GE HealthCare

# 12SL algorithm

Connected. Clinical. Excellence.

## Increased complexity. Endless data. Burned out.

Today, complexity is at an all time high—from patients to disease states—and the magnitude of data keeps growing.

By the end of the day—or in an urgent case—it's exhausting trying to spot those subtle changes that matter. At times it can feel like searching for a needle in a haystack.

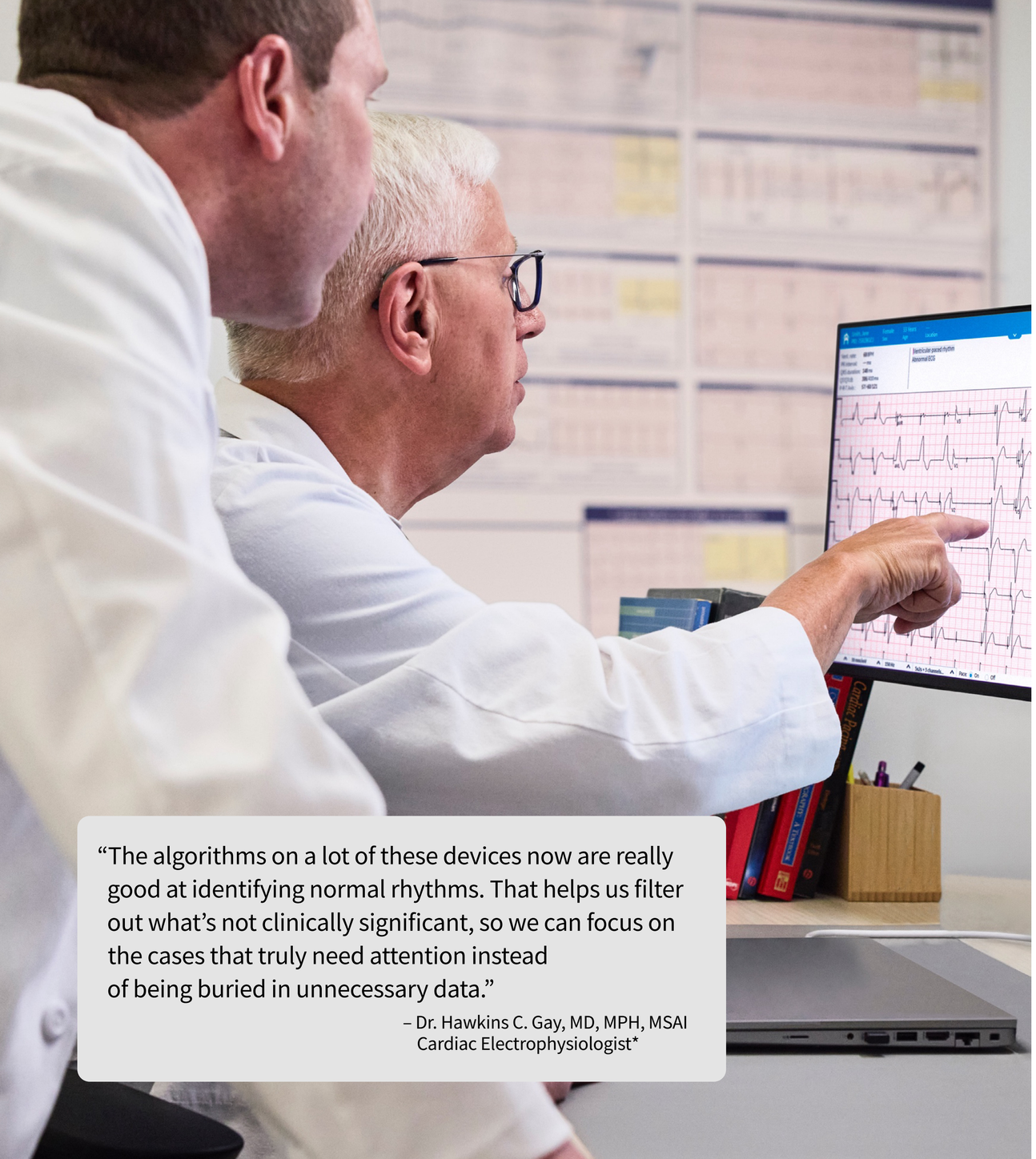
Add poor signal quality and the risk of misinterpretation, and it's hard to feel confident knowing one missed detail could change everything for patients.

**19.8M**
CVS deaths annually[1]

**126M**
People living with coronary artery disease[2]

**51%**
US adults with multiple chronic conditions[3]

**54%**
Misinterpretation of ECGs[4]



"The algorithms on a lot of these devices now are really good at identifying normal rhythms. That helps us filter out what's not clinically significant, so we can focus on the cases that truly need attention instead of being buried in unnecessary data."

– Dr. Hawkins C. Gay, MD, MPH, MSAI
Cardiac Electrophysiologist*

# Clinical decision support for your ECG

Continuously refined for 40+ years, the 12SL™ algorithm does more than interpret ECGs—it reveals subtle changes in waveforms over time, may help predict risks, and is proven to improve diagnostic precision.[6] Because diagnostic certainty isn't a goal—it's the foundation to empower you to act with confidence for improved patient care.

## Revealing what matters—fast, accurate, reliable

- Detects **subtle** changes in waveforms since prior ECGs, per clinical recommendations and guidelines
- **Consistent** measurements to support you in a **reliable** interpretation
- **Automated** alerts for long QTc>500ms

## Clarity for diagnostic confidence

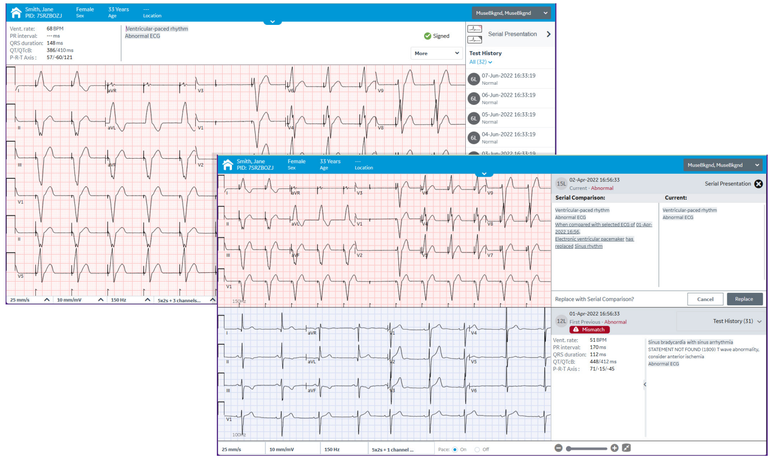
- **Real-time** signal and lead feedback revealing possible lead reversals and poor signal quality
- High **accuracy automated measurements** including amplitudes, durations and intervals
- Automatic detection and annotation of the presence of **bi-ventricular pacing** to enable accurate recognition[5]

## Proven expertise, trusted worldwide

- Continuously refined and validated across **100+ peer-reviewed studies** and clinical trials[6]
- Exceeds current standards for 12 and 15 lead measurements[6]

# Serial comparison

The Serial comparison program identifies changes between a patient's current and prior ECGs, applying interpretive statements, measurements, and waveform analysis to improve detection of clinically significant variations—demonstrating how longitudinal comparison enhances diagnostic specificity and supports informed patient management.



## Benefit

- 12SL's serial comparison feature automatically analyzes waveform morphology and measurements across ECGs, detecting clinically significant changes. This enables faster, more confident decision-making in complex cardiac cases, while reducing unnecessary interventions and improving triage efficiency.[6]
- Meets industry guidelines and society recommendations for comparing ST-T waveforms for the assessment of evolving changes for ACS**.

# Pediatric analysis

Pediatric patients span over 12 different age groups and are extremely complex to evaluate and diagnose. Increased right ventricular size, increased heart rate and narrower complexes lead to different ECG interpretation compared to that of an adult. When an age of less than 16 years is entered into the 12SL program, the pediatric criteria are employed.

The option to apply 15 leads allows for varied positions to accommodate the nuances of identifying pediatric clinical conditions. GE HealthCare can display waveforms at a cutoff frequency of 300Hz, higher than the clinical recommendation of 250Hz and the standard of 150Hz.

## Objective pediatric ECG interpretation—backed by 27K cases

Age-specific z-scores from 12SL measurements reduce bias and improve diagnostic confidence, enabling accurate, automated ECG readings for high-volume pediatric screening.[7]

## Benefit

- Provides age-appropriate ECG interpretation for pediatric patients, accounting for physiological differences from adults. This supports early detection of congenital and genetic conditions, improves diagnostic accuracy, and enables better risk stratification.


## ECG recording: why quality matters

The outcome of the ECG measurement and interpretation improve with the quality of the ECG recording and processing. Therefore the AHA/ACC established ECG standards and recommendations to improve the accuracy and usefulness of the ECG in practice.[9]

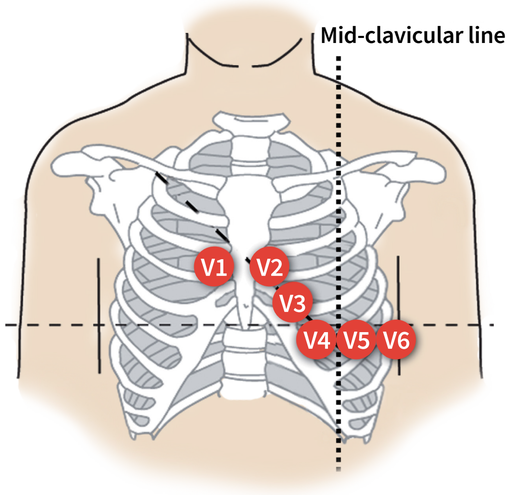
### Recommendations for electrode positioning

Electrodes must be positioned in accordance with AHA or IEC recommendations and guidelines. If any of the electrodes need to be sited in non-standard positions the recording must be labeled with this information to avoid misinterpretation of altered ECG waveforms.[9]

# Hookup Advisor & lead detection

Hookup Advisor™ measures the signal quality of the ECG leads by assessing electrode contact with the skin, the ECG signal and noise due to muscle tremor, movement, or AC.

Lead reversal detection informs the user of possible limb and chest electrode reversals, on the screen, in real time. 12SL, in conjunction with Hookup Advisor, enhances accuracy by detecting 19 pairs of specific electrode reversals—**before the ECG is acquired**. It identifies common misplacements like LA/RA and V1/V2 and extends it to V4-V6—helping prevent errors and misdiagnosis.[6]

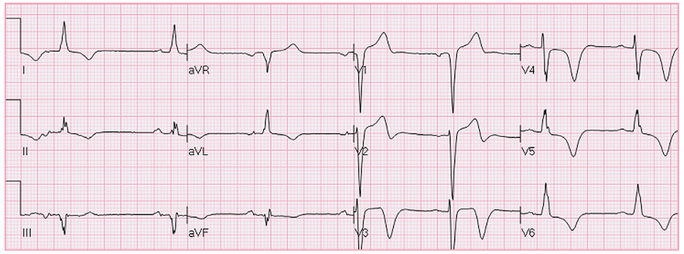



## Benefit

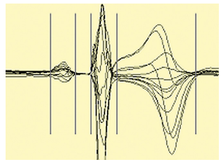
- The system indicates the cause of interference, so that the root cause can be eliminated without using higher filters.
- Real-time feedback helps eliminate noise and electrode issues, while lead reversal detection reduces the risk of misinterpretations that can mimic serious conditions—helping reduce errors, incorrect diagnosis, and the need for repeat tests.

# QT algorithm

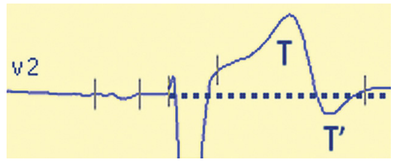
QT prolongation is a powerful predictor of short-term mortality, and even small increases—just 10ms in the QTc interval—can raise the risk of developing TdP by 5-7%.[10] That's why consistency in QT measurement is vital. The 12SL algorithm uses all leads of the median complex to define ventricular depolarization and repolarization, calculating highly accurate and reproducible QTc values. This consistency empowers clinicians to act early and decisively, especially when managing patients on QT-prolonging medications or with cardiac comorbidities.




T-wave in lead V2 is bi-phasic. Do not define baseline based on the end of the T-wave. This can lead to the mistake of defining T offset within the T wave. QRS onset should define baseline. The entire wave of repolarization includes T and T'. Use all leads to assist in defining the end of repolarization.



All medians superimposed



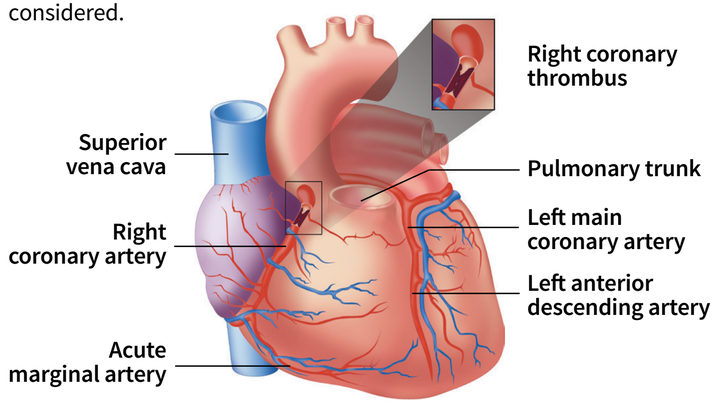

Median—lead V2

## Benefit

- Consistent, reproducible and accurate measurement and interpretation
- Offers multiple QT correction factors including Bazett, Framingham, and Fridericia to improve accuracy across varying heart rates and patient populations

# Right Ventricular Involvement (RVI)

Right Ventricular Involvement (RVI) is associated with a significantly greater risk of in-hospital mortality and major in-hospital complications.[11] Following the AHA/ACC standards[11] 12SL will call out from the regular 12-lead ECG that RV involvement should be considered.



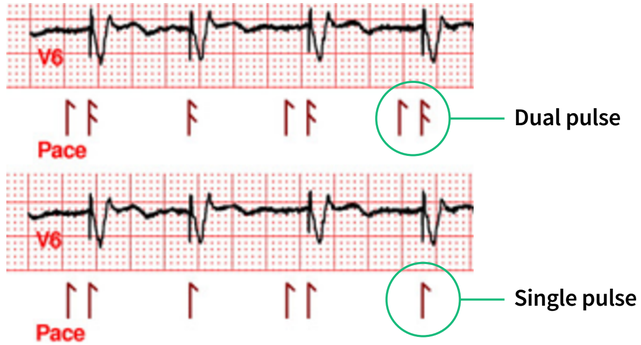

Treatment of infarction may vary with right ventricular involvement, therefore recording of additional right-sided precordial leads during acute inferior wall, left ventricular infarction is recommended. Routine recording of these leads, in the absence of acute inferior infarction, is not recommended.[11]

## Benefit

- Reduced risk of death, shock and arrhythmias through improved diagnosis on the 15-lead ECG on the basis of an ST-segment elevation in the right precordial leads (e.g. lead V4R)[11]
- 12SL is assisting the user on when to consider RVI and apply 15-leads
- Validated on a multi-site database of over 1,300 chest pain ECGs[6]

# Pace statements

Low energy atrial, ventricular and biventricular pacing can be challenging to identify on the ECG, especially for care teams without access to pacemaker programmers and specialized ECG training. The 12SL algorithm automatically detects pacemakers by analyzing pacing spike patterns and ventricular activation timing—enabling accurate recognition even in noisy environments. This capability supports timely and appropriate care decisions, reduces diagnostic uncertainty, and helps avoid misinterpretation that could delay treatment or lead to unnecessary interventions.[12]




## Benefit

- 12SL provides analysis for detecting pacemakers, identifying the underlying rhythm, in addition to the chamber(s) being paced

# Acute Coronary Syndrome (ACS) tool**

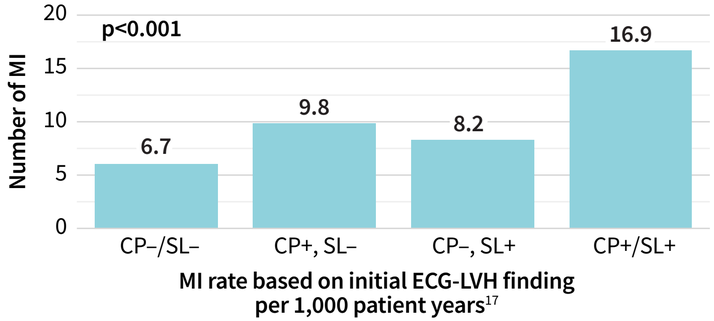
The 12SL ACS tool increases sensitivity for ST-Elevated myocardial infarction or acute ischemia in patients suspected of having an acute cardiac event. The tool heavily weighs the finding of ST elevation with reciprocal ST depression. This is a very important and highly-specific indicator of STEMI and ACS that has been found to "identify patients who stand to benefit most from early interventional strategies."[13]

# Updated criteria for left ventricular hypertrophy (LVH)

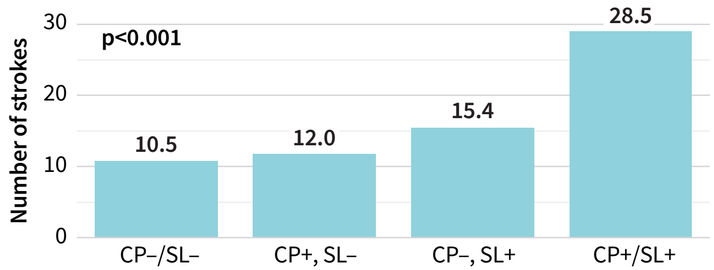
In accordance with AHA/ACCF/HRS recommendations ECG interpretation for hypertrophy,[22] 12SL:

- Uses only validated criteria, without deviation from validated formulas.
- Specifies which diagnostic criteria were used and which were abnormal.
- Uses four commonly-used criteria for the detection of LVH:
  - R wave amplitude in lead aVL
  - Sokolow-Lyon criteria (SV1 + max(RV5, RV6))
  - Cornell product
  - Romhilt-Estes criteria[16]

During antihypertensive therapy such an interpretation markedly increases risks of cardiovascular end points and all-cause mortality.[17]




**MI rate based on initial ECG-LVH finding per 1,000 patient years**[17]




**Stroke rate based on initial ECG-LVH finding per 1,000 patient years**[17]

## Benefit

A study evaluated on over 1,900 clinically correlated ECGs[6] from patients suspected of having ACS showed that the ACS tool:

- Improved the sensitivity of emergency physicians' interpretation of acute myocardial infarction by 50% and cardiologists' interpretations by 26%, with no loss of specificity.[14]
- Improved the sensitivity of emergency physicians' acute ischemic syndrome interpretation by 53% while maintaining a specificity of 91%.[14]
- A normal ECG interpretation from the 12SL ECG software at ED triage has a very high accuracy and a very low probability of clinically relevant change in patient outcome and ED trajectory.[15]

## Benefit

- Combining ECG criteria for left ventricular hypertrophy improves risk prediction in patients with hypertension.[17]
- Persistence or development of ECG LVH by both Cornell product and Sokolow-Lyon voltage criteria during antihypertensive therapy is associated with markedly increased risks of cardiovascular end points and all-cause mortality.[17]

# Filtering recommendations

The outcome of the ECG measurement and interpretation improve with the quality of the ECG recording and processing. Therefore the AHA/ACC established ECG standards and recommendations to improve the accuracy and usefulness of the ECG in practice.[9]

Potentially dangerous alterations to the ST-segment[18] for both rhythm and 12-Lead ECG can be avoided by applying Zero Phase Distortion filtering.

The global IEC recommendation for standardization of the ECG stipulate that frequencies below 0.67Hz can safely be removed from the ECG provided filtering is done with adequate phase response, for example using a zero phase distortion filter.[19]

One study conducted in an emergency department found, that as opposed to the 12-lead ECG reports, 93% of rhythm tracings had clinically significant alterations that could be construed as an acute coronary syndrome (ACS) due to the use of a baseline roll filter without ZPD at a setting of 0.5 Hz.[8] ZPD on both the rhythm and 12-lead report eliminates this confusion.

**Annually:**
**>300M ECGs**
**performed globally[2]**

**The ECG is a quick, non-invasive procedure that many patients undergo as the first test!**

# Clinically validated ECG measurement and interpretation

## The IEC Standard 60601-2-25:2011[21] defines the validation requirements:

### Measurement accuracy

- Rhythm interpretation accuracy must be tested on at least 1,500 ECGs, 100 with atrial fibrillation

### Diagnostic interpretation accuracy

- Accuracy must be validated via non-ECG data
- Performance information shall be disclosed in accompanying documents and readily available to customers who want to know the information

## The 12SL ECG analysis program is continually refined through the following processes:[6]

- Regular clinical input—continuous input is gathered from some of the world's top consulting cardiologists and physicians
- Clinically correlated databases—GE HealthCare utilizes different databases during the development and validation processes to enhance program accuracy
- Beyond clinically-correlated databases GE HealthCare measures its analysis program performance on a large database of ECGs (>50,000)
- This process challenges the program with multiple diseases and varying degrees of abnormality. ECGs with changed analysis results due to program modification can be further investigated with expert confirmation.

| Disclosure of Accuracy/Confirmation[6] | 12SL |
|---|---|
| IEC 60601-2-51 in product specification-performance standard for ECG analysis | ✓ |
| Measurement Accuracy via CSE database | ✓ |
| Stability of measurements in presence of noise—CSE recordings | ✓ |
| Rhythm interpretation accuracy on over 1,500 ECGs by cardiologist, includes at least 100 ECGs with atrial fibrillation | ✓ |
| Accuracy of conduction abnormalities by cardiologist | ✓ |
| Accuracy of LVH, RVH, old infarction via CSE database (NEJM 1991) | ✓ |
| STEMI confirmed by cardiac enzymes & clinical outcome | ✓ |
| Acute ischemia via longitudinal clinical outcome | ✓ |
| Accuracy of QT measurement by core lab and drug dosage | ✓ |
| Independent evaluation: articles where inventor/vendor is not an author | >30 |

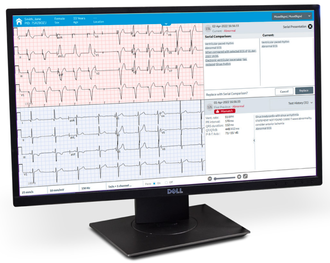
## Benefit

- Augmenting clinical judgment, reducing variability and detecting subtle, clinically significant changes fast, supports diagnostic accuracy for confident, timely care[6]

# Connected clinical excellence

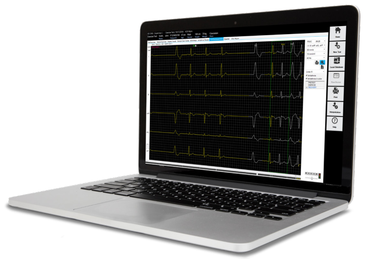
## CASE™**

## MUSE™ NX*



## MAC™ 3*

## CardioSoft™**



## 12SL PROGRAM

## MAC 5*

## Carescape™ Canvas™***


## MAC VU360™*

## MAC 7*

* Supported through V24

** Supported through V23

*** Supported through V22

## About GE HealthCare Technologies Inc.

GE HealthCare is a leading global medical technology, pharmaceutical diagnostics and digital solutions innovator, dedicated to providing integrated solutions, services and data analytics to make hospitals more efficient, clinicians more effective, therapies more precise and patients healthier and happier. Serving patients and providers for more than 125 years, GE HealthCare is advancing personalized, connected and compassionate care, while simplifying the patient's journey across the care pathway. Together our Imaging, Ultrasound, Patient Care Solutions and Pharmaceutical Diagnostics businesses help improve patient care from diagnosis, to therapy, to monitoring. We are a $19.6 billion business with approximately 51,000 colleagues working to create a world where healthcare has no limits.

Follow us on LinkedIn, X, Facebook, Instagram, and Insights for the latest news, or visit our website gehealthcare.com for more information.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Not all products or features are available in all markets. Contact a GE HealthCare representative for more information.

*Dr. Gay is a paid consultant for GE HealthCare and was compensated for participation in the interview. The statements by Dr. Gay described here are based on his own opinions and on results that were achieved in his unique setting. Since there is no "typical" hospital/clinical setting and many variables exist, i.e. hospital size, case mix, staff expertise, etc., there can be no guarantee that others will achieve the same results.

**The ACS tool option is intended for adult patient populations who are suspected clinically to have acute coronary syndrome.

Please visit www.gehealthcare.com. Data subject to change.




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