Ossa 3D
User Manual

iOS App v1.0.0

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DESCRIPTION

OSSA 3D is a disruptive mobile app that allows medical experts to easily create their own 3-D medical models and rapidly design personalised implants safely and efficiently without the need for long wait times and complicated, expensive CAD design software.

The app has tools that allows physicians and engineers to:
- Securely import medical images from cloud (DropBox) or iTunes.
- Perform simple automated transformation (segmentation) of CT DICOM images into 3-D models in seconds. Preloaded anatomical model samples are included with the option to upload your own patient scans (requires DropBox app installation).
- Use your medical expertise to select clinically relevant anatomical models that support patient specific treatment.
- Plan your treatment and design implants using our unique patented sketch and sculpt mesh drawing technology allows physicians to automatically fit personalised implants and rapidly 3-D print their customised treatment plan. Pre-loaded generic implant samples are included with the option to upload additional industry implant libraries.
- Perform measurements, such as lengths and angles.
- Visualize the clinically relevant anatomy and surgical results.
- Save your work progress and images for later review.
- Accurate and reliable print-ready STL files are then sent to your in-house 3D printer or manufacturer reducing the time and cost needed for production.

INDICATIONS FOR USE.
The OSSA 3D software is for EDUCATIONAL AND RESEARCH PURPOSES ONLY and is NOT FOR DIAGNOSTIC/CLINICAL USE.
OSSA 3D is HIPAA & HITECH compliant featuring secure passcode protection, download and model encryption ensuring patient privacy and security.

SYSTEM REQUIREMENTS.
This app is optimized for iPad 3 or later and iOS8 or later.

SUPPORT.
Please visit http://www.conceptualiz.com/Support.html to learn how to use the app.
Have a question? Ask Conceptualiz richard@conceptualiz.com

CONCEPTUALIZ is the mobile app software company for medical image viewing, planning and fabrication. We provide physicians, engineers, hospitals and OEM's with the ability to achieve surgical planning and 3-D printing of medical models and personalized implants safely and efficiently without the need for long wait times and complicated, expensive CAD design software.

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Icons provided by https://icons8.com/
Preloaded anatomical model and generic implant samples provided by http://thinkingrobotstudios.ca

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GETTING STARTED

1. USER INTERFACE
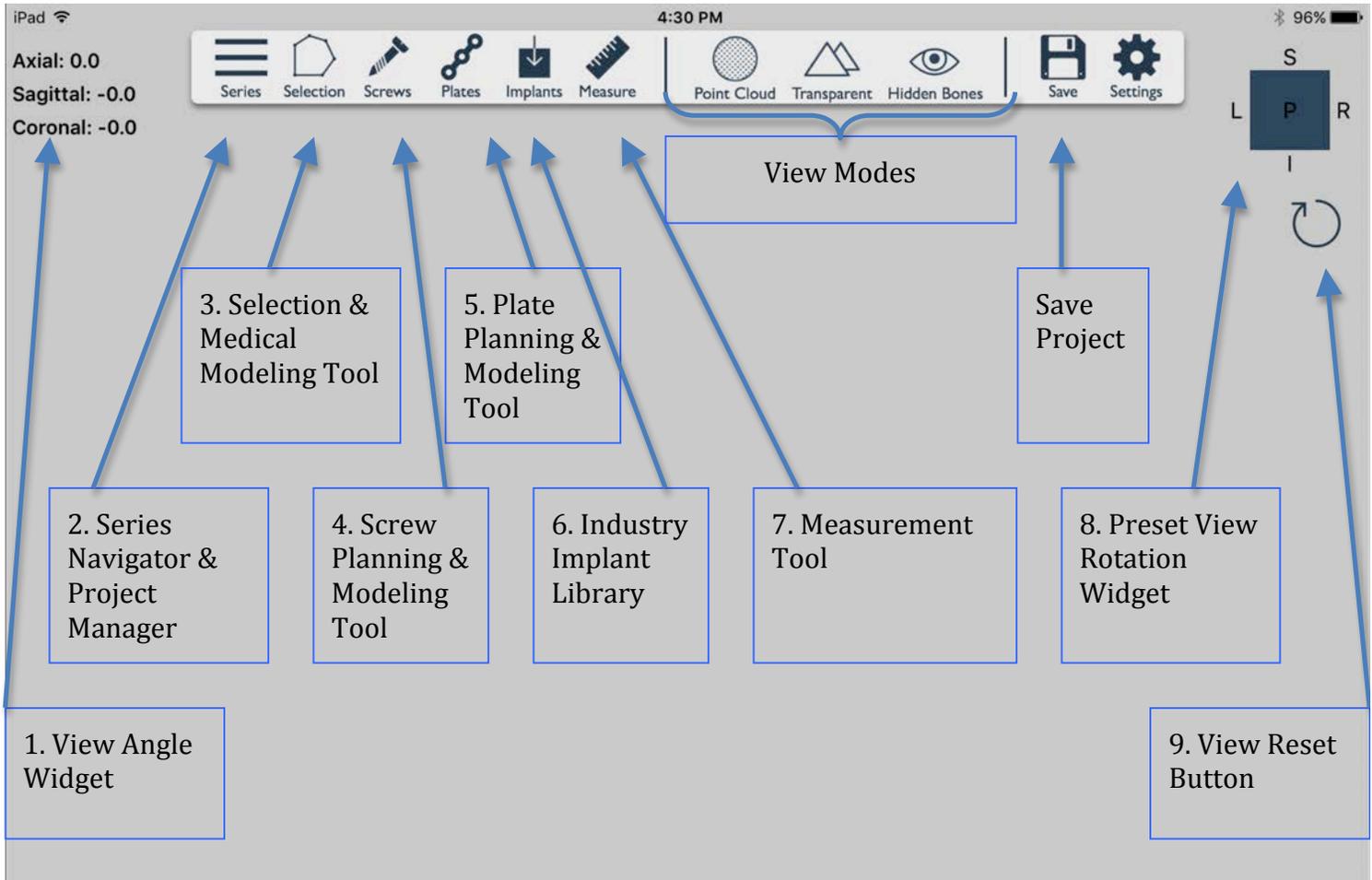
2. CONTROL GESTURES

- One finger pan (point and drag) gesture: *Rotates 3-D model in axial and sagittal planes.*

- Pinch/zoom gesture: *Zooms 3-D model in/out.*

- Two finger pan gesture: *Pans/translates 3-D model.*

- Two finger rotate gesture: *Rotates 3-D model in coronal plane.*

Speed up gesture performance using the Point Cloud view mode (see below).
If you notice that gesture responsiveness is suboptimal you can activate the Point Cloud view mode by tapping the *Point Cloud* button. This will render the solid 3-D model as a point cloud during gesture interaction thereby improving responsiveness for earlier generation iPads.

3. VIEW MODES

On/Off toggle buttons are located in the toolbar (highlighted when toggled On).

Point Cloud   Transparent   Hidden Bones

Point Cloud:
Speeds up gesture performance - if you notice that gesture responsiveness is suboptimal you can activate the Point Cloud view mode by tapping the *Point Cloud* button. This will render the solid 3-D object as a point cloud during gesture interaction thereby improving responsiveness for earlier generation iPads.

Transparent:
Simulates x-ray emulation – useful for surgical planning of instrument, implant or x-ray beam trajectories.

Hidden Bones:
Displays previously hidden objects – useful for retrieving previously hidden objects resulting from the medical modeling process (see below).
- Activating the *Hidden Bones* button will display all hidden objects in color grey.
- Tap on them and choose *Show* to unhide them.
- Be sure to deactivate the *Hidden Bones* view mode following object retrieval.

4. SAVE PROJECT

Save your work progress and images for later review by tapping on the *Save* button located in the toolbar.

Save

Taking screen shots:
Press and hold the Sleep/Wake button on the top or side of your iPad then immediately press and release the Home button.
You can find the screenshot in your Photos app.

5. SETTINGS MENU

Purchases: Buy Features
To import/export .DICOM files, .stl and .obj files you must purchase the in-app import feature.
- Tap *Settings* located in the toolbar and tap *Purchases > Buy Features*.
- Tap *Restore* to reactivate the product if previously purchased on your iPad.

Security: Enable Passcode
OSSA 3D is HIPAA & HITECH compliant featuring secure passcode protection, download and model encryption ensuring patient privacy and security.
- Tap *Settings* located in the toolbar and tap *Security > Enable Passcode*. Then enter desired passcode.
- To ensure complete patient privacy we also recommend patient scans be anonymised of all personal identifying data prior to uploading to Dropbox.

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TOOLS

1. VIEW ANGLE WIDGET
- Located in the top left corner of the screen.
- Indicates view angle of 3-D model in relation to orthogonal planes (axial, sagittal and coronal).
- Use *Transparent* view mode to simulate x-ray emulation for surgical planning of instrument, implant or x-ray beam trajectories.

2. SERIES NAVIGATOR & PROJECT MANAGER
- Tap the *Series* button located in the toolbar to:
    - Create and manage new 3-D model projects (see "How To's" section below).
    - Import .DICOM files from Dropbox for segmentation of 3-D models (see "How To's" section below).

3. SELECTION & MEDICAL MODELING TOOL
Use your medical expertise to select clinically relevant anatomical models that support patient specific treatment.

Selecting anatomical models:
- Load your desired 3-D medical model (see "Create a new project" below).
- Rotate the 3-D model to minimize tissue overlap and obtain an un-obscured view of the anatomical structure of interest.
- Tap on the *Selection* button located in the toolbar.
- Drag to draw a continuous loop around an object you want to select and tap *Select* from the pop up menu to complete the selection.
    - If and error is made drawing the loop tap *Cancel* to restart the loop.
- Now the newly selected anatomical model can be moved independently from the main 3-D model using the same control gestures as previously described above. This is useful for reducing fracture fragments and making virtual osteotomies.
- If you wish to undo your selection tap on the recently selected object, a pop up menu will appear allowing you to either *Lock, Hide, Undo or Export selection*. Tap *Undo selection*.
- To fine-tune or refine your model you may repeat the selection process multiple times. To do this tap on the *Selection* button and draw additional loops but instead tap *Refine selection*.
- Multiple anatomical model selections are possible.
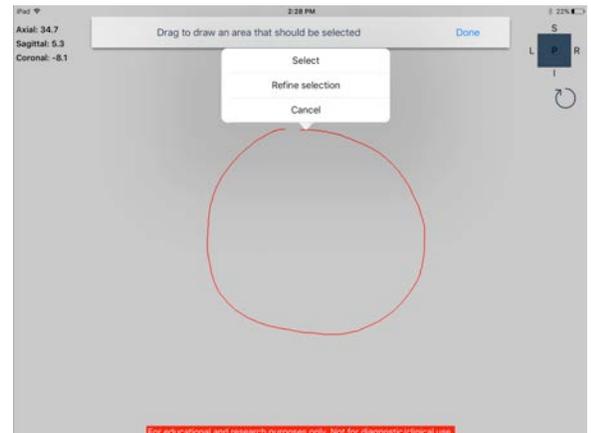
Hiding parts of anatomical models:
- Tap on the selected (or non-selected) part of the model.
- A pop up menu will appear allowing you to *Lock, Hide, Undo or Export selection*. Tap *Hide selection* and the object will disappear.

- To undo tap on the *Hidden Bones* view mode in the toolbar. This will show all hidden tissues colored in grey. Tap on them and choose *Show* to unhide them. Be sure to deactivate the *Hidden Bones* view mode again

Locking the position of anatomical models:
- Tap on the selected object.
- A pop up menu will appear allowing you to *Lock, Hide, Undo or Export selection*. Tap *Lock selection* and the object will be locked in the desired position. This is useful for surgical planning of fracture reduction or osteotomies.
- To undo tap on the selected object and select *Unlock.*

Exporting anatomical models to iTunes sharing:
- Tap on the selected object. A pop up menu will appear allowing you to *Lock, Hide, Undo or Export selection*. Tap *Export selection* and the selected model will saved to iTunes file sharing.
- To retrieve exported .stl files:
    - Open iTunes and connect your iPad to your computer.
    - View your iPad on iTunes.
    - Under *Settings > Apps* scroll down to *File Sharing*, select *Ossa 3D*.
    - Exported medical model .stl files will show up as fragment_#.stl
    - Click on the desired medical model and click *Save to…* to choose your destination folder.
Note: Exported .stl files can again be uploaded to Dropbox and imported as an individual 3-D model project or as an implant to use in other projects (import through the *Implants* button in the toolbar – see "6. INDUSTRY IMPLANT LIBRARY" section below).

4. SCREW PLANNING & MODELING TOOL
- Load your desired 3-D medical model (see "Create a new project" below).
- For best results switch to *Transparent* view mode by tapping on *Transparent* button in the toolbar.
- Rotate the 3-D model to obtain the desired start point and trajectory of your proposed screw.
- Tap the *Screws* button located in the toolbar. Choose either 3.5mm or 4.5mm diameter screws.
- Perform a single tap gesture on the model to add the screw. A 10mm length screw will automatically be placed starting at the near bone surface and desired start point with a trajectory that follows the screen view.
- Control points at the ends of each screw allow for modification of length and trajectory by pointing and dragging each control point - measurements are given in mm.
- Multiple screws are possible.
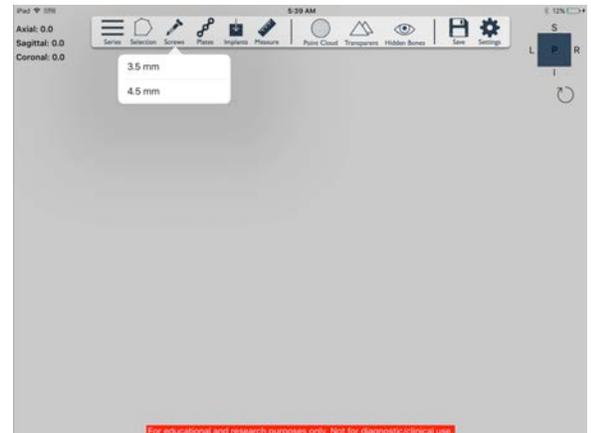
Note: Where a plate has been placed prior to screw placement (see below) green targets appear where the holes in the plate are. Tap on the green targets to fit the screw into the hole. Screws are automatically rotated to match the orientation of the plate.

Screw options:

Tap on the screw to access options.

- *Show Trajectory/Show Screw:* Replaces screw model with a trajectory line which is useful for surgical planning. Tap the line to show the screw again.
- *Hide/Show Length:* Hides/shows the screw length measurement
- *Edit/Done editing: S*hows/Hides control points.
- *Email Screw/ Email All Screws*: Converts desired screw models to .stl format for emailing to your 3-D printing manufacturer.
- *Delete:* Deletes the screw.

5. PLATE PLANNING & MODELING TOOL
- Load your desired 3-D medical model (see "Create a new project" below).
- Rotate the 3-D model to bring the desired anatomical area to be plated into view.
- Tap on the *Plates* button located in the toolbar. Choose the generic 3.5mm reconstruction plate.
- Simply tap on the model surface or draw a curve to place plate control points. The software will automatically design a plate that precisely matches the underlying surface shape of the bone (automatic out-of-plane contouring and twisting).
- Blue control points appear in the plate:
    - Drag them to modify the shape of the plate (in-plane contouring).
    - Drag the first/last control point to increase/decrease length of the plate.
- Green control points appear where the distance between blue points is too large and the plate does not accurately fit the underlying bone surface. Tap on the green control points to more accurately fit the plate to the underlying bone surface. This process creates a new blue control point that you can use to fine-tune the plate position as previously described.
- To finalise your plate design tap on any control point and choose *Done Editing.* This pop up menu also allows unwanted blue control points to be deleted if necessary.
- Multiple plates are possible.
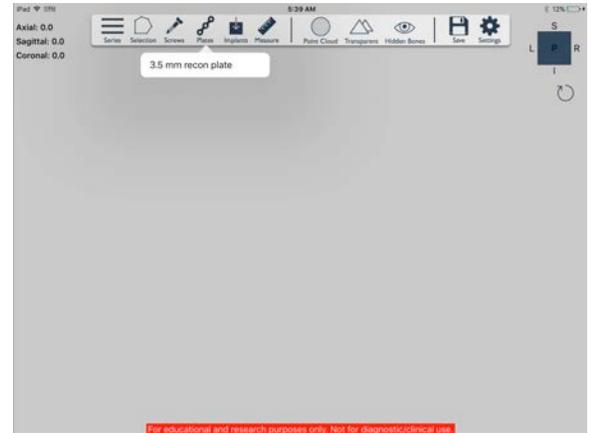
Plate options:

Tap on the plate to access options.
- *Edit:* Shows control points to allow further editing.
- *Email plate/ Export plate to iTunes:* Converts desired plate models to .stl format for emailing to your 3-D printing manufacturer.
- *View Plate:* shows the plate in a separate view in a 1:1 real life size ratio useful for analyzing plate contour. The plate can be manipulated in this view using the same control gestures as previously described above. To return the plate to its actual 1:1 real life size in mm select the icon in the top right corner.
Delete: Deletes the plate.

Note: Where a plate has been placed prior to screw placement (see below) green targets appear where the holes in the plate are. Tap on the green targets to fit the screw into the hole. Screws are automatically rotated to match the orientation of the plate.

6. INDUSTRY IMPLANT LIBRARY
Pre-loaded generic implant samples are included with the option to upload additional industry implant libraries.

- Load your desired 3-D medical model (see "Create a new project" below).
- For best results switch to *Transparent* view mode by tapping on *Transparent* in the toolbar.
- Tap the *Implants* button located in the toolbar.
- Choose an implant from the library of pre-loaded implants; scroll down to see all implants.
- Perform a single tap gesture on the model to place the implant.
- The implant can be moved independently from the main 3-D model using the same control gestures as previously described above.
- Adjust the implant to the desired position and size. Note: zooming in will help with this process.
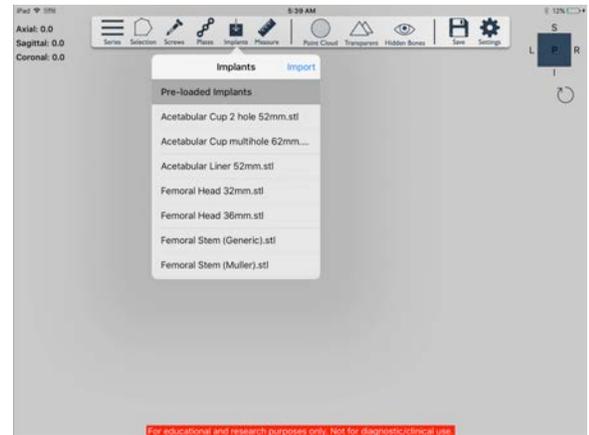
Note: You can import additional industry implants (or medical models) in .stl or .obj format from Dropbox to the Implants library by tapping *Import* in the Implants library. This requires an in-app purchase to unlock this feature. Go to the Settings in the tool bar and tap on *Purchases > Buy Features*.

7. MEASUREMENT TOOL
Perform measurements, such as lengths and angles.

- To measure distances tap on the *Measure* button located in the toolbar.
- Tap once on the 3-D model to create a start control point and tap again to create an end control point.
- Tap *Done* to complete one measurement or continue placing control points for multiple measurements.
- Modify the measurement line length and position by dragging control points.
- Length is provided in mm and changes value in real time as the measurement line is modified.
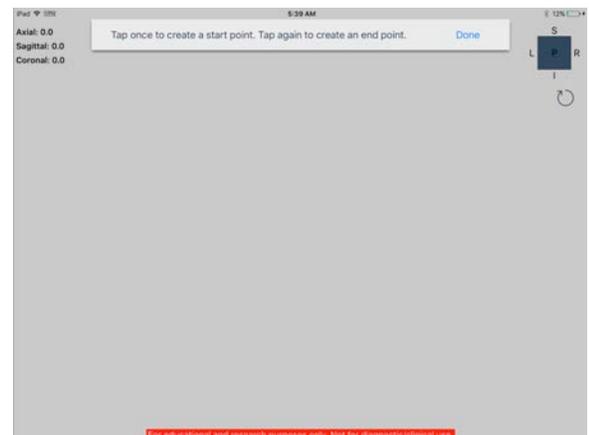
Measurement options:
Tap on a control point to access options.
- *Get Angle Relative To*: Tap on another measurement line to get angle between the two lines. Angle is provided in degrees and changes value in real time as measurement lines are moved relative to one another.

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*- Snap to bone On/Off (default is Off): W*hen placing or dragging control points they automatically snap to the underlying bone surface. Turn to Off for intramedullary measurements. Turn to On for surface measurements.

- Lock: Ignores drag gesture to avoid accidentally touching the control points and moving the line.

- Delete: Deletes the measurement line.

8. PRESET VIEW ROTATION WIDGET
- Located in the top right corner of the screen.
- Provides preset 3-D model rotations: A-anterior, P-posterior, L-left lateral, R-right lateral, S-superior/cephalad, I-inferior/caudad.
- Swipe the widget rectangle up/down/left/right to rotate the 3-D model to preset superior/inferior/left lateral/right lateral orthogonal views.
- Tap the widget rectangle once to toggle between anterior and posterior views.
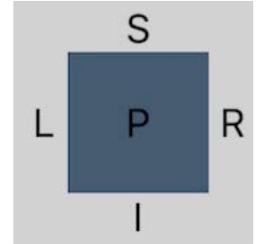
Correcting orientation of mal-rotated 3-D models:
- When loading 3-D models from .DICOM, .stl and .obj files, occasionally their anterior orientation can be incorrect.
- Correct for this by manually rotating the 3-D model to the desired anterior position, then long press on the *preset view rotation rectangle widget.* This will reset the 3-D model orientation to the new desired anterior reference plane.

9. VIEW RESET BUTTON
- Located in top right corner of screen.
- Tapping on the *Reset* button returns the 3-D model to its original size and anterior orientation but retains modeling and planning work.
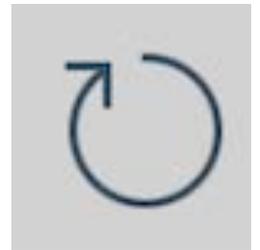
HOW TO'S

CREATE A NEW PROJECT
On application launch the popup menu for creating new projects is presented.
- Tap on the *New Project* button to create a project.
- You are provided with a library of pre-loaded anatomical models to allow you to trial the app.
- Alternatively you can import your own patient's models from Dropbox or through iTunes file sharing (see IMPORT DICOM SCANS FROM DROPBOX below).
- Name your project and tap the *Create Project* button to quickly load the model.
- To load another model tap the *Series* button to go back to the *Project* popup menu again.

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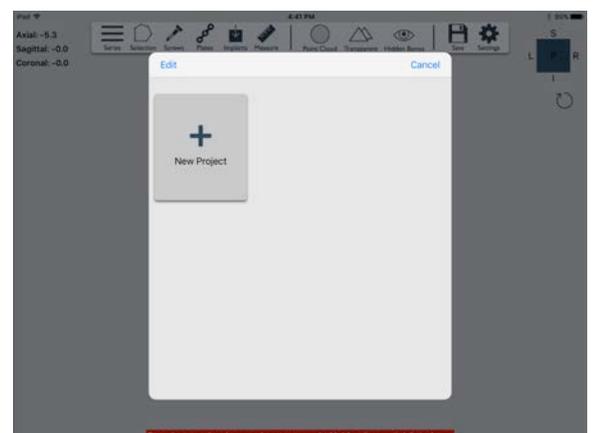
IMPORT .DICOM SCANS FROM DROPBOX

You can import .DICOM files, .stl and .obj files to create 3-D models by following these steps:

- First purchase the in-app import feature, tap *Settings > Purchases > Buy Features*.
- Secondly, upload your patient's CT scan .DICOM image series as a compressed .zip file to your desktop web browser DropBox account. To do this simply select all contiguous DICOM files (.dcm .DICOM) in your patient's standard axial soft tissue CT series and compress them into one .zip file. Rename the .zip file as desired and upload it to your DropBox account, taking note of its location.
- Thirdly, install the DropBox app separately onto your mobile device and log into the DropBox app using your usual credentials.
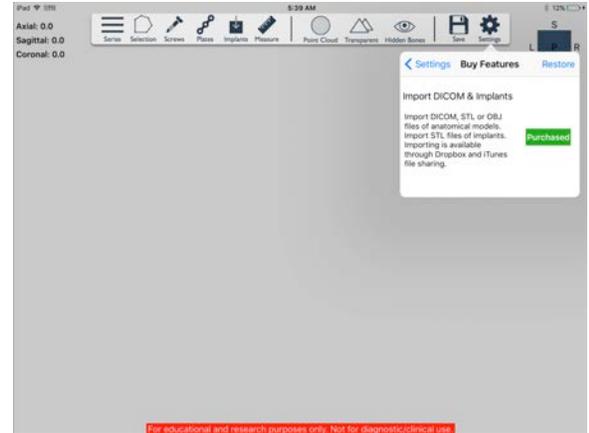
On application launch the menu for creating new projects is presented (see CREATE A NEW PROJECT above).

- Tap on *New Project* button to create a project.
- Tap on *Import* button (top right of *Choose File* screen) and activate DropBox by toggling the radio button to on.
- Browse the DropBox location of your patient's .zip file and tap on it to download the file.
- After the file is downloaded it will appear under the heading "Models Imported From DropBox" in the *Choose File* screen. Scroll down to see all imported files.
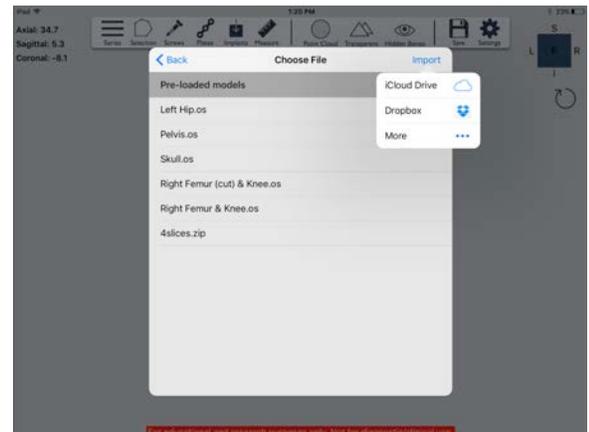
AUTOMATIC SEGMENTATION OF 3-D MODELS

- Tap on the .zip file to open it and segment the DICOM series: the app will automatically parse the DICOM files and list the various series' available for segmentation in the *Choose Series* popup screen.
- Scroll through the available series' and tap the standard axial soft tissue series for best results.
- The *Segmentation* screen will appear and is preset to automatically process .DICOM files at a Hounsfield Unit tissue threshold of +300 HU which is most optimal for bone.
  - Housefield Unit tissue threashold levels can be adjusted using the slider and plus/minus buttons depending on the desired tissue type to be displayed and known HU tissue threshold levels (see Tissue Densities in Hounsfield Units table below). Increasing the HU threshold value will typically display more bone and less soft tissue, decreasing the HU threshold level will typically display less bone and more soft tissue.
- Tap *Next*.
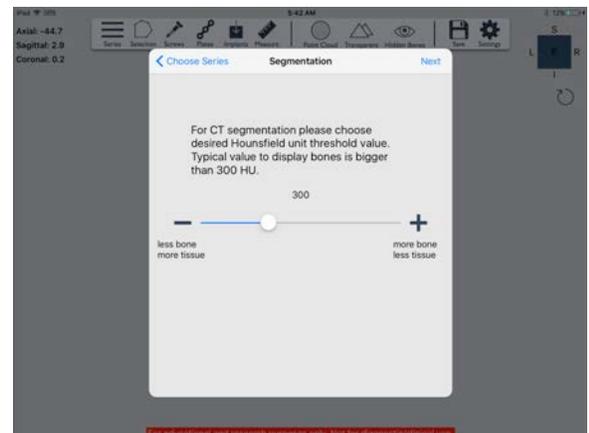
- Name your project and tap the *Create Project* button. Note it may take a few seconds to load the 3-D model based on CT slice thickness and series size.
- Once the 3-D model has been created you can clean up the model by using the *Selection* button to remove unwanted noise, artifact and objects such as the CT scanner bed for example (see 3. SELECTION & MEDICAL MODELING TOOL above).
- Tap *Save* to store your project.

Tissue Densities in Hounsfield Units (Radiodensity)
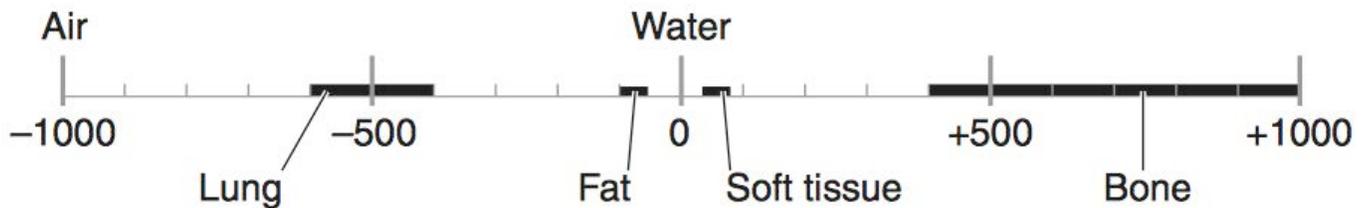
Ref. "Introduction to CT physics" Elsevier Health

Air: -1000
Lung: -400 to -600
Airway Mucosa: -150
Fat: -100 to -60
Water: 0
CSF: +15
Blood: +30 to +45
Soft Tissue: +40 to +80
      Muscle: +10 to +40
      Brain: White Matter +20 to +30, Grey Matter +37 to +45
      Kidney: +30
      Liver: +40 to +60
Contrast: +100 to +300
Calculus: +100 to +400
Bone: +300 to +1000 (up to +3000 for dense bone)

MANAGE SAVED PROJECTS

- Tap *Series* to go to the *Project Menu.*
- Tap *Edit* and then tap the "X" to delete the project.
- Tap *Done* to exit Edit mode.
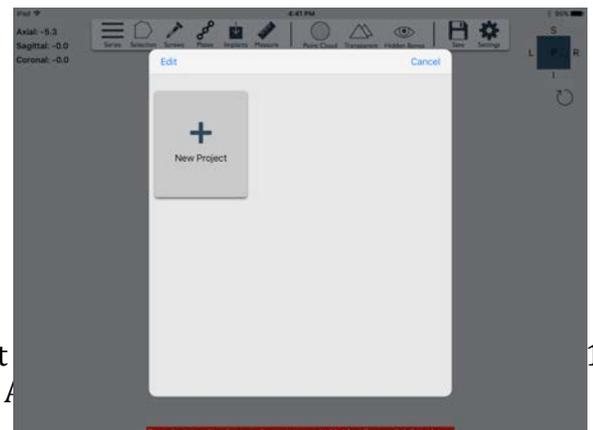
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MANAGE IMPORTED DICOM .zip, .stl and .obj FILES

- Tap on the *New Project* button to get to the *Choose File* screen.
- Scroll down to the .zip files that appear under the heading "Models Imported from DropBox" or the .stl files that appear under the heading "Models imported from iTunes Sharing".
- Left swipe on the file to be deleted and tap *Delete.*

Frequently Asked Questions:

1. How do I create the most accurate 3-D model?
> For optimal 3-D model accuracy, resolution and performance we recommend using standard soft tissue axial cuts at 0.5-1mm slice thickness. Thicker cuts >1mm will result in a less precise 3-D model and thinner cuts <0.5mm will result in slower performance.

2. Can I use reformatted coronal and sagittal CT slices for 3-D modeling?
> Yes you can, however, reformatted coronal and sagittal reconstructions typically have larger slice thickness and will result in a less accurate 3-D model. For best results we recommend using axial cuts 0.5-1mm thickness and soft tissue windows. Axial cuts provide the most accurate scan data.

3. How do I improve a "stepped" looking model?
> Larger slice thickness >1mm will result in a stepped looking model. We recommend a slice thickness of 0.5-1mm for optimal model resolution and accuracy.

4. The tissue I want to 3-D model does not display on the screen after segmentation?
> The table seen above titled "Tissue Densities in Hounsfield Units" provides a guide when segmenting certain tissue thresholds using soft tissue windows. Obtaining the perfect tissue threshold may require a few segmentation trials to obtain the desired 3-D model. If bony windows are used instead of the recommended soft tissue windows then the typical Hounsfield unit thresholds may be less than expected.

5. I get an error message "Could not process files" during segmentation?
> This means that the 3-D model size is exceeding the memory restrictions placed on iOS applications. To overcome this problem you can:
> - Adjust the Hounsfield Unit threshold to a slightly higher level so that less tissue is rendered
> - If you do not want to sacrifice tissue resolution you can reduce your CT slice series volume size to focus in on certain anatomical structures. This will result in a thinner 3-D model but will provide the tissue accuracy and resolution that you desire.

6. After segmentation I get a lot of noise or artifact around the 3-D model?
> There is a balance between accurately rendering desired tissue thresholds and reducing model noise/artifact. When modeling bone this is best optimised at +300 HU. You can reduce noise/artifact by increasing the HU threshold level but this may affect 3-D model accuracy. If high accuracy models are required then we recommend using your desired HU threshold and use the *Selection* tool from the tool bar to highlight and delete unwanted structures/noise/artifact.

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7. How do I import .DICOM, .stl or .obj files of anatomical models or import .stl files of implants?

This requires an in-app purchase to unlock this feature. Go to the *Settings* button in the tool bar and tap on *Purchases > Buy Features.*
- For importing .DICOM, .stl or .obj files of anatomical models see the section above titled "IMPORT DICOM SCANS FROM DROPBOX FOR SEGMENTATION OF 3-D MODELS".
- For importing .stl files of implants see the section above titled "6. INDUSTRY IMPLANT LIBRARY".

8. How do import/export medical models or implants in .stl format to iTunes file sharing?

This requires an in-app purchase to unlock this feature. Go to the *Settings* in the tool bar and tap on *Purchases > Buy Features.*
- See the section above titled "3. SELECTION & MEDICAL MODELING TOOL - Exporting anatomical models to iTunes sharing.

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