



An Executive Guide To

# SEPSIS COMPLIANCE BEYOND DETECTION

Meeting FDA Requirements  
for Sepsis Care



# According to CMS, roughly 58% of patients get appropriate sepsis care beyond detection.

The problem lies in two areas. First, most hospitals today use solutions that don't meet FDA requirements, and second, those solutions fail to automate the delivery of the CMS bundle elements for care.

Sepsis continues to be a leading cause of death in hospitals and health systems around the globe. Early detection and rapid delivery of the sepsis treatment bundle are vital to improving survival.

Using FDA Class II cleared solutions, combined with automated sepsis detection and rapid

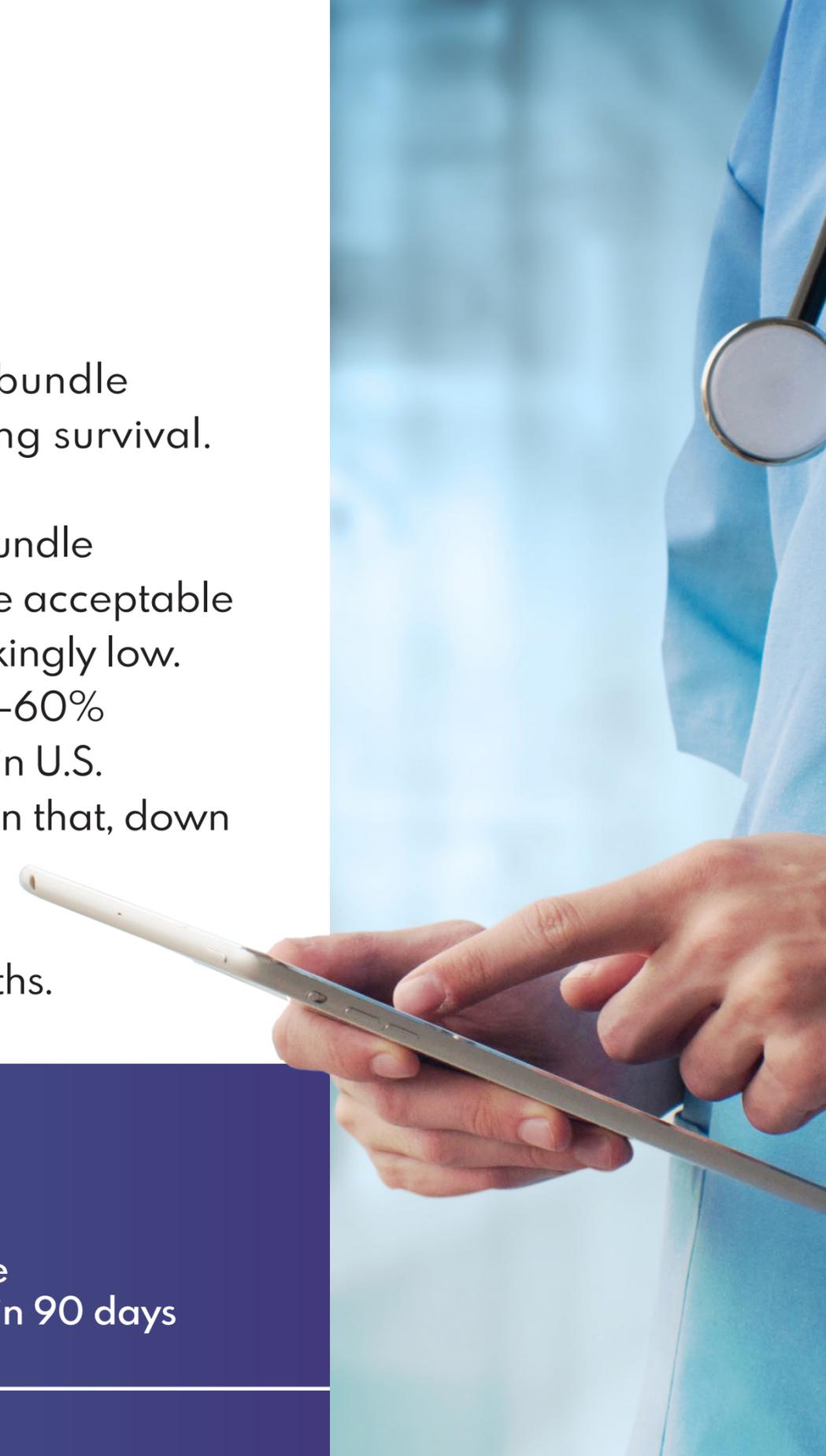
delivery of the sepsis treatment bundle elements, is essential to improving survival.

The lack of compliance with the bundle elements is so widespread that the acceptable standard for performance is shockingly low. A sepsis bundle compliance of 50-60% is considered a "passable grade" in U.S. hospitals, but many fall below even that, down to the 9-25% range, making sepsis the leading cause of both readmissions and in-hospital deaths.

**1.7M** More than 1.7 million people in the US are diagnosed with sepsis every year – 1 every 20 seconds.

**6%** of all hospitalizations are due to sepsis

**40%** of sepsis patients are re-hospitalized within 90 days



# Sepsis Impacts on Patients and Hospitals

Any hospital stay is costly to a patient, but extended stays or readmissions for acute sepsis is devastating, resulting in crushing financial burdens and fear of hospitals. Additionally, poor sepsis care heightens disproportionate care, creating racial & ethnic health disparities, especially in underfunded and underserved populations.

The financial costs overwhelm all parties when CMS Bundle compliance is unmet. Small hospitals lose approximately \$10M annually in net margins. For large hospitals, that number increases to \$34M. In April 2023, [CMS adopted the Severe Sepsis and Septic Shock: Management Bundle measure](#) into the Safety

Domain beginning in the 2025 performance year, notifying those not meeting certain thresholds to be subject to the Hospital Value-Based Purchasing Program (VBP) payment penalties. Hospitals must address this VBP program that reduces low-performing (bottom quartile) hospitals' total DRG payments by 1%.

Sepsis is the most preventable cause of death in hospitals, and EHRs have not made a substantial impact on sepsis care. However, FDA Class II-approved platforms can improve sepsis compliance and care. Healthcare executives and practitioners must aim for better compliance and seek solutions beyond the EHR to improve sepsis outcomes significantly.

#1

Sepsis is the leading cause of hospital deaths

double

The average cost per sepsis hospital stay is double all other conditions

\$17,000

Average hospital/health system loss per sepsis patient



You can't improve sepsis care or bundle compliance with the EHR alone. It requires an FDA Class II-approved platform built for sepsis detection and driving care delivery.

**Here are the seven items your platform must address:**

# Requirements to **Significantly Impact Sepsis Care** →

**1.**

## **FDA COMPLIANCE**

Meet the updated  
FDA Class II  
requirements from  
September 2022

**2.**

## **MONITOR & TRACK**

Visually monitor and  
track the delivery of  
the sepsis treatment  
bundle

**3.**

## **EARLY DETECTION & TIMELY INTERVENTION**

Improve early detection  
& care delivery in the  
critical first hours per  
CMS guidelines



**CMS BUNDLE  
COMPLIANCE REDUCES  
MORTALITY UP TO  
10.5%**

**4.**

**AUTOMATION**

Reduce errors and eliminate omissions in care with automation

**5.**

**NOTIFICATION  
& CARE  
COLLABORATION**

Enhance communication & care coordination oversight across the institution

**6.**

**EHR &  
COMMUNICATION  
PLATFORM  
INTEGRATION**

Provide notifications with remote & distributed monitoring for better sepsis outcomes

**7.**

**REDUCE BURNOUT  
& INCREASE  
EFFICIENCY**

Reduce physician and nurse cognitive burden and increase their efficiency



**THE ONLY FDA CLASS II-CLEARED & CE MARKING-APPROVED END-TO-END SEPSIS SOLUTION ON THE MARKET**

**Sepsis DART™, part of the Ambient Aware™ platform, is an FDA Class II cleared solution automating sepsis detection and intervention based on configurable client-defined detection parameters while monitoring sepsis care bundle delivery toward the CMS treatment protocols. We Fix Sepsis™**

 FDA Class II clearance	 CE Marking	 ISO 13485:2016 certification
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**DART™ delivers:**

- FDA Class II Cleared Software as a Medical Device (SaMD)
- Meets 2022 revised FDA guideline requirements for sepsis solutions
- CE Marking Certification & ISO 13485:2016 Certification
- Real-time & client configurable platform following patients from unit to unit
- Integrates with and into the EHR to keep clinicians in established EHR workflows
- Smart Notifications™ delivered through existing communication platforms like Vocera, Tiger Connect, Spok, EHR, Desktops, & others
- Proven Return on Investment with Annual savings of \$450K+ for 400-bed hospitals
- Increased sepsis compliance by 20% in under 30 days in high-performing organizations and even more in low-performing facilities
- Provides analytics & tools automating the processes needed to treat sepsis on time
- Delivers at-a-glance situational awareness & allows tele-sepsis outsourcing



# Ambient Sepsis DART™

## Saving Money, Patient Lives, and Clinician's Time

**Sepsis DART™ uses Mayo Clinic co-developed technologies**, giving providers real-time point-of-care visualization of patients' holistic condition and care bundle delivery status. DART™ detects and treats conditions like sepsis, reducing Length of Stay and saving lives by driving timely interventions and completing the appropriate clinical process. DART™ is also malleable to other conditions & clinical processes, including ALI, VILI, Shock, Decompensation, AKI, MI, CHF, SSI, CLABSI, CAUTI, ERAS, etc.

Maximizing clinical efficiency allows physicians and nurses to care for larger numbers of patients more efficiently, helping minimize the effects of today's labor shortage. Hospitals using the AWARE™ or Sepsis DART™ platform will save, on average, 25% of the time it takes to assess, diagnose, and deliver care to a patient. Resulting in an overall 5% or greater physician and nursing staffing time relief, helping ease clinical staffing shortages.



## CASE STUDY

# Kevin Kronmiller Overcomes 30% Chance of Survival

### THE PROBLEM:

When Kevin Kronmiller was 22, he found out he had 5 years to live if he didn't receive a liver transplant. Beating the odds, Kevin made it to 50 before having one. After his surgery, Kevin went into Septic Shock. He found out later from his physicians that he had a 30% chance of survival and even if he did survive, doctors were very concerned about long-term complications.

### THE OUTCOME:

Kevin's physicians relied on Ambient Clinical Analytics' AWARE Sepsis DART™ solution to notify them he was potentially septic. Using DART, physicians and nurses were guided through the care process, making sure Kevin received all the required Sepsis Bundle Elements. Because of this, Kevin not only survived sepsis but was able to return to living a normal life with no long-term sepsis complications.

### WATCH VIDEO:

[ambientclinical.com/2022/04/20/extra-innings-kevin-kronmillers-story](https://ambientclinical.com/2022/04/20/extra-innings-kevin-kronmillers-story)

## CASE STUDY

WATCH  
HERE!



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into a safer environment with their advanced digital health, clinical decision support, and data visualization solutions. We Fix

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# Your Sepsis Detection Partner

Ambient is proud to partner with Zebra for all of your sepsis detection hardware needs at the point of care. Zebra's decades of mobile technology expertise and purpose-built devices are ideal for receiving alerts, monitoring bundle elements, communications, data capture, video conferencing, and much more.

## TC52-HC MOBILE COMPUTER

- 5-inch Android touchscreen works when wet, with gloves, or a stylus
- Highest quality voice calls
- Customizable soft keys for frequent-used features
- PowerPrecision+ battery – up to 14 hours of power



## ET40-HC TABLET

- Rugged and built to withstand drops and environmental conditions
- 10.1-inch bright touch display
- Dedicated emergency alert button
- Wi-Fi 6 & Bluetooth 5.1 connectivity