Cardiogen·82™
(Rubidium Rb 82 Generator)

Nuclear Medicine Suite

The individuals who appear are for illustrative purposes only. All persons depicted are models and not real patients or healthcare professionals.

We are **Cardiac PET™.**

CardioGen-82® (Rubidium Rb 82 Generator) offers diagnostic confidence, safety, and efficiency plus the professional training, service, and expertise Bracco is known for.

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Committed **to You.™**

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Generating Confidence in cardiac PET for more than 25 years.

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Indications and Usage:

CARDIOGEN-82® (Rubidium Rb 82 Generator) is a closed system used to produce rubidium Rb 82 chloride injection for intravenous administration. Rubidium Rb 82 chloride injection is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease.

IMPORTANT SAFETY INFORMATION:

WARNING: HIGH LEVEL RADIATION EXPOSURE WITH USE OF INCORRECT ELUENT AND FAILURE TO FOLLOW THE ELUATE TESTING PROTOCOL

Please see full prescribing information for complete boxed warning

High Level Radiation Exposure with Use of Incorrect Eluent

Using the incorrect eluent can cause high Strontium (Sr) 82 and Sr 85 breakthrough levels (5.1)

- **Use only additive-free 0.9% Sodium Chloride Injection USP to elute the generator (2.4)**
- **Immediately stop the patient infusion and permanently discontinue the use of the affected CARDIOGEN-82® generator if the incorrect solution is used to elute the generator (4)**
- **Evaluate the patient's radiation absorbed dose and monitor for the effects of radiation to critical organs such as bone marrow (2.7)**

Excess Radiation Exposure with Failure to Follow the Eluate Testing Protocol

Excess radiation exposure occurs when the levels of Sr 82 or Sr 85 in the rubidium Rb 82 chloride injection exceed limits. (5.2)

- **Record eluate volume, including waste and test volumes (2.4)**
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- **Stop using the generator if it reaches any of its Expiration Limits (2.6)**

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You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit https://www.fda.gov/Safety/MedWatch/default.htm or call 1-800-FDA-1088.

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Since 1989, Bracco has been building upon its legacy of leadership in cardiac positron emission tomography (PET) myocardial perfusion imaging (MPI) and the field of nuclear medicine. We were the first to invest heavily in cardiac PET MPI, and our continued commitment to the patients we serve each day is evident in the passion of our dedicated and experienced team. Join the growing number of world-class cardiac care facilities and teaching institutions that have discovered the benefits and clinical value of cardiac PET MPI with CardioGen-82® (Rubidium Rb 82 Generator).

Our benefits are clear:

- Rb-82 cardiac PET is highly sensitive and highly specific for greater diagnostic accuracy compared to SPECT[1]
- Low radiation exposure, along with industry-leading safety protocols, training, and support, helps safeguard your patients and occupational staff[2-4]
- Convenient on-demand, generator-based imaging agent provides robust images and fast image acquisition times
- Reduced serial testing for positive patient experiences[5]
- Reduced downstream costs provides value to your practice, payers, and patients[5,6]
- Locally based, easily accessible field team of trusted clinical and account support specialists, many with extensive clinical experience using CardioGen-82 (Rubidium Rb 82 Generator)
- Reimbursement professionals offer unparalleled support, saving time for staff and patients

"…Myocardial perfusion PET, because of its unique properties, **is the right test, at the right time** for certain patient populations."[7]

– Brian Abbott, MD, ASNC President

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"There are no clinical scenarios where PET should not be considered a preferred test for patients who meet appropriate criteria for a stress imaging test and who require pharmacologic stress."[7]

– ASNC/SNMMI Position Statement

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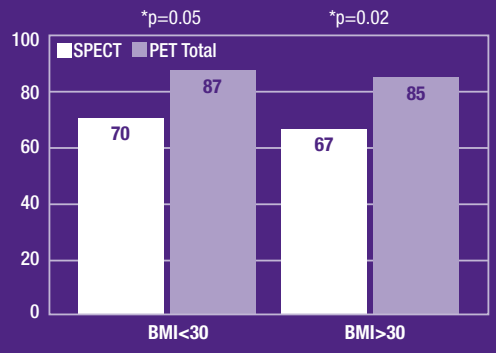
Cardiac PET MPI is considered first-line preferred imaging for your diverse patient population:

- **Women**—Less soft tissue attenuation with PET MPI can result in better image quality, regardless of breast size[6,8,9]
- **Real-time, true pharmacologic stress imaging** for those unable to perform a treadmill test[7]
- **Patients who have challenges with proper body positioning** during imaging studies[7]
- **Cardiac catheterization**—PET's high sensitivity and specificity can ensure more appropriate use of invasive and costly CABG (coronary artery bypass grafting)[5,10]
- **Patients with chest wall deformities** and other body habitus that can affect image quality[7]
- **Patients with areas of myocardium** that can benefit from revascularization[11]
- **High-risk patients** for whom diagnostic errors carry greater negative consequences such as those with kidney disease or diabetes[7]

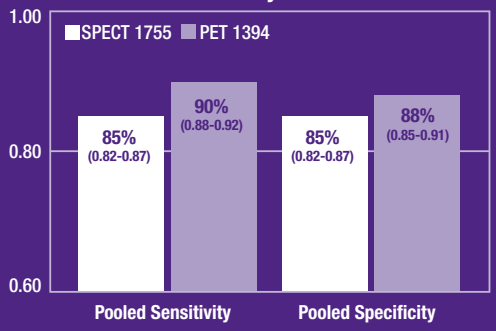
Diagnostic Accuracy vs. Body Mass Index[8]



Cardiac PET MPI:

- Outperforms other noninvasive approaches for determination of coronary artery disease (CAD)[1,7]
- Produces more artifact-free scans than SPECT[7,8]
- Provides stronger diagnostic confidence at true peak stress compared to SPECT[7]
- Less soft tissue attenuation for patients with body characteristics that can affect image quality[7,8]

Pooled Sensitivity and Specificity Results of Individual Rb-82 PET and Tc-99m SPECT Studies Included in the Analysis with 95% CIs[1]



Tc-99m SPECT performed with ECG-gating and AC.
CI=confidence interval

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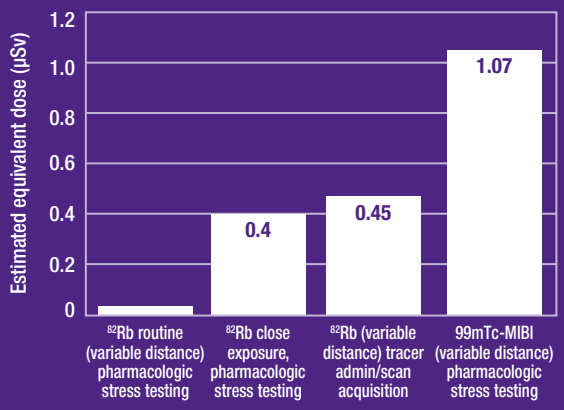
CardioGen-82® (Rubidium Rb 82 Generator) delivers safe, efficient cardiac PET MPI:

- "A clinical Rb-82 injection of 2x1,480 MBq (80mCi) would result in…only slightly above the average annual natural background exposure in the United States (3.1 mSv)"[2,3]
- Occupational "radiation doses for all tasks during routine Rb-82 stress-rest PET are lower than measured Tc-99m MIBI values"[4]
- Low radiation exposure for patients, staff, and nurses due to inherent safety of CardioGen-82 (Rubidium Rb 82 Generator), Bracco's rigorous safety protocols, and extensive training provided by our field experts

Dose (Per Stress Study) During Infusion of Radiotracer and Conduct of Pharmacologic[4]



Comparison of radiation exposure from pharmacologic stress Rb-82 and Tc-99m studies. *Rb-82 routine*, variable distance measurement; *Rb-82 close*, fixed 0.5-m distance starting at 7 minutes after rest injection. *admin*, Administration.

Support optimal patient management for your practice:

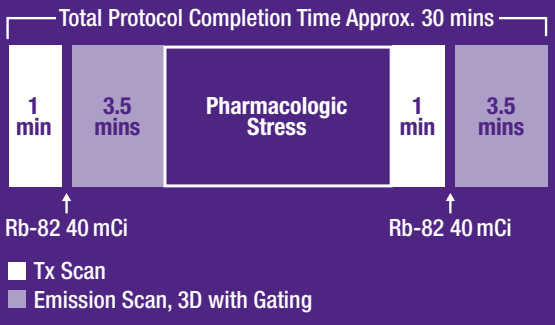
- Greater diagnostic certainty help reduce costly serial testing[5,8]
- PET's high sensitivity and specificity help ensure more appropriate use of invasive treatments like coronary artery bypass grafting (CABG)[5,8]

"PET scans routinely expose patients to <5 mSv and as little as 1 mSv effective dose using 3D protocols—**well below levels known to be associated with long-term adverse effects.**"[7]

Greater efficiency and convenience for patients vs SPECT:

- A complete Rb-82 rest-stress PET study can be acquired in approximately 30 minutes[12]
- CardioGen-82 (Rubidium Rb 82 Generator) is a predictable, fixed cost with fewer logistic hassles compared to unit dose agents

Typical 82Rb ECG-Gated Rest-Stress Acquisition Protocol for a Line-Source or Hybrid PET/CT System[12]



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"Myocardial perfusion PET is a robust nuclear cardiology test that supports the Centers for Medicare & Medicaid Services' initiatives to **improve the quality and efficiency of healthcare while controlling costs.**"[7]

– Brian Abbott, MD, ASNC President

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REFERENCES: 1. Mc Ardle BA, Dowsley TF, deKemp RA, et al. Does Rubidium-82 PET Have Superior Accuracy to SPECT Perfusion Imaging for the Diagnosis of Obstructive Coronary Disease? *J Am Coll Cardiol.* 2012;60:1828-1837. 2. Senthamizhchelvan S, Bravo PE, Esaias C, et al. Human biodistribution and radiation dosimetry of 82Rb. *J Nucl Med.* 2010;51(10):1592-1599. 3. Senthamizhchelvan S, Bravo PE, Lodge MA, et al. Radiation dosimetry of 82Rb in humans under pharmacologic stress. *J Nucl Med.* 2011;52(3):485-491. 4. Schleipman AR, Castronovo FP Jr, Di Carli MF, et al. Occupational radiation dose associated with Rb-82 myocardial perfusion positron emission tomography imaging. *J Nucl Cardiol.* 2006;13(3):378-384. 5. Merhige ME, Breen WJ, Shelton V, et al. Impact of myocardial perfusion imaging with PET and 82Rb on downstream invasive procedure utilization, costs, and outcomes in coronary disease management. *J Nucl Med.* 2007;48(7):1069-1076. 6. Yoshinaga K, Chow BW, Williams K, et al. What is the Prognostic Value of Myocardial Perfusion Imaging Using Rubidium-82 Positron Emission Tomography? *J Am Coll Cardiol.* 2006;48:1029-1039. 7. Bateman TM, Dilsizian V, Beanlands RS, et al. American Society of Nuclear Cardiology and Society of Nuclear Medicine and Molecular Imaging Joint Position Statement on the Clinical Indications for Myocardial Perfusion PET. *J Nucl Med.* 2016; 57(10):1654-1656. 8. Bateman TM, Heller GV, McGhie AI, et al. Diagnostic accuracy of rest/stress ECG-gated Rb-82 myocardial perfusion PET: comparison with ECG-gated Tc-99m sestamibi SPECT. *J Nucl Cardiol.* 2006;13(1):24-33. 9. Sampson UK, Dorbala S, Limaye A, et al. Diagnostic Accuracy of Rubidium-82 Myocardial Perfusion Imaging With Hybrid Positron Emission Tomography/Computed Tomography in the Detection of Coronary Artery Disease. *J Am Coll Cardiol.* 2007;49:1052-1058. 10. Patterson RE, Eisner RL, Horowitz SF. Comparison of cost-effectiveness and utility of exercise ECG, single photon emission computed tomography, positron emission tomography, and coronary angiography for diagnosis of coronary artery disease. *Circulation.* 1995;91(1):54-65. 11. Gould KL, Johnson NP, Bateman TM, et al. Anatomic versus physiologic assessment of coronary artery disease. Role of coronary flow reserve, fractional flow reserve, and positron emission tomography imaging in revascularization decision-making. *J Am Coll Cardiol.* 2013;62:1639-1653. 12. Bateman TM. Advantages and disadvantages of PET and SPECT in a busy clinical practice. *J Nucl Cardiol.* 2012;19:Suppl 1:S3-11.

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Bracco has been a longstanding innovator and leader in cardiac PET MPI, and we are committed to improving your practice and patient management for years to come.

Learn more at www.cardiogen.com or talk with your Bracco representative at 1-877-BRACCO-9 (1-877-272-2269)

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CardioGen-82 is manufactured for Bracco Diagnostics Inc., Monroe Township, NJ 08831, by GE Healthcare, Medi-Physics, Inc., South Plainfield, NJ 07080.

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