mysafety insight

TrueBP™ (Mindray Linear Inflation Non-Invasive Blood Pressure Measurement)

Clinical Information Leaflet

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Non-Invasive Blood Pressure (NIBP) measurement and monitoring:

Monitoring arterial blood pressure (BP) has become a standard of care in the hemodynamic monitoring of acutely or critically ill patients. In fact, BP monitoring is vital for early detection of hyper- or hypotension, which can impair the function of vital organs such as the brain, heart, and kidneys [1].

The direct measurement of BP by cannulating an arterial catheter is still considered the "gold standard". However, due to the time and resources required and the potential complications derived from the invasiveness of this technique, in many cases, when the severity of the clinical scenario allows, a non-invasive method to measure BP is selected.

Non-invasive techniques estimate the BP by analysing changes in blood flow, while direct methods deliver an actual measurement of BP. Therefore, a minor difference is always expected between the results of these two techniques.

Quicker measurement helps nurses better focus on their patients:

Most patients admitted to healthcare institutions are not critically ill, and they are treated in general wards and outpatient departments, along with anaesthesia and other units. However, non-critically ill patients are not immune from experiencing a sudden deterioration. Therefore, aiming for a smooth workflow that maximises use of time and allows for a better focus on patient care is fundamental to optimise results and ensure patient safety.

In line with the above, research based on the UK National Cardiac Arrest Audit database shows that up to 56% of patients admitted in general wards can experience a sudden cardiac arrest [2]. To aggravate that, there is evidence showing that repetitive direct patient care routines (such as medicine preparation, spot checks, etc.) will cost 56% of a nurse' s daily time, 38% of which is for routine vital sign spot checks (Figure 1) [3] that, due to time pressure, may generate transcription errors of up to 19% when recording patient data [4].

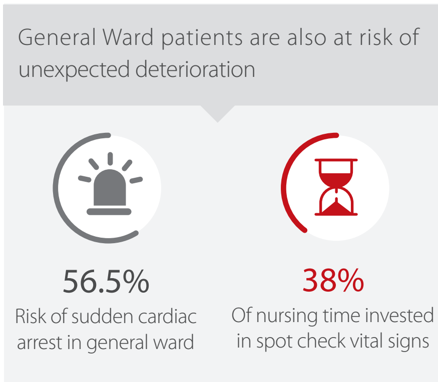


Figure 1. Figures based on the UK National Cardiac Arrest Audit database

Reducing the measurement time in emergency and triage settings as well as on routine and repetitive BP spot checks will have a positive impact on workflow by optimising procedures and reducing monitoring time.

The maximum pressure reached by the cuff must also be taken into consideration to ensure patient safety and avoid undesired complications. The application of too high a cuff pressure, combined with continuous monitoring and/or other clinical settings, like prone positioning or surgery, can result in adverse events like limb oedema, pain, erythema, ecchymoses, compressive neurapraxia, thrombophlebitis, and, ultimately, necrosis and compartment syndrome. Patients with pre-existing peripheral neuropathies, arterial or venous insufficiency, diabetes mellitus, impaired limb perfusion and on anticoagulant or thrombolytic therapy are more susceptible to these complications[5-8].

Combined with the above, the impact that a BP measurement technique will have on a patient's comfort as, for example, the anxiety derived from the "alerting phenomenon" (white-coat hypertension), can be aggravated by longer and more aggressive measurements, and may impact the accuracy of the obtained data [9, 10].

One step forward on the NIBP measurement technique

NIBP measurement with oscillometry by step deflation method:

There are many methods to measure BP non-invasively, but the most widely used is the indirect measurement of BP according to the principle of oscillometry by step deflation. This method is based on the interruption and release of the arterial blood flow by inflating and deflating a cuff. During the measurement, the pressure oscillations are detected in the cuff pressure, their amplitude is measured and analysed (depending on the cuff pressure), and their frequency under different pressures are measured (depending on patient's pulse rate).

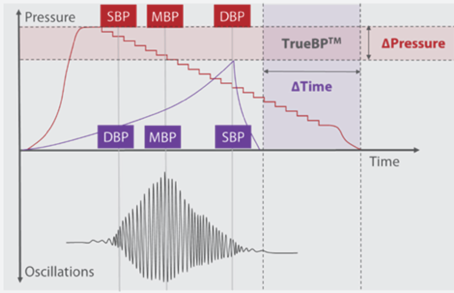
The sphygmomanometer uses an air pump to inflate and pressurize the cuff, which then constricts the artery, so it is completely occluded. Then, the deflation valve initiates the deflation so that cuff pressure is slowly reduced step by step. The pressure sensor reads the pressure changes in the cuff, which are converted into digital signals by A/D sampling to calculate the diastolic blood pressure (DBP), systolic blood pressure (SBP), and mean blood pressure (MBP). The cuff pressure corresponding to the maximum oscillation amplitude is MBP; SBP and DBP are then estimated indirectly according to an empirically derived algorithm.

NIBP measurement with oscillometry by linear inflation method:

In the inflation measurement method, the cuff is inflated and pressurized by an air pump to constrict the artery gradually, from completely open to completely occluded. The pressure sensor collects the pressure changes in the cuff, which are then converted into digital signals by A/D sampling to calculate the DBP, SBP and MBP. The cuff pressure corresponding to the maximum oscillation amplitude is MBP; SBP and DBP are then estimated indirectly according to an empirically derived algorithm.

The main advantage of this method is that it can meet the requirements of speed and comfort, but its anti-interference performance is lower than the step deflation.

Mindray TrueBP™ technology is a new non-invasive blood pressure measurement algorithm developed by Mindray. It can measure blood pressure quickly and comfortably using linear inflation technology. To ensure reliable and safe monitoring, when the measurement result is inaccurate during inflation, TrueBP™ automatically switches to step deflation to obtain the value.



For electronic sphygmomanometers using oscillography, blood pressure calculation is based on the amplitude of the pulse oscillation wave in cuff pressure, so inflation speed is the main influencing factor of measurement accuracy. The slower the inflation measurement speed is, the higher the accuracy will be, but the measurement time will also be longer. To meet the measurement error specified in the standards in the shortest time possible, the inflation rate set for TrueBP™ is 10 mmHg/s [7, 8].

Figure 2. The principle of Mindray TrueBP™ technology

Faster, gentler, and reliable NIBP measurement with TrueBP™

Faster:

When target inflation is higher than the SBP, the cuff will keep unnecessarily inflating above the SBP (Figure 3), which increases measurement time and may result in discomfort to the patient.

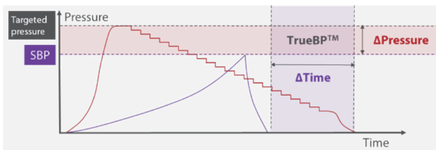


Figure 3. Unnecessarily high target pressure results in prolonged measurement time and discomfort to the patient

When the patient' s blood pressure is higher than the current target pressure, this will lead to one or more repeated inflation and deflation cycles (Figure 4), increasing measurement time, potentially causing discomfort to the patient, and possibly even measurement failure.

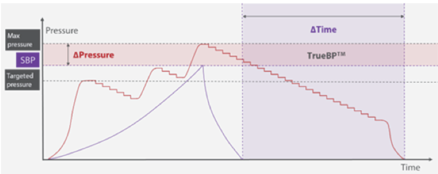


Figure 4. Low target pressure leads to repeated inflation and deflation cycles

Gentler:

Besides the reduced inflation pressure achieved when compared to the step deflation method, and in order to prevent injury to patients caused by excessive inflation pressure, TrueBP™ is designed with a safety protection circuit, which is independently equipped with an auxiliary pressure measurement circuit and an auxiliary microprocessor circuit. During a normal blood pressure measurement, the auxiliary microprocessor circuit samples the cuff pressure at regular intervals through the auxiliary pressure measurement circuit and compares the sampled cuff pressure with a calibrated overpressure protection value. If the sampled cuff pressure exceeds the calibrated overpressure protection value, the auxiliary microprocessor circuit will send a control signal to open the deflation valve until the cuff pressure goes back to a safe pressure range (patented in the U.S. and China)[11, 12]

Reliable:

TrueBP™ vs auscultatory BP measurement: During the development of TrueBP™, the technology was compared against the deflation auscultatory method using a stethoscope, which is still considered the gold standard for measuring BP non-invasively. The test protocol included 86 samples, covering adults and children with different blood pressure ranges, and a total of 258 sets of measured data. The statistical results displayed in the table below showed that when compared to the deflation auscultatory method values, the Mindray linear inflation measurement (TrueBP™) results met the requirements of clinical standards (Table 1) [13, 14].

Category	Number of Date Sets	Scope	Mean Difference(mmHg)			Standard Deviation(mmHg)		
		(mmHg)	Result	Acceptance Criteria	Conclusion	Result	Acceptance Criteria	Conclusion
SBP	258	74~178	1.2	Absolute value ≤ 5.0	Meets the requirements	6.3	≤ 8.0	Meets the requirements
DBP	258	40~120	-0.5	Absolute value ≤ 5.0	Meets the requirements	6.8	≤ 8.0	Meets the requirements

Table 1. Comparison results of Mindray inflation measurement with stethoscope

TrueBPTM vs electronic step deflation BP measurement: During its development, the accuracy of TrueBPTM was compared with that of the existing step deflation measurement by Mindray. For these tests, the stethoscope method was used as a reference to verify the accuracy of Mindray inflation and deflation measurements. The test protocol included 86 samples, covering adults and children with different blood pressure ranges, and a total of 258 sets of measured data. The statistical results displayed in the graphs below show that the accuracy of the Mindray linear inflation measurement (TrueBPTM) results and the Mindray step deflation measurement results were comparable, and both met the requirements of clinical standards (Figure 5) [13, 14].

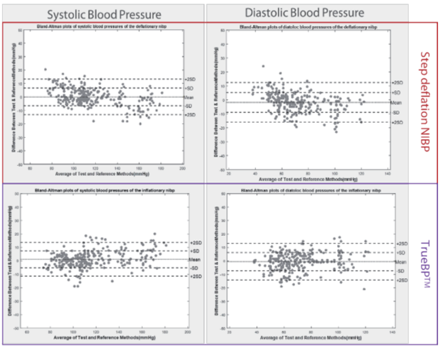


Figure 5. The accuracy test results of TrueBPTM compared with that of the existing step deflation measurement by Mindray

TrueBPTM measurement speed: In order to evaluate the Mindray inflation measurement time, 302 clinical samples were analysed, including 1,934 sets of Mindray inflation measurement data and 2,035 sets of Mindray deflation measurement data. The data were collected from multiple departments, including emergency, respiratory, urology, and nephrology departments.

The test results shown in the table that follows showed that the time of Mindray inflation measurement was between 13 and 25 seconds less than that of the Mindray step deflation measurement (Figure 6).

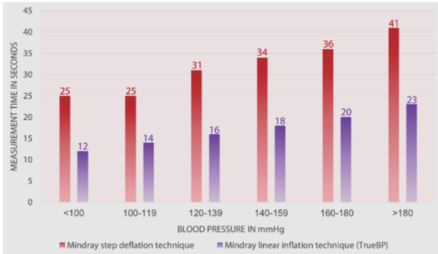


Figure 6. A comparison of Mindray inflation measurement time and that of the step deflation method

TrueBPTM maximum inflation cuff pressure: The maximum inflation cuff pressure is related to the comfort of measurement. Based on the statistical analysis on the maximum inflation pressure of Mindray inflation and deflation measurements, the results indicated that maximum inflation pressure in the Mindray linear inflation measurements (TrueBPTM) was on average 18 mmHg lower than that of the Mindray step deflation measurements (Figure 7).

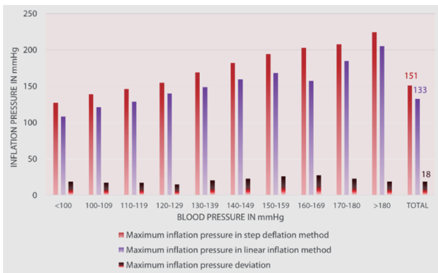


Figure 7. Maximum inflation pressure comparison of two methods (inflation and step deflation)

Faster, gentler, and reliable NIBP measurement with TrueBP™

The Mindray TrueBP™ cuff features a unique design with "hook & loop" fastener position and width, which ensures that the vibration interference noise of the cuff balloon is low during cuff inflation (Figure 8). Especially when worn by patients with the smallest applicable arm circumference declared by the cuff, it can effectively restrain the micro-displacement (oscillation) caused by the volume expansion of the cuff balloon and improve the success rate of inflation measurement and the accuracy of measurement results [15, 16]. The buckle and cuff are connected by the sewing process, and the fully-welded edges and cuff body can effectively prevent indentation and damage to the patient' s skin caused by buckle edges and ensure comfort during BP measurement.

Mindray TrueBP™ technology requires the use of cuffs with the TrueBP™ silk-screen and logo.

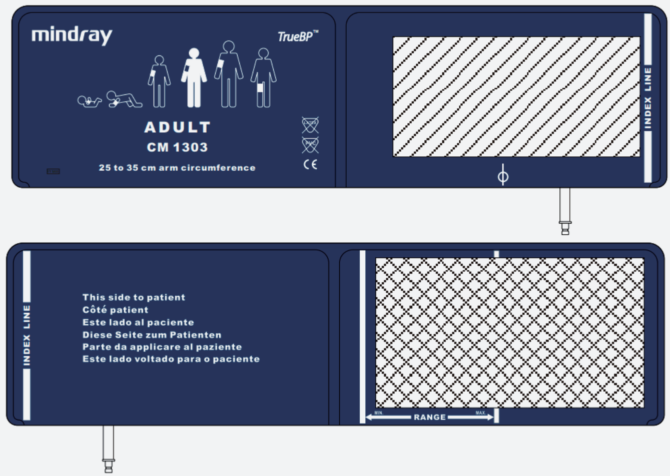


Figure 8. Dedicated cuff design for the TrueBP™ technology

Mindray's innovative TrueBP™ technology was designed to support caregivers' workflow by significantly reducing the time required for non-invasive blood pressure measurement without sacrificing accuracy. The use of TrueBP™ technology and TrueBP™ cuffs enhance patient safety by administering adequate cuff pressure required for measurements and avoiding undesired complications.

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