

Validation results of the EVOLV (HEM-7600T-E)

Part 1	Pass Req.		Achieved	
	Two of	All of	SBO	DBP
≤ 5mmHg	73	65	131	134
≤ 10mmHg	87	81	135	135
≤ 15mmHg	96	93	135	135
Grade I			Pass	Pass
Mean mmHg			-0.7	-0.1
SD mmHg			2.3	1.8

Result **Pass**



OMRON

OMRON

At OMRON we promise to help you minimize the impact of health conditions to help your patients live a better, longer and more active life. Making sure you can recommend clinically proven instruments for their home care - with zero compromise.

Going for zero compromise on healthier lives.



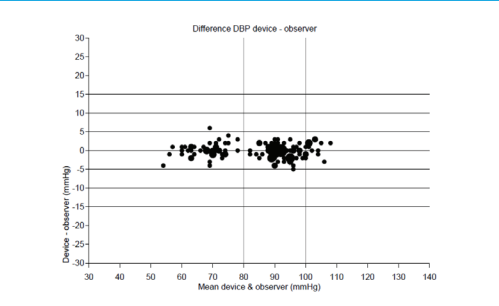
List of OMRON Blood Pressure Monitor devices validated in Pregnancy and Pre-eclampsia

- EVOLV
- M6 Comfort
- M7 Intelli IT
- M3 Comfort

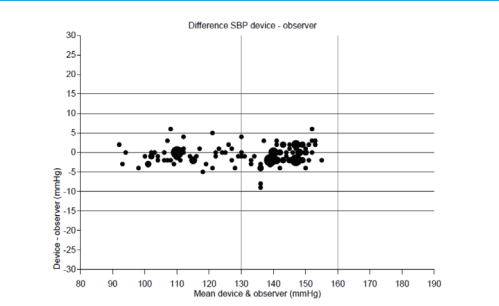
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Results in Diastolic Bloodpressure



Results in Systolic Bloodpressure



The OMRON® EVOLV (HEM-7600T-E) ® device fulfils the recommendations of the modified international validation protocol with grade A classification for both systolic and diastolic BP. Therefore, it can be recommended for clinical use in a population of Pregnant Women with and without pre-eclampsia.

OMRON



VALIDATED  
for pregnant  
women

RECOMMEND

WITH ZERO  
COMPROMISE



EVOLV  
Successfully validated  
in pregnant women  
with and without  
pre-eclampsia

EVOLV

Automatic Upper Arm  
Blood Pressure Monitor

GOING FOR ZERO

www.omron-healthcare.com/en

PM-1703-01-10/2017

GOING FOR ZERO

## ○ PREGNANCY, HIGH BLOOD PRESSURE AND PRE-ECLAMPSIA

### Blood pressure variability in pregnancy

As a woman progresses in her pregnancy, her blood pressure may change. The blood volume increases by as much as 45% during pregnancy [1]. This is an extra amount of blood that the heart must pump throughout the body.

### Hypertensive disorders during pregnancy

Most women will not develop any problems with their blood pressure during pregnancy. However, in up to 10% of the women, hypertensive disorders can develop [2]. High blood pressure can become severe and can be harmful to both the mother and the unborn baby. In fact, researchers found that hypertension is the most common medical problem encountered complicating pregnancies [2]. If untreated this could result in organ damage in the kidney and brain for the mother and the baby.

### Pre-eclampsia can lead to hypertension after pregnancy

Some women with high blood pressure during pregnancy develop pre-eclampsia which is a serious medical condition. Usually pre-eclampsia is diagnosed by the presence of hypertension. Literature suggests that 39% of patients diagnosed with pre-eclampsia also have hypertension [3]. Moreover pre-eclampsia may even have an impact on women’s health beyond their pregnancies, and has been associated with increased risks up to 3.5-fold for future hypertension [4,5].

## ○ MEASURE THE MOTHER, MANAGE THE BABY

### Measuring blood pressure in pregnant women can be challenging

Accurate blood pressure measurement is fundamental to early diagnosis of hypertensive disorders in pregnancy by a doctor [6]. Automated blood pressure devices require validation of accuracy in a general population [7,8], but even more so in specific subgroups. It has been shown that the standard blood pressure devices tend to underestimate blood pressure in pre-eclamptic patients due to haemodynamic changes caused by the pregnancy [9].

### Monitoring the pregnancy using blood pressure measurements

Women with pre-existing, or chronic, high blood pressure are more likely to have certain complications during pregnancy than those with normal blood pressure. Clinical guidelines therefore recommend that pregnant women should have regular blood pressure checks [10].

### The advantages of measuring at home

Automated home blood pressure devices have been used to assess women at home, aiming to overcome the low sensitivity and specificity of clinic blood pressure measurement [9]. In the home setting, readings enable differentiation of true white-coat hypertension from hypertensive disorders in pregnancy, while it can also improve surveillance and reduce scheduled visits [2].

# OMRON’S DEVICES EXTEND TO ACCURACY for pregnant women

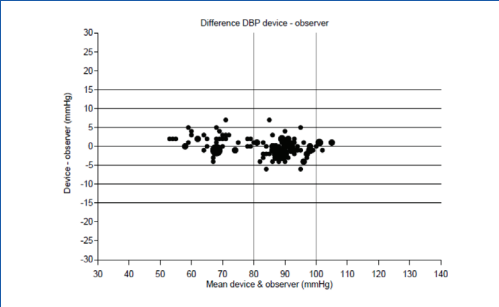


OMRON devices with **Intelli Wrap Cuff** have successfully passed validation of International Protocol defined by European Society of Hypertension (ESH-IP) for pregnant women with and without pre-eclampsia [11]. They can now be recommended for pregnant women to use at home ensuring accurate readings that would support the doctor to timely diagnose possible hypertensive disorders

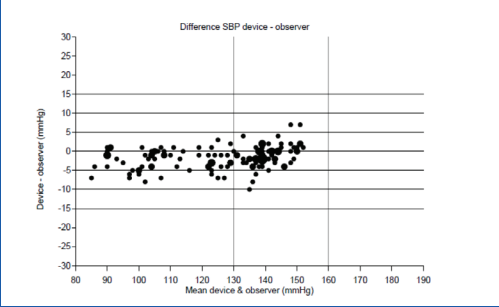
## ○ Validation results of the M3 Comfort (HEM-7134-E)

Part 1	Pass Req.		Achieved	
	Two of	All of	SBO	DBP
≤ 5mmHg	73	65	121	131
≤ 10mmHg	87	81	135	135
≤ 15mmHg	96	93	135	135
Grade1			Pass	Pass
Mean mmHg			-1.6	-0.1
SD mmHg			2.8	2.3
Result <b>Pass</b>				

### Results in Diastolic Bloodpressure



### Results in Systolic Bloodpressure



The OMRON® M3 COMFORT (HEM-7134-E) \* device fulfils the recommendations of the modified international validation protocol with grade A classification for both systolic and diastolic BP. Therefore, it can be recommended for clinical use in a population of Pregnant Women with and without pre-eclampsia.