



Instructions for use



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3.0.0



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Notified body:
mdc medical device certification GmbH,
Kriegerstrasse 6, 70191 Stuttgart, Germany



ARCSolver is a medical device



UDI-DI	Operating System
(01)09120109830160	Linux (Desktop)
(01)09120109830184	Windows (Desktop)
(01)09120109830191	Mac (Desktop)
(01)09120109830207	Android (Mobile)



Caution: Please read paragraphs marked with this symbol carefully as they contain important safety information.

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1 What is the Intended Purpose of ARCSolver?

The ARCSolver is a computational analysis module for retrospectively analyzing recorded digital signals from a suitable pressure sensor or transducer that meets the specifications and limitations in section "Limitations and Exclusions". The analysis includes the execution of algorithms to determine specific characteristics of the pulse wave, reflecting certain aspects of the cardiovascular system.

The software module does not provide any interactive components for user interaction, nor does it produce any graphical output itself.

The transfer of pulse wave and user specific data to the software module is done using a documented application programming interface (API), which manufacturers can integrate into their systems. Hence, **ARCSolver** is provided as microservice.

1.1 Intended User

The intended users for interpreting the output of **ARCSolver**, i.e., parameters of the cardiovascular system, are physicians, persons who perform medico-technical assistance professions and nursing staff with a respective relevant qualification.

Furthermore, this microservice is intended to be integrated into other software systems by qualified software developers.

1.2 Patient population

ARCSolver is intended to be used on pulse wave recordings of humans in the age range of 18 to 100 years. Furthermore, limitations in section "Limitations and Exclusions" apply on individual basis.

1.3 Medical indication

The software module **ARCSolver** serves as a module for retrospectively analyzing recorded data from a suitable pressure sensor or transducer. The analysis includes algorithms to determine specific characteristics of the pulse wave, reflecting certain aspects of the cardiovascular system. In addition, an error code is returned as to whether the calculation was successful or the reason for premature termination of the calculation. Furthermore, a quality indicator representing the degree of credibility is returned.

ARCSolver is intended to be integrated into other software systems, especially those that support professional medical users in the assessment of cardiovascular characteristics. This software module is intended to be integrated into other software systems by qualified software developers using a defined API.

ARCSolver performs the calculation of a set of quantitative measures from the pulse wave form intended to describe and reflect the state of the cardiovascular system. These quantitative measures should always be interpreted by qualified medical practitioners in conjunction with review of the original wave forms, medical history, and professional judgement.

ARCSolver does not provide any diagnostic conclusion about the patient's condition.



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1.4 Contraindication and unwanted side effects

There are no known contraindications or unwanted side effects.

1.5 Limitations and Exclusions

The **ARCSolver** microservice must be professionally integrated into the target system by qualified software developers, according to specifications enclosed with the product, and the correctness of the integration must be verified and validated.

The results of the **ARCSolver** software module for the automatic analysis of pulse wave recordings should always be interpreted by qualified medical practitioners in conjunction with review of the original wave forms, medical history, and professional judgment. As with any automatic procedure, inaccuracies can occur during the analysis. Values that do not seem plausible must therefore be ignored. Professional judgement always takes precedence over the automatic evaluation.

ARCSolver does not provide any diagnosis, diagnostic recommendation, or conclusions of the patient's state. It remains the responsibility of the medical practitioner to decide on the diagnosis or to induce treatment.

The pulse wave data must be recorded with a suitable pulse wave recorder and from a suitable pressure sensor or transducer. These components and the recording are deemed suitable if:

- The recording is performed in homeostasis, i.e., the patient is at rest and not moving.
- The recording is performed in a stable clinical haemodynamic presentation of the patient. ARCSolver must not be

used in emergency situations.

- The recording is performed at constant diastolic to sub-diastolic (5 mmHg below diastolic) pressure level.
- The raw pulse wave recording is sampled with 100 Hz for 10 seconds and with a resolution of at least 10 bit.
- The recording is performed at the brachial or radial artery.
- The provided pulse wave signal is band-pass filtered with a filter of first order within a range of 0.1 Hz and 25 Hz or equivalent.
- The recording system provides a resonant frequency greater 50 Hz

Limitations regarding the patient data:

- Valid range for the peripheral arterial blood pressure in Millimeters of Mercury (mmHg):
 - Systolic (SBP): 45 to 300 mmHg.
 - Diastolic (DBP): 0 to 255 mmHg.
 - Mean (MAP): 35 to 290 mmHg (only applicable if used for calibration).
- The person's heart rate must be in the range of 40 to 140 beats per minutes (bpm).
- The person's height must be in the range of 45 to 250 centimeters.
- The person's weight must be in the range of 11 to 300 kilogram.

The use in children aged under 18 is not allowed, because there are not enough clinical evaluation and validation data available for a reliable use in children.

	<i>The use in children aged under 18 is not allowed, because there are not enough clinical evaluation and validation data available for a reliable use in children.</i>
	<i>ARCSolver must not be used in emergency situations.</i>

2 What are the main functions of ARCSolver?

ARCSolver aids the qualified user in the retrospective analysis and review of data from a suitable pressure sensor or transducer. **ARCSolver** offers an API to hand over suitable pulse waves, medical and patient data (e.g., peripheral blood pressure, age, sex) and to return cardiovascular parameters (i.e., values reflecting certain aspects of the cardiovascular system).

The transfer of pulse wave and user specific data to the software module and return of the results is done using a documented application programming interface (API), which manufacturers have to integrate into their systems. The medical device consists of a single software component, as all functions and calculations are closely interlinked. It is provided as single stand-alone microservice with two interfaces.

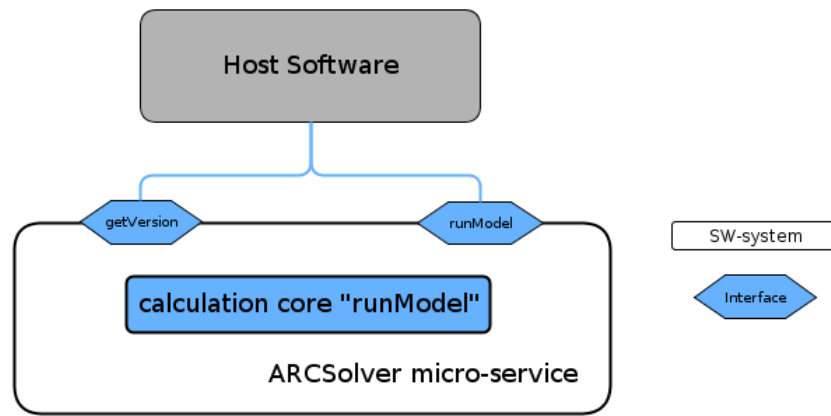


Figure 1 Overview main software components

getVersion

This function returns the device label, including the version of ARCSolver, the UDI, and further information, as a JSON string or PNG graphic.

runModel

This function takes the following input parameter:

- sBP (systolic blood pressure in mmHg)
- dBP (diastolic blood pressure in mmHg)
- curve (10 seconds pulse wave recording at 100Hz, see figure below for example)
- hr (heart rate during blood pressure measurement)
- age (age of the patient at the time of measurement)
- sex (biological sex of the patient)
- height (height of the patient in cm)
- weight (weight of the patient in kg)
- calibrationMethod (to indicate the calibration method: systolic or mean pressure)
- huckDetection (to indicate the artifact detection method)
- map (mean arterial pressure in mmHg)

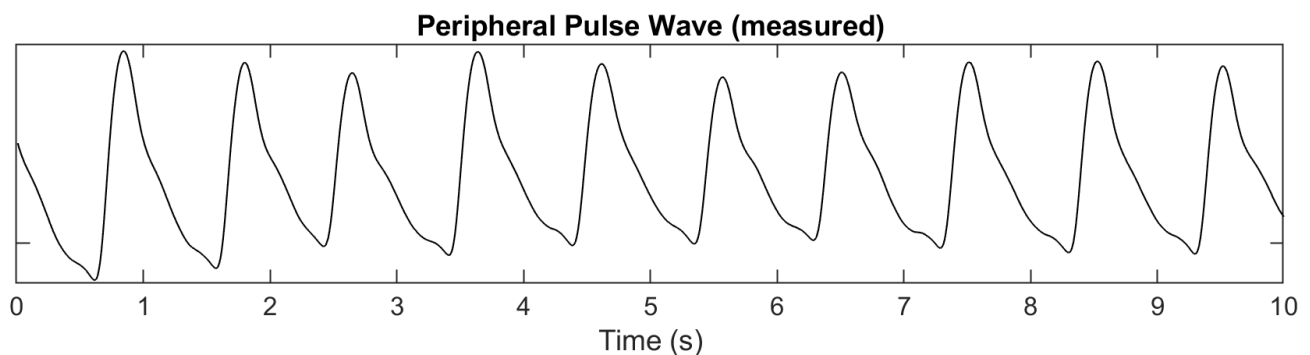


Figure 2 Example of a recorded peripheral pulse wave

The parameter sex can have the values below. Only biological sex is relevant for ARC solver calculations. Therefore, one of the following two options must be selected here.

- Male = 1

- Female = 2

The parameter calibration can have the values:

- calibration_mean = 1
- calibration_systolic = 2

The parameter huckDetection can have the values:

- huckDetection_no = 0
- huckDetection_yes = 1

Explanation for the input parameter "huckDetection":

The "Huck" artifact type is an unphysiological slow increase in pressure before the actual systolic upstroke (marked in red in the figure below). Reasons for the occurrence of this artifact include a too high (above the diastolic) recording pressure and certain signal filters. Activating Huck detection causes ARCSolver to reject such recordings. Deactivating Huck detection causes ARCSolver to recognize the first pressure rise as the start of systole, which leads to incorrect results if the Huck artifact is present.

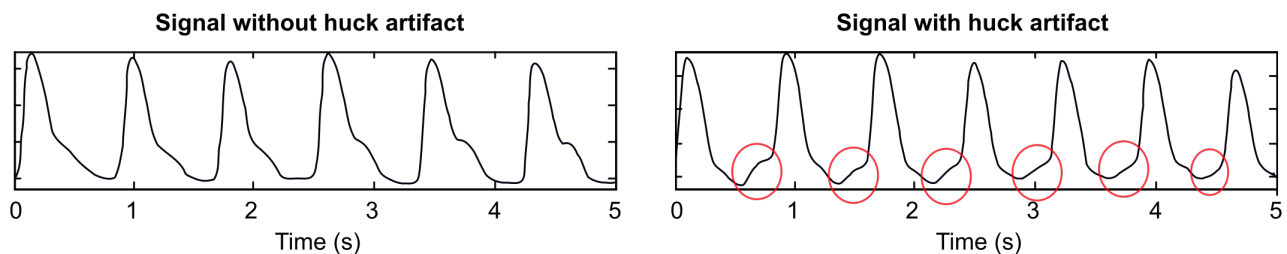


Figure 3 Comparison between an input signal without (left) and with (right, marked in red) "Huck" artifacts

The function returns the following output parameter:

- hr (heart rate during pulse wave measurement)
- sv (stroke volume in ml)
- ca (compliance in ml/mmHg)
- rp (Peripheral resistance in s*mmHg/ml)
- aix (augmentation index as ratio)
- CDBP (central diastolic blood pressure in mmHg)
- CSBP (central systolic blood pressure in mmHg)
- IBP (inflection point blood pressure in mmHg)
- tCSBP (time of systolic blood pressure in s)
- tIBP (time of inflection point in s)
- mean central curve (in mmHg)
- error code
- quality
- reflection magnitude (as ratio)
- central forward wave (in mmHg)
- tmaxpf (time of maximum of forward wave in s)
- tmaxpb (time of maximum of backward wave in s)
- tbeginpb (time of initiation of backward wave in s)

- pf_amp (Amplitude of the forward propagation wave in mmHg)
- pb_amp (Amplitude of the backward propagation wave in mmHg)
- pwv (Pulse wave velocity in m/s)
- mean central curve with enhanced AIX detection point (in mmHg)

2.1 Description and recommendations for Output parameters

The following table provides an overview of the ARCSolver output parameters and recommended settings for the input parameter "calibration". The table provides parameter descriptions, their units as well as the assignment to the parameter group (e.g. PWA, HD etc.). In order to achieve the best possible results for the calculation with ARCSolver for the respective output parameters, the following table contains recommendations for the input parameter "Calibration" (see input parameters in chapter 2) for each output parameter.

Furthermore we recommend displaying primary parameters of a related group together. However, there is no obligation or physiological necessity to follow this recommendation. Auxiliary graphics parameter can be used to display pulse waves and mark certain features in the waves.

Abbr.	Parameter Group Parameter Name	Unit	Primary Parameter	Auxiliary graphics parameter	Recommend- ed calibration	Range	Comment
Pulse Wave Analysis (PWA)							
hr	Heart Rate	bpm (1/min)	X		2 (Systole)	40 to 140	
aix	Augmentation index	1 (ratio)	X		2 (Systole)	-0.2 to 0.6	Recommended to be transformed to % by multiplying with 100
centralWave	Central pulse wave	mmHg		X	2 (Systole)	0 to 900	150 values within one heart beat (length/s = 60 / Central heart rate)
enhancedCentralWave	Central pulse wave with enhanced inflection	mmHg		X	2 (Systole)	0 to 900	150 values within one heart beat (length/s = 60 / Central heart rate)
CSBP	Central systolic blood pressure	mmHg	X		2 (Systole)	0 to 900	
CDBP	Central diastolic blood pressure	mmHg	X		2 (Systole)	0 to 300	
tIBP	Inflection time	s		X	2 (Systole)	0 to 1.5	
IBP	Inflection pressure	mmHg	X		2 (Systole)	0 to 900	
Hemodynamics (HD)							
sv	Stroke volume	ml	X		1 (MAP)	30 to 130	
ca	Compliance	ml/mmHg	X		1 (MAP)	0.5 to 2.2	
rp	Peripheral resistance	s*mmHg/ml	X		1 (MAP)	0.5 to 2.8	
tCSBP	Systole time	s		X	2 (Systole)	0 to 1.5	
Wave Separation Analysis (WSA)							
refCoeff	Reflection coefficient	1 (ratio)	X		2 (Systole)	0 to 1	Recommended to be transformed to % by multiplying with 100
forwardWave	Central ejection (forward) wave	mmHg		X	2 (Systole)	0 to 900	150 values within one heart beat (length/s = 60 / Central heart rate)
tmaxpf	Time of maximum of forward wave	s		X	2 (Systole)	0 to 1.5	
tmaxpb	Time of maximum of reflection (backward) wave	s		X	2 (Systole)	0 to 1.5	
tbeginpb	Time of initiation of reflection (backward) wave	s		X	2 (Systole)	0 to 1.5	

pf_amp	Amplitude of ejection (forward) wave	mmHg	X		2 (Systole)	0 to 900	
pb_amp	Amplitude of reflection (backward) wave	mmHg	X		2 (Systole)	0 to 900	
	Pulse Wave Velocity (PWV)						
pwv	Pulse wave velocity	m/s	X		2 (Systole)	0 to 50	
	Quality Parameters						
	Error Code	Enum	X		2 (Systole)	0 to 4	
	Quality	Enum	X		2 (Systole)	1 to 4	

The parameter errorCode can have the values:

- NoError = 0, // no Error
- BadQuality = 1, // Abort due to bad signal quality
- StrokeVolume = 2, // Error in stroke volume calculation
- InputSignal = 3, // Error in input signal format
- InputParameter = 4 // Error in input parameters

The parameter quality can have the values:

- Good = 1
- Medium = 2,
- Poor = 3, // Treat results with caution
- Canceled = 4 // Calculation aborted

2.2 User interface

ARCSolver is a stand-alone microservice with two interfaces. ARCSolver does not provide any graphical user interface.

The following figure provides an example of typical results with the central pulse wave, the wave separation and some of the parameters mentioned in the section above:

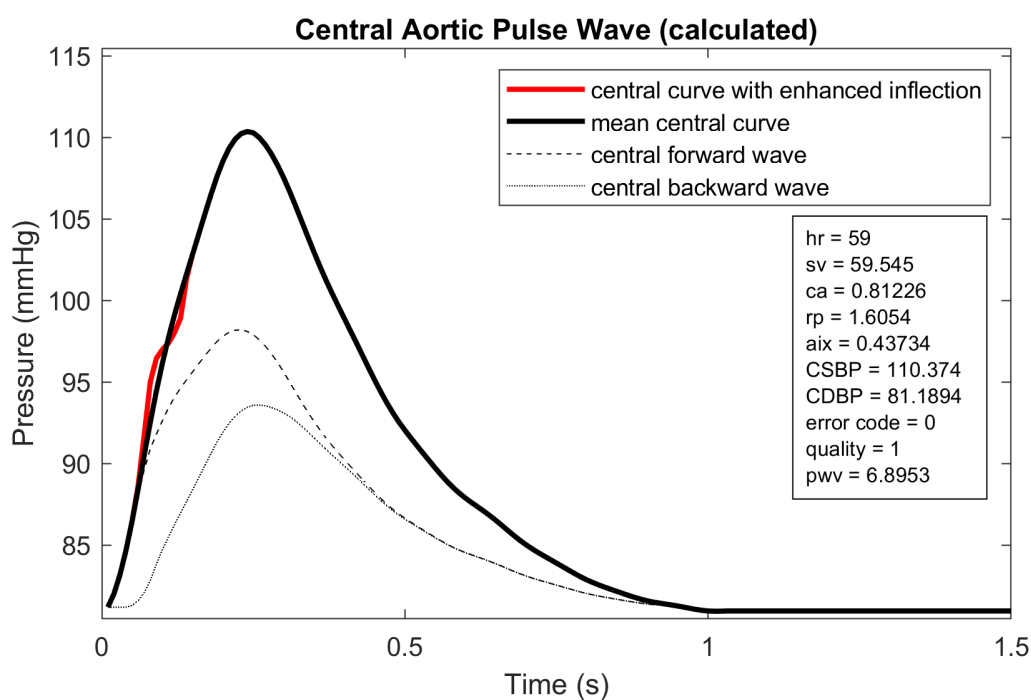


Figure 4 Graphical representation of returned raw data.

3 How long is the lifespan of ARCSolver?

The lifespan of the **ARCSolver** ends on December 31, 2029, which is also the average and expected lifetime or support life of compatible pulse wave recorders. Furthermore, **ARCSolver** must not be used on computers running an operating system that is not longer maintained by the manufacturer. As of these dates, no more error corrections will be performed for **ARCSolver** on the named operating system and this version of **ARCSolver** may no longer be used.

4 What are the restrictions on use?

	The ARCSolver microservice must be professionally integrated into the target system by qualified software developers, according to specifications enclosed with the product, and the correctness of the integration must be verified and validated.
	ARCSolver does not provide any diagnosis, diagnostic recommendations or prognoses about the condition of the patient. It remains the physician's responsibility to decide on diagnoses and treatment.
	ARCSolver must not be used in emergency situations.
	The use in children aged under 18 is not allowed, because there are not enough clinical evaluation and validation data available for a reliable use in children.
	The results of the ARCSolver software module for the automatic analysis of pulse wave recordings should always be interpreted by qualified medical practitioners in conjunction with review of the original wave forms, medical history, and professional judgment. As with any automatic procedure, inaccuracies can occur during the analysis. Values that do not seem plausible must therefore be ignored. Professional judgement always takes precedence over the automatic evaluation.

5 Which application environment is necessary?

The medical device is a supplement to software systems capable of loading compatible data from a pulse wave recorder. The output of the medical device can be used within a hospital, a doctor's office, or other qualified medical facilities. Also mobile use on a laptop outside a doctor's office or a hospital is possible. The medical device can be used wherever the proper use of the required computer hardware is ensured. The supported operating systems are described in the chapter "Technical Data".

The instructions for use are provided in .pdf-format. To be able to visualize the PDF or rather open it, the professional user requires a software which is capable of reading PDFs of version 1.5 and above (e.g. Adobe Reader 6.0 or higher).

6 How is ARCSolver installed and launched?

The medical device is a pure software product, which will be delivered as a single configuration, therefore this section is not applicable. The software module will be given to customers for integration into their existing software packages. A description for integrating the ARCSolver as a microservice by using the interface is described in detail in the "Integration Manual".

7 Which service and maintenance measures are prescribed?

ARCSolver does not require any particular service. The manufacturer has nevertheless the possibility to issue updates in irregular intervals. The manufacturer or the distributor will inform the user about these updates. It is recommended to promptly install these updates. Although the computer hardware is not part of encevis it is recommended to service the computer hardware running encevis in regular intervals. Particular attention should be given to ensure that sufficient free storage space is available for the operating system to run faultless. The user needs to ensure that the hardware of the computer system fulfills the minimum requirements that are listed in this document.

8 Can ARCSolver be combined with other medical products?

The device is a stand-alone microservice. In order to function, it must be integrated into a host software using an external interface. This interface is used by the integrator who wants to integrate the ARCSolver into their system. The external interface contains one function to retrieve product information (e.g., version number and UDI), and one to analyze the pulse wave data and retrieve the results. ARCSolver does not control the unit that integrates and accesses the microservice. The integrating unit must always actively ask for any type of data.

Furthermore, a description for integrating the microservice using the interface can be found in the "Integration Manual".

9 How is ARCSolver disposed?

ARCSolver can be completely removed by the uninstall mechanisms that are provided by the integrating host system.

10 Clinical Performance

Parameter	Mean Difference / Standard Deviation	Reference
Central systolic blood pressure (cSBP)	MD 5 mmHg +/- SD 8 mmHg, 85 Subjects	EN 81060, AAMI SP10
Central diastolic blood pressure (cDBP)	MD 5 mmHg +/- SD 8 mmHg 85 Subjects	EN 81060, AAMI SP10
Augmentation index (AIx)	MD 5 % SD 8 %	No norm existent, comparison against Gold Standard
Inflection pressure Augmentation pressure	MD 5 mmHg +/- SD 8 mmHg	EN 81060, derived parameter from central systolic and diastolic blood pressure and augmentation index.
Characteristic Impedance	Arbitrary Units MD 10% SD 20%	No norm existent, comparison against Gold Standard

Pulse Wave Velocity (PWV)	MD 1 m/s SD 1.5 m/s	Wilkinson et al., ARTERY Society guidelines for validation of non-invasive haemodynamic measurement devices: Part 1, arterial pulse wave velocity
Amplitude (Forward) ejection wave	MD 5 mmHg SD 8 mmHg	EN 81060, AAMI SP10
Amplitude (Backward) reflection wave	MD 5 mmHg SD 8 mmHg	EN 81060, AAMI SP10
Reflection Magnitude	AU	Index derived from forward/backward wave
Stroke Volume	MD 10 ml SD 20 ml	No norm existent, comparison against Gold Standard and dedicated medical guidelines.
Total Vascular Resistance (TVR)	N.A.	Total Vascular Resistance is directly linked to Stroke Volume via Mean Arterial Blood Pressure. Therefore correct Stroke Volume estimation will lead to correct TVR.

11 Technical Data

Supported operating systems	- Windows (10 - 11 with x64 CPU) - macOS (10.14 - 13 with x64 or Apple Silicon CPU) - Linux (kernel 4.18 – 6.6.1 with x64 CPU) - Android (5.1 and 8.0 - 13 with ARM CPU)
Minimum requirements for Hardware	- x64 or ARM compatible CPU 64 MB disk space 512 MB RAM
Main interfaces between software components	As the device consists of one component only, there are no interfaces between several components.
Main interfaces to external components	- getVersion - runModel
Raw Data Description	- Pulse wave recordings as provided by any kind of analog/digital pressure sensor/transducer sampled with 100 Hz for 10 seconds (i.e. 1000 data points) - data from sensors with at least 10 bit (or higher) resolution
Limitations regarding the patient data:	- Systolic (SBP): 45 to 300 mmHg. - Diastolic (DBP): 0 to 255 mmHg. - Mean (MAP): 35 to 290 mmHg (only applicable if used for calibration). - heart rate during blood pressure measurement - persons's age between 18 and 100 years - gender (1: male, 2: female) - the patients heart rate must be in the range of 40 to 140 beats per minutes (bpm).

- person's height must be in the range of 45 to 250 centimeters.
- person's weight must be in the range of 11 to 300 kilogram.

12 How can feedback and problems be reported?

The user can report feedback and/or problems in combination with ARCSolver to the distributor, that has provided the software, or directly to the manufacturer by using the email address **arcsolver@ait.ac.at**.

Any serious incidents that occur in relation to the device should be reported directly to the manufacturer using the email address **arcsolver@ait.ac.at** and the competent authority of the member state in which the user and/or patient is established.

13 Where can I get a printed version of the instructions for use?

A printed version of the instructions for use is available directly from the manufacturer by using the email address **arcsolver@ait.ac.at**.

14 Cyber Security measures important for the safety of ARCSolver

Please follow these advices carefully to minimize any security issue due to cyber security:

- Do not enable the guest account on the computer
- Use the database export function for regular backups
- Keep your operating system, firewall and anti-virus software up-to-date
- Do not run this software on Windows operating systems for which the support has been discontinued by Microsoft
- Ensure that access to your computer is restricted to authorized personnel

15 Explanation of the symbols in this user manual

Symbol	Meaning
	Special attention
	Manufacturer
	CE mark with identification number of the Notified body
	Unique Device identifier
	Use by date. This symbol indicates the date after which the medical device may no longer be used
	Medical Device