

Manufacturer and Product Information

Mission Diagnostics
A Division of Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
Diamond Diagnostics Technical Services at 1-508-429-0450

Intended Use: Mission 238 Slope is used to provide a second calibration point for pH, pCO₂, and pO₂ on 238 pH/Blood Gas Analyzer.

Summary And Principle: This product is intended to serve as a functional equivalent to pre existing material distributed by the Original Equipment Manufacturer (OEM).

Reagents: CD-473692D pH/Blood Gas Slope 50 x 2 ml
Containing: NaCl, Na₂HPO₄, KH₂PO₄, NaHCO₃, tonometry gas, and preservative.

For *in vitro* diagnostic use only

Values Assignment: pH and pCO₂/pO₂ values are based on testing representative samples from each lot referenced to the OEM pH/Blood Gas Calibrator and testing on 2 pH/BG Analyzers.

Cautions: Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amount of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately.

Stability: Package stability is listed on the product label. The product should not be used beyond this date. Store at room temperature, 18°-25 °C. Store away from direct sunlight. Product is intended for single use.

Procedure

Procedure: The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.

Quality Control: Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance.

Limitations

Limitations: If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

Verify that the reagents and internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.

Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.

Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.

If problems still exist, contact Diamond Diagnostics' Technical Service Department.



ATTENTION

These pH/Blood Gas ampules are coded A, B or C. The code is shown on the ampule labels and on the box integrity label. The appropriate code **must** be entered into the software (see the Instruction Manual – Set Gas Values, Page 2-3) before the ampules are used. If these ampules are of a different code to the previous box, remember there may be ampules of that previous code in the ampule heater.

ATTENTION

Ces ampoules de pente pour pH/gaz du sang portent les lettres A, B et C. Ces lettres sont imprimées sur les étiquettes des ampoules et sur la boîte. La lettre appropriée doit être entrée dans le logiciel (se reporter au mode d'emploi – Réglage des valeurs de gaz, page 2-3) avant d'utiliser les ampoules. Vérifier que l'ampoule du chauffe -ampoule porte bien la même lettre que celle introduite dans le logiciel de l'instrument. Ce réactif a fait l'objet d'un enregistrement auprès de l'Agence Du Médicament.

ACHTUNG

Diese pH/Blutgas Ampullen sind mit A, B oder C codiert. Diese Codierung befindet sich auf dem Etikett der Ampulle und in der Packungsbeilage. Der entsprechende Code muß in die Software eingegeben werden, bevor die Ampulle benutzt wird. Es können bis zu 3 Ampullen im Ampullen-Reservoir sein. Sollte die Codierung der Ampulle mit der Codierung der zuletzt benutzten Packung nicht übereinstimmen, bitte zuerst die Ampullen der letzten Charge aus dem Ampullen-Reservoir benutzen.

ATENCION

Estas ampollas de pendiente para pH/Gas en Sangre estan marcadas con las letras A, B o C. El código aparece en las etiquetas de las ampollas y en la caja. Debe introducirse la letra apropiada en la programación (ver el Manual de Instrucciones - Fijar los Valores de Gas, página 2 -3). Si estas ampollas son de una letra diferente a las ampollas usadas anteriormente, por favor tenga en cuenta que pueden quedar ampollas del código anterior en el calentador de ampollas.