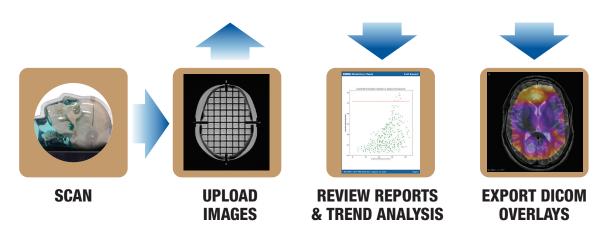
Distortion Check Software

Model 603S





USER GUIDE

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Product Description

CIRS Distortion Check Software is an online application that allows the user to quantify the geometric distortion present in MRI images due to, among others, nonlinearity of gradient fields and inhomogeneity of the static magnetic field (B0). Manufacturers' specific distortion correction algorithms correct mostly distortions due to nonlinearity of gradient fields but do little to correct distortions due to inhomogeneity of the static magnetic field (B0) and due to susceptibility specific to patients. The Distortion Check Software works by analyzing images of a known geometry (orthogonal grid). The true locations of the grid intersections (ground truth reference frame) are registered against the detected locations for the very same grid intersections and the differences between the two spatial positions are computed as 3D vectors. These 3D vectors are used as sample points for interpolating the distortion over the entire MRI imaged volume covered by the orthogonal grid of CIRS MRI distortion phantoms.

Product Specifications

- Online application => no minimum hardware and software requirements.
- License => allows for three levels of user accounts: Manager, Medical Physicist and Therapist. Each user account
 requires individual activation (see details in Home -> Configuration -> Add User for privileges related to each user
 level).
- Automatic analysis of MR and CT modalities. Capable of analyzing Secondary Captions, which are assumed to be CT.
- Analyzes CIRS model 603-GS (859 points in Gold Standard Points set).
- Analyzes CIRS model 604-GS (2152 points in Gold Standard Points set).
- Analyzes 2D and 3D MRI imaging with no spacing between slices.
- Analyzes maximum distortions up to 6.75 mm for CIRS model 603-GS.
- Analyzes maximum distortions up to 9.0 mm for CIRS model 604-GS.

License/User Account Creation

CIRS' Distortion Check Software is an online application. It does not require any installation on a user's PC. Once a User Account is created the software can be accessed from any device that is connected to internet.

Follow the steps below to create a New User Account:

- 1. From any web browser go to https://tools.cirsinc.com/login/
- 2. Click on Register New Account and follow the on screen instructions to create your User Account.

Notice:

- In order to create a new user account you must provide a valid serial number of a CIRS 603-GS or CIRS 604-GS phantom. If you have not purchased either of these phantoms at the time the software was purchased, because you already own at least one of these phantoms, you will need to provide CIRS with the serial number (SN) of at least one phantom in order for you to be able to create the account. In case you have not purchased either of these phantoms, but would like to know more about the Distortion Check Software, please contact CIRS support for more information.
- All fields from the Register New User Account must be completed in order for the New User Account creation process to be successful.
- The same e-mail address cannot be used to register two User Accounts due to the fact that the e-mail is used for log in purposes.
- 3. Once the Register New Account form is completed and submitted, an e-mail with the content shown below is automatically sent to the e-mail address used during the New User Account creation.

An account has been created for you on CIRS Distortion Check. Please follow the link below to create your password. https://cirsinc.com/create-password/MzE/4x7-f0ee2f04ac4c8e4ec079/

4. Click on the link from the e-mail and follow the on screen instructions to create a password for your account. Upon successful password creation you will be prompted to log in to your newly created account. The e-mail address used during the New User Account registration process is to be used for log in.

License Terms Notice:

CIRS Distortion Check Software is a licensed product. The licensing of this product is based on the number of scans successfully analyzed by the end user within a period of time. For licensing purposes, a successful analyzed scan is defined as follows: more than 50% of the grid intersections are matched to a gold standard point for both model 603-GS and model 604-GS. The license will expire based on which terms of the license expire first (time or number of scans).

Upon User Account creation and log in, you will be able to use the software with or without any license restrictions as follows:

- If you log in before CIRS assigns the license terms to the institution you provided during the New User Account registration process you will see no messages with respect to license time or number of scans left.
- If you log in after CIRS already assigned to your institution the license expiration terms, based on the product you bought, you could see a notification message prompting you to renew your license due to time or scans expiration. The license time notification will prompt you for license renewal 30 days in advance. The licensed number of scans processed notification will prompt you for license renewal 20 scans in advance.

User Account Customization

- Upon registration of a New User Account and log in, the Configuration tab will allow you to add additional phantoms that your institution might own (use Phantoms tab), MRI Scanners and MRI sequences. Follow the on screen instructions to add these items to your User Account profile. The on screen instructions and cursor tips should be self-explanatory.
- The Configuration page contains a tab that allows you to assign sub-users to your account. Explanations about the privileges of each user level are provided for this tab.

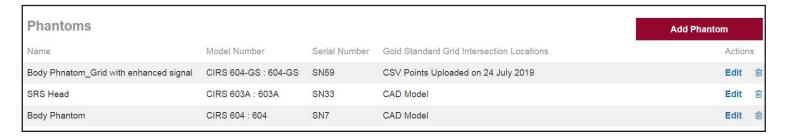
Home > Configuration
Add User
First name
Last name
Email address
Required.
User type
Manager Medical Physicist Therapist

The maximum allowed distortion for a Machine-MRI Sequence combination can be set up from the Edit MRI Sequence page.

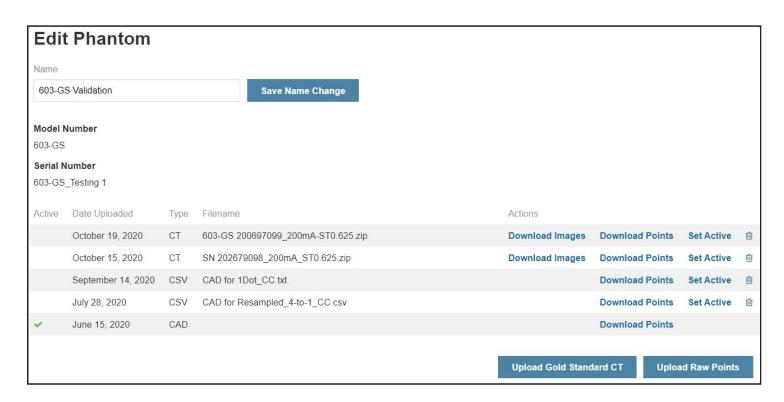


Change Gold Standard Grid Intersection Locations

The Gold Standard Grid Intersection Locations can be changed for each phantom from the User Account Configuration page in the Phantoms section.



Click on the Edit button to access the Edit page for the phantom. From the Edit page you can upload a new Gold Standard set of points from either a new CAD model, if available in CSV or zipped DICOM CT data set. Upon uploading a new Gold Standard set of points, click on the Set Active button to make it the current reference frame to be used by the software algorithm. The CT Gold Standard is uploaded as a DICOM zip archive (do not use other types of compressing/archiving) and is processed once you click on the Upload CT button. Once the CT is analyzed you can make it the current reference frame by clicking the Set Active button. In addition to Set Active, Download Images, Download Points and Delete actions are available for each uploaded Gold Standard.



Phantoms Recommended Setup

The quality of results from Distortion Check Software is highly dependent on the quality of the images uploaded for processing. The best results in terms of grid location positioning accuracy and subsequently, registration of the reference frame, are obtained when the phantoms are aligned to an MRI machine so that:

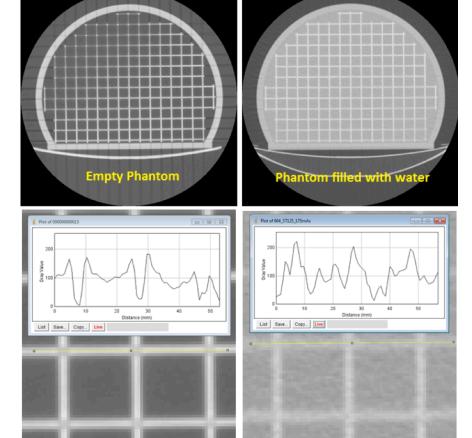
- The phantom is rotated no more than +/- 5° with respect to MRI machine axes.
- The phantom's grid ISO-center is at 45.4 mm (for 603-GS) & 60 mm for 604-GS respectively, from the ISO-center of the FOV. The phantom's grid ISO-center is at the intersection of the axes extending from the skull for model 603-GS and at the intersections of the planes that go through the largest dimensions of the grid for model 604-GS.
- The field of view (FOV) is setup such that its center is as close as possible to the ISO-center of the MRI
- The pixel size and slice spacing should be selected so they are sufficient to clearly resolve the phantom grid inter sections.

CT and MRI Image Acquisition Recommendations

Due to the nature of how CT images are reconstructed, especially for orthogonal grids, there might be cases when the signal drops at the intersections, which can lead to failure of the software algorithm to correctly detect said grid intersections. This can happen more often if model 604-GS, is scanned empty (not filled with any liquid) or with low energy settings. Model 603-GS should not exhibit such signal drops in the grid intersections due to the fact that it has a water-based gel as background.

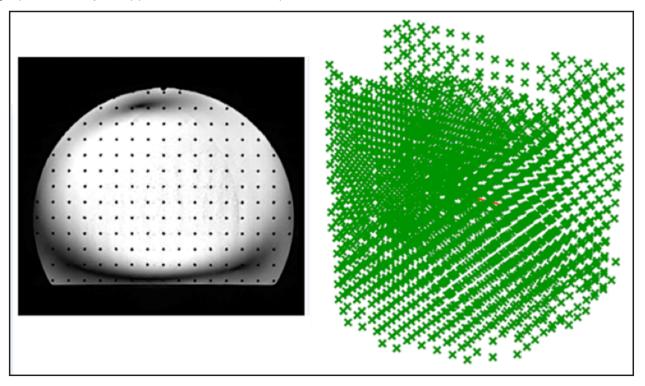
It is recommended that you:

- Open the CT scan in a DICOM viewer or another application that allows you to create a plot profile.
- Go through slices and observe the signal at the intersections of the grid for signs of signal drop.
- Once signal drop cases are suspected zoom in and create a plot profile like the one shown below (plot profile created in ImageJ).
- If the plot profile shows signal drops corresponding to the grid intersections, it is recommended the phantom be rescanned after being filled with a suitable liquid as suggested below. Use high-energy settings for the re-scan. The signal has to have peaks corresponding to the grid intersections not drops.page.



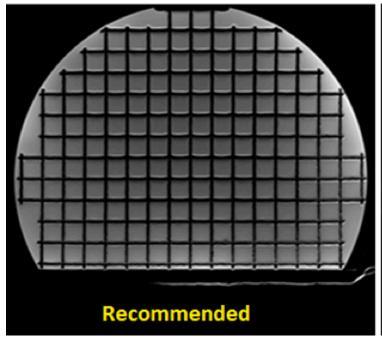
CT and MRI Image Acquisition Recommendations (cont)

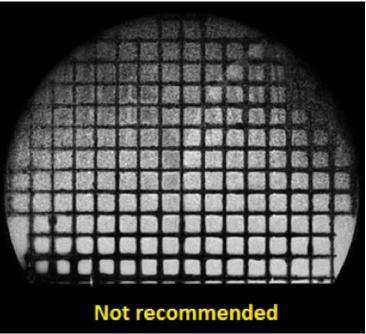
Model 604-GS is susceptible of producing artifacts in MRI, especially at 3T, if the phantom is filled just with water. Such artifacts (see below) affect the performance of the algorithm in detecting the grid intersections. It is recommended model 604-GS be filled with a solution as recommended by AAPM Report 100 for field strengths ≤ 2T. For field strengths ≥ 2T, it is recommended that you consult published specialty literature for choosing the most appropriate filling liquid. Mineral Oil and a mixture solution of water and Triethylene glycol are reported as being effective in reducing the artifacts similar to the one shown below. However, Mineral Oil can introduce chemical shift artifacts. Use caution and due diligence when researching a filling liquid best for your application. For more info please refer to model 604-GS User Manual.



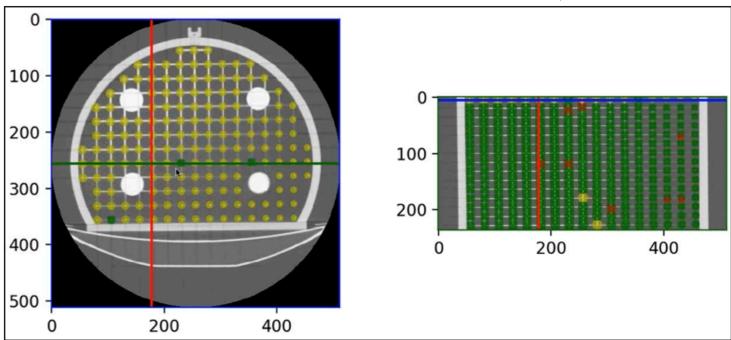
CT and MRI Image Acquisition Recommendations (cont)

The phantom grids are made of rods 3mm in diameter spaced 15mm apart for model 603-GS and 3mm in diameter spaced 20mm apart for model 604-GS respectively. For both CT and MRI, use imaging protocols with pixel size and slice thickness that are less than the diameter of the grid rods so they are sufficient in resolving the phantom grid intersections. Ensure the signal is consistent throughout the imaging volume occupied by the phantoms.





When selecting the FOV, make sure it does not end close to a plane that can be constructed through grid intersections, which are supposed to have the same X or Y or Z coordinate. If the FOV ends close to such a plane, the grid intersections from that plane will be rejected (see below) due to lack of signal from all 6 sides of the intersections. Make sure, based on the slice thickness, the FOV extends more than 5mm on each side of the intersections from the plane.



Upload a Scan for Processing

The upload of a new MRI or CT scan (secondary captions are also supported) for analyzing, is done from the Home page of the User Account, which lists the Machines and MRI Sequences. It also lists the Date of Latest Scan and pass/fail of the 'Latest Scan Within Tolerance?' for the Machine-MRI Sequence combination.

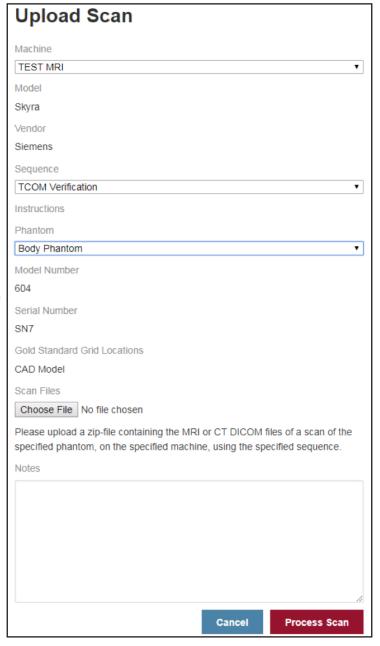


Alternatively you can upload a new scan from the Machine-Sequence page, which can be accessed by clicking on the View Details button.

Regardless from where you choose to upload a new scan, you need to complete all of the fields from the form in order to have the results reported for a combination Machine-MRI Sequence. Verify that the phantom scanned matches the info of the

phantom selected especially if a Gold Standard Grid Location other than the CAD is to be used.

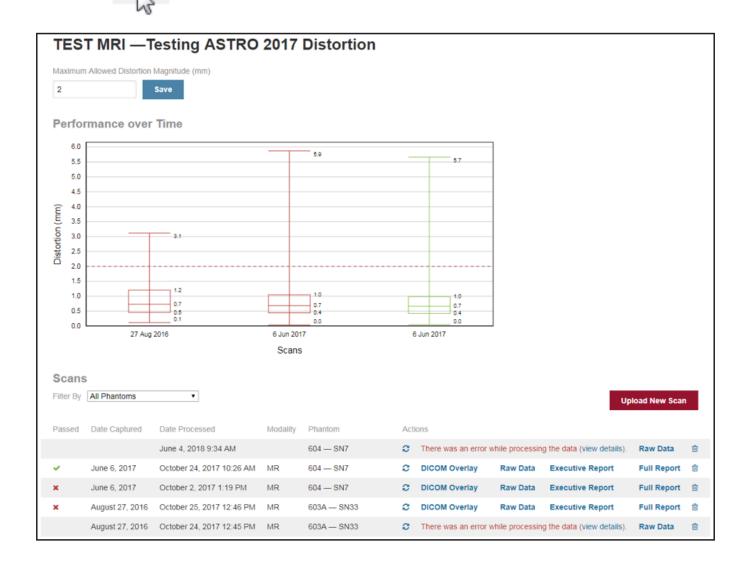
The upload process requires you to use an archive containing the DICOM data set of the scan. Compress this archive in a ".zip" format. [Do not use other types of compression, as they will not work with the software.] Once the uploading is complete click on the Process Scan button.



Review Scan Processing Results

Upon completion of scan processing, results are presented on the User Account Home page, where you can see the Date of Latest Scan and pass/fail for 'Latest Scan Within Tolerances?'.

The complete suite of results is presented on the Machine-MRI Sequence page. Result formats include: DICOM Overlay, Raw Data, Executive Report (in PDF format) and Full Report (in PDF format). This page also presents a bar and whiskers graph of the scans analyzed, info about the scans and a set of actions that you can take to access detailed results or to view errors encountered during the processing of a scan. A scan can be re-processed from this page by clicking on the re-analyze button without the need to re-upload the scan.

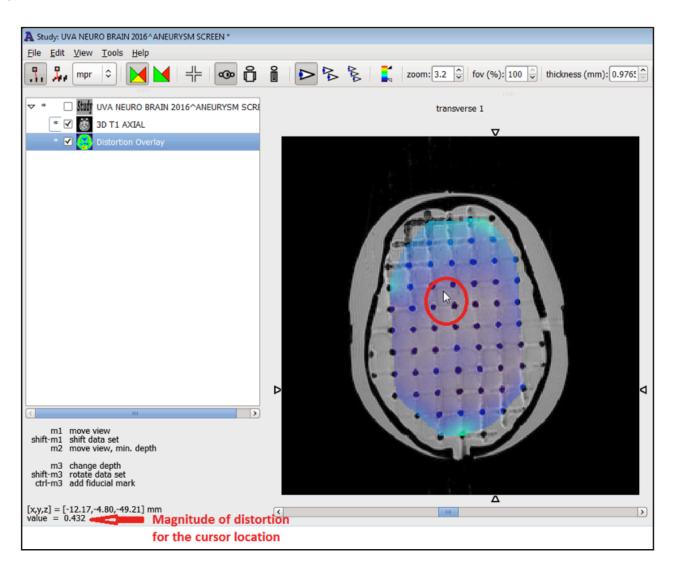


DICOM Overlay

The distortion between the detected grid intersections is interpolated after the distortion for these intersections is computed. The interpolation results cover the imaged volume occupied by the phantoms' orthogonal grids. The interpolation results are presented as a DICOM data set with each slice having associated a specific distortion map. The voxel of the generated Overlay is $1.5 \times 1.5 \times$

The DICOM Overlay can be downloaded and used to visualize the magnitude of the distortion when one uses a DICOM viewer that allows for image fusion/overlay. The DICOM Overlay is generated as a PET DICOM data set with the magnitude of the distortion being displayed as units. Overlays have been validated for use with ImageJ, 3D Slicer, AMIDE and MIM. To overlay directly onto treatment planning software, please consult with your TPS vendor for assistance on DICOM formatting requirements.

The examples shown below were created in AMIDE. CIRS does not endorse a specific application to be used to visualize the image fusion of a phantom scan and its associated DICOM Overlay. However, there are numerous options available on the market.



DICOM Overlay (cont)

In addition, the DICOM Overlay can be generated to fuse with a patient scan so that conclusions can be drawn about how the magnitude of the distortion could affect the scan. In order to facilitate the orientation of the DICOM Overlay to the patient scan complete the fields in the DICOM Overlay generation form. If the fields are not completed, then the values of the phantom scan corresponding to the fields will be used instead.

Home > TEST MRI — Testing ASTRO 2017

DICOM Overlay

Generate DICOM overlays that display the geometric distortion magnitude in mm. Many DICOM viewers can overlay these images on top of an MRI, allowing you to visualize the amount of geometric distortion present in an image.

In order to generate the overlays for a DICOM MRI, you will need to provide several pieces of information from the DICOM metadata. If you leave the fields blank, they will default to the tags present in the phantom DICOM MRI which was analyzed to calculate the distortion.

StudyInstanceUID

PatientID

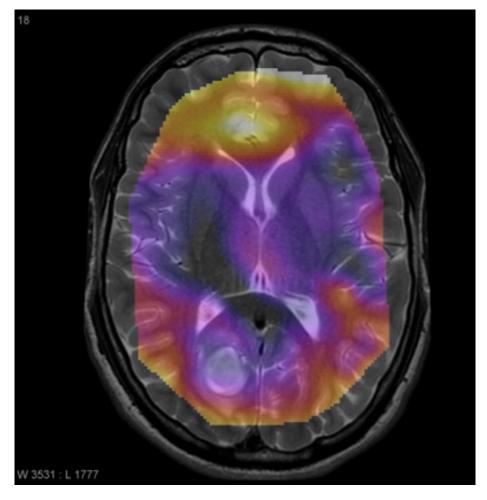
Isocenter (mm)

X

Y

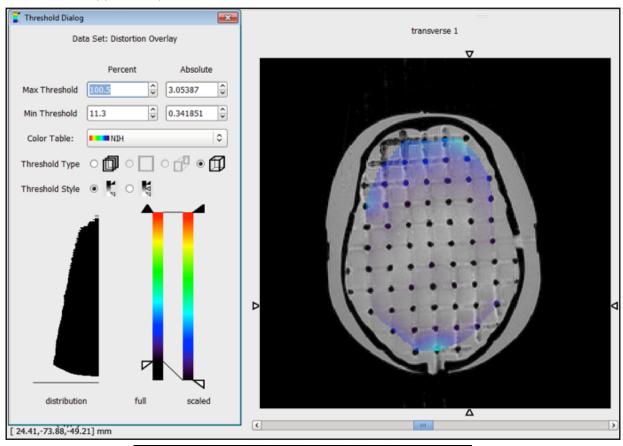
Generate DICOM Overlay

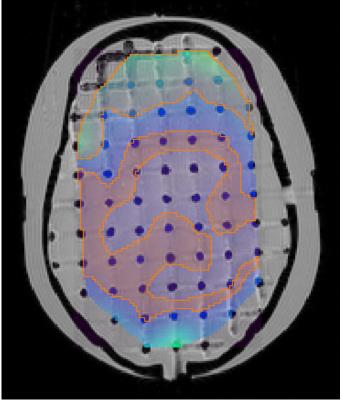
Generate DICOM Overlay



DICOM Overlay (cont)

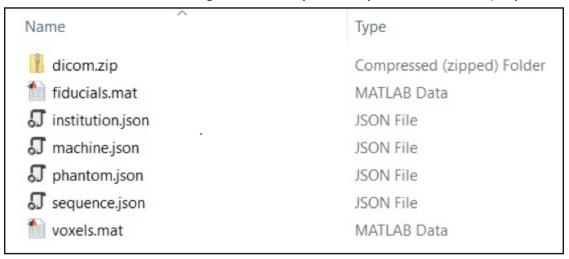
Depending on viewing software capabilities, you might be able to threshold the DICOM Overlay or create ROI's based on ISO-contours, which could show distortions with magnitudes that satisfy certain criteria (above a value, below a value or between a lower and an upper value).



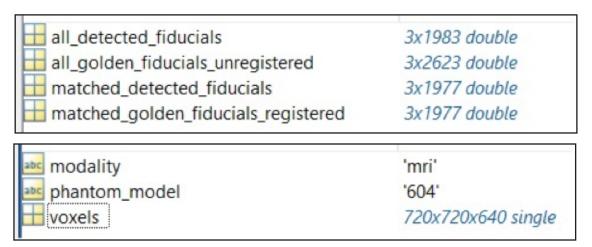


Raw Data

The Raw Data archive, which is downloadable, contains an archive of the DICOM data set that was analyzed. This is provided as a convenience for users who might want to analyze the very same scan in third party software.



To analyze the scan in Matlab (or other software that can import Matlab file formats like Octave) open either the "fiducials. mat" or "voxels.mat" in Matlab.



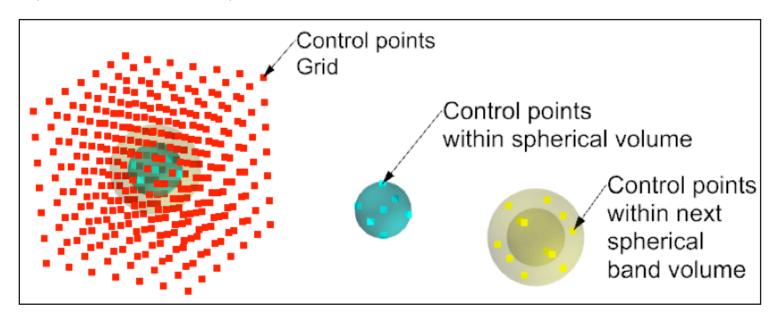
Executive Report

The Executive Report presents the results in a brief format exceeding the recommendations of NEMA Standards Publication MS 12-2016 Quantification and Mapping of Geometric Distortion for Special Applications

It includes:

- Institution Table (institution information)
- Data Acquisition Table (info about the parameters used during image acquisition)
- Phantom Description
- Scatter Plot of Geometric Distortion vs. Distance from ISO-center
- Axial Contour Plot
- Sagittal Contour Plot
- Coronal Contour Plot
- Frror Table*
- 3D Plot of Detected Grid Intersections versus Actual Grid Intersections (Gold Standard points).

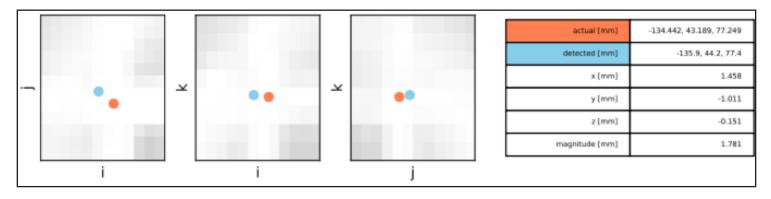
Note: * The Error Table recommended by NEMA MS12-2016, presents the points detected, the maximum error and average error within a spherical volume defined by the distance (the radius of the spherical volume) from the ISO-center. The Distortion Check Software presents the number of points, the maximum error and the average error within a spherical band. A spherical band is easy to visualize if one thinks of a sphere from which an inner, smaller, sphere was removed. This approach helps the end-user choose which spherical volume satisfies the tolerance for the distortion.



Full Report

In addition to the results presented in the Executive report, the Full Report contains localization info about the Top 100 Most Distorted Grid Intersections (see below). For each intersection from the Top 100 Most Distorted Grid Intersections the following are presented:

- Actual X, Y and Z coordinates (expected coordinates after the registration of the Gold Standard points)
- Detected X, Y and Z coordinates
- X difference in mm
- Y difference in mm
- Z difference in mm
- Magnitude (in mm) of the 3D distortion vector.



Warranty

All standard CIRS products and accessories are warranted by CIRS against defects in material and workmanship for a period as specified below. During the warranty period, the manufacturer will repair or, at its option, replace, at no charge, a product containing such defect provided it is returned, transportation prepaid, to the manufacturer. Products repaired in warranty will be returned transportation prepaid.

There are no warranties, expressed or implied, including without limitation any implied warranty of merchantability or fitness, which extend beyond the description on the face hereof. This expressed warranty excludes coverage of, and does not provide relief for, incidental or consequential damages of any kind or nature, including but not limited to loss of use, loss of sales or inconvenience. The exclusive remedy of the purchaser is limited to repair, recalibration, or replacement of the product at manufacturer's option.

This warranty does not apply if the product, as determined by the manufacturer, is defective because of normal wear, accident, misuse, or modification.

NON-WARRANTY SERVICE

If repairs or replacement not covered by this warranty are required, a repair estimate will be submitted for approval before proceeding with said repair or replacement.

RETURNS

If you are not satisfied with your purchase for any reason, please contact your local distributor prior to returning the product. Visit https://www.cirsinc.com/distributors/ to find your local distributor. If you purchased your product direct through CIRS, call Customer Service at 800-617-1177, email rma@cirsinc.com, or fax an RMA request form to 757-857-0523.. CIRS staff will attempt to remedy the issue via phone or email as soon as possible. If unable to correct the problem, a return material authorization (RMA) number will be issued. Non-standard or "customized" products may not be returned for refund or exchange unless such product is deemed by CIRS not to comply with documented order specifications. You must return the product to CIRS within 30 calendar days of the issuance of the RMA. All returns should be packed in the original cases and or packaging and must include any accessories, manuals and documentation that shipped with the product. The RMA number must be clearly indicated on the outside of each returned package. CIRS recommends that you use a carrier that offers shipment tracking for all returns and insure the full value of your package so that you are completely protected if the shipment is lost or damaged in transit. If you choose not to use a carrier that offers tracking or insure the product, you will be responsible for any loss or damage to the product during shipping. CIRS will not be responsible for lost or damaged return shipments. Return freight and insurance is to be pre-paid.

With RMA number, items may be returned to:

CIRS
Receiving
900 Asbury Ave,
Norfolk, Virginia, 23513 USA

PRODUCT	WARRANTY PERIOD
Model 603S - Distortion Check Software	2 years



900 Asbury Ave Norfolk, Virginia 23513 USA

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