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ECGScan: a method for conversion of paper electrocardiographic printouts to digital electrocardiographic files

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Abstract

Background: Measurements of parameters from electrocardiograms (ECGs) are still largely performed from paper ECG records. Recent guidelines from regulatory agencies and, in particular, the requirement of the Food and Drug Administration to enforce the digital submission of annotated ECGs have triggered significant efforts in the pharmaceutical industry, which, to comply with the new guidelines, is adopting digital ECG technology. At the same time, the new requirements justify the need for tools to convert existing paper ECG records into digital format, particularly for retrospective studies.

Methods: This article presents ECGScan, a computer application developed for the conversion of paper ECG records to digital ECG files. An image processing engine is used to first detect the underlying grid and, subsequently, to extrapolate the ECG waveforms using a technique based on active contour modeling.

Results: ECGScan was validated using a set of 60 ECGs for which both the original digital waveform and paper printouts were available. Sample-by-sample comparisons provided evidence of a robust wave reconstruction (root mean square value from 169 PQRST complexes was 16.8 ± 11.8 μV). Semiautomatic measurements of QT intervals performed on 144 complexes also indicated a strong agreement between original and derived ECGs (ΔQT = 0.577 ± 5.41 milliseconds).

Conclusions: ECGScan provides a robust reconstruction of a digital ECG, both in waveform reconstruction and in QT measurements performed on original (digital) ECGs and on digitized ECGs from paper printouts.

Keywords: Paper ECG; Digital ECG; Core laboratories

1. Introduction

The 12-lead electrocardiogram (ECG) is widely used in clinical research to determine primary and secondary end points and to assess the effect of drug-induced relevant changes.

Despite a technology that permits storage of raw data in digital format in many years, many ECG analyses are still performed on paper printouts, either directly on paper copies or with the support of on-screen caliper methods applied to the scanned printout converted to a digital image format [1].

Recently, the Food and Drug Administration has launched an initiative intended to recommend to the pharmaceutical industry the use of digital annotated ECGs for the submission of new drug applications [2]. Although intended to provide a more efficient way to review submitted data, this effort has also triggered the interest toward algorithm-based and semiautomated ECG analysis. The digital ECG format chosen by the Food and Drug Administration has been already adopted by several manufacturers, thus facilitating the exchange and the usage of digital ECGs in the pharmaceutical arena. More importantly, the new regulatory guidelines will magnify

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the need for efficient and widely applicable tools for the conversion of paper ECGs to digital ECGs, particularly for retrospective studies.

Academic research will also indirectly benefit from these efforts; indeed, there still exist today many large databases collected on paper ECGs that must be converted to digital format to be efficiently archived.

The task of actually deriving a digital ECG from a paper printout has been already approached, although it was generally limited to research applications [3,4] and often specifically designed to the execution of well-defined studies [5-7]. Moreover, the methods used were often based on commercial products the main objectives and contexts of which were not in the ECG arena and that could not be optimized and tuned for the task of deriving an ECG waveform from a grid-supported image.

This article presents ECGScan, a patented computer application that has been specifically developed to provide a tool for the conversion of paper ECGs to digital ECGs. The overall features of ECGScan will be described, and the result of a validation study will be reported. Two dedicated tests aimed to demonstrate the fidelity of derived digitized ECG with respect to the original digital ECG will be reported. The first test makes a sample-by-sample comparison between the original and derived ECG, whereas the second provides a comparison of QT intervals measured with a semiautomatic algorithm. We focused on the QT interval, as this measurement is currently of primary concern in pharmacologic research and by regulatory agencies.

2. Methods

2.1. Description of ECGScan system

2.1.1. Overall description

ECGScan is a standalone computer application that opens image files under different graphic file formats including Microsoft Windows bitmap, Joint Photographic Experts Group, graphics interchange, tagged image file, and Portable Network Graphics. User interaction turns around the concept of an active rectangle, which is a rectangular portion of the loaded ECG image that the user selects using the computer mouse. Fig. 1 shows an example of an ECG image with the active rectangle drawn around lead I.

Input parameters consist of paper speed, gain of the original ECG, and the resolution used to scan the image (in dots per inch [dpi]). Output parameters are the sampling rate (Hz) and amplitude resolution (μV) of the digitized ECG, which, by default, are set to 500 Hz and 5 μV. At digitization time, ECGScan will resample and rescale the digitized waveforms to the required sampling rate and amplitude resolution using a nonlinear interpolation technique previously described [8].

2.1.2. Detecting the grid

In ECGScan, detecting the grid means to identify the exact localization of all the grid lines in the image bitmap. The grid detector is able to eliminate nonrepetitive elements (such as marks or stains) and to estimate the angle of the grid (ie, the presence of a tilt effect). A reliability index quantifying the regularity of the identified grid lines notifies

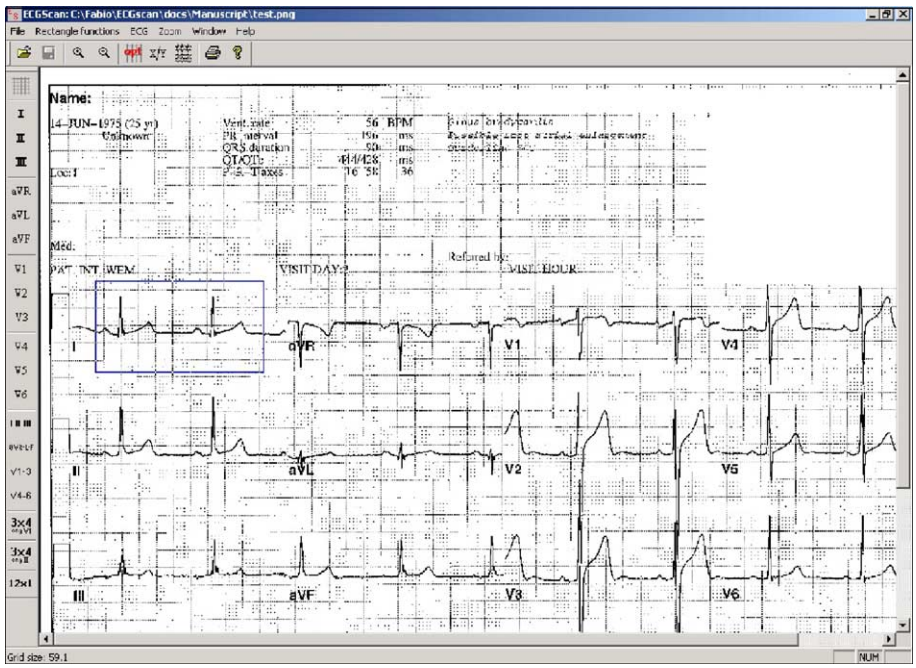

Fig. 1. Main screen of ECGScan with 1 paper ECG image opened; the working rectangle is drawn around lead; the digitizing toolbar is organized vertically on the left side of the panel.

the user on the degree confidence of grid detector (a typical scenario that would generate a poor reliability is when the paper itself is warped, folded, or torn) so that scanned ECGs of poor quality can be automatically discarded.

ECGScan includes 3 separate modes to detect ECG grid: *manual*, *range*, and *exact.* With *exact* grid mode, the input parameters of scanned ECG image (ie, the paper speed, the scanning resolution, and the time distance between grid lines) are used to mathematically derive the distance in pixel units between grid lines with the following formula:

$$Pixels/grid = \frac{\text{grid time [sec/grid]} \times \text{paper speed [mm/sec]} \times \text{dpi [pixels/inch]}}{25.4\ \text{[mm/inch]}}$$

For instance, with a standard paper speed of 25 mm/sec and a scanner resolution of 300 dpi and with a standard grid time of 0.2 seconds per grid, the number of pixels between grid lines is 59.055. Assuming a priori, the value of pixels per grid greatly simplify and speed up the task of the grid detector, which only needs to determine the angle and reliability index.

With *range* grid mode, the formula is still applied; however, a (user-selectable) confidence level on the exactness of the formula is assumed, and ECGScan will redetect the grid on the basis of this confidence level. This situation is typical of cases where input parameters are known but some potential deviations from their expected value do exist (eg, when a photocopy or a fax copy of the original paper ECG record is used).

With *manual* grid mode, no assumptions on the input parameters are made. The user selects an active rectangle including at least 4 or 5 squares of clean grid. Clean grid means an area where the grid lines are clear, regardless of the presence of ECG or text within the same area.

2.1.3. Detecting the ECG waveform

The task of actual extraction of the ECG waveform uses the concept of the working rectangle. The user has the option to digitize a single lead at a time, a group of simultaneous leads, or the full ECG record. All this is handled via a dedicated toolbar, which is activated once the grid has been detected. The digitizing toolbar consists of either individual or simultaneous waveform detection options (the digitizing toolbar can be seen in Fig. 1 on the left side of ECGScan main window). A set of 12 buttons is used for the digitization of single leads, whereas "specialized" buttons handle the situation where groups of leads are simultaneously selected. Currently, ECGScan can handle 3 scenarios where all 12 leads are digitized at once:

- 3 × 4 with 1 long V1 lead at the bottom;
- 3 × 4 with 1 long lead II at the bottom; and
- 12 × 1, that is, all 12 leads, 1 for each row.

We developed a novel method to digitize an ECG waveform based on the concepts of active contours (aka "snakes") and dynamic programming. The active contour model was first introduced by Kass at al [9] as a parametric waveform that minimizes a cost function defined in terms of the attributes of a digital image. A dynamic programming approach was first used by Amini et al [10] to minimize the cost function and, hence, to solve for the optimum waveform via a numerical algorithm suitable for computer programming. The active contours approach was previously used by one of the authors to track the motion of object boundaries in a video sequence in Fu et al [11].

In our method, we represent a digital ECG waveform as an active contour that has a vertical position at every horizontal pixel location in an ECG image rectangle. The vertical position corresponds to the voltage level, and the horizontal location corresponds to the time instance. The desired digital representation of the ECG waveform is defined as image that minimizes a cost function, defined as a sum of several weighing functions of different nature as explained in the following.

A "line" function is used to attach the active contour toward the waveform drawn on the ECG image. A "smoothness" function is used so that the digitized waveform does not exhibit large discontinuities. A "length'' function is used so that the active contour reaches the very end points of the maximum and minimum points on the ECG waveform. Certain weights are applied in the definitions of these functions so that the digitized waveform is not attracted to extraneous lines, marks, or letters while avoiding the white space on the ECG image. The mathematical definitions of the above functions are as follows:

$$C(s(x)) = \lambda_{\text{line}} C_{\text{line}}(s(x)) + \lambda_{\text{smooth}} C_{\text{smooth}}(s(x)) + \lambda_{\text{length}} C_{\text{length}}(s(x))$$

where

$$C_{\text{line}}(s(x)) = \sum_{k=0}^{N-1} I(x_k, s(x_k))$$

$$C_{\text{smooth}}(s(x)) = \sum_{k=0}^{N-1} \left\| (x_{k+1}, s(x_{k+1})) - 2(x_k, s(x_k)) + (x_{k-1}, s(x_{k-1})) \right\|^2$$

$$C_{\text{length}}(s(x)) = \sum_{k=0}^{N-1} \left\| (x_{k+1}, S(x_{k+1})) - (x_k, S(x_k)) \right\|^2$$

where $s(x)$ represents the waveform amplitude at location x; N denotes the number of samples in the digitized waveform; $I(x,s)$ denotes the image intensity at location (x,s); $C_{\text{line}}(s)$, $C_{\text{smooth}}(s)$, and $C_{\text{length}}(s)$ represent the line, smoothness, and length functions, respectively; and λ_{line}, λ_{smooth}, and λ_{length} denote the weights associated with the line, smoothness, and length functions, respectively. Fig. 2 shows an example of a

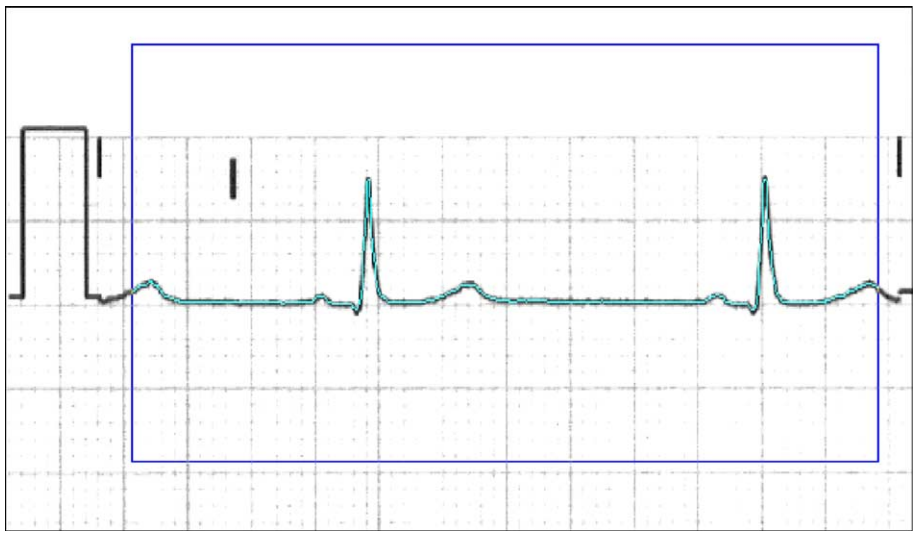

Fig. 2. Example of lead I digitization: the light blue–colored pixels represent the digitized information extracted from the image processing engine.

single-lead waveform extraction obtained using the active contours method.

Note that the proposed digitization algorithm accounts for any tilting in the paper placed on the scanner bed. It computes the amount of tilt in the form of a rotation angle and removes the tilt during the digitization process. Furthermore, although the proposed algorithm does not require the removal of the grid lines for digitization, any gaps that may otherwise exist in a paper waveform are automatically interpolated during the digitization process, thanks to the smoothness property of the active contours.

2.1.4. Setting anchor points

ECGScan includes the possibility for the user to manually set anchor points. An anchor is a point on the

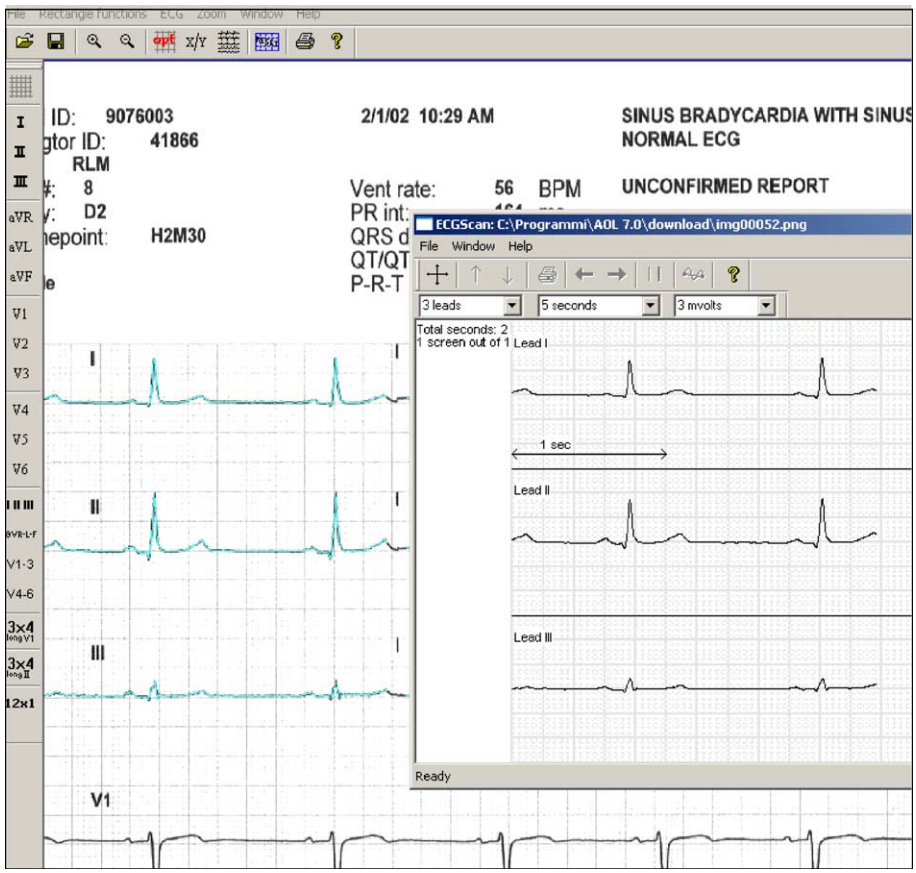

Fig. 3. Example of lead digitized window. The smaller window displays leads I, II, and III as digitized from the scanned ECG.

loaded image where the user imposes the passage of the ECG waveform. The setting of anchor points is straightforward and simply consists of a single right click of the mouse on the point to be anchored. A small circle is drawn to indicate the presence of the anchor point. This feature can be time-consuming, but it allows waveform reconstruction in difficult noisy tracings.

2.1.5. Displaying and saving the digitized ECG

The digitized waveform can be displayed in a dedicated window. The display organization of this window (ie, how many seconds to show per lead, how many leads to display in 1 screen and in which order, which gain to use, etc) can be set by the user. Fig. 3 is an example of this digitized ECG window. The support of this additional display is crucial for the user to verify in detail the actual performance of the digitization process. The digitized waveform is finally saved in an optional format which can be Extensible Markup Language, American Standard Code for Information Interchange, or binary.

2.2. Validation of ECGScan

Two separate validation studies have been executed with the aim to understand how digitized ECGs represent the original digital ECG (the raw ECG). The first study provides quantitative information of the actual voltage differences between raw and digitized ECGs, and the second compares semiautomatic measurements of QT intervals performed on original and on the derived (digitized) waveforms.

2.2.1. The data set

The data set consisted of 60 12-lead ECGs provided by University of Rochester Heart Research Follow-Up Program. Thirty ECGs are from normal subjects, whereas the remaining 30 are extracted from the International Long QT Syndrome Registry [12]. The ECGs were acquired with a MacView electrocardiograph (General Electric Healthcare Technologies, Milwaukee, WI, USA) and stored in digital format onto floppy disks. The same ECGs were also printed with a standard output mode: 25 mm/sec, 10 mm/mV, 3 × 4 display mode (first 2.5 seconds for each of the 12 leads), and full 10 seconds of 1 lead (V1) printed at the bottom. Digital ECGs were subsequently extracted from floppy disks using Magellan software (General Electric Healthcare Technologies) [13], which converts internal proprietary format into a standard binary format, inclusive of subject information and rhythm data saved at 250 Hz with 4.88 μV resolution.

Paper ECG printouts were scanned (EPSON GT-7000 scanner, EPSON, Long Beach, CA, USA) at a 300-dpi resolution using an 8-bit grayscale color depth. All scanned images were subsequently stored in a Portable Network Graphics format (lossless compression) to be submitted to ECGScan.

To obtain a proper quantitative assessment of the differences between original and derived digital ECGs, we produced an ad hoc test application where the original and the derived ECG sequences are analyzed. This test application automatically computes the shift between the original and derived leads and subsequently derives the QT intervals on each lead with a method previously described [14]. The sample-to-sample comparisons were expressed computing the mean, the median and root mean square (RMS) value of the differences between the original and derived ECG sequences.

2.2.2. ECGScan options used in validation analysis

ECGScan was run using 10% range grid detection mode (ie, knowledge of paper speed and scanning resolution, respectively, 25 mm/sec and 300 dpi. For each ECG, between 2 and 2.4 seconds of leads I, II, and III were digitized and saved into an output American Standard Code for Information Interchange file. The characteristics of output signals were user-imposed to match those of original digital ECGs, that is, a sampling rate of 250 Hz and an output amplitude resolution of 4.88 μV. During the validation studies, the possibility to set anchor points was disabled. Thus, the only user interaction was the selection of the active rectangle around leads I, II, and III. In this way, the potential source of variability associated with the user was minimized.

3. Results

3.1. Test 1 results: comparison of raw digital ECG as acquired and digital ECGs as obtained by ECGScan

Among the 180 (60 × 3) available complexes, 11 were excluded because of either very high noise (n = 6) or a flat-line ECG (n = 5). Thus, a total of 169 digitized leads were used for this comparison.

A least square fit analysis was run to inspect how closely the samples would fit the $y_i = x_i$ ideal line (ie, a perfect 45° line). Table 1 summarizes the results of the test. In the table, MeanΔ, MedianΔ, and RMS indicate the mean, median, and RMSs of the sample-by-sample differences (digitized ECG minus original ECG) obtained for each PQRST complex, analyzed after taking into account the computed shift between the 2 signals. Mean values of both MeanΔ and MedianΔ are well below the sampling interval (4 μV at 250 Hz).

Results on least square best fit are remarkable: both correlations and slopes are very close to 1 with very narrow variations between ECGs (minimum correlation is 0.86, and

Table 1
Summary of test 1 results

n = 169	MeanΔ	MedianΔ	RMS	Slope	Correlation
Mean	−1.37	−0.32	16.8	0.977	0.95
SD	4.29	4.56	11.8	0.04	0.03
Minimum	−14	−9.76	0.2	0.78	0.86
Maximum	9.2	9.76	58.2	1.08	0.99

MeanΔ, MedianΔ, and RMS columns are expressed in μV. Mean and median are based on the differences between the derived (digitized) vs the original ECG waveforms.

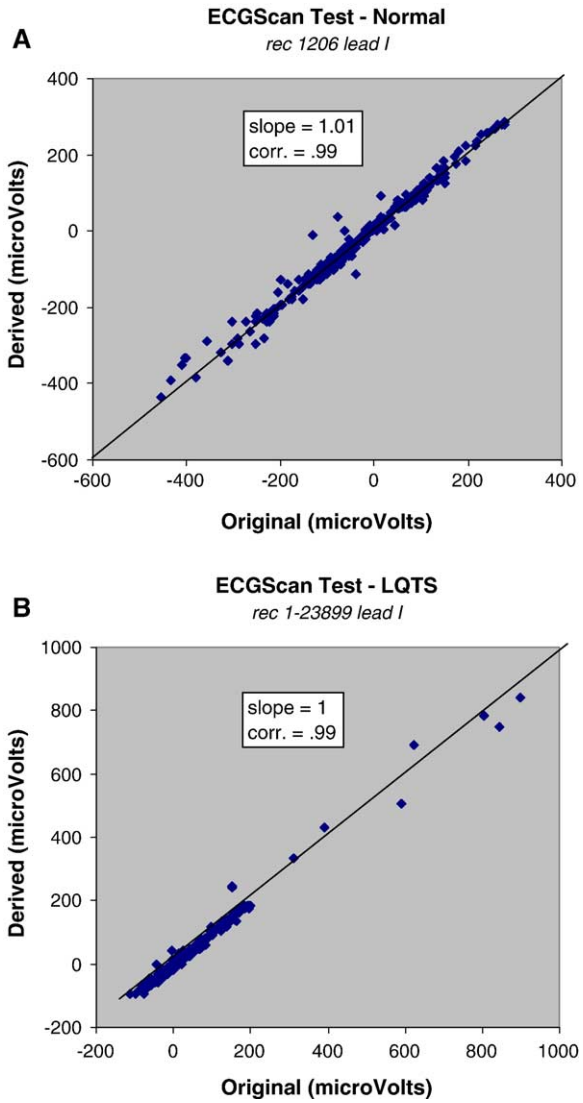

Fig. 4. Paper vs digital plot for a normal subject (A) and for a patient with long QT syndrome (B). In both examples, the plot is based on 2.4 seconds of data from lead I.

in only 2 of 169 cases, the correlation was below 0.90). Fig. 4A and B are 2 representative examples of linear fit analysis for a normal subject and a patient with long QT syndrome, respectively. Both examples are run for 600 samples and the observed pairs of derived/original samples are systematically close to the $y = x$ line.

Worst case reconstruction was observed for a lead where the automatic waveform detector missed the upper half of the QRS complex, as reported in Fig. 5. This resulted in a larger RMS value (58.2 μV) for the PQRST complex (see maximum value of RMS in Table 1). However, using a single anchor point placed at the top of the QRS, the wave reconstruction was correctly recovered and the RMS of the PQRS complex reduced to 8.1 μV.

We have actually repeated the analysis of all the 169 PQRST complexes with the possibility to place anchor points restored. Results confirmed the same levels of Table 1

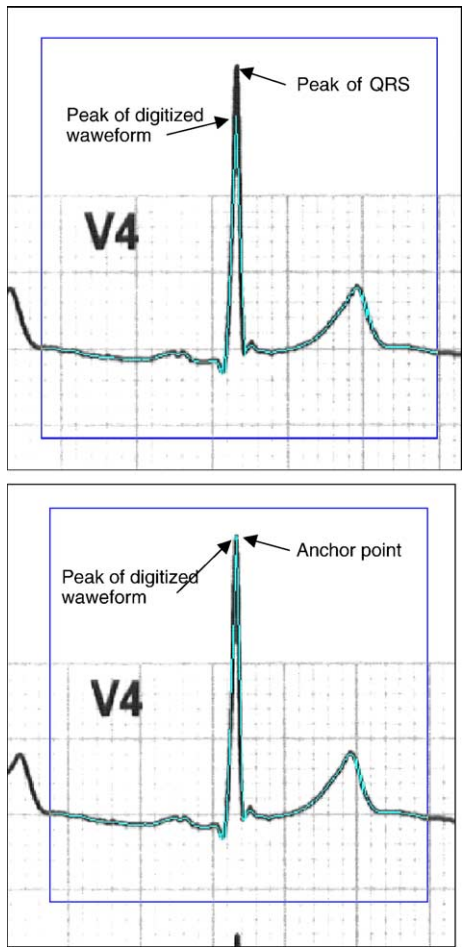

Fig. 5. Example of anchor point placement for the worst case reconstruction from the validation data set. The QRS apex is missed by the automatic detector and is completely recovered after the placement of a single anchor point.

expected for the RMS values which were (expectedly) reduced to 11.3 $\pm$ 6.8 μV, with a maximum value (worst case) of 22.5 μV.

3.2. Test 2 results: comparison of outputs of a semiautomatic algorithm applied to raw original ECG and that derived by ECGScan.

Using the ad hoc test application, the test user chose a time window containing the first complete PQRST complex available for each pair of original and derived digital ECGs (leads I, II, and III). A semiautomatic method was then applied. The Q-onset and T-offset calipers were first automatically computed using a previously published

Table 2
Summary of test 2 results

n = 144	QT original	QT derived	ΔQT (derived − original)
Mean	404	405	0.755
SD	55.7	56	5.41
Minimum	292	288	−12
Maximum	612	604	12

All values are expressed in milliseconds.

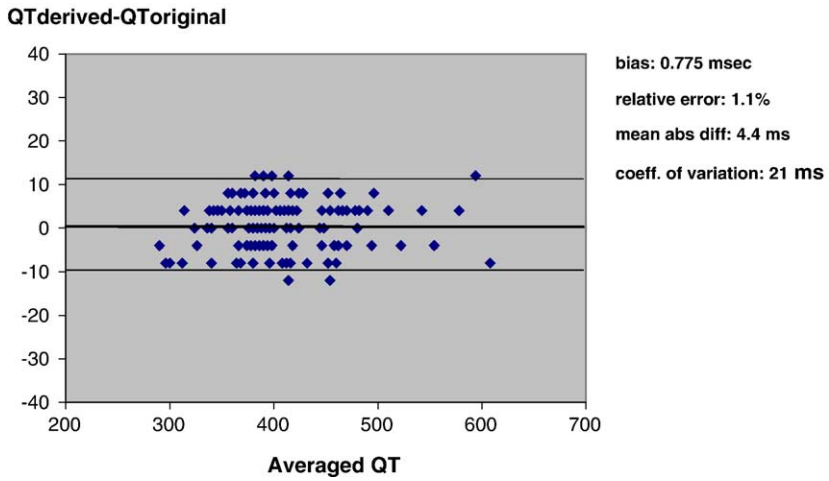

Fig. 6. Bland-Altman plot of QT differences between original and derived ECGs. The relative error is computed as the ration between the difference of QT intervals and their average. The coefficient of variation depends on the standard deviation of absolute differences and gives an estimate of the 95% CI of the expected difference.

method that first determines automatic measurements [8] corrected, when needed, by a user [14]. The editing process occurred in a blinded mode (ie, the user could not visualize the derived ECG when editing an original and vice versa).

The computer algorithm applies exclusion criteria (for example, beats with a T wave smaller than 100 μV are excluded) and 25 of the 169 analyzed complexes were excluded, resulting in a total of 144 PQRST complexes used for this comparison.

Q onset was modified 16 times in original ECG and 20 times in derived ECG; T offset was modified 17 times in original ECG and 16 times in derived ECG.

Table 2 summarizes the results for the 144 analyzed complexes, whereas Fig. 6 is the Bland-Altman plot of the QT intervals, as measured on original and derived sequences. The mean difference between QT intervals is less than 1 millisecond. A paired t test run on the QT intervals indicated nonsignificant differences in the QT intervals measured on original and on derived ECGs ($P > .1$).

4. Discussion

The results of the 2 tests reported indicate that ECGScan can reliably digitize the waveform information from a paper ECG. Sample-by-sample comparisons between original and digitized tracings provided evidence of a robust wave reconstruction with well-contained deviations, and analysis of QT intervals computed by a semiautomatic method indicated a good agreement between the measurements performed on the original and derived PQRS complexes.

One problem in performing such type of comparisons is that the ECG reproduced on paper may already deviate from the original digital ECG. In this case, the comparison between original and derived ECG can be biased by factors

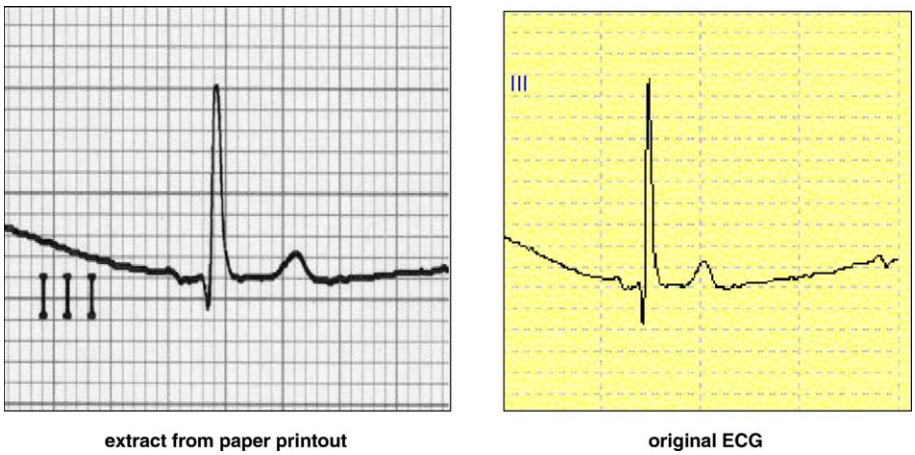

Fig. 7. Loss in the amplitude of R and Q waves between original digital ECG and paper ECG (extract from record 1209 of the data set). In both panels, the vertical distance between horizontal grid lines is 100 μV. In the digital ECG (right panel), the amplitude of R wave is 1 mV, whereas on paper (left panel), it is slightly above 900 μV. Thus, on paper, there is already about a 10% reduction in R wave, which will be reflected into the digitized ECG that is going to be derived by ECGScan. Even the Q wave (particularly sharp in this example) shows some loss: in the original ECG, it is slightly less than 200 μV, whereas on paper, it is about 150 μV. The T wave is reproduced correctly (no cases of T-wave amplitude reduction were found in the entire data set).

independent of ECGScan. Indeed, the drawing process of high-frequency portions of the ECG (Q and R waves) can sometimes produce smaller amplitude peaks that would determine larger sample-by-sample comparisons. Fig. 7 shows one extreme example from our validation database where the difference between original and paper ECGs is apparent, with an R-wave reduction of about 100 μV.

Based on this discussion, the slightly larger absolute value of MeanΔ from Table 1 and, more importantly, the levels or RMS from the same table are clearly a consequence of the amplitude loss (eg, in R- and/or Q-wave peaks) related to the printing process (which could be seen as a low-pass filter) rather than to errors associated with ECGScan. Thus, measurements of amplitudes as performed on either paper ECG printouts or on their derived digitized counterparts could underestimate the real amplitude values from the original digital ECG. A more complete quantitative assessment on ECGScan should include a broader set of environmental conditions, using different scanning resolutions and verifying a more complete set of ECG measurements, with special emphasis on amplitude-related parameters.

The validation design we have used aimed to provide quantitative data on the paper-digitized vs truly digital comparison, that is, toward the assessment on how well the digitized ECG is representative of the original ECG. A secondary level of validation would be to compare measurements from the actual paper ECG and measurements from the digitized ECG.

One legitimate criticism to a method such as ECGScan could be that paper ECGs analysis should be an obsolete technique today. Why should we waste time and energy to convert paper ECGs when most electrocardiographs commercialized for many years are already digital devices? In the author's opinion, the answer to this question is simply that the number of clinically valuable ECGs that are still stored on paper records and that are often retrieved to derive measurements is still very large and justifies the need of reliable tools to digitize these valuable tracings for storage into digital databases.

The availability of tools such as ECGScan should not encourage the prospective design of studies with paper collection. On the contrary, the experience learned from the validation study confirmed what was already known by experts of the field, that is, some information is already lost with the printing process, and even with a 100%-accurate reconstruction, we will never be able to fully restore the original information. Thus, usage of tools such as ECGScan should be limited exclusively to situations where the digital ECG is either no longer available in retrospective studies or with the purpose to build representative digital databases.

5. Limitations

Although obtained with standard settings (paper ECG printouts at 25-mm/sec speed, 10 mm/mV-gain, scanning resolution of 300 dpi), the results presented in this article cannot be extrapolated to conditions different from those imposed in these tests. It particular, the noise level of the ECGs chosen only represent a well-controlled research environment. Real-life scenario would undoubtedly increase the rejection rate observed. For example, using black and white photocopies can easily double or triple the rejection rate.

Another limitation is the risk of losing the relative timing between the different leads. This problem is, of course, limited to the "one lead at a time scenario," and can be minimized or eliminated when the user uses a multiple-lead detection criteria (as described in section 2.1.3) where the relative time between the leads can be reconstructed in the output digitized ECG.

6. Conclusions

Results obtained with dedicated tests showed a significant agreement between acquired digital ECGs and digitized ECGs derived from scanned paper printouts processed by ECGScan computer application. Results are positive both in sample-to-sample comparisons and in QT measurements performed on the 2 separate types of digital ECGs. The few inconsistencies found seem to be independent of ECGScan, but rather due to the internal printing process of electrocardiograph system, which can cause a low-pass filter effect and, consequently, a reduction of peaks in high-frequency waves (R waves and Q waves). These differences do not seem to affect the measurement of QT interval, although even better results (smaller coefficient of variation) could be obtained when comparing QT measurements, as performed on paper ECG and on derived digitized ECG (using on-screen tools).

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