Dear EKOS Customer;

EKOS Corporation is moving to the GS1/GTIN labeling and bar code standards as part of our continuing efforts to meet customer expectations, to remain compliant with the FDA Unique Device Identification rule and improve supply chain efficiency. This document contains answers to some of the more frequently asked questions.

1. **What are the GS1 Standards?**

GS1 standards are the most widely used supply chain systems in the world, spanning many industries. They drive supply chain efficiency, traceability and accuracy. Examples of GS1 supply chain applications include Global Trade Item numbers (GTIN), Global Location Numbers (GLN) and the Global Data Synchronization Network (GDSN.) To learn more about GS1 Healthcare, please visit, www.gs1.org/healthcare.

2. **What does the new label look like?** The new label features the addition of the Global Trade Item Number (GTIN), and the removal of the HIBC bar code. Note that the previous part number is still present and may be found in the reference/Catalog field of the label.

3. **What is a GTIN?**

A GTIN (Global Trade Item Number) is a globally unique identification number of an item in the supply chain that identifies a product from manufacturing through distribution and use. The GTIN is typically a 14-digit numeric code which includes a company prefix followed by product identification numbers. The GTIN, as well as other key product attributes, are automatically identified when a bar code is scanned.
4. Why is EKOS moving to the GS1/GTIN now?

EKOS Corporation is moving to the GS1/GTIN Healthcare Standard as part of our continuing efforts to meet customer expectations, remain compliant with FDA UDI labeling and improve supply chain efficiency. We recognize the value of standardization for the medical device industry and are working closely with healthcare providers to ensure that we are delivering what they need related to GS1 standards.

5. What is the expected impact of this change?

The impact of this change is associated with scanning product bar codes for inventory tracking. If hospital equipment is set for scanning only HIBC codes, an update to the MMIS (materials management information systems) with the GTIN part numbers will be required.

6. Is the GTIN replacing the HIBC numbers and bar codes on all current products?

The majority of EKOS Corporation products are currently labeled with Health Industry Bar Codes (HIBC), which will be replaced by a GTIN & GS1 Datamatrix bar code.

7. Where are GTINs used?

GTINs are used on product packaging labels.

8. What is the timeline for products transitioning to GTINs?

EKOS will begin GTIN labeling in September 2016. Over the next year, you will see a mixed inventory of products as our supply chain pipeline is flushed and HIBC-labeled product is consumed. There is no difference between products that are HIBC labeled or GTIN labeled. As such, HIBC-labeled products need not be returned.

9. Where can I get a list of GTIN bar codes?

A complete listing of our products transitioning to the GTIN part numbers along with their original HIBC part number may be requested by contacting Ekos Customer Care at 888-400-3567 or 425-415-3100.

10. Are other companies using these GS1 Standards?

Yes. Numerous companies across the healthcare industry have adopted GS1 standards.

11. How do the GS1 standards relate to the new Unique Device Identification (UDI) rule?

The FDA recently published their final rule on a Unique Device Identification (UDI) System for medical devices. They will require that all medical device packaging labels contain Unique Device Identifiers from FDA Accredited Issuers. The compliance date EKOS is working to is September 24, 2016.

12. Do I need to return inventory that doesn’t have the new GTIN labeling?

No. You may receive inventory that contains the HIBC only product labels during the transition period to the new labeling. It is not necessary to return products that do not contain GTIN bar code labels.

13. Who can I contact for more information or help with GTIN bar code scanning?

For more information, please contact your EKOS local representative, or our EKOS Customer Care team at 888-400-3567 or 425-415-3100.

Thank you for your business.

Sincerely;

Jocelyn Kersten
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EKOS Corporation