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April 1, 2016

Re: AutoPulse® 80 compressions per minute rate

Dear Valued Customer,

The purpose of this letter is to provide information regarding the compression rate of the AutoPulse Resuscitation System, which is set to 80 compressions per minute.

Chest compression rate in the 2015 Guidelines – manual and load-distributing band

The compression rate of the AutoPulse Resuscitation System, which is set to 80 compressions per minute, is compliant with the 2015 AHA and ERC Guidelines.

Regarding what's indicated within the 2015 AHA and ERC Guidelines, **the 100-120 compressions per minute rate specifically applies to manual CPR** (sternal compressions). The AHA Guidelines states "there is an interdependent relationship between compression rate and compression depth during **manual** chest compressions: as rate increases to greater than 120/min, depth decreases in a dose-dependent manner…In adult victims of cardiac arrest, it is reasonable for rescuers to perform chest compressions at a rate of 100/min to 120/min."[1]

The AutoPulse utilizes a load-distributing band technology to deliver patient-customized circumferential compressions, as described in the 2015 AHA Guidelines: *Alternative Techniques and Ancillary Devices for Cardiopulmonary Resuscitation*. It states "the load-distributing band (LDB) is a circumferential chest compression device composed of a pneumatically or electrically actuated constricting band and backboard."[2]

Furthermore, the 2015 ERC Guidelines specifically indicate the 80 compressions per minute rate of the AutoPulse. In *Section 3. Adult advanced life support*, it states "[The AutoPulse] encircles the patient's chest. **Compressions are delivered at a rate of 80 min**[1] by tightening of the band."[3]

The 2015 AHA Guidelines also gives the AutoPulse a Class IIb rating (benefit ≥ risk), which is the same rating given to all mechanical chest compression devices in the Guidelines.[2]

AutoPulse design – 80 compressions per minute

When the AutoPulse was designed, the 80 compressions per minute rate that the device is currently set to was targeted to achieve improvements in multiple clinical outcomes (i.e. hemodynamics, ROSC, etc.) when compared to manual CPR and piston-driven mechanical CPR devices, which have since been clinically proven with the AutoPulse.

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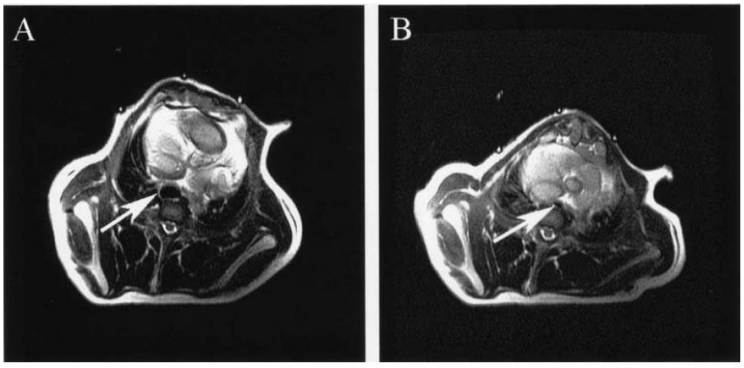
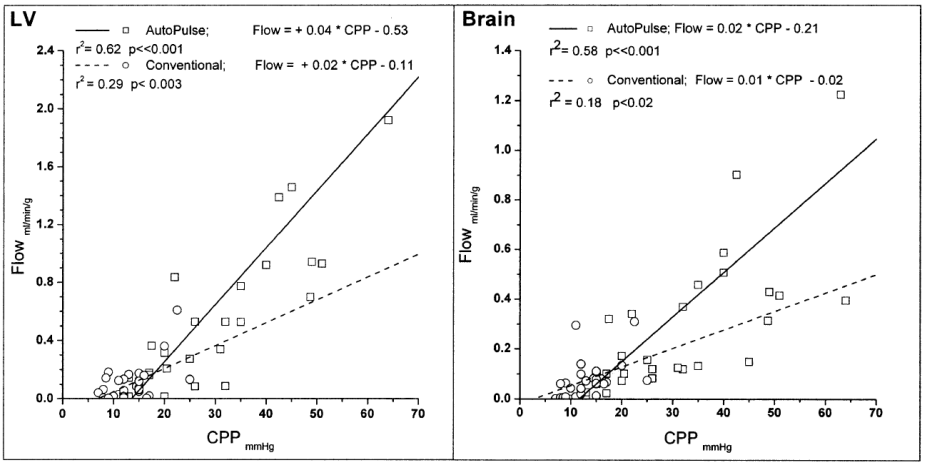
The AutoPulse delivers patient-customized circumferential compressions, which are fundamentally different than sternal compressions. As a result, the AutoPulse compresses a larger area of a patient's chest than is possible with a sternal compression. During AutoPulse CPR, high airway pressures have been noted distal to the carina, which corresponds to an area of airway collapse. This is due to a nearly closed trachea during the compression phase of AutoPulse CPR (Figure 1, below), which maintains a higher intrathoracic pressure and results in increased blood flow to both the heart and brain (Figure 2). Conversely, during sternal CPR delivered manually, no such high airway pressures have been noted.[4]

Figure 1



Magnetic resonance imaging of the thorax during AutoPulse cardiopulmonary resuscitation. The trachea is widely patent in the uncompressed state **(A, arrow)** but is nearly fully collapsed during peak compression **(B, arrow)**.

Figure 2



Correlations between left ventricular (LV) and brain flows, and coronary perfusion pressure (CPP), for AutoPulse cardiopulmonary resuscitation (A-CPR) and conventional (piston) cardiopulmonary resuscitation (C-CPR). For both the LV and brain, A-CPR produced more flow at given levels of CPP than C-CPR ($p < 0.05$).

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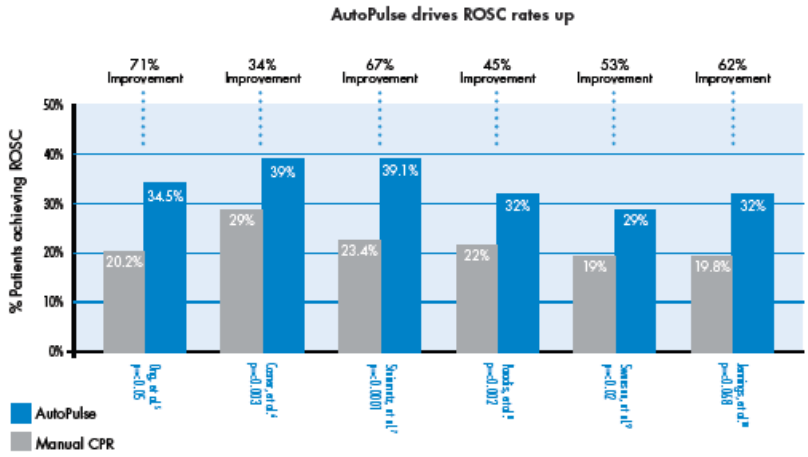
Additionally, because the AutoPulse provides a circumferential compression, thereby collapsing the airway and resulting in intrathoracic pressure manipulation, **blood flow has been found to be insensitive to the rate of compression when the duration of compression is fixed**. When the entire thoracic contents are pressurized, blood moves from the compliance in the thorax through a resistance to the compliance in the periphery. The flow of blood is determined by the amount of time the thorax is compressed (duty cycle), rather than the rate.[5] As the AutoPulse performs CPR at a uniform 50% duty cycle, its rate of 80 compressions per minute has been proven to improve myocardial flow, cerebral flow, aortic pressure, as well as coronary perfusion pressure when compared to manual CPR.[4,6-8]

<u>The AutoPulse advantage – clinical outcomes</u>

Multiple comparative studies have demonstrated improved vital signs because the AutoPulse drives superior blood flow. When it comes to increasing a patient's odds of ROSC, these studies confirm that the AutoPulse, with its unique circumferential compressions, is superior to manual sternal CPR[9-14].



We hope you find this information beneficial. We look forward to working with you, and we remain committed to providing you with high-quality products that help save patients' lives.

Sincerely,

TJ Rivera
Global Director, AutoPulse

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