



THE STORAGE AND HANDLING OF BLOOD GLUCOSE TEST STRIPS

ISSUE

Research undertaken by MEDEC members who represent diabetes care device manufacturing companies suggests that further education among all parties in the supply chain (wholesalers/distributors, sales representatives, pharmacies, and healthcare providers) is required to maintain product integrity by ensuring proper handling, shipment, and documentation procedures for blood glucose test strips.

Compliance with the Establishment License requirements of the Medical Devices Regulations is also a key expectation.

MEDEC'S POSITION

- Patients and health professionals are entitled to test strips that meet strict safety, quality and performance standards. The availability of accurate results is critical to proper diabetes care.
- The safety and integrity of test strips is a joint responsibility of all parties in the supply chain. This includes wholesalers/distributors, sales representatives of companies that manufacture diabetes test strips, pharmacists and other appropriate healthcare providers.
- MEDEC believes that the most effective ways of ensuring the integrity and safety of test strips is through adherence to industry best practices and compliance with the Health Canada labeling requirements and the Health Products and Food Branch Inspectorate (HPFBI) guidance on Medical Device Establishment License (MDEL) requirements.
- Ongoing monitoring and education are key to the maintenance of high quality diabetic test strips.
- For the direct distribution of test strip samples, a record of the distribution should be kept.
- Healthcare providers involved in diabetes management should also be informed of best practices.



MEDEC

CANADA'S MEDICAL DEVICE TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIE DES
DISPOSITIFS MÉDICAUX



WHAT MEDEC MEMBER COMPANIES ARE DOING

To ensure proper and consistent compliance to the MDEL requirements, and to continue to improve the handling of blood glucose test strips, MEDEC member companies will:

1. MEDEC member companies will develop and issue best practices for product management and tracking, including handling, temperature and documentation instructions for companies distributing test strip samples via representatives.
2. MEDEC member companies will equally review internal procedures regarding the handling of test strip samples for continued compliance with MDEL requirements, working with external partners including healthcare providers and distributors as required.
3. MEDEC member companies will undertake an educational program with wholesalers/distributors and diabetes Healthcare Providers to inform and educate them on MDEL requirements including optimal handling of sensitive products, and the need to focus on pay attention to product labeling.

These initiatives will be undertaken in 2006.

BACKGROUND

Blood glucose test strips are sensitive medical diagnostic tools that regularly impact the lives of patients with diabetes. These strips are stable for a limited period of time and carry explicit environmental storage instructions, and expiration dates. It is therefore critical to diabetic patients that these strips are properly stored and handled throughout the supply chain process, prior to sale or delivery to patients.

UNDERSTANDING MDEL REQUIREMENTS

The HPFBI Medical Device Establishment License (MDEL) guidance document (http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/mdel_gd_20040220_e.pdf), published Feb 2004, outlines the obligations for holders of an MDEL. According to the guidance document, holders of establishment licenses must have a set of procedures in place to handle and store equipment in a safe and effective manner. According to Appendix 2 of the guidance document that addresses sensitive devices, procedures must be in place for protecting test strips from environmental factors, including appropriate storage and stock rotation (point 1). HPFBI inspectors would also expect to see objective evidence that procedures are being followed. This is a shared responsibility of all in the supply chain and is mandatory for those holding an MDEL. Manufacturers, wholesalers/distributors and sales representatives should also maintain complete distribution records for tracking purposes.

Healthcare providers in diabetes care may receive quantities of test strips directly from company sales representatives. The management of these test strip samples en route to and in the pharmacy, should also comply with the procedures for storage and handling outlined by the companies. That is, test strips are stored at the appropriate temperature and environmental conditions, and distribution records are maintained.