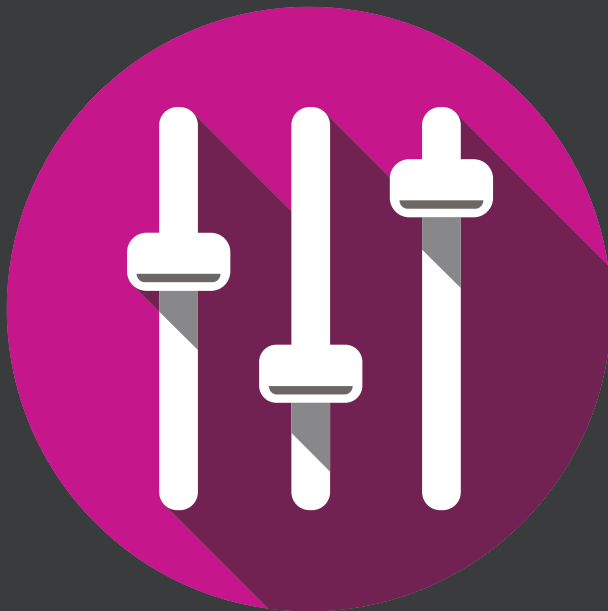


Instructions for use

Genie 2
2020.2



Introduction

The following instructions for use are valid for Oticon Genie 2 2020.2.

Genie 2 is a fitting software used for Oticon More™, Oticon Opn S™, Oticon Opn™, Oticon Xceed, Oticon Opn Play™, Oticon Xceed Play, Oticon Ruby, and Oticon Siya hearing instrument families.

If you have additional questions about the use of Genie 2, contact your local distributor.

A printed version of this booklet can be obtained through your local distributor.

For your convenience, this booklet contains a navigation bar to help you easily navigate through the different sections.

| **Start-up** | Working in Genie 2 | Warnings | More info |

Intended use

| | |
|----------------------------|---|
| Intended use | The fitting software is intended for fitting and updating of hearing solutions. The fitting software can facilitate access to real-ear measurement equipment. |
| Indications for use | There are no indications for use (diagnoses) for the fitting software itself. |
| Intended user | <p>The fitting software solution is intended to be used by Hearing Care Professionals (HCP) who in this document are referred to as, but are not limited to, Hearing Aid Professionals (HAP), audiologists, ENT (ear, nose and throat) doctors, and Hearing Aid Dispensers (HAD).</p> <p>The user of the fitting software shall be a hearing care professional who is appropriately trained, and has proven competency in professionally assessing hearing, selecting, fitting and delivering hearing instruments and rehabilitation care to persons with hearing loss. The training of the hearing care professional is in accordance with their specific educational background following national or regional regulations.</p> |
| User environment | Clinical setting. |
| Contraindications | No contraindications. |
| Clinical benefits | See clinical benefits of the hearing aid. |

Intended use of Tinnitus SoundSupport™

Tinnitus SoundSupport is a tool intended to generate sounds to provide temporary relief for patients suffering from tinnitus as part of a tinnitus management program.

Tinnitus SoundSupport is not intended for users below 18 years of age.

Tinnitus SoundSupport is targeted to licensed hearing care professionals (audiologists, hearing instrument specialists, or otolaryngologists) who are familiar with the evaluation and treatment of tinnitus and hearing loss.

Fitting of Tinnitus SoundSupport must be done by a hearing care professional participating in a tinnitus management program.

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First installation

The Genie 2 fitting software installation is provided on a DVD/USB drive that contains the installation file.

The installation program starts automatically when you insert the Genie 2 DVD/USB into the drive/port.

Otherwise, open Windows Explorer, browse to the relevant drive and double-click the **Setup.exe** file. When you run the installer, follow the installation instructions on the screen.

Genie updater

The Genie updater is installed with Genie 2. When the installation is complete, a small icon appears on your Windows taskbar.

The icon informs you if there is an update to Genie 2. You can also change the settings on how often the software checks for updates.

You can open Genie updater from the Windows taskbar or Windows Start Menu.

Upgrading from older versions of Genie

If you are running an older version of Genie (19.2 or earlier), you must first update it to version 20.1, and then you can install version 20.2.

If you already have a previous version of Genie 2 installed, user/client sessions are still visible.

System requirements

The following are the recommended minimum requirements to install and use Genie 2:

Hardware requirements

- CPU: Intel Core i5, 4 cores, 3.2 GHz or faster
- 8 GB RAM or more
- 8 GB free hard drive space
- Hard drive: 256 GB Solid State Drive (SSD)
- Screen resolution: minimum 1920 x 1080 pixels
- DVD drive for DVD installation
- USB 2.0 port for USB installation and programming devices
- Keyboard and mouse
- Stereo or 5.1 surround sound card (recommended)

Operating System requirements

- Windows 7 SP1 (32/64 bit)
- Windows 8.1 (32/64 bit)
- Windows 10 Anniversary Update, or later (32/64 bit)

Optional tools

- NOAH 4 audiology software
- An Internet browser to access the Oticon website
- Adobe™ Acrobat Reader™ software
- It is recommended that you protect your system by installing anti-virus protection software

Stand-alone Genie 2 database

When you run Genie 2 without the NOAH database module, or in stand-alone mode, a Client module is automatically installed, and an additional **Client** step appears.

In the **Client** module, you can enter or edit user data, such as name, date of birth, address and audiogram. User data is then automatically saved in the Genie 2 database and used for any subsequent fittings.

Genie 2 overview

This is an overview of the functionality, features, and tools in Genie 2. You can use it to learn about the typical steps and tools used for fitting.

The procedures contained in this booklet help you with the most essential steps, such as connecting the instrument, performing a fitting and saving your changes.

For further information about any of the features in Genie 2, refer to the built-in help guide. To access the help guide within Genie 2, press the F1 key or go to the **Help** menu, and then click **Help on Genie 2**.

The Organiser steps - horizontal navigation

The organiser, which is divided into five parts, helps you navigate through the entire fitting process by structuring the fitting flow in a series of steps.

- **Client:** Appears when you run Genie 2 without the NOAH database module (or in stand-alone mode). It lets you enter a hearing instrument user's data.
- **Welcome:** Lets you connect the hearing instruments to Genie 2 or run a simulation without having hearing instruments connected.
- **Selection:** Lets you select an instrument family, styles and features.
- **Fitting:** Lets you verify, adjust and fine-tune the settings of instruments.
- **End Fitting:** Lets you verify and set individual user operational settings for buttons, indicators and accessories to finalise the fitting session with the user. You can save settings, session information on the database and hearing instrument, and exit Genie 2.

The Task Pane - vertical navigation

In each organiser step there is a task pane, located on the left-hand side of the screen. The task pane gives you access to tools and links that are relevant to where you are in the fitting process.

Welcome step

After you add the user in the NOAH database, the next step in the fitting flow is the **Welcome** step.

However, if you select an already existing fitting, you are taken to the **Fitting** step.

You can have Genie 2 connect to the hearing instruments or you can choose simulation mode to help you check possible configurations of a hearing instrument, or to see how tools look and work.

To connect hearing instruments in Genie 2

1. Connect hearing instruments to one of the programming devices, either with cables or wirelessly.

Note

The Oticon More family of hearing instruments can only be connected using NOAHlink Wireless.

2. On the toolbar, click **CONNECT**. Connected hearing instruments are listed in a dialog box. If no hearing instruments are detected, an error message appears.

If you use Wireless programming, you must assign the hearing instruments to left and right, or confirm the side selection.

If you have not selected acoustics, you are prompted to do so depending on the type of hearing instrument.

At this point you can proceed with a new fitting or transfer settings from selected source instruments.

To simulate an instrument being connected to Genie 2

- In the **Welcome** step, in the bottom pane, click **SIMULATE**. You are then taken to the **Selection** step, where you can manually choose the instrument(s) you would like to simulate, including family, style and features.

Transfer Settings

This tool lets you transfer settings from a fitting session to a new selection of hearing instruments, even if the instrument is from a different family.

The Transfer Settings tool starts automatically when new hearing instruments that are different from the current session are connected or selected.

To manually open Transfer Settings, in the menu bar, click **Tools** and then click **Transfer Settings**.

Programs and settings that are not available in the target instrument are not transferred, and settings that cannot be transferred correctly are set to default or prescribed.

The tool transfers standard insertion gain from the source hearing instrument as closely as possible, given the limitations of the target hearing instrument, and adjusts it to the new acoustic setup.

After transferring settings, you can print a report that describes which settings were transferred.

Note

If you want to generate a report, be aware that you must do this before ending the session, as the report is not available after closing the session with the client.

Selection step

In the **Selection** step you can select family, styles, features and fitting level. This step also includes the **Connection status** section.

The **Select instruments** screen is the entry screen for the **Selection** step. You can connect hearing instruments or continue in simulation mode.

In the **Connection status** section, the color of the Connection Bar indicates whether the instrument is:

- Not connected - Grey.
- Connected and settings are programmed and stored in the instrument - Green.

Tools

In the **Selection** step, the following are the available tools in the Task pane.

- **Personalisation**

Helps you customise the fitting for a user's specific listening needs. It is recommended that you use it in the first fitting session or when the user's experience level changes.

Be aware that your selections in the **Personalisation** tool only influence the prescription for certain families of instruments, for example Oticon Opn, Oticon Opn S and Oticon More.

- **Acoustics**

Helps you select acoustic coupling to the ear, for example, earpiece, tubing, and vent. Genie 2 applies gain according to the acoustical parameters and the options displayed depend on the instrument style.

If you do not select any acoustics, you are prompted to verify the default before you leave the **Selection** step.

This tool is also available in the **Fitting** step.

- **Audiometric Data**

The **Audiometric Data** tab consists of three tools, Audiogram, Real Ear to Coupler Difference (RECD) and Real Ear Unaided Gain (REUG), and it helps you verify and update audiometric parameters to ensure correct gain prescription. This is mainly relevant when fitting hearing instruments for infants and children.

- **Audiogram**

- Use this tool to specify the measurement method, the transducer and measurement unit used for the audiogram.

- **RECD (Real Ear to Coupler Difference)**

- The RECD tool is useful when fitting children and users who are difficult to test. When you perform a RECD measurement, the degree of cooperation and amount of time required from the user is greatly reduced compared to other REM measurements.

- You can import a RECD measurement from NOAH or enter it manually.

- **REUG (Real Ear Unaided Gain)**

- The REUG tool measures the individual ear canal and makes the fitting more precise according to the individual ear canal of each client. You can import REUG measurements from NOAH, or enter it manually.

- **Firmware Update Tools**

- Helps you update the firmware of hearing instruments and accessories.

- **Instrument Updater**

- You can find firmware version information, what is new in the update and information about the update process.

- Depending on the hearing instrument family, the firmware update can be performed wirelessly.

- **Accessory Updater**

- You can find serial number information for your accessories, current firmware version, available firmware version and status.

Fitting step

In this step, in the **Fine-tuning** screen, you can adjust the gain and use a broad range of tools that you can find in the task pane.

If you have to adjust gain and before you adjust individual controls, consider using the **Adaptation Manager** prior to fine-tuning individual frequency bands.

Tools

In the **Fitting** step, you can find the following tools in the Task pane:

- **Fine-tuning**

- Lets you adjust the gain controls at different output levels and the Adaptation Manager steps.

- **Feedback Analyser**

- Lets you analyse the feedback path and apply feedback margins to the instruments.

- **REM AutoFit**

Lets you automatically and manually fit your client's hearing instruments to the prescribed target using a compatible REM system.

- **REM**

When you use the REM tool, the fitting software automatically sets the hearing instruments in measurement mode for use with your Real Ear Measurement equipment.

Adaptation Manager is set to level 3, and you can select feature settings for measuring with either speech or a noise signal.

- **MoreSound Intelligence™**

Clarifies the sound and effectively suppresses noise when needed to make meaningful sounds stand out from the background. This feature is available in the Oticon More family of instruments.

- **OpenSound Navigator**

Processes sound in simple to complex listening environments. The feature is available in the Oticon Opn, Opn S, Opn Play as well as Oticon Xceed and Xceed Play instruments.

- **Support in Noise**

Adjusts noise reduction and directionality in Oticon instruments. This feature is available in the Oticon Siya and Oticon Ruby instruments.

- **Program Manager**

Lets you add, change, and delete programs. You can configure up to four programs in an instrument.

- **Acoustics**

For more information, read the **Selection** step's **Tools** section.

- **More Tools**

- **Automatic Adaptation Manager**

A three-step process to help the user gradually adjust to the full response of an instrument. There is also a manual Adaptation Manager which can be adjusted during follow-up visits.

- **Automatics**

Helps you control the automatic features such as Transient Noise Management, Spatial Noise Management, Binaural Broadband, Silencer control, and Feedback management.

- **Tinnitus**

Enable and adjust Tinnitus SoundSupport (Read the **Tinnitus SoundSupport** section in this booklet).

- **Speech Rescue / Speech Rescue LX™**

Helps you to enable and adjust frequency lowering.

- **Data Logging**

Provides statistics regarding the use of the hearing instruments for a particular user.

- **In-situ Audiometry**

With this tool you can measure the user's hearing by using the hearing instruments as transducers.

In-situ Audiometry tool

The In-situ Audiometry tool lets you find the user's hearing thresholds using the hearing instruments as transducers.

This means the fitting can be fine-tuned to better match the individual ear canal, taking into account the instrument and the acoustic coupling.

Ensure that the user's instrument is connected to Genie 2 before you open the In-situ Audiometry tool.

To open the in-situ Audiometry tool

- In the **Fitting** step, in the task pane, in the **More Tools** section, click **In-situ Audiometry**.

Tone controls - To change the level and frequency presented

1. In the in-Situ Audiometry tool, in the audiogram graph, the conventional audiogram is represented as a gray curve. On your keyboard, press the **up** or **down** arrow keys to increase or decrease the level of the signal that is presented.

Alternatively, with your mouse, turn the scrolling wheel to increase or decrease the level of the signal.

2. On your keyboard, press the **right** or **left** arrow keys to switch between frequencies. Alternatively, with your mouse, click the graph to select frequency, and turn the scrolling wheel accordingly.

Talk over - To communicate with the user or give instructions during the Audiometry

- To turn ON Talk over, in the In-situ Audiometry tool, in the center of the screen, click the Talk over icon. ↵

Click the button again to deactivate it.

The Talk over icon is turned OFF by default. The amplification for Talk over is based on the conventional audiogram. If there is no audiogram, there will be no amplification.

Play tone - To play a tone in the hearing instrument

- In the middle pane, click the Play Tone button. The tone is played in the hearing instrument and continues as long as you hold the mouse key.
 - To change the tone type, in the bottom left pane, under Tone type, select Continuous or Pulsed.

Audiogram use - To choose the type of audiogram

- To change the type of audiogram used, in the bottom right pane, under Audiogram use, select **Use conventional audiogram** or **Use in-situ audiogram for the measured side(s)**.

Tinnitus SoundSupport

The Tinnitus SoundSupport feature is a tool that generates sounds for use in a Tinnitus management program, to help users suffering from Tinnitus.

You can select and modify sounds to suit the user's preference. Also, the tool is available in all programs except Phone and Telecoil.

To turn Tinnitus SoundSupport ON or OFF

1. In the **Fitting** step, on the Task pane, under the **More tools** group, click **Tinnitus**.
2. In the bottom pane, on the right-hand side of the screen, click the **ON** or **OFF** button respectively.

Ensure that your hearing instrument is connected and that it supports Tinnitus SoundSupport. If you do not see the Tinnitus option in the Task pane, it is possible your instrument does not support it.

End Fitting step

The **End Fitting** step is the final step in the fitting process.

This step helps you connect the accessories to instruments, see all the information about the current fitting, complete your programming of the instrument, as well as save the settings and exit Genie 2.

Tools

The following tools are available in the Task pane:

- **Save and Exit:** Shows you a summary of the connected hearing instruments' features and settings, and lets you save and exit Genie 2.
- **Buttons and Indicators:** This tool helps you define button operation, volume control, beep setting and LED patterns.
- **Batteries:** It shows current battery level, battery health and instructions on how to replace the battery. This is only visible if you are fitting an instrument with a rechargeable battery.
- **Accessories:** You can manage accessories such as smartphones, ConnectClip, TV Adapter, EduMic, Remote Control and DAI/FM.
- **Generate Report:** Print, save or email a selection of reports according to your needs and the user's needs.

To save settings and end fitting session

1. In the **End Fitting** step, click the **Save and Exit** button.
 - If you are running Genie 2 in stand-alone mode, click the **Save and Go to Client Step** button.

You are now presented with the options to save in NOAH or in the stand-alone database. Clear the checkboxes to discard all changes since you last saved.

Note

You cannot discard changes if there is a conflict between the hearing instrument settings and Genie 2 settings.

Optionally, if you want to add a session comment, in the **Save settings** dialog box, in the **Session** comment field, enter your comment or note. The comment appears in the NOAH and Genie 2 stand-alone session lists.

2. When you are finished, click **OK**.

Battery protection mode

The battery protection mode setting preserves battery life for rechargeable hearing instruments, and you can use it when you send an instrument for service or for storing hearing instruments for later use.

To access the Battery protection mode tool, in the top menu click **Tools** and then click **Battery protection mode**.

Note

Battery protection mode is available for the Oticon More™ family of instruments

Oticon RemoteCare™

Oticon RemoteCare enables you to communicate with the user and make real-time adjustments to a user's hearing instrument(s) remotely.

Be aware that if you cannot upload your changes remotely, a physical visit is necessary.

Oticon RemoteCare can be used when a valid audiogram is on record, and it has not changed.

In extraordinary circumstances you may not be able to perform a hearing evaluation in person.

If this occurs, it is recommended that you use an approved remote diagnostic device. For further information, contact your local distributor.

System requirements for the hearing care professional

- Internet Explorer 11
- Internal webcam or external camera device
- Microphone and speakers or headset
- A RemoteCare account. To sign up for an account, contact your local Oticon representative.
- Ensure you have a stable internet connection suitable for both sound and video streaming, with a recommended minimum speed of 1/1 Mbit/s (check with your internet provider).

System requirements for the user

- Oticon More™, Oticon Opn S™, Oticon Opn Play™, Oticon Opn™, Oticon Xceed, Oticon Xceed Play, Oticon Ruby, or Oticon Siya hearing instruments - paired to a user's smartphone / tablet.

- A compatible Apple or Android phone / tablet. To check for compatibility, see the following website:

www.oticon.global/compatibility

A stable internet connection suitable for both sound and video streaming with a recommended minimum speed of 1/1 Mbit/s.

- An email account.

Launch Oticon RemoteCare

To use RemoteCare, you must first create an account and then launch RemoteCare directly from within Genie 2.


IMPORTANT NOTICE

The hearing care professional is responsible to obtain the license needed to use Oticon RemoteCare with users. Oticon does not assume any responsibility.

Create account

To create an account, open the Oticon RemoteCare invitation email sent by your local representative and follow the instructions.

To run RemoteCare

1. In Genie 2, in the Task Pane, in the lower left-hand side, click the RemoteCare button. 
2. In the **RemoteCare** dialog box, in the **Email address** field, enter your email address, and in the **Password** field, enter your password.
3. Click **Sign in**.
4. In the **Tinnitus SoundSupport** dialog box, select the checkbox stating that Tinnitus SoundSupport is not intended for fitting during a RemoteCare session.
5. Click **Continue**.
6. In the **Connect to your client** dialog box that appears, in the field provided, enter the email address of the user you want to connect to, and click **Continue**.

To sign in and start a visit






Note

It is only possible to start a visit when the user has started the visit first, and is waiting for the hearing care professional to join the session.

1. To establish communication with the user, in the **Waiting Room** dialog box, click the **Start a visit** button.
2. To connect to the hearing instruments remotely, in the communicator window, click the **CONNECT** button.
3. If the fitting software recognised the instrument, in the **Wireless Connection Status** dialog box, you can see the detected instruments.
4. Click **OK**.

RemoteCare communicator


The RemoteCare communicator is the interface used to communicate with the user. It allows for text messaging and communication via audio and video between you and the user. The following icons describe the communicator window.


- The  icon enables or disables your camera.
- The  icon mutes or unmutes your microphone.
- The  icon hides the chat dialog box.
- The  icon refreshes the video stream.
- The  icon uploads the fitting settings to the hearing instruments.

To perform a fitting, upload settings, and save

1. In the **Fitting** step, if needed, adjust the hearing instruments as you normally would.

Be aware that not all options are available during a remote fitting session.

2. When you are finished changing the settings of the instruments, you must upload the new settings to your instrument. To do this, in the RemoteCare communicator window, click the **Upload** button. 

It is recommended to click the **Upload** button  after every change made to the hearing instrument, to ensure the user receives the changes in real-time, and to act as a safeguard in the event of a sudden lost connection.

3. To save and end the session, go to the **End Fitting** step and click the **Save and exit** button. If you are using Genie 2 in stand-alone mode, this button may be called **Save and go to Client step**.

Clicking the **Save and exit** button ends the RemoteCare session with the user.

Warnings

For your personal safety and to ensure correct usage, you should familiarise yourself fully with the following general warnings before using your fitting software. Contact your local distributor if you experience unexpected operations or serious incidents with the fitting software during use or because of its use. Serious incidents should also be reported to the national authorities.

General safety precautions

For safety reasons, it is important that you read the Intended Use of the fitting software in the **Introduction** section of this booklet. If you are fitting a hearing aid with Tinnitus SoundSupport, please familiarize yourself with the risks related to the fitting level of the Tinnitus SoundSupport feature, and the recommended wearing times.

Connection

It is important that you do not lose the wired or wireless connection to the hearing instrument or let communication errors interrupt the fitting flow.

Choking hazards

For safety reasons, caution must be taken when fitting children younger than 36 months. Children younger than 36 months must always use a tamper-resistant battery drawer.

For safety reasons, always use ear moulds when fitting children younger than 36 months.

Firmware

During a firmware update, ensure that the user is not wearing the hearing instrument(s) due to the updated instrument being reset to factory settings after the update.

Moreover, do not give the instrument back to the user before restoring user settings, and ensure that the serial number of the connected instrument corresponds to the serial number registered in the office automation system for the relevant user.

It is also important that you are aware of the firmware version of the hearing instrument before and after an update, and that the firmware version of the programming device is compatible with the firmware version of the fitting software.

Avoid interruptions or connection failure to the hearing aid or connectivity device during a firmware update.

REM System

Pay attention to any error messages from the REM system caused by incorrect or unintended data sent to the REM system.

Tinnitus

For safety reasons, always caution the user about limiting the use of Tinnitus SoundSupport feature to ensure safe listening levels.

Be aware of the high sound-pressure level generated by the Tinnitus SoundSupport feature.

Note the recommended limits to the wearing time of the Tinnitus SoundSupport feature as shown in the fitting software. In the print report and the Instruction for Use for the hearing aid, always enter the maximum wearing time per day.

Tinnitus SoundSupport is not intended for users below 18 years of age.

Power instrument

Special care should be exercised in selecting, fitting and using a hearing aid where maximum sound pressure capability exceeds 132 dB SPL (IEC 6038-4) as there may be a risk of impairing the remaining hearing of the hearing instrument user.

Transfer Settings

Ensure that while transferring settings, the user does not wear the hearing instruments.

In-situ Audiometry

Do not use In-situ Audiometry for diagnostic purposes.

Also, before you conduct the In-Situ audiometry, ensure that you add an audiogram in NOAH or in the Client step in Genie 2.

Before you conduct In-situ Audiometry, ensure you remove any REM AutoFit results, and carry out the Audiometry in a quiet area.

Disclaimer

The manufacturer does not take responsibility for the consequences of using this fitting software outside its intended use or warnings.

Technical information



SBO Hearing A/S
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DK-2765 Smørum
Denmark

2020

Declaration of Conformity is available from the headquarters.

Oticon A/S
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Denmark
www.oticon.global/doc

CE 0123



Waste from electronic equipment must be handled according to local regulations.

Description of symbols used in this booklet



Warnings

Text marked with a warning symbol must be read before using the device.



Manufacturer

The device is produced by the manufacturer whose name and address are stated next to the symbol. Indicates the medical device manufacturer, as defined in EU Regulations 2017/745 and 2017/746.



CE mark

The device complies with all required EU regulations and directives. The four digit number indicates the identification of the notified body.



Medical Device

The device is a medical device.



Electronic waste (WEEE)

Recycle hearing aids, accessories or batteries according to local regulations. Hearing aid users can also return electronic waste to their hearing care professional for disposal. Electronic equipment covered by Directive 2012/19/EU on waste and electrical equipment (WEEE).



Global Trade Item Number

A globally unique 14-digit number used to identify medical device products including medical device software.

Description of additional symbols used on labels



Catalogue number

Indicates the manufacturer's catalogue number so that the medical device can be identified.



Consult electronic instructions for use

Indicates the need for the user to consult electronic instructions for use.



Consult instructions for use

Indicates the need for the user to consult instructions for use.

