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Basic UDI-DI: 935677500001JG
(UDI-DI) 9356775000006
(UDI-PI) V1.1.1

Instructions For Use

Limitations to use: Microsoft Chrome Browsers

Note use on other web browsers may inhibit the device layout display functions.

StrAx1.0 – Intended Use

StrAx1.0 software uses data from computed tomography scans of the Distal Radius to produce a StrAx1.0 analysis report on the bone microarchitecture and its fragility. This information can be used as an aid in the clinical assessment by healthcare professionals of general bone health disorders, specifically it can aid in the assessment of fracture risk and in monitoring the effects of treatment over time of bone disorders such as osteoporosis & osteomalacia.

StrAx1.0 – Intended User

StrAx1.0 is intended to aid the healthcare professional in their clinical assessment of the CT image for a diagnosis.

StrAx1.0 – Intended Patient Group

The intended patient group is postmenopausal women over 50 years of age.

StrAx1.0 Warnings

The use of CT imaging equipment is contraindicated in patients with a metal implant. Although the use of StrAx1.0 at the radius is designed to reduce radiation exposure, any use of CT imaging equipment produces radiation. The risks associated with patient exposure to radiation should be assessed and justified by the healthcare professional before subjecting the patient to any such exposure.

This analysis is not a diagnosis, it is intended to aid the healthcare professional in their clinical assessment of the CT image for a diagnosis or monitoring of the effects of treatment over time.

If any serious incident that has occurred in relation to StrAx1.0, it should be reported to StraxCorp Pty Ltd and the European Competent Authority of the Member State according to the user's location.

For The Doctor: Doctor's Referral Letter Submission

1. Go to the "Straximages" website: <http://www.straximages.com>
2. Following on-screen directions, create a new customer account or log into an existing account as a "Doctor".
3. The registration will be approved by the Strax admin. Once the registration is accepted, you will receive a confirmation email. Click on the link to confirm your registration.
4. Enter or assign your password and user ID (email address used during registration) allowing you to log into StrAx1.0 (Straximages).
5. Open the "Submit Referral" tab located in the Left of the screen in black lettering.
6. If new patient Click "Add New Patient" button and fill in patient's information including title, name, date of birth, gender, ethnicity, email, phone number, weight and height. If not, click the "Select From Existing Patients" Button
7. Follow the prompts and drop down boxes to create a referral letter for your patient as shown in the screen shots below.

Enter Patient Details

Patient

Patient Info

Full name: Mr Stephanie Jenkins	Previous fracture:
Date of birth: 21 / Sep / 1969	Parent fractured Hip:
Gender / Ethnicity: female / caucasian	Current smoking:
Email:	Glucocorticoids:
Phone number:	Rheumatoid Arthritis:
Height (in cm): -	Secondary Osteoporosis:
Weight (in KG): -	Alcohol 3 or more unit...

Actions

Clear Selection

Next

Enter Radiology Center or select existing Center

Centre

Centre Info

Full name: Mr Centre Test	Address: Level 1, collin street, Melbourne 3000, Australia,
Institution: Clinical Labs	Phone: 1234567890

Actions

Clear Selection

Next

This is a testing referral number 1

Doctor's Referral Continued:

Confirm Details Entered

Referral Info
▼

Patient

<p>Full name: Mr Stephanie Jenkins</p> <p>Date of birth: 21 / Sep / 1969</p> <p>Gender / Ethnicity: female / caucasian</p> <p>Email:</p> <p>Phone number:</p> <p>Height (in cm): -</p> <p>Weight (in KG): -</p>	<p>Previous fracture:</p> <p>Parent fractured Hip:</p> <p>Current smoking:</p> <p>Glucocorticoids:</p> <p>Rheumatoid Arthritis:</p> <p>Secondary Osteoporosis:</p> <p>Alcohol 3 or more unit...</p>
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Actions

Scanning Centre

<p>Full name: Mr Centre Test</p> <p>Institution: Clinical Labs</p>	<p>Address: Level 1, collin street, Melbourne 3000, Australia, Australia</p> <p>Phone: 1234567890</p>
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Comments

This is a testing referral number 1

8. Once all information has been added and confirmed as correct click "Submit" Button.
9. Your referral letter has now been sent to the imaging center via the internet and is available to your imaging center immediately.
10. If needed you may add other patient referrals by repeating the process from step 4. If no other referrals are required proceed to the next step.
11. If you wish, you may print and sign copy of the referral letter to give to your patient for them to take along to the imaging center, however this is not essential as the referral has been sent electronically.
12. Log out and close the web browser.

Radiology Centre

Instructions for CT Machine *Calibration & Phantom Image uploads*

Collect an image of the phantom for calibration purposes.

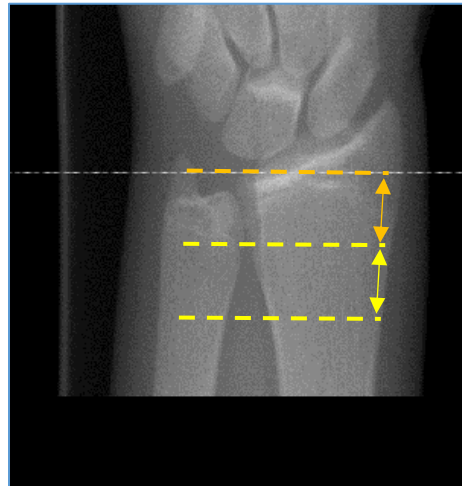
- A new QC (Quality Control) phantom image is not required if a recent phantom image (less than 13 weeks) was uploaded to the Straximages website, and no repair or maintenance has been conducted on the scanner within the 13 weeks. Any maintenance and/or repair work should be immediately followed by the collection and uploading of a new QC phantom image onto the Straximages website.
- A new phantom image is required if the most recent phantom image is more than 13 weeks old and/or maintenance work has been done on the scanner.
- When required, the QC StraxCorp phantom image must consist of at least four rods of hydroxyapatite with different concentrations. The four rods must differ in concentration in milligrams of hydroxyapatite (mgHA/cc) by at least 100 to 400 mgHA/cc. Ideally, we recommend that the phantoms should be made of hydroxyapatite of 100, 200, 400 and 800mgHA/cc respectively. Phantoms with material equivalent to hydroxyapatite such dipotassium hydrogen phosphate (K_2HPO_4) are acceptable.
- Once you have obtained your CT image(s) and the QC phantom as described above, please continue onto the instructions as documented on the following pages to enable you to upload your image and send us your analysis request.

Image Acquisition - Scanco XtremeCT

Image Location: Ultra-Distal Radius

Collect a computed tomographic axial image at the ultra-distal radius. The image must be collected at the illustrated region of interest in order to capture the required region of interest.

When using the **Scanco XtremeCT 1 & 2 Equipment** the fixed standard scout view setting in HRpQCT as shown below will apply.



Measure 9.5mm from landing

9.02mm Scan Area

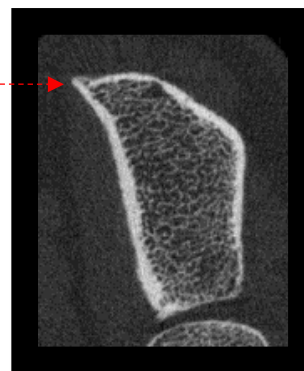
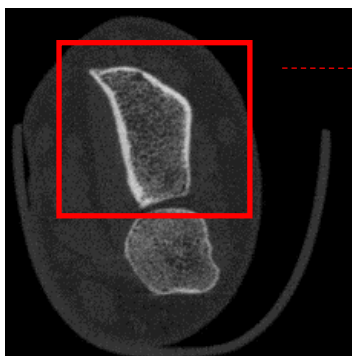
Image Specifications:

Format:	AIM / DICOM/ ISQ
Location:	Ultra Distal Radius
Plane:	Transverse
Voxel size:	82 Micron

Note on Image Quality

- All images must be clear and free of noise artefact.
- Only images with no visible or minimum motion artefact are to be uploaded.
- An example of an acceptable image is shown in the figure below.

The Radius bone is to be cropped out as shown



Once the image has been cropped, you may upload the image for StrAx1.0 analysis via your client account as described on page 7 of this document.

Patient Positioning for Scanco CT Imaging



Place the patient's non-dominant arm into the Scanco wrist support / grip and secure in place with the straps provided



Please ensure that the straps are secure and the patient is comfortable to ensure minimum chance of movement artefact



Place the wrist support into the Scanco machine and lock into place. Close the access plate and commence the scan of the patient's wrist

StrAx1.0 Image Analysis Instructions

1. Using Microsoft Chrome internet browser, go to the “Straximages” website: <http://www.straximages.com>
2. Following on-screen directions, create a new customer account or log into your existing account. Select the account type by choosing ‘Doctor’ or ‘Radiology Centre’.
3. The registration will be approved by the Strax admin. Once the registration is accepted, you will receive a confirmation email. Click on the link to confirm your registration.
4. Enter or assign your password and user ID (email address used during registration).
5. Following the on screen prompts, add a new CT Machine or select a pre-existing device.
6. Upload your CT “QC Phantom” Image (Required to renewed every 13 weeks & you will receive notification when required)
7. If no “Phantom” is found or your previous Phantom has expired, you will be notified of expiry & required to submit a new “Phantom” for calibration purposes.
8. Open Referrals tab.
9. Obtain a new CT image of the patients Ultra Distal Radius as described on page 2 to 6 of this document using Scanco equipment.
10. Following the on screen prompts, upload your obtained CT image of the Ultra Distal Radius.
11. Once upload is complete, check the image details are correct and add comments in the comments box if required.
12. Your CT image is then converted into a viewable image in the Strax images website, and is allocated a unique traceable “lot number”.
13. If the image details appear correct & meet the image specification requirements, proceed by clicking “Request Analysis” button.
14. If the image or details are not correct, you must delete the image and resubmit a new image re-starting at step 5 in this document.
15. You may now choose to “logout” & return at a later time, or wait for the image analysis to be processed by StrAx1.0 (Approx. 2-5 minutes)
16. Strax1.0 Conducts the Image analysis and when complete notifies Strax Staff to check and conduct QC checks on the Analysis.
17. Strax staff release the analysis after QC checks are complete.
18. The StrAx1.0 image analysis report and an invoice is sent to the customer account. Note: Both an invoice and the analysis report shall contain the analysis unique StrAx1.0 traceable “Lot Number”. This number should be quoted for any further correspondence regarding this analysis report.
19. Notification of a new report is sent to you via email.
20. If you previously opted to log out you must re-Log in or if you opted to stay logged in, please refresh your Internet browser by pushing the F5 key on your computer keyboard.
21. Your image analysis report is now visible in your account.
22. After opening the report, select “Send Report to Doctor” to send the analysis report to the patient referring Doctor’s StrAx account.
23. The patients Doctor receives a notification via their email that the analysis is complete and available to view in their StrAx account.
24. The Doctor accesses the image analysis report by viewing it on normal computer via their StrAx Images account, or is given the option to print the analysis report as an uncontrolled document using any normal printer connected to their PC. The doctor may wish to then contact the patient for a further consultation.



25. Analysis records remain in the customer's account. Backup records of all analyses are held securely on file by the StrAx1.0 device for an indefinite period for regulatory record keeping purposes.
26. Please log out of your account and close the internet to close the device.