

# Multi-Functional Device for Cardiology Telemedicine and Diagnostic Holter

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## Abstract

*Although different systems are available on the market to record ECG and to send it to an analysis station, there is still demand for a more versatile, easy to use device that shorten the time the diagnosis is available, avoiding the patient to move to a healthcare center: the purpose of our work was to validate a solution that fulfill this requirement. Twenty family doctors and two cardiologists were involved in the evaluation of the whole solution and 400 exams were performed. The results showed that the device is well tolerated by patients and the workflow allures the practitioners for the combination of its simplicity and effectiveness in reducing the time to reach the diagnosis, although a remarkable number of cardiac traces were not good enough to formulate a diagnosis, mainly due to contact loss in the patient's electrical circuit. An investigation was carried on to identify the causes of bad electrical connections and corrective measures were taken to improve the number of good quality signals.*

## 1. Introduction

A major requirement for cardiologist is to prevent severe injuries by monitoring the patients not only during the hospitalization but also when the patient is at home, followed by the family doctor. Moreover, the possibility to perform standard ECG at patient's home or at family doctor ambulatory is mandatory to reduce the costs of hospitalizations and cardiology rehabilitation procedures [1-7]. Nowadays, different systems are available to record ECG and to send it to the hospital via phone or internet connection, where a specialist can read the data and decide the best strategy to improve the therapy. [8-11] These devices can present different levels of complexity, depending on their clinical aim: from the standard ECG recorder able to acquire 12 signals to the simplified system to acquire up to 3 channels at a low resolution but for a longer time to evaluate arrhythmias. Both these approaches present some problems connected or to the difficulty for the patient to manage the

acquisition and then the transmission to the hospital or to the high specialization and the low versatility of the devices [12-13].

The purpose of our work was to validate a versatile solution that comprises a powerful and easy to use instrument (TH16, Q&S, Reggio Emilia, Italy) and an internet application (QS-32 NET) verifying the feasibility of: (a) performing standard ECG or 24 hours holter recordings in a general practice context; (b) sending data to a telemedicine centre to be stored and completely managed by an user-friendly software; (c) making the specialist able to connect to the server from a remote client, analyse ECG recordings and make the diagnosis; (d) allowing the family doctor to connect to the server from a remote client as well and consult the specialist's report.

## 2. Methods

TH16 was designed for family doctors, making them able to perform standard ECG, holter recordings during pathologic events and then to transmit the data to the server station via phone line. By simply programming the device, TH16 can be configured to acquire and store up to 20 standard ECG recordings or a 3 channels 24 hours holter monitoring. Firmware on TH16 allows self background analysis to identify and mark suspicious events to help the doctor in the diagnosis. After acquisition, data are sent to the telemedicine centre using the integrated modem. The software on the server automatically links the data to the patients archive, allows the specialist to view the recordings and make the diagnosis, allows the family doctor to view the specialist's report to adapt the therapy of the patient. The system (fig. 1) is set up by a central server with a dedicated software (QS-32 NET) to store and manage ECG data. Doctors and specialists can access the system through a simple internet connection to insert new patients and analyse the ECG recordings. Communication between the TH16 and the server is digital and is performed via either a PSTN or a GSM modem, according to the particular assembly of the device.

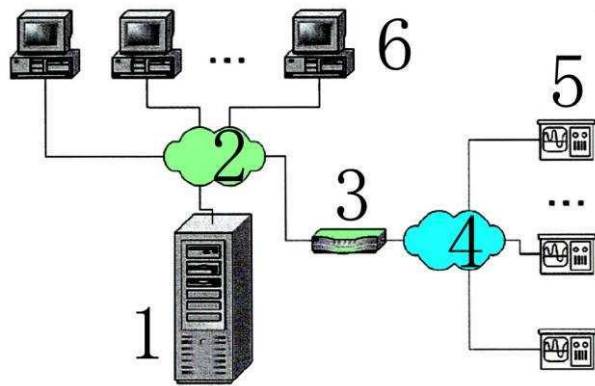


Figure 1: System architecture. (1) Server; (2) Internet connection; (3) Router; (4) Phone Line; (5) TH16, (6) Clients.

Although it is a light handheld device, TH16 is equipped with a six keys keyboard and a 240x320 display, which make the device capable of performing sophisticated user interface features, such as checking the correctness of the electrode positions before starting the acquisition, reviewing the acquired data and managing the internal ECGs archive, allowing the patient to insert notes and the symptoms that he/ her feels during the holter monitoring, driving the patient or the doctor during the transmission of the ECGs to the server.

TH16 is equipped with a modem supporting a software interface capable of performing PPP connection and the main internet protocols, such as DNS and FTP, which allows the device to send the central server the recorded ECGs. The transferred data are kept in binary format and encrypted with a proprietary algorithm for safety reasons. The application software assures the integrity and the completeness of the transmission, allowing a self retry functionality in case of unexpected errors and providing the user with transmission report on the display.

On the other hand, data exchange between the central server and the family doctor or the specialists is carried on via internet through an SSL connection, which ensure data encryption and integrity. The job of doctors for evaluating the ECG and making the reports is done in an easy way due to the user friendly web interface. The web server application connects to an Oracle database and is designed to support the archiving of additional patient data, including any kind of document format.

TH16 testing involved 2 cardiologists and 20 family doctors previously skilled about the functioning and the employment of TH16. 174 ECG and 230 holter recordings were performed in the ambulatory or at the patient home and transmitted to the telemedicine server. Each patients gave the written consent to participate at the study and no selection on the basis of the subjects clinical conditions was made.

The correctness of the transmission was evaluated by comparing the original signal with the received one; then both the specialists analyzed the recordings to evaluate the quality of the signals and to make the diagnosis.

### 3. Results

An example of good transmitted signal is shown in figure 2.

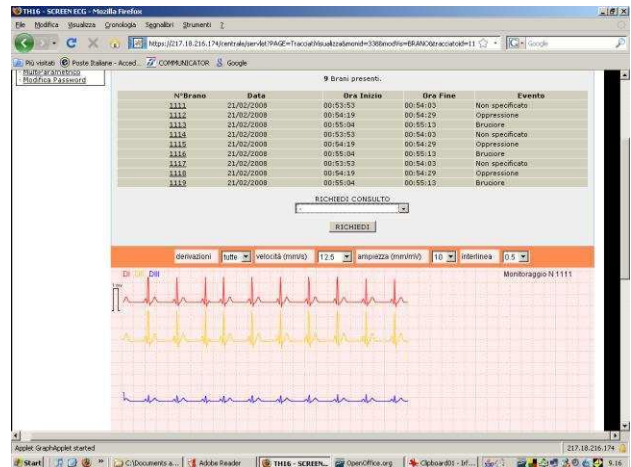


Figure 2: example of ECG signals transmitted from TH16 to the server.

All the recordings were correctly transmitted and received from the server. In 10 (6+4) cases, transmission was repeated twice because of lack in phone line connection. Nevertheless, all the data were properly received from the server. The 86% of ECG recordings were classified of good quality from both the specialists and then an analysis was performed. Only the 48% of holter signals were considered readable from the 2 specialists and so only 110 recordings were analysed. The 14% of ecg and the 52% of holter signals were impossible to analyse because of the artefacts due to unstable or wrong positioning of the electrodes or the whole lack of the electrical connection between the patient skin and the device.

Results are summarized in table 1.

Number of	ECG		Holter	
Recorded signals	174		230	
Received signals	174	100%	230	100%
Readable signals	150	86%	110	48%
Written Reports	150	86%	110	48%

Table 1: results of the experimentation

All the diagnosis were performed within 24 hours from the transmission and the feedback to the family doctor

was immediate.

#### 4. Discussion and conclusions

TH16 demonstrated to be a powerful and easy to use device, well tolerated by patients. The intermediary role of the family doctor between patient and specialist represent the best solution in order to optimize the procedures and refine the diagnosis [2, 3, 4, 7, 13]. More improvements are necessary in order to minimize bad quality acquisitions: 48% of correct holter recordings is a very poor percentage and must be enhanced. A more accurate investigation has been performed about the way the signal quality could be improved, which finally lead to both a new design of the mechanical connection between the patient cable and the device, in order to make it more secure, and the necessity of a firmware revision to force the practitioners to use the feature of the device for immediate control of the acquired signal quality. Such corrective measures should reduce the possibility to acquire ECG signal with artefact or completely unreadable. Moreover, for it is needed to avoid bad acquisitions due to incorrect usage of the device, including erroneous electrode positioning, a closer collaboration between family doctors, specialists and technicians, beginning from the initial training, is desirable.

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