Qualifying Patients for a Normals Database

CLINICAL IMPORTANCE

Quick Reference Guides that you may find useful are: **Create a Normals Database**, **Add Patients to a Normals Database**, and **Edit a Normals Database**.

Nuclear Medicine departments have their own set of unique protocols and patient populations. Imaging systems between vendors have slightly different imaging results. For these reasons, users may want to create their own unique set of normals databases to ensure consistent quantitative results. For example, male patients have different normal perfusion distributions than female patients due to different physical characteristics (e.g., breast attenuation in females vs. diaphragmatic attenuation in males). Therefore, male patients should be compared to a normals database containing only datasets acquired with males, and female patients should be compared to a normals database containing only datasets acquired with females.

The Corridor4DM DB Generator screen (see Figure 1) provides the ability to generate a normals database and add patients to user-defined normals databases. Users can create normals databases that are indicative to a specific patient population, stress protocol, imaging protocol, etc. Additionally, the DB Editor screen (see Figure 1) allows the user to edit user-created normals databases. Userdefined normals databases integrate seamlessly into the 4DM application for routine clinical operation or research.

To activate the **DB Generator** and **DB Editor** screens, go to the **Screen Layout** section of **Preferences** in 4DM. Navigate to the **Inactive Screens** list, select the screen name from the list, and click **Activate Screen**.

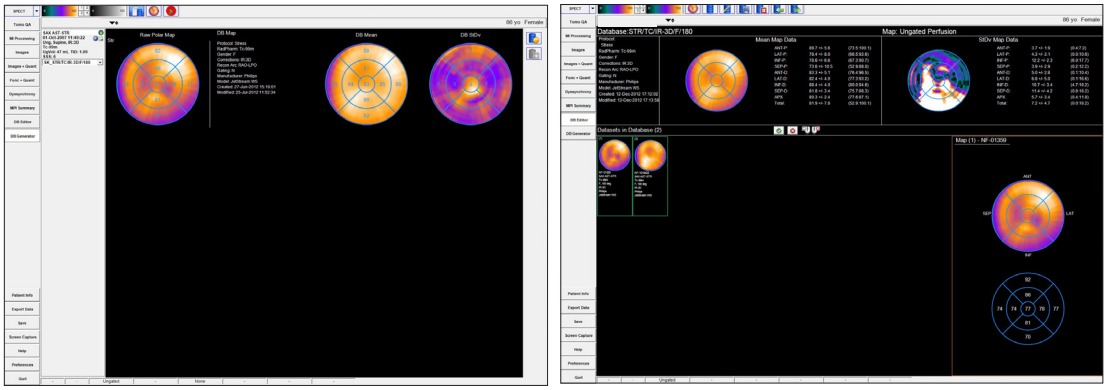

Figure 1: DB Generator and DB Editor screens

PATIENT SELECTION GUIDELINES

PATIENT OR VOLUNTEER SELECTION

The dataset that is incorporated into a user-created normals database used by 4DM is selected from a clinical population consisting of patients or volunteers. This dataset should consist of a transverse or short axis (SA) reconstruction volume from a myocardial perfusion imaging study.

The user-defined normals database must have a minimum of 20 patients added before it is available for use.

INVIA recommends a normals database population of 60 patients due to the wide range of normal variability between patient datasets.

- To qualify for use in a normals database, the patients or volunteers should exhibit symptoms that indicate a 5% or less prediction of heart disease from a nuclear cardiology study following an ECG stress test per criteria published by Diamond and Forrester (refer to Table 1).
- 4DM requires a minimum of 20 patients or volunteers to be included in a user-defined normals database before it can be used clinically. INVIA recommends a normals database population of 60 patients due to the wide range of normal variability between patient datasets.
- Patients who underwent coronary angiography should have no angiographic evidence of luminal irregularities approaching 50% diameter stenosis and no hemodynamic evidence of impaired coronary or hyperemic reserve or ventricular dysfunction, to be used for a qualifying dataset.

Percent Likelihood of Coronary Artery Disease

S-T Depression	Age	Asymptomatic		Nonanginal Chest Pain		Atypical Angina		Typical Angina	
		M	F	M	F	M	F	M	F
≥ 2.5	30-39	43	11	68	24	92	63	99	93
	40-49	69	28	86	53	97	86	100	98
	50-59	81	56	91	78	98	95	100	99
	60-69	84	76	94	90	99	98	100	100
(2.0-2.49)	30-39	18	3	38	8	76	33	96	79
	40-49	39	10	64	24	90	63	99	93
	50-59	54	27	75	50	94	84	99	98
	60-69	61	47	81	72	96	93	100	99
(1.5-1.99)	30-39	8	1	19	3	54	16	91	59
	40-49	20	4	41	11	78	39	97	84
	50-59	31	12	53	28	86	67	98	94
	60-69	37	25	62	49	90	83	99	98
(1.0-1.49)	30-39	4	1	10	2	38	8	83	42
	40-49	11	2	26	6	64	24	94	72
	50-59	18	6	37	16	75	50	96	89
	60-69	23	15	45	33	81	72	97	95
(0.5-0.99)	30-39	2	< 1	5	1	21	4	68	24
	40-49	5	1	13	3	44	12	86	53
	50-59	9	3	20	8	57	30	91	78
	60-69	11	7	26	17	65	52	94	90
(0.0-0.49)	30-39	< 1	< 1	1	< 1	6	1	24	7
	40-49	1	< 1	4	1	16	3	61	22
	50-59	2	1	6	2	25	10	72	47
	60-69	3	2	8	5	32	21	79	69

Modified from Diamond, G. and Foster, J., New England Journal of Medicine, 300, 1350 (1979)

Table 1: Percent Likelihood of Coronary Artery Disease

HOW TO USE THE TABLE

The table provides percent values for the prediction of heart disease in patients after an ECG stress test. Follow the table from left-to-right and identify the patient's S-T depression from their ECG stress test and age. Next, correlate their chest pain classification (see criteria below) with their gender (e.g. a patient with an ECG stress test S-T depression of 0.95 who is a 45-year-old female with nonanginal chest pain has a pre-test likelihood of 3%). The chest pain classification is typically obtained from the diagnosing physician. Patients or volunteers included in a normals database should have a percent likelihood less than or equal to 5%.

- Chest pain classification:
  - Asymptomatic: meets none of the chest pain criteria
  - Nonanginal chest pain: meets only one of the chest pain criteria
  - Atypical angina: meets two of the chest pain criteria
  - Typical angina: meets all three chest pain criteria
- Chest pain criteria:
  - Substernal location
  - Onset with exertion or emotion
  - Relief with nitroglycerin or rest

The accuracy of a user-defined normals database will depend on the quality of patient selection, study acquisition, and image reconstruction.

- Patients included in a normals database should:
  - Represent the population to which the normals databse is compared (e.g. age, body habitus, and gender)
  - Not include individuals with an extreme body habitus (e.g. BMI > 40) - unless the databse is designed specifically for patients of this type
  - Be acquired with radiotracer injection and image acquisition in the same phsyiologic state (i.e. Rest or Exercise Stress).

DATA ACQUISITION, RECONSTRUCTION, PROCESSING

- Datasets that are included in a user-defined normals database should be **acquired** using a similar imaging protocol (e.g. One-Day Ungated Rest/Gated Stress, Two-Day Gated Stress/Ungated Rest, etc.) and the number of frames for gated datasets should be consistent - either 8 or 16 frames.
- Datasets should be acquired using the same camera model and tracer.
- Datasets should be **reconstructed** using the same type of filtering, reconstruction method, and attenuation correction techniques, if applicable.
- Long axis and valve plane orientation should be verified for accuracy during **processing**. Polar map sampling is affected by varying angulations.

QUALIFYING A DATASET - AN OVERVIEW

- Launch 4DM using a patient qualified with the patient selection guidelines by selecting the raw datasets and properly reconstructed transverse or SA datasets.
- Review each of the raw datasets on the **Tomo QA** screen for artifacts.
- Assess each dataset within the **MI Processing** screen to verify the following:
  - Endocardial and epicardial contours
  - Valve plane, basal, and apical limit placement
  - Left ventricular centering and orientation
- Datasets should be carefully reviewed by experienced individuals (e.g. physicians, technologists, or physicists) to differentiate obvious artifacts due to patient motion, excessive hepatic activity, or incorrect reconstruction techniques. If any of these artifacts are observed, the patient data should be re-acquired (patient motion), re-reconstructed (incorrect reconstruction), or excluded.
- Datasets should be carefully reviewed by experienced physicians for perfusion defects. If abnormal perfusion is present, then it should be excluded.

For processing assistance, refer to the **MI Processing** Reference Guide.

BUILDING THE DATABASE

After qualifying and reviewing at least 20 patient datasets, create a user-defined normals database in 4DM, then add each dataset to it. Refer to INVIA's Quick Reference Guides 1) **Create a Normals Database**, as well as 2) **Add Patients to a Normals Database**, for guidance.