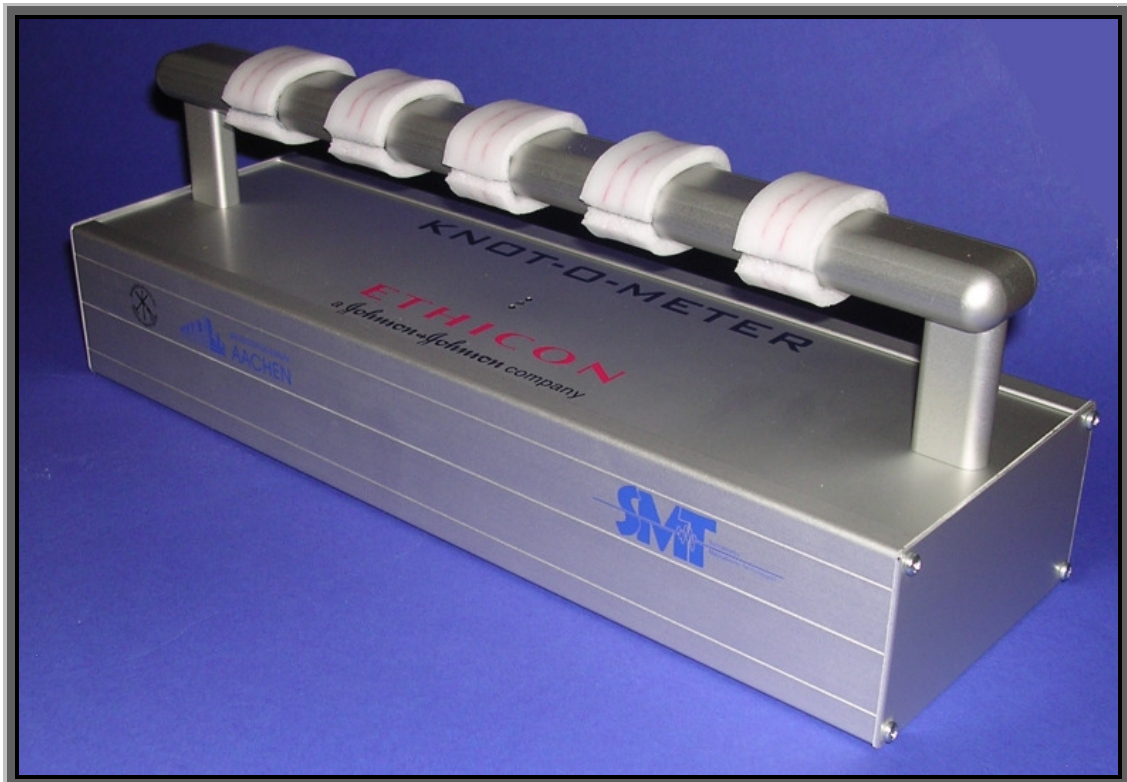


# User Manual for KNOT-O-METER

- For operating the Knot-O-Meter
- For the Knot-O-Meter's data-recording program
- For the Knot-O-Meter's analysis program
- Version 2.3 01/2011



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# 1 General operating instructions for the Knot-O-Meter

## 1.1 PC requirements

### 1.1.1 For using the Knot-O-Meter software

- RAM memory  $\geq 500$  MB
- CPU frequency  $\geq 1,3$  GHz
- Operating system Windows XP (min. Service pack 2), Windows Vista
- USB Interface
- Free HDD capacity  $\geq 500$ MB

### 1.1.2 For using a second display or beamer

- Interface for separate display
- Graphic board capable for two displays

### 1.1.3 For using the analysis program

- Microsoft Access 2007

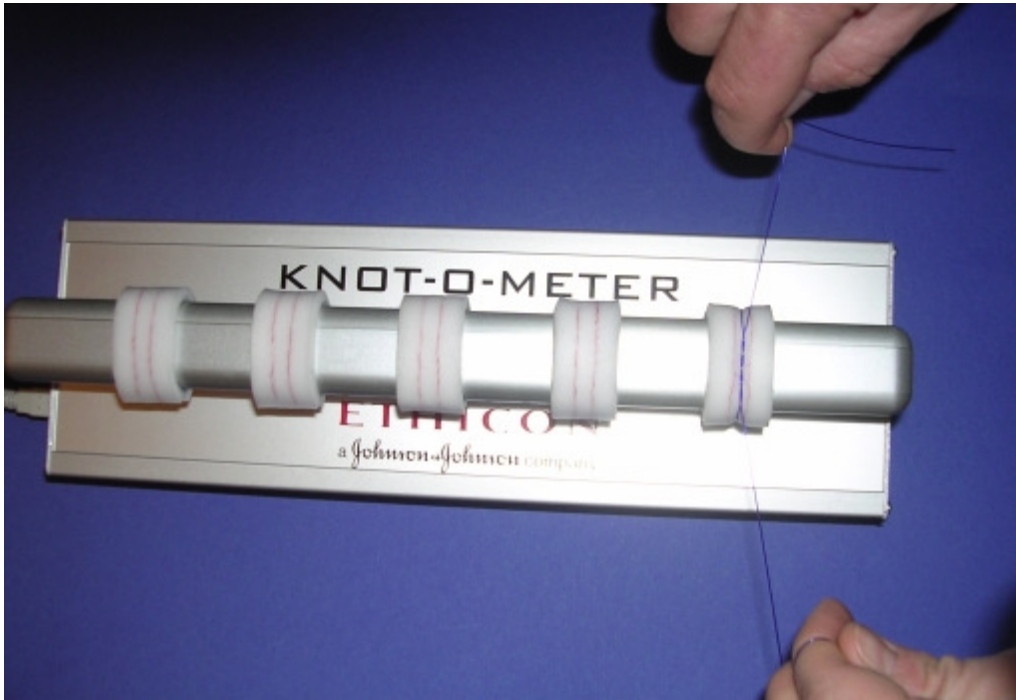
## 1.2 Connecting the Knot-O-Meter to PC

Connect the USB (type B) interface of the Knot-o-meter with included USB cable to your USB interface (type A) on your PC. The Knot-O-Meter's LED-display will light.



### 1.3 Usage of the Knot-O-Meter

Important: The knots have to be done within the red markings on the silicone pads.



Cut the string at the cut slots on each side of the silicone pads only. Make sure the silicon pads do not get damaged while removing the strings.



## 1.4 General operating instructions

The basic idea of the Knot-O-Meter is to achieve most consistent knots on the Knot-O-Meter and it's possible to arrange a competition with the included data recording software. There is no study which force is the best for each tissue layer.

Accuracy: +/-0.5 N

Only use in internal locations.

Operating temperature: Ambient temperature 15 – 25 °C.

Storage temperature: Ambient temperature 10 – 35 °C

Don't expose to high temperature fluctuations, e.g. take care of solar beams.

Operating during adverse ambient conditions is not allowed.

E. g.

- Wet and too high air humidity
- Dust and flammable gases, fumes or solvents

Do not twist or put high pressure onto the silicon measuring pads, otherwise the measuring sensors might get damaged!

**BEWARE OF FORCES ON THE SILICONPADS DURING TRANSPORTATION!!!**

## 1.5 Maintenance

If the silicone pads show any kind of wear and tear send back the Knot-O-Meter to the manufacturer for replacing it.

The Knot-O-Meter should be calibrated every 2 years. For calibrating the sensors please get in contact with the manufacturer.

## 1.6 Imprint

### Operating instructions **SMT** Knot-O-Meter

Issue 1.0 E

Issuing date: January 2010

### **SMT** Mechatronic Technologies

Sonnenwiechser Str. 23

D-83052 Bruckmuehl, Germany

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### **Important advice:**

All information included in this manual was collected with great care and in the best of knowledge. Mistakes however can not be completely excluded. For this reason **SMT** Mechatronic Technologies would like to let you know that no warranty (apart from the agreed warranty claims), any legal responsibility nor any liabilities for consequences, which go back to incorrect data, exist. We are always grateful for any notification of malfunctions.



## 2 Operating the data-recording program

### 2.1 Measuring with the data-recording program

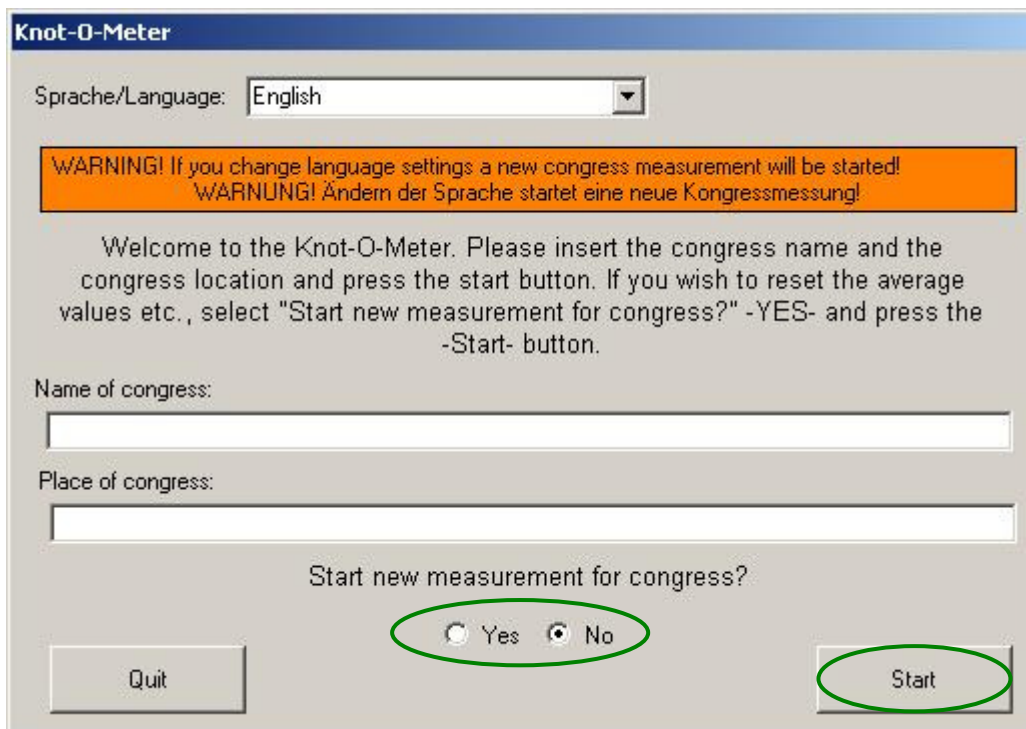
#### 2.1.1 Starting the data-recording program

Connect the Knot-O-Meter to your laptop via the USB-cable. If the connection has been established successfully, the Knot-O-Meter's LED-display will light.

Start the program by selecting *program / SMT-k<sup>2</sup>bytes Knot-O-Meter / Knot-O-Meter recording program*.

#### 2.1.2 First start

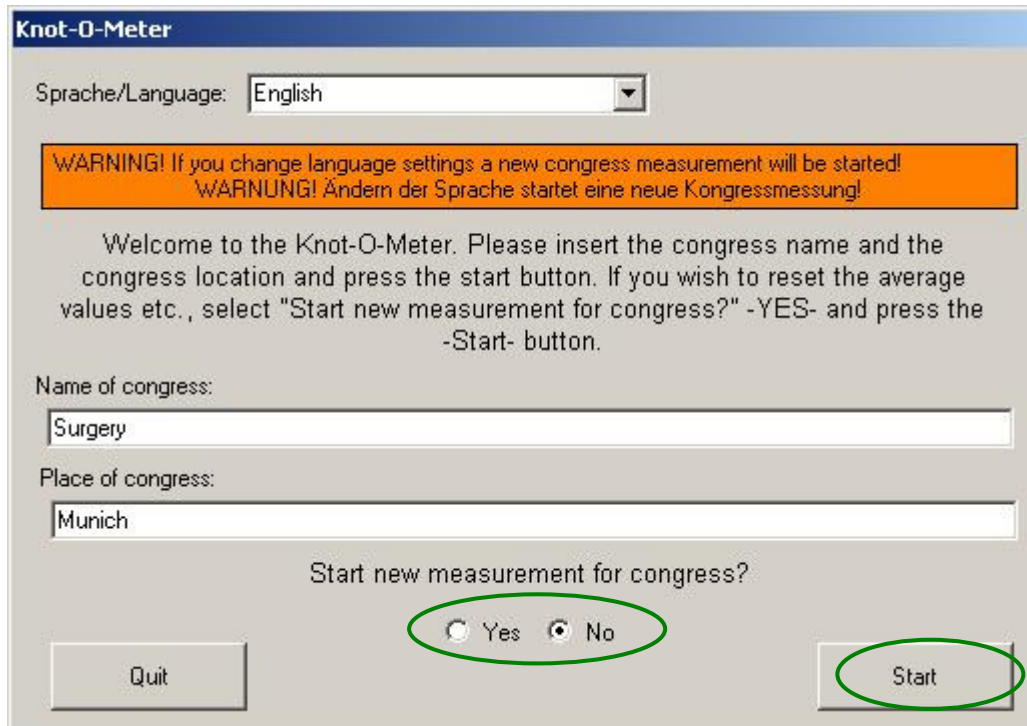
When the program is started for the first time, following screen pops up:

The screenshot shows the 'Knot-O-Meter' software window. At the top, there is a title bar with the text 'Knot-O-Meter'. Below the title bar, there is a dropdown menu for 'Sprache/Language:' with 'English' selected. A prominent orange warning box contains the text: 'WARNING! If you change language settings a new congress measurement will be started!' and its German equivalent. Below the warning, a welcome message reads: 'Welcome to the Knot-O-Meter. Please insert the congress name and the congress location and press the start button. If you wish to reset the average values etc., select "Start new measurement for congress?" -YES- and press the -Start- button.' There are two text input fields: 'Name of congress:' and 'Place of congress:'. Below these fields, a question 'Start new measurement for congress?' is followed by two radio buttons: 'Yes' and 'No'. The 'No' radio button is selected. At the bottom left is a 'Quit' button, and at the bottom right is a 'Start' button. Both the 'No' radio button and the 'Start' button are circled in green.

Welcome to the Knot-O-Meter. Please enter your congress name and congress location and press „start“. Should you want to reset your average levels, please select „Start measurements for new congress?“ “Yes” and press “start”.

## Running system

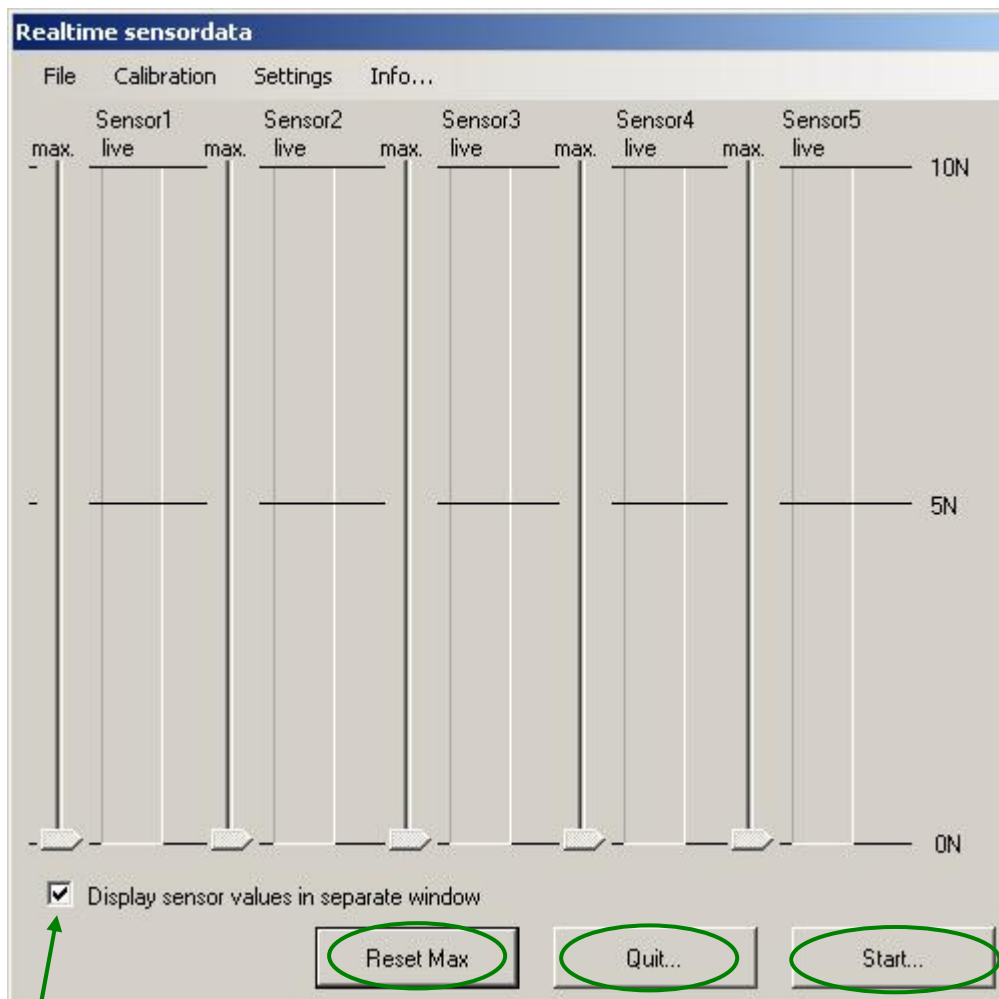
If the program was already running before, the following screen will pop up, e.g.:

The screenshot shows the 'Knot-O-Meter' software interface. At the top, there is a title bar with the text 'Knot-O-Meter'. Below the title bar, there is a dropdown menu for 'Sprache/Language' set to 'English'. A warning message in an orange box reads: 'WARNING! If you change language settings a new congress measurement will be started! WARNUNG! Ändern der Sprache startet eine neue Kongressmessung!'. Below the warning, there is a welcome message: 'Welcome to the Knot-O-Meter. Please insert the congress name and the congress location and press the start button. If you wish to reset the average values etc., select "Start new measurement for congress?" -YES- and press the -Start- button.' There are two input fields: 'Name of congress:' with the text 'Surgery' and 'Place of congress:' with the text 'Munich'. Below these fields, there is a question: 'Start new measurement for congress?' with two radio buttons: 'Yes' (unselected) and 'No' (selected). At the bottom, there are three buttons: 'Quit', 'Start', and a button that is partially obscured by the 'Start' button. The 'Start' button and the 'No' radio button are circled in green.

Should the reference data from the evaluation (average of the measurements so far and the standard deviations) be used for the congress, the program can be started by selecting "no". If the reference data needs resetting select "yes".

You can end the program by selecting the "Quit" button.

### 2.1.3 Online display



The window „real time sensor data“ is the calling screen for all further measurements. All measurements can be seen here. If there is no knot pressure touching the sensors, no value is displayed (0 N).

With the button „Reset Max“ the max-value flags for all sensors will be set back to zero.

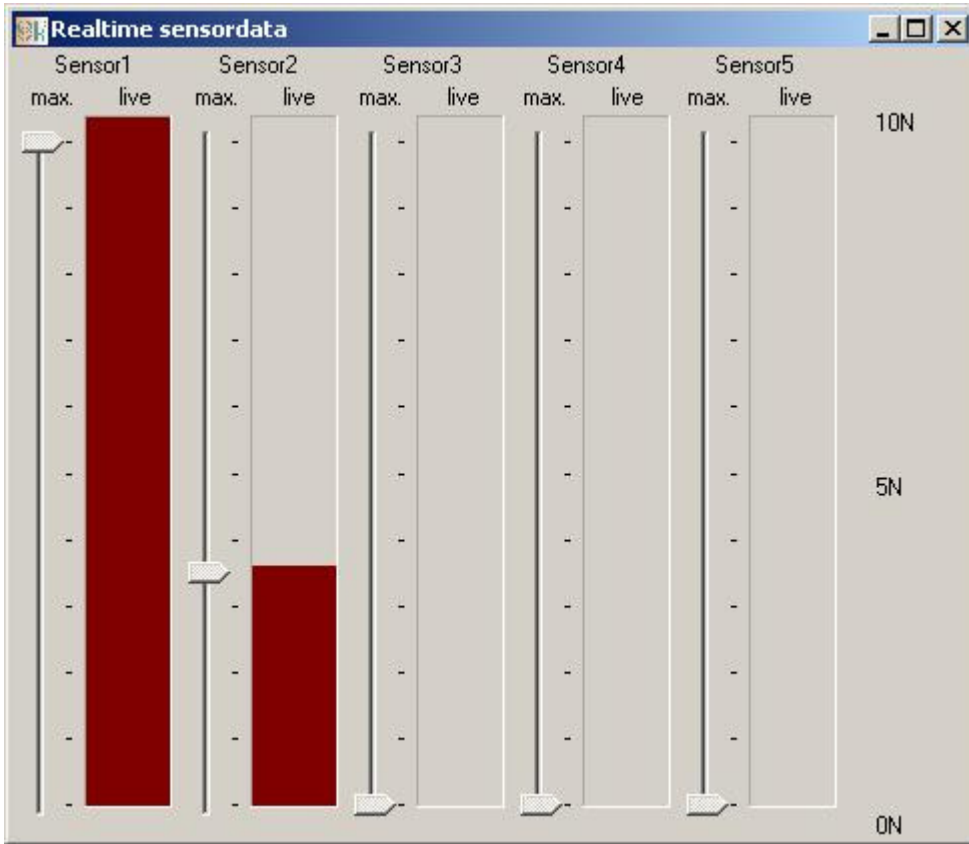
„Quit“ closes the program.

To start the measurement of a participant, press the button „Start“

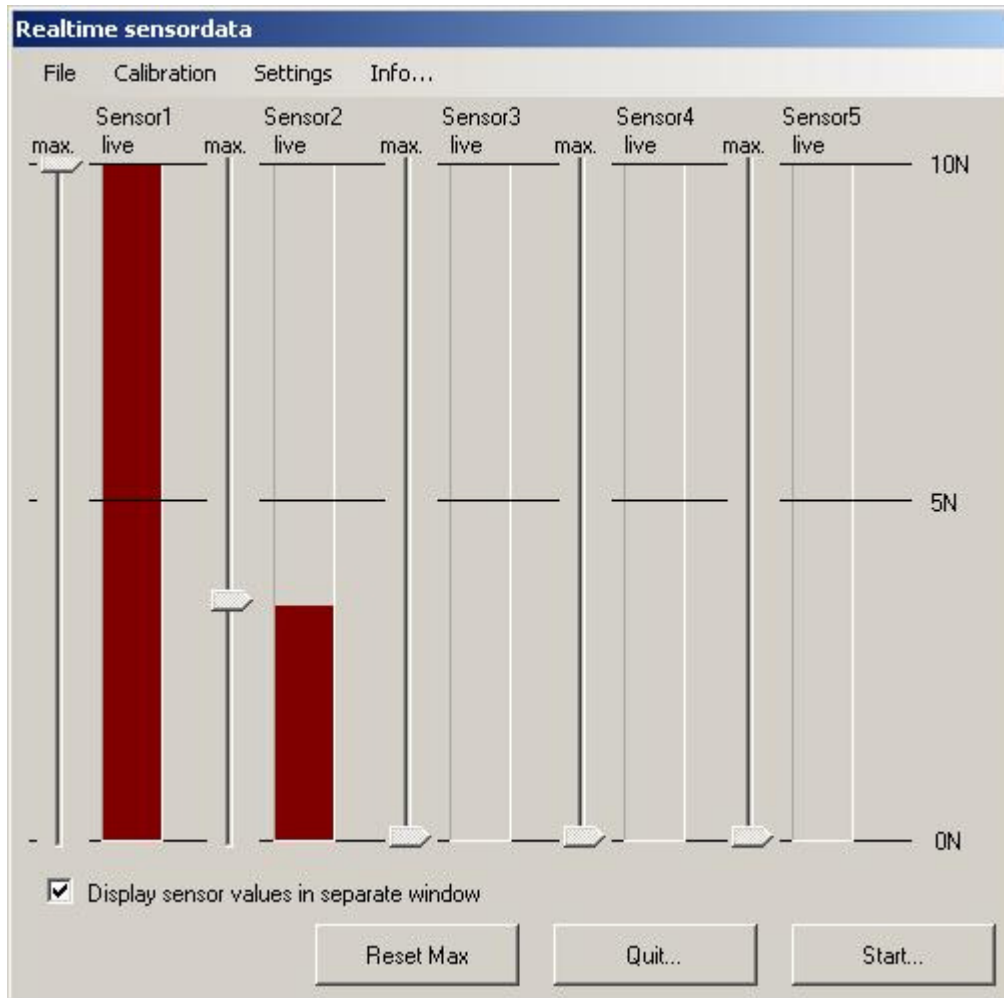
The second display window is activated for all further inputs through the option „Show sensor values in separate window“.



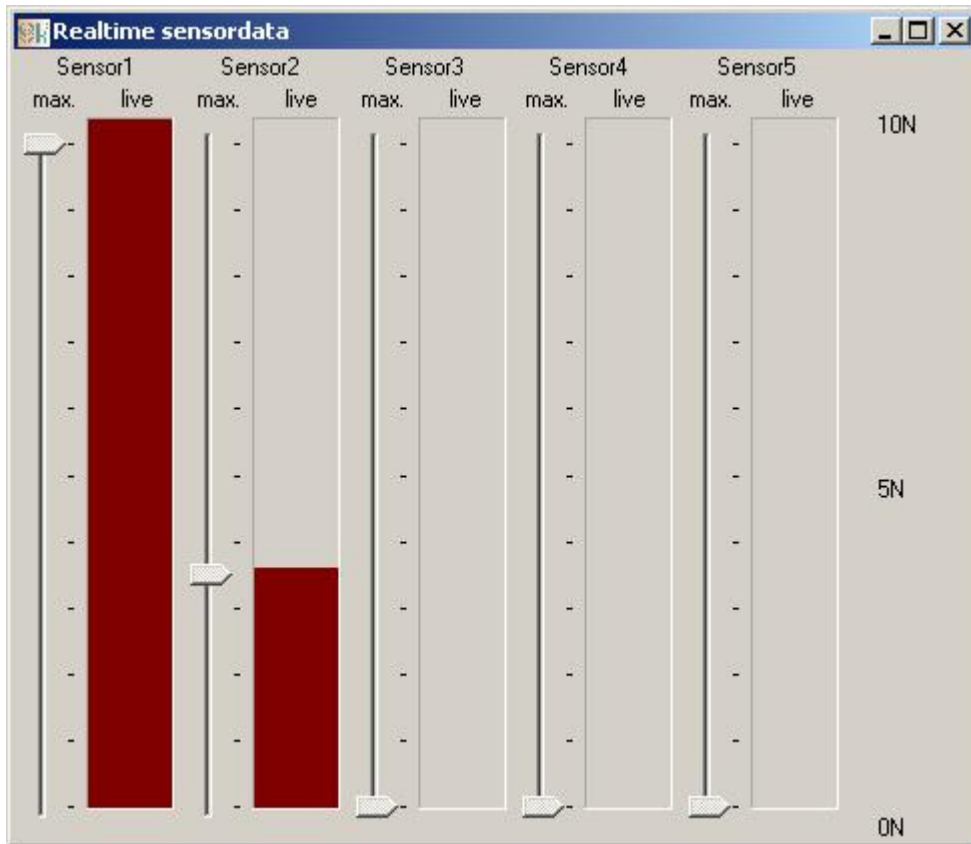
Separate window *realtime sensordata* display:



Are the knots made on the sensors, the real-time display could look like the following example:



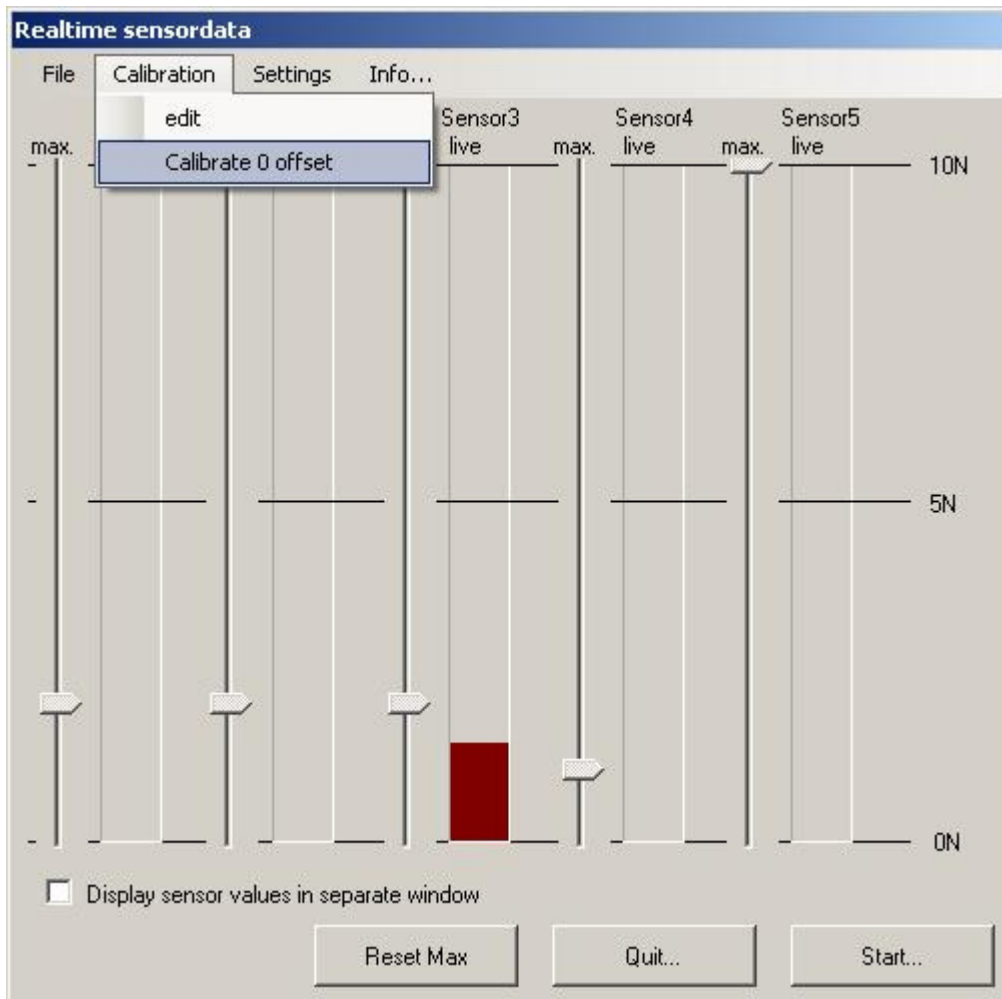
Display in a separate window:



#### 2.1.4 Calibrating the 0-offest on the sensor

Under the menu item calibration - calibrate 0-offset of all sensors can be set back to zero. This is need when the ambient temperature of the device defers to the original temperature during calibration. This could be necessary during the operation of the device in a day.

**Important:** If this function is carried out it must be made sure that all sensors have no pressure on them!



Select the item 0-offset-calibration in the menu item Calibration.

Following window will appear which will point out that the sensors are not to be under pressure. If this applies press “Yes” to confirm.

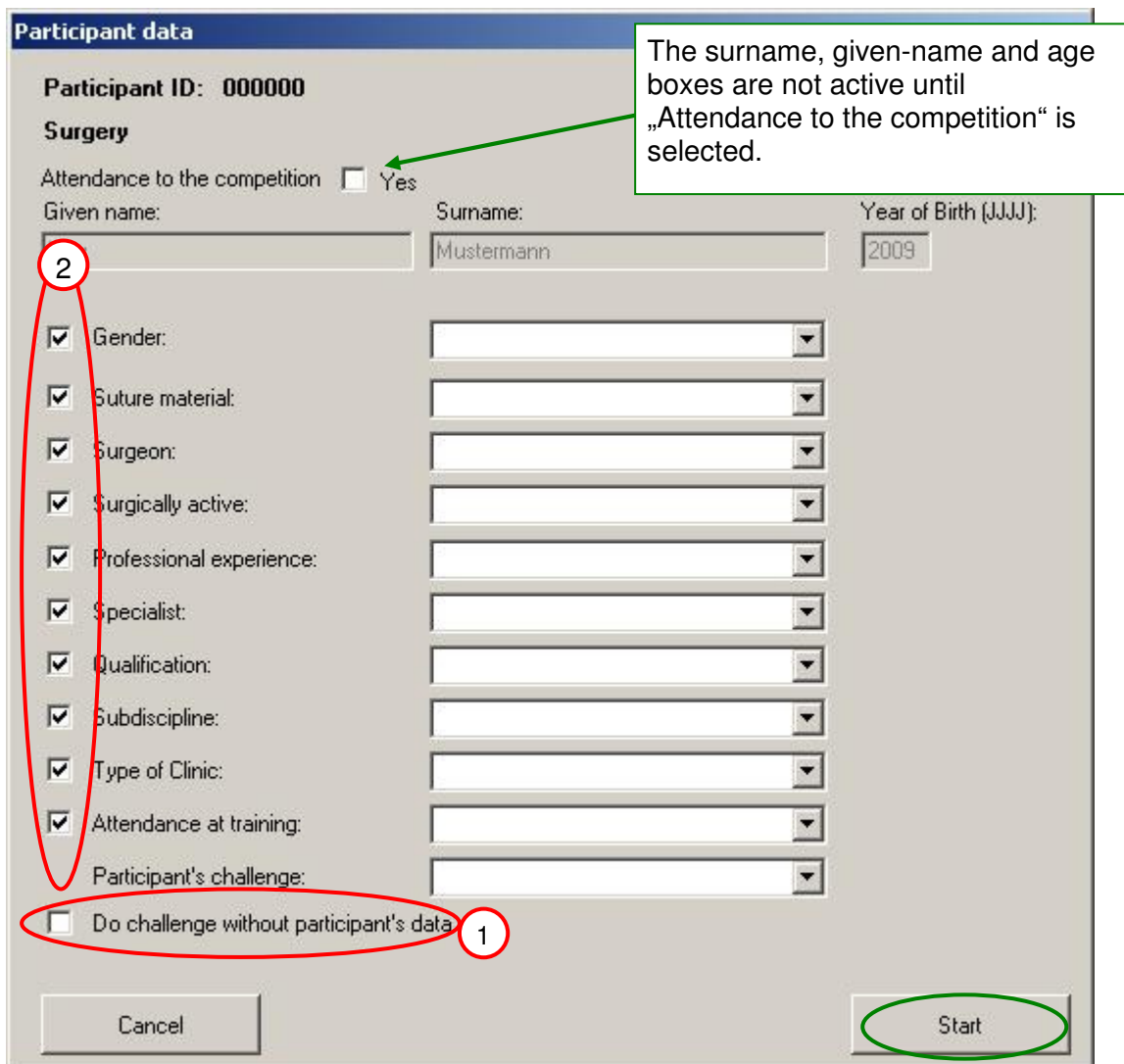
If „no“ is chosen, the 0-offset-calibration will not be carried out.



If the 0-offset-calibration has been carried out successfully, the following window will pop up which is to be confirmed with OK and you will return to the window real-time sensor data.



### 2.1.5 Input of the participants data and starting the measurements



The surname, given-name and age boxes are not active until „Attendance to the competition“ is selected.

2

1

Item 1: Measurement without participant data can be chosen with the checkbox “Do challenge without participant’s data”. In the participant’s data now will be saved “nu” (not used).

Item 2: Participant data can be selected and/or deactivated in any needed constellation. When checking out one of the data “nu” (not used) will be saved.



2.1.5.1 Following options can be selected in the list for participant's information:

- |                               |   |
|-------------------------------|---|
| 1. Gender:                    | Male / Female   |
| 2. Suture material:           | Monocryl 2-0 / Prolene 4-0 / Vicryl 1/ Ethibond   |
| 3. Doctor?                    | Yes / No  |
| 4. Surgeon?                   | Yes / No  |
| 5. Professional experience:   | 0-1 years / 1-5 years / 5-10 years /10-30 years/<br>30 and more years   |
| 6. Medical specialist:        | Yes / No  |
| 7. Qualification:             | Assistant / Senior physician / Chief surgeon /<br>others  |
| 8. Sub discipline:            | Trauma surgery / Hand surgery / Visceral<br>surgery / Cardiac and vascular surgery /<br>Paediatric surgery / others                                   |
| 9. Participant's clinic type: | n/a (not applicable)  |
| 10. Attendance at training:   | No training / Skill training / Knot training  |
| 11. Participant's challenge:  | Fixatin valve / Knotting "fascia" / Knotting<br>"liver" / Knotting "enteroanastomosis" / Knotting<br>with 1 N / Knotting with 5 N / Knotting with 9 N |

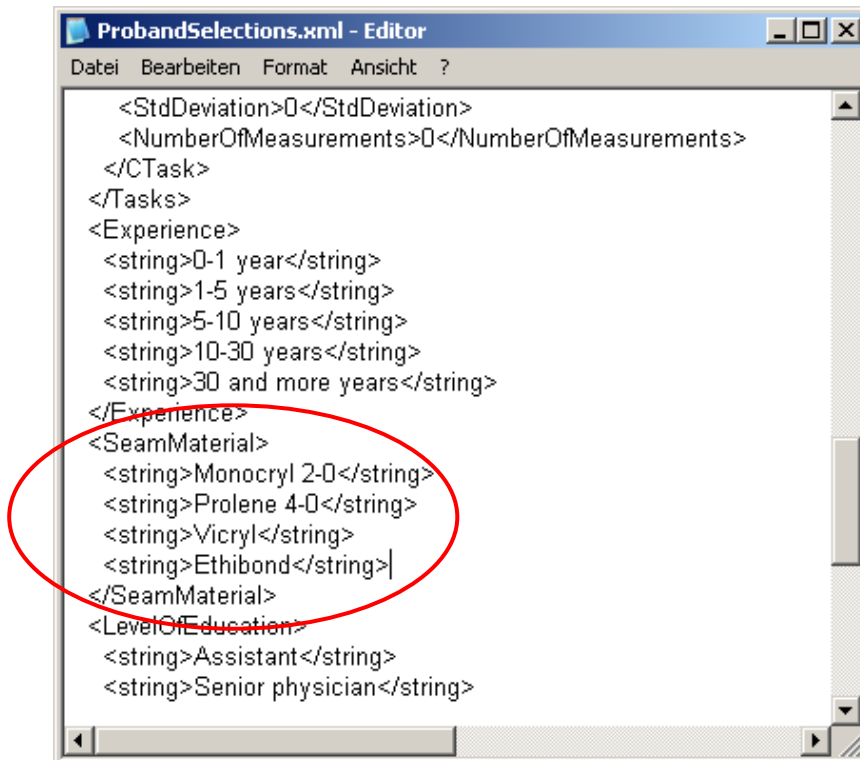
The participant's information can be edited in the file *ProbandSelections.xml*, located in the folder *c:\Dokumente und Einstellungen\<USER>\Eigene Dateien\Knot-O-Meter\en\*

**Important:** Don't change the participant challenge Fixatin valve / Knotting "fascia" / Knotting "liver" / Knotting "enteroanastomosis" / Knotting with 1 N / Knotting with 5 N / Knotting with 9 N. If you change this it is not possible to get the correct statistic data.

### 2.1.5.2 Example for adding the suture material Prolene 2-0:

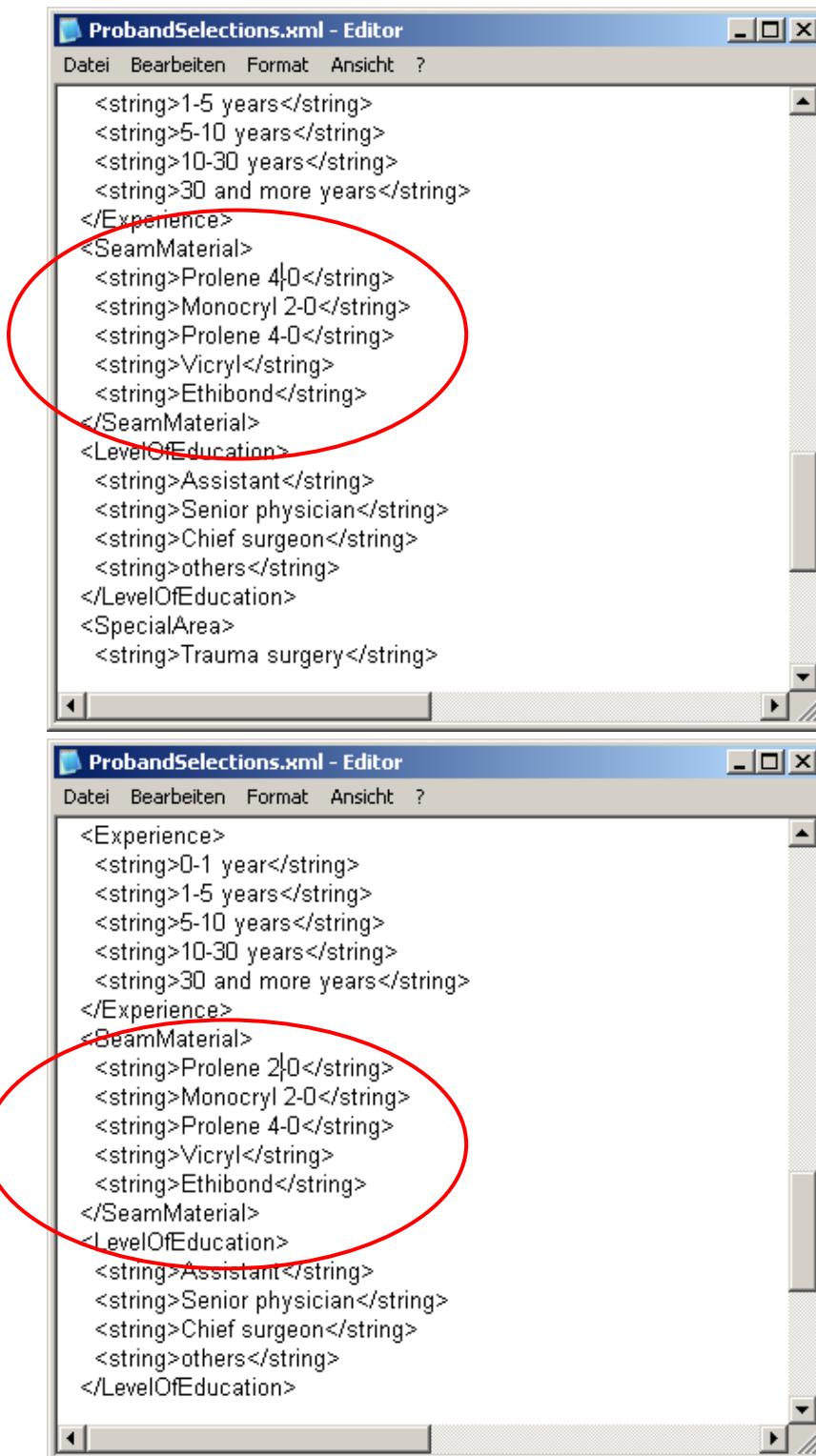
Close the recording program.

Open file *ProbandSelections.xml* with an editor (not with double click) and go to `<SeamMaterial>`

A screenshot of a text editor window titled 'ProbandSelections.xml - Editor'. The window contains XML code. The section between `<SeamMaterial>` and `</SeamMaterial>` is circled in red. The XML code is as follows:

```
<StdDeviation>0</StdDeviation>
<NumberOfMeasurements>0</NumberOfMeasurements>
</CTask>
</Tasks>
<Experience>
<string>0-1 year</string>
<string>1-5 years</string>
<string>5-10 years</string>
<string>10-30 years</string>
<string>30 and more years</string>
</Experience>
<SeamMaterial>
<string>Monocryl 2-0</string>
<string>Prolene 4-0</string>
<string>Vicryl</string>
<string>Ethibond</string>
</SeamMaterial>
<LevelOfEducation>
<string>Assistant</string>
<string>Senior physician</string>
```

copy e.g. `<string>Prolene 4-0</string>` and insert it on the first position. Change the name to `<string>Prolene 2-0</string>`



When the name is changed save the file. You can see the new information after a new start of the program.

### 2.1.5.3 Start measurement

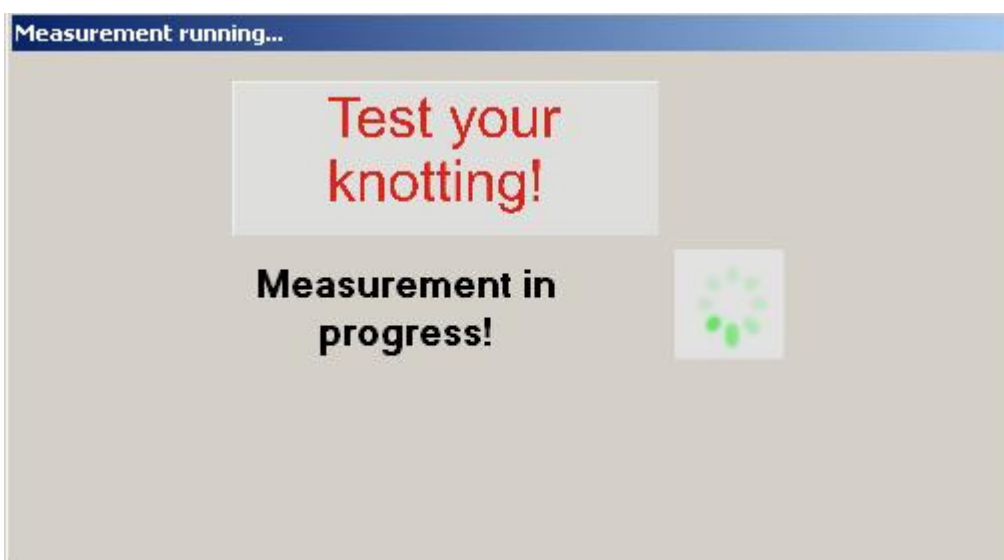
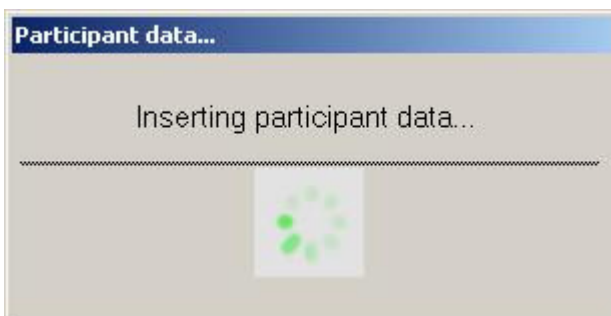
By pressing „Start measurements“ the measuring of the participants begins. The window “Measurement running...” will pop up and the participant can start knotting.



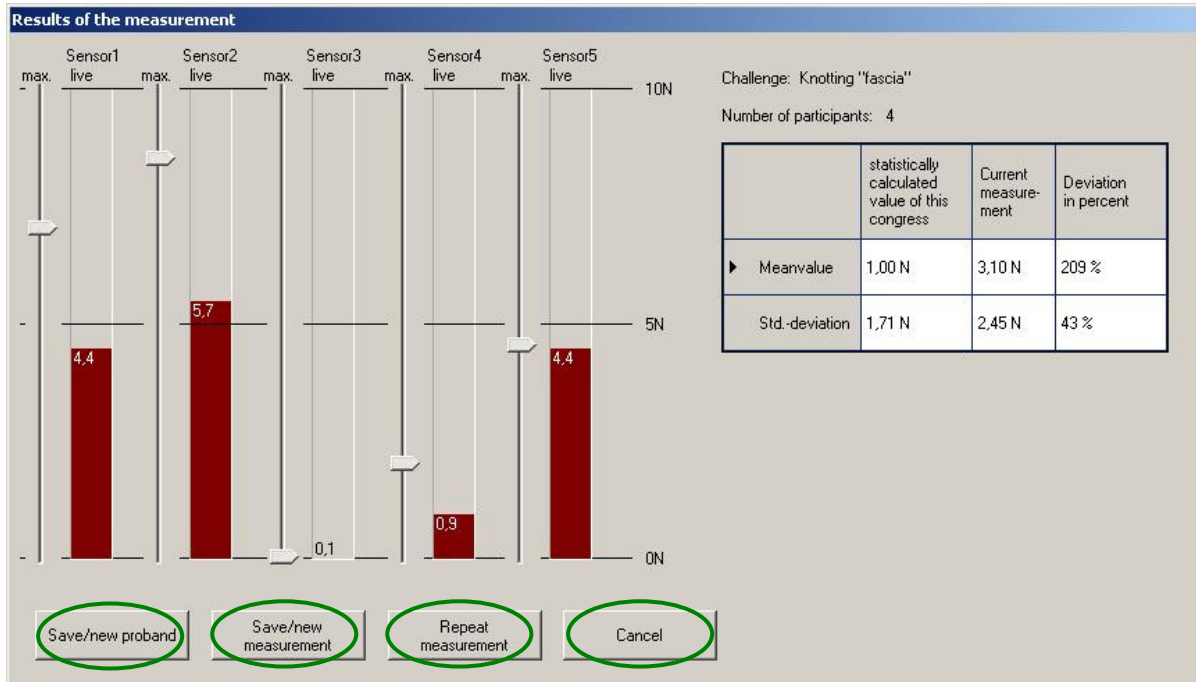
The measuring results can not be seen online during the knotting process, to avoid influences on the final knotting result. As soon as the participant has finished the knots the measurement reading will end by pressing “finish measurement”.

The participant may require max. 30 minutes for knotting.

The following appears during the participant’s data input and measurement:



### 2.1.6 Measurement results:



In the window “measurement results” the final results (red bar) as well as the max-values (marker) of the knotting are shown.



Display on the right:

- the challenge the participant knotted with
- the number of participants who have knotted with this challenge
- the statistically determined value of the current congress according to the challenge average value and standard deviation
- the value of the current measurement, average value and standard deviation
- the percentage deviation of the current measurement of the statistically determined value of the congress.

Usage of the buttons:

*Save/new participant:*

The measurement has successfully been carried out and needs saving – return to online display (real-time sensor data)

*Save/new measurement:*

The participant wants to start a measurement with a new challenge. Return to input screen for the participant's information to edit the input

*Repeat measurement*

The participant would like to repeat the measurement. Return to the input screen without repeating the measurement. Now it is possible to edit the data and start the measurement new.

*Abort*

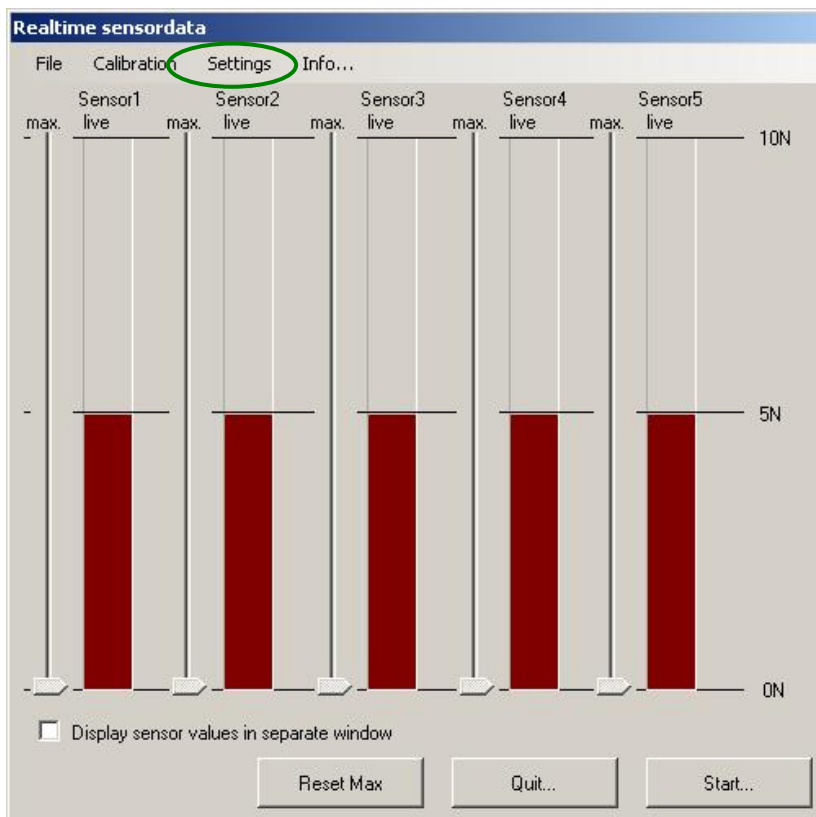
The participant and the measurement are not to be saved. Return to online display (real-time sensor data).

## 2.2 Importing/Exporting calibration data and settings for the participants data to another PC

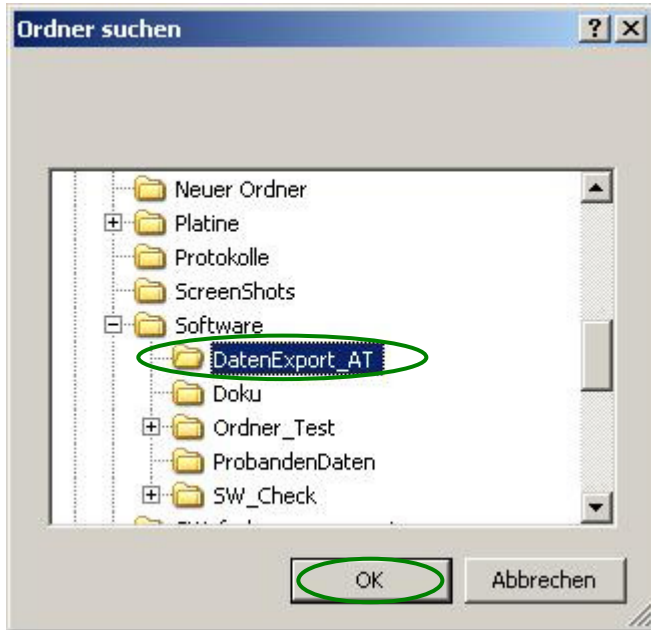
### 2.2.1 Importing the calibration data

If the Knot-O-Meter will be used on another PC and the calibration data were not installed yet, the necessary file can be imported. All calibration data will be saved in the delivered CD together with the Knot-O-Meter.

The calling screen for importing is the online display (window: real-time sensor data):



Through *settings* / *Import* following screen will appear: *search file*



Select files in which the calibration data have been saved, e.g. data-export\_AT. Accept with **OK**.

If the data has successfully been imported, following message will pop up:



Press **OK** to return to the online display (window: real-time data)

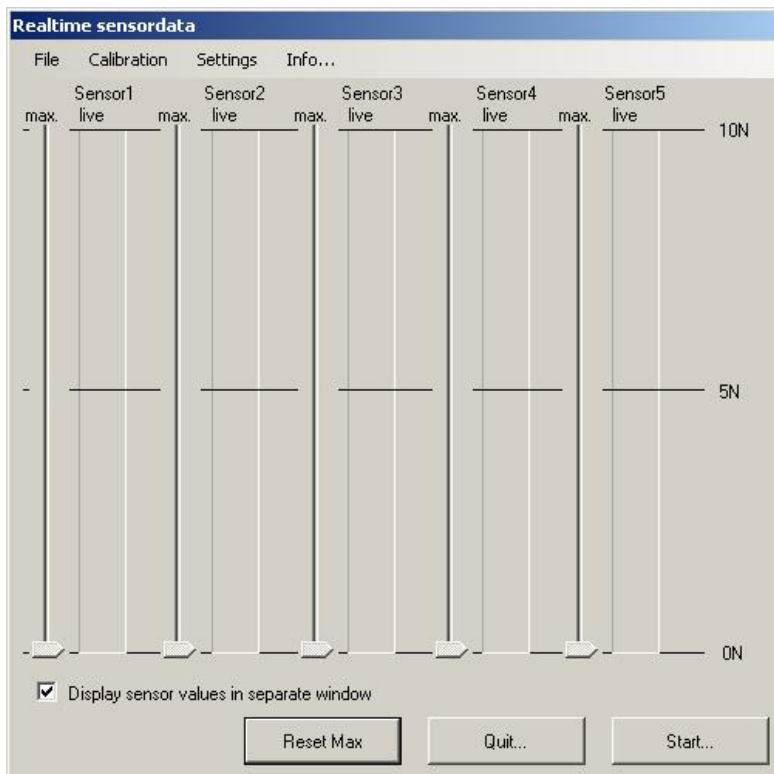
If a calibration table already exists, the message will ask if the existing table should be overwritten:



Select **Yes** to use the table.

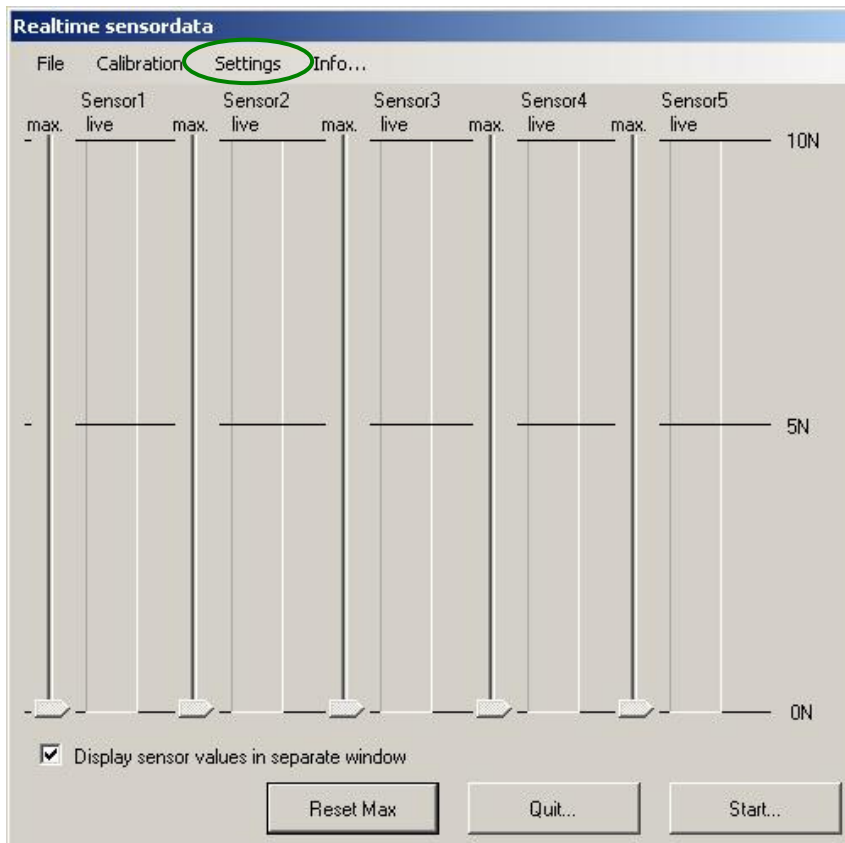
By selecting **No** the already existing calibration table will be used.

If the import of the table with the calibration values was successful, all sensors without pressure show 0 N.



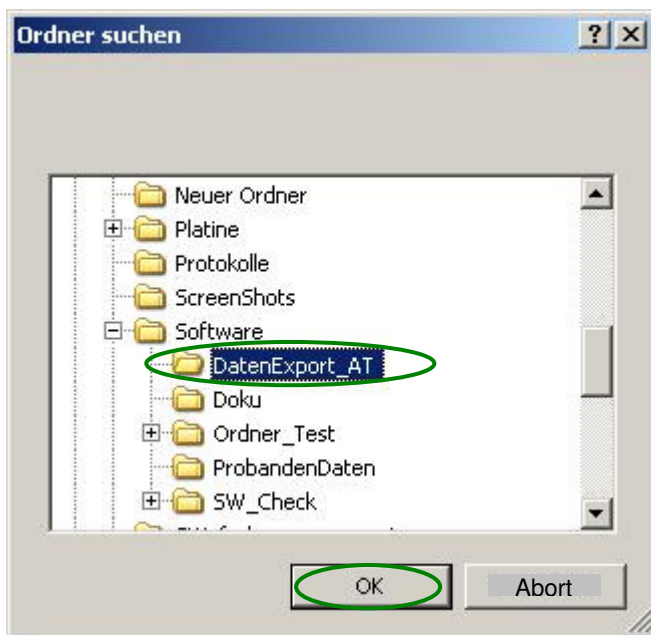
## 2.2.2 Importing the selection file for the participants data

If a new / changed XML-File selection-list for participants was already created on another PC, the file can be used by importing the recording program, so the measuring station offers the same selection. The calling screen for the import is the online display (window: real-time sensor data)



By selecting *Settings / Import* the following selection window *search for files* is activated:





Select the folder in which the XML-file *Selections.xml* was saved. E.g. *DataExport\_AT*. Accept with OK.

If the data has successfully been imported, this message will pop up:



Press OK to return to the online display (window: real-time sensor data).

If the file *ProbandSelections.xml* already exists, the message, if the file should be overwritten will appear:

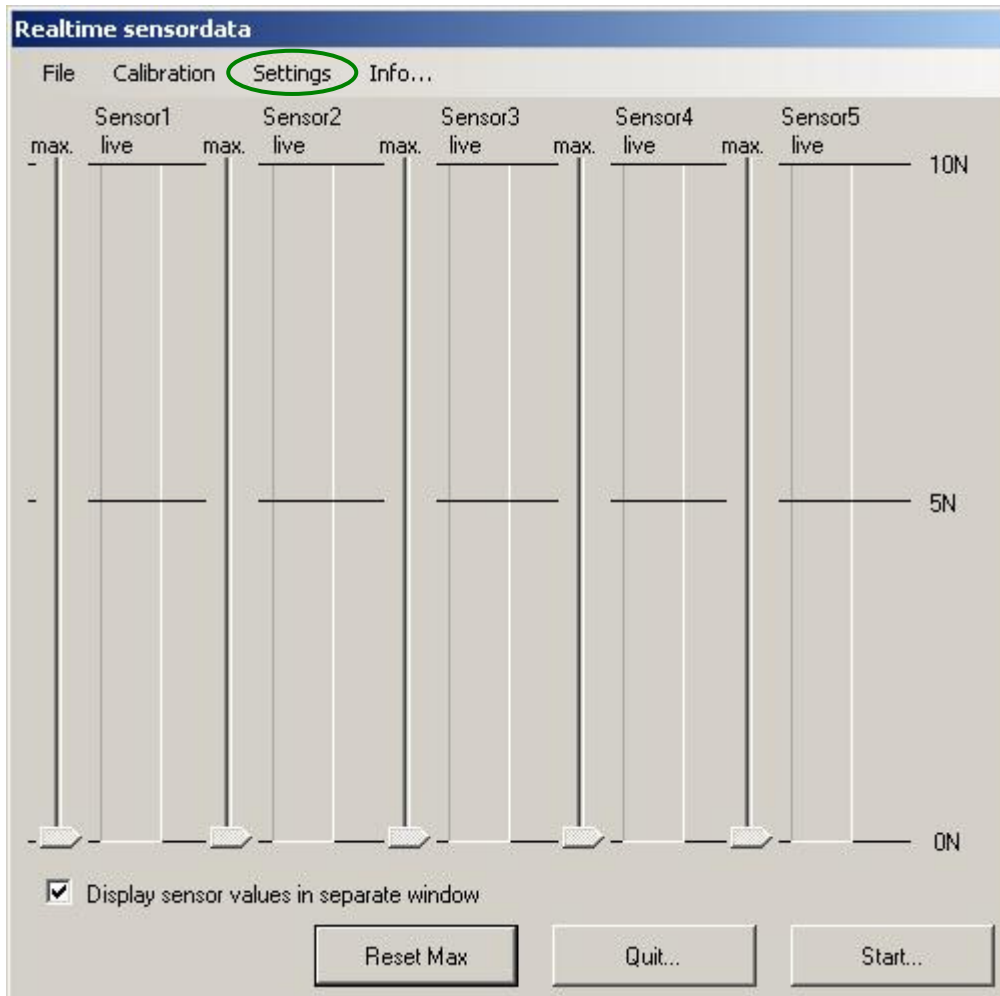


Select Yes to use the file.

Select No and the already existing XML-file will be used further on.

If importing the table was successful, the selection list will show the participant's changed / new values.

- 2.2.3 Exporting the calibration files and the XML-File for the participants-information-selection lists  
The calling screen for doing the exporting is the online display (window: real-time sensor data).



By selecting *Settings* / *Export* the following selection window *search for files* is activated



Select the folder in which the XML-file *Selections.xml* will be saved. E.g. DataExport\_AT. Accept with OK.

If the data has successfully been exported, this message will pop up:



Press OK to return to the online display (window: real-time sensor data).

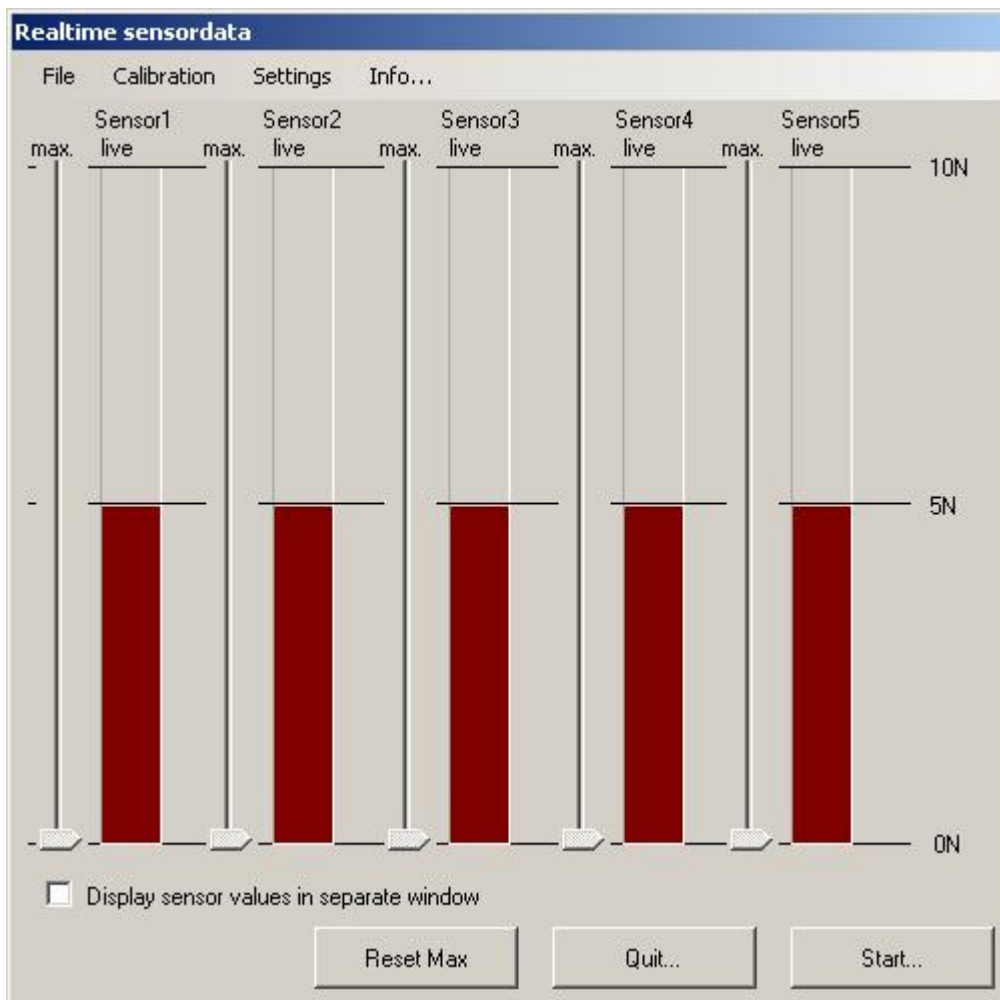
## 2.3 Trouble shooting

- Recording program was started before the Knot-O-Meter was connected



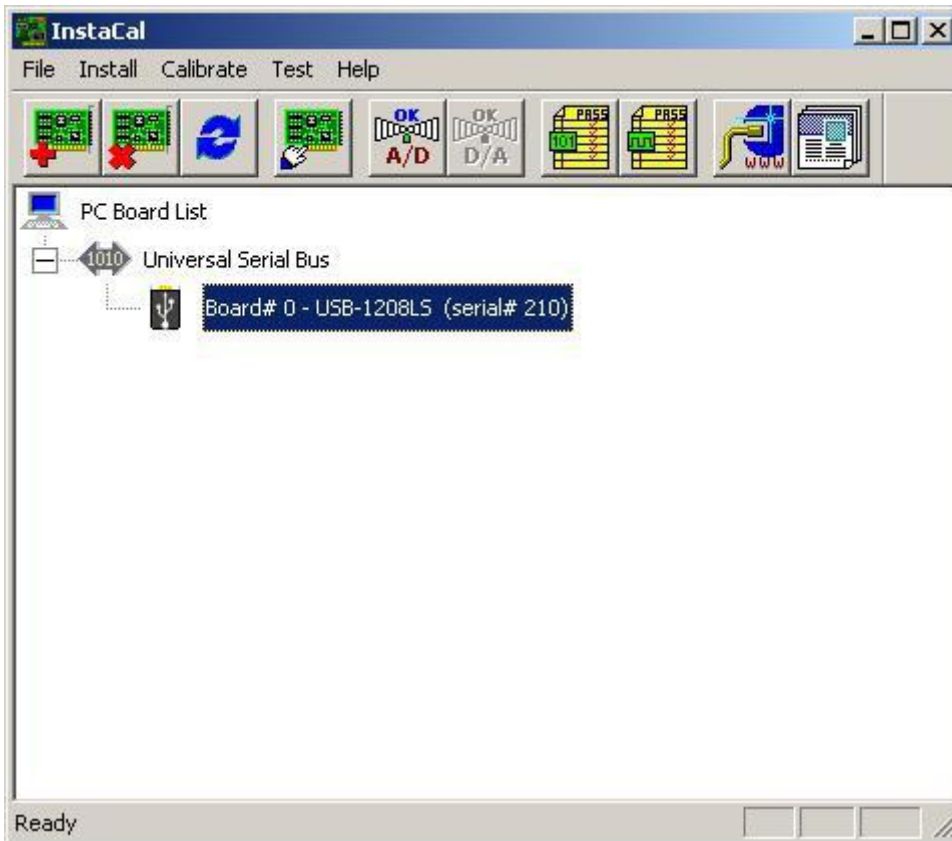
Corrective action: End program, connect Knot-O-Meter, restart program

- Online Display (window: *real-time Sensor Data*) shows no values although the calibration of the device was done.

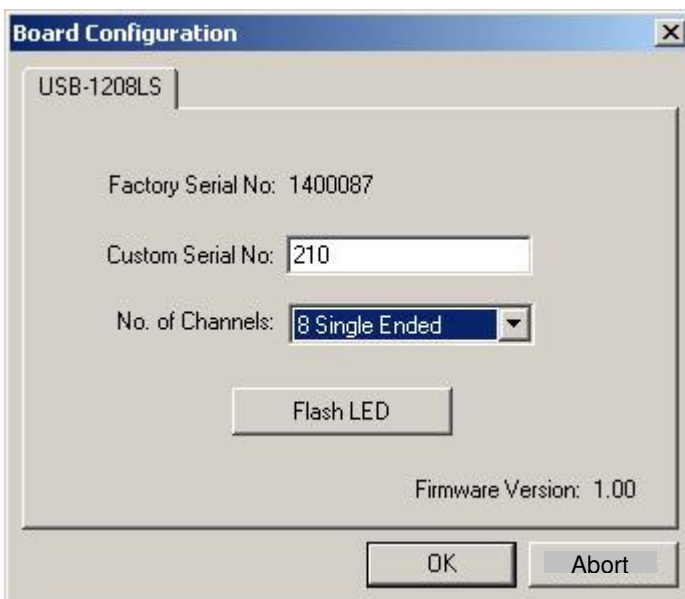


Corrective action: check settings of the Redlab Cards:

Start Redlab-Program InstaCal and double click on *Board# 0 – USB-1208LS (serial# 210)*.



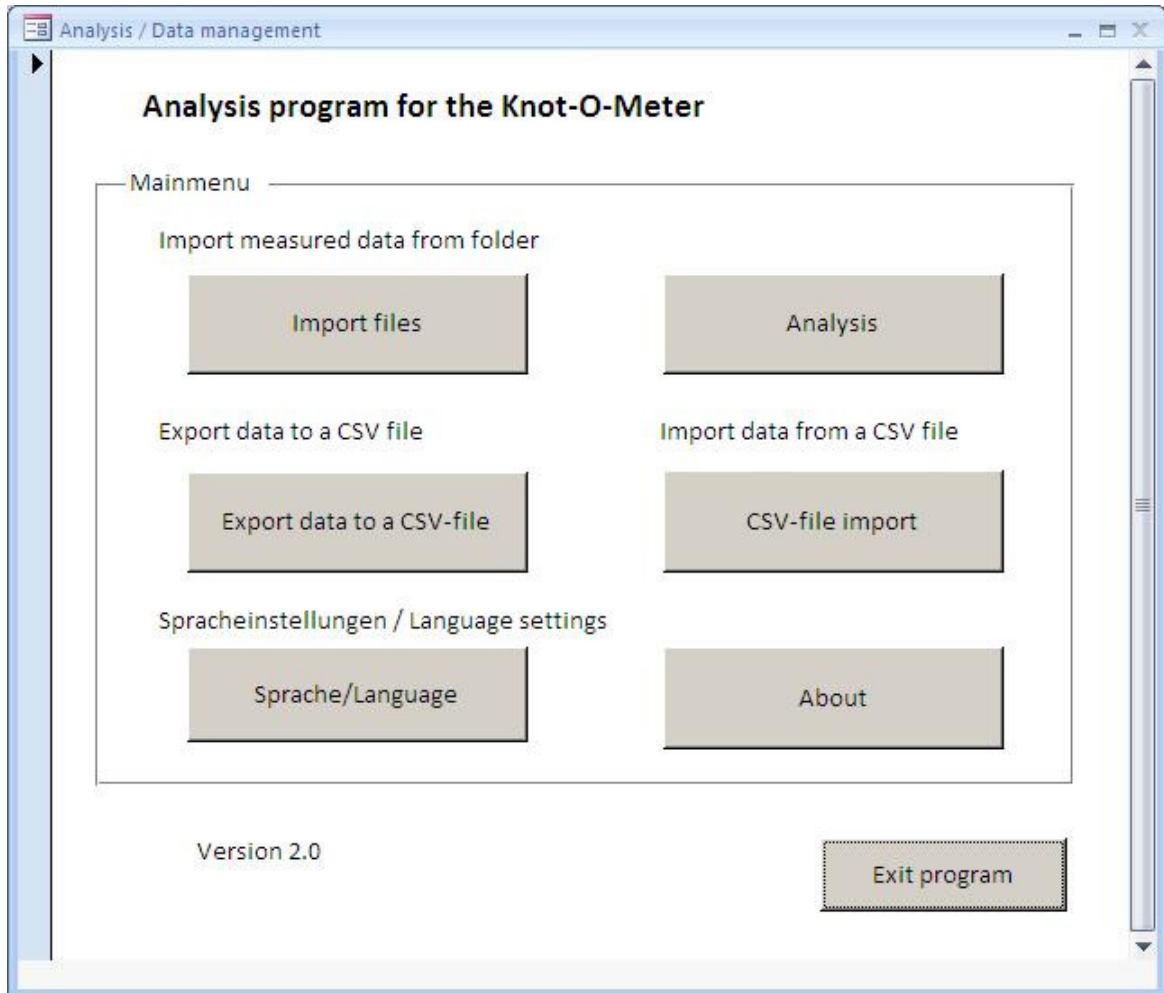
In the window “Board Configuration” in the pick box “No. Of Channels”: „8 Single Ended“ has to be selected!



### 3 Operating the analysis program

Select the analysis program for the Knot-O-Meter over Program / SMT-k<sup>2</sup>bytes/ Knot-o-meter/Knot-o-meter analysis program

The main map *Data Administration / analysis starting* opens.



Program ends by selecting the button “*Exit Program*”.

### 3.1 Importing the participants data

By selecting the button *import* the participant's data are loaded into the analysis program. For this select the folder in which the participant's data were saved.



The memory location for the participants data from the Knot-O-Meter's analysis program is:  
*C:\Dokumente und Einstellungen\<USER>\Eigene Dateien\Knot-O-Meter\Participants\*

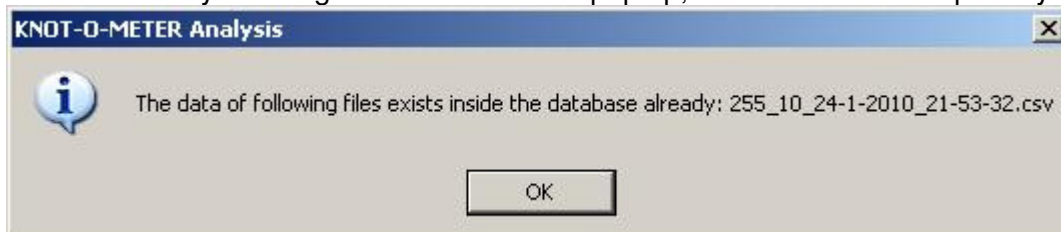
Select file and accept with *OK*.

When files were successfully imported following message will be showed:



Return to the main map with *OK*.

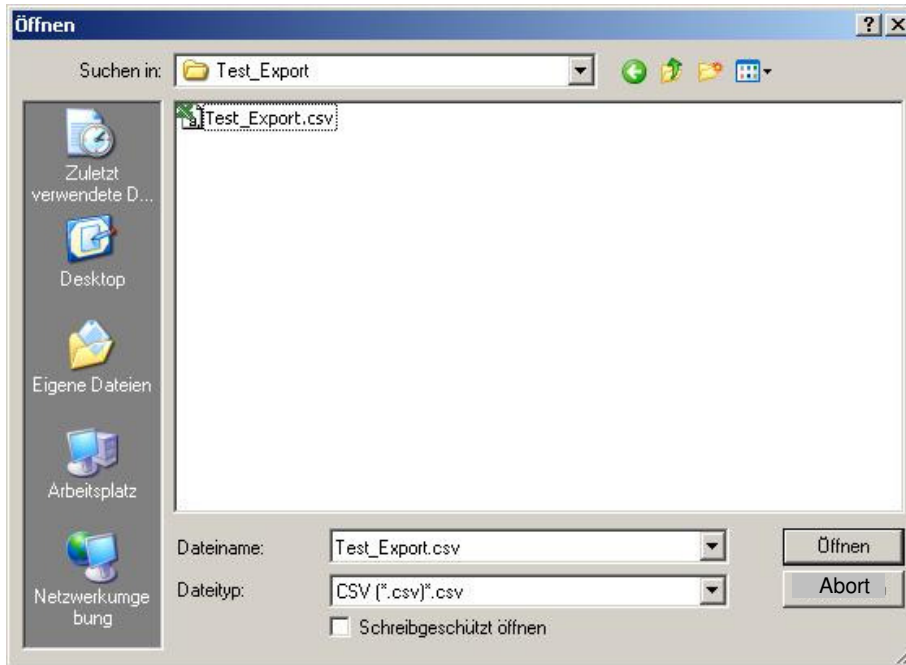
If a participant already exists in one or more databases, from which the data is to be imported, indicates this by showing the data name in a pop up, which must be accepted by selecting *OK*.





### 3.2 Importing the participants data from a CSV-File

By selecting the button *CSV file import* the participant's data are loaded into the analysis programme. Select the folder in which the participant's data were saved.



The memory location for the participants data from the Knot-O-Meter's analysis programme is:  
*C:\Dokumente und Einstellungen\<USER>\Eigene Dateien\Knot-O-Meter\Participants\*

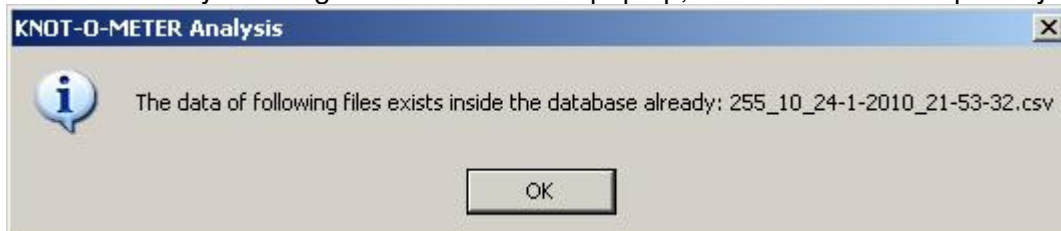
Select file and accept with *OK*.

When files were successfully imported following message will be showed:



Return to the main map with *OK*.

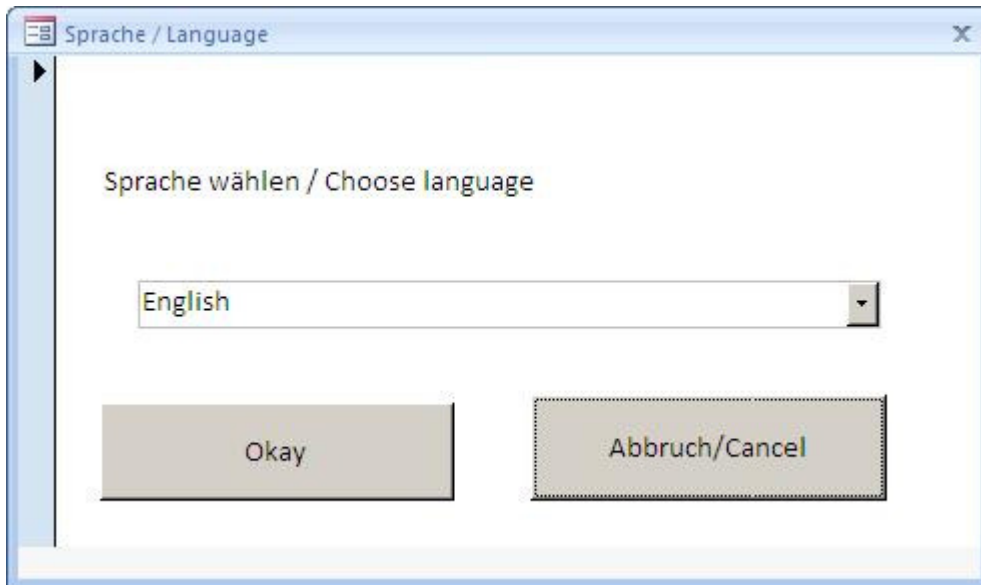
If a participant already exists in one or more databases, from which the data is to be imported, indicates this by showing the data name in a pop up, which must be accepted by selecting *OK*.





### 3.3 Select language:

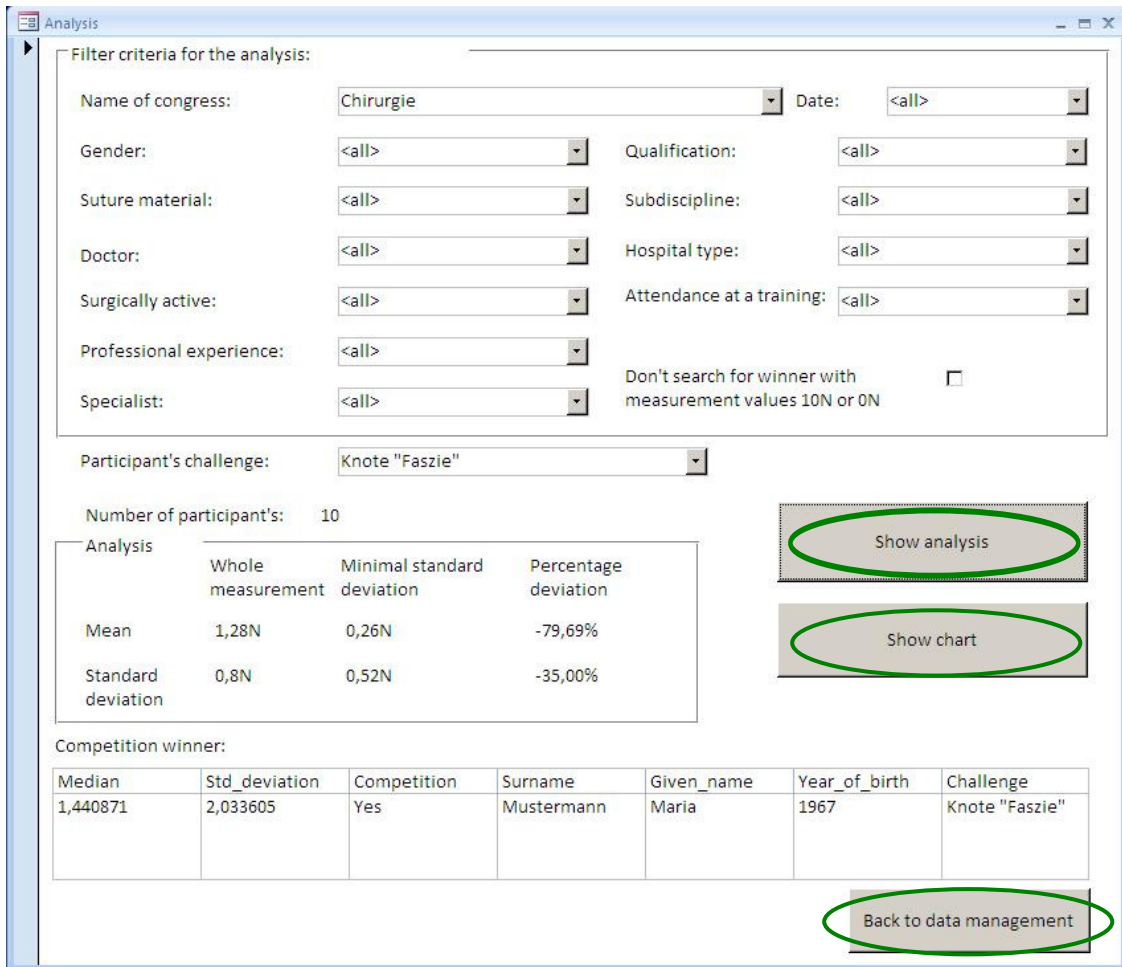
With the button *Sprache/Language* the language German / English can be chosen:



Chose language in the list and accept with „Okay“.

### 3.4 Analysing the participants data

By selecting the button “Show analysis”, the import of the analysis data is started.



The screenshot shows the 'Analysis' window with the following elements:

- Filter criteria for the analysis:** A grid of dropdown menus for Name of congress (Chirurgie), Date (<all>), Gender (<all>), Qualification (<all>), Suture material (<all>), Subdiscipline (<all>), Doctor (<all>), Hospital type (<all>), Surgically active (<all>), Attendance at a training (<all>), Professional experience (<all>), and Specialist (<all>). There is also a checkbox for 'Don't search for winner with measurement values 10N or 0N'.
- Participant's challenge:** A dropdown menu set to 'Knote "Faszie"'. Below it, 'Number of participant's: 10' is displayed.
- Analysis Results Table:**

Analysis	Whole measurement	Minimal standard deviation	Percentage deviation
Mean	1,28N	0,26N	-79,69%
Standard deviation	0,8N	0,52N	-35,00%
- Competition winner:** A table with columns: Median, Std\_deviation, Competition, Surname, Given\_name, Year\_of\_birth, Challenge.
 

Median	Std_deviation	Competition	Surname	Given_name	Year_of_birth	Challenge
1,440871	2,033605	Yes	Mustermann	Maria	1967	Knote "Faszie"
- Buttons:** 'Show analysis' and 'Show chart' are circled in green. 'Back to data management' is also circled in green.

All records which were read out over the participants' data can be filtered in the overview. E.g. was the data only put in with the participant's challenge: knot „Faszie“ only this challenge can be selected.

#### Usage of the buttons:

##### *Show analysis*

The analysis of the selected filter criteria is started and the result shows up in the area analysis.

##### *Show chart*

The result shows up in a separate window in a diagram.

##### *Back to the data management*

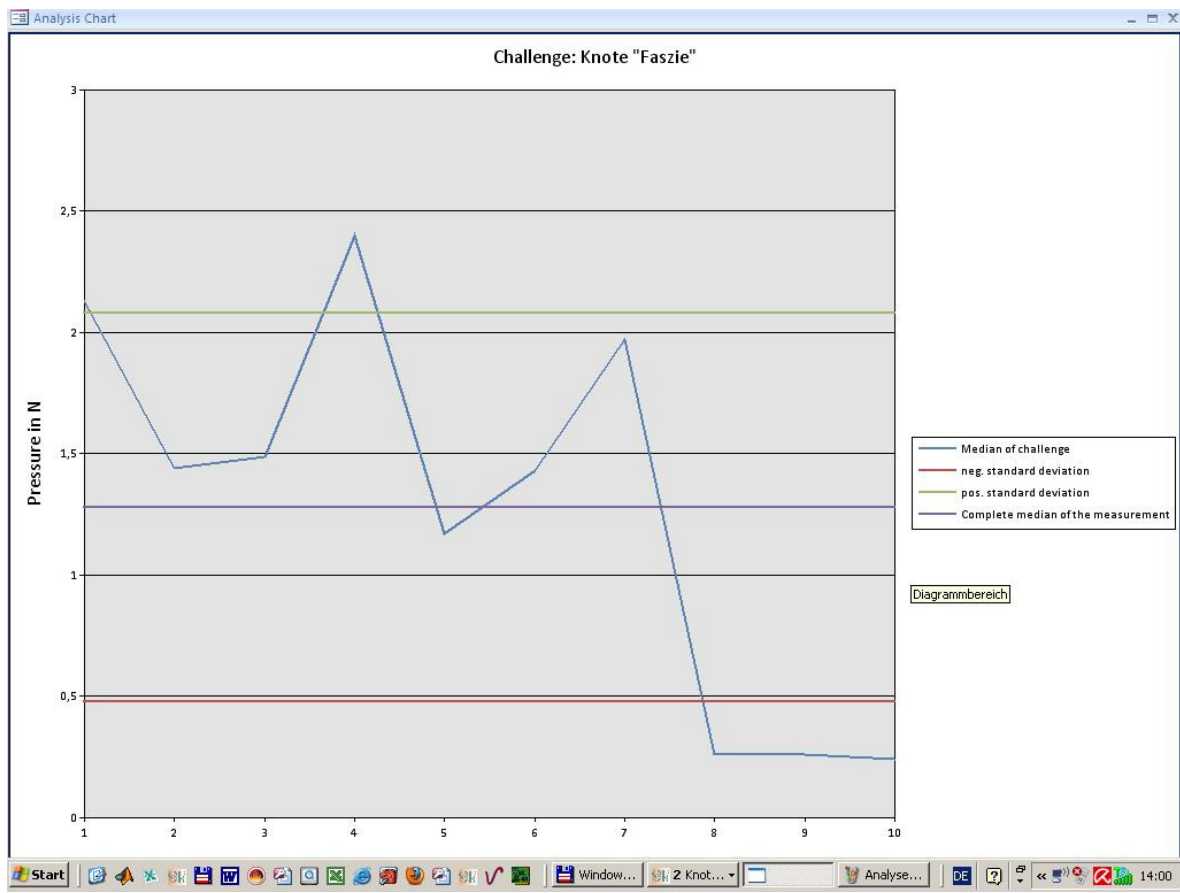
Ends analysis and returns to the overview.

#### Displayed:

- The challenge the participant had to knot with (at the same time to the selection that was filtered).
- The number of participants knotting in the same challenge

- The average value of all filtered measurements and the standard deviations of the whole measurement (in relation to the average value of the complete measurement and not the single sensors).
- The value of the current measure, the average value and the standard deviations
- The percentage deviation of the current measurement from the value of the selection.
- Prize-list with the least standard deviation between single knots and selected filter criteria.

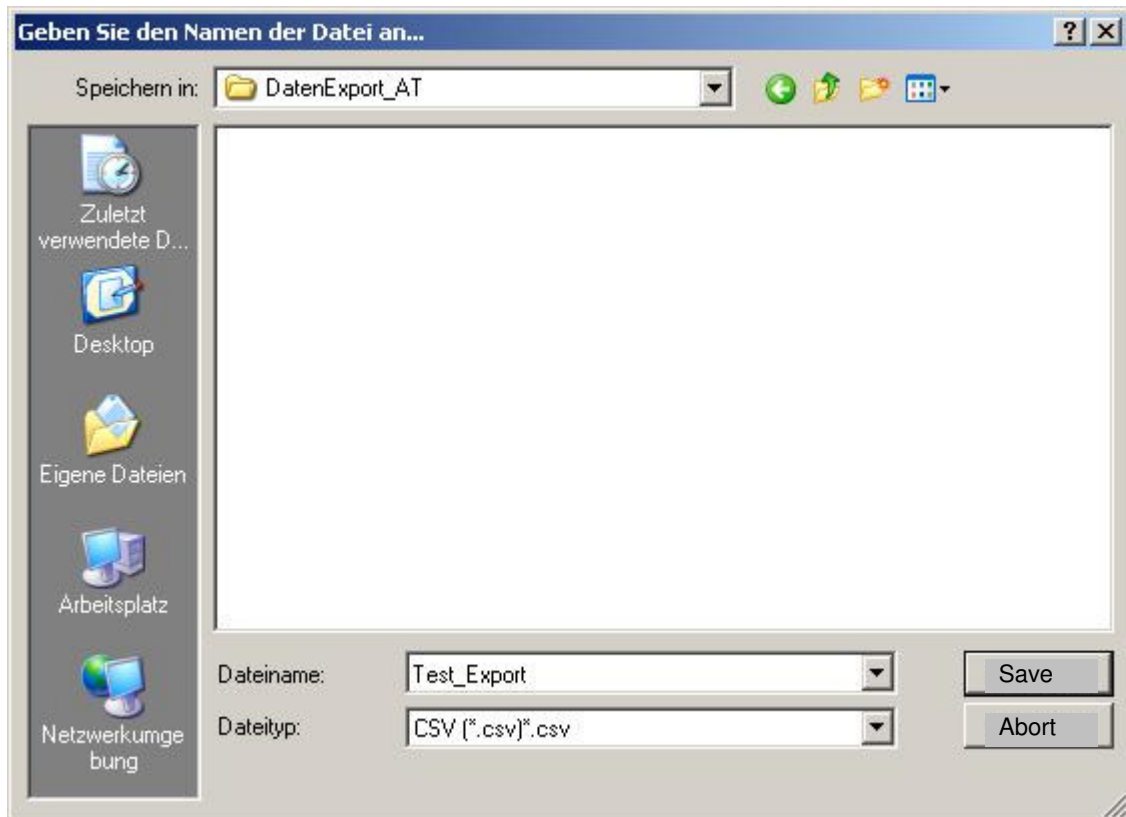
E.g. for the presenting in a diagram:



### 3.5 Exporting the participants' data

Has the analysis finished and the data should be imported into a general CSV-File, the button *Export Data* needs selecting.

For this, the memory location for the participants' data from the analysis program and the name of the file are selected in this window:



E.g. *Test\_Export.csv*

To save the file, select *Save*.

When files were successfully exported following message will be showed:



Select OK to return to the main menu

All values from all measurements (of one participant) are in the exported CSV-file in a row with 32 columns, containing following values:

A	B	C	D	E	F
Device-ID	Date and Time	Participant ID	Given Name	Sir Name	Year of Birth
1	25.04.2009 00:07	20	Max	Mustermann	1900
1	26.04.2009 07:29	2	Maria	Mustermann	1967

G	H	I	J	K	L	M	N	O	P
Max-Value Sensor1	Max-Value Sensor 2	Max-Value Sensor 3	Max-Value Sensor 4	Max-Value Sensor 5	End-Value Sensor 1	End-Value Sensor 2	End-Wert Sensor 3	End-Value Sensor 4	End-Value Sensor 5
1,1772	0	0,04905	0	0	1,1772	0	0	0	0
7,510781	5,529273	8,688857	4,745919	9,442125	2,905269	0	0	0	4,299088

Q	R	S	T	U	V	W	X	Y
Average of the End Values	Standard Deviation of the End Values	Congress	Place	Attendance to Competition	Gender	Suture material	Surgeon ?	Surgically active?
0,23544	0,5264598	126. DGCH	Munich	no	male	Vicryl 1	yes	yes
1,440871	2,033605	126. DGCH	Munich	yes	female	Vicryl 1	yes	no

Z	AA	AB	AC	AD	AE	AF
Professional experience	Specialist	Qualification	Subdiscipline	Participant's type of clinic	Attendance at a training	Participant's challenge
0 - 1 years	yes	Assistant	Hand surgery	Basic and regular medical care	no training	Knot "Enteroanastomosis "
0 - 1 years	no	Assistant	Andere	Basic and regular medical care	No training	Knot "Fascia"

**Important:** If in one table element is displayed “nu” (not used) this particular setting were not used by the participant.