



## Clinical Studies:

Validation of Tensoval Blood Pressure Measurement Devices for Self Control





“...For consumers, whether medical or lay, accuracy should be of prime importance when selecting a device to measure blood pressure...”

(Blood pressure measuring devices: recommendations of the Europea-Society of Hypertension (2001) BMJ (322): 531).

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### Why validation is necessary?

The European Union and international organisations of specialists in hypertension have recommended that all devices for measuring blood pressure for clinical use or self control should be independently validated for accuracy according to standard protocols. These standardized validation protocols define requirements for the accuracy of blood pressure measurement devices and are taken as basis for recommendation of devices.

### Which validation protocols do exist?

The Association for the Advancement of Medical Instrumentation (**AAMI**) published a standard for electronic aneroid sphygmomanometers in 1987 that included a protocol for evaluating the accuracy of devices, this being followed in 1990 by the protocol of the British Hypertension Society (**BHS**). The BHS protocol was revised in 1993. It covers a wide range of blood pressure and sets a minimum standard to be achieved for device recommendation. The standard protocol released by the European Society of Hypertension (**ESH**) added specific requirements for intra-patient accuracy that had to be fulfilled for clinical recommendation. The **EN 1060-Part IV** is a further recognized standard protocol which makes similar demands on accuracy like the quality seal. This highly qualified accredited award is approved by the German Hypertension League. Basis of clinical proof is the DIN EN 540 which is expanded by further requirements like selection of observer and evaluation of results.

The protocols have a common objective, namely the standardization of validation procedures to establish minimum standards of accuracy and performance, and to facilitate the comparison of one device with another.

## Validation of Tensoval

HARTMANN products have undergone and passed independent validation procedure according to the most accredited national or international standard protocols:

	DIN EN 1060-4:	German Quality Seal	BHS	ESH	AAMI
Device					
Tensoval duo control	✓	✓	✓	✓	✓
Tensoval comfort	✓	✓			
Tensoval mobil	✓	✓	✓		
✓ = passed					

For detailed information about the validation procedures of Tensoval blood pressure measurement devices for self control see page 7 ff.

For insights into the performance of Tensoval duo control in patients with blood pressure arrhythmias see page 15 ff.

### Tensoval® duo control

Increased measurement accuracy through combining oscillometric and Korotkoff measurement technology.



### Tensoval® mobil

Fully automatically blood pressure watch for measurements on the wrist based on the oscillometric method with innovative inflation technology for individually adjusted inflation pressure.



### Tensoval® comfort

Fully automatically blood pressure monitor for measurements on the upper arm based on the oscillometric method.



## Clinical Studies - Validation

The following summaries give an overview about the performance of Tensoval Blood Pressure measurement devices undergoing validation according to national and international standard protocols.

### **1. "Quality seal of the German Hypertension Society" – Tensoval Blood Pressure Measurement Devices for Self Control passed all requirements<sup>7, 8</sup>**

Dr. med. Ulrich Tholl

[Tensoval duo control](#)

[Tensoval comfort](#)

[Tensoval mobile](#)

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### **2. Tensoval Blood Pressure Measurement Devices fulfill requirements of the EN 1060 – Part IV<sup>6, 7, 8, 9</sup>**

Dr. med. Ulrich Tholl, Ikufumi Tajima

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### **3. Tensoval Duo Control achieved best results for accuracy according to the British and European Hypertension Societies' standards<sup>2</sup>**

Annemarie De Greef, Jasleen Arora, Simon Hervey, Bing Liu and Andrew H. Shennan

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## **“Quality seal of the German Hypertension Society” – Tensoval Blood Pressure Measurement Devices for Self Control passed all requirements<sup>7,8</sup>**

Dr. med. Ulrich Tholl, Chief Physician of Internal Medicine, Klinikum Bremerhaven Reinkenheide, Bremerhaven.

**“...The quality seal is of high value on the market...”.**

(Dr. Siegfried Eckert, senior attending physician at the North-Rhine Westphalian Heart and Diabetes Centre in Bad Oeynhausen, Germany.)

**“...The quality seal is a recognized proof of quality that in specialist circles is a prerequisite for a recommendation – and thereby for me...”**

(Julie Strobach, PTA (pharmaceutical-technical assistant) and director of the FAKTOR X Pharma Academy in Berlin, Germany.)

### **Validation procedure:**

A minimum of 96 subjects<sup>1</sup> who fulfilled the protocol criteria were recruited from different sites. Six same arm measurements according to the manufacturer’s instructions were taken from each subject by two observers alternating between mercury sphygmomanometers and the test device.

The Quality Seal of the German Hypertension Society required a minimum of three comparative measurements of each subject to be valid for the evaluation (Tab.1).

<sup>1</sup>Validation of Tensoval Mobile included 85 patients.

## Result:

Table 1: Requirements and results.

	mean pressure difference <sup>+</sup>	standard deviation	Score <sup>++</sup>
<b>Required</b>	< 5 mmHg	< 8 mmHg	50 %
<b>Achieved</b>			
Tensoval duo control			
SBP*	-1.7 mmHg	7.1 mmHg	68.5 %
DBP**	-0.7 mmHg	5.3 mmHg	
Tensoval comfort			
SBP*	-2.8 mmHg	7.3 mmHg	59 %
DBP**	-2.1 mmHg	6.0 mmHg	
Tensoval mobile			
SBP*	0.1 mmHg	7.4 mmHg	56.9 %
DBP**	1.6 mmHg	6.9 mmHg	

\*) systolic blood pressure

\*\*\*) diastolic blood pressure

+) value difference between mercury sphygmomanometer and the test device

++) percentage of comparative measurements that are valid for evaluation

## Conclusion:

- All tested blood pressure measurement devices for self control fulfilled requirements of the Quality Seal of the German Hypertension Society.
- They can be recommended for self control in an adult population.



## Tensoval Blood Pressure Measurement Devices fulfil requirements of the EN 1060 – Part IV <sup>6, 7, 8, 9</sup>

Dr. med. Ulrich Tholl

Klinikum Bremerhaven Reinkenheide, Bremerhaven.

Ikufumi Tajima

Medical Corporation Juzankai Tajima Hospital, Nakanojo, Japan.

### Validation procedure:

A minimum of 96 subjects<sup>1</sup> who fulfilled the protocol criteria were recruited from different sites. Six same arm measurements according to the manufacturer's instructions were taken from each subject by two observers alternating between mercury sphygmomanometers and the test device. The EN 1060 – Part IV required:

- Blood pressure values of one participant that are considered for calculation may not differ more than 12 mmHg for the systolic value and 8 mmHg for the diastolic value, respectively.
- From six pairs of measured values the first group of three consecutive pairs of measured values are considered (Tab.1).

### Results:

All tested blood pressure measurement devices for self control passed the protocol according to the EN 1060 – Part IV. They fulfilled criteria for the mean pressure difference and the corresponding standard deviation.

<sup>1</sup>Validation of Tensoval Mobile included 85 patients.

Table 1: Requirements and results according to the EN 1060 –Part IV

		mean pressure difference <sup>+</sup>	standard deviation
<b>Require</b>		≤ 5 mmHg	≤ 8 mmHg
<b>Achieved</b>			
Tensoval duo control			
	SBP*	-1.9 mmHg	7.9 mmHg
	DBP**	-0.7 mmHg	7.3 mmHg
Tensoval comfort			
	SBP*	-2.6 mmHg	8.5 mmHg
	DBP**	-0.9 mmHg	8.0 mmHg
Tensoval mobile			
	SBP*	1.2 mmHg	6.5 mmHg
	DBP**	2.3 mmHg	6.5 mmHg

\*) systolic blood pressure

\*\*\*) diastolic blood pressure

+) value difference between memory sphygmometers and the test device.the measurements of the two observers

### Conclusion:

- All tested blood pressure measurement devices for self control fulfilled requirements of the Quality Seal of the German Hypertension Society.
- They can be recommended for self control in an adult population.



## Tensoval duo control achieved best results for accuracy according to the British and European Hypertension Societies' standards<sup>2</sup>

Annemarie De Greef, Jasleen Arora, Simon Hervey, Bing Liu and Andrew H. Shennan.

Maternal and Fetal Research Unit, Division of Reproduction and Endocrinology, King's College London, North Wing, St. Thomas' Hospital, London, UK.

### Aim:

To evaluate the accuracy of Tensoval duo control in adults according to

1. **British Hypertension Society (BHS)**,
2. **American Association for the Advancement of Medical Instrumentation (AAMI)**
3. **European Society of Hypertension (ESH)**.

### Validation procedure:

85 subjects who fulfilled the protocol criteria were recruited from different sites. Nine sequential same arm measurements according to the manufacturer's instructions were taken from each subject by two observers alternating between mercury sphygmomanometers and the test device.

### Results:

- Tensoval duo control achieved an A grade for both, systolic and diastolic pressure values according to the BHS protocol (Table 1).
- The device also fulfilled the AAMI criteria (Table 2).
- The device successfully achieved all requirements of the International ESH protocol guidelines and showed excellent inpatient accuracy with more than 80% of participants having at least 2 out of 3 differences within 5 mmHg of the mercury standard.

Table 1: Grading criteria and results according to the BHS.

		Difference between the test device and standard			
		Grade	< 5 mmHg	< 10 mmHg	< 15 mmHg
<b>Required</b>		A	60	85	95
		B	50	75	90
		C	40	65	85
		D	< C		
<b>Achieved</b>					
SBP*	A	60%	91%	98%	
DBP**	A	73%	91%	98%	

\*) systolic blood pressure      \*\*) diastolic blood pressure

Table 2: Grading criteria and results according to the AAMI.

		Mean difference	Standard deviation
<b>Required</b>			
SBP*		≤ 5 mmHG	≤ 8 mmHG
DBP**			
<b>Achieved</b>			
SBP*		-2.4 mmHG	6.0 mmHG
DBP**		0.9 mmHG	6.0 mmHG

\*) systolic blood pressure      \*\*) diastolic blood pressure

### Conclusion:

- Tensoval duo control is the first automated auscultatory device to maintain an A/A grading throughout the low, medium and high pressure categories.
- The device can therefore be recommended for clinical and home care use in an adult population.



## Clinical Studies – Validation in Patients

Tensoval duo control has been internationally validated in patients with blood pressure arrhythmias:

### **1. Tensoval duo control meets European standard requirements (DIN EN 1060-4) for accuracy in patients with atrial fibrillation<sup>4</sup>**

Siegfried Eckert

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### **2. In-Use-Study confirmed accuracy of results of Tensoval duo control in patients with atrial fibrillation<sup>5</sup>**

Štefan Farský, Katarín Benová, Jana Sirotková, Petra Vyskocilova and Darina Krausová

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### **3. Tensoval duo control meets requirements for clinical usage in patients with blood pressure arrhythmias<sup>1</sup>**

M. V. Borshchevskaja, T. I. Tserkovnikova

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### **4. Tensoval duo control achieved A/B-grading in pregnant women according to the BHS standards<sup>3</sup>**

Fiona Tasker, Lauren Bolt, Annemarie de Greeff, Andrew Shennan

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## Tensoval duo control meets European standard requirements (DIN EN 1060-4) for accuracy in patients with atrial fibrillation<sup>4</sup>

Siegfried Eckert  
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Bad Oeynhausen, Germany

### Patients

- A total of 15 patients with atrial fibrillation already planning to undergo diagnostic cardiac catheterization

### Methods

- 5 measurements with Tensoval duo control
- Control: Simultaneous invasively measurements were carried out during diagnostic cardiac catheterization device
- Evaluation according to the DIN EN 1060-4

### Results

- Tensoval duo control performed in all blood pressure measurements successfully.
- Tensoval duo control met the requirements of measurement accuracy. (Table 1).

Table 1: Requirements and results.

	mean pressure difference <sup>+</sup>	standard deviation
<b>Required</b>	< 5 mmHG	< 8 mmHG
<b>Achieved</b>		
SBP*	-0.3 mmHG	2.4 mmHG
DBP**	2 mmHG	3.8 mmHG

\*) systolic blood pressure

\*\*\*) diastolic blood pressure

+) difference between standard and test device measurements

## Conclusion

- According to EN-1060-4 standard Tensoval duo control passes the requirements for accuracy in patients with atrial fibrillation.
- Performing measurements reliable, the upper arm blood pressure measurement device Tensoval duo control device can reliably be used for patients with atrial fibrillation.

**“...The combination of two measuring technologies makes blood pressure measurement more reliable and will help to improve the treatment of high blood pressure. All patients, even patients with high blood pressure and various forms of heart rhythm disorder will benefit from the Duo Sensor Technology...”**

**“...The device measures reliably and accurately. With Tensoval® duo control the patients do not have the frustration of measurements being interrupted – that is what distinguishes the device...”**

(Dr. Siegfried Eckert, senior attending physician at the North-Rhine Westphalian Heart and Diabetes Centre in Bad Oeynhausen, Germany.)



## In-Use-Study confirmed accuracy of results of Tensoval duo control in patients with atrial fibrillation<sup>5</sup>

Farský Štefan<sup>a</sup>, Benová Katarína<sup>b</sup>, Sirotiková Jana<sup>c</sup>,  
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<sup>e</sup>) Nemocnice s poliklinikou Nový Jicín, Nový Jicín,  
Czech Republic.

### Patients

- A total of 255 patients with atrial fibrillation

### Methods

- Test device: Tensoval duo control
- Control device: mercury sphygmomanometer

### Results

	mean pressure difference <sup>+</sup>	standard deviation
SBP*	0,06 mmHG	4.67 mmHG
DBP**	-0.68 mmHG	4.68 mmHG

\*) systolic blood pressure    \*\*) diastolic blood pressure

+) difference between standard and test device  
measurements

### Conclusion

- Minimum differences in the values of the diastolic blood pressure were clinically insignificant.
- According to the investigators  
**"...Measuring blood pressure using Tensoval duo control provides accurate results even in case of an absolute arrhythmia, such as atrial fibrillation..."**



## Tensoval duo control achieved A/B-grading in pregnant women according to the BHS standards<sup>3</sup>

Annemarie De Greef, Jasleen Arora, Simon Hervey, Bing Liu and Andrew H. Shennan.

Maternal and Fetal Research Unit, Division of Reproduction and Endocrinology, King's College London, North Wing, St. Thomas' Hospital, London, UK

### Patients

- 30 pregnant women
- 15 pregnant women suffering from pre-eclampsia

### Methods

- according to the BHS-protocol

### Results

Table 1: Grading criteria and results according to the BHS.

		Difference between the test device and standard				
		Grade	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	
<b>Required</b>		A	60%	85%	95%	
		B	50%	75%	90%	
		C	40%	65%	85%	
		D	worse than C			
<b>Achieved</b>						
Pregnancy	SBP*	A	68%	86%	97%	
	DBP**	B	62%	83%	98%	
Pre-eclampsia		SBP*	D	40%	73%	82%
		DBP**	B	67%	80%	98%

\*) The device should achieve percentages greater than or equal to those in the table in order to achieve a particular grade.

Table 2: Grading criteria and results according to the AAMI.

	Mean difference	Standard deviation
<b>Required</b>		
SBP*	≤ 5 mmHG	≤ 8 mmHG
DBP**		
<b>Achieved</b>		
Pregnancy		
SBP*	-3.3 mmHG	6.2 mmHG
DBP**	0.9 mmHG	7.1 mmHG
Pre-eclampsia		
SBP*	-7.5 mmHG	9.0 mmHG
DBP**	-0.1 mmHG	7.4 mmHG

\*) systolic blood pressure

\*\*\*) diastolic blood pressure

- Tensoval duo control achieved A grade for systolic and B grade for diastolic pressure values in pregnant woman according to the BHS protocol (Table 1).
- The device also fulfilled the AAMI criteria in pregnant women (Table 2).
- In pregnant women suffering from pre-eclampsia Tensoval duo control achieved B grade for diastolic pressure and D grade for systolic pressure according to the BHS protocol.
- For systolic pressure values the device did not fulfil AAMI criteria.

## Conclusion

According to the investigators

**“...Tensoval duo control can be recommended for clinical use in pregnancy ... according to the BHS protocol ...”**

## Tensoval duo control meets requirements for clinical usage in patients with blood pressure arrhythmias<sup>1</sup>

M. V. Borshchevskaja<sup>a</sup>, T. I. Tserkovnikova<sup>b</sup>

<sup>a</sup>) Clinical Functional Diagnostics Department of the Faculty of Professional Development of Russian State Medical University.

<sup>b</sup>) State Health Institution of Moscow, War Veterans Hospital, Department of Health.

### Patients

- 36 patients with normo- or tachystolic form of arrhythmia
- 14 patients with bradystolic form of arrhythmia

### Methods

- Test device: Tensoval duo control
- Control device: mercury sphygmomanometer
- Each patient was 3 times measured with each device by three independent observers.

### Results

	mean pressure difference <sup>+</sup>	
	normo- or tachystolic form of arrhythmia	bradystolic form of arrhythmia
SBP*	2.19 mmHG	3.83 mmHG
DBP**	1.17 mmHG	2.29 mmHG

\*) systolic blood pressure

\*\*) diastolic blood pressure

+) difference between standard and test device measurements

### Conclusion

- According to the specialists  
“...the positive reports and current evidences give a basis to recommend Tensoval duo control for the clinical usage...”

## References

- 1.) Borshchevskaja, M.V.; Tserkovnikova, T.I. 2007 Record about the clinical evaluation of the automatic BPM Tensoval Duo Control, Moscow.
- 2.) De Greef, A. et al. 2008 Accuracy assessment of the Tensoval Duo Control according to the British and European hypertension Societies' standards. *Blood Pressure Monitoring* 13 (2) 111ff.
- 3.) Tasker, F. et al. 2009 Does a Novel Automated Auscultatory Device Measure Blood Pressure Accurately in Pregnancy and Pre-eclampsia: Tensoval duo control. 19<sup>th</sup> European Meeting on Hypertension, Milano, Italy.
- 4.) Eckert, S. Validation of the blood pressure self-measurement device Tensoval duo control from PAUL HARTMANN AG through simultaneous invasive comparative measurements in patients with atrial fibrillation during diagnostic cardiac catheterization. Herz- und Diabeteszentrum Nordrhein-Westfalen, Bad Oeynhausen, Germany.
- 5.) Farský, Š. et al. 2009 Validity of Blood Pressure Measurement Using Electronic Devices in Patients with Atrial Fibrillation. 19<sup>th</sup> European Meeting on Hypertension, Milano, Italy.
- 6.) Tajima, I. 2008 Clinical Validation of the "Tensoval Mobil IV" in an Adult Population by the EN1060-4 protocol, (Nakanojo, Gunma, Japan).
- 7.) Tholl, U. 2002/2003 Validierung: HARTMANN Tensoval Comfort II, Bremerhaven.
- 8.) Tholl, U. 2006/2007 Validierung: HARTMANN Tensoval duo control, Bremerhaven.
- 9.) Tholl, U. 2009 Validierung Tensoval Mobile, Bremerhaven.



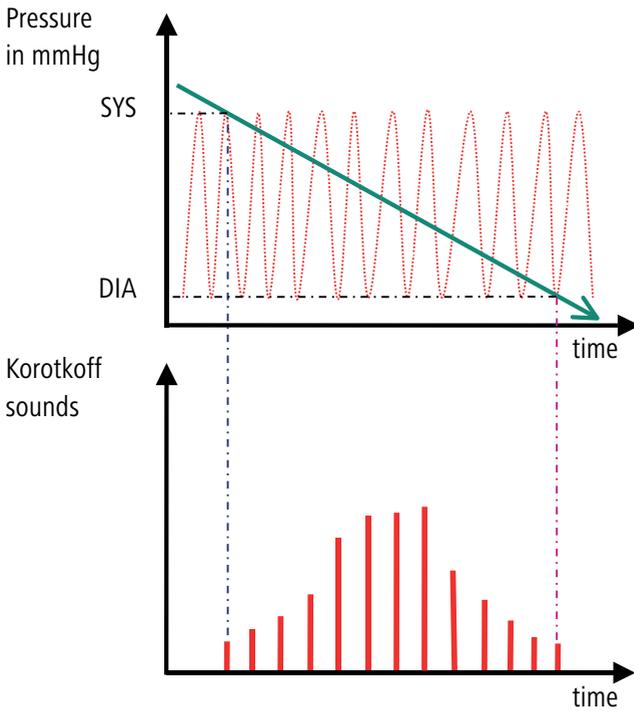




## Compendium

**atrial fibrillation** is a cardiac arrhythmie due to progressive fibrosis of the atria which in turn is the consequence atrial dilation. This may be caused by a structural abnormality of the heart leading to a rise of intra-cardiac pressure, hypertension or congestive heart failure. Due to strongly fluctuating pressure levels in these cases pressure self-measurement with automatic devices is often impossible or the reliability of these measurements is questionable.

**auscultatory method** determines blood pressure by monitoring Korotkoff sounds. An inflatable cuff is placed around the upper arm at roughly the same vertical height as the heart, normally attached to a mercury manometer. The cuff is fitted and inflated manually by squeezing a rubber bulb or – as it is the case in Tensoval duo control – automatically until the artery is completely occluded (about 30 mmHg above the systolic pressure). Then the pressure in the cuff is slowly released. When blood starts to flow in to the artery, the turbulent flow creates a pulse synchronic pounding (first Korotkoff sound). The pressure at which this sound is first detected is the systolic blood pressure. The cuff pressure is further released until no more sound can be detected at the diastolic arterial pressure.



- Decreasing cuff pressure.
- Audibility of the first Korotkoff sound which responds to the systolic blood pressure.
- Korotkoff sounds increase at the beginning and then decrease.
- The last audible sound corresponds to the diastolic blood pressure.

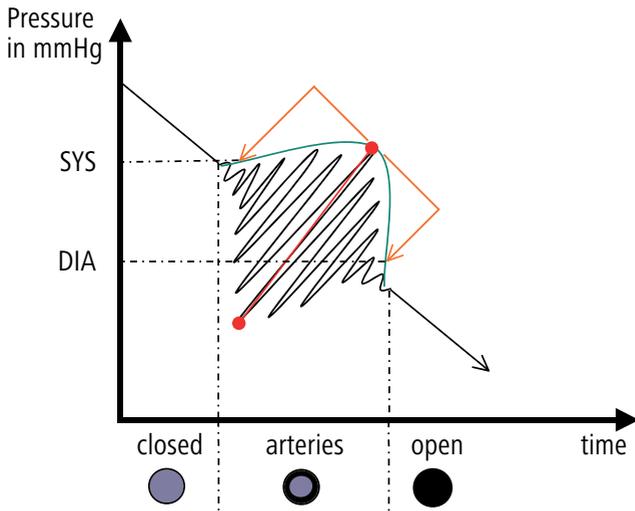


**blood pressure** value normally refers to arterial pressure, i.e., the pressure in the larger arterial blood vessels that take blood away from the heart. For each heartbeat, blood pressure varies between systolic and diastolic pressures. An example of normal measured values for a resting, healthy adult human is lower than 140 mmHg systolic and lower than 90 mm Hg diastolic (according to the WHO).

**diastolic pressure** is the lowest pressure within the arterial blood stream occurring during each heart beat. The diastole is the period of time when the heart fills with blood after systolic contraction.

**Korotkoff sounds** are named after Dr. Nikolai Korotkoff, a Russian physician who described them in 1905.

**oscillometric method** uses an electronic pressure sensor with a numerical readout of blood pressure. In most cases the cuff is inflated and released by an electrically operated pump and valve, which may be fitted on the wrist (elevated to heart height), although the upper arm is preferred. Initially the cuff is inflated to a pressure in excess of the systolic arterial pressure, and then the pressure reduces to below diastolic pressure. Once the blood flow is present, but restricted, the cuff pressure will vary periodically in synchrony with the cyclic expansion and contraction of the brachial artery. The values of systolic and diastolic pressure are computed from the raw data, using an algorithm.



- All oscillations will be recorded.
- The highest pulse wave is determined.
- An envelope will be recorded.
- Based on the highest point of the envelope SYS and DIA are calculated with the help of an algorithm.

Modern oscillometric blood pressure measurement devices provide sufficiently accurate values in patients with slight dysrhythmias. In patients with strong dysrhythmias, however, the irregular pulse signals result in a displacement of the envelope. Thus the algorithm calculates wrong values and results are questionable or the envelope can not be determined and the device provides error message.

Tensoval duo control uses both, oscillometric and auscultatory technology to measure blood pressure. The auscultatory method records the first and the last sound for the determination of the blood pressure. Irregularities within the corridor of the systolic and diastolic blood pressure are not relevant. Thus, the auscultatory method provides also in the presence of dysrhythmias reliable results.

**pre-eclampsia** refers to pregnancy –induced hypertension

**sphygmomanometer** is a device used to measure blood pressure, comprising an inflatable cuff to restrict blood flow, and a mercury or mechanical manometer to measure the pressure. It is always used in conjunction with a means to determine at what pressure blood flow is just starting, and at what pressure it is unimpeded. Manual sphygmomanometers are used in conjunction with a stethoscope.

**systolic pressure** is the highest arterial pressure during each heart beat and is produced during the contraction of heart chambers, driving blood out of the chambers.





helps healing.

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