

# PROJECT NO: FP6- CRAFT- 2003 - 508252

# MUST

*"Multidimensional Ultrasonic Scanning Technology to reduce cancer death rate through fast and accurate diagnosis - particularly of breast cancer"* 

Co-operative Research (Craft)

Horizontal Research Activities Involving SMEs



Developed MUST Prototype

**Created Baby phantom 3D image** 

Overall Activity Report - Reporting Period 1 + 2 including the final plan for using and disseminating knowledge D27 Deliverable reference number and title: D30 (+D27) Date of issue of this report: 2nd April 2007

Start Date: 1st September 2005 Lead Contractor: MEDCOM GmbH, Germany Duration: 24 Months

Version 01

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# **PROJECT INFORMATION**

# **PROJECT NO:** FP6-CRAFT- 2003 – 508252

**CONTRACT NO:** COOP-CT-2003-508252

**TITLE OF PROJECT:** MUST – "Multidimensional Ultrasonic Scanning Technology to reduce cancer death rate through fast and accurate diagnosis particularly of breast cancer"

COORDINATOR:

MEDCOM

SME EXPLOITATION MANAGER: Mr. Novikov

#### SME CONTRACTORS:

- 1 MEDCOM GmbH, D
- 2 SK Trade GmbH, D
- 3 PI-Medical Ltd, G
- 4 S&S Plastics Ltd, UK
- 5 Telemed, LT

# **RTD PERFORMER CONTRACTORS:**

- 6 Fraunhofer TEG and IBMT, D
- 7 Pera Innovation Ltd, UK

# PUBLISHABLE EXECUTIVE SUMMARY

This report covers the work carried out in the overall twenty four months of the project.

The main body of this report is a précised overview. However more detailed appendices are attached to cover the technical work programme.

The MUST project proposes to develop a three dimensional scanning system which:

- is a patient friendly scanning system available at the point of care
- does not require a significant fixed installation,
- that is fully affordable by the most modest of facilities with a target price of €10k
- is highly portable
- has great ease of use.
- gives immediate results for further decision making

The technical work over the second twelve month period (01/09/2005 - 31/08/2006) is spread over the tasks in Work Packages 2 to 7.

These tasks cover the

- initial preliminary characterisation phase (WP 1)
- development of the orientation tracking unit of WP 2
- intermediate state of the position tracking unit development (WP 3)
- intermediate state of the 3D ultrasound unit
- intermediate state of the system integration (WP 5)
- start of the dissemination and use planning (WP 6) and
- continuous consortium management activities (WP 7).

A 3D fan scan navigation unit was successfully developed, consisting of

- miniaturised orientation tracking hardware
- specially designed housing for the same
- optimised filtering hardware
- working 3D image data processing unit
- defined steps for post-project product realisation
- estimated aggressively low target price of 400€.

3D position tracking could not be précised to 1° precision. But Fraunhofer MEDCOM cooperation is working continuously post-project on improved inertal sensor and sensor fusion based solutions.

All meetings have been well attended and the partners have been actively involved in the research work.

The project web site can be see under

#### http://www.medcom-online.de/projects/must/must.htm

serves both as an on-line administrative tool for the partners (pass word protected) and as web presence.

# SECTION 1 - PROJECTIVE OBJECTIVES & MAJOR ACHIEVEMENTS DURING THE REPORTING PERIOD

# 1.1 Overview of General Project Objective

# **Overall Project Objective:**

The purpose of the MUST project is to create a three dimensional scanning system which:

- Is a patient friendly scanning system available at the point of care
- Does not require a significant fixed installation,
- That is fully affordable by the most modest of facilities with a target price of €10k
- Is highly portable
- Has great ease of use.
- Gives immediate results for further decision making

The SME proposers have identified three main barriers that must be overcome to achieve this:

- 1. To improve the accuracy of data derived from the gyroscope. This will be achieved by the application of estimation theory and the Kalman principle with the software.
- 2. To improve the accuracy of the data derived from the accelerometer. This is likely to be more complex as there is error build up through the double integration process required to generate distance data from acceleration, errors are in effect compounded.
- 3. To gain new knowledge in the signal processing techniques (pulse compression, correlation, stochastic estimation etc.) to enable processing of raw RF-data for improved accuracy and tissue characterization.

There are three particular technological objectives:

- To overcome the drift in gyroscopic orientation. This is currently of the order of 4° in 5 minutes. The technological objective is to reduce this drift to 1°.
- The overcome the drift error in accelerometer positioning. This is currently of the order of 5mm in 5 minutes. The technological objective is to reduce this to better than 1mm. This includes the particular challenge of overcoming the compounded errors associated with the double integration of the accelerometric data.
- To secure a 3D image directly from the 'raw' ultrasound data. This is currently achieved using a data slice reassembly technique which is relatively slow and introduces additional potential errors by transitioning through a 2D 'layer'. The objective is to achieve a full video reconstruction of 25 data packages per second with less than one second delay.

# 1.2 Summary of Project Objectives & Major Achievements for Overall Period

The specific objectives for the twelve-month period of 01/09/2005 to 31/08/2006 of the project are summarised in the table below.

WP	Objective	Achievements During Reporting Period	
2	Orientation Tracking Unit	Hardware realised. Orientation tracking model realised Sufficient accuracy of 1°achieved.	
3	Position Tracking Unit	Hardware realised. Position tracking model realised. Insufficient accuracy of approx. 10° achieved. Decission to realise orientation tracking based MUST system.	
4	Ultrasound Unit	Hardware realised. Scanconverter realised. Volumes visualised	
5	Integration and validation.	INS hardware miniaturised. System integrated. System tested and validated. CE documentation prepared.	
6	Innovation related activities	Patentingbeingprepared.Technologytransferred.Diseminatioactivitiesrealised, furtheractivitiesplanned.Socio-economicaspectsreflected.Exploitation promoted.	
7	Consortium management	Realised.	

# 1.3 Summary of Project Objectives & Major Achievements for Overall Period

The specific objectives for the twenty four -month period of 01/09/2004 to 30/11/2006 of the project are summarised in the table below.

Deliverable	Task	Partners Involved	Objective	Achievements During Reporting Period
1	1.1- 1.3	all	Document detailing the overall system demands	Submitted: general system demands + hardware software interfaces defined
2	7.2	all	Periodic Report (Month3)	submitted
3	7.2	all	Periodic Progress Report (Month6)	submitted
4	7.2	all	Periodic Report (Month9)	submitted
5	7.2	all	Midterm assessment report (Month12)	submitted
6	7.2	all	Cost statements (Month 12)	submitted
7	2.3	MEDCOM, Sk Trade, PI- Medical, S&S Plastics, FhG-TEG, FhG-IBMT	Description of the developed state model of the orientation tracking system	Submitted: Version 1 of the documentation of the implementation progress with flowcharts and interface diagrams for Kalman filter, drift compensation & quaternions, to be completed, once the Kalman filter is implemented with the target precision.
8	2.2	MEDCOM, Sk Trade, PI- Medical, S&S Plastics, FhG-TEG, FhG-IBMT	Description of the reached gyroscopic orientation accuracy	Submitted: Version 1 of the test report about gyroscope accuracy using zero velocity update alone as the Kalman filter is not yet integrated in the system, to be completed, once the Kalman filter is implemented with the target precision.
9	7.2	all	Periodic Report (Month15)	submitted

Deliverable	Task	Partners Involved	Objective	Achievements During Reporting Period
10	3.2	MEDCOM, Sk Trade, PI- Medical, S&S Plastics, FhG-TEG, FhG-IBMT	Description of the developed state model of the position tracking system	submitted
11	3.1	MEDCOM, Sk Trade, PI- Medical, S&S Plastics, FhG-TEG, FhG-IBMT	Description of the reached accelerometers position accuracy	submitted
12	7.2	all	Periodic Progress Report (Month18)	submitted
13	7.2	all	Periodic Report (Month21)	submitted
14	7.2	all	Cost statements (Month 24)	submitted
15	3.4	MEDCOM, Sk Trade, PI- Medical, S&S Plastics, FhG-TEG, FhG-IBMT	Procedure- description and software for the adaptation of different ultrasonic diagnostic devices to the 3D-tracking unit.	submitted
16	4.1	MEDCOM, Sk Trade, PI- Medical, S&S Plastics, FhG-TEG, FhG-IBMT	Function model of the 3D ultrasound system.	submitted
17	4.4	MEDCOM, Sk Trade, PI- Medical, S&S Plastics, FhG-TEG, FhG-IBMT	Interface specification to provide supplier of ultrasonic systems the opportunity to adapt the 3D- tracking system to their machines.	submitted

Deliverable	Task	Partners Involved	Objective	Achievements During Reporting Period
18	4.5	MEDCOM, Sk Trade, PI- Medical, S&S Plastics, FhG-TEG, FhG-IBMT	A documentation of the functional model will be prepared including in technical drawings of the overall system.	submitted
19	4.5	all	A documentation of the components and overall system testing results.	submitted
20	5.3	all	To put the necessary papers together and include information from the functional validation of the system from Task 5.2 in writing.	submitted
21	6	all	A report plan on patent applications and exploitation agreements between the partners.	submitted
22	6.1	all	A draft of the plan for using and disseminating knowledge	submitted
23	6.3	all	Production of support material for transfer of the knowledge to the partners through case studies and a generic design guide	submitted
24	6.5	All	Report on the presentations and publications for the dissemination related activities of task 6.3.	submitted

Deliverable	Task	Partners Involved	Objective	Achievements During Reporting Period
25	7.2	All	A report on the ethical and regulatory aspects of the exploitation of the results.	submitted
26	7.2	All	A report on the dissemination of exploitation activities including the market introduction and identification of other possible applications.	submitted
27	7.2	All	The final plan for using and disseminating knowledge	submitted
28	7.2	All	Documentation of the consortium agreement management.	submitted
29	7.2	all	Report on gender, societal and ethical issues of exploitation.	submitted
30	7.2	all	Final report	submitted

# 1.4 Problems/ Issues During Overall Period

# Year 1

Only minor deviations from the plan are to be reported:

According to Sections 2.3 "Deviation from the plan and corrective actions" and according to Section 3.3.3 "Clarification of Changes to Work Programme" of the Periodic Activity Report D5 there was a development delay in Work Package 2, Task 2.2 (the Kalman filter development): Task 2.2 will be prolonged by 3 months to month 16 of the project. This delayed task 2.3 implementation fulfilment to approx. month 16 of the project.

# Year 2

# Issue:

Within the project no position unit of 1mm accuracy could be realised. Research of the team will continue post-project.

As fan-scan (mere orientation tracking) for 3D structure detection could be a stand alone MUST product, it was decided to realise this solution within the project.

# Delay in work programme:

Due to the Kalman filter development delay task 2.2 was be prolonged by 3 months to month 15 of the project.

This led to a delay of task 2.3 implementation fulfilment to approx. month 16 of the project.

# SECTION 2 - WORK PACKAGE PROGRESS REVIEW FOR Overall PERIOD

# 2.1 Work Package Objectives

The specific work package objectives for the twelve-month period of 01/09/2005 to 31/08/2006 of the project are summarised in the table below.

Work Package No.	Work Package Title	Lead Contractor Short Name	Start Month	End Month
1	Preliminary Characterisation	MEDCOM	1	2
2	Orientation Tracking Unit	PI Medical	2	12
3	Position Tracking Unit	PI Medical	2	16
4	3D ultrasound unit	F-Ibmt	1	24
5	Integration and Validation	Pera	1	24
6	Innovation Related Activities	MEDCOM	12	24
7	Consortium Management	MEDCOM	1	24

# 2.2. Overview of Work Package Technical Progress

Work Package 1 – Preliminary Characterisation

Task 1.1:Overall system demandsTask Leader:S&S PlasticsPartners Involved:all

Objectives: To specify the overall system demands

#### Progress:

The relevant report for this task is D1, which also incorporates the Quality Function Deployment chart. The task is completed.

#### The customer demands

The customer demands were compiled by asking a potential customer, Dr Ulrich Kramer, a radiologist of the university hospital Tuebingen and by using the knowledge of the consortium members. They are listed below and are cut into umbrella terms. 1 benefits

- low cost 3D-ultrasound solution
- wider distribution of 3D ultrasound technology
- improvement of medical care in Europe

2 area of application

- scanning system available at the point of care
- affordable for private practices, hospitals, east + west

3 measurement

- creates a 3D integrated model/picture
- high reliability
- measuring x, y, z shift of positions A, B, C (yaw, roll, pitch) change of orientation, 6 degrees of freedom

4 handling / ergonomics

- fool proof handling
- easy to install
- movable
- choice between 2D and 3D imaging

#### 5 economics

- hospital cost reduction
- value for money

6 legal bearings

• medical device

#### Quality characteristics and their specifications

The quality characteristics are derived from the customer demands and were intensively discussed and worked out during the kick-off meeting by the consortium members.

#### 1 area of application

- applicable for different users
  - hospitals (not necessary on ICU or emergency room, according to Dr. Kramer) and private practices
- requiring a domestic level power supply

o battery based laptops, USB for the sensors

• improvement of examination quality during biopsies o yes

2 measurement

- high accuracy
  - o product target resolution: 0,5mm-1mm / 0,5°-1°
- high accuracy of navigation data
  - o 50 Hz
- giving immediate results
  - o 3D picture has to be compiled after 30 sec, depends on PC-system
- only selected scans have to be compiled to a 3D image
  - o yes
- change between 2D and 3D mode at choice
  - o examiner can choose 3D mode after/during examination
- secure a 3D image directly from the 'raw' ultrasound
  - o full video reconstruction of 25 data packages per second with less than one second delay (depends on PC, only possible with digital interface)
- no interference between INS and probe during data transfer
  - o yes
- temperature steady
  - o yes

3 handling / ergonomics

- upgrade of already purchased 2D instruments o yes, if the system has a digital scanner
- portable
  - o small inertial navigation system
- low weight
  - o no restriction of probe handling
- low volume
  - o no restriction of probe handling
- does not require a significant fixed installation
- o yes
- patient friendly
  - o EMC, protection, good design
- handy probe
  - o no restriction of probe handling
- removable sensor unit
  - o steady fitting
- simple cleaning

- o desinfactable, maybe sterile packaging
- low education effort
- o 1. low cost application: usage without reading a manual o 2.high cost application: 2-3 days of training acceptable
  ordless data transmission between INS and PC o no interference with other hospital devices

4 economics

- low sales price
  - o below 5000€
- different markets
  - o east + west Europe, low-end applications (baby faces) and high-end applications (cancer diagnostics, cardiology)

5 legal bearings

 developing according to standards o MDD

Task 1.2:Required system interfacesTask Leader:SK TradePartners Involved: all

**Objectives:** To specify the required system interfaces based on the Task 1.1 results. **Progress:** 

#### **RF-Data-Interface:**

The raw RF-data that are transmitted from the Diphas are received through a PCI-IO-board. After this they are processed and stored for the 3d-scan conversion. Processed in this case means, that the data are prepared for the 3d-scan-converting without any additional functional signal processing.



Figure: IBMT's Diphas (Digital Phased Array System)

#### **Programming Interface:**

DiPhAS is a research platform (ultrasonic research interface) that can be programmed freely from a PC via an EPP-Interface. Programming means that the settings for beam-forming and the signal shape (wave form) can be programmed by the user.

Task 1.3:	Inertial system demands
Task Leader:	SK-Trade
Partners Involved:	F-teg

# **Objectives:** To specify the inertial system demands **Progress:**

# Inertial Sensor:

The inertial sensor solution consists of a system that incorporates three miniature gyroscopes and three miniature accelerometers which detect and measure angular turn rate and linear acceleration. Based on the measuring data the system can detect the three dimensional orientation and linear movement respectively. The combination of these two inputs define how far a device moves and in what direction. Hence the exact position of the device and its orientation is defined at any time.

#### Acceleration Sensor VTI SCA 61T

The Acceleration Sensor SCA 61T (Figure 3) by VTI Technologies is a capacitive sensor, which is micromechanically made of single crystal silicon.



The analysis principle is based on the mass inertia of the test bulk. If acceleration is acting on the sensor element, the test bulk receives a force which causes a deflection of the bulk. Thereby the slit between two planar analyse electrodes is changing.

The changing of the slit width is capacitive analysed and thereby an electric signal, proportional to the acting acceleration, is produced.

The analysis is technically realised with a pair of differential capacitors. That improves the symmetric characteristics and the zero point stability. An ASIC with an EPROM-memory for calibration data is integrated for signal analysis. The SCA 61 T also has a digital engageable self test and a continuous error checking.

#### Gyroscope Murata ENC-03J

The Gyroscope ENC-03J (Figure 4) by Murata is mainly used for servo- and position tasks. The rotation rate analysis is based on the principle of Coriolis acceleration, which is acting on a vibrating and rotating system. The sensor element is micromechanically made of piezo electric ceramics. The ENC-03J sensor is characterised by its small size, fast reaction time and low consumption of electricity.



Figure 4: Murata ENC-03J

The detection of camera shakes is the field of application of the used sensor. It is originally not developed for using it in inertial object tracking. As the sensor comprised a sensitive element which is detecting the rotation rate around a sensitive axis, three of the sensors are inserted. They are orientated insomuch the sensitive axes according the orthogonal coordinate axes of the sensor platform.

# Task 1.4:3D ultrasound unit demandsTask Leader:MEDCOMPartners Involved:F-ibmt

**Objectives:** To specify the 3D ultrasound unit demands. **Progress:** 

#### 1. DiPhAS:

A digital phased array system that is provided by IBMT (Figure 2). The system is an implementation of IBMT's proprietary technology of an open research interface for ultrasonic applications. It is connected via PCI-IO to a PC. It acquires and processes ultrasonic RF-data and transfers them as raw data to the PC. The acquisition and processing modules include: Transmitter: beam-forming by delay, focusing apodisation, signal shaping (coded excitation) Receiver: filtering, amplifying, AD-converting, delay, dynamic focusing, apodisation Interface: programming and data-interface to the PC.

#### 2. 3D-RF-Scan-Converter:

The data coming from the RF-data-Interface and the navigation data handler are converted in a special form that can be handled by the visualization module.

#### 3. Visualization Module:

The data coming from the 3D-scan-converter are displayed graphically (3D-B-Image) on a monitor.

In the first part of the project, those parts of the demonstrator have to be specified technically and functionally that will be developed in the project:

- RF-Data-Interface
- Navigation Data Handler
- 3D-RF-Scan-Converter
- Visualization Module

The main feature of the demonstrator has to be considered in this specification:

- What will be the frame rate and accuracy for the display of volumetric data on a monitor and what tasks are necessary to ensure this. Beyond the pure programming and debugging work appropriate in vitro-tests have to be performed and the evaluation and calibration environment has to be set up (phantom, reference-systems, etc.).
- Which degree of interactivity will the visualization module include if any?

#### 4. Probe:

The probe will be a linear array transducer from Vermont which is working at a frequency of 3.5 MHz. This standard probe is submitted from IBMT. One probe will be delivered to TEG to use it for the mechanical implementation of the inertial sensor.

Abbreviations:

AD	Analogue Digital
DiPhAS	Digital Phased Array System
IBMT	Institute for Biomedical Technology (Institut für Biomedizinische Technik)
PC	Personal Computer
PCI-IO	Personal Computer Interface Input Output
RF	Range Frequency (high frequency)
TEG	Technology Development Group (Technologie Entwicklungsgruppe)
US	Ultrasound
3D	Three-dimensional
3D-B	Three-dimensional brightness (greyscale)

#### Work Package 2 – Orientation Tracking Unit

Task 2.1:State Model DesignTask Leader:PI-MedicalPartners Involved:F-teg

**Objectives:** Development of a state model of the system to realize a 3D orientation tracking unit.

#### Progress:



#### Schematic overview over the system

The demonstrator consists of a digital ultrasound device with a transducer connected to it, the inertial sensor system built on the transducer and a software system that uses the interfaces to the hardware components to process the data to a 3D reconstruction for visualization.

The software system has interfaces to the ultrasound device, the sensors and the visualization system.

# System Architecture

As amplified in report D3 the orientation tracking system has the following architecture:



Figure: The 3D algorithm procedure

The system receives three mean angular velocity measurements ( $\omega_A$ ,  $\omega_B$ ,  $\omega_C$ ) from the six pairwise and orthogonal arranged gyroscopes. After the integration step the rotation angles  $\alpha$ ,  $\beta$  and  $\gamma$  are available for subsequent processing.

First, a non-orthogonal compensation matrix is applied to the input values. This is necessary because even minimal deviation in the gyroscope alignment will result in significant errors if not corrected. Afterwards, the drift vector is updated to adjust to the dynamic bias and the angle information goes through the quaternion algorithm. From the - in such a way - optimized angle information of the three gyroscopes, the Kalman filter algorithm estimates the actual orientation of the system in three dimensional space.

Important parts of the system, particularly drift vector update, quaternions and the Kalman filter shall be analyzed in more detail in the following sections.

# Task 2.2:Developing the Kalman algorithmTask Leader:F-tegPartners Involved:PI-Medical

Objectives: To develop the Kalman algorithm based on the system model and the noise model

Progress:

As quantified by our measurements in D8 bias stability is a serious issue in low-cost INSsystems. After initial calibration the gyroscope sensor bias will inevitably drift with time due to variances in temperature, vibration, electro-magnetic interferences etc. The bias may or may not be constant.

For computational reasons the measurement model can only be an approximation of the actual system dynamics and not possible take all this distinct factors into account. In the Kalman Filter bias stability is modelled as a Gauss-Markov process, however, as the bias wanders with time, the model parameters have to be updated at regular intervals.

There are different approaches to compensate bias with software, for the gyroscopes currently in use the so-called "Zero Velocity Update" was chosen which yet again is based on Idle State Detection.

Idle State Detection has two major advantages:

- Position and orientation will remain precise for a much longer time, because the velocities are manually reset to zero.
- Moreover it allows the Kalman algorithm to validate and calibrate its error models.

The algorithm assumes that angular rates beyond a certain threshold are not likely due to actual rotation of the probe but in fact caused by the changing bias. Consequently, whenever the output from the gyroscopes is small for a given period of time (~300ms), the error model (or more exactly the drift vectors) is adapted accordingly.

Task 2.3:	Software implementation
Task Leader:	PI-Medical
Partners Involved:	F-teg

**Objectives:** To implement the theoretic algorithm with the Software LabView in a program for data acquisition, data processing and data visualization.

#### Progress:

#### Algorithm Implementation



# Interface Diagram of the RestPositionGyro-Class plus input and output

#### Input

To determine whether the system is at rest, the software continuously observes the turn rates of the three sensor pairs (6 channels). The measurements are stored in a buffer by the **BufMeas()**-Function until a pre-defined **observation time** is reached. Afterwards the collected values are examined, depending on the **mode** of Idle State Detection. Mode **One** analyzes whether all measurements lie beneath a given **threshold**, thus detects the over-all system Idle State. Mode **Two** on the other hand evaluates the axis separately.

#### Functions

- *Init():* Initializes the local variables
- BufMeas(): Takes the current sensor data and stores it in the buffer
- StartDriftvector(): Initial drift vectors
- **DetRP():** Compares the measurements with the threshold and returns true if the system is at rest
- **DriftVector():** Calculates the new drift vectors (= Zero Velocity Update)
- ChannelZero(): Sets channels to zero after Idle State Detection
- **ChangeChannels():** If the system is not in Idle State the drift vector has to be compensated
- StoreRP(): Stores the detected rest positions

#### Outputs

After processing the data the algorithm corrects the sensor data (either by nulling the channels after Idle State Detection or by compensating the drift). Moreover the new drift vectors are available for the Kalman Filter.



#### Flowchart drift vector update

#### Flowchart

The flowchart sums up the basic steps of the algorithm. The corrected gyroscope channels can then be integrated to receive the orientation of the sensor system.

For details on the algorithms see report D7.

# Work Package 3 – Position Tracking Unit

Task 3.1:Development of a sensor alignmentTask Leader:SK-TradePartners Involved:F-teg

**Objectives:** To develop a sensor alignment.

# Progress:

# The supporting sensors:

Extra sensors, which supply redundant information, are used because the general algorithm of the inertial sensor data results in a time dependant increasing of the position and orientation error. The information goes weighted in the movement motion, so that by means of estimation process, regarding the selected criterion an optimal, although still faulted solution can be found or be used by detection for error compensation. In the following different possibilities are designated by supporting sensors for INS. The parallel redundant alignment from sensors to the increasing of the availability and accuracy takes place via a new alignment of parallel and antiparallel

availability and accuracy takes place via a new alignment of parallel and antiparallel acceleration sensors in the 3D-case. Thus redundant information for accelerations and turn rates can be got around the respective directions in the space. By such alignments, an improved position and orientation detection can be accomplished based on the indirect Kalman filtering.

# **Evaluation of supporting possibilities:**

As the position or rather the orientation error rises rapidly, the use of micromechanical INS without supporting information is even in short measurement times a less meaningful. An example of inaccuracies of the used inertial sensors was determined within a preliminary study.

The represented processes of estimation make the improvement for the accuracy of the position and orientation sensor technology in real time possible, whereby the Kalman filter - above all - as one dimensional optimal predictor for unsteady applications, causes this improvement. It permits the processing of the inertial sensor signals for improvement for the position and orientation detection.

So, there are concepts of the supporting present, which don't limit the flexibility of the measurement system and without additional expenditure according, to device an improvement of the position and orientation accuracy.

# Supporting by redundant sensors alignment:

The available concepts emanate from the existence of supporting information. The difference from sensor and supporting information serves as input signal of the Kalman-filter. Due to the demand of the referencelessness, supporting information is basically not available during the position and orientation detection. In order to make the application of indirect Kalman filter possible, a second parallel or anti-parallel arranged acceleration sensor will be used in this concept. The difference of the sensor signals serves here as an input signal for the Kalman filter.

# ax1 ax3

# Redundant parallel system:

By the concept of the redundant parallel system, two sensors are arranged in such a way that their sensitive sensor axes are in parallel direction (fig. 3.3-1).



Fig. 3.3-1: Parallel system for the positioning

# Redundant anti-parallel system:



Fig: Anti-parallel system for the positioning

By the concept of the redundant anti-parallel system, two sensors are arranged in such a way that their sensitive sensor axes are in anti-parallel direction (fig. 3.3-2).

Based on detailed studies in the context of this project, it can be held constant that no fundamental differences result from the different alignment as parallel system and as anti-parallel system in the case of the evaluation tests.

Therefore, only the parallel system is also regarded in the context of this work.  $a_{x1} a_{x2}$ 

13

The sensor:



Fig: The Sensor system to evaluate the concept

By the detection of the position and orientation, the supporting information is gained using the new sensor alignments (fig. 3.3-3) and supplied these with

the conventional sensor data into the Kalman filter, in order to determine the position and orientation.

# The used sensor components – accelerometer VTI SCA 61T:

The accelerometer SCA 100T from the company VTI Technologies is a capacitive sensor, which is manufactured micromechanically from singlecrystal silicon.

The evaluation principle is based on the mass inertia of a test load. If acceleration affects the sensor element, the test load experiences a strength, which causes a dropping of the mass. Thereby a gap between two planar evaluation electrodes is changing. The change of gap width is evaluated capacitive and so, proportional to the influencing acceleration an electrical signal is produced.

Technically, the evaluation is implemented with a pair of differential condensers. The symmetry characteristics as well as zero point stability will be improved. An ASIC with EPROM memory for calibration values is integrated for the evaluation of the signals. The SCA 100T has also a digital activatable self check and a continuous error control.

Task 3.2:	State Model Design
Task Leader:	PI-Medical
Partners Involved:	F-teg

**Objectives:** Developing of a state model of the system to realize a 3D position tracking unit.

**Progress:** 



The state model design was incorporated into the Kalman filter design process. Three onedimensional models are used which describe the path in the X-, Y- and Z-axis, respectively. The system state vector of each model consists of the path  $\mathbf{s}$ , velocity  $\mathbf{v}$  and acceleration  $\mathbf{s}$ . All three models combined form a 3D model of the tracking system. As the error signal from the accelerometers does not quite satisfy the white noise approximation that is typical in Kalman filtering, a first order Gauss-Markov model is used instead.

Details on the models can be obtained from report D4.

# Task 3.3:Development of a Kalman algorithmTask Leader:F-teg

**Objectives:** To develop the Kalman algorithm based on the system model and the noise model as a viewer on this model.

#### Progress:

The developed filter is fully described in report D4.

Supporting information for the indirect Kalman filter is retrieved through redundant sensor alignment. Parallel and anti-parallel alignments were evaluated for their suitability and found to be equally apt for the task.

Finally, special emphasis was put on precise error modelling, as drift compensation is crucial for accurate position estimation. A Gauss-Markov process was proposed to model the dynamic sensor bias, making it possible to create an error model which adjusts dynamically at run-time.

The original, more elaborate, test assembly was condensed when the first trials showed that the target accuracy could not possibly be reached with the available software and hardware. Further tests would not change that fact. We are aware that current precision diverges from the desired accuracy by magnitude of ten (1cm instead of 1mm).

To reach the desired accuracy of 1mm **additional support** of the inertial measurement unit will be necessary.

A couple of options are presented in the following section:

#### Kalman Filter and Movement Patterns

The Kalman Filter can only reach its full potential if the mathematical model upon which it is based is a very accurate description of reality. Therefore one cannot really speak of "the Kalman Filter" – there is no such thing. Each application and each assembly of sensors requires a customized filter. The noise characteristics of the sensors and the movement itself (How fast can a physician move the probe? How quickly does (s)he change directions? What kinds of movement are typical? etc.) has to be described in mathematical terms.

Initially a very general model of movement was developed (see report D4) that allows for random freehand movement in 3 dimensions. This model proved to be too broad to effectively support the drift-prone data from the MEMS sensors. As a consequence it seems reasonable to restrict possible movements to a set of common patterns without limiting the radiologist's freedom. Such patterns include e.g. the well-known fan-scan, a translational scan or a rotational scan.

In ultrasound diagnostics the physician is accustomed to pick from a number of pre-defined modes for different scan regions. By extending these modes with a "movement parameter", the patterns can be integrated in an existing and well-established user interface. Customer acceptance of the movement pattern approach is therefore expected to be high.

#### Combination with Optical Tracking (or other tracking technologies)

As proposed in the Annex a combination of INS and an optical correction system would be an option if the desired precision cannot be reached albeit profound estimation algorithms. The two navigation techniques complement each other very well as one balances the other's shortcomings. Optical tracking is long-term stable and accurate, yet requires a clear line of sight between the tracked object and the cameras. Blocking is a huge issue. INS on the other hand is prone to drift but self-composed and independent of an external reference. An integration of INS and optical tracking would thus lead to a robust and exact system.

Flaws of the approach:

The greatest issue of this alternative is that it will most likely exceed the target prize of 10k and thus make the product less attractive for potential clients. It would also make the product less innovative and cutting-edge which is an issue both for marketing and IP. There are already several approaches to hybrid tracking systems and the solution might even infringe one or more patents. Due to these numerous issues this option is rejected.

#### Image-based Approach

The "Medical Imaging Group" at the University of Cambridge currently attempts to build a sensor-less freehand 3D ultrasound system. Their approach to determine position and orientation of the B-scans is purely image-based. The research project has not yet left the stage of in-vitro and phantom tests, though, and they also face huge drift-related issues. A more detailed description of the approach and an outline how INS could be successfully combined with the Cambridge method is given in Appendix A.

A combination seems most promising as the nature of the respective drift errors is complementary. Moreover the method would not introduce additional costs, as it is purely software-based.

#### **Restriction to Orientation Tracking**

As illustrated the measurements in report D8 the orientation can be determined far more accurately than the position. Partly this is due to the twofold integration of the accelerations and partly due to the dependence of position estimation on exact orientation data.

Orientation measurements with the desired accuracy of 1° are well within reach. With more elaborate calibration procedures and the newly introduced alignment correction the FhG TEG developers were able to reduce the error to below 1° for a single axis under lab conditions. Evidently the cumulative drift for the 3-dimensional case will lie beyond that value, still it is most probable that the target precision for orientation alone can be reached. 8

There is a series of ultrasound examinations where positioning information is not strictly necessary, e.g. echocardiograms. A orientation-only system could be quite successful in that niche.

Flaws of the approach:

While the idea in itself is not bad it clearly clashes with the designated target of MUST to reduce cancer death rate through fast and accurate diagnosis - particularly of breast cancer. An orientation-only system could be a by-product of MUST, but shall not be the primary goal. Therefore this option is discarded for the time being.

#### New Generation of Inertial Sensors

A new generation of digital inertial sensors is currently in development and the first evaluation boards are already available. The main advantages of the new sensors are that they have digital outputs and usually incorporate more than one axis in a single chassis (e.g. the Bosch Sensortech Accelerometer in figure 3.5-1 which can measure acceleration in all three axes).

Multi-axis accelerometers are superior to common accelerometers regarding their even more compact frame size and – more importantly – error due to misalignment of the axes is de-facto non-existent.

#### Conclusion

Within project budget and time no position unit of 1mm accuracy could be realised. Research of the team will continue post-project.

As fan-scan (mere orientation tracking) for 3D structure detection could be a stand alone MUST product, it was decided to realise this solution within the project.

1. Free movement of hands on the human body would not lead to the planned MUST 3D imaging.

2. But a low cost navigation unit for rotation around a horizontal axis of the sensor head would also create 3D images in obstetrics or oncology.

#### Task 3.4 Software implementation

Task Leader:<br/>Task Objective:PI-Medical<br/>To implement the theoretic algorithm with the Software LabView in a<br/>program for data acquisition, data processing and data visualization.

# Progress:

#### Software Development

A large portion of the position tracking unit is available in **LabView**.

#### **Enhancing Accuracy with Movement Patterns**

The Fhg TEG developers evaluated different **movement patterns** for their suitability to support the measurements as part of the Kalman filter. The most common probe movements were identified, including fan scan, rotational scan and translational scan. The ensuing volumes resemble a fan, a cone or a prism.



Figure: Fan-scan, rotational scan and translational scan

The main issue is to permit variations in speed and consider the **unsteadiness of freehand movement** in general. Consequently the developed pattern has to be flexible enough to tolerate such variations while simultaneously stringent enough to be of use as a subsidy.

Moreover a series of **other support algorithms** and techniques is currently assessed for their suitability to enhance the position measurements (see *report D11* for details). The outcome of this enquiry will of course be considered in further software development cycles.

# Work Package 4 – 3D Ultrasound Unit

Task 4.1	Adaptation of a phased array probe to the Digital Phased Array System
	(DiPhAS).

Task Leader:	MEDCOM
Task Objective:	To make available an ultrasound hardware for the project

# Progress:

According to the specifications of the MUST System the ultrasound probe LA 5.0/128-663 from Vermon, France was selected for implementation into the system. The probe is a 128 element linear array probe with a center frequency of 5.0 MHz +- 10 % and a pitch value of 0.3 mm. This resembles a spacing of the elements in the order of the sound wavelength and allows for combined linear-phased beamforming with a maximum beam angle of approximately 30 ° to the normal 0° beam.



Fig.: Mechanical dimensions of the selected ultrasound probe

# 4.1.1. Mechanical modifications of the probe

According to the technical drawings first concepts for mechanical adaptation of the sensor unit to the ultrasound probe have been elaborated. The connection has to be easily applicable by the medical user, preferably without the use of any specialized tools. For needs of sterilization the connenction has to be designed in that way, that the sensor unit and the ultrasound probe can be seperated for cleaning purposes. Prototypes of these concepts will be set up <sup>15</sup>

after delivery of the probe, which is estimated to be during March 2005 and tests for usability and mechanical security will be performed.

4.1.2. Electrical Modification of the connector of DiPhAS

The MUST- Diphas system is a 64 channel digital beamformer which is connected to a pc via a digital 16 bit PCI-IO for raw ultrasound data transfer

and EPP connnection for beamformer control. The connection of the ultrasound probe is done via a ZIF (DL 1-156 ITT Cannon) connector. A specialized multiplexer device for the connection of the 128 element probe to the 64 channel MUST DiPhAS System has been designed and is in the process of fabrication. The multiplexer allows direct connection of 64 elements leading to a maximum active aperture size of 19,2 mm. The multiplexer hardware will be set up in the first quarter of 2005.

# 4.1.3. Adaptation and test

The beamforming strategy for driving the probe with 64 active transmit receive channels has been developed. The system running in linear multi-aperture zone mode can generate an image of maximum dimensions of 33,6 mm width and 150 mm depth. Using single aperture zone mode the maximum dimensions of the image are 19,2 mm by 150 mm.

# Task 4.2 3D-Scanconverter

Task Leader :TelemedTask Objective:Programming of the 3D-Scanconverter that reads the position and<br/>orientation information from the 3D-tracking unit and combine this with the<br/>ultrasonic data (frame). Reconstruction of the 3D-volume from the frames.

# Progress:

The implementation of the simple scan-converter included in the demonstrator has been replaced by a linear scan-converter that has been newly programmed for the MUST project. The data acquisition using a PCI I/O card has been prepared instead of the TCP/IP solution used in the demonstrator of the 9 month meeting. The corresponding data flow has been programmed and optimized.

Task 4.3	Volume visualization
Task Leader:	MEDCOM
Task Objective:	Programming of an algorithm that displays the volume on a monitor.

In order to visualise the scanned object, the data received from the scanner has to be processed. Therefore a programming software has to be developed.

The output of the conventional ultrasound device is connected with the frame grabber card in the PC. During the data acquisition all images are digitised by the frame grabber and then stored in the main memory.

At the same time, a small tracking device which is attached to the probe acquires the spatial position and orientation of the ultrasound transducer.

The digitised sequence of images, together with their position and orientation, is then converted, with a spezial algorithm to a volume dataset.

The following pictures will clarify the principle mentioned above.





Figure : Build up of the ready 3D image out of the data received from the ultrasound and tracking device.

Due to the volume visualisation, various other possibilities are included within the visualization software:

- 2D multi-image alternator
- 3D viewer with image generation in realtime
- Various imaging modes (MIP, Surface, X-ray, semi-transparent)
- Loop, Zoom, Pan
- Segmentation-tools
- 3D image processing
- Server-client configuration
- Arbitrarily oriented oblique cuts, cine loops in all directions in realtime
- Distance, angle & volume measurements in 3D
- Integrated database & archiving of patient data, video and images on MO-disk
- User defineable pre-sets for all applications

The images below will show some examples out of different clinical application areas. 5







Figure: Clincal examples (gynaecology, foetal diagnosis / radiology, oncology and tumor measurements / cardiology)

# Work Package 5 – Integration and Validation

# Task 5.1 Integration of overall system

# Task Leader: SS plastics

**Objective:** To integrate the components of the tracking system and the 3D ultrasound system

#### Progress:

A plastic housing of the inertial system hardware was designed and manufactured. An interface to the sensor unit was designed.

The inertial system electronics has been successfully assembled.

The electrics hardware was integrated into the housing.

There is even an improved board in the meantime available.

Parts of the inertial software system are already programmed in C++ for microcontroller integration.



test system overview



First generation functional model for fan scan freehand use



Final design and setup of miniaturised navigation unit.

# **INS-Unit-Housing**

The INS-Unit for the new boards could be designed smaller due to the very compact size of the new boards. For that, ergonomics and design could be extremely improved to make the hole package a sound looking and highly precise unit.



Type 1

In this particular type the INS-Unit is hold in place by 2 additional levers integratet in the tongue of the bottom part of the unit. These levers will stop the

unit from moving while using the ultrasound head. By pushing both levers you can release the unit quickly.



# Type 2

This specific type is using hooks to hold the unit in a fix position. It yields when moving the unit back and forth



# Type 3

Clips are use to force the unit in a fix position. As with Type 2 it yields when moving the unit back and forth.



# Type 4

With Type 4 the top part of the groove of the connectors is extendet and functions as a clip which has to be pushed to loosen the connection between the connectors and the inertial unit.

# Conclusion

All four types have their advantages and disadvantages.

Type 4 was chosen to be the most reliable and effective solution to hold the INS-Unit in a forced position while working with the ultrasound head. Ultrasound head, Connectors and INS-Unit need to be seen as one Unit to meet the technical objectives and Type 4 seems to be able to eliminate most errors integrated and should be able to improve the accuracy of the data derived from the accelerometer.

# Task 5.2 Validation and testing

# Testing of the integrated system with movement patterns



Figure: Fan-scan, rotational scan and translational scan

The three introduced movements patterns consist of an superposition of basic movements. The quality and accuracy of these basic movements are describe in 1.2 and 1.3. The processing of the rotational scan benefits from the circular pattern fitting described below which was implemented in the software and during testing.

# **Circular Pattern**

Initially neither radius nor position of the circle that the physician will describe with the transducer are known. To aid the user's hand movement during the examination, these parameters have to be estimated in an early stage of acquisition from existing data points. A least-squares circle fitting algorithm is used to estimate the best curve through the scattered data. The resulting circle serves as nominal movement pattern in subsequent processing (e.g. via Kalman Filter or other stochastic filters).



**Figure :** The circle fitting algorithm refines the estimated movement pattern when more data is available

The movement model can dynamically adjust itself by re-fitting the circle with additional data. Moreover it is possible to weight the individual measurement points (e.g. the influence of new measurements on the estimation could decrease with time to acknowledge the time-dependent drift).

# Testing of the system with cubes

Subsequently to the basic test a sophisticated method was used for testing the overall system. We used several phantoms for the measurements to look at the performance

of the inertial sensors. The first one was a phantom build of two cubes of GM900 material inside a agar agar bath.



Figure: GM 900 cubes in agar agar

With this phantom we could prove that position data are correct and we can record a volume data set with the configuration of this demonstrator.

The first results of the quadratic surface of the cube shows dimensions of 19-21 mm in the data set with a real size of 20 Millimetres.

**Figure:** Due to drift the measurements (in light grey) do not describe a full circle. The algorithm therefore weights the data according to measurement time (the longer the measurement the less reliable the measurements)



Figure: 2D data acquisition of the cube surface, 3D volume data

With some further improvements in software and configuration of the inertial sensor package we went on to a phantoms that consists of a sphere (a ball) inside an agar agar container. In the 2D ultrasound image the border of the sphere can be seen clearly on the top and partially on the sides and the bottom so that a half-sphere should be seen in the data set.

The used procedure for data acquisition is the fan scan where the transducer is guided with different angles on only fixed position on the phantom surface. We archived good results with this acquisition method and this phantom that can be even seen just by looking at the images of the data set. The sphere can be seen and it has a spherical form. By doing the measurements on a sphere data set we see also that the diameter of the ball fits good to the phantom build values of a diameter of 40 millimetres. Doing some distance measurements across the centre of the sphere from one wall to another we get a distance of 38,7 mm to 40,8 mm as the maximum diameter.

# Testing of the system with standard ultrasound training phantom



**Figures**: screenshots of sphere data sets After the measurement of these values we tried to image a more complex structure like a foetus inside a standard ultrasound training phantom:



The imaging targeted the face of the baby to see if small structures like the nose or the lips can be distinguished from the rest of the head on the one side and an arm with the fingers on the hand on the other side. The following resulting images show us that we definitely can separate these small structures from the rest of the data set structures:



**Figure**: fetal head and arm of the training phantom In the following we see data slices of two volumes fused manually using the SWIFT v3.0 imaging and treatment planning software. We compare the 3d geometry of the volume acquired with the MUST demonstrator with a reference scan made with ScanNT v3.6 using a magnetic tracking system (Ascension PCI bird) and a Esaote Technos US device:



**Figure**: left: MUST fan scan (volume border marked with white line) middle: Reference fan scan right: fusion of MUST fan scan and reference scan The deviations we can see at the chin and the top forehead is caused by different fan geometries.

# Task 5.3 Preparation of CE certification

# Task Leader: SS plastics

**Objective:** To prepare the certification of the developed components of the overall system. As the system will be used as medical diagnostic device and an add-on tool on current systems, the following steps need to be realized:

#### Progress:

The technical produced to prepare for CE is made up from three separate files. This will consist of the following setions.

Technical File One: Sensors, Interfaces and Drivers. Technical File Two: Visualisation System. Technical File Three: Ultrasound system and driver.

The INS sensor of Technical File One is connected to the ultra-sound device and Visualisation System

The Visualisation file uses an adapted version of an existing MEDCOM CE Technical File.

All the above Technical Files are integrated into a small technical file for "MUST".

# Work Package 6 – Innovation Related Activities

# Task 6.1 Protection of IPR

# Task Leader: MEDCOM

**Objective**: To ensure that all project results are formulated and compiled into a protectable form and all necessary patents are made.

#### Progress:

A patent is now being written as the orientation unit is now defined. The reseached patents are shown below.

#### **General Description**

This document describes the patent research and the assurance of property rights regarding the results of the cooperative research project MUST (508252).

#### Background

The purpose of the MUST project is to create a three dimensional scanning system which:

- Is a patient friendly scanning system available at the point of care
- Does not require a significant fixed installation,
- That is fully affordable by the most modest of facilities with a target price of €10k
- Is highly portable
- Has great ease of use.
- Gives immediate results for further decision making

The aim of this development is a 3D-ultrasonic system which will be able inertially to detect the position and location of the medical 2D-ultrasonic scanner, namely without external reference. The upgrading is achieved with the help of integrated and inertial system which is able to detect the position of the scanner and transmit information to the image processing system which generates the 3D-US-image. Thereby, the implementation of the low-priced 3D-ultrasonic system is possible with revision in diagnostics.

# Patent search

A patent search was conducted using

- European Patent Office
- Deutsches Patent- und Markenamt
- United states Patent and Trademark Office

Thereby the patents named in the following sections are worthy of mention.

#### Imaging

#### US 6,733,448:

This patent describes the transmitting of scan data from an ultrasonic scanning device to a computer by creating single frames in a sequential manner based on a format used by a viewer application. The system is designed for reporting purposes based on 2D images. The stored frames are not further used for diagnostics.

# Sensors

#### US 5,645,077:

This patent describes the orientation of a sensor device to be carried on the human body (on the head) in order to measure the orientation of the head of the user in space using inertial orientation tracking. The system does neither include drift reduction

software for orientation tracking, nor position tracking at all.

# US 5,953,683:

This patent describes an inertial orientation tracking system which consists of 1 to 2 gyroscope sensors. This system is not a complete orientation tracking system, still requiring further sensors to determine the orientation.

# DE 10110428:

This patent describes the object tracking using inertial sensors. The tracking is reduced to the movement on a plain surface. Rotation is not tracked.

# 1.5.6 3D Systems

# WO 9600425:

This patent describes a method and system for constructing and displaying 3D images taken from an ultrasound probe. Thereby the system uses a probe actuating assembly controlled by the computer to define the 2D image location.

# DE 10004764 A1:

The patent describes a procedure and system for position tracking of a medical instrument based on three-dimensional graphic CAT data, which, besides not giving orientation information, is a typical optical tracking system.

# 1.5.7 Main Innovation

The crucial innovation of the project is the single stage generation of the 3D image directly from the raw data coming from the ultrasound scanning probe itself, and the combined positional data coming from the gyroscopes and accelerometers. The absolute position of the source of the ultrasound echo is then derived from its depth (displacement from the sensor) the location of the sensor (accelerometric data) and which way it is pointing (gyroscopic data).

Thereby the algorithms developed for this project, namely to overcome the high drift characteristic of the low cost gyroscopic sensor for orientation detection, are the most specific innovation.

# 1.5.8 Property Rights

The reservation of industrial property rights is under preparation although, according the current state of the project where the required accuracy is not achieved, no official steps are initiated. Depending on the progress within the next month this task can be continued 14 expeditiously.

# **Patent Abstracts**

# US 6,733,448

Method of transmitting ultrasonic scan data

# Abstract

A method of transmitting scan data from an ultrasonic scanning device to a computer. A desired number of individual scan images are acquired as frames within a buffer, after which the contents of the buffer are frozen. The number of frames in the frozen buffer are counted, and the dimensions and pixel format of each frame in the frozen buffer are determined. The frames from the scanning device are transmitted to the computer via a connection device, and the transmitted frames are written to an image file in a sequential manner.

Inventors: Kelly; Kevin M. (Venice, CA); Royce; Roger (Venice, CA); Smith; Matthew Warren (Tulsa, OK)

Assignee: Sonocine, Inc. (Venice, CA)

Appl. No.: 328227

Filed: December 23, 2002

# US 5,645,077

Inertial orientation tracker apparatus having automatic drift compensation for tracking human head and other similarly sized body

# Abstract

A self contained sensor apparatus generates a signal that corresponds to at least two of the three orientational aspects of yaw, pitch and roll of a human-scale body, relative to an external reference frame. A sensor generates first sensor signals that correspond to rotational accelerations or rates of the body about certain body axes. The sensor may be mounted to the body. Coupled to the sensor is a signal processor for generating orientation signals relative to the external reference frame that correspond to the angular rate or acceleration signals. The first sensor signals are impervious to interference from electromagnetic, acoustic, optical and mechanical sources. The sensors may be rate sensors. An integrator may integrate the rate signal over time. A drift compensator is coupled to the rate sensors and the integrator. The drift compensator may include a gravitational tilt sensor or a magnetic field sensor or both. A verifier periodically measures the orientation of the body by a means different from the drift sensitive rate sensors. The verifier may take into account characteristic features of human motion, such as stillness periods. The drift compensator may be, in part, a Kalman filter, which may utilize statistical data about human head motion. Inventors: Foxlin; Eric M. (Cambridge, MA)

Assignee: Massachusetts Institute of Technology (Cambridge, MA) Appl. No.: 261364

Filed: June 16, 1994

#### US 5,953,683

Sourceless orientation sensor

#### Abstract

In a sourceless orientation sensor, the sensor measures the three orientation angles azimuth, elevation and roll in a fixed reference three-dimensional coordinate frame. The sensor utilizes a three-axis magnetic sensor to measure changes in the Earth's magnetic field in order to determine the azimuth and roll (or elevation) angles after the elevation (or roll) angle has been determined by other means. A first embodiment utilizes a separate sensor to measure the elevation (or roll) angle in a fixed reference three-dimensional coordinate frame while a three axis magnetic sensor is used to measure the Earth's magnetic field. The azimuth and the roll (or elevation) angles are then determined from these measurements. A second embodiment utilizes a combination of a three-axis accelerometer to sense the Earth's gravity to measure the absolute elevation and roll angles for slow motions and a two-axis rate sensor to measure the azimuth and elevation velocities in the sensor frame. A direct method employing translation and integration is used to find the azimuth and elevation angles in the fixed reference three-dimensional coordinate frame. The roll angle is then found from the magnetic sensor measurements. Other embodiments are disclosed. Inventors: Hansen; Per Krogh (Burlington, VT); Kogan; Vladimir (S. Burlington, VT)

Assignee: Ascension Technology Corporation (Burlington, VT) Appl. No.: 946916 Filed: October 9, 1997

#### DE 10110428

Method and device for tracking an object

# Abstract

The invention relates to a method for tracking an object, wherein acceleration measurement data is determined with the aid of an input device which comprises inertial sensors and which can be moved along a flat surface, e.g. a computer mouse. Position data relating to the movement of the input device can be calculated on the basis of said acceleration measurement data, which can be displayed or sent for further data processing in any seemingly fit manner or used for control processes. During the execution of the method it is possible to recognize if the input device is in a rest position. The method is characterized in that a threshold value check for the determined acceleration measurement data is carried out in order to improve long-term stability.

Inventors: Breitenbach, Jan (DE)

# Assignee: FRAUNHOFER GES FORSCHUNG (DE) Appl. No.: DE20011010428 20010305 Filed: September 12, 2002

#### WO 9600425

Method and system for constructing and displaying three-dimensional images

16

# Abstract

A three-dimensional ultrasound imaging system includes an ultrasound probe to direct ultrasound waves and to receive reflected ultrasound waves from a target volume of a subject under examination. The ultrasound probe is swept over the target volume and the reflected ultrasound waves are conveyed to a computer wherein successive twodimensional images of the target volume are reconstructed fo form a three-dimensional image of the target volume. The three-dimensional image is displayed on the monitor of the computer. A user interface allows a user to manipulate the displayed image. Specifically, the entire displayed image may be rotated about an arbitrary axis, a surface of the displayed image may be translated to provide different cross-sectional views of the image and a selected surface of the displayed image may be rotated about an arbitrary axis. All of these manipulations can be achieved via a single graphical input device such as a mouse connected to the computer. Inventors: FENSTER AARON (CA); DUNNE SHANE (CA); CHAN THOMAS K C (CA);

DOWNEY DONAL (CA)

Assignee: LONDON HEALTH ASS (CA); FENSTER AARON (CA); DUNNE SHANE (CA); CHAN THOMAS K C (CA); DOWNEY DONAL (CA)

Appl. No.: WO1995CA00375 19950623

# Filed: April 1, 1996 **DE 10004764 A1**

# Abstract

Note: Abstract only available in German language

Die Erfindung betrifft ein Verfahren zur Bestimmung der Position eines in ein Untersuchungsobjekt teilweise eingeführten medizinischen Instruments in einem dreidimensionalen Bilddatensatz des Untersuchungsobjekts sowie eine Anordnung zur Durchführung dieses Verfahrens.

Inventors: ZYLKA WALDEMAR (DE); SABCZYNSKI JOERG (DE); WEESE JUERGEN (DE) Assignee: PHILIPS CORP INTELLECTUAL PTY (DE) Appl. No.: DE20001004764 20000203 Filed: August 9, 2001

Filed: August 9, 2001

# Task 6.2Absorption of results by proposers

Task Leader:TelemedObjective:To transfer specific knowledge from the RTD performers to the<br/>SME participants to enable them to rapidly apply and embed the<br/>technology onto specific products.

Technology results were continuously transferred to all members in the past meetings and reports, and were layed down for al partners in the technical documentation of D7,8,10,11,15, 16,17,18,19 reports.

# Task 6.3Dissemination of Knowledge

Task Leader: **Objective:** 

#### Pi-Medical

To broadcast the benefits of the developed technology and knowledge beyond the consortium to potential medical user communities and SMEs working in the field of medical ultrasound manufacturing and distribution.

# Progress:

MUST system was presented during development at

- MEDTEC Show, Stuttgart March, 2005
- MEDICA Duesseldorf, November 2005
- MEDTEC Show, Stuttgart March 2006
- Deutscher Radiologenkongress 2006, Berlin May 2006
- MEDICA Duesseldorf, November 2006
- Workshops in radiology departments und units of Heidelberg and Tuebingen university hospitals were executed.

Therefore presentations and hand outs had been produced. A demonstration video is being prepared.

Publications for navigation and radiology journals are prepared.

# Task 6.4 Socio-economic aspects

Socio-economic aspects of the research work and product were layed down in D 29. report.

As well as the direct impact of lives saved through early diagnosis MUST will ensure an easier care cycle, reducing suffering for patients and localising the process of cancer healthcare. MUST also demonstrates considerable savings in pollution through the reduction on road fuel and electricity consumption. MUST will also reduce the exposure to potentially damaging x-ray radiation for patient and healthcare professional alike. These factors all make a contribution to the quality of life and safety

# Task 6.5Promotion of exploitation

Task Leader:MEDCOMObjective:To promote the broad application of the results by addressing at<br/>early adopters to insure the wide spreading in the medical<br/>community, and also to other industries outside of the consortium.

# Progress:

Heidelberg and Tuebingen medical experts had been made acquainted with the system.

As possible secondary market outside the consortium technical ultrasound quality control was identified and needs further clarification between partners concerning the strategy.

# Work Package 7 – Consortium Management

# Task 7.1Co-ordination of Knowledge Management and Innovation<br/>Related Activities

#### Task Leader: MEDCOM

**Objective:** To ensure that the knowledge management and innovation related activities processes are conceived and implemented in a coherent manner.

#### Progress:

The draft technology implementation plan was set-up discussed with our SME. All tasks were closely discussed among all partners in meetings, via phone or email. The IPR management was started with the inertial navigation patent research and was led to our current patent writing.

#### Task 7.2 Co-ordination of Technical Activities at a Consortium Level

#### Task Leader: MEDCOM

**Objective:** To ensure that all aspects of the EC requirements for communication and reporting are met.

MEDCOM as co-ordinator will be the sole point of contact between the EC and the partners, and is responsible for:

#### Progress:

Communication was running well, so all deliverable reports, cost statements had been collected and submitted. The technological progress was monitored by us continuously.

#### Task 7.3 Co-ordination of Legal Aspects

# Task Leader: MEDCOM

**Objective:** To co-ordinate the overall legal, contractual, financial and administrative

management of the consortium.

#### Progress:

The consortium agreement contence was updated within the SME partners in the second half of this project.

# Task 7.4 Co-ordination of Other Issues

#### Task Leader MEDCOM

**Objective:** To co-ordinate gender equality, ethical and society aspects of the project.

#### Progress:

This was summed up in report D29.

Work Package No.	Title	Deviations from Plan	Corrective Action
2	Orientation Tracking Unit	Longer development time necessary than planned	Development time delay could be caught up within the 24 month time.

# 2.3 Deviation From the Plan and Corrective Actions

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# 2.4 Work Package Deliverables Update

Del. No.	Deliverable Name	Work Package No	Lead Participant	Date Due	Planned/Actual Delivery Date	% Complete
D1	Document detailing the overall system demands in a QFD chart created by all members of the consortium, including detailed research for interfering needs using a triangle matrix comparison to discover project killers early.	WP1	MEDCOM	2	31.10.04/ 05.11.04	100%
D2	Periodic Report (Month3)	WP7	MEDCOM	3	30.11.04/ 30.11.04	100%
D3	Periodic Progress Report (Month6)	WP7	MEDCOM	6	28.02.05/ 11.03.05	100%
D4	Periodic Report (Month9)	WP7	MEDCOM	9	31.05.05/ 16.06.05	100%
D5	Midterm assessment report (Month12)	WP7	MEDCOM	12	31.08.05/15.10.05	100%
D6	Cost statements (Month 12)	WP7	MEDCOM	12	31.08.05/15.10.05	100%
D7	Description of the developed state model of the orientation tracking system	WP2	PI- Medical	12	15.10.05	100%
D8	Description of the reached gyroscopic orientation accuracy	WP2	PI- Medical	12	15.10.05	100%
D9	Periodic Report (Month15)	WP4	F-ibmt, F-teg	15	30.11.05	100%
D10	Description of the developed state model of the position tracking system	WP3	PI- Medical	16	31.12.05	100%
D11	Description of the reached accelerometers position accuracy	WP3	PI- Medical	16	31.12.05	100%
D12	Periodic Progress Report (Month18)	WP7	MEDCOM	18	28.02.06	100%
D13	Periodic Report (Month21)	WP7	MEDCOM	21	31.05.06	100%

Del. No.	Deliverable Name	Work Package No	Lead Participant	Date Due	Planned/Actual Delivery Date	% Complete
D14	Cost statements (Month 24)	WP7	MEDCOM	24	31.08.06	100%
D15	Procedure-description and software for the adaptation of different ultrasonic diagnostic devices to the 3D-tracking unit.	WP5	S&S Plastics	24	31.08.06	100%
D16	Function model of the 3D ultrasound system.	WP5	S&S Plastics	24	31.08.06	100%
D17	Interface specification to provide supplier of ultrasonic systems the opportunity to adapt the 3D-tracking system to their machines.	WP5	S&S Plastics	24	31.08.06	100%
D18	A documentation of the functional model will be prepared including in technical drawings of the overall system.	WP6	MEDCOM	24	31.08.06	100%
D19	A documentation of the components and overall system testing results.	WP6	MEDCOM	24	31.08.06	100%
D20	To put the necessary papers together and include information from the functional validation of the system from Task 5.2 in writing.	WP6	MEDCOM	24	31.08.06	100%
D21	A report plan on patent applications and exploitation agreements between the partners.	WP6	MEDCOM	24	31.08.06	100%
D22	A draft of the plan for using and disseminating knowledge	WP6	MEDCOM	12	31.08.05	100%
D23	Production of support material for transfer of the knowledge to the partners through case studies and a generic design guide.	WP6	MEDCOM	24	31.08.06	100%
D24	Report on the presentations and publications for the dissemination related activities of task 6.3.	WP6	MEDCOM	24	31.08.06	100%
D25	A report on the ethical and regulatory aspects of the	WP6	MEDCOM	24	31.08.06	100%

Del. No.	Deliverable Name	Work Package No	Lead Participant	Date Due	Planned/Actual Delivery Date	% Complete
	exploitation of the results.					
D26	A report on the dissemination of exploitation activities including the market introduction and identification of other possible applications.	WP6	MEDCOM	24	31.08.06	100%
D27	The final plan for using and disseminating knowledge	WP6	MEDCOM	24	31.08.06/28.2.07	100%
D28	Documentation of the consortium agreement management.	WP7	MEDCOM	24	31.08.06	100%
D29	Report on gender, societal and ethical issues of exploitation.	WP7	MEDCOM	24	31.08.06	100%
D30	Final report	WP7	MEDCOM	24	31.08.06/28.2.07	100%

# 2.5 Work Package Milestones Update

Milestone No	Milestone Description	WP No	Date Due	Actual Forecast Delivery Date	Lead Contractor
1	QFD chart & Identification of theoretical obstacles	1	1	05.11.04	MEDCOM
2	Hardware & software of the orientation tracking unit	2	10	16.06.05	PI-Medical
3	Hardware & software of the position tracking unit	3	14	29.12.05	PI-Medical
4	3D-ultrasonic imaging system for image based intra- operative navigation	4	24	31.08.06	F-ibmt, F-teg
5	Documentation of functional model, overall system tests & CE preparation to consortium	5	24	31.08.06	S&S Plastics
6	Month 12: Report on strategy, implementation & patent preparations	6	12, 18, 24	21.10.05	MEDCOM
	Month 18: Technology transfer			27.02.06	
	Month 24: Promotion of benefits			31.08.06	
7	Demonstration of project outcome to the EC	7	12, 24	07.09.05, 31.08.06	MEDCOM

# **SECTION 3** - Consortium Management

# 3.1 Consortium Management Tasks & Achievements

The technology implementation plan was set-up discussed with our SME partners and was worked on until month 24 of this project.

All tasks were closely discussed among all partners in meetings, via phone or email. The IPR management was started with the inertial navigation patent research.

The consortium agreement content was updated within the SME partners in the second half of this project.

# 3.2 Consortium Status Overview

The consortium worked well together...

# 3.3 Project Timetable & Status

#### 3.3.1 Work Programme (Original)

		Leader	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
WP1	Preliminary Characterisation	MEDCOM																							-	
1.1	Overall system demands	S&SPlastics																								
1.2	Required system interfaces	SK Trade																								
1.3	Inertial system demands	SK Trade																								
1.4	3D ultrasound unit demands	MEDCOM																								
WP2	Orientation Tracking Unit	PI Medical																								
2.1	State Model Design	PI Medical																								
2.2	Developing the Kalman algorithm	F-teg																								
2.3	Software implementation	PI Medical																								
WP3	Position Tracking Unit	PI Medical																								
3.1	Development of a sensor alignment	SK Trade																								
3.2	State Model Design	PI Medical																								
3.3	Development of an Kalman algorithm	F-teg																								
3.4	Software implementation	PI Medical																								
WP4	3D Ultrasound unit	F-ibmt																								
4.1	Adaptation of a phased array probe	MEDCOM																								
4.2	3D-Scanconverter	Telemed																								
4.3	Volume visualization	MEDCOM																								
4.4	Implemantation and Test	MEDCOM																								
4.5	Documentation and Procedure- Despription	Telemed																								
WP5	Integration and Validation	S&Splastics																								
5.1	Integration of overall system	S&Splastics																								
5.2	Validation and testing	PI Medical																								
5.3	Preparation of CE certification	S&Splastics																								
WP6	Innovation Related Activities	MEDCOM																								
6.1	Protection of IPR	MEDCOM																								
6.2	Absorption of results by proposers	Telemed																								
6.3	Dissemination of Knowledge	PI Medical																								
6.4	Socio-economic aspects	Telemed																								
6.5	Promotion of exploitation	MEDCOM																								
WP7	Consortium Management	MEDCOM																								
7.1	Co-ordination of Knowledge Management	MEDCOM																								
7.2	Co-ordination of Technical Activities	MEDCOM																								
7.3	Co-ordination of Legal Aspects	MEDCOM																								
7.4	Co-ordination of of Other Issues	MEDCOM																								

# 3.3.2 Work Programme (As Updated)

		Leader	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
WP1	Preliminary Characterisation	MEDCOM																								
1.1	Overall system demands	S&SPlastics																								
1.2	Required system interfaces	SK Trade																								
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3.1	Development of a sensor alignment	SK Trade																								
3.2	State Model Design	PI Medical																								
3.3	Development of an Kalman algorithm	F-teg																								
3.4	Software implementation	PI Medical					1	1																		
WP4	3D Ultrasound unit	F-ibmt																								
4.1	Adaptation of a phased array probe	MEDCOM																								
4.2	3D-Scanconverter	Telemed																								1
4.3	Volume visualization	MEDCOM																								1
4.4	Implemantation and Test	MEDCOM																								
4.5	Documentation and Procedure- Despription	Telemed																								
WP5	Integration and Validation	S&Splastics																								
5.1	Integration of overall system	S&Splastics																								
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6.4	Socio-economic aspects	Telemed																								
6.5	Promotion of exploitation	MEDCOM																								
WP7	Consortium Management	MEDCOM				1	1	1	·					·	·				·	1	·					
7.1	Co-ordination of Knowledge Management	MEDCOM																								
7.2	Co-ordination of Technical Activities	MEDCOM																								
7.3	Co-ordination of Legal Aspects	MEDCOM			-					-																
7.4	Co-ordination of of Other Issues	MEDCOM																								

FP6 - CRAFT MUST Project CEC Contract No. COOP-CT-2003-508252

# **SECTION 4 - OTHER ISSUES**

#### 4.1 **Overall Contributions of Consortium**

All project partners us MEDCOM together with PI-medical, Telemed, S&S Plastics and SK Trade work on the software and hardware development of MUST and were strongly supported by Fraunhofer and PERA.

#### 4.2 Periodic report on the distribution of the Community's contribution

The first share of the community's contribution to the project was distributed through the coordinator's escrow account as follows:

Beneficiary	Role in Project	Amount Received
MedCom GmbH	SME-Participant, Co-ordinator	€18,214.00
SK Trade GmbH	SME-Participant	€3,574.53
Pi-Medical	SME-Participant	€3,934.96
S&S Plastics Ltd.	SME-Participant	€3,574.53
Telemed	SME-Participant	€6,553.30
Fraunhofer TEG	RTD-Performer	€206,422.29
Pera Innovation Ltd	RTD-Performer	€108,371.39
	Sun	n €350,645.00

# **APPENDIX 1**

Plan for Dissemination and Use

Plan for Dissemination and Use

Project number: FP6-508252 Contract No.: COOP-CT-2003-508252 Project Acronym: MUST

Project title:

"Multidimensional Ultrasonic Scanning Technology to reduce cancer death rate through fast and accurate diagnosis - particularly of breast cancer"

# SME CONTRACTORS:

- 1 MEDCOM GmbH, D
- 2 SK Trade GmbH, D
- 3 PI-Medical Ltd, G
- 4 S&S Plastics Ltd, UK
- 5 Telemed, LT

Exploitable Knowledge	Exploitable Product(s) or Measure(s)	Sector(s) of Application	Timetable for Commercial Use	Patents or Other IPR protection	Owner and Other Partners Involved
Orientation tracking system	MUST fan scan navigation unit	Oncology, gynaecology, obstetrics; gastroenterology; general practitioners, orthopeadics	Plan for 2008	software algorithms confidential as unreadable DLL	MEDCOM
MUST fan scan navigation hardware	MUST fan scan navigation unit	Oncology, gynaecology, obstetrics; gastroenterology; general practitioners, orthopeadics	Plan for 2008	Patent planned for overall system	MEDCOM
INS-3D imaging software	MUST fan scan navigation unit	Oncology, gynaecology, obstetrics; gastroenterology; general practitioners, orthopeadics	Plan for 2008	software algorithms confidential as unreadable DLL	MEDCOM PI Medical
Software interfaces for flexible adaption	MUST fan scan navigation unit	Oncology, gynaecology, obstetrics; gastroenterology; general practitioners, orthopeadics	Plan for 2008	Interfaces open, software confidential as unreadable DLL	MEDCOM Pi Medical
Adaptable shoe for navigation unit adaption to sensor head	MUST fan scan navigation unit	Oncology, gynaecology, obstetrics; gastroenterology; general practitioners, orthopeadics	Plan for 2008	Design protection planned	MEDCOM SS PLASTICS
MUST system for technical ultrasound guality control	Modified sensor housing unit	Ultrasound based control for non-destructive testing	Plan for 2009	Design protection planned	MEDCOM SS PLASTICS

The exploitation plan concerning MUST 3D ultrasound technology foresees:

MEDCOM	IPR holding, system sales to Northern and Western Europe
SK Trade	Electronics integration and sale into the consortium
PI Medical	IPR holding and system sales to Southern Europe
S&S	Production of housings and sale into the consortium.
Plastics	
Telemed	Electronics integration and sale into the consortium, system sales to Eastern Europe and Asia.

The estimated market size will be as follows:

- After 1 years 500 units
- After 3 years 2000 units
- After 5 years 5000 units

And the second market is ultrasound based control for non-destructive testing.

# MEDCOM

Medcom, as initiator of the project, will become central IPR holder of the MUST system. Medcom will also benefit directly through their existing distribution network to Northern and Western Europe.

# SK Trade

The role of SK Trade post-project is to sell exclusively the complete electronics to MEDCOM.

# Pi Medical

PI Medical in Athens will benefit by becoming IPR owners. This not only has the obvious benefits associated with license fees on system sales going forward, but also offers the opportunity for the future of further development on the next generation of MUST and on associated technologies. PI Medical will also benefit directly through their existing distribution network to Southern Europe.

# **S&S** Plastics

The role of S & S Plastics post-project will be to produce and sell exclusively the plastic housing to MEDCOM.

# TELEMED

The role of Telemed in the project is to distribute one of its own products alongside the existing range of current product it distributes for other firms.

TELEMED will integrate the MUST units supply them to MEDCOM and Pi Medical for sales and will live on selling the units to Eastern Europe and Asia.

The cost calculation is

- Estimated market price: 400€
- Production costs incl. integration and packaging 200€
- Housing moulds for first 500 units 450€, moulds for future production 5000€
- Integrated electronics 80€
- Software licence costs (delivered in CD) 95€

# Section 2 – Dissemination of Knowledge

MUST system was presented during development at

- MEDTEC Show, Stuttgart March, 2005
- MEDICA Duesseldorf, November 2005
- MEDTEC Show, Stuttgart March 2006
- Deutscher Radiologenkongress 2006, Berlin May 2006
- MEDICA Duesseldorf, November 2006

- Workshops in radiology departments und units of Heidelberg and Tuebingen university hospitals were executed.

Therefore presentations and hand outs had been produced. A demonstration video is being prepared.

Publications for navigation and radiology journals are prepared.

More trade show presentations and end-user experts workshops are planned once the working prototype is developed to a completed product in 2008.

# Section 3 – Publishable Results

The EC supported development stage and the rached gyroscopic precision for fan scanning will be published for ultrasound press (focus on journals foroOncology, gynaecology, obstetrics; gastroenterology; general practitioners, orthopaedics) and in electronics journals.