BESA Connectivity 2.0 - Instructions for Use				
Document ID	Revision Number	Edited by	Reviewed by:	Released by / Date
94860	001/12.2022	Kornwebel, Michael 2022-11-07	Bornfleth, Harald 2022-12-02	Scherg, Tobias 2022-12-03

Description:

This document contains the instructions for use and safety instructions, as well as technical description for BESA Connectivity 2.0.0.0

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Instructions for Use

This document, and following documents form the complete Instructions for Use for this BESA product:

BESA Connectivity 2.0.0.0 - IntendedUse+ProductClassification

BESA Connectivity 2.0.0.0 - User Manual

BESA Connectivity 2.0.0.0 - Update History

BESA License Agreement

BESA Product Symbols - Meaning

BESA License Key - Instructions for Use (and within referred documents)

Current and previous versions of documents are available on BESA website:

eIFU Indicator   https://www.besa.de/downloads/user-documentation/

It is mandatory to read the complete Instructions for Use documents, before using the product.

Product Name

BESA Connectivity 2.0.0.0

Manufacturer

BESA GmbH
Freihamer Strasse 18
82166 Graefelfing/Germany

Symbols used for Product

All symbols used for BESA Connectivity 2.0.0.0 are described in document:
"BESA Product Symbols – Meaning", available on BESA website

Representative inside the European Union

☐ Yes ☒ No

Life cycle

The life cycle of the product ends on 2026-11-11.

Safety Instructions and Technical Description

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System Requirements

This BESA product is a stand-alone SW product compatible with personal computers running under the following hardware/OS:

Operating system:

- o Windows® 10 (64bit version, touch not supported)
- o CPU: minimum 2.5 GHz, >= 4 cores
- o RAM: minimum 8 GB
- o Display resolution: minimum Full-HD 1920 x 1080 pixels
- o Graphics card: OpenGL 3.3 with 128 MB RAM or more

This BESA product was tested on the following operating system configurations:

- Windows 10   Professional 64bit version 22H2

Please note that changes of the hardware or software platforms (e.g., with patches/updates of antivirus/firewall software, system libraries, firmware, and others) and/or changes to the IT network may result in the possibility of safety and/or security vulnerabilities, and/or reduced functionality of BESA products. It is recommended to use the system combinations as defined within this document.

Please also note that the use of BESA products in an IT-network could result in previously unidentified risks to patients, users or third parties, and that the user is responsible to identify, analyze, evaluate, and control these risks. Any subsequent changes to the IT-network could introduce new risks and require additional analysis.

The BESA License Key is an essential accessory product to BESA products, and shall either be subject to constant supervision, or shall be connected to machines located in areas with access restriction. Failure of the IT-network and/or operating system on which the BESA License Key is used, or failure of the BESA License Key in general, may render BESA products which use the BESA License Key as an accessory product unusable.

Data Protection

BESA applications offer the possibility to save files that may include „personal data" as specified in GDPR (Directive 95 /46 EC, General Data Protection Regulation). These files may also include protected health information. Users are strongly advised to inform themselves about applicable regulations. With respect to BESA applications, we especially recommend to not use patient names as part of file names (e.g. for exported data), or to store any data that includes personal data or protected health information on a shared network drive, to which multiple users may have access.

Use in combination with other products

BESA releases are constantly checked with other installations (e.g. MS Office etc.) on the same hardware or software platforms as defined in section System Requirements.

If any incompatibilities are observed, they are documented within the Update History of the product. For further questions and information please use the channels provided on www.besa.de.

Application Environment

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BESA GmbH is not liable for any use/installation beyond the defined PC network.

Installation and Un-Installation

The installation and un-installation of the product must be carried out by the system administrator or an authorized person. This staff bears full responsibility for correct setup of the product within the network.

This BESA product shall only be installed on PC with password-protected user accounts.

Product updates must also be carried out by the system administrator or an authorized person.

Please note, that in case of any problems during the installation, the setup.exe will trigger a rollback of current changes. In that case, please figure out and eliminate the issue, and run the setup.exe again.

To install the product, please follow these steps:

1. Please download the BESA product from our website:
   <Download link will be provided upon release to the market>
2. Run the downloaded setup.exe
3. Please follow the on-screen instructions
4. Towards the end of the installation process, the installation of the BESA License Key setup is triggered, please follow the on-screen instructions, and please refer to "BESA License Key – Instructions for Use" for further information.

Once the installation is complete, proceed with the initial setup as explained in the User Manual.

Exclusions for Use

It is NOT ALLOWED to use this software directly or indirectly for medical purposes and / or treatment of humans.

It is not allowed to use this software in a medical environment, or with any whatsoever intended medical purpose.

Not for diagnostic use in the United States of America!

Contraindication to patients

N/A

BESA is not liable for the use outside of the rules defined in the instructions for use documents.

Manufacture, Transport, Storage and Usage conditions

Environmental conditions for manufacturing

N/A

Environmental conditions for Transport, Storage and Usage

N/A

Countries and Markets

This BESA product may be sold in the following countries and markets:

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Austria	Germany	Malta	Spain	China	Russia
Belgium	Greece	Macedonia	Sweden	Colombia	Saudi Arabia
Bulgaria	Hungary	Netherlands	Switzerland	India	Singapore
Croatia	Iceland	Norway	Turkey	Iran	South Africa
Cyprus	Ireland	Poland	United Kingdom	Israel	South Korea
Czech Republic	Italy	Portugal	Australia	Japan	Taiwan
Denmark	Latvia	Romania	Argentina	Malaysia	Thailand
Estonia	Liechtenstein	Serbia	Brazil	Mexico	Turkmenistan
Finland	Lithuania	Slovakia	Canada	New Zealand	UAE
France	Luxembourg	Slovenia	Chile	Qatar	USA

<The final list of countries will be updated upon release to the market.>

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