



BESA License Key

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 Instructions¹⁾

Intended User

The intended users within BESA are:

- BESA personnel:
 - Configuration of the licenses provided by the BESA License Key to support specific BESA products.

The intended users at 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 configuration of BESA License Key has been done correctly, no action from user of BESA products with respect to license key required.

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

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

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:

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 20H2

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 Workstation 15
- VMware ESXi 6.5, 6.7
- Microsoft Azure

Note: information supplied by the manufacturer (Thales)

Source:

https://docs.sentinel.thalesgroup.com/ldk/LDKdocs/RN/ReleaseNotes/130-Supported_Platforms_for_Sentinel.htm#Sentinel4, downloaded on 2021-09-07, available in

S:\External Programs\HASP (SafeNet, Sentinel, Gemalto)\Sentinel_LDK_Run-time_setup V. 8.21\ Supported Platforms for Sentinel LDK End Users and Vendors.pdf).

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).

The BESA License Key has been tested by BESA on the following operating systems:

- Windows® 10 Professional 64bit version 2004
- Windows® 10 Professional 64bit version 20H2
- Windows® 7 Professional 64bit Service Pack 1

Please note: changes of the hardware and 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 License Key. It is recommended to use the system combinations as defined within this document.

Please note: the use of BESA License Key on 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 as an essential accessory product shall be kept under personal observation or shall be connected to machines located in areas with access restriction. Failure of the IT-network and/or operating system where the BESA License Key is used, or failure of the BESA License Key in general, may result in unusable BESA products, to whom the BESA License Key is used as an accessory product.

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 (3.X; incl. all sub-versions)
- BESA Connectivity (1.X; incl. all sub-versions)

The license key is allowed to be used with the following support tools of BESA:

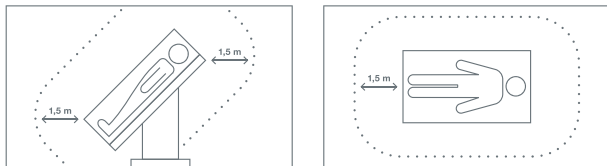
- Diagnostics.exe (8.X; incl. all sub-versions)
- License Search.exe (3.X; incl. all sub-versions)
- HLUpdate.exe (1.X; incl. all sub-versions)

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 2020) or your national Operator Laws.
- 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 ¹⁾

Contraindications to patients: Not applicable.

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

Intended Use ¹⁾

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.

- The BESA License Key is designed for use with the following BESA products:
 - BESA Research (7.X; incl. all sub-versions)
 - BESA MRI (3.X; incl. all sub-versions)
 - BESA Connectivity (1.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 “HASPUserSetup.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 4 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 Thales.

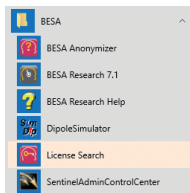
The licensing system requires a USB key – that is, the BESA License Key – and the device drivers to access the USB key. If you selected the **Install BESA License Key drivers** option at the final stage of the installation, the device drivers for the BESA License Key have been installed automatically 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.

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.



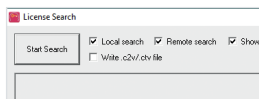
License Search

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.

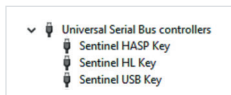
Troubleshooting

If BESA License 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 BESA License Key is accessible in order to run the program. If BESA License 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 firewall 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.

Note: that changes to **Configuration** page may result in restriction of availability of licenses for BESA products, and thus provide these products from running. Access to machines where Sentinel Admin Control Center (ACC) is installed shall therefore be restricted.

Product Classification²⁾

The BESA License Key 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.

Conclusion of Assessment of Medical Device Class and Software safety classification

Medical Device Class	
BESA License Key is an accessory for a medical device	according to MDR - EU Regulation 2017/745; Article 2
Designed for long term use	according to MDR - EU Regulation 2017/745; ANNEX VIII: CLASSIFICATION RULES; CHAPTER I: DEFINITIONS SPECIFIC TO CLASSIFICATION RULES; 1. DURATION OF USE; Section 1.3
Class I	according to MDR - EU Regulation 2017/745, ANNEX II; 6.3. Rule 11 and 6.5. Rule 13
Software Safety Classification	
Software Safety Class A	Is assigned to BESA License Key, according to IEC 62304:2006/AMD1:2015

Disposal Information

The BESA License Key and the box in which it is delivered must be disposed of in compliance with national guidelines on environmental protection.

Environmental Conditions for Transport, Storage and Usage ¹⁾

Temperature: -20°C to 60°C

Humidity: 0 % to 95 %

Product Labelling ³⁾

Products and accessory products are labelled with symbols as described in: BESA Product Symbols

Regulatory Requirements

The BESA License Key shall be certified at least according to the following standards or normative documents by the manufacturer:

- EMC Directive 2014/30/EU.
- EU Regulation 1907/2006/EC for Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- EU Directive 2011/65/EU for Restriction of Hazardous Substances (RoHS 2.0) and amending Annex II (EU) 2015/863.
- GB/T 26572-2011 for Requirements of concentration limits for certain restricted substances in electrical and electronic products (China RoHS).
- 2012/19/EU WEEE (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

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.

Installing Sentinel Runtime

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/>

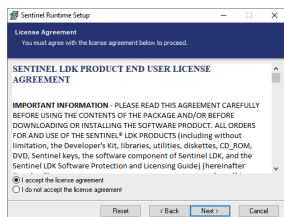
If you apply updates to HASPUserSetup.exe, make sure to roll out the updates to all machines running BESA products, or to update the machine to which the BESA License Key is physically attached.

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.

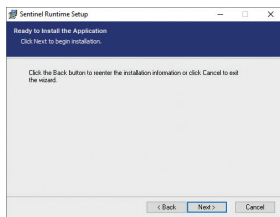
1. The **Sentinel Runtime Installation Wizard** opens. Press the **Next** button to continue.



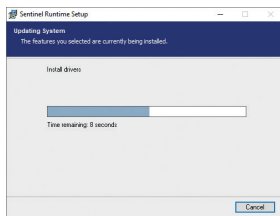
2. Please read the license agreement. If you agree to the terms, select **I accept the license agreement** and press the **Next** button to continue..



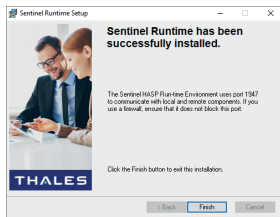
3. The runtime is ready for installation. Please press the **Next** button to continue



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



5. 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 that 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.

Uninstalling Sentinel Runtime

Uninstallation of the product must be carried out by the system administrator or an authorized person. This person bears full responsibility for correct deinstallation of the product within the network.

In the Windows operating system, open “Control Panel\All Control Panel Items\Programs and Features”. Search for “Sentinel Runtime”, click on the name and select Uninstall.

The uninstallation wizard will run, uninstalling the **HSAPUser-setup.exe** (Sentinel Runtime).

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REFERENCES

- 1) BESA License Key – Intended Use + Product Classification
Revision 007/10.2021; Document ID: 87311
- 2) BESA License Key – Product Classification
Revision 005/09.2021; Document ID: 87318
- 3) BESA Product Symbols
Revision 005/09.2021; Document ID: 86227

RoHS 2011/65/EU – SafeNet Inc., a subsidiary of Gemalto, certifies that to its knowledge our products conform to RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment for ten regulated substances, and comply with the limits set by RoHS Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU.

This product is marked with 

BESA License Key is an accessory product for medical devices according to Regulation (EU) MDR 2017/745, Article 2.

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