

cprINSIGHT™ Analysis Technology

Lay Rescuers

Introduction

No one expects to resuscitate a victim of sudden cardiac arrest (SCA) in a public setting. Yet SCA can happen anywhere, anytime, to anyone and affects approximately 366,807 people in the United States each year¹. Automated external defibrillators (AEDs) like the LIFEPAK® CR2 defibrillator are essential to treating the fatal heart rhythm (ventricular fibrillation) that often is associated with SCA. However, it is also critical to provide as much continuous CPR as possible throughout a resuscitation for the best chance of survival. When performing compressions, you are essentially taking over the heart function for the victim when his own heart has failed. Many people do not survive if several shocks are unsuccessful or the victim initially has a non-shockable rhythm. Dismal and unmovable survival rates prompted professional organizations like the American Heart Association (AHA) to establish new and more vigorous CPR guidelines for medical professionals. These changes included: a rate at least 100 compressions/min., a depth of at least 2 inches, full release of pressure on compression upstroke, and minimizing pauses². They are also teaching trained lay rescuers these steps.

When it comes to CPR, more is better. More CPR means less interruptions and pauses. Interruptions to CPR time include AED analysis, defibrillator charging time and lengthy voice prompts on CPR instructions. So how can you get more CPR time if you are following the prompts of an AED? cprINSIGHT Analysis Technology is a new technology introduced in the CR2. Its goal is pure and simple: More CPR time during resuscitation with an AED.

What is cprINSIGHT Analysis Technology?

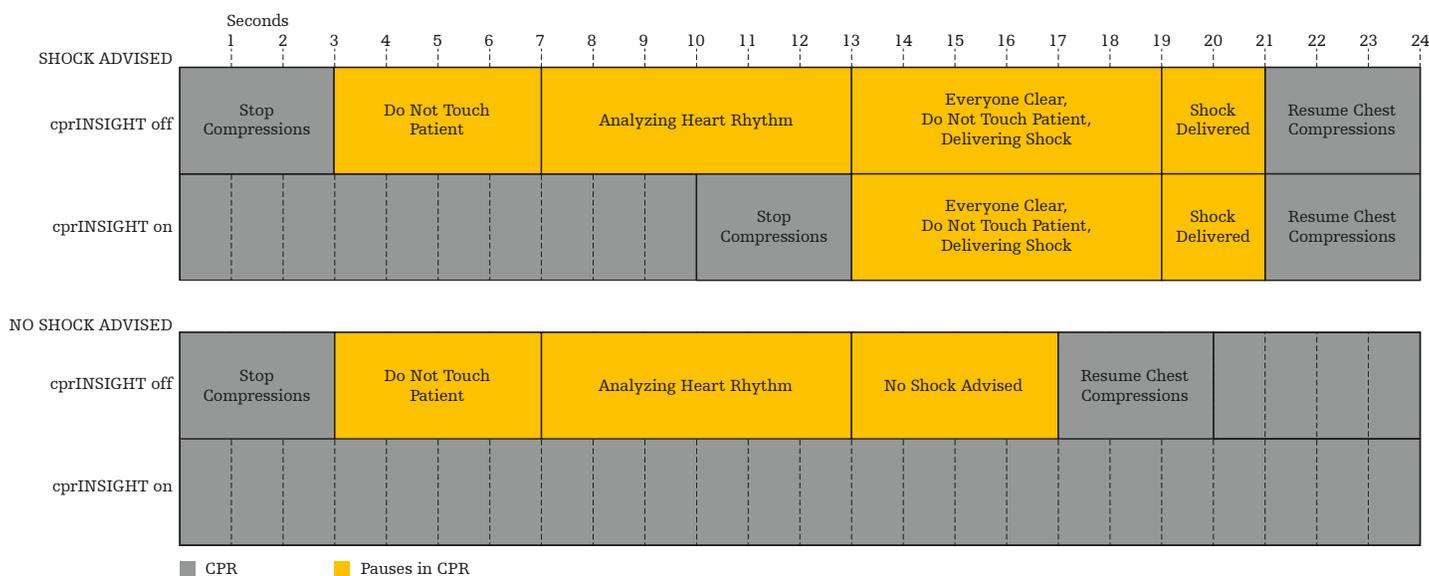
This proprietary algorithm decreases hands-off time during resuscitation of a cardiac arrest patient by reducing or eliminating pauses associated with ECG analysis and defibrillator charging by processing the patient's ECG and impedance data during chest compressions to classify the rhythm as:

1. shockable (S)
2. non-shockable (NS)
3. 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 because they now occur during chest compressions. 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 Analysis Technology can be used on adult and pediatric patients

cprINSIGHT accuracy

A study showed about 25% of errors in AED decisions were caused by movement of the patient during AED rhythm analysis, mainly due to continuing chest compressions despite AED prompts to stop compressions³. 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 analyzed⁴. 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 use 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.

LIFEPAK CR2 defibrillator

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE:

LIFEPAK CR2 AED is indicated for use on patients 1 year of age or older in cardiopulmonary arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation (for example, no pulse, no coughing, or no movement). cprCOACH™ Feedback Technology in CR2 AED is indicated for use on cardiopulmonary arrest patients and provides CPR guidance in accordance with AHA Guidelines for patients 1 year of age or older. AED is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support/AED, advanced life support, or a physician-authorized emergency medical response training program. The LIFEPAK CR2 Defibrillator is indicated to be used with the QUIK-STEP™ Pacing/ECG Defibrillation Electrodes and the LIFEPAK CR2 Lithium Battery.

CONTRAINDICATIONS:

LIFEPAK CR2 AED is not indicated for patients who are conscious and responsive.

DANGER:

Do not use LIFEPAK CR2 in presence of flammable gases or anesthetics.

WARNINGS:

- LIFEPAK CR2 AED delivers up to 360 joules of electrical energy. Unless used properly by following AED's visual and audio prompts, this electrical energy may cause serious injury or death.
- When instructed EVERYONE CLEAR, do not touch AED, patient, electrode pads or any material/fluid in contact with patient. Make sure no one is touching patient when AED shocks patient.
- Do not immerse AED in water or other fluids. Avoid spilling fluids on AED or its accessories.
- Do not store in presence of flammable gases, anesthetics or in direct contact with flammable material. Use care when operating close to oxygen sources. Turn off gas source or move it away from patient during defibrillation.
- Equipment operating in close proximity may emit strong electromagnetic interference (EMI) or radio frequency interference (RFI) which could affect performance of AED.
- Keep AED away from magnetic resonance imaging (MRI) equipment as it is unsafe.
- AED should not be used adjacent to or stacked with other equipment.
- Do not touch patient and USB connector on back of AED simultaneously.
- Replace battery immediately when AED indicates battery is low.
- Use only accessories specified by Physio-Control or Stryker. Using other manufacturers' accessories may cause AED to perform improperly and may invalidate safety agency certification. Contact authorized service personnel for repair.

- QUIK-STEP electrode pads: Place pads so they adhere to skin completely.
- Do not allow pads to touch each other or any material on patient's chest.
- Do not use damaged, expired, or dried-out pads. Dried out or damaged pads may cause electrical arcing and skin burns during defibrillation.
- Do not pull red handle to open electrodes until immediately before use.
- QUIK-STEP electrodes provided with CR2 are not compatible with LIFEPAK 500 device. Emergency medical personnel should not connect these electrodes to LIFEPAK 500 device.

CAUTIONS:

- Damaged batteries may leak and cause personal injury or equipment damage; handle with extreme care.
- Do not open device lid unnecessarily as this will reduce internal battery power.

POTENTIAL ADVERSE EFFECTS (for example, complications):

- Failure to identify shockable arrhythmia
- Failure to deliver a defibrillation shock in presence of ventricular fibrillation (VF) or pulseless ventricular tachycardia, which may result in death or permanent injury
- Inappropriate energy delivery which could cause failed defibrillation or post-shock dysfunction
- Myocardial damage
- Incorrectly shocking a pulse-sustaining rhythm and inducing VF or cardiac arrest
- Bystander shock from patient contact during defibrillation shock
- Interaction with pacemakers
- Skin burns around electrode pad placement area
- Allergic dermatitis due to sensitivity to materials used in electrode construction
- Minor skin rash
- Fire hazard in presence of high oxygen concentration or flammable anesthetic agents
- EMI from AED impacting other devices especially during charge and energy transfers

U.S. Federal law restricts this device to sale by or on the order of a physician.

Please consult Operating Instructions at www.strykeremergencycare.com or call 800.442.1142 for complete list of indications, contraindications, warnings, cautions, potential adverse events, safety and effectiveness data, instructions for use and other important information.

References

1. Benjamin E, Virani S, Callaway C, et al. Heart disease and stroke statistics – 2018 Update. *Circulation*. 2018; 137:e355.
2. Kleinman M, Brennan E, Goldberger Z, et al. Part 5: Adult basic life support and cardiopulmonary resuscitation quality. 2015 American Heart Association Guidelines.
3. Zijlstra J, Bekkers L, Hulleman M, et al. Automated external defibrillator and operator performance in out-of-hospital cardiac arrest. *Resuscitation*. 2017;118:140-146.
4. de Graaf C, Beesems S, Stickney R, et al. Analyzing heart rhythm during chest compressions in out-of-hospital cardiac arrest patients using new algorithm for automated external defibrillators. *Circulation*. 2018;138(Suppl_2). Abstract 18.

For further information, please contact Stryker at 800 442 1142 (U.S.), 800 668 8323 (Canada) or visit our website at strykeremergencycare.com

Emergency Care

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