

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, it is also critical to provide as much continuous CPR as possible throughout a resuscitation for the best chance of survival.

Compression pauses

The American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines for high-quality CPR have stressed the importance of minimizing pauses in chest compressions. They also recommended the goal of chest compression fraction as high as possible, with a target of at least 60% (Class IIb).^{1,2}

- Data demonstrated the longest compression pause, for any reason, was associated with decreased survival.³
- Studies also show that higher compression fractions (hands-on compression time) and shorter pre/post-shock pauses are associated with increases in rates of return of spontaneous circulation (ROSC) and survival.^{4,5,6,7}
- Compressions during defibrillator charging may shorten shock pause duration and improve chest compression fraction in shockable out-of-hospital cardiac arrest (OHCA).⁸

Rhythm accuracy in AEDs

A study evaluated the diagnostic performance of rhythm detectors used in standard AEDs, including possible causes for inappropriate shock delivery or the failure to deliver shock that was advised. About 25% of errors were caused by movement of the patient during AED rhythm analysis, mainly due to

continuing chest compressions despite AED prompts to stop compressions.⁹

cprINSIGHT technology

With the introduction of cprINSIGHT analysis technology in the LIFEPAK CR2 defibrillator, pauses for ECG analysis and device charging are reduced (and many of the pauses are eliminated altogether), allowing more time to deliver chest compressions, thus increasing compression fraction.

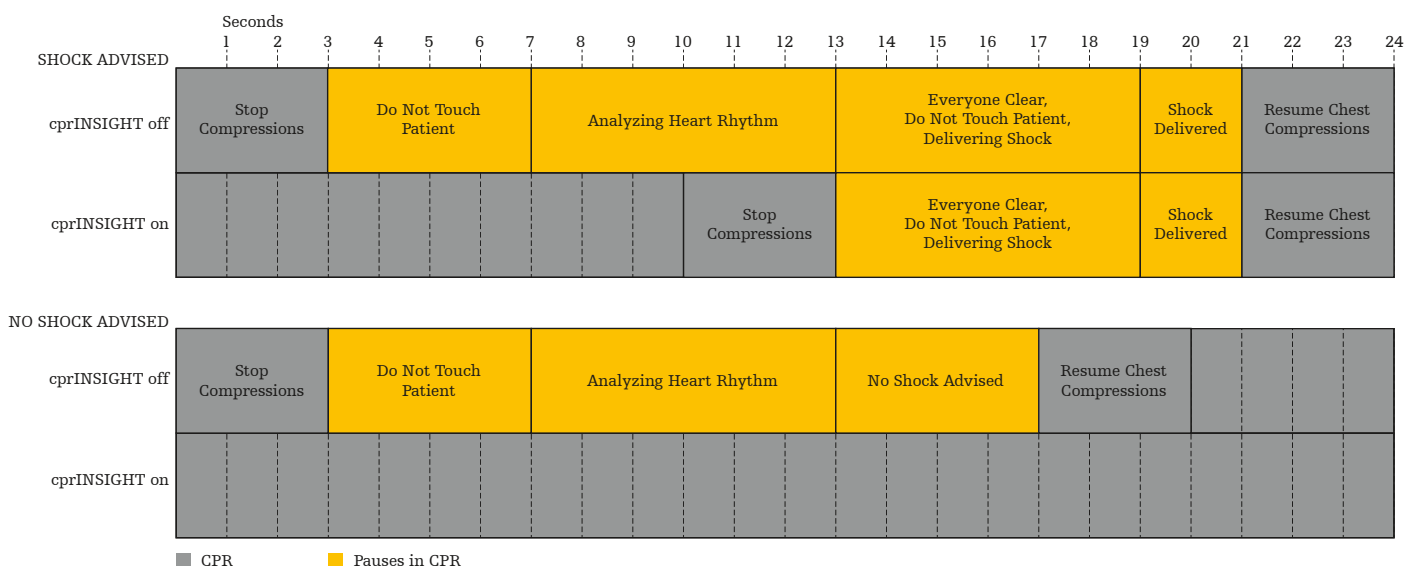
This proprietary algorithm processes the patient's ECG and impedance data during chest compressions to classify the rhythm as:

- shockable (S)
- non-shockable (NS)
- no decision (ND)

When the rhythm is classified S, 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 ECG analysis and charging the AED are eliminated. When the rhythm is classified NS, the pause for analysis can be eliminated altogether, allowing for continuous CPR. If the rhythm is classified ND, the CR2 prompts for a pause in CPR and uses its conventional shock advisory system algorithm.

cprINSIGHT compression pause reduction

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.* 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.



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

cprINSIGHT accuracy

Since cprINSIGHT is designed to assess the patient's rhythm during compressions, erroneous rhythm decisions previously caused by movement related to compressions would be greatly reduced, if not eliminated in most cases.

The algorithm was validated by inputting ECG waveform segments collected from cardiac arrest patients 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 validating 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 used. 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 Stryker Emergency Care. 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 in Table 1 in the context of requirements from the IEC 60601-2-4 defibrillator standard and the recommendations from the American Heart Association (AHA). 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
Non-shockable (specificity)	>95%	Met

After commercial release of the CR 2 defibrillator, data from 132 consecutive OHCA cases were analyzed¹⁰. Analyses 2-4 covered 90% of all cprINSIGHT analyses (the first analysis uses the traditional shock advisory system [SAS] analysis; subsequent analyses use the cprINSIGHT algorithm).

cprINSIGHT reached a S or NS decision about 70% of the time, with a sensitivity of 90-100% and a specificity of 100%. Patients with a shockable rhythm have the best chance to be resuscitated. cprINSIGHT reached a decision in 94% of analyses of shockable rhythms and those decisions were correct in all but one case.

In this study, chest compression fraction was 85-88%.

Conclusion

cprINSIGHT Analysis Technology was designed to reduce pauses and increase compression fraction (hands-on time) during the treatment of SCA patients with the CR2 AED. The algorithm can be used on children and is compatible with the LUCAS chest compression system. The algorithm has been shown to be very accurate through test and published data.

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Physio-Control, Inc.
11811 Willows Road NE
Redmond, WA, 98052 U.S.A.
Toll free 800 442 1142
strykeremergencycare.com

Stryker European
Operations B.V.
Herikerbergweg 110
1101 CM Amsterdam
Netherlands
 for Physio-Control, Inc.
Tel +31 (0)43 3620008
Fax +31 (0)43 3632001

Stryker UK Ltd
Stryker House
Hambridge Road
Newbury, Berkshire
RG14 5AW
United Kingdom

Stryker Australia Pty Ltd
8 Herbert Street
St Leonards NSW 2065
Australia
Toll Free Tel 1800 987 982
Toll Free Fax 1800 890 982