INVIA

Corridor4DM v2018
Instructions for Use

English (en-US)

Overview

Corridor4DM (4DM) is a software medical device that is utilized for review of radiographic medical images.

Intended Use

INVIA's Corridor4DM application is intended to provide processing, quantification, and multidimensional review of the biodistribution of radionuclides in the body using planar and tomographic images. The application performs quantitative measurements of tracer uptake over time to aid in the interpretation of myocardial perfusion images.

The application supports correlative review and measures of physiologic, functional, and anatomic datasets from multidimensional radiographic images. Corridor4DM provides analytical tools to help the user quantify and document changes in these measures.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate multimodality datasets. The Corridor4DM application is a complement to these standard procedures.

℞only

Contraindications

None.

Intended Patient Population

Any patient, independent of gender, race, or body habitus, who is clinically indicated for this imaging procedure, e.g. known or suspected cardiac disease.

Use Environment

The intended user is a healthcare professional operating the software in a healthcare facility as a component of an imaging system for the detection of cardiac disease.

Operator Skill Level

Corridor4DM is intended to be used only by trained medical professionals. These are primarily certified imaging technologists, cardiologists, and radiologists as well as their equivalents. The clinicians retain the ultimate responsibility for making the pertinent assessment based on their standard practices and visual assessment.

Corridor4DM utilizes images acquired and processed with approved radiographic imaging systems (SPECT, PET, CT, MR and hybrid combinations thereof) using approved imaging protocols operated by trained medical professionals. If you require further information about training in the use of Corridor4DM, please contact your Corridor4DM sales representative.

Product Description

Corridor4DM is a comprehensive application designed to process, review, and quantitatively analyze nuclear medicine, PET, and CT patient studies. The application provides tools to process, quantify, and display static, whole body, dynamic, gated planar, standard ungated ECT images, ECG gated ECT images, and dynamic ECT images. ECT data is displayed on both a slice-by-slice basis and as 3D surface-rendered images in many user selectable formats. All of the image formats can be viewed as a single dataset or as a comparison of related datasets (e.g. stress and rest conditions, pre- and post-revascularization). Among several optional display screens are side-by-side displays optimized for the review of uncorrected and attenuation corrected cardiac images.

Corridor4DM algorithmically determines and displays the left ventricular endocardial and epicardial surfaces. These surfaces provide quantitative assessments of cardiac function, e.g. systolic and diastolic function, regional wall thickening, wall motion, transient ischemic dilation (TID), phase analysis, and the analysis of dynamic sequences.

Corridor4DM provides regional assessments of myocardial perfusion, metabolism, wall thickening, wall motion, time to peak contraction, time to peak thickening, perfusion reversibility between stress and resting conditions, viability, inflammation, and coronary flow and reserve. Corridor4DM provides this regional information in 2D polar maps and 3D surface-rendered images and it provides a comparison of the patient-specific regional information in comparison to a similar patient population with a low likelihood of cardiac disease.

The normals database generator is an integrated feature of Corridor4DM that provides the users with a set of tools for generating site, patient population, or protocol specific normal data files. Site specific Normals Databases are integrated seamlessly into the application for research or daily clinical use.

Tomographic dataset reconstruction is an optional feature integrated into Corridor4DM. The reconstruction feature permits the user to generate slice volumes from nuclear medicine tomographic and gated tomographic datasets.

Corridor4DM provides several options for verifying the quality of the input data and processing of that data. Data cines, image co-registration, surfaces, valve plane, and polar map QA displays of all selected studies are provided and available both during processing and subsequently during image interpretation.

Corridor4DM supports the review of nuclear medicine static, dynamic, whole body, gated planar, tomo, and gated tomo datasets. Additionally, the application permits image manipulation, adding image labels, and the quantification of these nuclear medicine datasets. The application permits the user to review and interpret NM studies in a familiar user interface.

Multi-Gated Acquisition (MUGA) quantification is feature integrated into the application. 4DM can be used to display the left and right ventricular endocardial surface, wall motion, amplitude, phase analysis, stroke volume, ejection fraction, ventricle chamber volumes, and 2D images of first pass and planar MUGA studies. Planar MUGA images can be viewed as a single dataset or as a comparison of related datasets.

Cardiac CT interpretation and cardiac calcium quantification are optional features integrated into Corridor4DM. The CT Viewer provides the user with a clinically tested image layout that supports basic volume and distance quantification in multiple image types, MIP, and/or MPR. The program provides tools for the quantification of coronary artery calcification with results tabulated with Agatston score, volume, and number of lesions.

Corridor4DM includes the ability to save and export diagnostic findings in a variety of formats. The application generates DICOM multi-frame (MFSC) and secondary screen captures (SSC) in addition to producing static (JPEG, TIFF) and dynamic (WMV) image files. The user can export results to relational database, XML, and text formatted reports for data analysis.

Corridor4DM is not intended to provide diagnoses or therapeutic recommendations, but is intended only to be a visual aid for use by trained medical professionals. The Clinician should never rely solely on it in making diagnostic or therapeutic decisions, nor to determine the presence or absence of a condition, but instead interpret all of the patient's clinical and diagnostic information to make a final diagnosis regarding a patient. The Clinician retains the ultimate responsibility for making a diagnosis.

Miscellaneous Instructions

There are no special operating instructions for the Corridor4DM software.

Additional instructions for using the Corridor4DM software can be found in the English-only User Guides which are available electronically within the application. For a print copy send your street address to marketing@inviasolutions.com.

Hardware Requirements

4DM is compatible with desktop and laptop computers running a Windows® operating system.

Supported Operating Systems:	Windows® 7 (64-bit) Windows® 8 (64-bit) Windows® 10 (64-bit) Windows® Server 2008 R2 Windows® Server 2012 R2 Windows® Server 2016
Processor Speed:	2.0 GHz or greater
Memory:	3 GB recommended
Disk Space:	1 GB required for installation; 2-4 GB additional disk space for image files
Display:	1280x1024 or higher recommended 24 bit color
3D Graphics Card:	256 MB or higher recommended 3D graphic card supporting OpenGL 3.0 is recommended
Networking:	Networking adapter card (ethernet or wifi) required

Windows is a registered trademark of Microsoft Corporation in the United States and other countries

Installation and Licensing Instructions

The steps for installing and licensing the 4DM software are dependent on the platform for which it was integrated. Please refer to the Instruction for Installation provided with the software. For 4DM Personal, these Instructions for Installation are provided as an insert with the packaging.

To verify the installation and operation of 4DM, choose a patient study and launch 4DM. Based on the imaging data selected, 4DM will choose the default workflow for the data type. Ensure all transmitted data displays correctly within 4DM Screens according to the following table where screens that correspond to workflows are designated with an **X**:

	4DM Workflows						
4DM Screens	**SPECT**	**SPECT-CT**	**PET-CFR**	**PET-CT**	**FDG-Viability**	**GBPS**	**FDG-Inflammatory**
NM Viewer						**X**	
MUGA						**X**	
Tomo QA	**X**	**X**				**X**	
MI Processing	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Fusion		**X**	**X**	**X**	**X**		**X**
Images	**X**	**X**				**X**	
AC Images		**X**	**X**	**X**	**X**		**X**
Images + Quant	**X**	**X**					
AC Images + Quant		**X**	**X**	**X**	**X**		**X**
Func + Quant	**X**	**X**				**X**	
AC Func + Quant			**X**	**X**	**X**		**X**
Dyssynchrony	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Viability					**X**		
MPI Summary	**X**	**X**	**X**	**X**	**X**		**X**
Reserve			**X**				
CT Viewer		**X**		**X**			**X**
Ca Scoring		**X**		**X**			**X**
Inflammatory							**X**

Getting Started and Closing the Application

While the specifics for starting the 4DM software are dependent on the platform for which it was integrated, in general the steps are as follows.

1. Select a patient.
2. Select the 4DM icon to launch the application.
3. Select the **Quit** button or the **X** in the upper right-hand corner of the 4DM application window.

Accuracy

4DM is not intended to provide diagnoses or therapeutic recommendations, but is intended only to be a visual aid for use by trained medical professionals. The Clinician should never rely solely on it in making diagnostic or therapeutic decisions, nor to determine the presence or absence of a condition, but instead interpret all of the patient's clinical and diagnostic information to make a final diagnosis regarding a patient. The Clinician retains the ultimate responsibility for making a diagnosis.

Additionally, the 4DM program and/or it's methodologies have been validated through a variety of studies which have been widely published. A short sampling of the published data is as follows.

1. El Fakhri GE, Kardan A, Sitek A, et al. Reproducibility and Accuracy of Quantitative Myocardial Blood Flow Assessment with 82Rb PET: Comparison with 13N-Ammonia PET. J Nucl Med 2009; 50:1062–1071.
2. Ficaro EP, Corbett JR. Advances in quantitative perfusion SPECT imaging. J Nucl Cardiol 2004;11(1):62-70.
3. Ficaro EP, Lee BC, Kritzman JN, Corbett JR. Corridor4DM: The Michigan method for quantitative nuclear cardiology. J Nucl Cardiol 2007;14(4):455-465.
4. Ficaro EP, Corbett JR. Chapter 11: Technical Considerations in Quantifying Myocardial Perfusion and Function. In: Nuclear Cardiology: Technical Applications. Heller GV, Mann A, Hendel RC (eds.) McGraw Hill. 2009, 167-185.
5. Ficaro EP, Quaife RA, Kritzman JN, et al. Validation of a New Fully Automatic Algorithm for Quantification of Gated Blood Pool SPECT: Correlations with Planar Gated Blood Pool and Perfusion SPECT. J Nucl Med. 2002;43(5):97P.
6. Ficaro EP, Kritzman JN, Corbett JR: Automatic Segmental Scoring of Myocardial Wall Thickening and Motion: Validation of a New Semi-Quantitative Algorithm. J Nucl Med 2001; 42:171P.
7. Johansson L, Lomsky M, Marving J, Ohlsson M, Svensson S, Edenbrandt L. Diagnostic evaluation of three cardiac software packages using a consecutive group of patients. EJNMMI Research 2011:1-22.
8. Mahmarian JJ, Iskandrian AE, Cerqueira MD, et al. High Reproducibility of Serial Adenosine Single Photon Tomography Myocardial Perfusion Studies: A Quantitative Analysis From the ADVANCE MPI 2 Study. Circulation 2008;118:S607.
9. Schaefer WM, Lipke CSA, Nowak B, et al. Validation of QGS and 4D-MSPECT for quantification of left ventricular volumes and ejection fraction from gated 18F-FDG PET: comparison with cardiac MRI. Journal of Nuclear Medicine. Jan 2004;45(1):74-79.
10. Schaefer WM, Lipke CSA, Standke D, et al. Quantification of left ventricular volumes and ejection fraction from gated 99mTc-MIBI SPECT: MRI validation and comparison of the Emory Cardiac Tool Box with QGS and 4D-MSPECT. Journal of Nuclear Medicine. Aug 2005;46(8):1256-1263.

Product Use Information and Warnings

- **Product Use Information:** Information that assists in the proper use of 4DM
- **Warnings:** Messages indicating conditions which have to be corrected or changed in order to proceed with the use of 4DM.

This section is presented as explanation, followed by the information or warning. For each message, its intent is followed by the actual text of the information or warning. Bracketed text within the message represents a placeholder for values, parameters, or phrases extracted from the application or dataset. For example the message "User preferences for '{UserName}' do not exist" would display as "User preferences for 'John Doe' do not exist."

Product Use Information

Data Input

1. Quality assurance of tomographic data.

Tomographic data should be evaluated prior to reconstruction and corrections should be applied to minimize artifacts (e.g. motion), when possible. Failure to perform such corrections may result in misleading data, which may lead to misdiagnosis.

2. Quality assurance of reconstructed data.

Image data to be quantified by 4DM should be evaluated for accurate motion correction, reconstruction, and reorientation. Poorly motion corrected, reconstructed, and/or reoriented data can result in inaccurate quantification and may lead to misdiagnosis.

3. Quality assurance of defining imaging protocol (e.g. Stress, Rest) for dataset.

Matching a dataset to wrong protocol type could lead to the misinterpretation of a study. The user must verify that the string is entered in the proper protocol category and that a dataset can't be matched to multiple protocol types.

4. Quality assurance of defining file type (e.g. TOMO, RECON) for dataset.

Matching a dataset to the wrong file type could cause the program to load the wrong dataset into a display screen.

Surface Processing

5. Verification of the cardiac limits used for processing cardiac contours

The user should visually verify the processing limits-

- Heart Centering
- Basal and Apical Limits
- Volume Orientations

6. Verification of the estimated cardiac contours and quantification

The user should verify that the estimated cardiac contours are correct and track the myocardial walls. Inaccurate contours can result in incorrect computation of quantitative data, which can lead to misdiagnosis.

7. Effect of modifying the algorithm settings used to find cardiac contours.

Changing the Algorithm settings can have a significant impact on the accuracy of the surface generator. Only users familiar with the surface generator algorithm should adjust the values from the default settings.

Database Matching Issues

8. Importance of matching normals database for the computation of quantification data.

The user must verify that the Normals Database is compatible with the dataset being reviewed to ensure correct computation of quantitative data.

Database Creation or Modification

9. Importance of creating or modifying a normals database used for quantification.

Creating or modifying a Normals Database must be done with extreme caution. Users should match Acquisition and Processing Options when generating or modifying Normals Databases. Using databases that contain conflicting or incompatible patient data can result in inaccurate quantification and the potential for a misdiagnosis.

Quantification Thresholds

10. Importance of changing thresholds used to quantify perfusion defects.

Changing thresholds used to classify defects can significantly impact the accuracy of myocardial perfusion data.

Only users familiar with Receiver Operating Characteristic (ROC) curves and the impact that changing defect thresholds can have on test sensitivity and specificity should adjust the values from the default settings.

11. Importance of changing thresholds used to compute semi-quantitative segmental scoring maps.

Changing thresholds used to classify defect severity can significantly impact the prognostic value of the summed score index.

Only users familiar with Receiver Operating Characteristic (ROC) curves and the impact that changing defect thresholds can have on test sensitivity and specificity should adjust the values from the default settings.

12. Verification of DICOM parameters used to compute Standard Uptake Values (SUV).

The user must verify that the patient's weight, radiopharmaceutical, dose, and injection time are accurate. Incorrect values can result in an inaccurate estimate of the Standard Uptake Value (SUV).

13. Verification of DICOM parameters used to compute Radiation Dose.

The user must verify that the radiopharmaceutical and injected activity are accurate. Incorrect values can result in an inaccurate estimate of the patient's radiation dose.

CT Review and Quantification

14. Verification that CT study on Calcium Scoring screen was not acquired with contrast agent.

Users must ensure that a non-contrast Calcium Scoring CT dataset is input to the Ca Scoring screen prior to assigning scores.

Volumetric Fusion

15. Verification that fused datasets are from the same protocol (e.g. stress, rest).

When viewing NM data fused to CT data on the Fusion screen, verify they represent the same portion of the protocol (e.g. Stress NM to Stress CT).

Saving Results

16. Quality assurance of secondary capture images for image interpretation.

The user should ensure that any screen capture output (print, static pictures, movies) that is intended to be used for interpretation is of diagnostic quality. Interpretation using nondiagnostic output may lead to a misdiagnosis.

17. Quality assurance of exported results to formatted reports.

Prior to signing the report, verify that all of the information included in the report (demographics, qualitative, and quantitative data) is accurate.

Warnings

System Problems (Memory, Disk Space)

1. A system resource, e.g. memory, disk space, has been exceeded and the program must end.

4DM Fatal Error

"An unexpected error occurred: {*ErrorType}*
{ErrorDescription}
Should 4DM attempt to continue running?"

Errors saving surface files to tmpdata

"Failed to save <numberOfFiles> surface files.
<fileList>"

<numberOfFiles> is the number of files that could not be saved and <fileList> is a list of the associated filenames.

Installation and Configuration

2. A required configuration file for 4DM cannot be found.

"The file ConfigPolicy.xml either cannot be read or does not exist. Please reinstall the application."

3. The specified user preference file could not be found.

"User preferences for '{*UserName*}' do not exist.
Reverting to default configuration."

Data Input

4. The image dataset has properties that are not supported by 4DM

"Data Set Errors for Patient: {*PatientName*}

Dataset Description: {*SeriesDescription*}

- Invalid number of time slots (accepted range is (1,16)): {*value*}
- Pixel Size must be greater than {*MinSize*} mm
- Dynamic range of the data is too small (accepted range should be > 3): {*value*}
- Invalid Volume Dimensions {*VolumeError*}: {*value*}

- Invalid Voxel Dimensions: {*value*}"

Surface Processing

5. Processing is failing because the length of the left ventricle exceeds the surface algorithm's capability.
"This heart has exceeded size limitations (pixel units) of 4DM.

To process this study with 4DM you will need to manually adjust the basal and apical limits and reprocess. If processing still fails, you will need to reconstruct the dataset with a pixel size greater than the current value of {*value*} mm."

6. The basal and apical limits are too close the edge of the matrix which does not permit accurate estimation of the left ventricular surfaces.
"The center and axial limits in panel ({*SeriesDescription*}) do not provide enough space to accurately estimate the endocardial and epicardial surfaces of the left ventricle.

If the center and axial limits are properly defined, try reslicing the heart so that the center of the heart is approximately in the center of the SA volume and there is a 2 slice cushion beyond the apical and basal limits."

7. User attempts to leave the MI Processing screen with unprocessed changes
"Changes made to the processing limits have not been applied.

Select OK to process with your updated processing limits or select Cancel to discard the changes."

8. User attempts to leave Reconstruction screen with unprocessed changes
"Changes made to the processing filters have not been applied.

Select OK to Process with your updated limits or select Cancel to discard the changes."

9. User makes changes in dataset info popup that require reprocessing
"The changes that were made require one or more datasets to be reprocessed.
Please select OK to confirm the change or select Cancel to discard the changes."

10. User makes changes in dataset info popup that change quantification but do not require reprocessing
"The changes that were made may change the 4DM quantitative results.
Please select OK to confirm the change or select Cancel to discard the changes."

MUGA Processing

11. Background ROI placement on planar MUGA processing has produced incorrect results.
"Background counts are higher than some region counts. Reposition or redraw the background region of interest to correct."

12. Counts during ED/ES Only analysis indicate that the user placed a ED frame ROI on the ES frame
"User defined ED frame does not match the estimated ED frame for the study based on the regional counts.

Select OK to use the estimated ED "{*value1*}" and ES "{*value2*}" frames.
Select Cancel to reset regions and start over."

Coronary Flow Reserve Processing

13. Error when processing a coronary flow reserve study

"Flow Reserve Processing Failed:
{*SeriesDescription*} – {*ErrorMsg*}

where ErrorMsg is one of the following
Timing data is missing.
Unsupported or Invalid Data (Radiopharmaceutical)."

Database Matching Issues

14. The selected database is invalid due to insufficient studies in the database.

"The selected database has only {*value*} studies. The recommended minimum number of studies is 20. The defect severity and extent results from this database should be used with extreme CAUTION."

"The selected database has only 1 study. The recommended minimum number of studies is 20. The defect severity and extent results from this database should be used with extreme CAUTION."

15. Dataset and database mismatch for an imaging dataset.

"The selected database does not match the dataset.
- Gender Mismatch (Dataset={*value1*}, Database={*value2*})
- Imaging Orientation Mismatch (Dataset={*value1*}, Database={*value2*})
- Manufacturer Mismatch (Dataset={*value1*}, Database={*value2*})
- Model Mismatch (Dataset={*value1*}, Database={*value2*})
- Pharmaceutical Mismatch (Dataset={*value1*}, Database={*value2*})
- Polar Map Algorithm Mismatch (Dataset={*value1*}, Database={*value2*})
- Protocol Mismatch (Dataset={*value1*}, Database={*value2*})
- Recon Arc Mismatch (Dataset={*value1*}, Database={*value2*})
- Recon Corrections Mismatch (Dataset={*value1*}, Database={*value2*})

The defect severity and extent results from this database should be used with extreme CAUTION."

16. Mismatch Usages between Imaging and Comparison Databases

"You have selected an imaging database for use with a comparison study (e.g., Reversibility, Washout, etc.). This is incorrect and is not permitted. Please choose a database that matches the study."

"You have selected a comparison database (e.g., Reversibility, Washout, etc.) for use with an imaging protocol. This is incorrect and is not permitted. Please choose a database that matches the study."

"The database and study represent different comparison maps. This is incorrect and is not permitted. Please choose a database that matches the study."

17. Unable to find database that was used to quantify values in saved result file.

"An exact match for the normals databases referenced in the processed data files could not be found for every data set. Reverting to auto-matching for:
- *series Description of file #1*
- *series Description of file #2*"

18. ROI is too small to detect the surface contours of the ventricle.

"ROI drawn are too small to detect the surface contours of the ventricle. Redraw or zoom and then redraw appropriately."

Symbols

	**MANUFACTURER**
	**DATE OF MANUFACTURE**
	**CATALOGUE NUMBER**
	**CONSULT INSTRUCTIONS FOR USE**
	**EUROPEAN CONFORMITY: CE MARK**
	**AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY**
 (01)00864974000257(10)2018	**UNIQUE DEVICE IDENTIFIER (UDI) FOR V2018**
	**PRESCRIPTION DEVICE**

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