IMPRINT ENTERPRISES

SINCE 1975

- 05/19/2015

(855) 745 - 4464

customer_service@imprint-e.com

http://udi.imprint-e.com

Mike Hess

Bob Conti

UDI Labeling

Christine Weber
UDI Product Manager
Zebra Technologies
Phone: 847 955 4505
cweber@zebra.com
www.zebra.com

Agenda

- Label Design Key Considerations

- Barcode Printer Types and Settings

- Barcode Label ANSI Grades

- Label Material & Quality Considerations
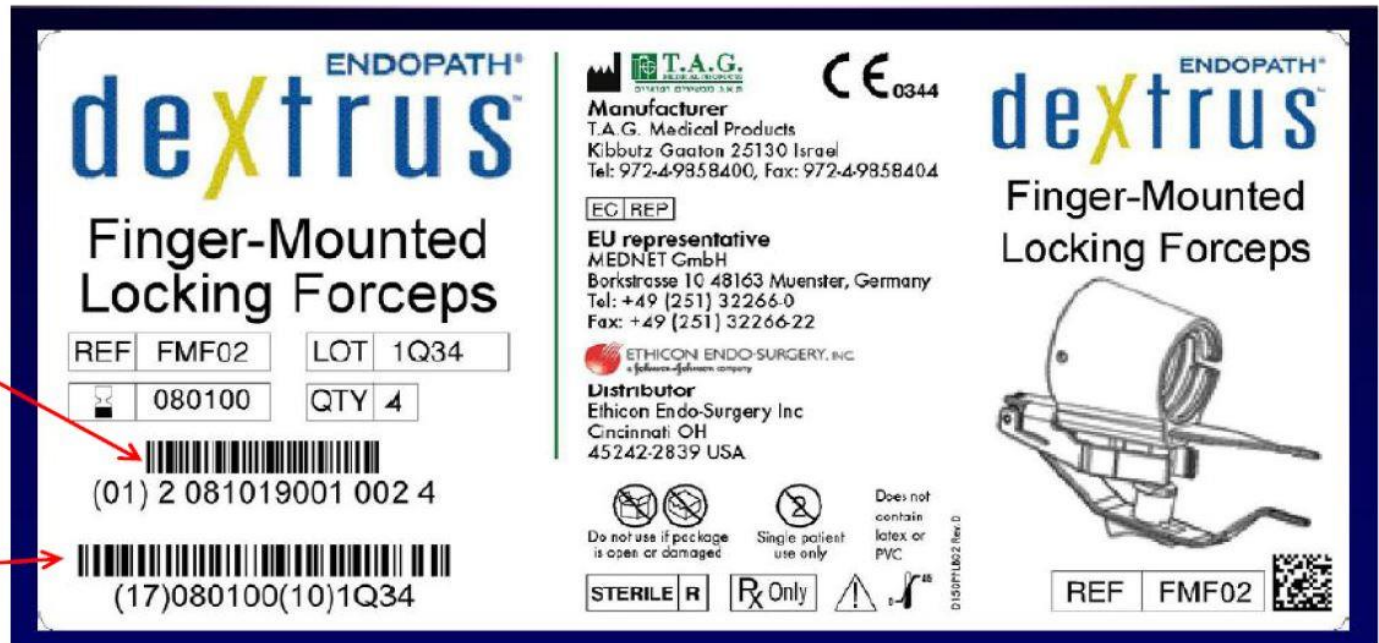
LABEL DESIGN CONSIDERATIONS

Label Design Impacts Readability and Scannability

- Identify Target Label Size

- Layout Required Information on Label to Ensure it Will Fit

- Determine Print DPI Required, by Taking into Consideration:
  - Text size
  - Use of regulatory symbols and their size
  - Print speed required
  - Barcode size

Label Size and Amount of Required Information

Device Identifier
(01) GS1 GTIN

Production Identifier
(17) Expiration
(10) Lot Number
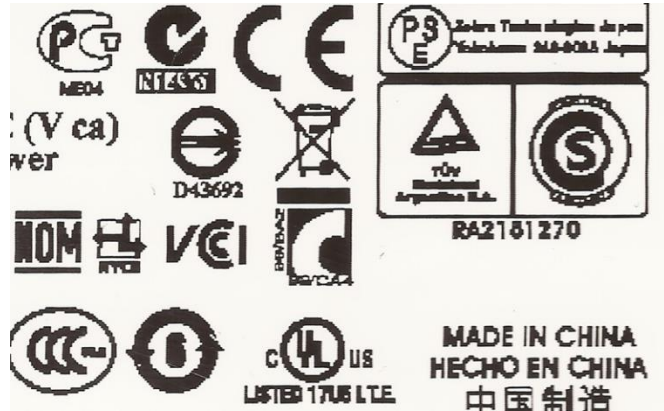
Device Identifier and Production Identifier Concatenated in a GS1 Data Matrix symbol

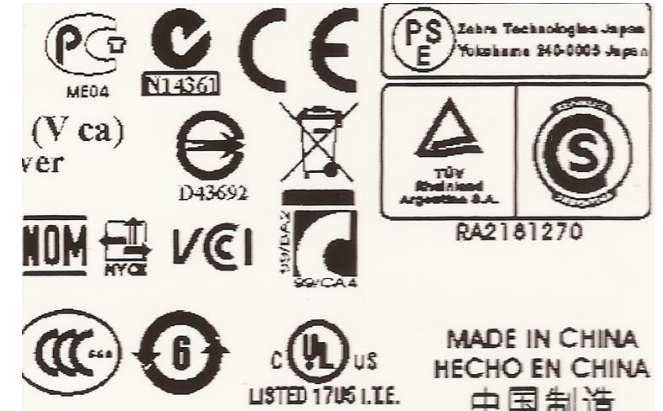## Determining DPI
Text & Regulatory Symbols

- If printing text or regulatory symbols less than 6 pt, 600 dpi is recommended

203 dpi

300 dpi

600 dpi
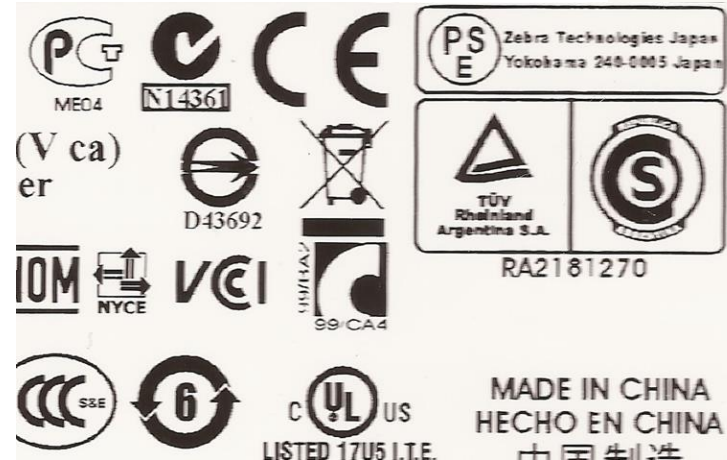
Determining DPI
Print Speed

- How fast do the labels need to print?
- As DPI increases, the maximum print speed of a printer decreases, for example:

Determining DPI
Bar Code Size

- For 2-D barcodes less than 3/10 x 3/10", 600 dpi is recommended
- Minimum size for 1-D barcodes varies based on the number of digits in the barcode (printing the DI and PI in one barcode or two)

BARCODE PRINTER TYPES & SETTINGS

Printer Considerations

- Where is the labeling being done?
  - Within company
  - Contractor

- How is the printing being done?
  - On-demand printing = many lower duty cycle printers
  - Batch printing = less higher duty cycle printers

Printer Types

Xi4

300 or 600dpi
24/7 Mission Critical
Unlimited Duty Cycle

ZT410

300 or 600dpi
Value-Performance
8-10 Rolls/Day

ZD500

300 dpi
Value
2 Rolls/Day

Printer Settings

- Determine the Best Settings for the Below To Obtain High-Quality, Consistent Print Quality.
  - Printhead Pressure. Adjust to insure right amount of pressure based on label material being used.
  - Print Darkness. Adjust to insure not
  - Print Speed

- Tips:
  - Verify print quality using a pause test
  - Print a printer configuration label (contains printer settings) and put in door (in case settings get changed)
  - Encourage contractor to use the same brand of printers you are using and provide them with printer setting guidelines to ensure consistent print quality

Barcode Label ANSI Grades

- ANSI Grades
  - Barcodes can appear "good" to the naked eye, but they may not be
  - Provide a measure for how well a barcode will scan
  - A to F scale

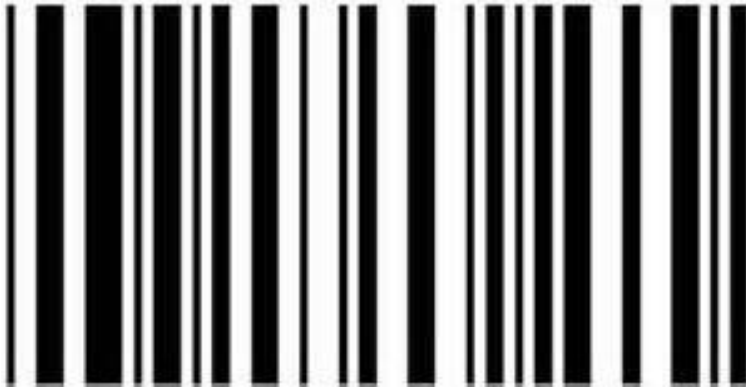- FDA ANSI Grade Requirements: C or better

What Affects Barcode Label ANSI Grades?

- Barcode Size
  - The larger the barcode, easier to scan.
  - Reducing the barcode size too much, can result in an unscannable barcode

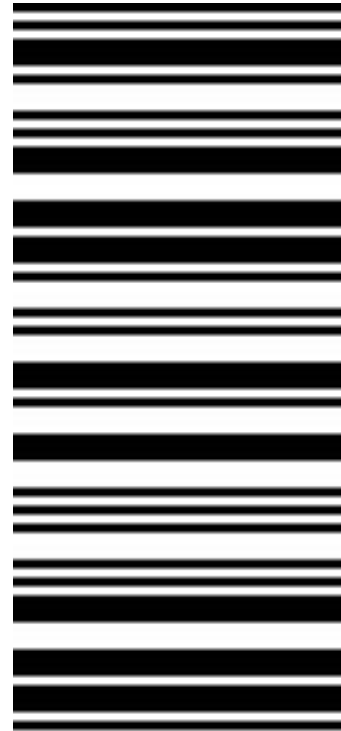# What Affects Barcode Label ANSI Grades?

- Barcode orientation
  - If printing 1-D barcodes, we recommend you print picket fence v. ladder

"Ladder"
Printhead element turns on and off, on and off

"Picket Fence"
Printhead element turns on and stays on

What Affects Barcode Label ANSI Grades?

- Quiet Zone
  - Need enough white space on each side of barcode or it won't scan

What Affects Barcode Label ANSI Grades?

- Dirty/Failed Printhead Element
  - Perform periodic print quality tests to check printhead
  - Perform printhead cleaning to remove any debris obstructing the printhead.

Dirty or Bad Elements
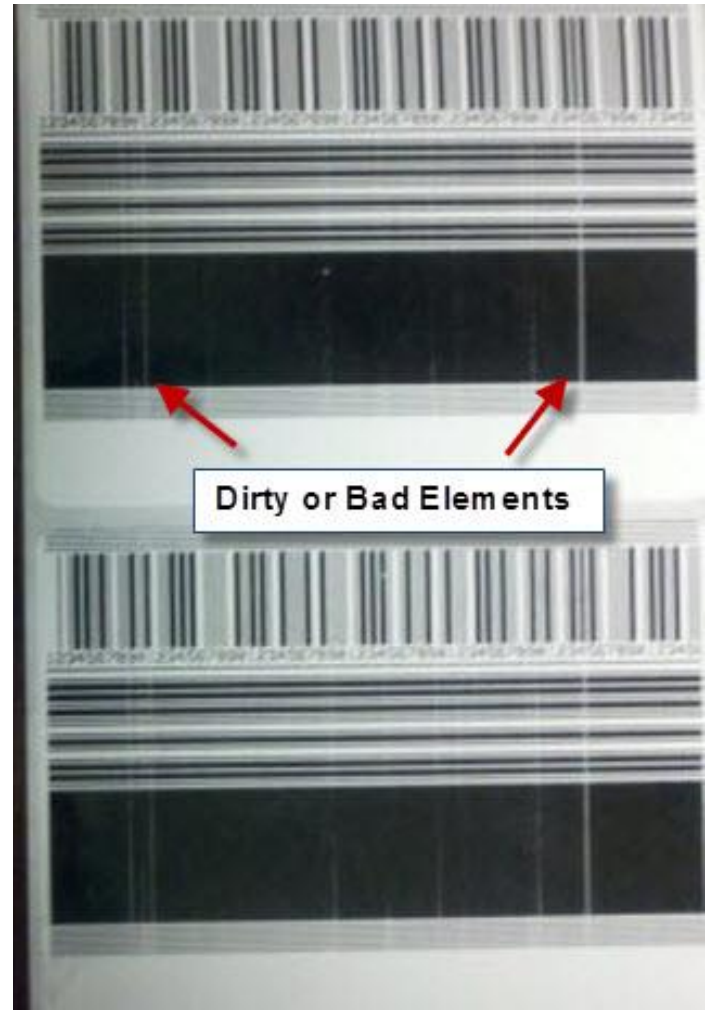
LABEL MATERIAL & QUALITY CONSIDERATIONS

Label Material Considerations

- Sterilization
  - Not every label with withstand Steam Autoclave, Gamma Radiation & Ethylene Oxide

- Chemical Resistance
  - Hospitals wipe-down reusable items with strong healthcare cleansers to prevent the spread of disease\

- UL-certified Label Required?

FDA Label Quality Requirements

- Title 21, Chapter 1 FDA, Subchapter H
  - Label Integrity
    - Remain legible and affixed during processing, storage, handling, distribution, and where appropriate use
  - Labeling Inspection
    - Need to verify info on the label is correct.
    - Need to document the release in the DHR, including the date and signature of the individual(s) performing the examination
  - Labeling Storage
    - Ensures proper ID and prevents mixups
  - Labeling Operations
    - The label and labeling used for each production unit, lot, or batch shall be documented in the DHR.

  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=820.120

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SEAGULL SCIENTIFIC

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