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). Early defibrillation for shockable rhythms drastically increases survival rates.[1,2,3] However, it is also critical to provide as much continuous CPR as possible throughout a resuscitation for the best chance of survival. In the 2020 American Heart Association Guidelines for Cardiopulmonary and Emergency Cardiovascular Care update, the importance of CPR during SCA is more direct:[1]

> "CPR is the single-most important intervention for a patient in cardiac arrest, and chest compressions should be provided promptly."
>
> **2020 AHA Guidelines for cardiopulmonary resuscitation and emergency cardiovascular care**

Compression pauses

The AHA and European Resuscitation Council (ERC) Guidelines for high-quality CPR have stressed the importance of minimizing pauses in chest compressions. They also recommended maintaining chest compression fraction (CCF) as high as possible, with a target of at least 60 percent (Class IIb).[1,4]

- Data demonstrated the longest compression pause, for any reason, was associated with decreased survival.[5]
- 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.[6,7,8,9]
- Compressions during defibrillator charging may shorten shock pause duration and improve chest compression fraction in shockable out-of-hospital cardiac arrest (OHCA).[10]

Rhythm accuracy in AEDs

Diagnostic performance of rhythm detection used in standard AEDs can be negatively impacted by movement of the patient during AED rhythm analysis. This can lead to inappropriate shock delivery or failure to defibrillate a shockable rhythm. Approximately 25 percent of errors can be caused by movement of the patient during AED rhythm analysis, mainly due to continuing chest compressions despite AED prompts to stop compressions.[11]

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 pauses are eliminated altogether), allowing more time to deliver chest compressions, thus increasing compression fraction.

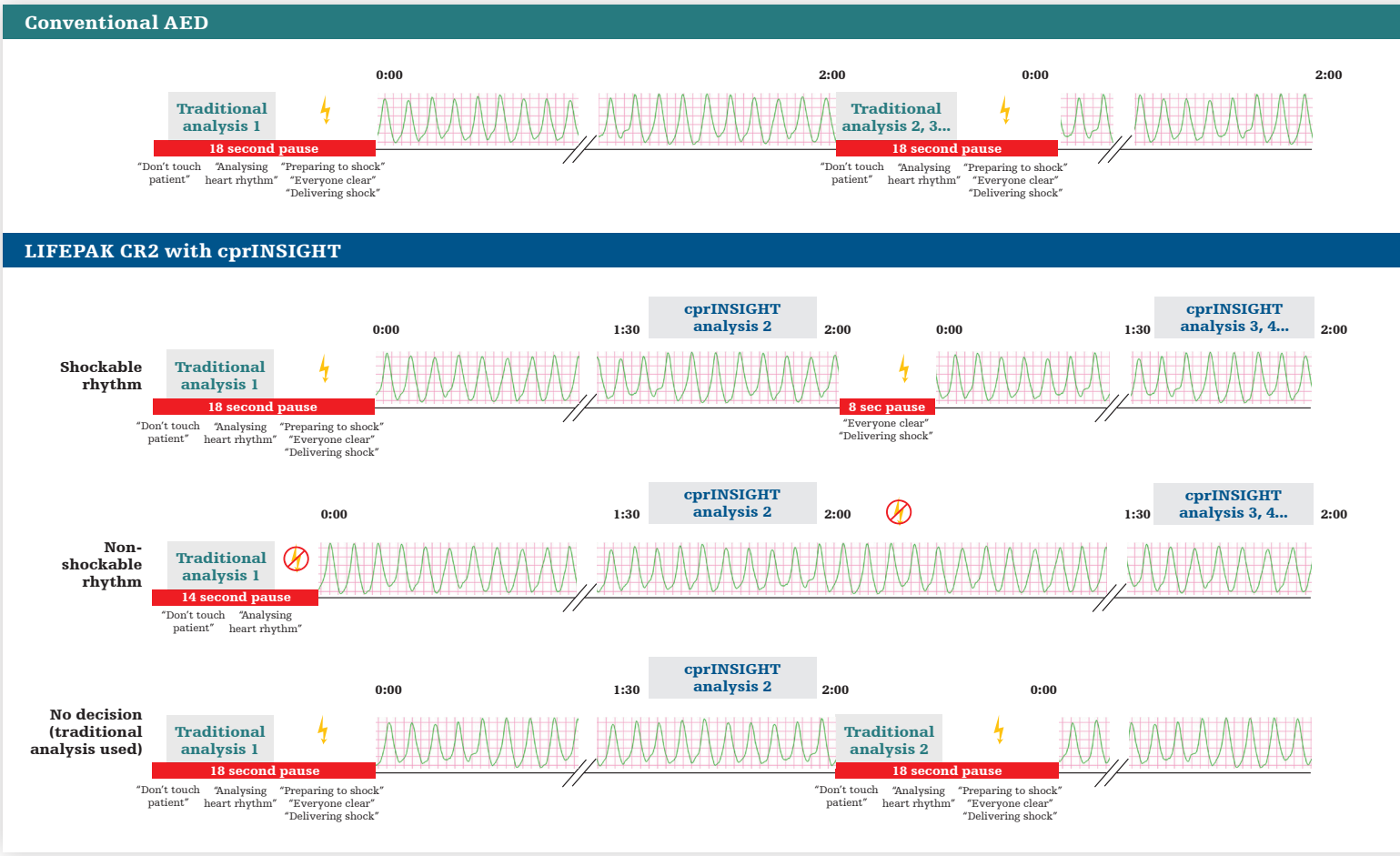
The LIFEPAK CR2 AED begins with traditional rhythm analysis then quickly transitions to cprINSIGHT analysis:

- The initial rhythm analysis is conducted using the Shock Advisory System™ (SAS), which is available on all of Stryker's LIFEPAK AEDs. This analysis requires rescuers to stop chest compressions in order to quickly determine if the patient is in a shockable rhythm.
- During subsequent analyses, cprINSIGHT analyzes the patient's ECG rhythm during chest compressions well before the end of the two-minute CPR cycle and classifies the rhythm as:

1. **Shockable (S)** - 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.
2. **Non-shockable (NS)** - When the rhythm is classified NS, the pause for analysis can be eliminated altogether, allowing for continuous CPR.
3. **No decision (ND)** - Occasionally, cprINSIGHT will reach ND, which means that the rhythm analysis is inconclusive. The LIFEPAK CR2 AED will prompt the rescuer to stop chest compressions to allow for a traditional analysis using SAS.

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, prompts are no longer needed for the rhythm analysis. Hands-off CPR time is significantly reduced or eliminated.



cprINSIGHT accuracy

A study published in January 2021 in *Resuscitation* compared Amsterdam first responders' use of the LIFEPAK 1000 AED vs. the LIFEPAK CR2 AED with cprINSIGHT.[12] Algorithm accuracy and CPR performance using both devices was reported.

- **Accuracy** - cprINSIGHT reached a treatment decision (S or NS) during chest compressions 70 percent of the time, with the remaining 30 percent of treatment decisions made by SAS. cprINSIGHT correctly identified shockable rhythms during chest compressions with 95.5 percent sensitivity and non-shockable rhythms with 98.2 percent specificity.
- **Improvements in CPR performance** – Pre-shock pauses were drastically reduced to an average of 8 seconds vs. an average of 22 seconds with the conventional AED. CCF with cprINSIGHT was 86 percent vs. 80 percent in the conventional AED group.

Median pre-shock pause time (seconds) [p<0.001]

cprINSIGHT on

8 seconds

conventional AED

22 seconds

Median chest compression fraction percent (CCF) [p<0.001]

cprINSIGHT on

86%

conventional AED

80%

Conclusion

cprINSIGHT analysis technology was designed to reduce pauses and increase CCF during the treatment of SCA patients with the LIFEPAK CR2 AED while maintaining highly accurate automated rhythm interpretations. The algorithm is safe and effective for use on adults and children one year of age or older. The LIFEPAK CR2 AED with cprINSIGHT is also compatible with the LUCAS® chest compression system, and the data from the LIFEPAK CR2 device can be downloaded to CODE-STAT™ data review software to allow for continuous quality improvement.

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 LIFEPAK 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-author ized 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 AED 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 Stryker. Using other manufacturers' accessories may cause AED to perform improperly and may invalidate safety agency certification. Contact author ized 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 LIFEPAK CR2 AED 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 **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

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

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