Original

Current status of quality management of standard 12-leads electrocardiography at ISO 15189 accredited medical institutes in Japan.

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ABSTRACT

Objective: To investigate the quality management status of standard 12-lead electrocardiography at ISO 15189 accredited institutes in Japan and to support to develop appropriate operational guidelines.
Methods: We conducted a questionnaire survey on the status of quality management at each of the institutes certified in the field of electrocardiography, and then conducted an external quality assessment for eight automatic measurement items by distributing waveform simulators and recording control electrocardiograms to those institutes that wished to participate. The target institutes were selected to include various environments to the extent possible (e.g., vendors used, regular maintenance, regions, etc.), and the factors affecting the results were evaluated. In addition, in order to determine the status of internal quality management, all target electrocardiographs were recorded three times a day for at least 10 days at each institute.
Results: Thirty institutes were selected, and we were able to conduct the actual survey at 27 institutes between April 2023 and December 2024. The total number of electrocardiographs was 131, and the total number of records was 4052 records. The results revealed that there were inter-instrument and inter-institutional differences in seven automatic measurement items. The vendor used, the filter used during recording, and the presence or absence of vendor maintenance were significant factors influencing the measured values. The X-R control chart for each electrocardiograph showed that when the control limit was set at three times the standard deviation of the measured value, more than one-fourth of the instruments showed fluctuations exceeding this limit for some measurement items.
Discussion: Regarding the accuracy control of standard 12-lead electrocardiogram examinations, it has become clear that there are multiple facilities that cannot be evaluated as appropriate in terms of both internal and external accuracy control, and that it is necessary to conduct a more extensive survey and establish appropriate operational guidelines.

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Key Words
electrocardiography, quality management, internal quality assessment, external quality assessent, ISO 15189

The electrocardiogram (ECG) is the most widely used physiological test in modern medicine in general. ECG recordings are used to capture the electrical activity of the heart. Abnormalities in this activity can be indicative of heart disease, and the identification of these abnormalities is important for diagnosis and screening. According to the World Health Organization (2024), ischemic heart disease is set to become the leading cause of death in 2021, accounting for 13% of global deaths [1]. Consequently, the early identification of patients at risk, the monitoring of diagnosed patients, and the enhancement of treatment are imperative. ECG recording is regarded as a potent instrument in this regard. Furthermore, contemporary research has investigated innovative approaches for diagnosis and prognostication, emphasizing the application of portable devices and artificial intelligence (AI) in the diagnostic procedure. The quality evaluation of these methods has also been a subject of active research [2) 3)]. However, the majority of research is focused on the evaluation of post-processing methods for obtained or already existing datasets, and there are few reports that mention the quality assurance of acquired signals.

In ECG recording, maintenance and quality management of measurement devices are considered important tasks that directly affect the reported results. However, the current related regulations (Medical Care Law) only state that "routine maintenance and inspection are necessary," but do not provide specific operational guidelines. In addition, with the digital ECG recorder that are currently in widespread use, the scope of institute personnel involvement in maintenance and inspection is limited, and work related to quality management continues to rely on vendors.

On the other hand, in third-party accreditation of clinical laboratories, physiological function tests, including ECG tests, have been included in the scope of ISO 15189 accreditation since 2015, and currently more than 200 institutes have obtained this accreditation. However, according to the results of a survey conducted among accredited institutes since 2020, it cannot be said that the accuracy control activities and accuracy assurance of ECG tests are appropriate. In particular, despite the fact that most institutes use the automatic measurement functions and automatic diagnostic results of ECG recordings as official reports from the department, the complete absence of external quality assessment (EQA) activities was considered a significant issue. Therefore, we planned and implemented the first EQA activity for standard 12-lead ECGs in Japan.

First, we conducted and reported on an EQA alternative approach activity as a feasibility study at six university hospital physiological function testing laboratories, including our own laboratory [4]. In the report, we found significant inter-institute differences in multiple measurement values. However, because it was a small-scale study, we were unable to obtain significant results regarding the factors affecting the measurement values. In this study, we conducted an EQA activity involving a wider range of participating institutes and examined the above factors. Additionally, since there is little published information on the internal quality acessment status of each institute, we simultaneously conducted a survey over a limited period.

This paper presents the results of an alternative approach to EQA for ECG test at ISO 15189 certified institutes, which was planned by the Physiological Testing Committee of the Japan Association of Clinical Laboratory Science (JCLS) and implemented from 2020 to 2024.

I. Method

Object: Of the institutes participating in the JCLS Physiology Committee survey in 2023, we contacted 109 institutes that responded "yes" or "yes depending on the content" to the question about participation in external quality control and alternative approach activities, and 79 institutes responded that they could actually participate. Of these, 30 institutes were selected for the survey based on their environment (vendors used, whether or not regular maintenance is required, and whether or not they are located in areas where delivery is possible).

Reference ECG: Three ECG simulators (ESIM-200, Fukuda Denshi, Tokyo) were used for recording. The manufacturer's official accuracy was 0.5% for time intervals rate and 2% for output voltage. The vendor also provided reference values for the measurement items to be measured this time. The simulator was used to record a reference ECG in normal form with a heart rate of 80 beats per minute (bpm).

After calibration by the manufacturer, the simulator was sent to the participating laboratories with instructions for recording. All ECG recorders (electrocardiograph) within the scope of ISO accreditation in each laboratory were evaluated and each recorder was recorded three times a day for at least 10 days. Recording was requested on consecutive days whenever possible, but non-consecutive days were allowed if holidays were included. After recording was completed, the simulators were sent to the next laboratory. Hard copies or measurement data were sent to the laboratory of Teikyo University Hospital, the administrative office. The recording conditions, including the filter settings of the ECG recorders, were instructed to be the same as the standard 12-lead ECG recordings routinely performed at each institution.

Analysis: In this study, the automated measurements of the reference ECG were used for analysis: heart rate, RR interval, PR interval, QRS width, mean QRS axis, QT interval, SV_1, and RV_5 amplitudes. The eight measured values were obtained either using values output from the filing system (system output) or reading from the values displayed on the screen or hard copy (visual reading).

Factors affecting the measured values were examined: inter-institute differences, simulator (numbers 1, 2, and 3), intra-day variation, inter-day variation, recorder, data format (system output or visual reading), vendor maintenance, vendors (two companies), and filter settings. Filter settings were classified as on/off for each of the three types of filters (drift, alternating current[AC], and electromyogram) equipped in ordinary ECG recorders, and analyzed in eight levels of classification, from all off to all on. Analysis software was JMP version 18.0 (CA, USA), and univariate and multivariate analyses were used as appropriate for evaluation. Hypothesis testing methods were non-parametric when possible, with a significance level of 5%.

To investigate the internal quality management status, an $\bar{X}$-R control chart was created for each individual ECG recorder, and the occurrence of outliers was evaluated. Since there is no unified guideline for setting control limits, we followed standard quality management procedures and set the upper control limit (UCL) as the value three times larger than the standard deviation from the mean of the measured values obtained by individual ECGs and the lower control limit (LCL) as the value three times smaller than the mean of the measured values obtained by individual ECGs, and the measured values outside this range were considered outliers.

II. Result

Of the 30 institutes contacted for participation, 3 declined to perform recordings, leaving 27 institutes with evaluable recordings. The vendor of the ECG system was either Vendor F (Fukuda Denshi, 14 institutes) or Vendor N (Nihon-Koden, 13 institutes) at these 27 institutes. The total number of ECG recorders was 131, with a total of 4,052 recordings. Six institutes used no filters at all, seven used only drift, two used only AC, four used both drift and AC, and eight used all drift, AC, and electromyogram filters. System output of measurements was available at 12 facilities, and routine vendor maintenance was performed at 23 facilities.

Figure 1 shows the actual recordings of the reference ECGs used in this study and the reference values for each measurement. The ECG waveforms are in the normal range with no particular characteristics. Of the eight measurements considered, the heart rate was excluded from the following study because it showed 80 bpm in all the recordings.

Figure 2 shows the distribution of the seven measurements under consideration. Each measurement does not show a normal distribution, but rather a multimodal distribution. Mean values and 95% prediction intervals are shown in the figure for reference.

Table 1 shows the results of univariate analysis of the differences between institutes and the factors considered to influence the measurements considered in this study,

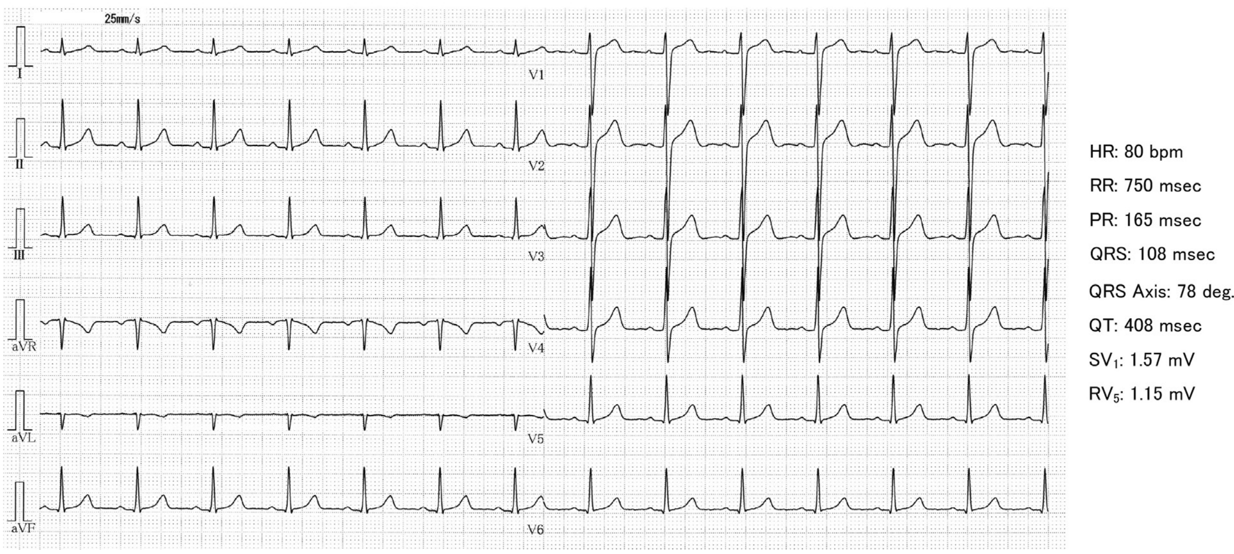

Figure 1 A recording of control ECG. Reference values of 8 items are presented in right part.

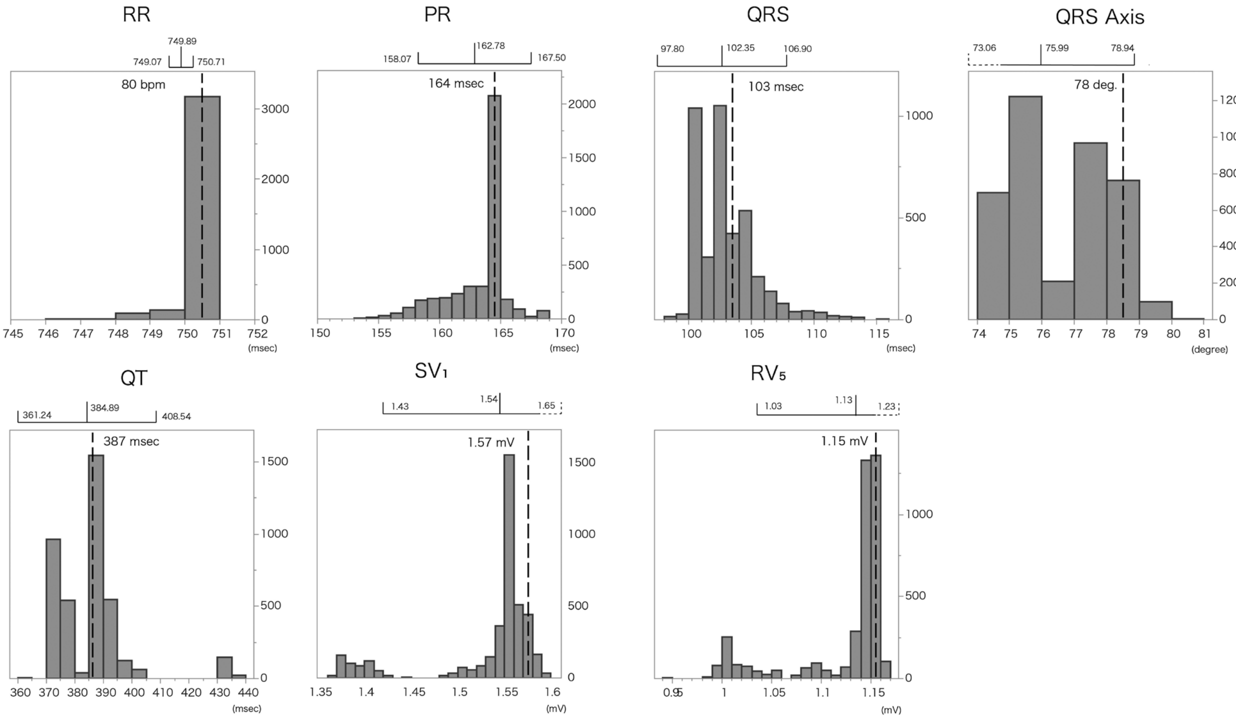

Figure 2 Histograms of measured values of 7 items in control ECG.
Average values of measured items and 95% prediction intervals as shown in each histogram.

Table 1 Effects of parameters to measured values.
Nonparametric monovaiate analysis (Kruskal-Wallis test) 21 were performed to each combination.

		RR	PR	QRS	Axis	QT	SV_1	RV_5
Recorder	SSM	82.052	17146	12691	7609.2	576404	12.5911	9.8386
	p	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*
Day to day	SSM	1.4220	16.325	30.612	7.2006	42.610	0.0008	0.0014
	p	0.5210	0.5700	0.3401	0.0729	0.0874	0.1774	*0.0012*
Intra-day	SSM	1.4304	0.9750	4.8230	1.0461	1.2100	0.0420	0.0001
	p	0.1027	0.9867	0.8332	0.6329	0.9905	0.9990	0.9988

as well as the results of univariate analysis of each measurement. Significant differences were found in all seven items for inter-institute differences, differences between recorders, and type of filter setting. In addition, all other factors considered had an effect on the measured values. However, no single institute was using multiple vendor instruments and multiple filter settings, and a significant correlation was found between data type/filter setting and Simulator ($p < 0.01$). Therefore, it was not possible to test the independent influence of all factors.

To further examine the factors influencing the measurements in more detail, we next evaluated the internal quality management status of the tests. **Table 2** shows the results of a multivariate analysis using the number of measurements on the same day, date of measurement, and ECG recorder as independent variables. All items showed no significant differences in the number of measurements (intra-day repeatability), but the differences between ECG recorders were significant for all items. As for the variation between measurement days (day-to-day repeatability), significant variation was observed in RV_5. Based on these results, $\bar{X}$-R control charts were created for each ECG for each measurement item. **Figure 3** shows an example of SV_1. In this figure, both the mean value ($\bar{X}$) and the range of variation (R) for each measurement day show measurements that exceed the control limits (outliers). **Table 3** shows the number of ECGs with measurements exceeding the control limits (the number of ECGs with outliers in $\bar{X}$ or R alone is shown simultaneously), along with the range of individual control limits. The percentage of ECGs with outliers varied by measurement item which ranged from 2-30% of

Table 2 Results of multivariate analysis for three factors concerning IQA.

n = 4052	level		RR	PR	QRS	Axis	QT	SV_1	RV_5
Institute	27	*p*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*
Recorder	131	*p*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*
Data type	2	*p*	*<.0001*	*0.0013*	0.0856	*<.0001*	*0.0007*	*<.0001*	0.2632
Vendor	2	*p*	0.1254	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*
Maintenance	+/−	*p*	0.1065	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*
Day to day	10	*p*	0.7221	0.0220	*<.0001*	*0.0005*	*<.0001*	*0.0005*	0.5650
Intra-day	3	*p*	*0.0159*	*0.0372*	0.2764	*<.0001*	0.987	0.2826	*<.0001*
Filter setting	5	*p*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*
Stimulator	3	*p*	*<.0001*	*<.0001*	*<.0001*	0.0032	*<.0001*	*<.0001*	*0.0062*

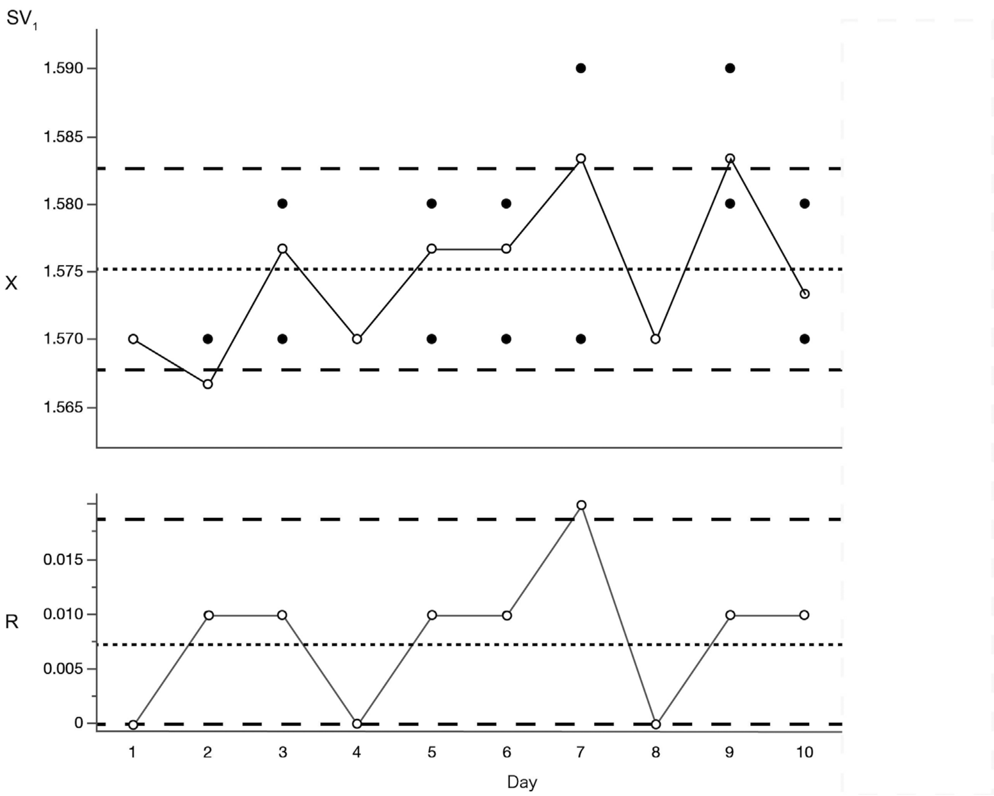

Figure 3 A sample of $\bar{X}$-R control chart of S wave amplitude in V1 lead. In $\bar{X}$ chart, actual measured values are shown as closed circle and mean values are shown as white circles. Averages of measured values are shown as dotted lines. UCL (upper control limit) and LCL (lower control limit) are shown as dashed lines.

Table 3 Summary for IQA.
The top of the table shows the number of ECGs in which outliers (total number: either mean or range, and the number of each) appeared. The lower part of the table shows the UCL: upper control limit, LCL: lower control limit, and the minimum and maximum values of the range of variation for each measurement.

	RR	PR	QRS	Axis	QT	SV_1	RV_5
Total	38 (29.0%)	34 (26.0%)	28 (21.4%)	11 (8.4%)	15 (11.5%)	21 (16.0%)	29 (22.1%)
Xbar	35 (26.7%)	29 (22.1%)	21 (16.0%)	10 (7.6%)	11 (8.4%)	19 (14.5%)	19 (14.5%)
R	36 (27.5%)	27 (20.6%)	19 (14.5%)	3 (2.3%)	5 (3.8%)	7 (5.3%)	17 (13.0%)
UCL	750.1 - 750.6	157.4 - 166.2	100.5 - 105.2	75.1 - 78.4	376.0 - 391.7	1.42 - 1.59	1.00 - 1.17
LCL	748.3 - 749.9	153.6 - 163.9	99.1 - 101.5	74.2 - 76.9	372.3 - 389.0	1.40 - 1.57	0.98 - 1.16
Range	0.23 - 2.83	0.94 - 6.44	1.03 - 6.44	0.51 - 2.06	1.45 - 11.84	0.01 - 0.03	0.00 - 0.04

the instruments.

Next, we evaluated the inter-laboratory variation of measured values (external quality management survey), which was the original purpose of the study. We examined the factors influencing the differences in detail. As mentioned earlier, it was not possible to examine the independent effects of all factors, so multivariate analysis was performed for the three factors considered important in actual operation: vendor (F or N), regular maintenance (yes or no), and filter settings. **Table 4** shows the results. The three factors had significant effects on all measurement items except the relationship between the presence of regurlar maintenance and the axis.

In particular, the vendor and filter settings were evaluated in all combinations, as they were considered important as findings in actual operations. **Figure 4** shows a plot of each measurement for each of the two ECG filing systems and each filter setting used by the institutes participating in this study. There were five filter settings. For all measurements except RR interval, the dotted line shows the ± 5% reference value of the simulator waveform used in this study. It can be seen that for each measurement value, there are measurements that exceed this value.

III. Discussion

This survey is the first report on external quality assessment (EQA, proficiency testing) of electrocardiogram (ECG) examinations ever conducted in Japan. Prior to this survey, a feasibility study was conducted at six laboratories as an alternative approach, which indicated the existence of inter-institutional differences in measured values. The results of this study confirm this and provide important insights into the factors that influence measurement values and the status of internal quality assessment (IQA).

Quality management operations of physiological function tests are not yet widespread in general, therefor we investigated the status of IQA of each institute in this survey in addition to EQA. Since it was clear that there were inter-instrumental differences in measurements, as observed in our previous study [4], an $\bar{X}$-R control chart was created for each ECG recorder. As a result, albeit for a limited period and scope, it was found that outliers occurred in nearly 30% of the ECG recorders, depending on the measurement item. This may indicate that daily internal quality management is necessary even for normal ECG recordings. However, since the majority of recorders did not show outliers in many measurement items, it is not necessary to require continuous daily quality management for all recorders and item combinations. It is considered realistic to evaluate the characteristics of each instrument for each item at the time of introduction and to construct internal quality management operations accordingly. In our previous study, for measurements with particularly large daily differences, errors in the lead connection between the ECG recorder and the simulator were presumed from comparisons of recorded waveforms, and such records were excluded from the analysis. Since the original waveforms were not collected in this survey and such operation could not be taken, there is a possibility that leads connection errors were included as a cause of fluctuations in measurements. We believe that it was appropriate to include such recorded values in the analysis for the purpose of the survey. The internal quality control at each institute is required to ensure the accuracy of measurements, including leads connection errors. In addition, it became a very narrow control limit range by the standard method of setting control limits used in this study. When the maximum UCL and minimum LCL values were compared, the RR interval was about 3 msec and the QRS mean electrical axis was about 2 degrees, which should not be a major problem from a clinical perspective. On the other hand, for wave height measurements such as SV_1 and RV_5, the range is nearly 20% of the wave height for the ECGs with the largest fluctuations, and the case in which daily variations actually affect clinical judgment should be considered. Guidelines for setting reasonable control limits for each measurement item are needed.

The results of the EQA (proficiency testing), which

Table 4 Results of multivariate analysis for three factors related to the inter-institute differences.

		RR	PR	QRS	Axis	QT	SV_1	RV_5
Vendor	SSM	15.556	5757.0	4545.1	4346.1	56118	2.5988	2.5241
	p	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*
Vendor Maintenance	SSM	6.4362	351.62	95.683	2.2757	20173	0.0366	0.0903
	p	*<.0001*	*<.0001*	*<.0001*	*<.0576*	*<.0001*	*<.0001*	*<.0001*
Filter setting	SSM	15.453	5096.5	2472.41	114.80	152965	5.5256	3.8698
	p	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*	*<.0001*

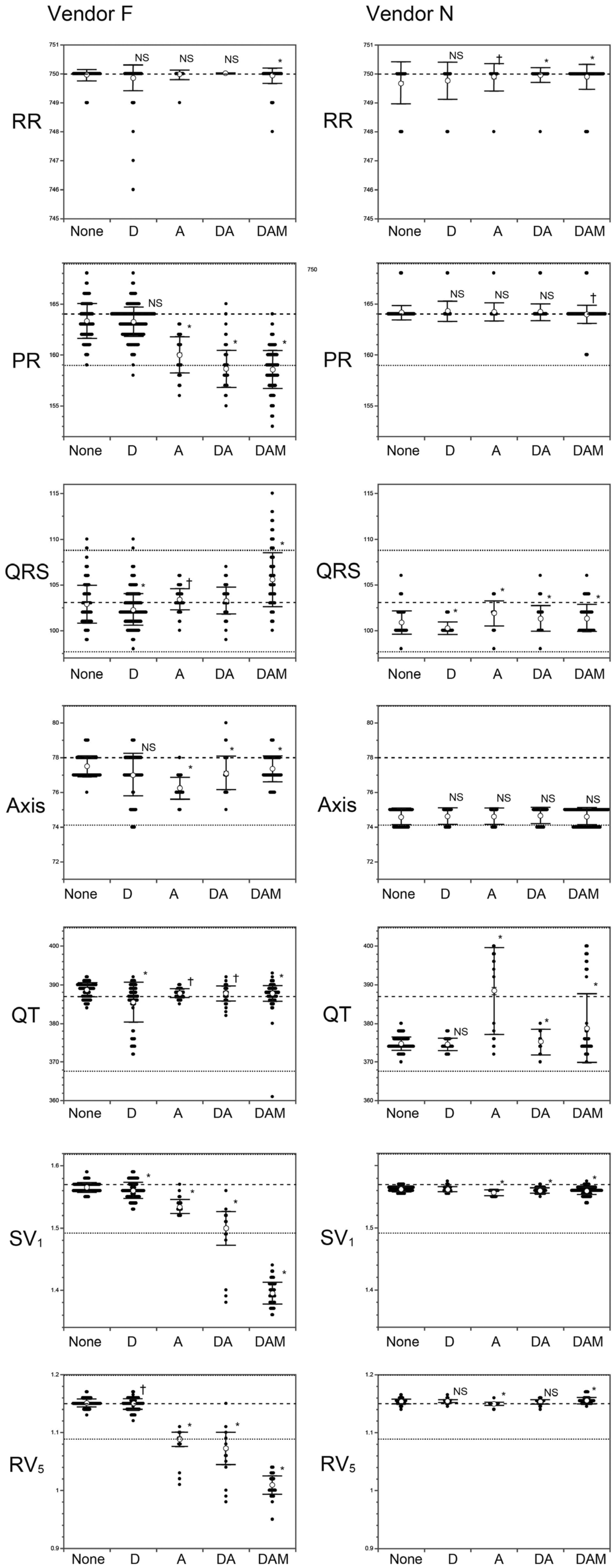

Figure 4 Distribution of each measurement by filter setting and vendor. The left column shows the recordings from Vendor F and the right column shows the recordings from Vendor N. Each measurement is shown for each of the five filter settings. Actual measured values are shown as dots, mean values are shown as white circles, and standard deviation ranges are shown as solid lines. The simulator's reference value for each measurement item is indicated by a dashed line. If the displayed range exceeds ± 5% of the standard value, this is indicated by a dotted line. The ± 5% range for each measurement is as follows; RR: 712.5-787.5 msec, PR: 155.8-172.2 msec, QRS: 97.85-108.15, Axis: 74.1-81.9, QT: 367.65-406.35 msec, SV_1: 1.4915-1.6485 mV, RV_5: 1.0925-1.2075 mV. Filter settings are None: none, D: drift filter only, A: AC filter only, DA: drift and AC filters, DAM: all drift, AC and EMG filters. significant difference, the following symbols are appended; *: $p < 0.01$, † : $p < 0.05$.

was the original purpose of this survey, are as follows: 1) The overall automated measurements had variations in both amplitude and time interval that could affect clinical judgment; 2) The variation in measurements was not normally distributed, clearly indicating inter-laboratory differences; and 3) The vendor and filter settings used by each laboratory had a large influence on the measured values.

One of the most important findings of this study is that filter settings have a significant impact on each measurement value on the ECG in actual operating environments. Although it has been technically reported that filter settings have an effect on measured values in digital electrocardiographs that are widely used today [5], users may not fully understand the effect of filter settings. In order to systematically evaluate the degree of influence in the actual operating environment, an external accuracy control evaluation such as the one conducted in this study is necessary, and there are no similar reports except for our previous study. In that study, the number of facilities was too small to analyze the factors affecting this variability. In the present study, however, this analysis was possible by selecting target institutes that included a variety of their environments (filter settings, vendors employed, whether or not regular maintenance was performed, etc.). As shown in **Figure 4**, the filter settings have a very large influence on the error of more than 10% from the reference value, which is a fact that should be understood by all personnel involved in physiological function testing. Of the filter settings examined in this study, the AC and electromyogram filters tended to be discouraged from use because of their widely recognized effects on waveforms. However, the drift filter was used by many facilities (19/27 facilities, 70%). The influence of either filter on the measured values cannot be considered negligible, and caution should be exercised. Even if the use of appropriate filters is unavoidable due to factors such as facility equipment, location, and surrounding environment forces, facilities that include automatic measurements within the scope of ISO 15189 accreditation must make every effort to keep errors in their measurements within acceptable limits (within control limits) as external accuracy control. If a department is unable to keep errors within control limits, it should clearly state that those measurements and automated diagnostic results are outside the scope of ISO 15189 accreditation.

Regarding control limits, the JIS standard for ECG recorder requires that the tolerance be within 5% (both wave height and time) as a standard for instrument calibration using square waves, but does not mention changes in waveforms at the time of reporting or automatic measurement results. However, according to the results of the preceding questionnaire, the measured values and waveforms reported by laboratories are in fact used as they are for clinical judgment. As mentioned in the discussion on internal accuracy control, we believe that a consensus needs to be formed as soon as possible on how to set control limits for each measurement item. Until this is established, it would be appropriate to apply the above JIS standards.

Furthermore, since it is rare for a single institute to use systems from multiple vendors, without conducting a institute-wide evaluation such as this one, it is likely that the difference in the scope of the filter's influence depending on the vendor would not have been clearly recognized. The scope of the filter settings' influence on the recorded data is both waveforms and filing data in the F vendor system, but only waveforms in the N vendor system. Vendor N uses pre-filtered values for filing data. This was confirmed through interviews with each vendor, but we are concerned that neither the personnel who actually use the ECG recorder nor the department members fully understand this.

While it would be desirable from the standpoint of ensuring test accuracy that filter settings have no effect on filing data, this raises another issue. **Figure 5** shows an example of V5 recordings from a institute where all filters are used. The recordings using the recorder of Vendor F on the left side show an R wave height (0.98 mV) that is clearly smaller than the reference value wave height, but the measured value stored in the filing system and the reported actual wave height are equal. On the other hand, the recording using the recorder of Vendor N on the right side shows an R wave height stored in the filing system equal to the reference value (1.15 mV), but the wave height of the actual waveform is clearly smaller (0.99 mV) and comparable to that of Vendor F. Considering that ECG testing is a diagnostic method traditionally based on visual waveform diagnosis, it is difficult to consider a situation where there is a discrepancy between the automatically measured value and the waveform to be desirable. On the other hand, the automatic diagnostic algorithm for ECG recorder first obtains a Minnesota code based on automatically measured wave height and time indices, which is combined with each vendor's additional evaluation indices to improve diagnostic accuracy and sensitivity, leading to the results. Since it is thought that the automatic measurements of each recorder are used to obtain the Minnesota code, it is assumed that the influence of the filter on the filing data will have a large

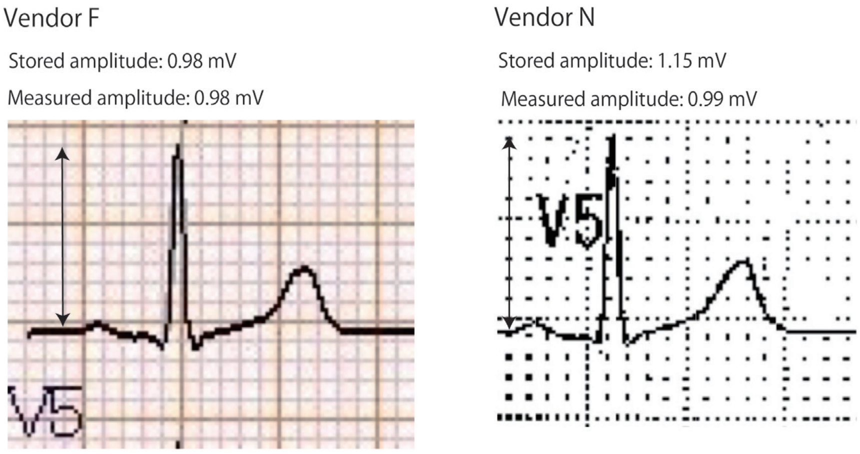

Figure 5 Sample recordings of control ECG to present discrepancies between wave amplitudes and filed data. See discussion for detail.

impact on the automatic diagnosis results. Although we were not able to evaluate the impact on the automatic diagnosis results this time, the aforementioned survey results [6] indicate that not a few institutes use the automatic diagnosis results for clinical judgment as well, and therefore, it is considered necessary to evaluate the automatic diagnosis results as part of EQA. In addition, as mentioned at the beginning, AI is currently being actively utilized in ECG diagnosis, but unless analysis is conducted after clarifying the effects of filters on the data used, such as waveforms and measurement values, it is unlikely that the expected results will be obtained.

As in our previous study, the limitation of this study is that the survey was conducted only among institutes that had obtained ISO 15189 certification, and the number of institutes was limited to 30, so the information is considered to have selection bias as to the actual status of laboratories in Japan. However, the participating laboratories obtained third-party certification as a department and voluntarily participated in external quality management activities. Therefore, we believe that the results of the survey were obtained from institutes that have a top-level awareness of quality management as physiology laboratories in Japan. The results of the two surveys were almost similar, and the survey method was appropriate. In addition, the results of both the internal and external quality control surveys clearly indicate that there are issues that need to be improved immediately. It is necessary to continue to conduct more extensive and precise quality management surveys.

Disclosure

No potential conflicts of interest were disclosed.

Appendics

The institutes contribuled to this work. RML number is an accreditation number distributed by the accreditation body.

RML number	Institution name
RML00480	Aso Co., Department of Central Clinical Laboratory, Iizuka Hospital.
RML00520	Department of Clinical Laboratories and Transfution Medicine & Cell Therapy and Department of Pathology, Yokohama City University Hospital.
RML00620	Social Walfare Organization Saiseikai Imperial Gift Foundation, Inc. Department of Clinical Laboratory, Osaka Saiseikai Nakatsu Hospital.
RML00640	Division of Blood Transfusion and Cell Therapy, Division of Clinical Pathology, and Department of Clinical Laboratory, Kagoshima University Hospital, Kagoshima University.
RML00800	Hakodate City Hospital Bureau Department of Central Laboratory, Hakodate Municipal Hospital.
RML00840	Keio University, Clinical Laboratory, Center for Transfusion Medicine and Cell Therapy, Diagnostic Pathology, Keio University Hospital.
RML00930	Japanese Foundation for Cancer Researth, Clinical Examination Center/Clinicopathology Center, The Cancer Institute Hospital of JFCR.
RML00960	Osaka University, Laboratory for Clinical Investigation, Department of Blood Transfusion, Department of Diagnostic Pathol-

ogy, Clinic of Radiology, Ultrasound Diagnostic Center, Osaka University Hospital.

RML00970 Incorporated School of Kurume University, Department of Clinical Laboratory Medicine, Department of Pathology, Kurume University Hospital.

RML01020 Teikyo University, Department of Clinical Laboratory, Teikyo University Hospital.

RML01030 Hyogo Medical University Hospital, Department of Clinical Laboratory, Center for Transfusion Medicine and Cellular Therapy, Ultrasound Imaging Center, Department of Surgical Pathology, Department of Clinical Technology.

RML01040 Nagoya University, Department of Clinical Laboratory, Department of Blood Transfusion Service, Department of Pathology, Nagoya University Hospital.

RML01070 National University Corporation Gunma University, Department of Clinical Laboratory, Gunma University Hospital.

RML01080 Chiba University, Department of Laboratory Medicine, Department of Pathology, Department of Transfusion Medicine and Cell Therapy, Chiba University Hospital.

RML01100 National University Corporation, University of Miyazaki, Department of Clinical Laboratory and Division of Pathology, University of Miyazaki Hospital.

RML01200 Department of Clinical Laboratory, Kyorin University Hopital, Kyorin Foundation.

RML01240 Japanese Red Cross Society, Japanese Red Cross Ashikaga Hospital Clinical Laboratory Department.

RML01280 Central Clinical Laboratory, Blood Transfusion Section, Pathology Section, General Diagnostic Imaging Center, Diagnostic Pathology Nara Medical Univesity Hospital.

RML01450 Aichi Medical University Corporation, Department of Clinical Laboratory, Department of Transfusion Mdicine, Department of Infection Control and Prevension, Department of Pathological Center, Aichi Medical University Hospital.

RML01500 Medical Laboratory, National Hospital Organization Saitama National Hospital.

RML01570 Gakkouhoujin Dokkyo Gakuen, Dokkyo Medical University Saitama Medical Center, Clinical Laboratory and Transfusion Service and Pathology.

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