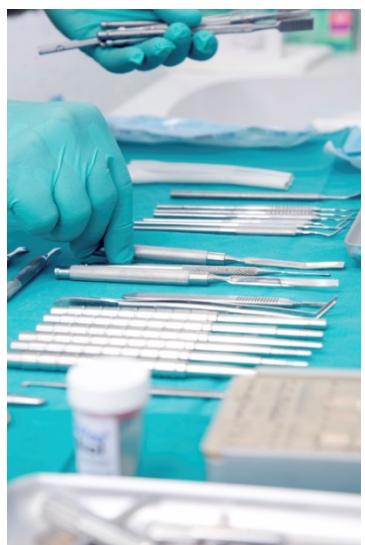
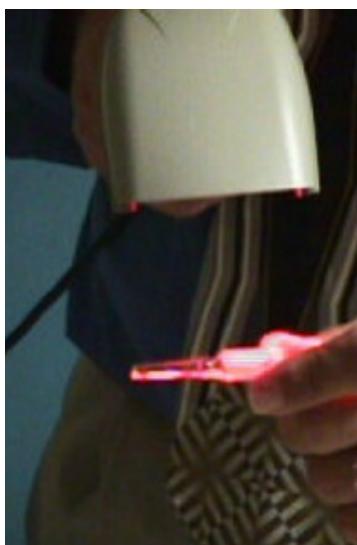


Procedure for



Responding to Troublesome Bar Codes For Healthcare Providers and Suppliers

Supplemental Guide to the Healthcare Provider and Supplier Tool Kits

GS1 Healthcare US would like to thank
the members of the GS1 Healthcare US Product Identification Workgroup
for their hard work and dedication in developing this guideline.

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Introduction

The procedure outlined in this guide is the process to follow when a U.S. healthcare facility front line user cannot read a bar code with a bar code scanner, whether that user is a nurse or loading dock personnel. The procedure outlined is progressive and broken into three parts:

Phase 1: Steps for the Front Line User at the Healthcare Provider Facility

The procedure begins with steps that a front line user can take to quickly resolve the problem. These steps offer quick resolution of commonly-faced issues. If these steps do not resolve the problem, the issue is escalated internally to a central review group in the healthcare provider facility.

Phase 2: Steps for the Central Review Group at the Healthcare Provider Facility

The procedure continues with the steps that the central review group in the healthcare facility can use to examine the problem more closely using a more structured process. If these steps do not resolve the problem, the issue is escalated externally to the supplier.

Phase 3: Steps for the Supplier

Finally, the procedure defines the steps that the supplier can use to examine the problem further. These steps define the recommended procedure that a supplier can use for resolution of the problem and reporting back to the customer and the FDA, if necessary.

! This procedure is one of a series of documents to assist the U.S. healthcare supply chain. Please see the **GS1 Healthcare US GTIN References** section for the other documents.

Purpose

The purpose of this document is to provide a standardized procedure for U.S. healthcare provider facilities and suppliers to follow when a “troublesome” bar code is encountered (i.e., bar code not reading). This guide includes both a written and “swim lane” pictorial representation of the procedure. The procedure was developed by the GS1 Healthcare US Product Identification Workgroup, whose primary mission is to promote the use of the Global Trade Item Number® (GTIN®) in U.S. healthcare.

This guideline is not static and will be revised on a regular basis as more lessons are learned from U.S. users. GS1 Healthcare US gladly welcomes comments, case studies and other criteria so that this guideline can be updated as more hospitals employ scanners. Please send any and all suggestions to:
GS1HealthcareUS@gs1us.org

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GS1 US is the Member Organization of GS1 that serves companies in the United States. As such, it is the national implementation organization of the GS1 System dedicated to the adoption and implementation of standards-based, global supply chain solutions in the United States. GS1 US currently serves over 200,000 U.S. member companies -- 16,000 of which are in healthcare.

About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers & distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US in the United States.

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GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of eighteen local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.

Phase 1: Healthcare Facility Front Line User

Because bar code scanners are used throughout a healthcare provider facility, front line users of bar code scanners can include nurses, pharmacists, receiving dock personnel, etc. The following steps can be used by any front line users whenever a bar code on a product does not scan. These steps resolve some of the most common issues related to bar code scanning. Front line users can follow the check list below to resolve simple, common problems quickly.

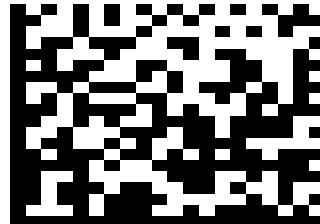
Steps

1) Check Human Interface Issues

- Vary the distance and angle between the scanner and the bar code. Focus on scanning one bar code instead of multiple bar codes on a package.
- Ensure you are scanning the correct bar code (i.e., GTIN or package control number).
- Ensure that the scanner you are using can read the type of bar code on the item:
 - Laser scanners (i.e., the red lines) can only read one dimensional (linear) bar codes like the GS1-128. They cannot read two dimensional bar codes like the GS1 DataMatrix.
 - Only imager lasers and camera orientation scanners can read 2 dimensional bar codes.



GS1-128
One Dimensional (or Linear) Bar Code



GS1 DataMatrix
Two Dimensional Bar Code

2) Check Mechanical/Electrical Scanner Issues:

- Check the battery status. If there is less than 50% of the battery life remaining, change (or recharge) the battery and try again.
- If the scanner is electrical, verify that it is securely plugged in to the outlet.
- Ensure that the scanner lens is clean. (This is the most frequent issue.)
- Check if the scanner lens is scratched. If so, it will need to be serviced.
- Try to scan the bar code with another scanner of the same model and manufacturer. If successful, then the problem is with the first scanner and it should be put in for service. If the second scanner also fails to read the bar code, escalate the issue to your internal review group for further analysis.

3) If none of the above efforts resolved the problem and enabled you to scan the bar code, then send the bar code to the central review group for troublesome bar codes.

Phase 2: Healthcare Facility Central Review

The central review group of troublesome bar codes can be an ad hoc or permanent group within the organization, depending on the number of troublesome bar codes encountered. The makeup of the group may vary from facility to facility. Nonetheless, it is recommended that the group include the following representatives at a minimum:

- **Information Services:** needed if minor programming of the scanners and/or database is required (e.g., adding a symbology type to a scanner)
- **Pharmacy Personnel:** needed to review small pharmaceutical packages (e.g., does the package meet FDA regulatory requirements?)
- **Purchasing Personnel:** needed to review the purchasing parameters of both the healthcare product and the scanner (e.g., do the terms and conditions require conformance to GS1 standards for bar codes?)
- **Materials Manager:** needed to contact the product supplier (pharmaceutical or medical device) to resolve if necessary

This department or ad hoc group can follow the check list of potential issues below to perform a more thorough examination of the bar code before contacting the supplier.

Steps

1) Check Scanner Issues

- Does the bar code on the product read successfully using a different scanner brand/model than what was used by the front line personnel?
- Does the bar code take too long to read? (Note: There is no ISO standard for length of time to read. This is a subjective user call.)
- Are multiple scans needed before the bar code is successfully read?

2) Check Scanner Programming Issues

- Identify the type of bar code symbology used on the product [e.g., GS1-128, GS1 DataBar™ (RSS)]. Does scanner require additional programming to accept that bar code type? Most bar code scanners can be easily programmed to read additional bar code symbologies. Check the scanner owner's manual/website for assistance, and/or call your scanner supplier for assistance.

3) Check Database Issue

- Is the product in your Item Master database file? If not, then update your master file.

4) Check ISO Grade

- Check the ISO grade of the bar code in question. The GS1 standard states that bar codes in commercial use should be an ISO Grade C or better. [Bar codes on shippers with corrugated material (i.e., brown cardboard boxes) are allowed an ISO Grade D.] Although these grades are the global standard, the facility contract terms may require a different ISO grade for the item in question. Checking the ISO grade may be done by personnel within the facility or sent to a vendor that supplies this service (including GS1 US).

5) If the above procedures have been followed and the bar code still will not read or the ISO grade is below the accepted minimum, then:

- Notify the initial complainant about the results of the review. Be sure to define a contingency process and document the cost of this process.
- Notify your product manufacturer. Document the problem solving procedures followed above, and provide a sample or picture if available. Communicate with your product manager by phone if urgent, in writing (see the sample letter in Appendix B), and/or electronically if available.

! If a resolution is not reached following the steps above, then you can notify FDA Med Watch, as an incorrect bar code/NDC on a product constitutes mislabeling. However, this step should only be taken as a last resort if you cannot reach a resolution with the product supplier.

Phase 3: Supplier/Product Manufacturer Review

Once a supplier receives notification of a problem from a user, they can follow the check list below to resolve the problem.

Steps

1) Document the complaint.

2) Determine if the bar code is the issue:

- Is the product specified as the supplier's product?
- Has the product been counterfeited?
- Is it the supplier's label?
- Has the product been relabeled?

3) Scan and verify the bar code with internal equipment.

- Verify with a sample label from the same lot.

4.) Notify the complainant of your findings and the resolution.

5.) Issue a report within your company about the issue.

6.) Institute corrective action to resolve the problem (if necessary).

7.) Notify the FDA (if it is a serious issue).

8.) Contact GS1 US if assistance is required.

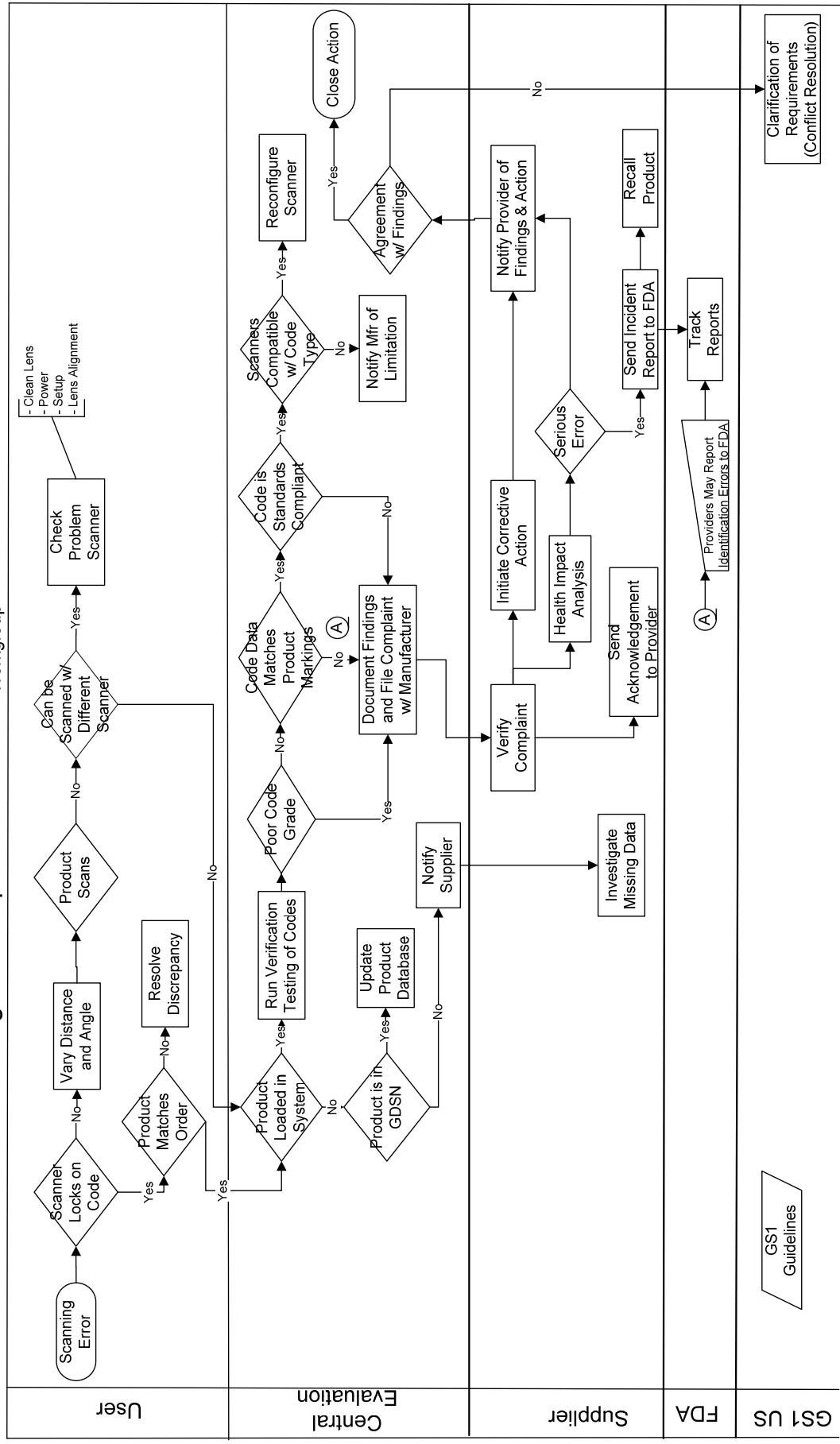
GS1 Healthcare US GTIN References

- Online Healthcare Provider Tool Kit – Global Trade Item Number (GTIN)
<http://www.gs1us.org/hcptoolkit>
- Online Healthcare Supplier Tool Kit – Global Trade Item Number (GTIN)
<http://www.gs1us.org/hcsuptoolkit>
- Simplified Guide for U.S. Healthcare Bar Code Scanner Acquisition Criteria
<http://www.gs1us.org/Communities/Healthcare/HealthcareDocumentLibrary/tabid/166/DMXModule/586/Default.aspx?EntryId=102>
- GS1 Verification Guideline
<http://www.gs1.org/barcodes/support>

Appendix A: Diagram of the Troublesome Bar Code Procedure

Troublesome Bar Code Investigation Proposal

GS1 US GTIN
Workgroup



Appendix B: Sample Letter to Supplier Reporting a Troublesome Bar Code

{Letterhead of Healthcare Provider Facility}

TO: Name
Address

Dear _____:

[Name of the healthcare facility] has made a strategic commitment and is an industry leader in improving patient safety through the use of bar codes. To maintain the integrity of our patient safety systems, we request our supplier partners to conform to bar code quality printing guidelines by providing products that meet American National Standards Institute (ANSI) / International Standards Organization (ISO) verification grade minimum C target A.

The [xxxxxx] product with the GTIN [xxxxxxxxxx], the lot number [xxxxxxxx] and expiration date [xxxxxx] was provided to the facility Verification Test Lab from a facility member. Bar code verification testing with [xxx] model verifier (Calibrated Conformance Standard Test Card for European Article Numbering / Universal Product Code Symbol Calibration # UPC2-4144) presented the following results:

Verification Criteria	Results
Symbology	GS1-128
Overall ANSI Grade	F
X-Dimension	9.9mils
Edge Determination	Fail
Minimum Reflectance	Pass
Minimum Edge Contrast	Pass
Decode	Fail
Contrast	C
Modulation	B
Decodability	F
Defects	B
Quiet Zone	Pass

The product tested is enclosed with this letter.

The healthcare facility contracts call for all bar codes on products to this facility meet ISO standards of Grade C, target A. The product tested had an overall ANSI grade of F. We request that you make appropriate adjustments based on the detailed information provided to meet or exceed our targeted minimum standards. Please respond with corrective action within thirty (30) days of receipt of this letter.

If you have any questions, do not hesitate to contact [-----].

Sincerely,

Director, Bar Code Office

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IAPMO

In this publication, the letters "U.P.C." are used solely as an abbreviation for the "Universal Product Code" which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.



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