










## Instructions for use

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	Notified body: mdc medical device certification GmbH, Kriegerstrasse 6, 70191 Stuttgart, Germany										
	ARCSolver is a medical device.										
	<table border="0"> <thead> <tr> <th>UDI-DI</th> <th>Operating System</th> </tr> </thead> <tbody> <tr> <td>(01)09120109830313</td> <td>Linux (Desktop)</td> </tr> <tr> <td>(01)09120109830337</td> <td>Windows (Desktop)</td> </tr> <tr> <td>(01)09120109830320</td> <td>Mac (Desktop)</td> </tr> <tr> <td>(01)09120109830306</td> <td>Android (Mobile)</td> </tr> </tbody> </table>	UDI-DI	Operating System	(01)09120109830313	Linux (Desktop)	(01)09120109830337	Windows (Desktop)	(01)09120109830320	Mac (Desktop)	(01)09120109830306	Android (Mobile)
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	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, or instantaneous arterial diameter by ultrasound, 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 or arterial diameter curves, 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, **ARC Solver** 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 or arterial diameter 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 microservice **ARCSolver** serves as a software for retrospectively analyzing recorded data from a suitable pressure sensor or transducer, or instantaneous arterial diameter by ultrasound. 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. It 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 and/or ultrasound recording, medical history, and professional judgement.

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



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

### 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 of the automatic analysis of pulse wave recordings should always be interpreted by qualified medical practitioners in conjunction with review of the original wave forms and/or ultrasound recording, 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.

Limitations regarding the patient data:

- Valid range for the 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.</i>
	<i>ARCSolver must not be used in emergency situations.</i>

### 1.5.1 Limitations and Exclusions for pulse wave data

If pulse wave data are to be evaluated, it 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. The lower cut-off frequency must be 0.05 - 0.1Hz for a second-order filter, or 0.1 - 0.25Hz for a first-order filter, to avoid unphysiological artifacts. The upper cut-off frequency must be between 20 and 25Hz.
- The recording system provides a resonant frequency greater 50 Hz.

### 1.5.2 Limitations and Exclusions for Ultrasound data

If instantaneous arterial diameter curves are to be evaluated, they must be recorded with a suitable ultrasound recorder and suitable ultrasound probe, and prepared by a suitable ultrasound processing software. 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 ultrasound images must be recorded with a sampling frequency greater than 26 frames/samples per second for several, but at least 2, seconds.
- The ultrasound processing software must be capable of extracting the arterial diameter as a 1D-curve from a 2D ultrasound image with a resolution of at least 10 bit and its associated timing information.
- The ultrasound processing software must replace deleted or missing data points with a value specified in the integration manual.
- The recording is performed at the carotid artery.

## 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, or instantaneous arterial diameter by ultrasound. **ARCSolver** offers an API to hand over suitable pulse waves or instantaneous arterial diameter curves, 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 or instantaneous arterial diameter curves and user specific data to the ARCSolver 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 several interfaces.

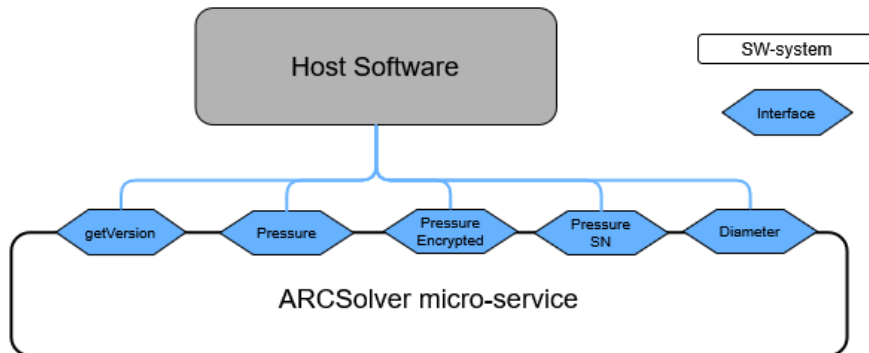


Figure 1 Overview main software components

### getVersion

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

### Pressure

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)

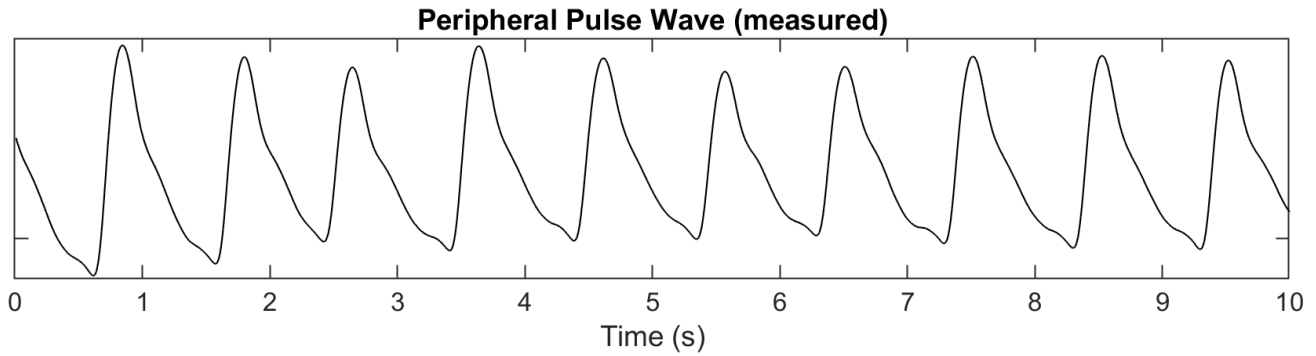


Figure 2 Example of a recorded peripheral pulse wave

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 indicates the pressure calibration method for the pulse wave. It can have the values:

- mean pressure = 1
- systolic pressure = 2

The parameter huckDetection controls wheter the "Huck" artefact is detected and affected pulse waves excluded from further processing. It can have the values:

- no = 0
- 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.

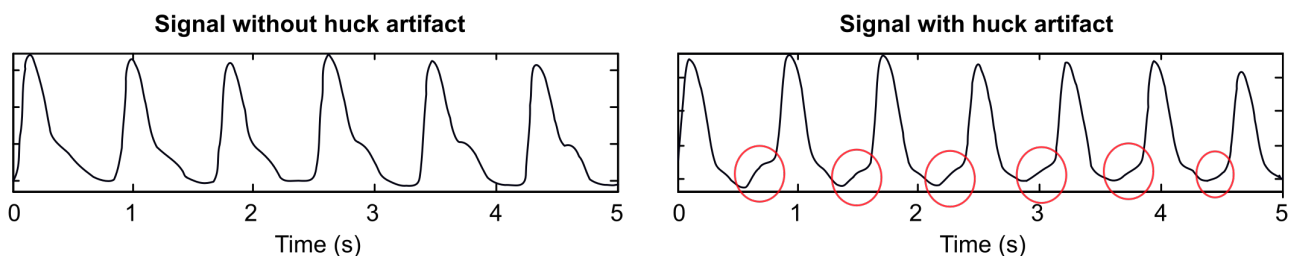


Figure 3 Comparison between an input signal without (left) and with (right, marked in red) "Huck" artifacts

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)

### Pressure Encrypted

This function takes the same input parameters as the interface "Pressure", with the only difference being that the parameter "curve" is encrypted using SHA256 encryption. It allows the transmission of encrypted pressure signals, for example to encrypt the signals already in the recording hardware and thus link the ARCSolver to this special hardware. For more information on using this feature, see the integration manual.

The function returns the same output parameter as the interface "Pressure".

### Pressure SN

This function takes the same input parameters as the interface "Pressure", and additionally the serial number of the device used to record the pressure curve. This allows to link the ARCSolver license to certain measurement devices.

The function returns the same output parameter as the interface "Pressure".

### Diameter

This function takes the following input parameter:

- sBP (systolic blood pressure in mmHg)
- dBP (diastolic blood pressure in mmHg)
- map (mean arterial pressure in mmHg)
- 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)
- diameterWave (Array for arterial diameter curve (several heartbeats), variable length, must be at least 2 seconds long)
- tDiameterWave (Time array for arterial diameter data in milliseconds, variable length, same length as diameterWave)

- calibration
- bpLocation

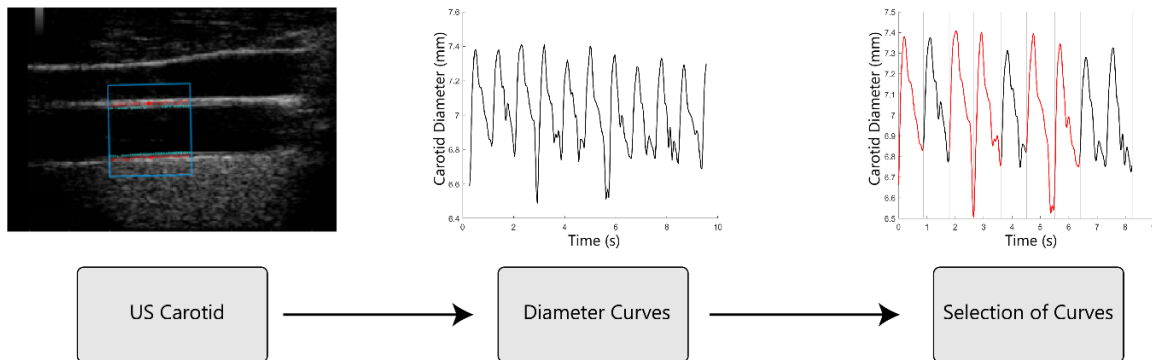


Figure 4 Example of arterial diameter curves: Using an external ultrasound processing software, arterial wall movement is detected, a continuous curve is derived and valid curves are selected. The result of the selection process is fed into the ARCSolver, using the parameters "diameterWave" for the diameter information and the parameter "tDiameterWave" for the according time information.

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 indicates the pressure calibration method for the pulse wave. It can have the values:

- mean pressure = 1
- systolic pressure = 2

The parameter bpLocation indicates the location where the blood pressure used for calibration was measured. It can have the values:

- carotid = 1
- brachial = 2
- radial = 3
- central = 4



**Using "carotid" blood pressure readings for calibration of diameter curves is the recommended method. "brachial", "radial", or "central" measurements require a transformation of the blood pressure readings and should only be used in exceptional cases.**

Furthermore, the "Diameter" method allows to process diameter curves without pressure calibration. In this case, the value "-1" must be used for the parameters "sBP", "dBP", and "map". In this scenario, only relative measures (i.e., measures not depending on the absolute blood pressure values) are calculated by the ARCSolver by internally assuming a pressure of 120/80. Note that even relative values might differ slightly from calculations using the correct absolute pressure, as the transfer function from diameter to pressure curves uses non-linear mathematical methods.



**The "Diameter" method allows to process diameter curves without pressure calibration. In this scenario, only relative measures are calculated. Note that even these relative values might differ slightly from calculations using the correct absolute pressure.**

The function returns the same output parameter as the interface "Pressure".

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

<b>pf_amp</b>	Amplitude of ejection (forward) wave	mmHg	X		2 (Systole)	0 to 300	
<b>pb_amp</b>	Amplitude of reflection (backward) wave	mmHg	X		2 (Systole)	0 to 300	
<b>Pulse Wave Velocity (PWV)</b>							
<b>pwv</b>	Pulse wave velocity	m/s	X		2 (Systole)	0 to 50	
<b>Quality Parameters</b>							
	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 Notes on input and output parameters

### 2.2.1 Heart rate

The functions *Pressure*, *Pressure Encrypted*, and *Pressure SN* require the heart rate (hr) as input. However, these functions also return hr as an output. These two parameters are not necessarily equal: While the input parameter is used as an initial estimate of pulse wave duration, based on the heart rate during blood pressure measurement, the output parameter reflects the actual heart rate during pulse wave analysis. Consequently, if further parameters are derived by the host software, e.g. the cardiac output in liters/minute, the output parameter hr should be used, not the input parameter.

### 2.2.2 Calculation method

Since the output of the functions *Pressure*, *Pressure Encrypted*, *Pressure SN*, and *Diameter* have the same structure, it can be hard to distinguish the used calculation method. Hence, if the host software supports more than one calculation method of ARCSolver, the used calculation method should be indicated to the user by the host software.

## 2.3 User interface

ARCSolver is a stand-alone microservice with five programming 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.

The backward wave can be calculated by subtracting the central forward wave from the mean central curve and adding the CDBP, i.e.,

$$\text{backwardWave}(t) = \text{centralWave}(t) - \text{forwardWave}(t) + \text{CDBP}$$

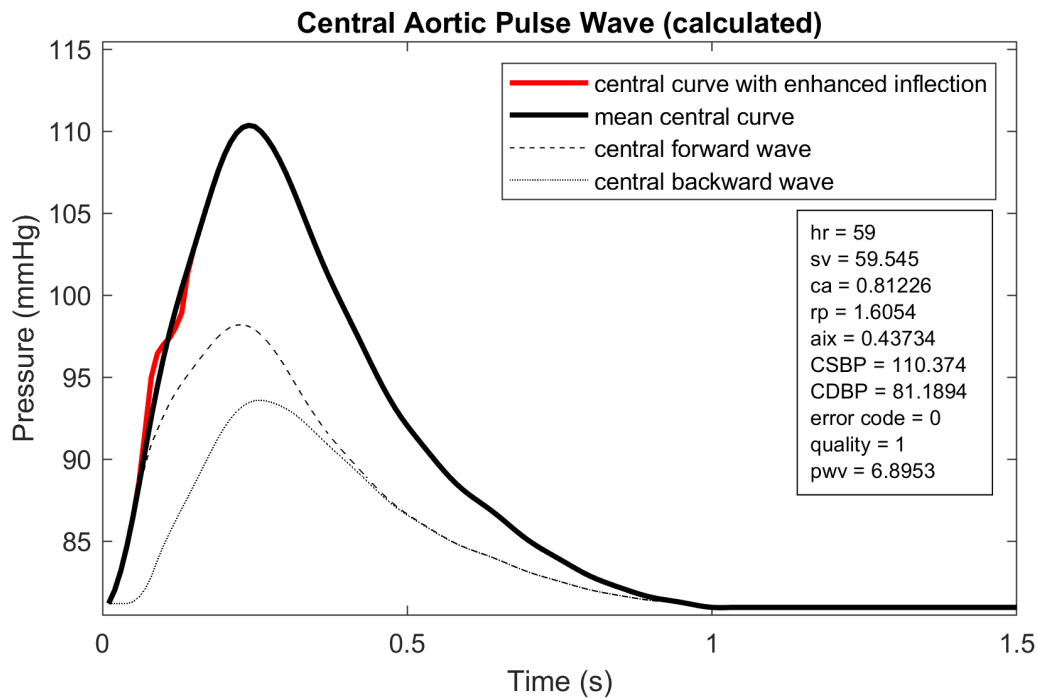







Figure 5 Graphical representation of returned raw data.

### 3 How long is the lifespan of ARCSolver?

The lifespan of the **ARCSolver** ends on Oktober 9, 2029, aligned with the expected lifetime of the supported operating systems. 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.
	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 or ultrasound 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 ARCSolver, it is recommended to service the computer hardware running ARCSolver in regular intervals. Particular attention should be given to ensure that sufficient free storage space is available for the operating system to run faultlessly. 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 three to analyze the pulse wave or arterial diameter 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

Parameter	Mean Difference / Standard Deviation	Reference
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	<ul style="list-style-type: none"> <li>• Windows (10 - 11 with x64 CPU)</li> <li>• macOS (12 - 15 with x64 or Apple Silicon CPU)</li> <li>• Linux (kernel 4.18 – 6.8 with x64 or ARM64 CPU)</li> <li>• Android (8.0 - 15 with ARM CPU)</li> </ul>
Minimum requirements for Hardware	<ul style="list-style-type: none"> <li>• x64 or ARM compatible CPU</li> <li>• 64 MB disk space</li> <li>• 512 MB RAM</li> </ul>
Main interfaces between software components	<ul style="list-style-type: none"> <li>• As the device consists of one component only, there are no interfaces between several components.</li> </ul>

Main interfaces to external components	<ul style="list-style-type: none"> <li>• getVersion</li> <li>• Pressure</li> <li>• Pressure Encrypted</li> <li>• Pressure SN</li> <li>• Diameter</li> </ul>
Raw Data Description	<ul style="list-style-type: none"> <li>• 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)</li> <li>• Data from sensors with at least 10 bit (or higher) resolution</li> <li>• Pulse wave recordings as described above, encrypted using SHA256 encryption as described in the "Integration Manual"</li> <li>• Diameter curve of variable length, but at least 2 seconds long, extracted from ultrasound recordings of the carotid artery wall by a compatible ultrasound processing software</li> </ul>
Limitations regarding the patient data:	<ul style="list-style-type: none"> <li>• Systolic (SBP): 45 to 300 mmHg.</li> <li>• Diastolic (DBP): 0 to 255 mmHg.</li> <li>• Mean (MAP): 35 to 290 mmHg (only applicable if used for calibration).</li> <li>• heart rate during blood pressure measurement</li> <li>• persons's age between 18 and 100 years</li> <li>• gender (1: male, 2: female)</li> <li>• the patients heart rate must be in the range of 40 to 140 beats per minutes (bpm).</li> <li>• person's height must be in the range of 45 to 250 centimeters.</li> <li>• person's weight must be in the range of 11 to 300 kilogram.</li> </ul>

## 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
- Keep your operating system, firewall and anti-virus software up-to-date
- Do not run this software on operating systems for which the support has been discontinued
- 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