Fundamentals and Aspects of Telemedicine ECG Transmission (TET) in combination with Telematic Heart Disease Support (THDS) including General Considerations concerning structure of Telemedicicine frameworks and adding of other relevant parameters, as lung function testing provided by PC based spirometers

The impact of telemedicine on health care management is growing since many years and will increase more and more in the future. Several years ago, MESA Medizintechnik GmbH introduced to the market the CARDIAX® 12-lead channel digital Tele Cardio Module (TCM), an ECG telemedicine system based on the technology of the CARDIAX PC-ECG. The latest generation is the new CARDIAX PC-ECG available as USB and as USB-/WiFi-Version with integrated telemedicine technology (Picture 1).

Picture 1

Some words about the company behind it all:

MESA GmbH was founded in 1987 and started with marketing and distribution of digital ECG Holter and Standalone ECG systems. In November 1990 we presented at the international MEDICA exhibition at Düsseldorf, Germany, our CARDIAX PC-ECG to the national and international market. The first feedback has been outstanding, but it was the time of MSDOS driven PC`s and this fact tightened down the benefits of such a kind of systems. During the next years up to MEDICA 1997 we succeeded in turning to WINDOWS™ Software with all additional features and benefits. In 1993 we received the FDA approval for CARDIAX and since 1995 the system is CE approved. Beside the experience and dynamic product development of being 15 years in the market in 2005 we integrated measurement of oxygen saturation by use of an addon pulse oximeter with different sensor types. This technology is now a standard parameter and represents the latest version of measuring oxygen saturation by an external Bluetooth™ handheld pulse oximeter. The oxygen saturation values and the pulse wave are integrated into the CARDIAX Software for operation up to WINDOWS™ 10 and 11. As we added in 2010 the PRO SPIRO PC based spirometer to the system our target was to develop a Medical Software DDC digital Diagnostic Center® (Picture 2) for management of patient data incl. the vital parameters ECG, Lung function, ECG-Holter, ABPM and others, all combined in a common data base and with fast access to the patient reports.

digital Diagnostic Center

Picture 2

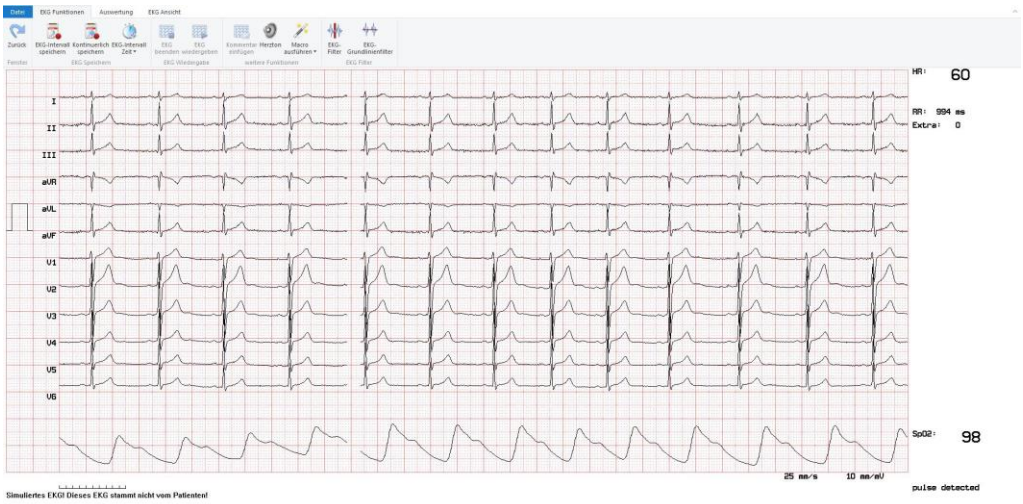
MESA is administrating a Quality Management System in accordance with EN ISO 13485:2016. Additionally, we received in 2021 the certification in accordance to the directives of MDR (EU) 2017/745.

Meanwhile about 11.000 systems of the CARDIAX PC ECG system are operational worldwide. The clients are GPs, cardiologists, hospitals, university clinics, CROs, Scientific Institutions, Pharmaceutical companies and departments for industrial medicine of many end users and companies (see Reference list attached on page 9).

Without any doubts one of the best references with utmost high reputation is the CARDIAX PC-ECG operation is the International Space Station ISS (Picture 3). The NASA is beside other locations also additionally operating CARDIAX at the NASA-Johnson-Space-Center, Life Sciences Research Labs, Houston, Texas, USA.

Picture 3

Let us explain now the basic system of a fully computerised ECG with all the features of a conservative standalone ECG and the additional benefits of the today PC based technology. CARDIAX is a computerised add-on ECG system for to be connected to the USB port of PC, Notebook or Tablet. The signal processor unit and the advanced software turn the computer into a high capacity 12-channel ECG with manual or automatic measurement (Picture 4), ECG interpretation, HRV analysis, Median ECG, stress test management, 3D Vector ECG, integrated measurement of oxygen saturation (SpO2) and other relevant features.



Picture 4

The Software provides the ECG interpretation for adults and children up from 2 years. By connecting an ergometer or treadmill the CARDIAX PC-ECG is going to operate as a complete stress test workstation with all features requested by an “UpToDate” stress test system (Picture 5). View of 12-channel ST-Online incl. superimposed ST signal averaging, ECG median processing and a continuous rhythm strip during stress test are available. Documentation of Heart Rate HR, Blood Pressure BP, Physical Working Capacity PWC and Workload (W) are going to be provided as alphanumeric values and by histograms. By using the XYZ leads, the Vector ECG can be calculated and shown in 2D with additional rotation function in 3D. All reports can be printed, but, more important is digital storage on HDD and by EDP server systems. The patient management will be done by an integrated database with storage of all patient data. The result is a fast and effective method of treatment and diagnosis. Of course, Software interfaces (GDT, DICOM and optional HL7) for data transfer to hospital administration software are integrated as well as possibility to export ECG data to e.g EXCEL where data can be worked on for scientific purposes as clinical studies of pharmaceutical companies, CROs and others.

Picture 5

Based on these fundamentals we developed the new CARDIAX PC-ECG USB-/WiFi generation with now integrated Tele Cardio Module (TCM). Telemedicine or Healthcare Telematics are involving the use of telecommunications Internet technology to provide abilities that extend the reach of the doctor or healthcare professionals. By using remote health care technology, the physicians and operators can investigate, analysis, diagnosis and are able to intervene clinically without direct “hands on contact” with the patient”. Defined broadly, telemedicine uses electronical signals to transfer medical data involved in investigation, monitoring and management of patients, using systems which allow fast access to expert advice and to patient information, no matter where the patients or relevant information are located. Despite the initial outlay costs of investing in the computer hardware, it is anticipated that there are considerable

savings to be made in long terms, by decentralising patient care and moving from the hospital to the patient in the field.

The global medical “scene” will be greatly completed during the next years, when advanced telecommunications, Internet, digital imaging, robotics, and other / automation/computer technologies will have been developed more sophistically and been adapted to the needs of medical care. This emerging infrastructure is or will be soon characterised by extensive use of electronically accessed medical information and remote expertise and a greater reliance on all the services for telemedicine applications. Although Telemedicine meanwhile is a huge medium to communicate knowledge in the global medical scene, there is no substitute for personal medical care. It will refocus the role of the physician from caregiver to coach and assign greater responsibility to patients and their families.

Ongoing reforms in the telecommunications and Internet sector are facilitating the rapid uptake of new valued services like telemedicine. Costs of the associated equipment are going to be lower and telecommunication costs are decreasing. The global standardization is an important step in allowing equipment from different vendors to work together and thus achieving a wider dissemination of telemedicine. Recently legislated international agreements to remove transmission and trade barriers in tele-communications and information technology equipment are further stimulation of the market for equipment and services. Naturally the aspect of data protection is going to be more and more relevant.

However, before telemedicine enters mainstream medicine, it must be formally adopted and reimbursed by payers, providers, and healthcare organisations. An integration into practice guidelines and clinical pathways has to be generated. Privacy issues must be resolved, telemedicine equipment will need to be simple and user friendly (for example suitable for the GPO and hospital) and it will need to come down further in price for to become a standard routine in providing medical services.

In general telemedicine could have a lucrative potential. We need to harness the skills – and greed – of our commercial partners to implement cost effective, practical applications with added medical value for our patients.

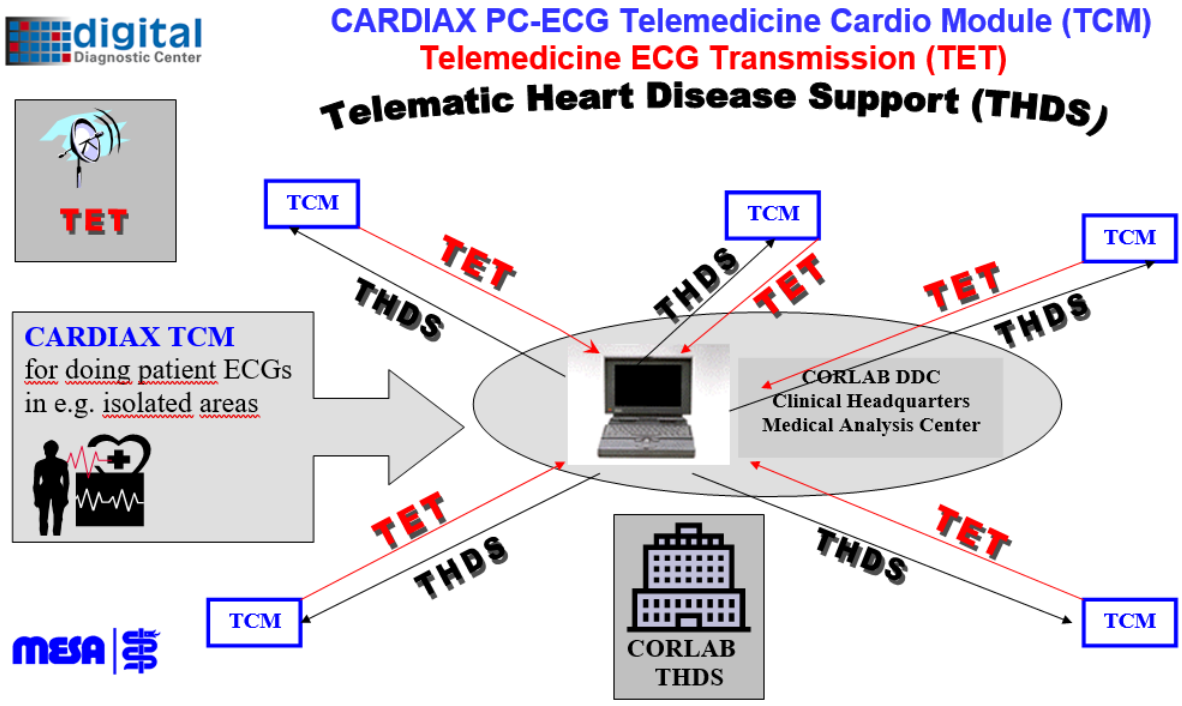
Now, what are the features of the new CARDIAX PC-ECG telemedicine system? Meanwhile there is a sophisticated hardware as USB or WiFi-/USB version available. The device is a transportable, small sized ECG box with LED control of correct operation and view on the PC, Notebook or Tablet screen whether the patient is correctly hooked up and the ECG leads are distinctive to guarantee ECG records for do ECG transmission to be evaluated by the recipient. This PC-ECG was designed for operation even in exposed arears for to assure that the ECG signal quality will be reproducible when sent to a central station (CORLAB). This ECG system could be used if a physician or nurse intending to do a first kind of screening diagnosis of the patient`s ECG before sending it to a central station for more differential diagnosis or recommendation concerning a prompt therapy and medication.

The CARDIAX PC-ECG with the integrated Telemedicine Cardio Module (TCM) transmits the complete ECG directly via Internet to a central analysing station. A central station, defined as the CORLAB DDC Analysis Center, could be established inside a hospital or a GP office by using the DDC digital Diagnostic Center Medical Software for management of all medical data. For to guarantee an optimal ECG signal it is recommended to use disposable ECG electrodes or a 12-lead ECG belt, provided by several manufacturers as a moulded, pliable silicon belt, which has been designed anatomically and which contains the electrodes and conductors within it (supplier

information on request). This belt is easily applied to the patient`s thorax and held in place simply by pressing the arms against the sides of the chest. The ECG cable with fixed disposable ECG electrodes or the ECG belt is connected to the CARDIAX PC-ECG. As one of the latest developments a potable electrode suction system is available. This portable system is light, easy to be operated and guarantees best signal quality.

Once the ECG is detected, it will be stored on the PC, Notebook or Tablet. The ECG (and or Lung function tests) can be worked on, edited or the Telemedicine ECG Transmission (TET) is going to be done by only pressing some bottom in the Software. This means, that an ECG can be applied and transmitted for example during first aid even from nonmedically trained persons. This technology opens new perspectives for fast diagnosis within emergency medicine and patient monitoring in any fields. The Telematic Heart Disease Support (THDS) will save incredible costs by decreasing the time for diagnoses and decisions based on them.

ECG data received from the CARDIAX PC-ECG by doing Telemedicine ECG Transmission (TET) can be received by the DDC digital Diagnostic Center® with integrated CARDIAX Software for doing all the analysis and editing of the ECG data. As mentioned before, advanced communication technology and faster Internet transmission technology will increase the operation of these kind of systems, especially in isolated areas (Picture 6).



Picture 6

The CARDIAX TCM telemedicine specification will include the range of urgent response activities that are necessary for e.g. 24 hours “on call Services”, could be the CORLAB DDC Analysis Center providing services for local GPs, hospitals, Airlines and other institutions. This equipment is expected to have a major impact on the uptake of services, and the market potential includes carers of all types as well as patients and the relatives of patients. Once the initial backbone structures are in place, other quality assured services could be added and made interoperable throughout the world for all patients.

Here are some more examples for usage of the CARDIAX PC-ECG with integrated Telemedicine Cardio Module (TCM) system in based on telemedicine disease management with Telematic Heart Disease Support (THDS):

For pacemaker control after implantation ECG telemedicine could be used for to make sure that the calibration of the pacemaker was done correctly. After surgery a reference ECG will be detected. The patient in the field will be monitored like described by a trained person and this person will be able to send the ECG to the DDC-CORLAB hospital, where the cardiologist compares this transmitted ECG with the reference ECG. The result is a fast analysis whether the cardiac problem is based on calibration of the pacemaker or other pathological reasons.

Professional patient transport services like ambulance cars in Sweden are already using CARDIAX TCM system for to guarantee the utmost possible health service for patients by being able to react in the sense in of first aid when cardiac problems at patients during transport to the hospital occur. Naturally airlines, ocean liners, trains and all other passenger services will have an optimal health service for their clients, too.

Pharmaceutical companies can do drug monitoring for clinical studies or do field studies to detect side effects and for testing of compliance in a very effective way. There are special software packages available for to guarantee an easy way of operation by trained persons as members of the sales crew.

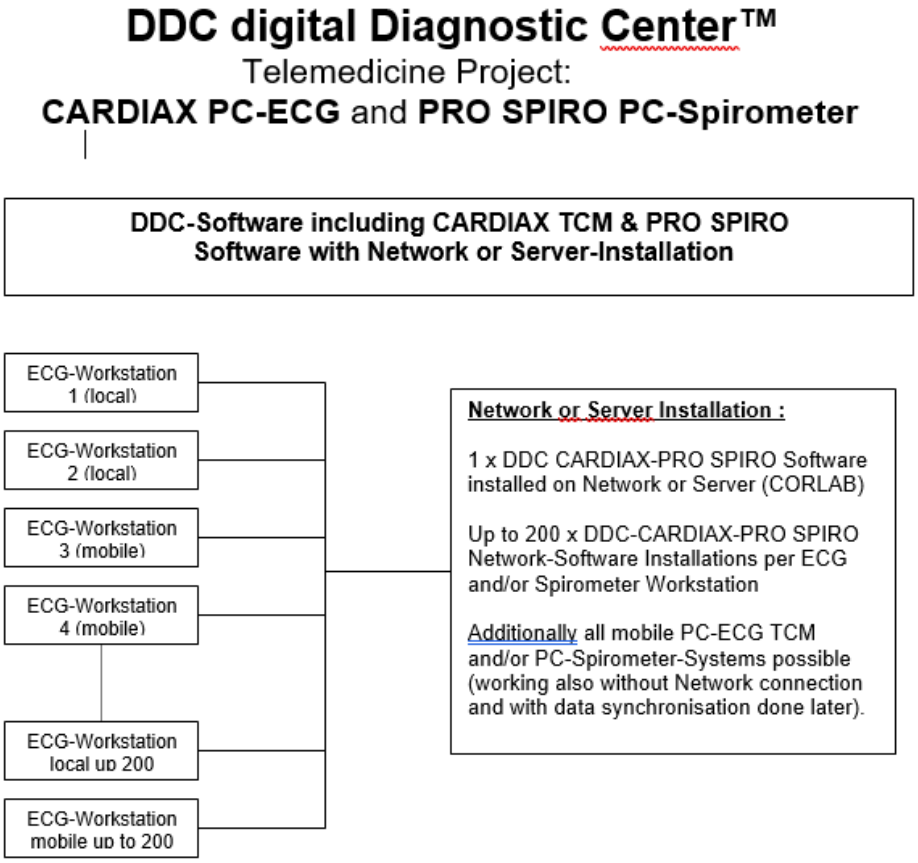
The CARDIAX TCM ECG telemedicine principle can be easily expanded by another important parameter, the lung function diagnosis. The PRO SPIRO N PC-Spirometer with the innovative PINK FLOW™ sensor flow measurement is like the CARDIAX PC-ECG available as USB version. The data transfer routine is the same as described by the TCM principle, but a wider range of diagnostic parameter is guaranteed (Picture7).

CARDIAX PC-ECG (USB- / WiFi-Version)

PRO SPIRO N (USB-Version)

Picture 7

There are several possibilities of setting up a network of DDC digital Diagnostic Center based telemedicine models. One structure is described in the chart below (Picture 8).



Picture 8

Generally, the DDC digital Diagnostic Center® telemedicine concept is indicated to be used for telemedicine monitoring of all cardiac and/or pulmonological risk patients

Conclusion:
For all medical professionals it is most important to organize and keep track of the patient`s medical reports, this means all relevant medical data. Maintaining this information is a big challenge especially with a great number of records and other documents that are going to be filed, all this done in the past as hardcopy versions in different ways.

The growing impact of communication technology, mobile phones and computers, along with the dynamic development of especially PC based medical devices, are becoming an integral part in the future of healthcare. The telemedicine capable medical devices are surely making their way towards becoming practical tools in offices of GPs, hospitals and other medical and healthcare services. With this innovative kind of equipment, filing of medical information of patients will become more efficient, comfortable in handling and more informative concerning the content. Naturally the DDC digital Diagnostic Center Software interfaces (GDT and/or DICOM) will enable having a fast access from alphanumeric data inside e.g. hospital EDP systems to graphical view of ECG curves and Spirometer flow-volume curves and to other treatment pictures with possibility to file these other medical data, too.

The different models described here are an overview about the utilization of a local or mobile telemedicine structure for the essential parameters ECG and lung function testing. The different configurations can use Web Services even in combination with mobile phone applications when the operators are sending patient information to an analysis center and receiving back fast results from experts from everywhere they are staying.

Many potential users of telemedicine have PCs, Notebooks or Tablets with local access to Internet or are owning a mobile telephone with access to Internet, too. With mobile phones, telemedicine user can take advantage of the technological capacity and geographically expand their service to more patients by bringing telemedicine applications to far distance areas where often the infrastructure for local medical healthcare services is missing.

This abstract is only showing some examples for the wide range of ECG and Spirometer telemedicine applications. Indeed, from a technological point of view, telemedicine is ready to assimilate the worlds different, often separated, healthcare systems into a single, global medical "village".

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Keywords:

TCM	=	Tele Cardio Module
TET	=	Telemedicine ECG Transmission
THDS	=	Telematic Heart Disease Support
CORLAB	=	Telemedicine ECG and/or Spirometer Data Analysis Center; CORLAB can be used for analysis of nearly all DDC medical data

Attachment, see next page – Reference list CARDIAX PC-ECG, Extract 11-2024

MESA MEDIZINTECHNIK GmbH

Quality Management
EN ISO 13485 : 2016

REFERENCE LIST - CARDIAX PC-EKG (Extract Rev.A11-2024)

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KABEG Clinics Klagenfurt, Dept of Heart Surgery, A-Klagenfurt, AUSTRIA
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NASA-Johnson Space Centre and ISS, Life Sciences Research Labs, Houston, Texas, USA
and many others