

General Questions Regarding STEMI Management Systems

The American College of Cardiology (ACC) along with the American Heart Association (AHA) have identified the importance of reducing door-to-balloon times for patients with ST-Elevated Myocardial Infarction (STEMI).¹ A major factor in reducing door-to-balloon times centers on the use of both performing and reviewing a prehospital 12-lead ECG to allow treatment decisions to be made while patients are still en route.²

There are a number of factors an organization should keep in mind when making decisions on how to setup a STEMI system ranging from how data is transmitted and received to data integrity, risk mitigation and patient data privacy.

Physio-Control, in developing the LIFENET® STEMI Management Solution, has tackled many of these questions. This document provides insight on factors and questions you need to evaluate when looking at implementing a STEMI management system.

Is the system I'm using classified as a medical device and does it follow the Food and Drug Administration (FDA) guidelines?

The FDA has established a stringent set of rules and regulations for medical devices. In order for a system to be considered a medical device used for diagnosis and treatment decisions, the system must undergo robust verification and validation testing. When evaluating a STEMI management system, be sure to assess whether it meets the requirements and classification of a medical device.

What data am I looking at?

In order to respond quickly to incoming patient data, you need to be able to depend on data being presented the same way each time. For instance, with the Physio-Control STEMI Management Solution, the patient's 12-lead ECG will have the same format each time, whether you are looking at it as a printed report or as a graphical file such as a PDF, GIF, TIFF, or JPEG on a computer screen or PDA. Regardless of how you look at the data, it will be the same each time and the system has been verified and validated so you can make diagnosis and treatment decisions.

What is the quality of the data I'm looking at?

In order to make diagnosis and treatment decisions, be sure transmitted data has not been corrupted during transmission. This is always a risk when using public systems such as cellular networks or the Internet. The LIFENET STEMI Management Solution has been designed with complex data integrity checks and secure data transmission interfaces. This ensures that the data you look at is not corrupted and accurately represents the data gathered by the LIFEPAK® 12-Lead ECG Monitor.

Can I make a treatment decision based on the information I'm looking at?

If the hospital staff is going to use a system to make treatment decisions, it is classified as a medical device. As such, a medical device must be verified and validated to produce a consistent result each time. Using devices not intended for medical applications, thus using general purpose articles to transmit and receive patient data, is placing both you and your organization at risk. Physio-Control has performed the required verification and validation process so its STEMI system can be used with confidence for diagnosis and treatment decisions.

How difficult and time consuming is it for the paramedic to transmit the data?

Ease of use and consistency are important factors from the transmitting organization's perspective. Paramedics should focus on patient care rather than on transmitting data and worrying about whether it was received at the hospital. For paramedics using the Physio-Control system and equipment, they just select the destination and push a button. The device tells them when the transmission was successful. The system will automatically retry if the transmission was not successful to allow paramedics to continue to focus on their patient priorities.

Are there mechanisms in place to alert clinicians when data is received?

Time is critical for in-bound STEMI patients. Careful thought should be given to how clinicians can be automatically alerted to new patient data received. Expeditious identification, triaging and preparation for a potential STEMI patient are crucial for successful patient management. For example, the LIFENET STEMI Management Solution uses audible and visual alerting features or automated emails and text messages so a wide audience can be automatically alerted to the arrival of new data.

Where did this information come from? Who is this patient? When was this data taken?

When a patient's 12-lead ECG comes in, the clinician needs to quickly identify the EMS agency, transmission time, and any other details needed for patient identification. This data should be displayed clearly and consistently so care teams do not need to research this information or wait for a phone call describing the details. The Physio-Control system handles this by automatically displaying the transmitting EMS agency's name, the time and date of the transmission, and the transmitting LIFEPAK device serial number. If the paramedic has entered the patient's name or alternative identifier, that information is also displayed. This allows you to make sure you know which patient you are discussing and not confuse that with data from another patient.

Is the patient information I'm sending safe? Am I sending this through a secure system?

Due to patient privacy concerns, great care needs to be taken anytime information is sent via a public system such as the Internet. Physio-Control has employed numerous safeguards to protect patient data, ensure encrypted data transmission and confirm data is delivered only to the intended recipients.

How will you be able to share patient data with other care teams?

In STEMI patient care, it is often necessary to share patient data with other care teams, whether it is the Cath lab within the same building or a Cath lab at another hospital. When sharing patient data, you want to do it quickly, consistently, and be confident that the data is not corrupted. You also want a log of the transmitted data and confirmation that it was delivered successfully. You want your system to be able to handle this rather than having care teams spend time on these aspects.

Since I'm dealing with patient sensitive information, am I complying with HIPAA rules?

HIPAA rules can be complex and difficult to comply with. The LIFENET STEMI Management Solution is designed with a high level of security both from an architecture and software standpoint and incorporates multiple security features so users can easily comply with HIPAA security standards.

There are many factors that need to be considered when implementing a STEMI management system so that you can ensure data transmission and reception is handled in a secure and efficient way and that you are mitigating your organization's risk appropriately. For more information on how Physio-Control may help you with this, please contact your local Physio-Control representative.

1 Antman et al, ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction. Circulation 2004;110:588-636

2 Bradley, E.H., Curtis, J.P., Herrin, J., et al. Reducing door-to-balloon time: hospital strategies that work. Circulation 2006, 114 (18), Abstract 2069.

