GE Healthcare

Study report

GE EK Pro Algorithm v14 Performance Comparison

Performance comparison of five patient monitors in detecting severe alarms using recording with verified ventricular tachycardia (VT) events.

ABSTRACT

GE Healthcare engineers conducted a comparison study to assess ECG monitoring devices capabilities to detect and present an alarm for serious cardiac arrythmias (accuracy) while minimizing the false alarms* (specificity). Performance testing was done by feeding** pre-recorded ECG signals into all the tested monitors simultaneously. For more information on the methodology and databases used, please refer to the Methods section of this document. The devices compared in this study were Philips Intellivue™, Philips Efficia™, Nihon Kohden Life Scope™ VS BSM-3000 series, Mindray iPM™ series and GE Healthcare CARESCAPE™ monitors.

The study found that the GE Healthcare and Philips Efficia devices were the most accurate in detecting VT events. They both raised true alarms*** for 45 out of 57 VT events. When also counting other ventricular alarms which are not labelled as VT (e.g. AV or NSVT / VT>2), the GE Healthcare monitor raised an alarm for 56 of 57 VT events, followed by the Mindray monitor (48 true alarms) and the Nihon Kohden monitor (46). Regarding false alarms, the GE Healthcare monitor triggered 8 times less alarms than the other monitors when tested with 210 hours of challenging ECG recordings. The Philips Efficia monitor raised the highest number of false alarms (494).

In comparing ventricular arrhythmia performance and asystole alarms to other monitoring solutions, the GE Healthcare monitor CARESCAPE B450 with EK-Pro V14 algorithm was shown to detect the most true alarms while presenting the lowest number of false alarms.

DISCLAIMER

This study only addressed one set of device configurations using default settings, and the VT and ASY criteria were set as close to identical as possible among the monitoring devices. Other device configurations may affect sensitivity to alarms in different ways with the specific databases used. Another limitation was that the true events database consisted of VT events only. These choices were made to keep the study comparable to the earlier study[1] and to ensure as fair a comparison as possible. Non ventricular events could be assessed in future studies.

It should also be noted that the ECG recordings used in this study were on average more challenging than with typical monitoring patients. Therefore, the performance data from the study should not be used to indicate device performances as such, but only for device-to-device comparison under these test conditions.

This document is intented to be used by Healthcare Professionals and is not directed at patients or other individuals.

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* False alarm is an alarm triggered by the monitor in the absence of the corresponding clinical event.

** Digitized signals were converted to electric signals using a 'data playback device'. All the monitors were connected to the 'data playback device' at the same time using their own lead wires simulating the patient.

*** True alarm/event is an alarm triggered accurately by the monitor in the presence of the corresponding clinical event as annotated by clinicians (see "Method" section).

PURPOSE

The purpose of the study was to determine how GE Healthcare monitors with the EK-Pro v14 algorithm perform in arrhythmia detection compared to other monitors on the market. The EK-Pro V14 algorithm runs in the CARESCAPE V3.0 and V3.1 patient monitoring family. To conduct this study, the databases clinical data was fed into the CARESCAPE B450 V3.1 monitor.

Accurate alarming of cardiac arrhythmias is essential to patient monitoring. The perfect alarm system would have 100% sensitivity (never missing an event) and 100% specificity (never raising a false alarm). While patient monitors are not intended to replace close observation of the patient by clinical staff, a monitor that accurately alerts for a potential cardiac arrhythmia is a useful tool to assist staff in monitoring patient condition.

The study compared the performance of five patient monitors in detecting severe alarms using recordings with verified ventricular tachycardia (VT) events. The alarm burden was evaluated by counting the false alarms.

The tracked alarms included:

- VT
- Asystole (ASY)
- Ventricular Fibrillation (VF)
- Non-Sustained Ventricular Tachycardia (NSVT, a run of three to five consecutive ventricular beats at a rate higher than or equal to VT rate)
- Accelerated Ventricular rhythm (AV) and Ventricular Beat Runs (VRUN).

These particular arrhythmias would be considered potentially life-threatening events and would trigger a high severity alarm by all the monitors.

METHODS

This study is the continuation of the 2018 study "Patient Monitoring Performance Comparison: GE Healthcare CARESCAPE B850 v3.0 vs. Philips IntelliVue X3"[1]. It uses a similar methodology with a different set of monitoring devices.

The devices used to perform the study were:

- GE Healthcare CARESCAPE B450 monitor with the latest-release software, Version 3.1 with EK-Pro algorithm v14, referred to in the remainder of this document as the GE Healthcare monitor.
- Philips IntelliVue MX430 with software version M.04.00-149, referred to as the Philips IntelliVue monitor.
- Nihon Kohden Life Scope VS BSM-3000 series with software version 05-20 (v0520t00), referred to as the Nihon Kohden monitor.
- Mindray iPM12 with system software version V5.0 (05.27.00-01 SVN:44952), referred to as the Mindray monitor.
- Philips Efficia CM120 with software version A.01.00 (064), referred to as the Philips Efficia monitor.

Test setup

Performance testing was done by feeding pre-recorded ECG signals into all the tested monitors simultaneously. Alarm notifications were then collected from the event histories and compared to the reference annotations confirmed by cardiologists. If more than one similar false alarm occurred within three seconds, they were calculated as one alarm only.

All the monitors were configured to their default settings, and the VT and ASY criteria were set as close to identical as possible. The VT criteria were set to six premature ventricular contractions in all but the Nihon Kohden monitor (set to nine), which did not allow changing the value without administrative privileges, which were not available during the test. The VT rate was 100 in all the monitors. The asystole duration was set to five seconds in all but the Philips IntelliVue monitor, which was set to its maximum value of four seconds. There were also some differences in QRS threshold settings, which were not modified from the default values. See table 1 for further details.

Performance testing was divided into two parts, one to test the detection of true events and the other to identify false alarms which is a cause of the alarm burden.

Test data used for sensitivity testing

Detection sensitivity was tested with 29 five-lead ECG recordings that included 57 annotated VT arrhythmias. The recordings were collected from different ICUs in Europe and Canada. Arrhythmia events in those recordings were annotated by cardiologists hired by GE Healthcare.

Test data used for estimating alarm burden

False alarm performance was tested with waveforms including motion artifacts and challenging ECG morphologies. The recordings were collected from 42 long-term post-percutaneous coronary intervention (PCI) patients with histories of myocardial infarction (MI).

Data originated from the Tampere University Hospital in Finland and was collected as part of the MADDEC study.[2] The selected recordings did not include any arrhythmias. The presence of alarms from the tested monitoring devices was accounted for to determine the amount of false alarms.

To challenge the devices, difficult traces were chosen: such as patients with histories of MI with significant changes in ECG morphology, but no identified arrhythmia events during the recordings. They were also monitored in a stepdown unit, where patients are moving and therefore subject to ECG motion artifacts. GE Healthcare principal scientist for ECG parameter reduced the selection of 90 recordings to 42 recordings with the help of internal clinicians. This was done to focus on patients who had difficult morphology in ECG, such as small QRS, high T-wave or P-wave, conduction abnormalities, significant damage caused by MI, or significantly noisy ECGs caused by patient movement. The original recordings were 24 hours long, but because of time limitations for testing, only the first five hours of data was used. This resulted in a total of 210 hours of testing.

Table 1. *Settings used in testing*

Settings	GE Healthcare	Philips IntelliVue	Nihon Kohden	Mindray	Philips Efficia
Default QRS threshold (mV)	Normal (~0.3)	0.15	0.15	0.15	0.2
ASY delay (s)	5	4 (Max value)	5	5	5
VT rate (BPM)	100	100	100	100	100
VT length (PVC's)	6	6	9 (Unchangeable)	6	6

RESULTS

True events

Both the GE Healthcare and Philips Efficia monitors alarmed correctly for 45 of 57 investigated VT events. The Philips IntelliVue monitor alarmed correctly 43 times. The Mindray monitor gave VT alarms for 31 events, and Nihon Kohden monitor for 19. It should be noted that since the GE Healthcare monitor had combined alarms for both VT and VF, the VT/VF and VF alarms given by other devices were classified as correct VT alarms to ensure a fair comparison. Three VT/VF alarms by the GE Healthcare, Philips Efficia and the Nihon Kohden, four by the Philips IntelliVue and seven by the Mindray were counted as true.

In checking true events and non-VT/VF alarms triggered when VT events occurred, the GE Healthcare monitor missed only one, raising an alarm in 56 of 57 cases. The Mindray monitor raised alarm in 48 cases, Nihon Kohden in 46 cases, Philips Efficia in 45 cases and Philips IntelliVue in 43 cases. Thus these four monitors missed 9, 11, 12 and 14 events, respectively. The non-VT/VF alarms counted were eight AV alarms and three NSVT (VT>2) alarms for GE Healthcare, 15 NSVT and two VRUN alarms for Mindray, and 27 VRUN alarms for Nihon Kohden. This investigation was done in the belief that it is better to alarm even for a different arrhythmia (other than VT) than to not alarm at all, as the alarm should still result in the caregiver action to check the patient. See Figure 1 for a graphical representation of the results.

Figure 1: *Alarming sensitivity. The table shows the numbers of true VT alarms, the numbers of VT events that were not identified correctly but still alarmed, and the numbers of VT events that were not alarmed at all.*
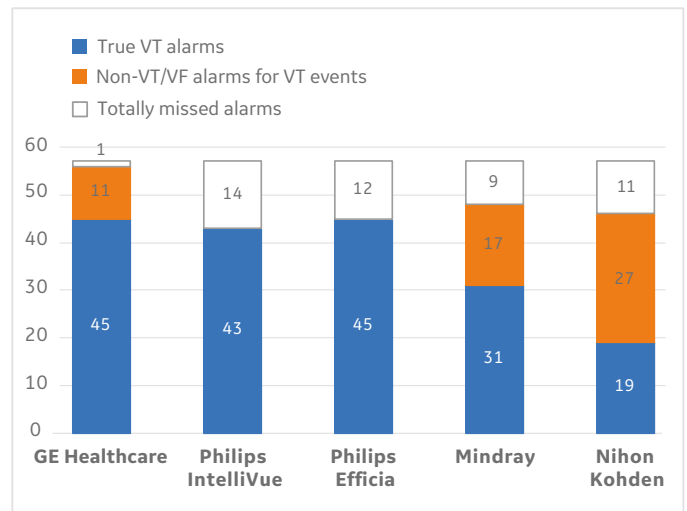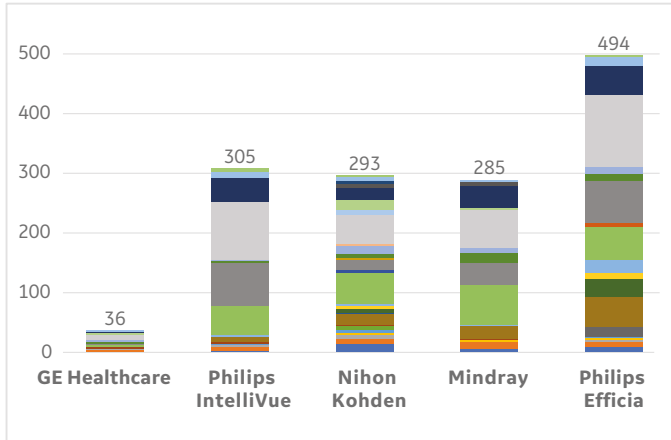

False alarms

The GE Healthcare monitor generated 36 false alarms, of which 26 were VT>2 alarms. This total was 8 to 13 times lower than for any of the other monitors in the study (Table 2). The Mindray monitor generated 285 false alarms, most of which were NSVT alarms. The Nihon Kohden monitor generated 293 false alarms, most of which were VRUN alarms. The Philips IntelliVue (306) and the Philips Efficia (494) generated the most false alarms.

Table 2. *False alarms by type*

Alarm	GE Healthcare	Philips IntelliVue	Nihon Kohden	Mindray	Philips Efficia
ASY	2	7	8	2	14
VT	5	295	2	35	476
VT>2	26	0	0	0	0
VF	0	3	56	84	4
VRUN	0	0	227	0	0
NSVT	0	0	0	164	0
AV	3	0	0	0	0
Total	36	305	293	285	494

Figure 2 shows the distribution of the alarms from record to record. It shows that a few cases (4-7) were responsible for the majority of the alarms. These were especially noisy recordings.

Figure 2: *Distribution of false alarms from record to record. Each color represents the amount of false alarms in one record in all the monitors.*

CONCLUSIONS

In this specific data set and under the conditions of this study (as detailed in the "Disclaimer" and "Methods" section), the GE Healthcare monitor produced the fewest false VT alarms, while also performing the best in detecting critical alarms (see Figure 3). The other monitors showed eight times more false alarms than the GE Healthcare monitor with EK-Pro V14 algorithm in testing of performance with these difficult recordings. The GE Healthcare monitor's alarm burden was also the lowest when focusing solely on critical ASY, VT and VF alarms (see Table 2).

Figure 3: *Combined representation of the true and the false alarms.*
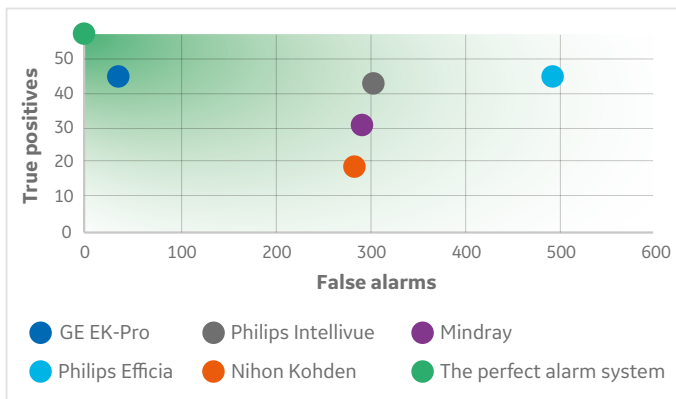
When evaluating VT detection accuracy, the GE Healthcare and Philips devices were the best in raising correct VT/VF alarms. On the other hand, the Nihon Kohden monitor suffered from a less sensitive setting in VT length (nine beats were required compared to six in the others). Therefore, its true VT/VF alarm rates are not directly comparable to the other monitors. When also including the VRUNs and other tracked ventricular alarms, this limitation did not apply, and the Nihon Kohden monitor rose to the third position, only two alarms behind the Mindray monitor, which took the second position. The GE Healthcare monitor outperformed the others also in this evaluation.

In comparing ventricular arrhythmia performance and asystole alarms to other monitoring solutions, the GE Healthcare monitor CARESCAPE B450 with EK-Pro V14 algorithm was shown to detect the most true alarms while presenting the lowest number of false alarms.

REFERENCES

1. Mikko Kaski, "Patient Monitoring Performance Comparison: GE Healthcare CARESCAPE B850 v3.0 vs. Philips IntelliVue X3", 2018. JB61943XX(1)

2. Arrhythmias in Post-Myocardial Infarction Patients, National Institutes of Health, U.S. National Library of Medicine (https://clinicaltrials.gov/ct2/show/ NCT03231826).