

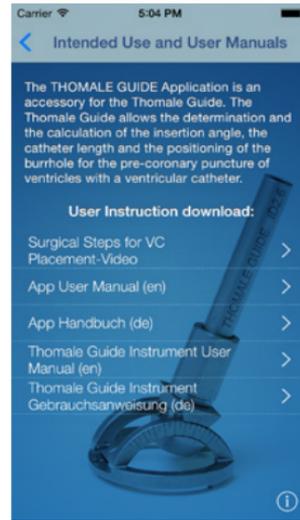


THOMALE GUIDE Application

© Software Manual

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INTENDED USE

The *THOMALE GUIDE Application* is a tool to assist ventricular catheter placement. It helps to determine and calculate the insertion angle, the catheter length and entry point using a frontal approach.



Starticon

TECHNICAL DESCRIPTION

The *THOMALE GUIDE App* allows the forecast of the ventriculopuncture with a VC via a frontal pre-coronary burrhole.

To achieve an individual measurement of the coronary insertion angle, a coronary cross-section of the patient, most suitable as a thin-layer chromatography or a MRI data set, is necessary.

The level of the entry point (burrhole) should be the starting point for the coronary-cross section.

The App asks for a definition of three spots: the burrhole, the position of the standing supports of the *THOMALE GUIDE* and the target point

of the ventricular catheter's tip. The *THOMALE GUIDE App* determines and calculates the insertion angle with this information, which later is used for the adjustment of the *THOMALE GUIDE*.

Further more, an integrated measurement operation mode allows the measurement of the ventricular catheter's length and the distance from the burrhole to the anatomic middle line.

The App stores the determined data in a database and it provides the data for a projected operation.

PRE-OPERATING INSTRUCTIONS

Before applying the *THOMALE GUIDE App*, an essential requirement for the intended use of the *THOMALE GUIDE App* is to have the relevant patient images already stored on the iOS device.

Notice: All calculations made with aid of the *THOMALE GUIDE App* should be done and completed before the start of the operation.

DEPLOYMENT OF IMAGE DATA

The following file formats for patient images are supported: .png, .jpg, .jpeg.

Two ways exist to provide image data for the intended use of the *THOMALE GUIDE App*:

Store image data in the iOS-image gallery:

To store images in the image gallery (called also Photo App or Camera Roll), send the image via e-mail to the iOS-device and store in the image gallery.

Principally, photostream pictures are not displayed in the *THOMALE GUIDE App*.

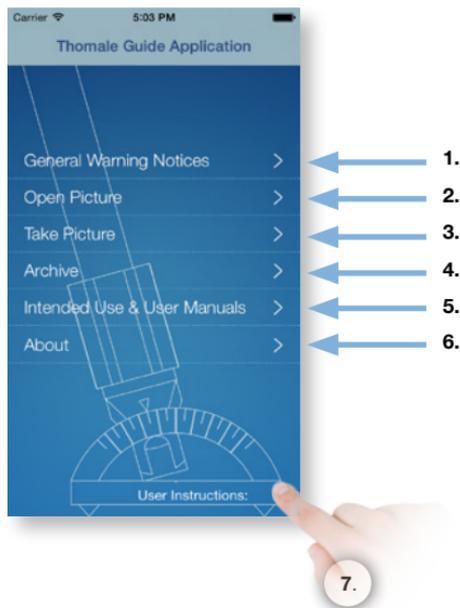
Store image data via iTunes und USB-cable:

Importing image data via iTunes or USB-cable directly to the App is possible. Therefore, a synchronisation of the iOS-device is not mandatorily necessary.

Method: Choose the respective device in iTunes, click on the tap „Apps“. Click on the button on the bottom of the *THOMALE GUIDE App* and move the image data inside.

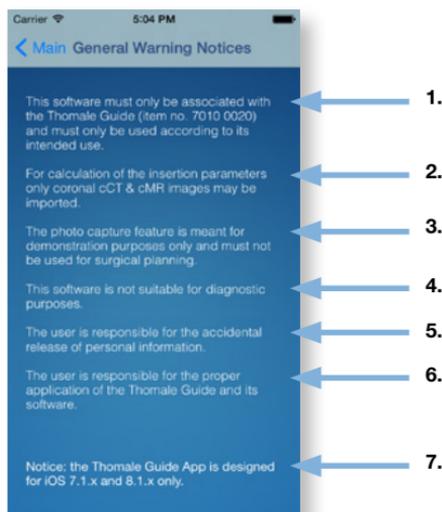
To avoid confusing images, we recommend to add an anonymous patient classification to the picture.

MAIN MENU



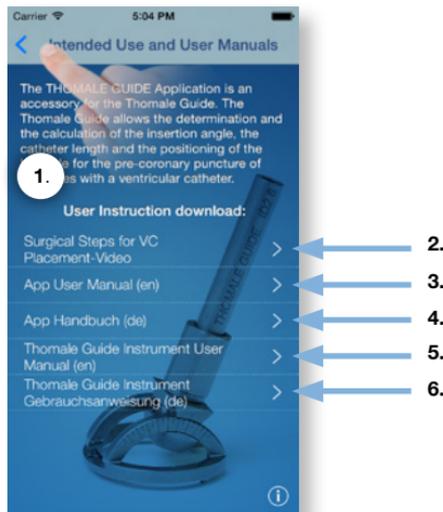
MAIN MENU	DESCRIPTION
1. General Warning Notices	General guidelines for a safe use of the App.
2. Import Picture	Select a cCT-, MRI-image from alternatively from the iOS image Gallery or from an iTunes import
3. Take picture	Take a picture of a CCT-, MRI-image using the internal camera of iPhone/iPad/iPod.
4. Archive	Share already stored patient data consisting of image/ insertion angle/ issue date.
5. Intended Use and User Manuals	Definition of intended use. Download area for instructions for use either for the <i>THOMALE GUIDE App</i> or the <i>THOMALE GUIDE</i> available.
6. About	Definition of normal use, software version, manufacturer, Miethke logo.
7. Help	Share auxiliary information referring to the Main Menu.

GENERAL WARNING NOTICES



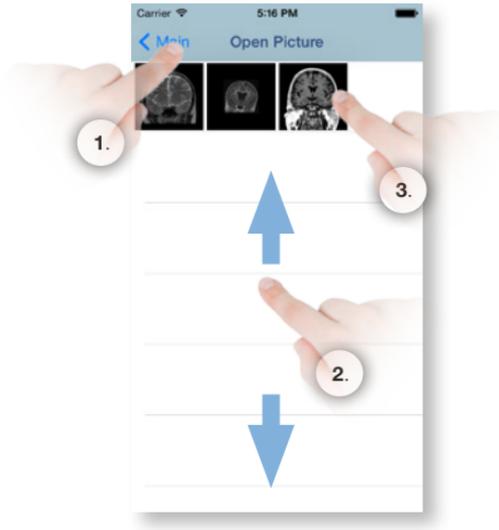
GENERAL WARNING NOTICES	DESCRIPTION
1. This software must only be associated with the TG, Item no. 7010 0020 and only be used according to the intended use.	The app-results of calculated angles and lengths serve only for the use with the <i>THOMALE GUIDE</i> .
2. For the calculation, only frontal CCT & MR images must be imported.	A precondition for the correctness of the calculated values is: the applied cross-sections must have the specified format.
3. The photo capture feature is not intended for surgical planning, it is meant for demonstration purposes only.	Taking images in an unprofessional way can lead to falsifications of the image and subsequently to alterations of geometrical dependencies.
4. This software is not suitable for diagnostic purposes.	No liability will be accepted for a diagnosis done using CCT or MR images.
5. The user is responsible for the accidental release of personal information.	The app organizes the results in the form of data stored in an image archive. The archive is not available for other applications. If personal data should become public, the manufacturer will assume no liability.
6. The proper application is the responsibility of the user.	Neurosurgical expertise is required to properly use the app.
7. This app is intended for use with iOS 7.1 and 8.1 only.	The app will be updated for future operating systems and currently only supports iOS 7.1 and 8.1 as certain features are not supported in earlier versions.

USER INSTRUCTION DOWNLOAD



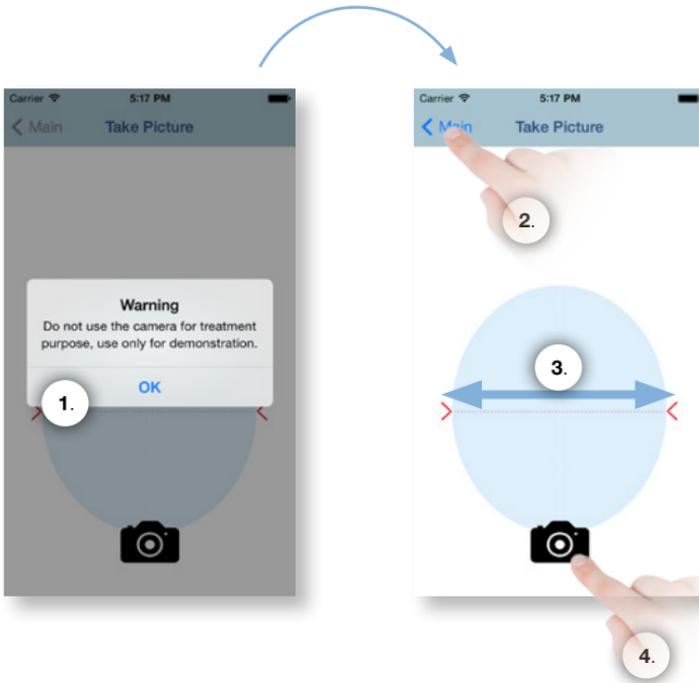
INTENDED USE AND USER MANUALS	DESCRIPTION
1. User Instruction download	The downloads below REQUIRE AN INTERNET CONNECTION. Once downloaded a document can be viewed offline. These support documents can be updated independently from this app. The <i>THOMALE GUIDE App</i> automatically checks for the latest version
2. Surgical Steps for VC Placement - Video	Touch SURGICAL STEPS FOR VC PLACEMENT - VIDEO to watch a 3 minutes Video with an example of using the <i>THOMALE GUIDE App</i> and the <i>THOMALE GUIDE Instrument</i> together on a patient.
3. App User Manual (en)	Touch APP USER MANUAL (EN) to see the full User Manual of the <i>THOMALE GUIDE Application</i> in English.
4. App Handbuch (de)	Touch APP USER MANUAL (DE) to see the full User Manual of the <i>THOMALE GUIDE Application</i> in German
5. THOMALE GUIDE Instrument User Manual (en)	Touch THOMALE GUIDE INSTRUMENT USER MANUAL (EN) to see the full User Manual of the <i>THOMALE GUIDE Instrument</i> in English.
6. THOMALE GUIDE Instrument Gebrauchsanweisung (de)	Touch THOMALE GUIDE INSTRUMENT GEBRAUCHSANWEISUNG (DE) to see the full User Manual of the <i>THOMALE GUIDE Instrument</i> in German

OPEN PICTURE



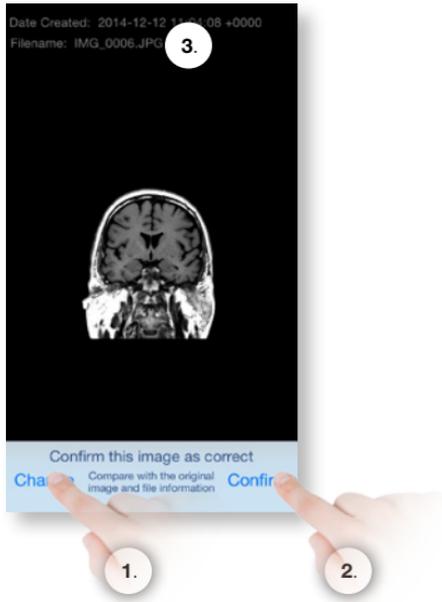
FUNCTION	DESCRIPTION
1. Main Button	Return to the main menu is possible by touching this button with your finger.
2. Scroll-Mode	CCT and MR images can be selected by swiping a finger up or down on the screen and by applying constant pressure with a finger on an image.
3. Selection	A selection is made by tapping on a specific image with the finger.

TAKE PICTURE



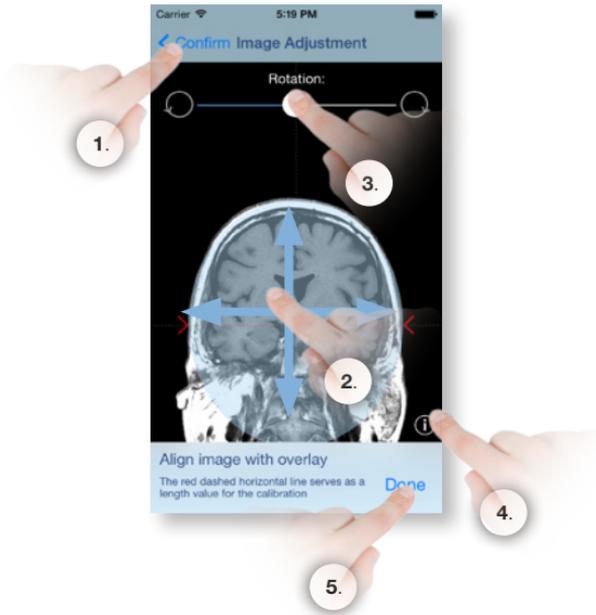
FUNCTION	DESCRIPTION
1. Warning: Do not use the camera for treatment purposes, use only for demonstration.	The amateur capture of images can lead to a distortion of the image and can thus lead to changes in the geometric constraints.
2. Main Button	A return to the main menu can be made at anytime by pressing this button.
3. Overlay	The skull should be fitted as good as possible into the gray oval mask. The focus should be on the temporal diameter roughly at the level of the horizontal dashed line. A precise alignment can be made in an extra step.
4. Camera Button	The image is recorded by pressing this button which is then archived into the photo album.

CONFIRM PICTURE



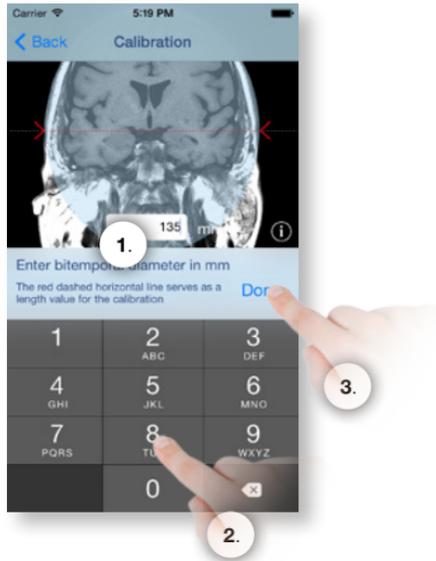
FUNCTION	DESCRIPTION
1. „Change“-Button	Selection will automatically redirect the user back to the „Open picture“ or „Take Picture“ - screen.
2. „Confirm“-Button	Initially, compare the indicated image with the original picture. Selection confirms this image and leads to „Image adjustment“.
3. Metadata	Displays metadata about the file: creation date, and file name.
4. „Compare with the original image and file information“	Compare the indicated image with the original picture.

IMAGE ADJUSTMENT



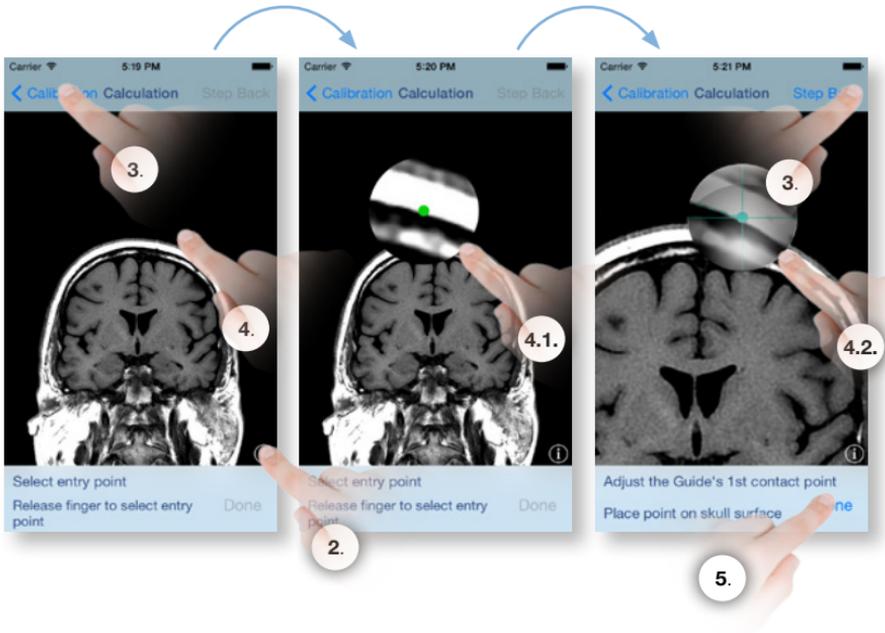
FUNCTION	DESCRIPTION
1. „Confirm“- Button	Selection will take the user back to the „confirm this image as correct“ - screen.
2. Align image with overlay	The image can be moved with the simultaneous continuous pressure on the screen with one or more fingers to achieve an accurate coverage of the skulls bitemporal diameter with the template at the level of red dotted line. By changing the distance between two fingers on the touch screen, the skull size can be fitted to the overlay.
3. Rotating the image	The skull can be rotated by adjusting the red slider thereby aligning the anatomical centre line perpendicular to the dashed line on the template. By touching the rotary symbols a rotation of 1° is made. As an alternative, rotate with two fingers inside the image section.
4. „Info“- Button	Access to help information related to the „Image adjustment“ - screen.
5. „Done“- Button	By selecting the „Done“ button, the proportions of the depicted skull will be transferred to the app.

CALIBRATION



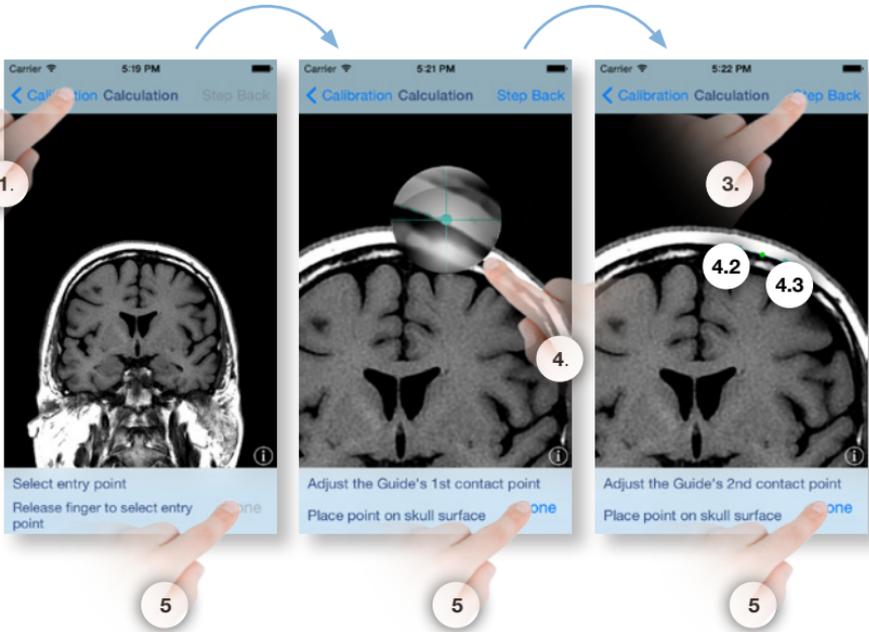
FUNCTION	DESCRIPTION
1. Enter the bitemporal diameter in mm	<p>Enter the bitemporal diameter of the skull in mm in the open text field. The number entered should not be less than 30 mm and not greater than 300 mm. The input is limited to three characters. Only whole numbers allowed.</p> <p>The input is mandatory. The calculation will not be released if no value is entered.</p>
2. Numeric keypad	<p>By entering the appropriate numbers they will appear in the text field. The values can be corrected with the „left arrow“ button.</p>
3. „Done“- Button	<p>The input will be confirmed by selecting the „Done“ button.</p>

CALCULATION: SELECT ENTRY POINT



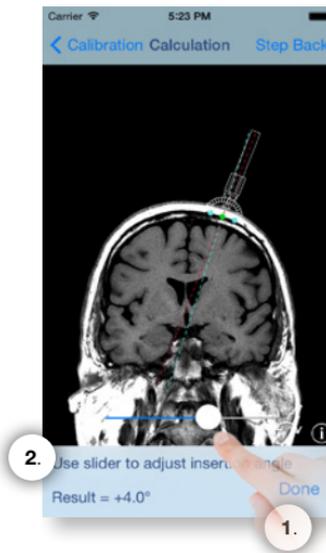
FUNCTION	DESCRIPTION
1. „Calibration“- Button	Selection will take the user back to the „Calibration“ - screen.
2. „Info“- Button	Access to help information related to the „Calculation“- screen.
3. „Step back“- Button	Selection will automatically return to the previous step.
4. Select Entry Point	The constant pressure with a finger on the screen will activate the magnifying lens function.
4.1 Select Entry Point	The position of the burrhole can be defined by moving the green crosshair to an anatomically meaningful place on the skull bone.
4.2 Select Entry Point	Removal of the finger leads to confirmation and selection of the burrhole. The position of the burrhole can be changed at any time by repeating steps 4. – 4.2..
5. „Done“- Button	Selection will confirm the changes.

CALCULATION: SELECT TANGENT POINTS



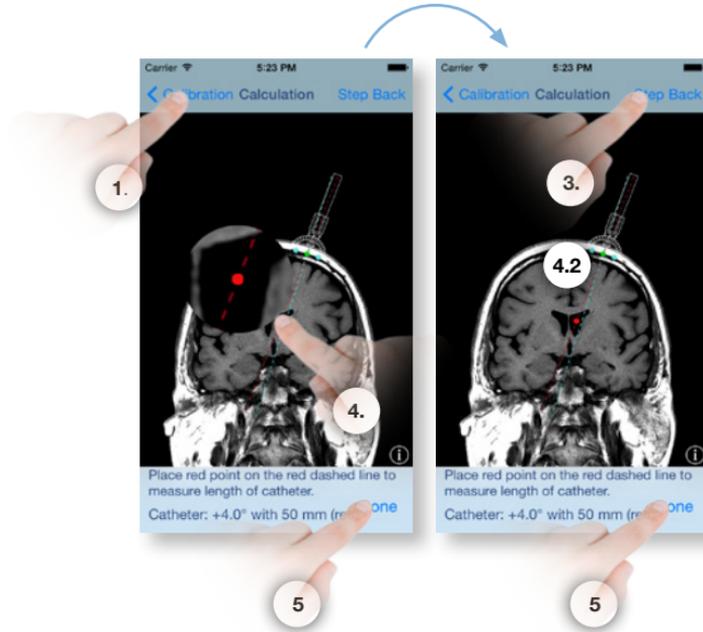
FUNCTION	DESCRIPTION
1. „Calibration“- Button	Selection will take the user back to the Calibration" - screen.
2. „Info“- Button	Access to help information related to the „Calculation" - screen.
3. „Step back“- Button	Selection will automatically return to the previous step.
4. Adjust First Tangent Point	The constant pressure with a finger on the screen will activate the magnifying lens function. The magnifying lens zooms into the space underneath the finger. It is displayed on the top left from the touched spot.
4.1 Adjust First Tangent Point	The first foot of the <i>THOMALE GUIDE</i> is placed by moving the green crosshair to anywhere on the skull bone.
4.2 Adjust First Tangent Point	Removal of the finger leads to confirmation and selection of the position of the first foot. The position of the feet can be changed at any time by repeating steps 4. – 4.2..
4.3 Adjust Second Tangent Point	Steps 4 – 4.2 are repeated for the second foot of the <i>THOMALE GUIDE</i> .
5. „Done“- Button	The input will be confirmed by selecting the „Done" button.

CALCULATION: INSERTION ANGLE ADJUSTMENT



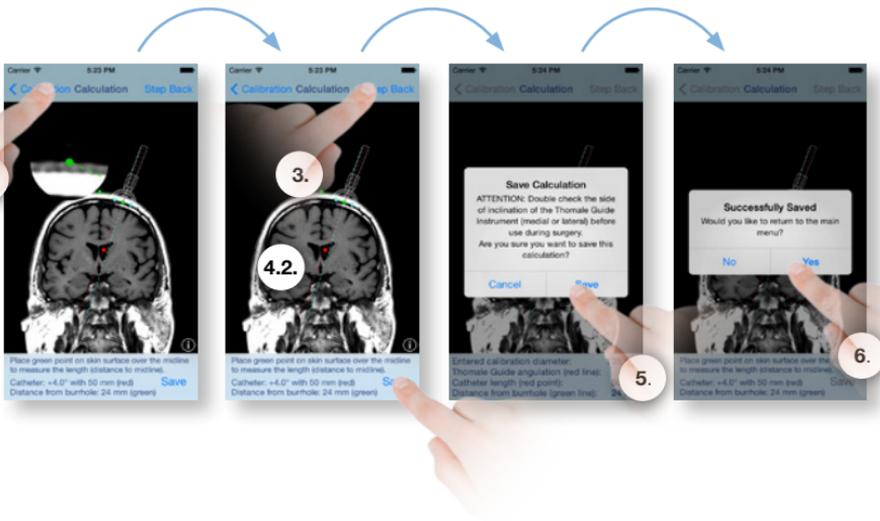
FUNCTION	DESCRIPTION
1. „Use slider to adjust insertion angle“	<p>The angle between the perpendicular to the tangent and the insertion length can be changed by moving the red slider to the left or right.</p> <p>An angular adjustment is possible only in 0.5° steps, the app automatically rounds.</p> <p>The angle will be confirmed once the finger is released.</p>
2. Result	<p>At this point, the measured angle will be displayed with a tolerance of + / - 1°. To avoid mistakes attention should be given to the direction in which the instrument is inclined (medial or lateral).</p>

CALCULATION: CATHETER LENGTH MEASUREMENT



FUNKTION	BESCHREIBUNG
1. „Calibration“-Button	Selection will take the user back to the „Calibration“ - screen.
2. „Info“-Button	Access to help information related to the „Calculation“ - screen.
3. „Step back“- Button	Selection will automatically return to the previous step.
4. Place red point to measure catheter length	The constant pressure with a finger on the screen will activate the magnifying lens function.
4.1 Place red point to measure catheter length	By moving and releasing the green crosshair anywhere on the image, the distance between burrhole and destination is defined and can be used for example to measure the ventricular catheter's length or the distance to the anatomic centre line. This action can be repeated more than once.
4.2 Place point to measure length	The length between the burrhole and the selected point used, will be displayed with a tolerance of ± 2 mm.
5. „Done“- Button	The input will be confirmed by selecting the „Done“ button.

CALCULATION: LENGTH MEASUREMENT



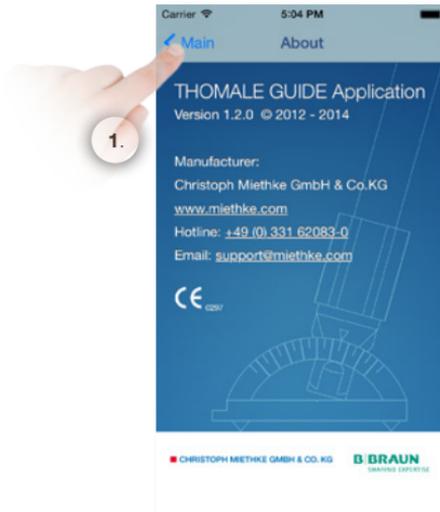
FUNCTION	DESCRIPTION
1. „Calibration“-Button	Selection will take the user back to the „Calibration“ - screen.
2. „Info“-Button	Access to help information related to the „Calculation“- screen.
3. „Step back“- Button	Selection will automatically return to the previous step.
4. Place green point to measure length	The constant pressure with a finger on the screen will activate the magnifying lens function.
4.1 Place green point to measure length	By moving and releasing the green crosshair anywhere on the image, the distance between burrhole and destination is defined and can be used for example to measure the ventricular catheter's length or the distance to the anatomic centre line. This action can be repeated more than once.
4.2 Place point to measure length	The length between the burrhole and the selected point used, will be displayed with a tolerance of ± 2 mm.
5. „Save“-Button	To confirm press „Save“ and to reject press the „Cancel“ button which will automatically take the user back to the last step.
6. „Successfully saved, would you like to return to the main menu?“	To confirm press „yes“ and to reject press the „no“ button which will automatically take the user back to the last step.

ARCHIVE



FUNCTION	DESCRIPTION
1. Main Button	Return to the main menu is possible by touching this button with your finger.
2. Edit	Selection will activate the delete function. All patient data will have the „lock“ symbol added to it.
2.1. Edit	By selecting the „lock“ symbol the delete function is activated.
2.2. Edit	The patient data can be deleted by selecting the „delete“ button.
3. Alternative - Deleting with swipe gesture	Alternatively the delete button can be activated by swiping a finger across the bar.
3.1. Alternative - Deleting with swipe gesture	The patient data is deleted by selecting the „delete“ button.

ABOUT



FUNCTION	DESCRIPTION
1. Main Button	A return to the main menu can be done at anytime by pressing this button.
2. „THOMALE GUIDE Application“	Official name of the app.
3. Version 1.2.0 Copyright 2012-2014 Christoph Miethke GmbH & Co. KG www.miethke.com Hotline: +49 (0) 700 643843 Email: support@miethke.com	Version, date of manufacture, manufacturer, contact information. Touching www.miethke.com open the website in Safari. Touch the Email opens this address in the mail app. Touching the phone number enables a call on an iPhone after prior consultation.
4. Logos Miethke & BBraun	
5. CE 0297	CE mark with endorsement of the admission board.

TROUBLE SHOOTING

In case of a software error it is possible to exit the *THOMALE GUIDE* app by clicking on the home button and then to restart the app. Thereby the initial state is restored and only changes to the archive and imported pictures will be saved.

If further software errors occur, please feel free to contact us: support@miethke.com.

CONTRAINDICATION

The use of the *THOMALE GUIDE* is not advised if: a frontal way to the ventricles is not possible or not indicated; a parietal or occipital entry to the ventricle is not possible; a irregular anatomy of the skull surface or a FOHWR smaller than 0,05 exists.

Explanation: with a smaller FOHWR-value particularly close slit ventricles exist. In this case use a navigation guide for the positioning of the VC.

NOTE ON THE INSTRUCTIONS FOR USE

The descriptions and explanations given in this document are based on the clinical experience available up to date. It is for the surgeon to decide if surgical procedures should be changed according to his or her experience and to surgical practice.

MEDICAL PRODUCT CONSULTANT

In compliance with the requirements of the European law MDD 93/42/EEC, Christoph Miethke GmbH & Co. KG names medical product consultants as the individuals to be addressed with all queries concerning the products:

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CE marking according to directive 93/42/EEC

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Manufacturer acc. MDD 93/42/EEC:

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