaseDesigner is for professional use only: clinicians, nurses, dental technicians and designers of individual surgical aids. The product is to be used in a clinic, private practice, dental laboratory or as a software tool in a design service for surgical aids.

Intended for patients needing to undergo craniomaxillofacial treatment.

Required Compatibility with Other Devices

IPS CaseDesigner is compatible with the most used operating systems Windows and Mac including the latest releases.

Valid DICOM characteristics to be used in IPS CaseDesigner® are:

- Minimum two slices
- The slices have an image orientation and image position.
- The modality is (CB)CT.
- The images are 2-byte images.
- The image orientation is [1 0 0] [0 1 0] [0 0 1].
- The maximum deviation from the ‘standard’ slice increment is smaller than 0.001 mm.
- The slice thickness is smaller than 1.3 mm.

Devices with Measuring Function

The measurement accuracy and precision are 0.1 mm for linear measurements and 0.1 deg for angular measurements based on the input of (conebeam) CT-scans, acquired according to the instructions for use of the scanner equipment, with a voxel size of 0.5 mm x 0.5 mm x 0.5 mm.

IPS CaseDesigner software reports the value, rounded to one digit after the decimal point, based on user-picked points.

Cybersecurity

Protecting your practice against cybersecurity threats is a shared responsibility between us as the manufacturer and you as the health care provider. The manufacturer has taken precautions to ensure that the software is protected against such threats.

It is recommended that active and up-to-date antivirus and anti-malware software, together with a correctly configured firewall, are installed on the computer where IPS CaseDesigner is to be used. Failure to do so may lead to unauthorized access.

It is recommended to enable audit logging in the settings and ensure the protection of these logs against unauthorized access. Failure to do so may prevent malicious activity from being detected.

Use two-factor authentication to access the software and always lock the computer when it is left unattended. Failure to do so may lead to unauthorized access.

Make sure the office network is protected from unauthorized access and separated from the visitor network. Failure to do so may lead to unauthorized access.

To quickly recover from any unexpected system failure or malicious event that may cause data loss, it is advised to regularly back up the patient data.

It is recommended to start IPS CaseDesigner without administrative privileges. Failure to do so may lead to unintended starting of malicious third-party executables

It is recommended to always update IPS CaseDesigner to the latest available software version. Failure to do so may lead to unauthorized access.

For more technical details concerning back-ups, firewall and security settings during installation, please refer to the IPS CaseDesigner installation guide.

What to Do in Case of a Cybersecurity Event?

In the event of a potential system compromise by intrusion or malicious software, the user may note unfamiliar product behavior and/or performance impact. In this case the user is advised to contact customer support immediately.

Contraindications

None identified for IPS CaseDesigner.

Compatibility

IPS CaseDesigner is not connected with other medical devices.

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

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 Computer Guidelines for IPS CaseDesigner.

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.

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. A wide range of courses for various levels of knowledge and experience can be offered by the support team.

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

System Requirements

We advise to check the System Requirements before starting the installation of the software to obtain information on minimum and/or recommended requirements. New versions of the software may require higher requirements for hardware or operating system.

Installation of the Software

Information on how to install the software, can be found in the IPS CaseDesigner Installation Guide. This document can be downloaded from the User Documentation Library (ifu.dtxstudio.com). If any issues occur or you need assistance, please contact an authorised technician or customer support (support@dtxstudio.com).

Cautions / Precautions and Warnings

Cautions / Precautions

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 lack of knowledge about the software and comprehension of its features may lead to unwanted results: a treatment may be delayed or rescheduled and osteosynthesis may be incorrect.

When using the diagnostic and surgery tools provided in the software, it is important to pay extra attention to:

- the correctness of made indications (measurements, critical functions or structures and file indications).

- the produced splints and their optimal fit to the patient's mouth according to the developed plan.

- the used scanners and the material used for the dental cast (changing them may lead to an incorrect default dental scan threshold)

Failure to do so increases the risk that the surgery plan needs to be revised. This, in turn, may lead to the delay in or rescheduling of the treatment. It even may result in an incorrect osteosynthesis.

After updating the software version, it is recommended to verify the critical settings of the open patient cases and/or surgery plans to make sure these settings are correct in the new software version. Incorrect settings may lead to incorrect osteosynthesis.

Not following these warning signals of the software may lead to incorrect osteosynthesis.

It is recommended to pay extra attention when loading DICOM data. Incorrect and incomplete data may lead to incorrect osteosynthesis.

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. Failure to do so may lead to unintended handling of the plan or treatment.

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.

Be aware that locally-produced surgical splints must be fabricated using validated processes and appropriate materials according to the manufacturer’s instructions for use. Optimal fit should be verified prior to surgery.

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.

After importing the surgery plan, please verify the imported osteotomies, movements and occlusion. Where necessary, adjust them before continuing your plan.

After importing the surgery plan, please verify the imported osteotomies, movements and occlusion. Where necessary, adjust them before continuing your plan.

System Requirements

Operating System[1]	Windows® 11 or 10 64-bit (Pro and Enterprise edition) on desktop and notebook. macOS Sequoia (15), Sonoma (14) or Ventura (13) (Intel-based Mac and Apple Silicon Mac with M1 Chip or Higher) on iMac, Mac Mini, Mac Pro, MacBook Pro, MacBook Air devices.[2]
CPU	Dual-core (3 Ghz)
RAM	8 GB
Graphics card	Dedicated graphics card with optimal 3D support (OpenGL® 3.3)[3] and 2 GB onboard memory or more (such as AMD or NVIDIA). 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® configurations has restrictions with regard to 3D rendering. Consider selecting planning mode for 3D lighting in the visualization setting if you experience issues.
Disk space	5 GB of free disk space
Network	Broadband Internet connection with 3Mbps upload and 30 Mbps download speed. It is recommended always to be connected to the Internet. If that is not possible, a connection should be established at least once every 14 days, because otherwise your access to IPS CaseDesigner may be temporarily suspended. When a connection to the internet is re-established, your access to IPS CaseDesigner will be restored.
Monitor	Full HD (1920×1080) or higher.

1 It is strongly recommended to install the latest available update of your Operating System (OS) version, as this will fix known bugs or vulnerabilities keeping users and computer systems more secure.

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

3 To check the OpenGL® version of your graphics card, go to http://realtech-vr.com/admin/glview.

Handling Instructions

For detailed information on how to use the software, please refer to the detailed instructions in the help files that can be accessed via the IPS CaseDesigner software.

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 detailed information on how to use the software, please refer to the detailed instructions in 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.

Known Issues

Occlusion Alignment May Fail

The occlusion alignment step might fail when using occlusion DICOM data with high noise levels.

Option 1 — Retake

1. Retake a scan of the final occlusion according to the occlusion scan protocol, described in the help file, annex 2.
2. Execute the occlusion alignment step again with the new occlusion DICOM data.

Option 2 — Convert

1. Convert the noisy occlusion DICOM data to an STL file of the occlusion model.
2. Execute the occlusion alignment step again using the occlusion model.

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