Telemedicine service
THOLOMEUS®

Presentation
Ver 10.0 of 14/01/2019
What is it?

- **THOLOMEUS®** stands for Telemedicine and Home teLeMonitoring for MEdical sUveillance of chronic diSeases
- It is a **web-based telemedicine service** provided to healthcare professionals and patients
- The service aims to facilitate the **screening and management of the most common chronic cardiovascular, pneumological or metabolic diseases**
- **THOLOMEUS®** is actually an **electronic health network**
THOLOMEUS® is a certified service

- THOLOMEUS® is a medical device certified according to 93/42/CEE directive by Bureau Veritas

- Biotechmed S.r.l is a company with a Quality Management System certified according to UNI EN ISO 9001:2015 13485:2016

- THOLOMEUS® is registered in the Repertoire of medical devices of the Italian Ministry of Health at no. 1106310
Tholomeus® is developed according to guidelines

- Medical-scientific support

- Guidelines of medical societies

- Guidelines of government agencies or institutions
Offered services

- The system offers **certified medical telereporting services** of professional diagnostic tests:
  - Blood pressure: at rest, at home and over the 24 hours
  - Cardiac function: electrocardiogram at rest, over the 24/48 hours or 7 days
  - Cardiovascular risk: arterial stiffness and atrial fibrillation
  - Lung function: simple spirometry and home monitoring
  - Diurnal and nocturnal SpO\textsubscript{2} monitoring (oximetry)
  - Cardiorespiratory polysomnography
  - Glucose and lipid profile from capillary blood taken from the fingertips
Blood pressure telemonitoring

24 hour ambulatory  Afib

At home over 7 days  Afib

“Hybrid” blood pressure measuring device for monitoring blood pressure over the 24 hours or in the doctor’s office. It embeds the patented AFIB technology for the screening of atrial fibrillation

Blood pressure measurements over 7 days according to Guidelines, with possibilities to take night sleep readings (during the first hours of sleep) and to screen atrial fibrillation (AFIB technology)
Cardiovascular telediagnosis

In-office telemonitoring

- Simultaneous both arm automatic measurement (screening mode)
- Central aortic pressure measurement (central mode)
- Calculation of the ankle-brachial index (ABI)
- Screening of atrial fibrillation (patented AFIB technology)
Cardiovascular telediagnosis

24 hour ambulatory telemonitoring

- Automated blood pressure measurement over the 24 hours
- Patented Vasotens technology for the evaluation of arterial stiffness:
  - Pulse Wave Velocity (PWV)
  - Augmentation Index (AI)
  - Reflect Wave Transit Time (RWTT)
  - Central aortic pressure
Telecardiology

12 channel ECG at rest

3 or 12 channel Holter ECG

Handheld 12 lead portable electrocardiograph, with memory, for a practical use in every occasion
Telespirometry

Simple spirometry

Easy-to-use device, measuring the most important spirometric parameters (VC, IVC, FVC, FEV1, FEV6, FEV1/FVC%, PEF, FEF 25-75%, FIVC, ELA - Estimated Lung Age)
Teleoximetry

At rest

Simple and clear continuous SpO2 and pulse rate measurement at rest

During sleep

Desaturation analysis during sleep with automatic storage of the events and automatic detection of body position, thanks to the triaxial movement sensor. Useful for the evaluation of sleep apneas
Cardiorespiratory polysomnography

The recorder allows to assess sleep apneas through 3 sensors which monitor 7 signals (physiological channels): thoracic effort, body position, nasal flow, snoring, oximetry (SpO2), heart rate and plethysmography.
Fields of application of the service

- Screening of healthy subjects (e.g. certification for sport activities, occupational medicine, pre-operative check, etc.)
- Screening of subjects at risk (e.g. positive family history for diseases or high risk for any disease)
- Specific diseases
  - Arterial hypertension
  - Heart diseases (e.g. ischemic heart disease, arrhythmias, syncope)
  - Vascular diseases (e.g. peripheral artery disease)
  - Metabolic diseases (e.g. diabetes mellitus, dyslipidemia)
  - Lung diseases (e.g. COPD, asthma)
  - Obstructive sleep apnea syndrome (OSAS)
How does THOLOMEUS® work?

- The medical devices linked to the system allow multiple vital sign monitoring.
- The data recorded by the devices are sent through an interface plugged to the PC (e-THOLOMEUS®), in case of professional diagnostic tests, or through a smartphone or tablet app (a-THOLOMEUS®), in case of home measurements, and thus through the Internet, to the web portal of the service.
- The data are analyzed with medical reporting.
- The test information can be integrated with the Patient’s clinical data, thanks to the availability of an electronic health record.
- The medical report can be viewed on the website or on the transmitting interface and/or sent via e-mail.
Transmission interface e-THOLOMEUS® or a-THOLOMEUS®

Webserver
https protocol (SSL certification) – Analysis and medical reporting

Physician
Other healthcare operator
What is THOLOMEUS®?

THOLOMEUS® is a web-based telemedicine software linked to various medical devices such as blood pressure monitors (for use over the 24 hours, at home or in the office), ECG (over the 24 hours or at rest), spirometers, pulseoximeters, devices for laboratory analysis. The data, collected at the patient’s or healthcare professional’s site, are forwarded to a webserver through a software running on a local PC, a smartphone or a tablet. The data are analyzed by the software, the report is signed by a doctor and the result of the test is made available to the patient. THOLOMEUS® may be used for the management of the most common chronic cardiovascular, pneumological and metabolic diseases.

THOLOMEUS® is a medical device certified according to 93/42/CEE directive by Bureau Veritas. CE 1370

Biotechmed S.r.l (Via Colombera, 29 - 21048 Solliate Arno, Varese) is a company with a Quality Management System certified according to UNI EN ISO 9001 and UNI EN ISO 13485

THOLOMEUS® is a medical device registered in the Repertorio of medical devices of the Italian Ministry of Health (BO / RDM) at no. 1106310.

Developed with the scientific support of the Italian Institute of Telemedicine

Developed in accordance with the guidelines of the following medical societies, institutions and government agencies:

Health Agenda

Are you a patient? Do you want to verify the appropriateness of your lifestyle with a click? Do you want to record and keep track of the time your blood pressure, your weight, your cholesterol, your blood sugar at home? Want to view the tests carried out by your doctor or pharmacy? You want to have an experienced healthcare team to provide you with useful tips to keep yourself healthy?

Free registration
The e-THOLOMEUS® solution allows the healthcare operator to manage the data of the medical devices using a dedicated software which can be downloaded from the website and which does not require installation.

This solution requires a Windows PC and an ADSL Internet connectivity.

Data are sent to the website by plugging the medical device to the PC, via a USB cable.

Once on the web, data can be viewed with any browser and any operating system.
Traceability of the report

The medical reports are marked with a proprietary seal (Digital Certification, TAS), certifying the source and the author of the report.
24 hour blood pressure monitoring
Simplified one-page report according to Guidelines

- Mark-up of artifacts
- Calculation of 24 hour, day and night mean values of blood pressure and heart rate
- Assessment of blood pressure and heart rate variability
- Evaluation of the blood pressure load
- Calculation of day-night blood pressure and heart rate difference (dipping status)
- Graph of single readings and hourly averages
- Simple and accurate diagnosis according to ESH and SIIA Guidelines
- Medical report
- Digital certification of the medical report
Electrocardiogram at rest
Simplified one-page report according to Guidelines

- Calculation of main intervals and measures
- 12 lead view
- Single lead rhythm tracing
- Simple and accurate diagnosis according to ACC and AHA Guidelines
- Medical report
- Digital certification of the medical report
24/48 hour Holter Electrocardiogram
Simplified multipage report

- Identification of main arrhythmic events (ventricular or supraventricular ectopic beats), bradycardia / tachycardia, pauses, ST events
- Hourly tables and graphic trends of the events
- Strips of most relevant events
- Simple and accurate diagnosis according to ACC and AHA Guidelines
- Medical report
- Digital certification of the medical report
24/48 hour Holter Electrocardiogram
Clinic spirometry
Simplified one-page report according to Guidelines

- Single report of the three best tests
- Calculation of the most common parameters of lung function: FVC, FEV₁, FEV₁/FVC, PEF, FEV₆, FEV₂₅-₇₅, ELA, FIVC
- Flow / volume and flow / time curves
- Simple and accurate diagnosis based on American Thoracic Society and European Respiratory Society guidelines
- Medical report
- Digital certification of the medical report
Sleep oximetry
Simplified one-page report according to Guidelines

- Summary tables for heart rate, SPO₂ and desaturation (ODI calculation)
- Trends of heart rate and SPO₂, with periods of desaturation
- Position and movement graphs for an objective assessment of the quality of sleep
- Simple and accurate diagnosis based on American Thoracic Society and European Respiratory Society guidelines
- Medical report
- Digital certification of the medical report
Polysomnography
Simplified one-page report

- Summary tables with details about respiratory events and intuitive graphical representation of the RDI
- Display of information regarding heart rate and SPO2
- Simple and accurate diagnosis based on Associazione Italiana Medicina del Sonno, Associazione Italiana Pneumologi Ospedalieri and American Academy of Sleep Medicine Guidelines
- Medical report
- Digital certification of the medical report
The a-THOLOMEUS® solution is recommended for home monitoring of vital and non-vital signs by the Patient through an app which links the smartphone or tablet to medical devices equipped with a **bluetooth technology**

- The Patient can record his/her own data on the web through the app and can create his/her own **Health Agenda**, and share his/her data with the Doctor
- Personal data can be uploaded on the service website and accessed by the Doctor and the Patient
- The Patient can ask for a medical consultation of the team of Doctors of **THOLOMEUS®**
- The app can also display the report of professional diagnostic tests performed in the Doctor’s office or in the Pharmacy and provides information on most common chronic diseases
### a-THOLOMEUS®

**Pressione Arteriosa**

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#### Grafici

- **PAS/PAD (mmHg)**
- **FC (bpm)**
**a-THOLOMEUS®**

**Blood pressure**

Electronic upper arm blood pressure measuring device with identification or arrhythmias (in particular atrial fibrillation)

**Body weight**

Multifunctional scale for measurement of body weight, body fat, body water, muscle and bone substance
a-THOLOMEUS®

Blood glucose

It allows to carry out a blood glucose test in few seconds with minimum amounts of capillary blood

Cholesterol and triglycerides

It allows to measure total cholesterol, HDL cholesterol, triglycerides (and to compute LDL cholesterol) in few seconds with minimum amounts of capillary blood
a-THOLOMEUS®

Oximetry

Device for the assessment of peripheral blood oxygen saturation (SpO₂) and pulse rate

Body temperature

For continuous monitoring of body temperature, particularly in the child
a-THOLOMEUS®

Spirometry

Home peak flow meter. It measures FEV₁ and PEF

Heart rate

Single lead (single channel) electrocardiograph with display, to check the accuracy of the measurement. Measurement at the palm of the hand, leg or chest
The portable monitor measures blood pressure, SpO₂, pulse rate, body temperature, single channel electrocardiogram and blood glucose. It is provided with a simple and practical briefcase.
The strengths of the service

- **THOLOMEUS®** allows to perform the diagnostic test in a simple and quick way and to constantly monitor the patient’s health status, with minimum effort and cost, and with the remote support of a team of qualified Physicians and Specialists
- No complex installation procedures required
- Portability and universal accessibility thanks to the use of the web
- Software always updated
- The service is developed by healthcare professionals according to national and international guidelines
- Data are transmitted real time, favoring a quick on line technical assistance and medical reporting
- Simplified test report for an easy and targeted evaluation by the Physician
- Service management complies with the privacy law, the law of Pharmacy of services, and the law on digital medical reporting
Compliance with the GDPR 2016/679 (privacy and security)

- Complete privacy policy available on the web site
- Informed consent obtained electronically, on the web site
- Login to the web site with username and password expiring every three months
- Automatic logout after 20 minutes of non-use
- Data encryption (HTTPS and SSL protocol, 256 bit encrypting)
- Management of data processing with the healthcare professionals through a letter of assignment
Compliance with the legislative decree 08/08/2013 (on line digital medical reporting)

Delivery through the web:
- Suitable authentication system by username and password
- Use of safe communication protocols based on data encryption (HTTPS and SSL protocol)
- Time limit for online availability of digital report (<45 days)
- Report with physician’s digital signature and proprietary digital certification (TAS) to confirm the identity of the signer

Delivery through e-mail:
- Digital report sent as an attachment to the e-mail message, and not as a text included in the body of the message

Additional services:
- The patient can download the report with his/her own credentials
- Electronic forwarding service of the medical report to the referring physician
Who is it for?

- Patients
- General Practitioners
- Specialists
- Pharmacists
- Hospitals
- Local Health Centers
- Home care health services
THOLOMEUS® is a Health network creating a modern network between patients and healthcare professionals in order to better manage chronic diseases and the individual health status.

Nurse:
- Education
- Counseling
- Medication management

Specialist:
- Complex patients
- Counseling with GP

Pharmacist:
- Education (life style)
- Counseling
- Medication management (safety and adherence)

GP:
- Diagnostic evaluation
- Follow-up (therapy and organ damage)
Benefits for the patients

- Constant monitoring of health status by the Physician through information sharing
- Short waiting lists
- Medical reports quickly available
- Test performed close to home (Doctor’s office or Pharmacy)
- Hospital-like quality of the test and medical report
- Cost saving
- Privacy and security management of the information
- Test and clinical information are always accessible thanks to the Internet
- The patient can monitor his/her own health parameters at home keeping his/her Physician constantly informed about his/her health status
Personal health agenda

- The **Patient** can enter and record his/her own home clinical data on the website through an app for smartphone or tablet (a-THOLOMEUS®). This information can help define the appropriateness of the life style and the health status.

- The Patients can consult his/her own Doctor or the team of Doctors of THOLOMEUS® through the app. This will help define a personalize approach to a healthy life style and control of risk factors for cardiac, lung and metabolic chronic diseases.
Advantages for the Physician

- A simple, quick and cost-saving diagnostic tool for his/her patients
- Quick medical reporting
- It does not need specific medical knowledge, thanks to the support of the Specialists of THOLOMEUS®
- The physician can get access to the confidential information of his/her patients and check the evolution of the patients’ health status over time
- Thanks to THOLOMEUS® the healthcare facility can be turned into a reference point for patients’ screening and follow-up
Advantages for the Pharmacists

- The **Pharmacist** provides a highly specialized service to his/her customers (patients) and their doctors through the Specialists of **THOLOMEUS®**

- The Pharmacy becomes a reference for the screening and follow-up of the patient in tight connection and synergy with the General Practitioner
Advantages of telemedicine in community pharmacies

- Short waiting lists
- Professional healthcare setting
- Use of appropriate clinically validated, accurate and reliable medical devices
- Medical reporting, as in the Hospital
- Medical reports quickly available
- Cost-saving
- Active involvement of the referring Physician, with quick response and update on the status of the patient
- Centralized analysis, detailed reporting, and active support to Physician’s decision-making processes
- Privacy and security management in accordance with the current legislation
- Active involvement of the patient in the management of his/her own condition and increase in the adherence to Physician’s therapeutic prescriptions
- Reduction in the number of office visits and costs of patient management
Compliance with the Legislative Decree 16/12/2010 (Pharmacy of services)

- Availability of all second instance tests foreseen in the legislative decree
- All tests are reported by a Physician
- Compliance with the privacy law
- Training and constant updating of the Pharmacists
Minimum requirements for the proper functioning of the THOLOMEUS® software

- PC with a Pentium IV processor (or similar) or superior
- At least 256 Mb RAM
- At least 40 Mb of available space on the hard disk
- Two free USB 2.0 ports
- Color monitor with a 1024x768 pixels resolution
- VGA graphic card, at least 256 colors
- Microsoft Windows® XP professional operating system or newer versions
- Access to the PC with administrator rights
- High speed Internet connection (ADSL or fiber optic)
- Microsoft Internet Explorer® 8 or Google Chrome® 17 or Apple Safari® 5 or Mozilla Firefox® 10 or newer versions
- E-mail manager software
- Adobe Acrobat® 9.0 or newer version
- b/w ink jet or laser printer
THOLOMEUS® is a service developed and marketed by Biotechmed

www.biotechmed.it - www.tholomeus.net