

# GS1 Bar Codes in Healthcare and Pharmaceutical Applications

Martin Fogg

July 2019



To maintain the integrity of the medical supply chain there is an increased need for traceability. The use of GS1-128 and GS1 DataMatrix bar codes allows a large amount of data to be placed on medicines and medical devices



## Serialisation for Medicines

The first level of traceability is provided by adding a batch number. If a randomised serial number is also used in the bar code for medicines then genuine shipments can be distinguished from counterfeit.

Expiry date and batch is also encoded.



## For Unique Device Identification (UDI)

Each instance of a device can  
be given a unique serial number



Using the new Axicon 15000 series verifiers you can check that your bar codes have high grade print quality and correctly formatted data content.



## Linear and Two Dimensional Bar Codes

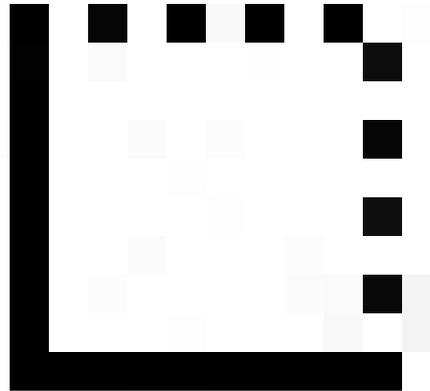
1D or linear bar codes, such as the EAN-13 bar codes that we encounter daily in shops, encode numbers using stripes of different widths.

2D bar codes such as Data Matrix encode their data using dark and light squares.



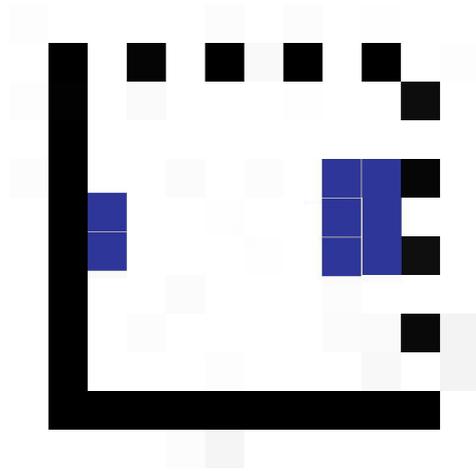
## Finder Pattern

The scanner locates the Data Matrix code using the “L” pattern on the left and lower sides. The other two sides have a “clock track”.

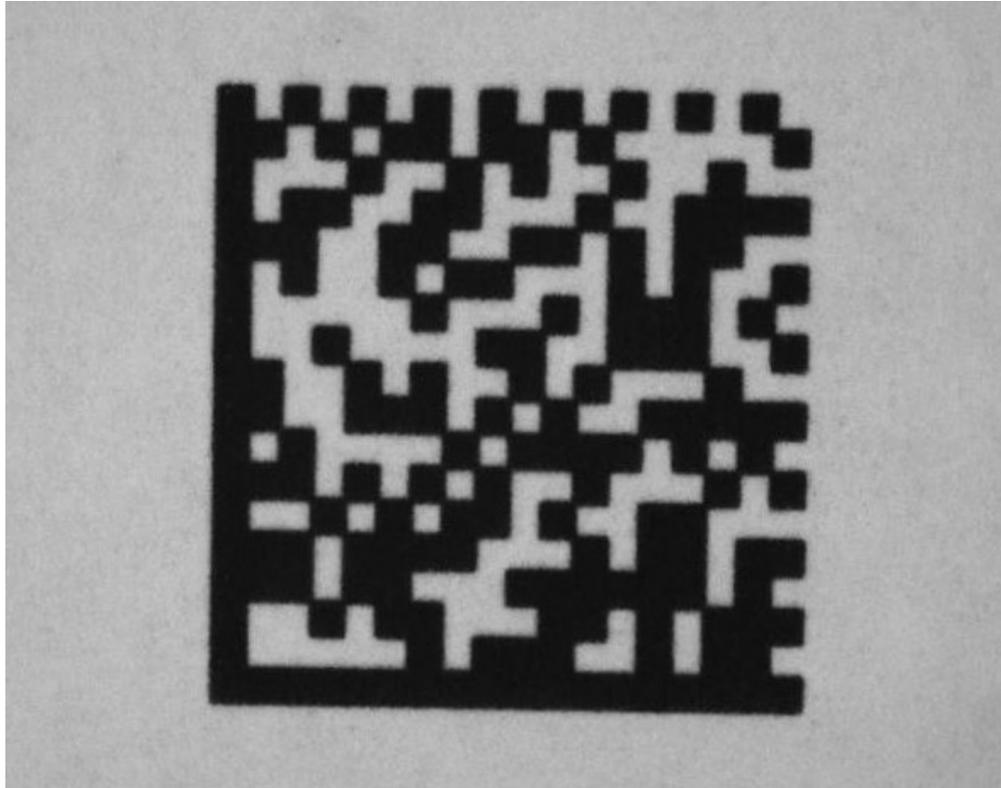


## Codewords

The code is populated with codewords made up from groups of eight squares



**axicon**



## Multiple region codes

Large codes can be made up from multiple regions each with their own finder pattern



## Error Correction

Data Matrix codes include extra codewords for error correction.

These codewords add to the size of the symbol but allow the encoded data to be recovered if part of the symbol is damaged.



## GS1 DataMatrix Codes

Start with a function 1 character and use the GS1 application identifiers (AIs)

The most important AIs are:

- 01 GTIN
- 10 Batch
- 17 Expiry Date
- 21 Serial Number



## 1D Bar Code Verification to ISO/IEC 15416

The Axicon verifiers measure to this standard.

The bar codes are measured as the scanners “see” them

Scanners read the codes by shining a red light beam and detecting the light reflected back

The spaces will reflect a lot of the light

The bars will reflect very little

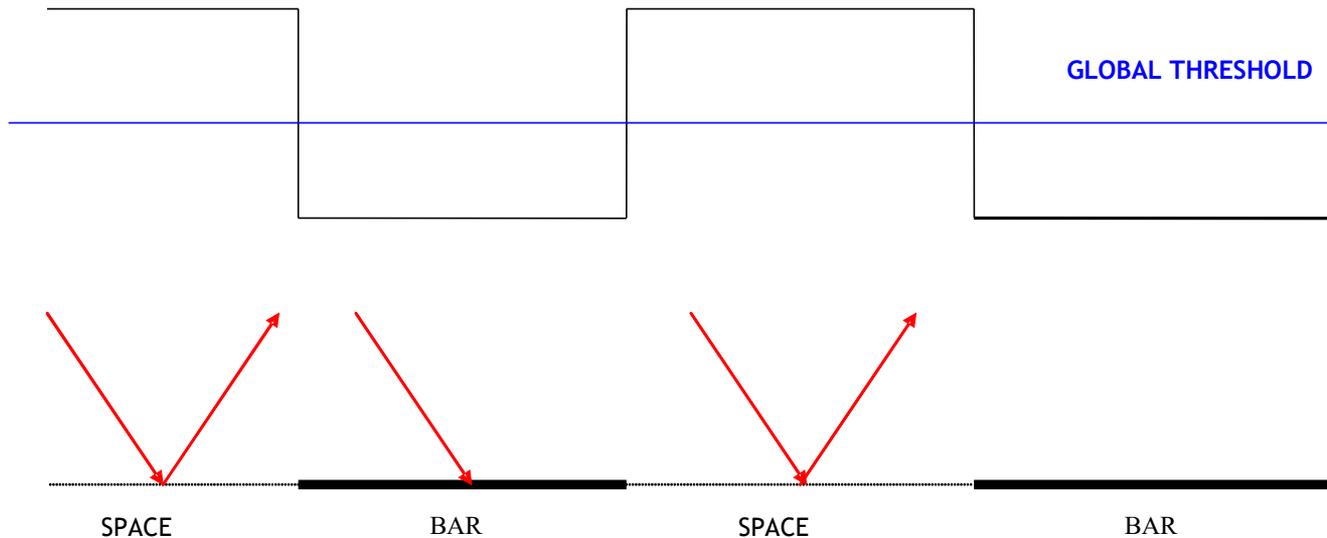


## If the scanner beam is very narrow

REFLECTED LIGHT IS ALL OR NOTHING (A SQUARE WAVE)

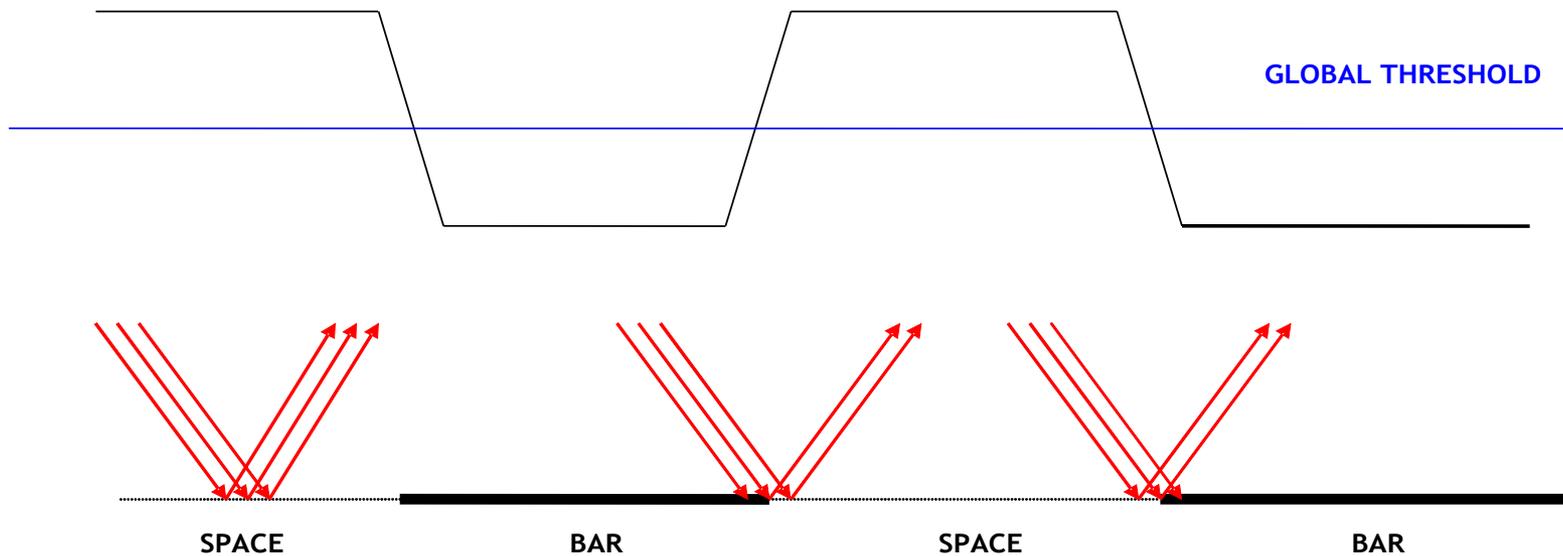
WHEN THE WAVEFORM IS ABOVE THE GLOBAL THRESHOLD THE VERIFIER SEES A SPACE

WHEN THE WAVEFORM IS BELOW THE GLOBAL THRESHOLD THE VERIFIER SEES A BAR

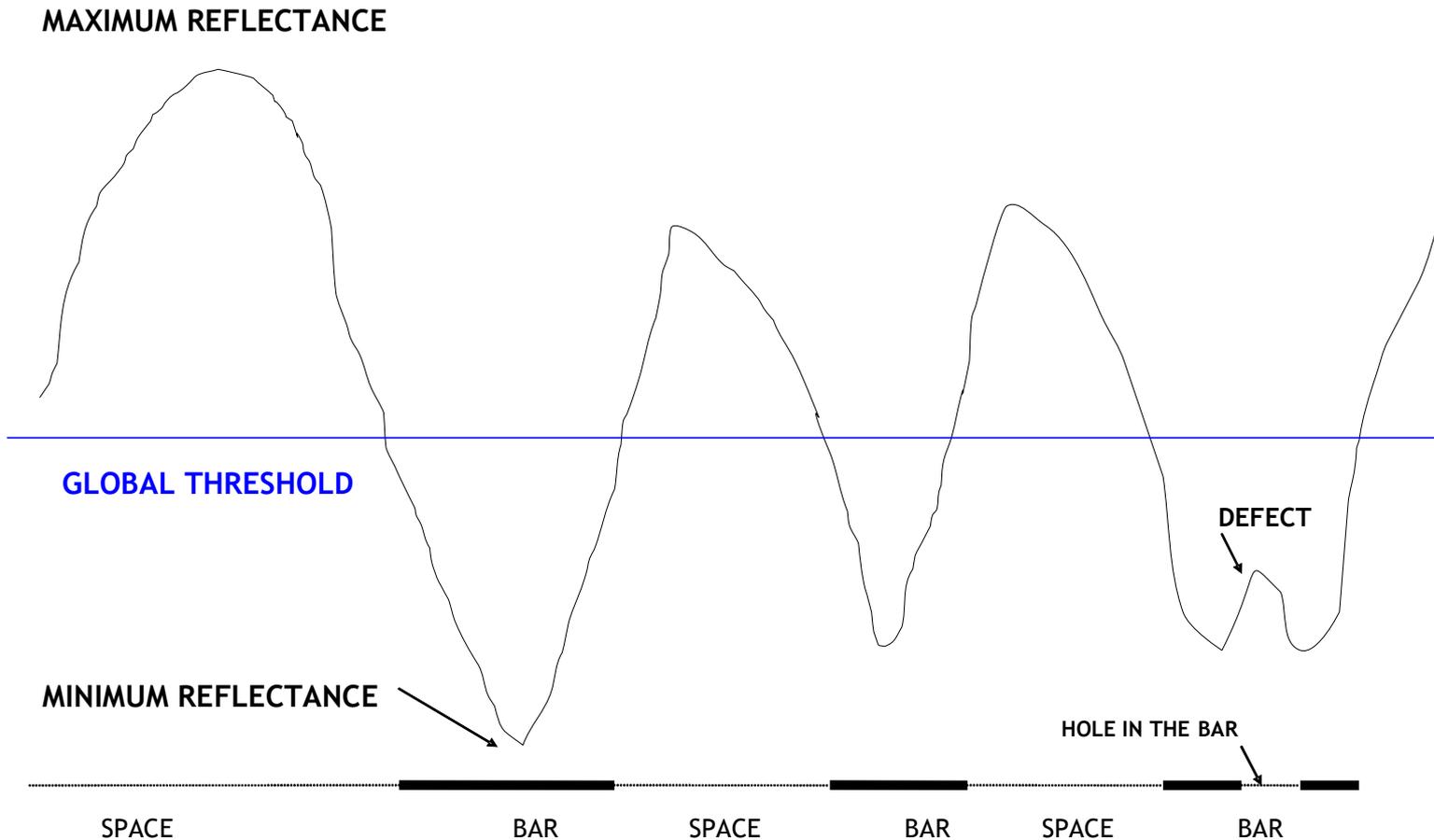


## A slightly wider beam

SCAN REFLECTANCE PROFILE IS NOT A SQUARE WAVE



## A more realistic scan reflectance profile



## Aperture

The verification standard refers to this beam size as “aperture”

Different code X dimensions are read with different apertures

Case codes will use a large aperture. This is less prone to seeing small defects.

Small codes need a small aperture



## Varying the aperture

Our linear verifiers use a CCD element like a camera but with just one row of pixels. The raw scan reflectance profile is filtered to synthesise the appropriate aperture size for the bar code

Aperture selection is automatic



## Verification Parameters

Decode

Symbol Contrast

Minimum Reflectance

Edge Contrast

Modulation

Defects

Decodability



## The final score

For each scan seven parameters are graded

The worst grade becomes the overall grade for that scan

If you make 10 scans at different heights the 10 overall grades are averaged



## Some causes of bad grades

Decode - Poor light margins

Decodability - Excessive print gain

Symbol Contrast - Poor choice of colours

Defects - Thermal transfer printer head  
element failure

Modulation - Small magnification bar code on  
translucent substrate



## 2D Bar Codes are Verified to ISO 15415 Using These Verification Parameters

Symbol Contrast

Decode

Unused Error Correction

Fixed Pattern Damage

Axial Nonuniformity

Grid Nonuniformity

Modulation

Reflectance Margin



## Grading the code

Each of the eight parameters is graded.

Decode is graded either 4 for good or 0 for bad.

The other parameters are scored on a descending scale from 4 down to zero.

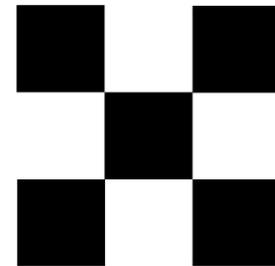
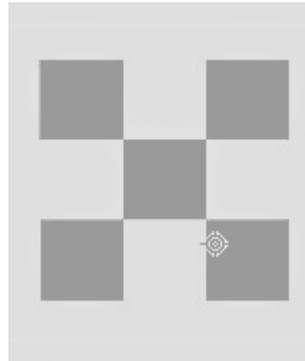
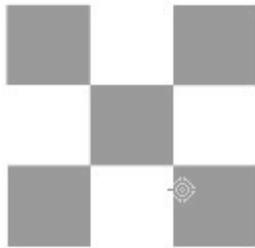
The overall grade is the lowest of the individual parameter grades

The equivalent ANSI standard uses letter grades A, B, C, D and F



## Symbol Contrast

This is a measure of the contrast between the colours chosen for the light and dark modules as viewed under red light



## Modulation and Reflectance Margin

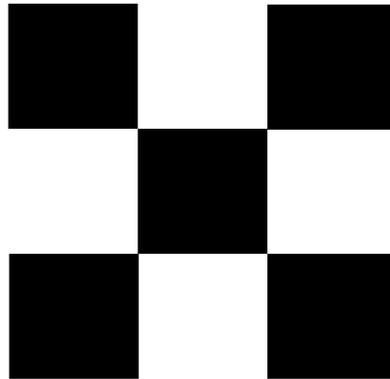
These parameters deal with the variation in symbol contrast throughout the symbol.



**axicon**

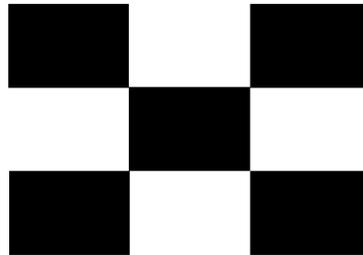
## Undistorted

Perfectly aligned squares



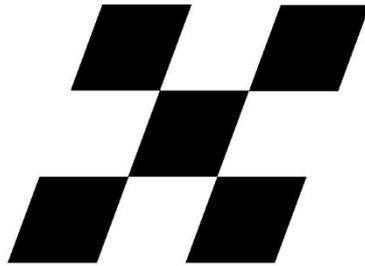
## Axial Nonuniformity

Square elements have become rectangles



## Grid Nonuniformity

Elements are not lying on a regular grid of horizontal and vertical lines



**axicon**

**Axicon 15200** 60mm x 45mm field of view  
Minimum X dimension 170 microns

**Axicon 15500** 95mm x 70mm field of view  
Minimum X dimension 250 microns

Both can verify 2D bar codes to ISO 15415  
and 1D bar codes to ISO 15416



## Main Features of the Axicon 15000 range

Shows you visually where there are problems in a code

There are plugins for specific applications which state what specification they are complying with.

They check the size and date structure as well as selecting the correct aperture



**axicon**

## Main Features of the Axicon 15000 range



## Verification Process

Locate the code and establish a grid

Decode the data

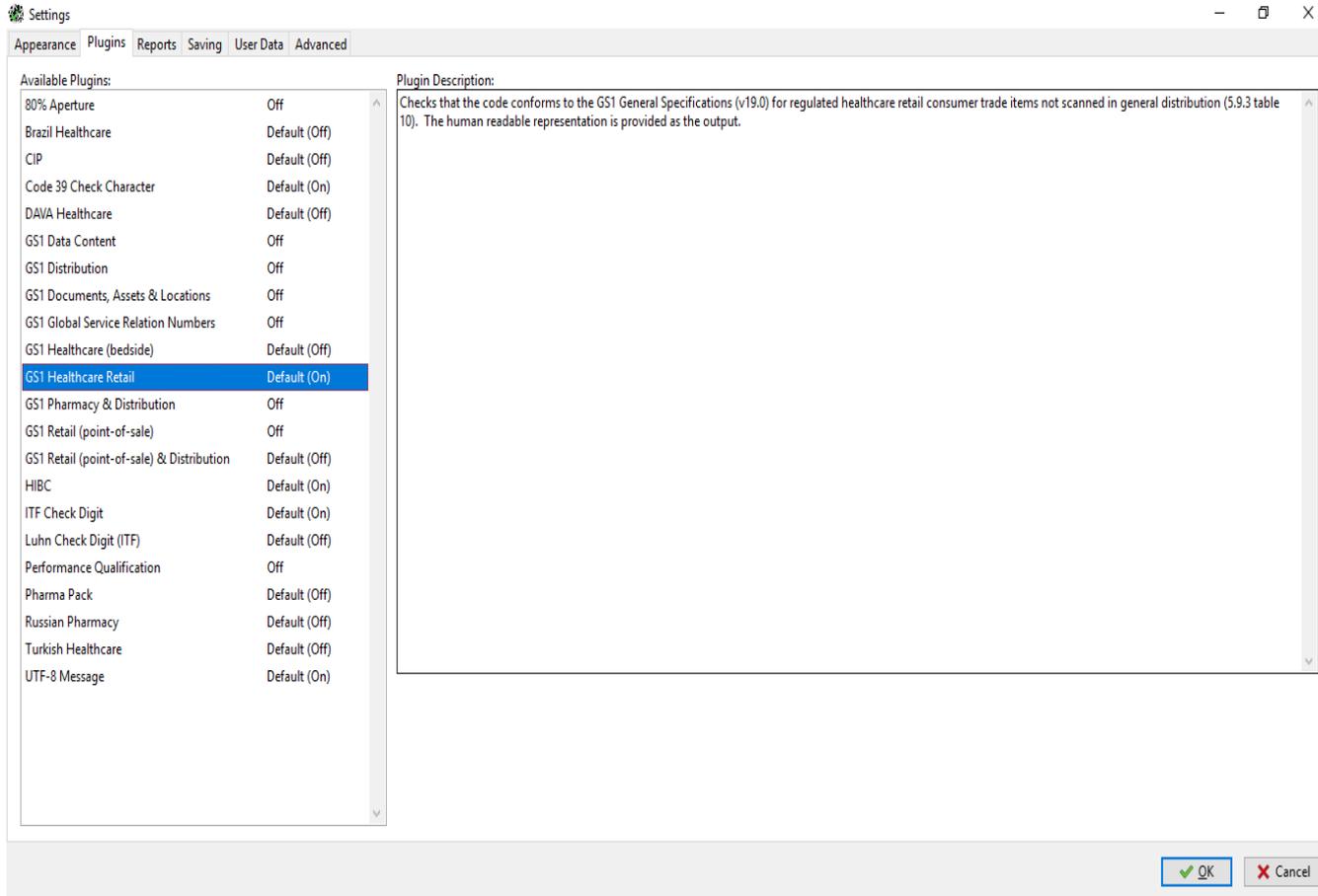
Apply the correct aperture

Calculate the ISO 15415 parameters  
(modulation, grid non uniformity etc)

Use the plugins to test the data structure and  
format of the code

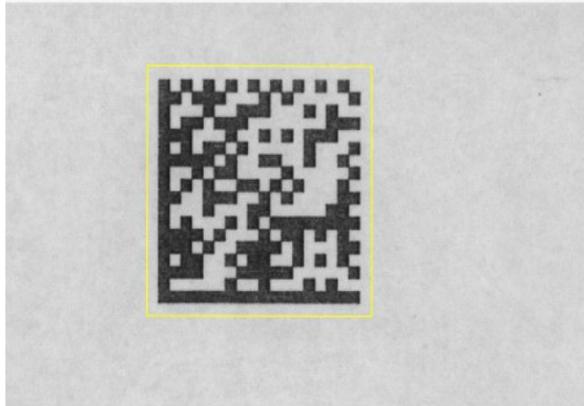


## Choosing a Plugin



We see which table of the GS1 General Specifications the plugin complies with





⚠ GS1 Healthcare (bedside)

(01)05012345678900(17)201030(10)ABCD

Status	Element	Value	Description	Notes	Errors	Warnings
Pass	(01)	05012345678900	Global Trade Item Number (GTIN) [n2+n14]			
Pass	(17)	30/10/2020	Expiration Date (YYMMDD) [n2+n6]	*		
Pass	(10)	ABCD	Batch or Lot Number [n2+an..20]	*		
Pass	Grade	3.0 (B)	Grade must be at least 1.5 (C)			
Pass	Aperture	200 µm (08)	Required aperture: 200 µm (08)			
Warning	X dimension	1006 µm	Allowed X dimension range: 254 µm to 990 µm			1
Warning	Y dimension	1007 µm	Allowed Y dimension range: 254 µm to 990 µm			1

Errors:	Warnings:	Note
	Out of range, but within ±2% acceptance criteria	

Found codes: 1

3.0/08/660 (B)

## Application Validation: Warning

General Reader Scan

01050123456789001720103010ABCD

GS1 DataMatrix

Pass grade	1.5
Minimum Reflectance	10%
Maximum Reflectance	86%
X Dimension	1006 µm
Y Dimension	1007 µm
X Print Gain	61 µm, 6%
Y Print Gain	56 µm, 6%
Aperture	200 µm

ISO

Overall	3 (B)
Decode	4 (A)
Symbol Contrast	4 (A), 76%
Axial Non-Uniformity	4 (A), 0%
Grid Non-Uniformity	4 (A), 6%
Modulation	3 (B)
Reflectance Margin	3 (B)
Unused Error Correction	4 (A), 100%
Contrast Uniformity	37%
Fixed Pattern Damage	3 (B)
Left "L"	4 (A)
Bottom "L"	3 (B)
Left Quiet Zone	4 (A)
Bottom Quiet Zone	4 (A)

## Plug in Results

⚠ GS1 Healthcare (bedside)

(01)05012345678900(17)201030(10)ABCD

Status	Element	Value	Description	Notes	Errors	Warnings
Pass	(01)	05012345678900	Global Trade Item Number (GTIN) [n2+n14]			
Pass	(17)	30/10/2020	Expiration Date (YYMMDD) [n2+n6]	*		
Pass	(10)	ABCD	Batch or Lot Number [n2+an..20]	*		
Pass	Grade	3.0 (B)	Grade must be at least 1.5 (C)			
Pass	Aperture	200 µm (08)	Required aperture: 200 µm (08)			
Warning	X dimension	1006 µm	Allowed X dimension range: 254 µm to 990 µm			1
Warning	Y dimension	1007 µm	Allowed Y dimension range: 254 µm to 990 µm			1

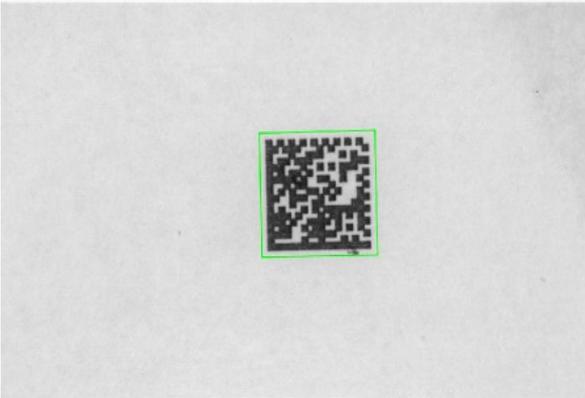
Errors:

Warnings:

Note

Out of range, but within  $\pm 2\%$  acceptance criteria





✓ GSI Healthcare (bedside)

(01)05012345678900(17)201030(10)ABCD

Status	Element	Value	Description	Notes	Errors	Warnings
Pass	(01)	05012345678900	Global Trade Item Number (GTIN) [n2+n14]			
Pass	(17)	30/10/2020	Expiration Date (YYMMDD) [n2+n6]	*		
Pass	(10)	ABCD	Batch or Lot Number [n2+an..20]	*		
Pass	Grade	3.0 (B)	Grade must be at least 1.5 (C)			
Pass	Aperture	200 µm (08)	Required aperture: 200 µm (08)			
Pass	X dimension	508 µm	Allowed X dimension range: 254 µm to 990 µm			
Pass	Y dimension	506 µm	Allowed Y dimension range: 254 µm to 990 µm			

Found codes: 1

3.0/08/660 (B)

Application Validation: Pass

General Reader Scan

01050123456789001720103010ABCD

GSI DataMatrix

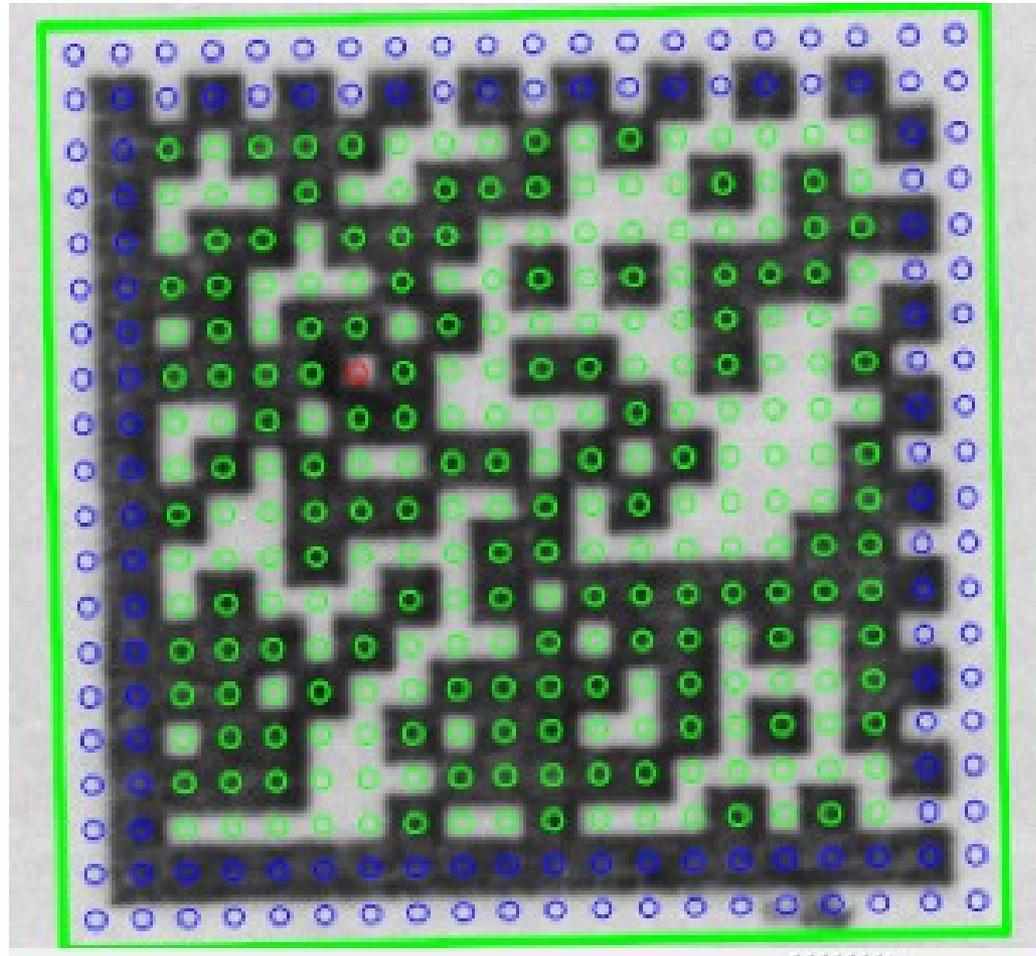
Pass grade	1.5
Minimum Reflectance	9%
Maximum Reflectance	88%
X Dimension	508 µm
Y Dimension	506 µm
X Print Gain	150 µm, 29%
Y Print Gain	151 µm, 30%
Aperture	200 µm

ISO

Overall	3 (B)
Decode	4 (A)
Symbol Contrast	4 (A), 79%
Axial Non-Uniformity	4 (A), 0%
Grid Non-Uniformity	4 (A), 19%
Modulation	3 (B)
Reflectance Margin	3 (B)
Unused Error Correction	4 (A), 86%
Contrast Uniformity	5%
Fixed Pattern Damage	3 (B)
Left "L"	3 (B)
Bottom "L"	4 (A)
Left Quiet Zone	4 (A)
Bottom Quiet Zone	3 (B)
Check Text	4 (A)

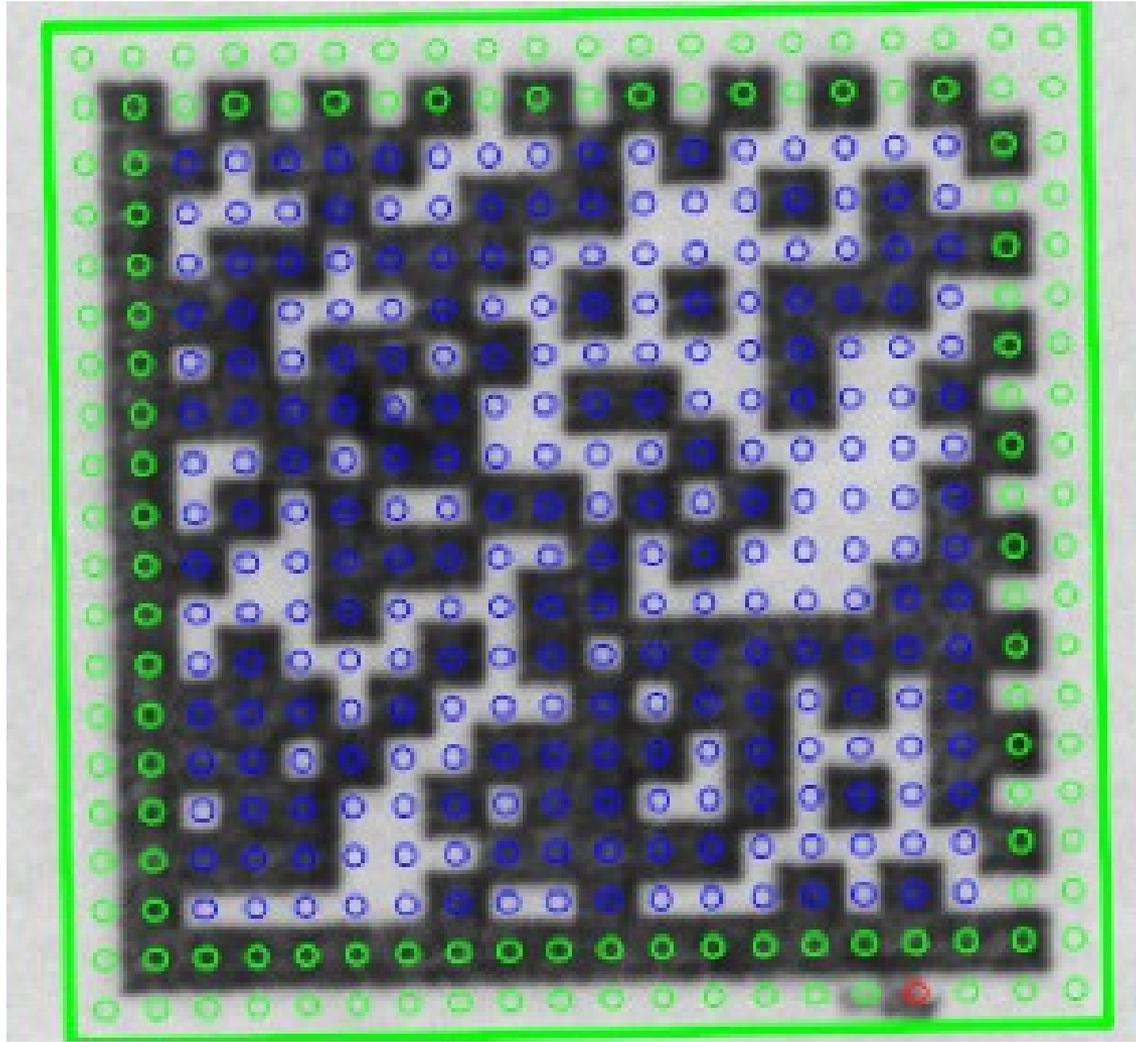
## Visualisation

The red square  
has  
bad modulation



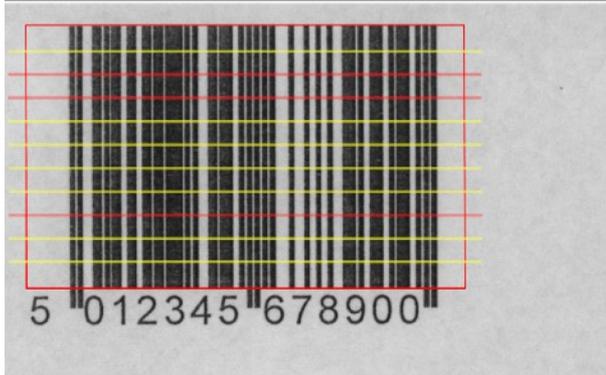
## Visualisation of fixed pattern damage

The red square shows damage in the quiet zone



Axicon Camera Verifier

File View Reader Help



GS1 Retail

5012345678900

Status	Element	Value	Description	Notes	Errors	Warnings
Fail	Grade	0.0 (F)	Grade must be at least 1.5 (C)			
Pass	Aperture	150 µm (06)	Required aperture: 150 µm (06)			
Pass	X dimension	332 µm	Allowed X dimension range: 249 µm to 660 µm	*		
N/A	Bar Height	23.0 mm	Height of bars should be at least 23.0 mm			

Found codes: 1

0.0/06/660 (F)

Application Validation: Fail

General Reader Scan

5012345678900

EAN-13

Pass grade	1.5
X Dimension	331.8 µm, 101% (80%..200%)
Print Gain	154.3 µm, 47% (±30.5%)
Check Character	OK: '0'
Height	23.0 mm
Width	37.8 mm
Aperture	150 µm
Left Quiet Zone	10 items
Right Quiet Zone	10 items

ISO Details

Overall	0.0 (F)
Minimum Reflectance	4.0 (A), 10.7%
Maximum Reflectance	83.8%
Threshold	47.3%
Reflectance Margin	2.9%
Symbol Contrast	4.0 (A), 73.1%
Minimum Edge Contrast	4.0 (A), 33.2%
Modulation	1.5 (C), 45.4%
Defects	2.9 (B), 20.5%
Decodability	0.0 (F), 4.1%
Decode	3.2 (B)

In this example we show the modulation for each scan

ISO	Details
+	Symbol Contrast 4.0 (A), 73.1%
+	Minimum Edge Contrast 4.0 (A), 33.2%
-	Modulation 1.5 (C), 45.4%
...	Modulation 1.5 (C), 44.6%
...	Modulation 1.2 (D), 41.7% *
...	Modulation 1.4 (D), 43.5%
...	Modulation 1.8 (C), 48.1% *
...	Modulation 1.6 (C), 45.9%
...	Modulation 1.5 (C), 44.8%
...	Modulation 1.7 (C), 46.9%
...	Modulation 1.4 (D), 43.8%
...	Modulation 1.5 (C), 45.3%
...	Modulation 1.9 (C), 49.2%
+	Defects 2.9 (B), 20.5%
+	Decodability 0.0 (F), 4.1%



## Modulation at different heights in the code

Green lines show scan lines with good modulation.

The yellow lines have C grade modulation

On the red lines the modulation is below the pass grade.

