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## BESA License Key

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An accessory product to BESA products, which constitute the most comprehensive signal processing toolbox for EEG/MEG source localization, classic ERP/ERF and brain connectivity analysis

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# Safety Instructions<sup>1)</sup>

## Intended User

The intended users at BESA are:

- BESA personnel:
  - Configuration of the licenses provided by the BESA license key to support specific BESA products.

The intended users at the customer site are:

- Administrator:
  - Installation of software required by the BESA license key.
  - Installation of license updates provided by BESA GmbH.
  - Configuration of network environment (if applicable).
- User of BESA programs:
  - If the BESA license key has been configured correctly, no action is required from the BESA product user.

BESA GmbH assumes no liability for unauthorized access to, or unauthorized use of the product.

The product shall not be used by children, laypersons or patients.

## System Requirements

**HASPUserSetup.exe** installs the runtime environment required by the BESA license key. The supplied runtime environment is provided by BESA “as is”, and according to the manufacturer is compatible with computers running the following operating systems or hardware:

**Note:** information supplied by the manufacturer (Thales)

Source:

[https://docs.sentinel.gemalto.com/ldk/LDKdocs/RN/Content/ReleaseNotes/130-Supported\\_Platforms\\_for\\_Sentinel.htm](https://docs.sentinel.gemalto.com/ldk/LDKdocs/RN/Content/ReleaseNotes/130-Supported_Platforms_for_Sentinel.htm) (downloaded 2019-10-29)

### Windows

- Windows 7 SP1
- Windows 8.1 SP1
- Windows Server 2008 R2 SP1
- Windows Server 2012 R2
- Windows Server 2016
- Windows Server 2019
- Windows 10 IoT Enterprise 2019 LTSC
- Windows 10 Version 1903

**Note:** Windows 10 Insider Preview builds are not supported. The latest service packs and security updates must be installed.

## **Virtual Machines**

The VM detection and VM fingerprinting capabilities provided by Sentinel LDK have been validated on the following technologies:

- VMware Player 6.0.3 (Free for non-commercial use)
- VMware Workstation 15
- VMware ESXi 6.5, 6.7
- Hyper-V Server 2019 (SL only)
- Microsoft Azure

Additional tools developed by BESA and required by the BESA license key are installed during the setup of the BESA programs. The operating systems which these tools are intended to run on are listed in the Intended Use document for the relevant BESA product.

The BESA license key is designed to be attached to a USB 2.0 or USB 3.0 port. Please note that you may need to use an adapter to attach the BESA license key to your PC (the adapter is not included).

## Use in Combination with Other Products

The license key is allowed to be used as an accessory product for the following BESA products:

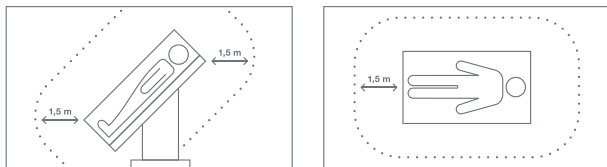
- BESA Research (7.X; incl. all sub-versions)
- BESA MRI (2.X and 3.X; incl. all sub-versions)
- BESA Connectivity (1.X; incl. all sub-versions)
- BESA Epilepsy (2.X; incl. all sub-versions)

## Application Environment

### a) Definition of Patient Environment

#### **IEC 60601-1-Ed.3.1 - Subclause 3.79 - Patient Environment**

It is difficult for this standard to define dimensions for the volume in which diagnosis, monitoring or treatment occurs. The dimensions for the PATIENT ENVIRONMENT given in the following Figure have been justified in practice.



- b) **Please Note:** It is the User's responsibility to ensure the safety of combined medical or medical-&-non-medical-devices particularly installed in the patient environment (whether in institutes, clinics or practitioners' location).

The user of our product has to ensure that such combination fulfils the same safety condition as a single medical device according to IEC 60601-1.

- c) Such combination with any non-medical device establishes an **"in-house medical system"** – observe the latest Medical Device Operator Ordinance (e.g. MedBetreiberVerordnung, Germany 2016) or your national Operator Laws covered by MDD 93/42/EEC.
- d) We recommend you to document / retrace our Software version / updates installed in your facility / network in a MPG Medizingeräte-Buch (medical facilities book), similar to those needed for Hardware.
- e) BESA License Key does not affect the possibility of using any medical computer within patient environment. Our software was tested on the specified IT environment. BESA GmbH is not liable for any use/installation beyond the defined PC network.

## Exclusions for Use <sup>1)</sup>

Contraindications to patients: Not applicable.

BESA is not liable for the use outside of the rules defined in this document.



# Intended Use <sup>1)</sup>

## Intended Use

- The BESA license key is designed for use with the following BESA products:
  - BESA Research (7.X; incl. all sub-versions)
  - BESA MRI (2.X and 3.X; incl. all sub-versions)
  - BESA Connectivity (1.X; incl. all sub-versions)
  - BESA Epilepsy (2.X; incl. all sub-versions)
- The BESA License Key is intended to be used
  - Locally – attached to the PC running the BESA program (see above) or
  - Remotely within a LAN

**Please note:** the BESA license key needs to be attached to the machine or the network throughout the entire session of the relevant BESA program.

**Please note:** in a remote access scenario, the required drivers for using the BESA license key (available for installation as “HASPUsetup.exe”) need to be installed locally on the machine running the BESA program, and on the machine to which the BESA license key is attached.

- The BESA license key is not intended to be used over a VPN tunnel or other remote LAN access methods.
- The purpose of the BESA license key is to provide the licensing for BESA products.

- The BESA license key is not for commercial use, such as fee-based analysis services.
- The BESA license key is only to be used in accordance with the intended use.

## Life cycle

The manufacturer of the BESA license key defines the battery life / warranty as four years after production (see “Sentinel HL Data Sheet.pdf”, roXtra ID 83890, revision 001/06.2018). In document “011-010189-001\_Sentinel HL\_Rev\_J-signed.pdf” (roXtra ID 82774, revision 001/10.2019), the China RoHS mark indicates an Environmental Protection Use Period (EPUP) of 10 years. There is no further information on the life cycle of the BESA license key in the accompanying documents supplied by the manufacturer.

In compliance with the statements of the manufacturer, BESA acknowledges the life cycle of the BESA license key as 10 years.

(Note: even if a battery has run out of power and is not functioning, the license key will still provide licenses for BESA products. The battery is only required if at least one license on the license key is a time-limited license. This scenario may apply if there is a transition phase where a BESA product has been ordered and delivered but payment has not yet been received by BESA. Once payment has been received, a perpetual license is provided to the customer).

BESA takes care only to supply BESA license keys with a life cycle which is at least as long as the life cycle of the accompanying BESA products.

# Licensing System

BESA products are protected by the Sentinel HL licensing system as developed by SafeNet Inc.

The licensing system requires a USB key – that is, the BESA license key – and the device drivers to access the USB key.

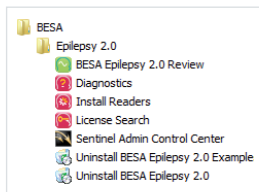
If you selected the **Install BESA license key drivers** option at the final stage of the installation, the device drivers for the BESA license key have been installed automatically on your computer. In order for BESA products to be run, a BESA license key with valid license information must be attached to a USB port on a computer in your local area network. If you have not yet received it, you can obtain the BESA license key from our sales department by contacting [sales@besa.de](mailto:sales@besa.de).

If you have attached the BESA license key (USB key) directly to your computer or server and are not able to start the relevant BESA product, please refer to this manual for troubleshooting tips.



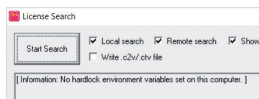
# License Search

1. To check if your BESA license key contains a valid license for starting the relevant BESA product, start the **License Search** application using the shortcut in the **BESA** program group in the start menu.



Alternatively, press the **Start** button and enter “License Search” in order to find the application. You will see the **License Search** application in the search results. Open it.

2. If the BESA license key is connected locally, select the **Local Search** option and press the **Start Search** button.



If you connected the key to a server or to another machine in your network, select the **Remote Search** option instead. If the dongle is displayed, please check the license state and start the relevant BESA product. If the dongle is not displayed, please see the next pages for a solution to the problem.

If installation of the BESA license key fails after carrying out the above steps, the most common reason is that the automatic installation of the device drivers has failed. Please proceed as follows:

3. Disconnect the BESA license key from the local personal computer.
4. Navigate to the **C:\Program Files (x86)\BESA\<Your BESA product>\Utilities\License\System\** folder located on the hard disk, and run the HASPUserSetup.exe to install the device drivers manually.

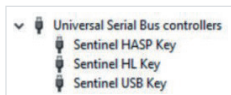
## Troubleshooting

If the key is still not working correctly, it may be due to one or more of the following reasons.

- BESA license key is not connected.

**Solution:** Ensure that the USB key is accessible in order to run the program. If the USB key is installed correctly, the Windows Device Manager lists three items in the “Universal Serial Bus controllers” section:

- Sentinel HASP Kkey
- Sentinel HL Key
- Sentinel USB Key



- USB port is defective.

**Solution:** Check if the LED light is illuminated on the BESA license key. If not, remove and re-insert the key. Wait for the operating system to detect the device. If it still fails to light up, try another USB port or request a replacement dongle.

- Dongle is faulty.

**Solution:** On rare occasions, the BESA license key may be faulty. The dongle does not light up in this case and is not detected in the Device Manager. Request a replacement dongle.

- Sentinel LDK License Manager Service is blocked by a fire wall or an antivirus application.

**Solution:** Add **C:\Windows\system32\hasplms.exe** to the list of the antivirus and firewall exceptions.

- Port 1947 is blocked by a firewall application.

**Solution:** Add port 1947 to the list of firewall exceptions.

- Sentinel LDK License Manager Service is stopped.

**Solution:** Restart the Sentinel LDK License Manager Service (**Control Panel** → **Administrative Tools** → **Services**).

# Individual License Settings: Sentinel Admin Control Center (ACC)

The Sentinel runtime environment includes the device drivers and the **Sentinel Admin Control Center (ACC)**. ACC can be used to monitor licenses and sessions when a protected application is operating, and to manage detachable licenses. To access the ACC, please start the **Sentinel Admin Control Center** program from the **Apps / BESA** program folder, or simply enter the following address in your internet browser (an internet connection is not required): <http://localhost:1947>.

Important administrative options:

The **Sentinel Keys** page shows which BESA license keys are currently present in the network, including locally connected keys.

The **Sessions** page lists all client sessions on the local machine, and also client sessions logged in remotely to the local machine. This page enables you to view session data and to delete sessions.

The **Configuration** page enables you to specify basic settings. You can also configure access to or from other computers. To determine that the license on the local BESA license key can be used only locally on that particular computer, for example, switch to the **Access from Remote Clients** tab and deselect the **Allow Access from Remote Clients** option.



# Product Classification<sup>2)</sup>

The BESA license key is not a medical device. It is used in combination with BESA products in order to provide the necessary licenses. The products cannot be used by intended users if the license key is not functional. Thus, we declare the BESA License Key as accessory product to all BESA products listed in the Intended Use section of this document.

## **Classification according to MDD**

**BESA License Key is an accessory to medical product according to MDD 93-42-EEC Article 1**

## **MDD 93-42-EEC ANNEX IX CLASSIFICATION CRITERIA**

### **Product Classification**

According to **MDD, Annex IX, II. IMPLEMENTING RULES**

2.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.

According to **MDD, Annex IX, III. CLASSIFICATION**, rule(s):  
Rule 12; All other active devices are in **Class I**.

**Note:** The software required to process the BESA license key is not developed by BESA, nor is the software which installs and provides the runtime environment. BESA customizes the default software settings of the BESA license key, however, and develops dedicated software to handle the BESA license key. BESA thus commits to follow the requirements of IEC 62304:2006/AMD1:2015.

*“IEC 62304:2006/AMD1:2015; Section 1 Scope, Subsection 1.2 Field of application – This standard applies to the development and maintenance of MEDICAL DEVICE SOFTWARE when software is itself a MEDICAL DEVICE or when software is an embedded or integral part of the final MEDICAL DEVICE.”*

According to safety classifications in IEC 62304:2006/AMD1: 2015, BESA declares the BESA License Key as software safety class A.

## Disposal Information

The BESA license key and the box must be disposed of according to the national guidelines on environmental protection.

## Environmental Conditions for Transport, Storage and Usage<sup>1)</sup>

Temperature: -20°C to 60°C

Humidity: 30 % to 85 %

## Product Labelling<sup>3)</sup>

Product and accessory products are marked by symbols, as described in:

- BESA Product Symbols

# Regulatory Requirements

According to the declaration of conformity provided by the manufacturer, the BESA license key conforms to the following:

- EMC Directive 2014/30/EU
- FCC Part 15, Subpart B, CLASS B
- VCCI V-3:2014
- ICES-003: Issue 6:2016
- AS/NZS CISPR32:2015
- KC (Korean Certification)
- IEC 60950-1:2005 (2ndEdition) +Am1:2009
- EN 60950-1:2006 +A11:2009+A1:2010+A12:2011+A2:2013
- UL 60950-1-07+A1:2011□CAN/CSA-C22.2 No. 60950-1-07
- AS/NZS 60950-1:2011+A1:2012
- EU Regulation1907/2006/EC for Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
- EU Directive 2011/65/EUfor Restriction of Hazardous Substances (RoHS2.0) and amending Annex II (EU) 2015/863
- GB/T 26572-2011for Requirements of concentration limits for certain restricted substances in electrical and electronic products (China RoHS)
- P&PW 94/62/EC
- 2012/19/EUWEEE (Waste Electrical and Electronic Equipment)

# Instructions for Use

Together with this booklet, the following documents form the complete Instructions for Use for the BESA license key:

- BESA License Agreement
- BESA License Key Manual
- BESA Product Symbols
- BESA License Key - Update History

# Installation Instructions

- Installing Sentinel Runtime

Installation and de-installation of the product must be carried out by the system administrator or an authorized person.

This person bears full responsibility for correct setup of the product within the network. If you need a separate setup file for **HASPUserSetup.exe** to install the driver on a server to which the BESA license key is attached but no BESA products are running, for example, you can download a current version of **HASPUserSetup.exe** that has been released for use with BESA products:

<https://www.besa.de/downloads/besa-license-key/>

If you apply updates to **HASPUserSetup.exe**, make sure to roll out the updates to all machines running BESA products, or to update the machine to which the BESA license key is physically attached. To install the software required to use the BESA license key, you need to have administrator privileges on your computer. The screenshots below are taken from an installation on a computer running Windows 10. They may look slightly different on other operating systems

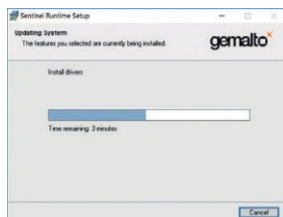
1. The **Sentinel Runtime Installation Wizard** opens. Press the **Next** button to continue.



2. Please read the license agreement. If you agree to the terms, select **I accept the license agreement** and press the **Next** button to continue..



3. It may take a few minutes to install the drivers and update the system..



4. Installation of the Sentinel Runtime is now complete. Press the **Finish** button.



- Installation of updates to the BESA license key

If you have ordered a license update, you will receive information by e-mail on how to proceed once the sales process has been finalized.

**Please note:** to run the license update correctly, you either need to attach the BESA license key locally to your PC, or establish a remote desktop connection to the PC/server to which the BESA license key is attached

## Interaction With BESA Programs

The BESA license key is a “Sentinel HL NetTime 10” dongle produced by Thales (formerly Gemalto, SafeNet, Aladdin). The BESA license key provides copy protection for BESA software, and can protect one or more BESA programs. Individual BESA products or modules can be activated using HASP features (slots) within the BESA license key. These are USB dongles which provide the license/s locally or within a network.

For the purposes of communication between BESA products and the BESA license key, the manufacturer uses TCP and UDP ports 1947. Please make sure to open these ports within your network or IT environment in order to enable the required communication.

Once the license key driver is installed, you can find more information on settings, security and general topics concerning the BESA license key under the following link:

[http://localhost:1947/\\_int\\_/ACC\\_help\\_index.html](http://localhost:1947/_int_/ACC_help_index.html)

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**REFERENCES:**

- 1) BESA License Key – Intended Use + Product Classification  
Revision 005/09.2020; Document ID: 87311
- 2) BESA License Key - Product Classification  
Revision 003/09.2020; Document ID: 87318
- 3) BESA Product Symbols  
Revision 004/06.2020; Document ID: 86227

RoHS 2011/65/EU – SafeNet Inc., a subsidiary of Gemalto, certifies that to its knowledge our products conform to the European Union's Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment, Directive 2011/65/EU for ten regulated substances shown as below, comply with the limits as set by RoHS directive (EU) 2015/863 amending Annex II to Directive 2011/65/E.

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The CE marking certifies that this product fulfills the essential requirements of the Medical Devices Directive MDD 93/42/EEC.

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