



**MEDEC**

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



# GENERIC PRODUCT REGISTRATION CARDS AND PIPEDA REQUIREMENTS

## ISSUE

- A few Canadian retailers have made recommendations to develop standardized or generic versions of warranty cards to replace company specific warranty cards.
- Retailers would like to track customer warranty card information and potentially become involved in the centralized transfer of patient information to manufacturers of blood glucose meters.

## MEDEC'S POSITION

- While the members of MEDEC understand the principle behind the retailers' desire for a generic warranty card, we believe that the use of a single warranty card to represent all device manufacturers is insufficient to offer consumers a warranty that is reflective of the product and may contravene PIPEDA.
- Further, we contend that:
  - › Due to differing product features and specifications, Warranty Cards must be product-specific.
  - › Each company must comply with PIPEDA. In doing so they cannot disclose customers' personal health information to third parties, such that third parties should not be involved in the warranty process.
  - › Pharmacies need to develop their own traceability system, outside of manufacturers' warranty records.
- Information collected for the purposes of warranty on blood glucose monitor products is obtained pursuant to positive consent provided by the customer to the device manufacturer. The manufacturer, and not the retailer, must retain an accurate record of the customer in case of device malfunction or product recall.
- PIPEDA requires manufacturers to protect client information by safeguarding the access to that information and restricting its potential uses. All MEDEC members, including manufacturers of blood glucose monitors, recognize patient safety and confidentiality as one of their core principles.

**MEDEC members feel fortunate to have a strong relationship with pharmacists that enables the improved collection of warranty cards. We encourage the continued use of product-specific warranty cards that will protect patient privacy by restricting the use of personal health information.**

## BACKGROUND

- Manufacturers of blood glucose monitors and test strips collect Product Warranty Cards to maintain accurate records of customers in order to provide optimal after sales service and support, and may contravene the Personal Information Protection and Electronic Documents Act (PIPEDA) legislation.
- All information on the Product Warranty Cards is considered confidential by the manufacturers, and is governed by the Personal Information Protection and Electronic Documents Act (PIPEDA) legislation.

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405 The West Mall, Suite 900, Toronto, Ontario M9C 5J1

T: 416.620.1915 • F: 416.620.1595 • Toll-Free: 1.866.58.MEDEC • [www.medec.org](http://www.medec.org) • Email: [medec@medec.org](mailto:medec@medec.org)

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