

# microlife®

## Clinically tested

Accurate in use with special patient groups and in detecting atrial fibrillation.

Further studies:



Microlife AFIB – the atrial fibrillation (AF) detection.

In addition to the validations mentioned in this leaflet, there are also studies conducted to other innovative Microlife technologies and measurement methods. They work with new technologies or measuring methods, which are used in blood pressure monitors. Well-known institutions, such as the universities of Oxford, Athens, Rome, Maastricht, Hong-Kong and New-York, have published clinical studies to the Microlife AFIB technology, which is applied exclusively in Microlife upper arm blood pressure monitors. All studies have shown that Microlife AFIB can automatically detect dangerous atrial fibrillation - the most frequent cause of a stroke - even with high precision.

Microlife AFIB as of today, is worldwide the only approved technology for AF screening during blood pressure measurement. (MDD93/42/EEC, MedDEV 2.7.1., FDA)



Recommended by NICE

The National Institute for Health and Care Excellence (NICE) officially recommends using the WatchBP Home A during routine blood pressure measurement for all general practitioners in the United Kingdom:

“The available evidence suggests that the device reliably detects atrial fibrillation and may increase the rate of detection when used in primary care.”

<http://guidance.nice.org.uk/MTG13>



MAM – 3 measurements with 1 click.

Other studies investigated the value of multiple blood pressure measurements – a technique that is also automatized in the Microlife models (so-called MAM technology). In these studies interval times between the individual measurements were observed in order to obtain valid measuring results at the end. A pause time of 15 seconds for oscillometric measurement was determined sufficient as a reference value, as is also the case with the MAM technology.

• Tip: Make sure that the functions (e.g. arrhythmia detection techniques) used in the devices, have been adequately tested for accuracy. At first sight, the differences in quality are often not easily distinguishable.

# microlife®

A partner for people. For life.

## Clinically tested

Microlife blood pressure monitors – measurement quality with the highest of standards.



Clinically tested

High accuracy and clinically validated

Clinical validations of blood pressure monitors: what you should consider.



Microlife blood pressure monitors - measurement quality with the highest of standards.

### Clinical validation – what is it?

Blood pressure monitors must be clinically validated before being sold on the market.

Clinical validation verifies the measurement accuracy of the monitor and tests are performed to selected subjects who meet certain criteria (blood pressure classification, age, sex, pre-existing diseases, etc.).

There are qualitative and quantitative differences between the various existing validation methods. Therefore, when choosing a blood pressure monitor, you should always ask to what extent it is “clinically validated”. Validation of a blood pressure monitor is a standard requirement, but what is more important is to what extent it has been validated.

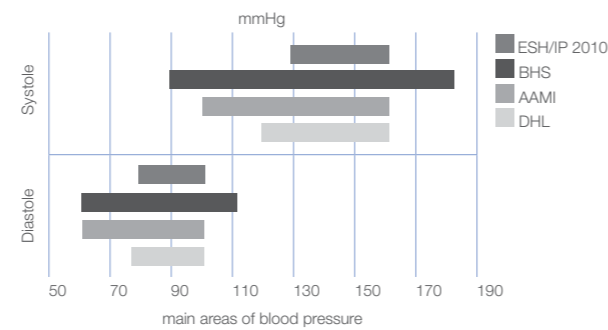
### Basic validations

Basic validation is performed on a group of subjects that is representative of an "average population without any diagnosed pre-existing conditions". The larger the number of subjects, the more statistically significant, thus more reliable, the validation test is. For example, basic validations can be based on the test protocols of the following institutions:



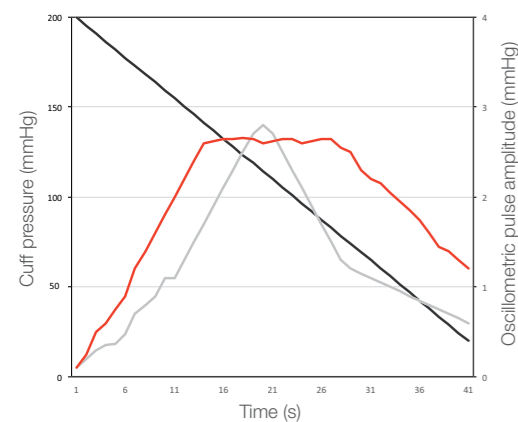
\*There are differences between the test protocols of the institutions; for example in respect of the group size.

Another difference is in the blood pressure ranges examined: The blood pressure ranges in which the blood pressure monitors are checked for measuring accuracy differ depending on the protocol (see graph). The broader the range is, the better the devices are checked to be reliable at extremely low or extremely high blood pressure.



### Special patient validations

Because of the technique that is used in automated oscillometric blood pressure monitors, they can be inaccurate when used in so-called special patient groups. This can lead to the fact that a blood pressure monitor that is validated in “regular subjects” may not give accurate readings when used e.g. during pregnancy or when used in children, elderly or diabetes patients. This can have serious clinical consequences. Therefore, medical standard authorities require that a blood pressure monitor may only be recommended for such a special patient group if it has been validated for this specific group. Microlife blood pressure monitors have passed several of these challenging validations so that they can now be recommended for all of the following special patient groups.



Comparison of normal pressure curve (grey) with pressure curve with modified vessels (red)  
 • The usual algorithm calculation no longer works (black line)

Microlife's upper arm blood pressure monitors are always a good choice.

These are especially validated for:



#### Diabetes

Patients with Diabetes Mellitus type 1 and 2 may have stiff arteries that can affect the blood pressure measurement. A recent validation study in diabetes patients type 1 and 2 showed that the Microlife monitor is accurate when used in this patient group.



#### Pregnancy and Pre-Eclampsia

Most oscillometric blood pressure monitors underestimate blood pressure in pre-eclampsia. For this reason, oscillometric blood pressure monitors may only be recommended for use in pregnancy when specifically tested in this special patient group. Microlife allows pregnant women to measure their blood pressure at home which could reduce the number of hospital visits and may help to make motherhood safer.



#### End-stage renal disease

Patients with moderate to severe renal disease have a very high incidence of hypertension, paired with stiff (calcified) arteries. As automated measurements can be influenced by stiff arteries, a special validation is required before blood pressure monitors can be recommended for use among patients with end stage renal disease.

12+ years

#### Children

As children have a high respiration rate and have difficulties in sitting still, one needs a blood pressure monitor with a high-quality algorithm that can filter out these artefacts. In addition, a wide cuff range is needed that covers very small to large arm circumferences. Microlife blood pressure monitor has proven to cover all these aspects and therefore can be recommended for children and adolescents aged 3 to 18 years (Microlife WatchBP Office and O3 Ambulatory) and 12 to 18 years (All Microlife automatic upper arm blood pressure monitors and WatchBP Home).

3+ years

However, other users can take advantage of specially validated blood pressure monitors as changes to the arteries can occur. This applies, in particular, to patients with the following risk factors:

- Diagnosed hypertension
- Senior citizens
- Heart diseases
- Obesity
- Smoking
- Stress
- Alcohol

### All Microlife's special patient validations at a glance:

	Stiff arteries						Very low BP values		Cuff fit		AF
	ESRD	Diabetes	Elderly	Dialysis	Pre-Eclampsia	Pregnancy alone	Hypotension	Children & adolescents	Obesity	Cuff wide-range	
Microlife	•	•	•	•	•	•	•	•	•	•	•

### Cuff validations

Validations are generally performed with the standard cuff-size of the respective device model. However, Microlife has put extra attention to validations with all type of cuff sizes and/or types (soft cuffs, rigid cuffs, wide-range cuffs, etc.). Due to the strong increase in overweighted persons, validations of XL cuffs are becoming more important. In order to ensure that correct blood pressure values are obtained in these patients Microlife has developed an XL-cuff which has been validated for accurate blood pressure measurement in patients with large arm-circumference. Microlife is the only provider for home BPM with an explicit validation for the XL cuff and comes highly recommended for overweight patients.

Cuff size	Arm circumference	Cuff size	Arm circumference
S (soft cuff)	17-22 cm	M-L (rigid cuff)	22-42 cm
M (soft cuff)	22-32 cm	L-XL (soft cuff)	32-52 cm
M-L (soft cuff)	22-42 cm		



**microlife**