

cprINSIGHT™ Analysis Technology

Introduction

Automated external defibrillators (AEDs) like the LIFEPAK® CR2 defibrillator are essential to treating fatal ventricular fibrillation/ pulseless ventricular tachycardia associated with sudden cardiac arrest (SCA). However, some victims may be difficult-to-defibrillate or may not have a shockable rhythm, so longer periods of CPR are needed.

The American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines for high-quality CPR have stressed the importance of minimizing pauses during compressions. This topic has been the subject of much clinical interest and investigation. Studies show increases in return of spontaneous circulation (ROSC) and survival rates with higher compression fractions (hands-on compression time) and less pre/post-shock pauses,^{1,2,3,4} while more recently published data demonstrated the longest pause time from any cause was associated with decreased survival.⁵ Another study concluded compressions during defibrillator charging may shorten shock pause duration and improve chest compression fraction in shockable out-of-hospital cardiac arrest (OHCA).⁶ Finally, one study determined first responders using AED voice prompts provide CPR less than half the time the AED is connected to the patient.⁷ In light of this data, the guidelines recommended the goal of chest compression fraction as high as possible, with a target of at least 60% (Class IIb).^{8,9}

With the introduction of cprINSIGHT analysis technology in the LIFEPAK CR2 defibrillator, pauses for ECG analysis and device

charging are eliminated, allowing more time to deliver chest compressions, thus increasing compression fraction.

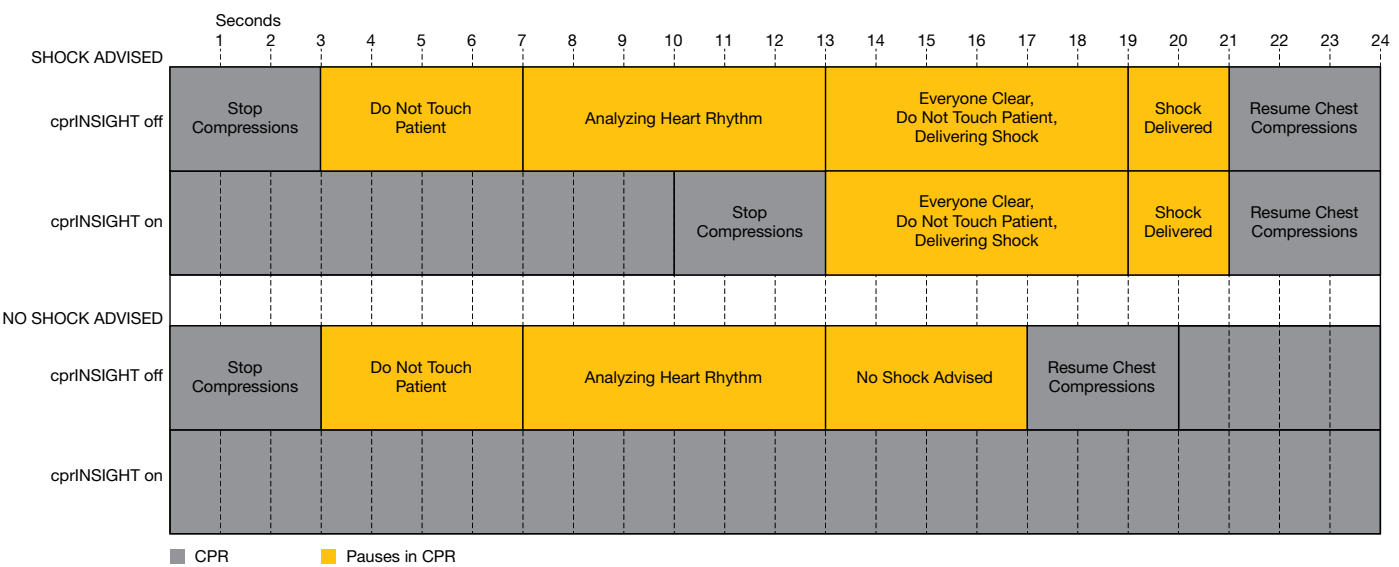
Description

This proprietary algorithm processes both ECG and patient impedance data during chest compressions to determine whether or not a shock is needed. When the ECG rhythm is determined to be shockable, the necessary pause time is shortened to only the time needed for the rescuer to stand clear and deliver the shock; hands-off time for the shock analysis and charging the AED are eliminated. When the rhythm is determined to be nonshockable, the pause for analysis can be eliminated altogether, allowing for continuous CPR.

The illustration below shows how cprINSIGHT analysis technology can shorten CPR pause time. In both the shock advised and no shock advised scenarios, two prompts are no longer needed during the rhythm analysis (“Do Not Touch Patient” and “Analyzing Heart Rhythm”).* Ten (10) seconds of no CPR time are eliminated in a shock advised scenario and 14 seconds are eliminated in a no shock advised scenario.

In a usability study, participants using the LIFEPAK CR2 defibrillator had a compression fraction (hands-on time) of 89%, the highest of any other AED tested.¹⁰

***Note:** These prompts are delivered during the first analysis after defibrillation pads are placed to obtain a baseline decision without compression artifact.



Benefits

- Increases CPR hands-on time during resuscitation of a cardiac arrest patient
- For use on both adult and pediatric patients, with the same electrodes
- For use during manual CPR or mechanical CPR
- No accelerometer or other additional sensors required; works with pre-connected QUIK-STEP™ electrodes for CR2

Accuracy

The algorithm was verified by inputting specific ECG waveform segments collected from cardiac arrest patients through the electrode connector, and recording the decision of 'shock' or 'no shock.' The 'shock' or 'no shock' decision made by the algorithm for each ECG waveform segment was compared to the decision made by three clinical experts when they classified these individual ECG segments into rhythm groups, thus making a treatment recommendation of 'shock' or 'no shock.'

The cprINSIGHT Test Set used for verifying the algorithm consists of 2,775 ECG and impedance segments gathered from ten emergency medical services with locations in North America and Europe. A separate cprINSIGHT Pediatric Test Set with 699 segments of known pediatric patients gathered from two emergency medical services was also evaluated. Included were patients that were treated with a LIFEPAK 1000 AED or a LIFEPAK 12 defibrillator/monitor, with CPR performed some time during the case. Cases were included in which the CPR was administered manually or with the LUCAS® chest compression system. The data was transferred

digitally from the LIFEPAK devices used to treat the patients and provided to Physio-Control. Clinical experts determined the patient's rhythm by interpreting pauses in CPR if there was excessive artifact that prevented interpretation during the CPR period. The segments used for testing the algorithm were at least 30 seconds long.

The results of tests with the cprINSIGHT Test Sets in the LIFEPAK CR2 defibrillator are shown below in the context of requirements from IEC 60601-2-4 and the recommendations from the American Heart Association. The recommendations from the AHA and the IEC 60601-2-4 reporting requirements are based on "artifact-free" ECG data. These results are provided for information only.

Table 1: IEC 60601-2-4 Requirements and cprINSIGHT Analysis Technology Performance for the cprINSIGHT Data Set

RHYTHM CATEGORY	REQUIREMENT	TEST RESULT
Shockable (Sensitivity) Coarse VF	>90%	Met
Nonshockable (Specificity)	>95%	Met
Positive Predictive Value	Report Only	>90%
False Positive Rate	Report Only	<5%

Conclusion

cprINSIGHT Analysis Technology has been shown to minimize pauses and increase compression fraction (hands-on time) during the treatment of SCA patients with the CR2 AED. Testing has shown the algorithm to be accurate. Utilizing the LIFEPAK CR2 defibrillator with this technology will help users meet the current ERC guidelines for CPR.

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10. Clinical Summary: AED Comparison Usability Study. GDR 3331412_B

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