

IPS CaseDesigner® 1.4

Instructions for Use

Important - Disclaimer of Liability

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, it is his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof.

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

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 cranio-maxillofacial procedures.

Indications for Use

IPS CaseDesigner® is software indicated for supporting the diagnostic and treatment planning process of 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.

Contraindications

None identified for IPS CaseDesigner®.

Devices with Measurement 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® reports the value, rounded to one digit after the decimal point, based on user-picked points.



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.

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

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.

To separate both jaws, normal 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 wish to use a different type of 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.

Intersecting models detected.

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



Cautions

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications.

Performance Characteristics

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® reports the value, rounded to one digit after the decimal point, based on user-picked point

Intended Users and Patient Groups

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.

Cybersecurity

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. Furthermore, always lock the computer when it is left unattended.

Note: It is recommended to save all your files as password protected files. Otherwise, this may lead to unintended distribution of patient information.

DICOM files

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.

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

Compatibility

IPS CaseDesigner® is not connected with other medical devices.

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

Note: 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. Wrong settings may lead to incorrect osteosynthesis.

Interoperability

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

Intended Lifetime

Intended lifetime is three (3) years.

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 can expect the software to support the diagnostic and treatment planning process.

No side effects known.

Facilities and Training

Users are advised to obtain training before undertaking a new treatment method or using a new device. This is achieved by reading the instructions in the IFU and help file.

Note: A lack of knowledge about and comprehension of the software may result in delay or rescheduling of a treatment and may lead to incorrect osteosynthesis.

Computer Requirements

IPS CaseDesigner® must be used with a compatible operating system. This version is compatible with Windows® 64-bit (Windows® 7, 8.1, 10) and with macOS® Sierra, macOS® High Sierra.

IPS CaseDesigner® 1.4

Instructions for Use

Recommended requirements for Windows

CPU	A CPU with at least a dual-core processor and a high clock rate (3 GHz) is recommended.
RAM	IPS CaseDesigner® consumes a considerable amount of memory due to the large datasets. A RAM memory of 8 GB is therefore recommended.
Graphics card	A graphics card with optimal 3D support (OpenGL®) is required, as IPS CaseDesigner® renders large amounts of 2D and 3D data. It is recommended that the graphics card has its own onboard memory (2 GB or more). 4 GB or more is recommended for 4K displays.
Monitor	The screen resolution is important. Full HD (1920x1080) or higher, such as 1920x1200, is recommended.
Internet	A broadband internet connection is required. Keep in mind that the upload and download speeds differ. An upload speed of 3 Mbps and a download speed of 30 Mbps or more are recommended.
Disk Space	5 GB of free disk space is required for a standard installation. More disk space is used based on the number of patient files. A typical patient file is about 250 MB.

Recommended requirements for Mac

CPU	A CPU with at least a dual-core processor and a high clock rate (3 GHz) is recommended.
RAM	IPS CaseDesigner® consumes a considerable amount of memory due to the large datasets. A RAM memory of 8 GB is therefore recommended.
Graphics card	A graphics card with optimal 3D support (OpenGL®) is required, as IPS CaseDesigner® renders large amounts of 2D and 3D data. It is recommended that the graphics card has its own onboard memory (2 GB or more). 4 GB or more is recommended for 4K displays.
Monitor	The screen resolution is important. Full HD (1920x1080) or higher, such as 1920x1200, is recommended.
Internet	A broadband internet connection is required. Keep in mind that the upload and download speeds differ. An upload speed of 3 Mbps and a download speed of 30 Mbps or more are recommended.
Disk Space	5 GB of free disk space is required for a standard installation. More disk space is used based on the number of patient files. A typical patient file is about 250 MB.
Devices	iMac®, Mac® Mini (*), Mac Pro®, MacBook Pro®, MacBook Air® (*). All models released since 2011 are supported.

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

Installation of the software

Before starting the installation of the software, check the IPS CaseDesigner® computer requirements for your operating system. Install the software according to the IPS CaseDesigner® Installation Guide.

Handling Instructions

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 set. 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.

Note: 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)

Otherwise, there is an increased risk of the need for revising the surgery plan or rescheduling the treatment. It even may result in incorrect osteosynthesis.

Known issues

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

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

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

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>



Manufacturer and Distributor Information:

Nobel Biocare AB,
Box 5190, 402 26
Västra Hamngatan 1,
411 17
Göteborg
Sweden
Phone: +46 31 81 88 00
Fax: +46 31 16 31 52
www.nobelbiocare.com

Canada - License Exemption: Note that not all products described in this IFU may have been licensed in accordance with Canadian law.



Medical device

Caution

Consult instructions for use

In order to receive a free printed copy, please contact customer service or your local sales representative and a hardcopy will be provided to you within 7 calendar days.

Basic UDI-DI Information

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Basic UDI-DI Name	Basic UDI-DI Code
Diagnostic and treatment software	733274700000016275

Symbols Glossary

The following table describes symbols which may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

		
Batch code	Catalog number	Caution
 symbol.glossary.nobelbiocare.com ifu.nobelbiocare.com		
Consult instructions for use	Contains or presence of phthalate	Date of manufacture
		
Do not re-sterilize	Do not re-use	Do not use if package is damaged
Rx Only	ID	
For prescription use only	Patient identifier	Keep away from sunlight
		
Keep dry	Manufacturer	Medical device
		
Magnetic resonance conditional	Non-sterile	Patient number
		
Serial number	Sterilized using irradiation	Use-by date

EN All rights reserved.
Nobel Biocare, the Nobel Biocare logotype and all other trademarks used in this document are, if nothing else is stated or is evident from the context in a certain case, trademarks of Nobel Biocare. Product images are not necessarily to scale.