CASMED®
FOR WHAT'S VITAL

OEM MAXNIBP®
Theory of Operation

GENERAL

Used world wide in a variety of vital signs monitors and clinical applications, the MAXNIBP OEM Module is a premier, medical grade blood pressure module noted for its superior performance, measurement accuracy and motion artifact extraction technology.

The MAXNIBP OEM Module provides non-invasive, indirect measurement of arterial blood pressure for adult, pediatric, infant and neonatal patients employing the oscillometric step deflation method for the determination of systolic, diastolic, mean arterial pressure (MAP) and heart rate.

The MAXNIBP OEM Module functions by inflating a cuff that is wrapped around a patient's limb to a pressure above systolic pressure. The module then releases the pressure in the applied patient cuff in steps. At each step, pressure pulses are generated by the flow of blood into the arteries of the limb. These pulses are transferred to the cuff and are measured by the MAXNIBP Module. The pulses measured over a complete deflation period follow a characteristic curve that can be used to determine mean arterial pressure, systolic pressure, and diastolic pressure.

OSCILLOMETRIC NIBP MEASUREMENT

Step Deflation

MAXNIBP technology uses the step deflation method to determine blood pressure, holding at each pressure step to observe pulse characteristics, qualify pulses and to reject noise artifact.

Pulses at a fixed cuff pressure, or step, are assumed to be at the same amplitude and rate. This fact allows for artifact rejection by rejecting non-matching pulses due to improper amplitude or time of occurrence. See "At the Heart of MAXNIBP – Motion Artifact eXtraction" for additional information.

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Obtaining an NIBP Measurement

A monitor employing MAXNIBP technology automatically inflates a blood pressure cuff above the patient's systolic pressure, occluding the artery. After initial inflation, the cuff pressure is automatically reduced in pre-determined increments or steps.

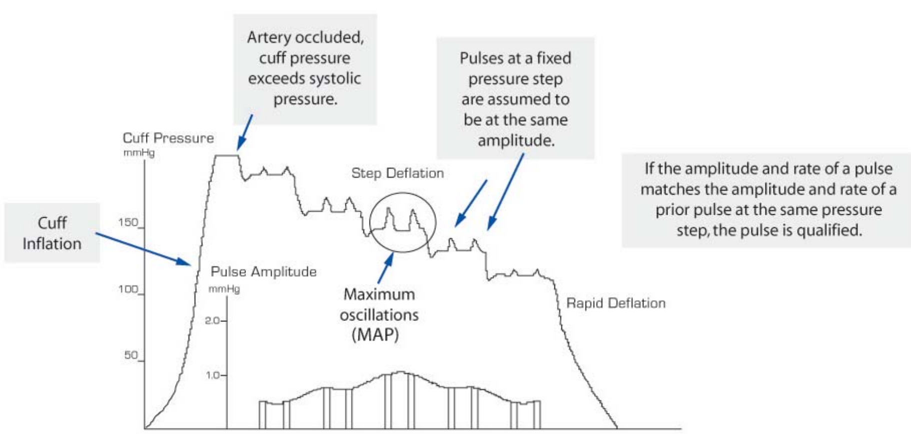
As the cuff deflates, changes in cuff pressure (oscillations) caused by the flow of blood through the artery are detected. At a point just below systolic, a pressurized volume of blood passes through the artery under the cuff causing the cuff-pressure oscillations to increase. During the measurement process, the cuff pressure will be maintained at a given step until at least two (qualified) matching arterial pressure oscillations have been detected or until a step time-out occurs.[1]

After the pulse amplitude is determined and qualified at the current pressure step, MAXNIBP releases cuff pressure and steps down to the next pressure level, repeating the process of qualifying the pulse amplitude and timing.

With continued controlled deflation of the cuff, the pulse oscillations increase in amplitude, reach a maximum and then decrease. When qualified pulse amplitude data has been captured over a range of cuff pressures sufficient for the measurement of a patient's blood pressure, the cuff is automatically deflated and post processing begins.

Throughout the entire measurement process, the proprietary MAXNIBP algorithm manages noise artifact (i.e., movement of the patient's arm, touching the cuff, tremor, shivering, transport and vehicle motion, etc.) ensuring the successful completion, accuracy and reliability of the blood pressure measurement.

Figure 1



(1) Note the increasing, peak and then decreasing pulse amplitudes as the pressure is decreased from initial inflation (above systolic) pressure.

(2) A minimum of 6 pressure steps (8 typical) are required to obtain a blood pressure measurement.

(3) A typical blood pressure measurement takes less than 20 - 25 seconds.

(4) The point of maximum oscillations identifies the mean arterial pressure (MAP).

Oscillometric Envelope

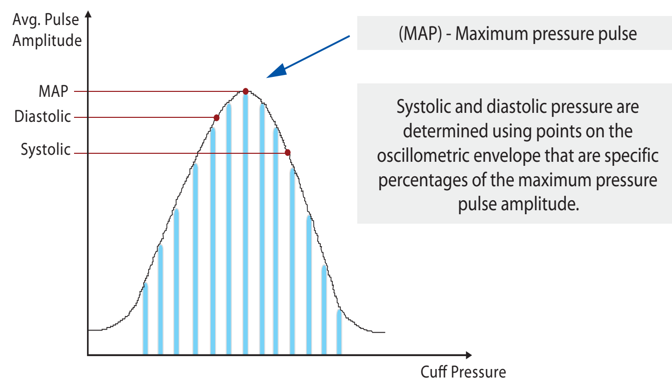
By controlling the cuff pressure over a range that extends above systolic and below diastolic pressures, and by graphing the change in amplitude of these pulses versus the cuff pressure, a curve can be created and used to determine the blood pressure parameters (systolic, mean and diastolic pressure), see Figure 2. This curve is called the oscillometric envelope.[2]

Mean Arterial Pressure (MAP)

The amplitude of the oscillometric signal changes over the course of cuff deflation. The pulse oscillations increase in amplitude, reach a maximum and then decrease (see Figure 2).

The patient's MAP is obtained during oscillometric measurements by determining the cuff pressure at which the maximum pressure pulse amplitude is obtained.[3]

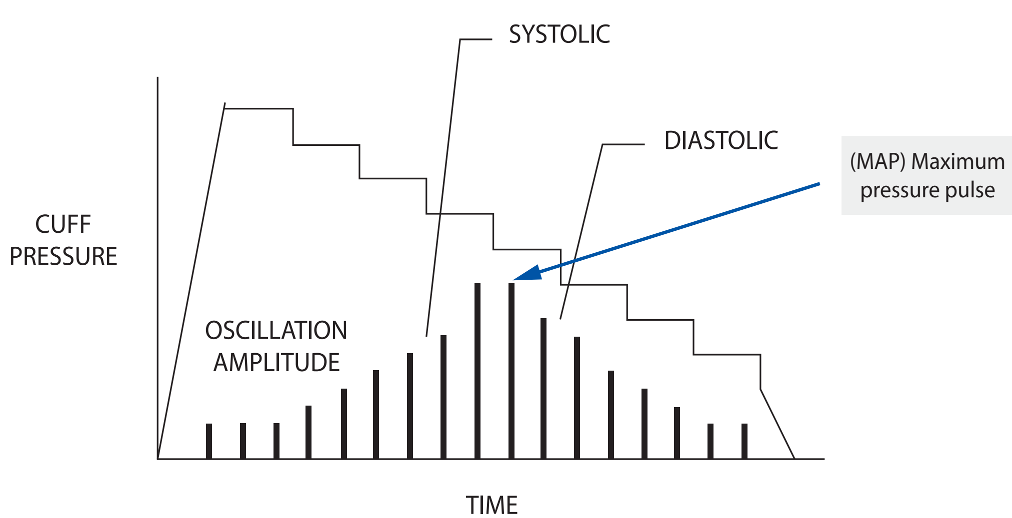
Figure 2



Systolic and Diastolic Pressure

The patient's systolic and diastolic pressure is determined using points on the oscillometric envelope that are specific percentages of the maximum pressure pulse amplitude. The exact percentages used by the MAXNIBP algorithm for the determination of systolic and diastolic pressure were determined empirically during CASMED clinical trials and will vary by patient depending upon the shape of the oscillometric envelope. See "Oscillometric Envelope" and Figure 3 for additional information.

Figure 3



At the Heart of MAXNIBP – Motion Artifact eXtraction

MAXNIBP Motion Artifact eXtraction technology, in combination with the step deflation method, renders superior accuracy of blood pressure measurements by qualifying each fixed pressure step in the oscillometric envelope.

Pulse Detection

Under ideal circumstances, every pressure fluctuation detected by the MAXNIBP module would be caused by the flow of blood into the patient's limb. In practice this is rarely the case. Movement of the patient's arm, touching the cuff, tremor, shivering, transport and vehicle motion all create pressure fluctuations (noise artifact) that will be detected by the MAXNIBP module's highly sensitive pressure transducer.

If the noise artifact is not properly managed, an inaccurate blood pressure determination will result. In the presence of motion artifact, pulse qualification is required to deliver an accurate blood pressure measurement.

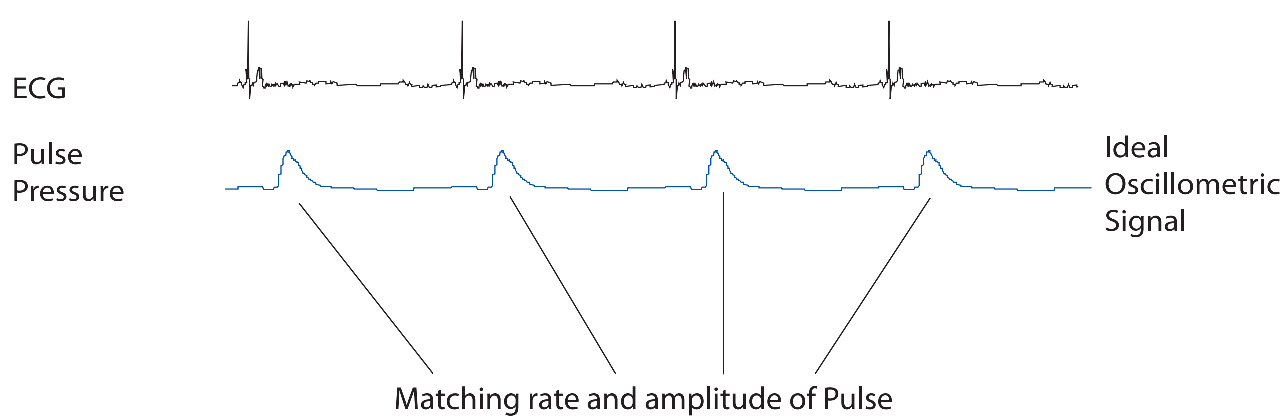
Pulse Qualification

Every pulse produces 3 important measurement characteristics. These include amplitude, rate and cuff pressure at which the pulse is detected. A pulse detected by the MAXNIBP module is always qualified before it is used as part of the oscillometric envelope.

Pulse qualification relies on pulse amplitude and rate matching. Pulses at fixed pressure steps are assumed to be at the same amplitude (or matched). This allows the MAXNIBP algorithm to eliminate non-matching pressure pulses that are heavily influenced by artifact.

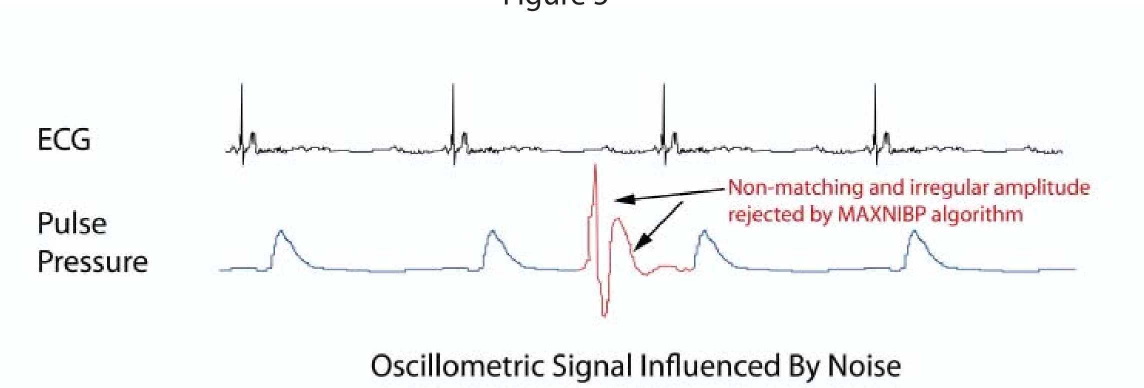
If the amplitude and rate of a pulse, matches the amplitude and rate of a prior pulse at the same pressure step, the pulse is qualified.[1] (See Figure 4).

Figure 4



Using CASMED's Motion Artifact eXtraction technology, non-matching and irregular amplitudes can be identified, isolated and then rejected or ignored. See Figure 5.

Figure 5



Pulse Qualification with Artifact

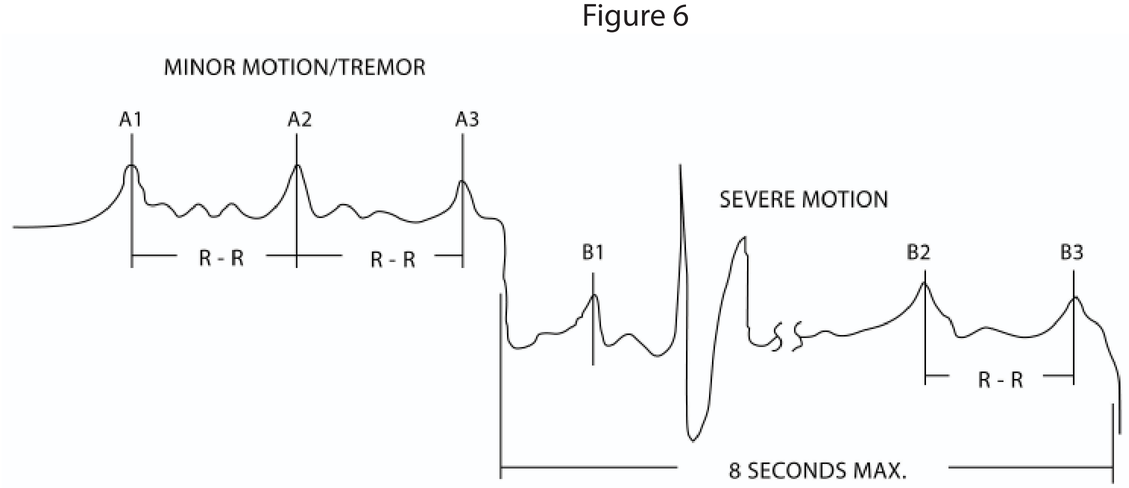
As shown in Figure 6, very small pulses (i.e. minor motion or ringing of the cardiovascular system) can occur between valid pulses (as shown by A1, A2 and A3). Once large pulses have been detected and are being analyzed, small intervening pulses are ignored.

If the MAXNIBP Module measures above the patient's systolic pressure, it may encounter very small, variable pulses compared to pulses detected within the systolic to diastolic range of cuff pressure. These small, variable pulses do not play a role in the determination of the patient's blood pressure.

Large or severe motion artifact may cause abnormally high pulse amplitudes that are out of the expected range (amplitude and timing). This is shown as the large signal disturbance between B1 and B2 in Figure 6 and would not be qualified as a valid pulse.

If noise artifact is detected at a given pressure step, the MAXNIBP algorithm will hold the cuff pressure at that step and wait for qualified pulses to be detected.

Figure 6



MAXNIBP uses complex pulse matching criteria and analysis tools each time a new pulse is detected. When the pulse matching criteria and analysis qualifies the pressure step, the module allows a step down to the next pressure level.

Step Qualification

As pressure steps are qualified and recorded, the MAXNIBP software builds and tracks the oscillometric envelope.

A state machine is used to track the oscillometric envelope. If very large amplitude pulses are found on the first pressure step, it is assumed that the measurement has begun somewhere in the middle of the envelope and the module automatically responds by pumping to a higher pressure, restarting the oscillometric measurement. Whenever the monitor re-pumps to a higher pressure, it effectively restarts the entire measurement. No qualifications made before the re-pump are retained.

When the envelope is completed, it is processed to produce the final results. To be complete, the envelope must have a minimum number of pressure steps and must extend above the systolic pressure and below the diastolic pressure.

Post-processing and blood pressure determination

When the state machine detects that it has enough pressure steps qualified over a broad pressure range, the cuff is deflated cuff and post-processing begins.

Mean arterial pressure is always determined first. The peak of the oscillometric envelope indicates the mean pressure. A parabolic fit of the highest amplitude pulses is used to determine the cuff pressure at which the maximum amplitude occurs.[3] This parabolic fit allows the mean to be resolved to the nearest 1 mmHg and provides more accurate peak amplitude for the systolic and diastolic calculations to follow.

The systolic and diastolic pressures correlate with points on the envelope that have amplitudes at a specific percentage of the peak amplitude. These percentages were found empirically through clinical trials and vary depending upon the shape of the oscillometric envelope.

Heart Rate Determination

In the course of pressure step qualification, a heart rate is established for all qualified pressure steps. Pulse rate is determined by measuring and storing the duration of each pulse between the beginnings of successive oscillation rises.

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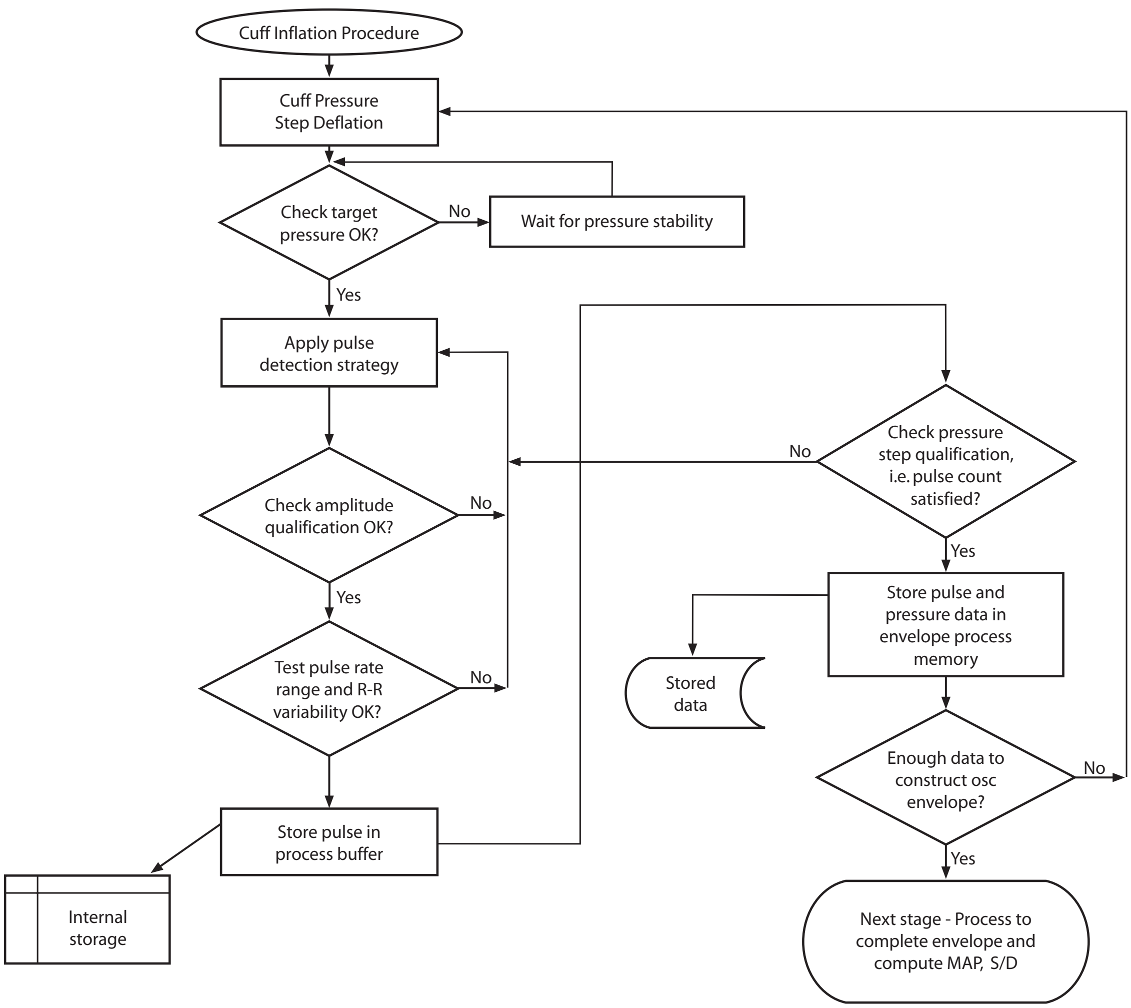
Block Diagram

The block diagram (Figure 7) provides a basic review of the MAXNIBP algorithm employed by the microcontroller to acquire and process pressure pulses.

As noted by comparative studies, the complex pulse matching criteria and analysis used by MAXNIBP is highly effective in discriminating motion artifact encountered during blood pressure measurements in a wide variety of clinical environments.

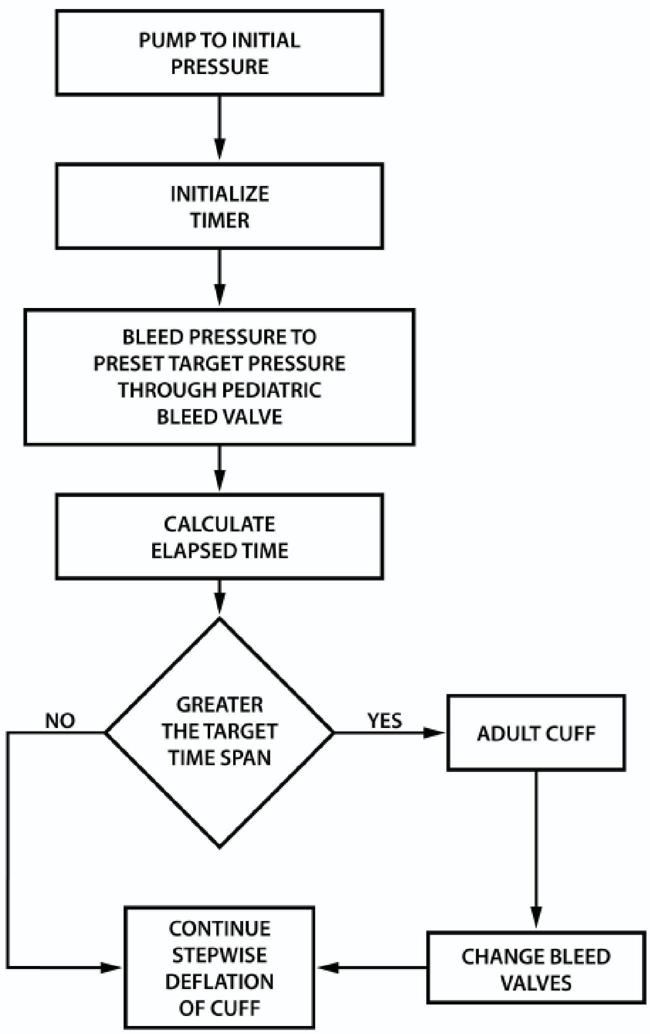
Figure 7



Blood Pressure Cuff Size Determination

The MAXNIBP module may be used with any commercially available blood pressure cuff, provided that the cuff meets the recommendations and guidelines of the American Heart Association.[6]

Requirements for blood pressure cuffs vary by care area and patient need. To accommodate different cuff sizes, the MAXNIBP module has more than one bleed orifice to control the deflation steps. The module's onboard computer is programmed to use a selected bleed orifice in the first bleed step to determine the size of the cuff being used. Once cuff size is determined, the proper bleed orifice for the determined cuff size is used and the blood pressure measurement testing continues.[5]



CASMED offers a complete line of disposable and re-usable blood pressure cuffs to meet your needs. Click on the link for additional product information. http://www.casmed.com/bpcuffs_us.html

For additional information visit our web site: http://www.casmed.com

NIBP Technology comparison: http://www.casmed.com/oemnibp.html

Additional OEM module product details: http://www.casmed.com/OEM_SellRev00.pdf

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