ANSI/HIBC 2.6

THE HEALTH INDUSTRY SUPPLIER LABELING STANDARD FOR PATIENT SAFETY & UNIQUE DEVICE IDENTIFICATION (UDI)

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THE HEALTH INDUSTRY SUPPLIER LABELING STANDARD: FOR PATIENT SAFETY & UNIQUE DEVICE IDENTIFICATION (HIBC / SLS / UDI)

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Foreword

Automatic identification technology is continually evolving. As technological advances prove applicable to the health care industry, they will be incorporated into revisions of this standard, wherever possible. However, every attempt will be made to maintain the existing data structures, thereby allowing new technology to be introduced into systems in a non-disruptive manner. HIBCC recognizes that this standard is a technology driven solution to improvement of health care delivery. As new technology becomes widely available, the standard will be modified to incorporate the advantages of the new technologies.

1.0 Scope

This document describes the voluntary HIBC Supplier Labeling Standard for products distributed within the health care industry. Labelers (manufacturers) of health care products are strongly encouraged to identify their products with consistently readable symbols in accordance with the standards described herein.

1.1 Symbol Quality Compliance and Printing Assistance

Printed bar code symbols must meet or exceed the quality requirements of Section 5 and be easily scannable by standard bar code scanners at the point of use. Labelers having questions about or problems meeting the requirements of this standard should contact HIBCC in Phoenix at (602) 381-1091.

2.0 Supplier Labeling Data Structures

It is intended that all health care products be labeled with a Primary Symbol, which identifies the labeler in an internationally consistent and unique manner, the product code, and the unit of measure. Secondary information is useful to distributors and providers and, at the discretion of the labeler, should be added.

2.1 Primary Data Structure (Device Identifier)

The primary data structure contains an indication of the labeler of the item, the item, the packaging level, and a Check Character. Once constructed from these four elements, these structures should not be parsed. The labeler identification is a data element that is controlled by the Health Industry Business Communications Council (HIBCC). A labeler that chooses to utilize the HIBC Labeler Identification Code (LIC) should follow the HIBC LIC data and symbology format.

2.1.1 HIBC LIC Primary Data Structure (Device Identifier)

The HIBC LIC Primary Data Structure format encodes a "+" data identifier of the HIBC Supplier Data Structure, a 4 character Labeler Identification Code (LIC), a 1 to 18 character Product or Catalog Number (PCN), a one-digit Unit of Measure Identifier (U/M), and a single Check Character (C).

The format for the Primary Data Structure format follows (for illustration purposes, the product identifier, or PCN, is shown at its maximum length, 18 characters, therefore the maximum symbol length is 25 characters): See Table 1

+ I I I I P P P P P P P P P P P P P P P P U C

where: (see below)

Table 1

Field Descriptor	Field Length	(F)ixed Length (V)ariable Length	Field Description
+	1	F	HIBC Supplier Labeling Flag Character "+"
I	4	F	Labeler Identification Code (LIC) an alphanumeric number, with the first character always being alphabetic.
P	1-18	V	Labelers Product or Catalog Number (PCN). Alphanumeric data
U	1	F	Unit of Measure ID, Numeric value only, 0 through 9, where 0 always represents a single unit.1 to 8 are used to indicate different packaging levels above the unit of use. The value 9 is used for variable quantity containers when manual key entry or scan of a secondary will be used to collect specific quantity data. The labeler should ensure consistency in this field within their packaging process.
C	1	F	Check Character calculated from the above characters. (see Appendix B2)

The Labeler Identification Code (LIC) is assigned and maintained by HIBCC. The first character of this field will always be an alphabetic character. The LIC may identify a labeler to the point of separate subsidiaries and divisions within a parent organization.

The Product or Catalog Number (PCN) shall be compressed to eliminate embedded spaces and special characters. Special characters shall not be used in this field. The allowed characters are A through Z and 0 through 9. Examples of this compression follow:

655-9 ..... would become 6559
24-86-2S ..... would become 24862S
84/XPG ..... would become 84XPG
MP 15 86-G…….would become MP1586G
92.885*BK ..... would become 92885BK

This compression impacts only the machine-readable representations of the PCN and its associated human readable interpretations. Other external package markings and catalog listings covered by this standard remain the prerogative of the individual labeler.

The Unit of Measure Identifier (U/M) is a numeric representation of the relative level of packaging (0 to 9) with 0 being the lowest level or "unit-of-use". For example, a labeler might pack unit-of-use items in a box, boxes in a carton, and cartons in a case. One way of labeling this example would be, unit-of-use = 0; Box = 1; Carton = 3; and Case = 5. It may be that a unit-of-use is packaged, however, in a box. For instance, individual cotton swabs would be considered the unit-of-use and may go unmarked. Consequently, the box in which the cotton swabs were packaged would be marked with the HIBC Supplier Primary Data Structure with a 1 or greater in the U/M field. Note that U/M identifiers are arbitrarily assigned by each labeler and must be internally consistent.

2.1.2 Primary Data Structure in Electronic Data Interchange

For information about communicating Primary Data in Electronic Data Interchange, refer to the HIBCC Electronic Data Interchange (EDI) Guidelines. When using the HIBC data formats in Electronic Data Interchange, the Check Character is not transmitted or stored in the database.

2.1.3 Reuse of HIBC Primary Identifier

A HIBC Primary Identifier shall not be reissued to any other item, even if the item to which it has been assigned has been discontinued, or superseded by another product.

2.1.4 Definition of the HIBCC Universal Product Number (UPN)

The HIBCC UPN is the Primary Identifier excluding the "+" character and the Check Character.

2.2 Secondary Data Structure (Production Identifier)

Optional secondary data elements are used in conjunction with primary data elements, for example to encode expiry date and/or Lot/Batch/Serial Number. Appendices E and F describe the secondary data fields in detail.

2.2.1 HIBC LIC Secondary Data Structure

The format for the HIBC Secondary Data Structure is shown in Table 2.

Table 2

Field Descriptor	Field Length	Field Description
+	1	Internationally recognized, unique, HIBC Supplier Labeling Data Identifier Flag Character, "+"
R	1, 2 , 3, or 5	Date/Lot or Serial Number Reference Identifier Numeric: If the first character is numeric, then R is a fixed 5-digit Julian date. No Lot/Batch or Serial Number is present (See Note 2) $: If the first character is a "$" and the second character is alphanumeric, then the Date fields are not used. $+: If the first two characters are "$+" and the third character is alphanumeric then a serial number only follows. This format is included for backward compatibility only. It is recommended that "$$+7" be used to indicate a serial number follows. $$: If the first two characters are "$$" followed by a digit, then the digit specifies the Date Field format. For use with lot numbers, not serial numbers. $$+: If the first three characters are "$$+" followed by digit, then the digit specifies the date field format. For use with serial numbers, not lot numbers. See Appendix E1.2 If the first character is a number then the 5-digit Julian Date format follows. This format is included for backward compatibility only. It is recommended that "$$7" be used to indicate a lot/batch.
D	0 or 4-9	Expiry Date Field, for use after the Reference Identifier (includes the date field format indicator).
B	0-18	Lot/Batch **or** Serial Number Field, Alphanumeric field. See Appendix E1.2
L	1	Link Character (Check Character from primary data field.) (See 2.2.1.1 for concatenation rule).
C	1	Modulo 43 Check Character (calculated from the above characters) See Appendix B2.0.

Note 1: The HIBC Secondary Data Structure is distinguished from the Primary Data Structure in that the Primary Data Structure has an alphabetic character following the HIBC Supplier Labeling Flag Character "+",while the Secondary Data Structure has a numeric character or a "$" following the HIBC Supplier Labeling Flag Character. See Appendices E and F for more information.

Note 2: Earlier versions of this standard permitted an optional variable length (0 to 13) alphanumeric lot/batch field to follow the five-digit Julian date field (for example +YYJJJDDDDDDDDDDDDLC). Software that interprets encoded HIBCC secondary data fields should allow lot/batch data following the fixed-length numeric Julian date. Users who wish to encode a five-digit Julian date followed by a lot/batch field should use the current format of the secondary data field "+$$5"."

Note 3: Quantity is no longer included in the Secondary Data Structure as it had been in previous versions of the standard, but can be included as Supplemental Data. For more information on how to include Quantity as Supplemental Data see section 2.3.2.4.

2.2.1.1 Combining Primary and Secondary Codes in One Symbol when Using the HIBC LIC Format

When combining the Primary and Secondary Code into a single symbol (known as concatenation), a forward slash (/) is used as a delimiter between the primary and secondary data. In addition, the primary data Link Character, the plus (+) at the start of the secondary data, and the secondary data Link Character are omitted. Only one Check Character at the end of the symbol will be used which will check the entire data string.

For example:
+ A 9 9 9 1 2 3 4 5 / $ $ 5 200 0 1 5 1 0 X 3 3
Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
$$5	Exp Date Flag
20015	Expiry Date is 15 day of year 2020 (15 January 2020) in the YYJJJ format (Julian Date format)
10X3	Lot Number
3	3 is the Check Character

2.2.2 Secondary Data Structure in Electronic Data Interchange

For information about communicating Secondary Data in Electronic Data Interchange, refer to the HIBCC Electronic Data Interchange (EDI) Guidelines. When using the HIBC data formats in Electronic Data Interchange, the Check Character is not transmitted or stored in the database.

2.3 Additional Supplemental Data

Additional Supplemental Data can be added to the Secondary data string. It is strongly recommended that Additional Supplemental Data be used in the concatenated format and with 2D symbologies to reduce the risk of creating a linear bar code that may be too long for practical use. Additional Supplemental Data can be used when a manufacturer wishes to encode both lot number and serial number in the same symbol, date of manufacture, expiry date in the YYYYMMDD format, and/or quantity. Quantity must be the last field in supplemental data when used in conjunction with other supplemental data.

2.3.1 Data syntax

The Secondary Supplemental Data field is constructed with a "/" character followed by a Data Identifier (DI), followed by data. Multiple Secondary Supplemental data fields are possible. The Secondary Supplemental Data will always follow the Secondary data, and the check character will be inserted at the end of the total string.

2.3.2 Data usage

2.3.2.1 Serial number when Lot number is used

For example, when serial number is encoded with the DI "S" using the following format.

Field Length - an1 + an18 S Serial number or code assigned by the Supplier to an entity for its lifetime, (e.g., computer serial number, traceability number, contract tool identification)

2.3.2.2 Date of Manufacture

Date of Manufacture is encoded with DI “16D” using the following format.

Field Length - an3+n8 16D Production Date (YYYYMMDD) – Date of manufacture

2.3.2 Example of HIBC data string with Secondary Supplemental Data

Following is an example with both a Date of Manufacture and a serial number added to a HIBC Primary and Secondary symbol containing a lot number and an expiry date.

+A99912345/$$52001510X3/16D20111212/S77DEFG457

Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
$$5	Exp Date Flag
20015	Expiry Date is 15 day of year 2020 (15 January 2020) in the YYJJJ format (Julian Date format)
10X3	Lot Number
/	Secondary Supplemental Data delimiter
16D	Date of Manufacture Data Identifier
20111212	December 12, 2011
/	Secondary Supplemental Data delimiter
S	Serial Number Data Identifier
77DEFG45	serial Number
7	7 is the Mod 43 Check Character

2.3.2.3 Expiry date formatted as YYYYMMDD

Where a manufacturer wishes to use an expiry date with the format YYYYMMDD, which is not one of the available options in the secondary data formats, the manufacturer can instead use the supplemental data option for expiry date.

When using the supplemental data option the expiry date is encoded with DI “14D” using the following format.

Field Length - an3+n8 14D Expiry Date (YYYYMMDD) – Date of expiry

Following is an example with both a Date of Manufacture and the expiry date are added to a HIBC Primary and Secondary symbol containing a lot number only.

+A99912345/$10X3/16D20111231/14D202001313

Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
$	Flag to indicate that Lot number only in secondary data
10X3	Lot Number
/	Secondary Supplemental Data delimiter
16D	Date of Manufacture Data Identifier
20111231	December 31, 2011
/	Secondary Supplemental Data delimiter
14D	Expiry Data Identifier
20200131	January 31, 2020
3	3 is the Mod 43 Check Character

2.3.2.4 Quantity

Where a manufacturer wishes to include quantity they shall use the supplemental data option for quantity.*

When using the supplemental data option the quantity is encoded with DI “Q” using the following format.

Field Length - an1+n1...n5 Q Quantity

Following is an example with a Date of Manufacture, YYYYMMDD expiry date, and quantity added to a HIBC Primary and Secondary symbol containing a lot number only.

+A99912345/$10X3/16D20111231/14D20200131/Q500V

Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
9	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
$	Flag to indicate that Lot number only in secondary data
10X3	Lot Number
/	Secondary Supplemental Data delimiter
16D	Date of Manufacture Data Identifier
20111231	December 31, 2011
/	Secondary Supplemental Data delimiter
14D	Expiry Data Identifier
20200131	January 31, 2020
/	Secondary Supplemental Data delimiter
Q	Quantity Identifier
500	Quantity
Z	Z is the Mod 43 Check Character

*Note: Quantity is an optional field and should only be used with the Unit of Measure "9" for packages containing variable quantities.

3.0 Label Symbologies

It is possible for a Primary (or a Primary and Secondary) Label to be encoded in one of two possible linear bar code symbologies, or alternatively in one of the approved 2D symbologies.

No special characters (-, ., $, /, +, %, and space) are used in the Primary data structure other than the use of the flag characters, "+" and "$", in the beginning of the HIBC LIC symbols. The use of the special characters "." and "-" are permitted in the Secondary data structure. Note that the generated Check Character may, however, be one of these special characters, including space. In addition, when combining both Primary and Secondary information in a single barcode, the "/" character is used as a concatenation character. (See section 2.2.1.1 for use).

The data structure and human-readable interpretation is identical regardless of symbology used.

See Appendix C for detailed printing information.

Specifications for these symbologies are available http://www.ansi.org and http://www.iso.org .

3.1 HIBC LIC Primary and/or Secondary Data – Linear Symbologies

Where a labeler decides to use a linear symbology, the labeler may use either of the linear symbologies in this section as directed.

- **Code 128:** HIBC primary and secondary data should be printed in separate Code 128 symbols but may be concatenated if space allows. More information on this symbology may be obtained from *ISO/IEC 15417 Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification.*

- **Code 39**: HIBC primary and secondary data should be printed in separate Code 39 symbols but may be concatenated if space allows. More information on this symbology may be obtained *from ISO/IEC 16388 Information technology -- Automatic identification and data capture techniques -- Code 39 bar code symbology specification.*

If Code 39 is used, the Regular setting (not Full ASCII) should be used. In addition, the full ASCII function shall be disabled in the reader. The wide to narrow ratio should be 3:1, the inter-character gap should be equal to the nominal narrow element dimension (X-dimension) and the optional Mod 43 symbology Check Character is used.

3.2 HIBC LIC Primary and/or Secondary Data – 2D Symbologies

Where a labeler decides to use a 2D symbology, the labeler may use any one of the 2D symbologies in this section. When using a 2D symbol, a single 2D code should be used to carry all Primary, secondary and supplemental HIBC data as required. For example, those requiring the use of Primary and Secondary data structures should concatenate both into a single 2D symbol (See section 2.2.1.1 for concatenation mechanism).

- **Aztec Code:** HIBC data should be printed in a single Aztec Code symbol. More information on this symbology may be obtained from *ISO/IEC 24778 Information technology -- Automatic identification and data capture techniques -- Aztec Code bar code symbology specification.*

- **Data Matrix ECC200:** HIBC data should be printed in a single Data Matrix ECC200 symbol. More information on this symbology may be obtained from *ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification,*

- **QR Code:** HIBC data should be printed in a single QR Code symbol. More information on this symbology may be obtained *from ISO/IEC 18004 Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification*

4.0 Label Features

HIBC Guidelines provide information on printing techniques, symbol placement, and symbol orientation.

See Section 5 for print quality requirements and Appendix C for specific 2D symbol rules, guidance and examples

4.1 Human-Readable Interpretation

References are made to the Human Readable Interpretation of the bar code or auto-ID symbol in this standard. This refers to the text representation of the data in the bar code or auto-ID symbol that can be displayed underneath the bar code or auto-ID symbol. For example:

+83278F8G9H0J2G%

On product labels or packaging for medical devices, the generally accepted convention for displaying “plain-text” information is by using the symbols as shown in the example below:

2016-09-30 (to indicate the expiry date of September 30, 2016)

2010-09-30 (to indicate the manufacture date)

16390082 (to indicate the lot number)

All product marking including marking required by law shall be printed on the package in a legible font in an area which does not intrude into the symbol region, including quiet zones, and shall not affect the scannability of the symbol.

The following are meant as guidance, and in no case are to be meant to replace appropriate regulations.

The preferred human-readable interpretation of a HIBC Supplier Labeling linear Symbol is a line of characters, preferably directly underneath the bar code symbol, representing all encoded characters. The human-readable interpretation is intended to be used for human recognition only, and not as a method of machine readability addressed in this standard.

It is the recommendation of HIBCC that the human-readable interpretation of zero be represented as “Ø”. The Check Character or Link Character in the symbol will sometimes be a space character. In this case, the human-readable interpretation shall use an “underscore” to represent the space character. See Appendix B.2.1 for further guidance.

While the asterisk, “*” is not encoded within the barcode symbols, the human-readable interpretation for both HIBC LIC Primary and Secondary linear symbols should be bounded in the beginning and at the end of the data string by an asterisk, “*”.

The recommended human-readable format for the linear HIBC LIC Primary and Secondary Symbol should always enclose the human-readable data with the “*” regardless of symbology and should be phased in if possible, but previously designed labels will remain acceptable indefinitely.

4.2 Label Placement

Transport package labels should be placed no closer than 1.25 inches (3.2 cm) from any package edge, and the bottom edge of the label should be within the range of 1.25 inches to 3.0 inches (3.2 cm to 7.6 cm) from the natural bottom of the package.

4.3 Bar Code Symbol Examples

Examples of formats and printed symbols are shown below

4.3.1 HIBC LIC Primary Data Structure

Shown below are examples of the symbols for the HIBC LIC Primary Data Structure.

Figure 1. Code 128
Note: the figures in this document are here as examples only, and due to the nature of the document their resolution may not conform to the specifications that are needed when using these symbols in a working environment

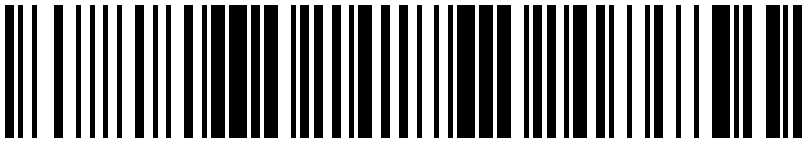
Figure 2. Code 39

+A123BJC5D6E71G

Figure 3 Data Matrix

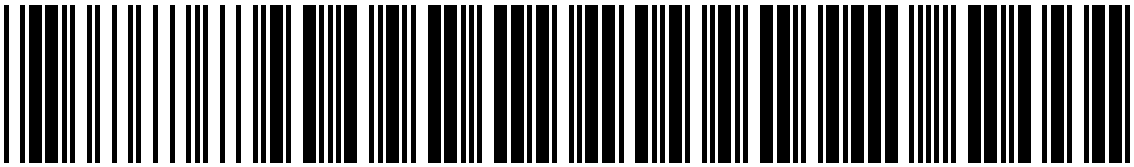
4.3.2 HIBC LIC Secondary Data Structure

Shown below are examples of the symbols for the HIBC LIC Secondary Code Data Structure. They are based on the primary message in example 4.3.1, +A123BJC5D6E71G. In this case, the Link character ('L' in table 2) is G, and the Check character in the example below is D.



+$$52001510X3GD

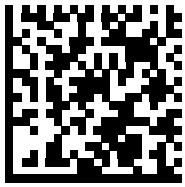
Figure 5. Code 128



+$$52001510X3GD

Figure 6. Code 39

4.3.3 HIBC LIC Concatenated Primary and Secondary Data in a 2D Symbol



***+A123BJC5D6E71/**
$$52001510X3C*

Note: the 2D concatenated symbol does not contain either check character of the primary symbols but rather has a new check character for the entire data string. The link character is not included in the concatenated symbol.

5.0 Print Quality

5.1 Code 128 or Code 39

The bar code symbol quality for a Code 128 or Code 39 symbol in its final configuration shall be no lower than a C/06/660 when measured according to *ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols.* Labelers should attempt to reach B/06/660 or better at the time of printing.

Labelers should use an X-dimension of 0.010 inches (0.25 mm). Those labelers with high-resolution printing capability may utilize X-dimensions as low as 0.0067 inches (0.17 mm) providing the print quality requirements are met.

Any X-dimension greater than 0.0067 inches is allowable if the print quality requirement is met. The height of the bars should be at least 15% of the symbol length. Quiet Zones should be at least 10 times the X-dimension.

5.2 Aztec Code, Data Matrix or QR Code

The bar code symbol quality for an Aztec Code, Data Matrix or QR Code symbol in its final configuration shall be no lower than a C/06/660 when measured according to *ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols.* Labelers should attempt to reach B/06/660 or better at the time of printing.

Labelers should use an X-dimension of 0.015 inches (0.37 mm). Any X-dimension greater than 0.010 (0.25mm) inches is allowable if the print quality requirement is met.

6.0 Radio Frequency Identification (RFID)

HIBCC has produced a Guideline for RFID – *Using HIBC Standards with RFID: An Implementation Guideline,* which is a specification of the coding schemas required for RFID tagging using the HIBCC standards. This guideline is available from HIBCC, and can be downloaded from the HIBCC website www.hibcc.org.

Appendix A – Julian Calendar

Table A1

DAY OF MONTH	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
1	001	032	060	091	121	152	182	213	244	274	305	335
2	002	033	061	092	122	153	183	214	245	275	306	336
3	003	034	062	093	123	154	184	215	246	276	307	337
4	004	035	063	094	124	155	185	216	247	277	308	338
5	005	036	064	095	125	156	186	217	248	278	309	339
6	006	037	065	096	126	157	187	218	249	279	310	340
7	007	038	066	097	127	158	188	219	250	280	311	341
8	008	039	067	098	128	159	189	220	251	281	312	342
9	009	040	068	099	129	160	190	221	252	282	313	343
10	010	041	069	100	130	161	191	222	253	283	314	344
11	011	042	070	101	131	162	192	223	254	284	315	345
12	012	043	071	102	132	163	193	224	255	285	316	346
13	013	044	072	103	133	164	194	225	256	286	317	347
14	014	045	073	104	134	165	195	226	257	287	318	348
15	015	046	074	105	135	166	196	227	258	288	319	349
16	016	047	075	106	136	167	197	228	259	289	320	350
17	017	048	076	107	137	168	198	229	260	290	321	351
18	018	049	077	108	138	169	199	230	261	291	322	352
19	019	050	078	109	139	170	200	231	262	292	323	353
20	020	051	079	110	140	171	201	232	263	293	324	354
21	021	052	080	111	141	172	202	233	264	294	325	355
22	022	053	081	112	142	173	203	234	265	295	326	356
23	023	054	082	113	143	174	204	235	266	296	327	357
24	024	055	083	114	144	175	205	236	267	297	328	358
25	025	056	084	115	145	176	206	237	268	298	329	359
26	026	057	085	116	146	177	207	238	269	299	330	360
27	027	058	086	117	147	178	208	239	270	300	331	361
28	028	059	087	118	148	179	209	240	271	301	332	362
29	029	*	088	119	149	180	210	241	272	302	333	363
30	030		089	120	150	181	211	242	273	303	334	364
31	031		090		151		212	243		304		365

The HIBC Supplier Labeling Standard Format for use of Julian dating includes the last two digits of the year followed by a three-digit day-of-the-year code. For example, November 7, 1994 is represented as “94311” (the 311th day of 1994).

*A leap year has 366 days with February having 29. Julian dating in leap years is the same through February 28 (059) with February 29 as 060. All dating from March 1 through December 31 is incremented by one during leap years.

Appendix B – Check Character Calculation

B.1.0 Check Character Calculation

Be sure to use the Modulo 43 calculation when using the HIBC LIC data structures regardless of the symbology used.

B.2.0 HIBC LIC Check Character Modulo 43 Generator

Each of the HIBC LIC Standard data structures employs a Modulo 43 Check Character for additional data security. The Check Character is the Modulo 43 sum of all the character values in a given message, and is printed as the last character in a given message, preceding the Stop Character. Leading and trailing asterisk "*" characters in the human-readable interpretation are not used in calculating the Check Character and are only represented in the human-readable interpretation. Check Character generation is illustrated by the following example with the table below:

Supplier Labeling Data Structure: + A 1 2 3 B J C 5 D 6 E 7 1
Sum of values: 41+10+1+2+3+11+19+12+5+13+6+14+7+1 = 145

Divide 145 by 43. The quotient is 3 with a remainder of 16. The Check Character is the character corresponding to the value of the remainder (see table below), which in this example is 16, or "G". The complete Supplier Labeling Data Structure, including the Check Character, would therefore be:

+ A 1 2 3 B J C 5 D 6 E 7 1 G

Table of numerical value assignments for computing the HIBC LIC data format Check Character

Table B1

0 = 0	F = 15	U = 30
1 = 1	G = 16	V = 31
2 = 2	H = 17	W = 32
3 = 3	I = 18	X = 33
4 = 4	J = 19	Y = 34
5 = 5	K = 20	Z = 35
6 = 6	L = 21	- = 36
7 = 7	M = 22	. = 37
8 = 8	N = 23	Sp = 38
9 = 9	O = 24	$ = 39
A = 10	P = 25	/ = 40
B = 11	Q = 26	+ = 41
C = 12	R = 27	% = 42
D = 13	S = 28	
E = 14	T = 29	

Note: The character corresponding to 36 is a dash or minus sign (ASCII decimal 45). The character corresponding to 37 is a dot or period (ASCII decimal 46). The character corresponding to 38 is a space (ASCII decimal 32).

B.2.1 Space Character Caution

The HIBC-LIC Check/Link character is **never** part of the **data message.** As such it should not normally be stored in a database or transmitted via EDI. It should be stripped away after the check and link functions have been executed. One of the possible values of the Check/Link Character is a space character (value 38). Although not recommended, if the link character must be stored or transmitted, the space character should be stored or transmitted explicitly as ASCII decimal 32 (ASCII Hex '20'). Note that some legacy systems and or software are unable to receive and or interpret trailing spaces as part of a data message.

Appendix C – Printing and Scanning Considerations

C.1 Printing Plates

Often, source printing requires the generation of a printing plate. Care should be given to produce the printing plate with smaller bars to compensate for ink spread. When “bar width reduction” or “X-dimension width reduction” is implemented, be sure that the spaces are enlarged by the same amount that the bars are reduced. The print quality requirement must be met on the final printed symbol. The printing plate can be fabricated using any method or accuracy as long as the final printed symbol meets the above specification.

C.2 Scanning Considerations

Scanners have different capabilities, be sure to match your scanner with your proposed symbol.

C.3 Example Symbols - Primary Data Structure

Example Data Structure:

+H123ABC01234567890D

Aztec Code

0.19" wide, 0.19" high
15 mil cell size, 19 x 19 matrix

Figure C1 Aztec Code

Data Matrix ECC200

0.18" wide, 0.18" high
15 mil cell size, 18 X 18 matrix

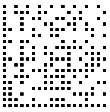


Figure C2 Data Matrix ECC200

QR Code

0.21" wide, 0.21" high
15 mil cell size, 21 X 21 matrix

Figure C5 QR Code

Appendix D – Reference Definitions

For the purposes of printing the HIBC Supplier Labeling Symbol, the following informative definitions are included for convenience.

D.1 Bars
The black or darker areas of the bar code symbol.

D.2 HIBC
Health Industry Bar Code.

D.3 HIBCC
HIBCC (Health Industry Business Communications Council) is the organization responsible for the development and maintenance of standards and services for use in the health care industry. HIBCC standards and information on its services, including the HIN System, Unique Device Identification (UDI) and other ecommerce applications are available from HIBCC at: 2525 E Arizona Biltmore Circle, Suite 127, Phoenix, Arizona. The telephone number for HIBCC is 602-381-1091. Fax: 602-381-1093. Email: info@hibcc.org Web site: http://www.hibcc.org.

D.4 Quiet Zone
An area free of printing, preceding and following all linear bar code symbols and surrounding 2D symbols, that is required for the decoding process. The quiet zones for Code 128 and Code 39 are at least ten times the X-dimension in size.

D.5 Scannability
A general term describing the property of a bar code symbol whereby an attempt to use bar code reading hardware is successful. Symbols that meet ISO/IEC 15415 and ISO/IEC 15416 with a print quality level of C/06/660 generally will be scannable with a broad range of hand held bar code reading hardware.

D.6 Spaces
The white or lighter areas of the bar code symbol including the quiet zones.

D.7 Symbology
A set of rules for encoding information in a bar code symbol.

D.8 Unit-of-Use
A packaging level containing the item (the each) that is to be individually administered in a health care provider facility.

D.9 X-Dimension
The intended width of the narrow bar and narrow space in a bar code symbol.

Appendix E – HIBC Secondary Data Fields

E1.0 HIBC LIC Secondary Data Field

Appendix E describes the Secondary Data Formats with some examples. See Appendix F for a complete listing of Secondary Data Format options.

E1.1 Date Fields

These examples are based on the primary message in example 4.3.1, +A123BJC5D6E71G. In this case, the Link character ('L' in table 2) is "G". Check characters have been calculated for these examples.

If the character following the leading "+" is a "$" but the next character is alphanumeric, then the Date Field is null, and the character following the "$" is the first character in the Lot/Batch Number.

For example:

+ $ A 1 2 3 4 G U *Lot # is A1234*

If there is a two character lot number flag "$$", or a three character serial number flag "$$+", following the leading "+", then the first digit following will specify the Date Field formats:

The digits 0 through 7 specify the Date Format:

0, 1 First digit of month in MMYY (month/year) Date format
2 MMDDYY (month/day/year) Date follows
3 YYMMDD (year/month/day) Date follows
4 YYMMDDHH (year/month/day/hour G.M.T.) Date follows
5 YYJJJ (year/Julian day) Date follows
6 YYJJJHH (year/Julian day/hour G.M.T.) Date follows
7 Date Field is null, Lot Field follows

E1.2 Lot/Batch and or Serial Number Field

The Lot/Batch or Serial Number field can be alphanumeric and vary in length up to a maximum of 18 characters. If the field is not required (because neither Lot/Batch nor Serial Number is desired), the field should be null. The string header +$$ is used for Lot/Batch cases, with +$$+ being used exclusively for Serial Number implementations.

E1.3 Link Character

The Link Character is intended to link the Primary and Secondary Code Data Structures when encoded in separate linear symbols. The Link Character for the Secondary Data Structure is the last character from the Primary Data String in the Primary Symbol (Check Character). The Link Character is not included in concatenated data structures.

Appendix F – Data Formats for HIBC Secondary Bar Codes

The following tables show the correct data formats for HIBC secondary bar codes. If a column is left blank, then that information is not used. The following field descriptions are used:

MM	2 digit expire date month indicator (fixed length of 2 numeric digits)
YY	2 digit expire date year indicator (fixed length of 2 numeric digits)
DD	2 digit expire date day indicator (fixed length of 2 numeric digits)
HH	2 digit expire date hour indicator (fixed length of 2, G.M.T. format)
JJJ	3 digit expire date Julian Day indicator (fixed length of 3 numeric digits)
LOT	up to 18-digit alpha/numeric lot/batch number
S/N	up to 18-digit alpha/numeric serial number
L	Link Character
C	Modulo 43 Check Character

The following example data is always used in table F1:

Lot Number	3C001
Serial Number	0001
Link Character	L (Check Character from Primary Symbol)
Check Character	C (1 character Modulo 43 Check Character)
Expire	Date September 28, 2005 at 10 PM

The following are the secondary data formats. As stated before, when encoding in separate linear symbols, the link character 'L' is the last character from the primary data string. If the primary message were +A123BJC5D6E71G as in example 4.3.1, the link character 'L' would have a value of 'G'. The Check Character 'C' has not been calculated in these examples.

Table F1

HIBCC Qty Flag	Exp Date Flag	Exp Date Format	Lot/Batch Field	Serial Number Field	Link Char	Mod 43 Ck Char	Example Data
+		YYJJJ	Note 1		L	C	+05271LC
+$			LOT		L	C	+$3C001LC
+$$		MMYY	LOT		L	C	+$$09053C001LC
+$$	2	MMDDYY	LOT		L	C	+$$20928053C001LC
+$$	3	YYMMDD	LOT		L	C	+$$30509283C001LC
+$$	4	YYMMDDHH	LOT		L	C	+$$4050928223C001LC
+$$	5	YYJJJ	LOT		L	C	+$$5052713C001LC
+$$	6	YYJJJHH	LOT		L	C	+$$605271223C001LC
+$$	7		LOT		L	C	+$$73C001LC
+$+				S/N	L	C	+$+0001LC
+$$+		MMYY		S/N	L	C	+$$+09050001LC
+$$+	2	MMDDYY		S/N	L	C	+$$+20928050001LC
+$$+	3	YYMMDD		S/N	L	C	+$$+30509280001LC
+$$+	4	YYMMDDHH		S/N	L	C	+$$+4050928200001LC
+$$+	5	YYJJJ		S/N	L	C	+$$+5052710001LC
+$$+	6	YYJJJHH		S/N	L	C	+$$+605271200001LC
+$$+	7			S/N	L	C	+$$+70001LC

Note 1: Earlier versions of this standard permitted an optional variable length (0 to 13) alphanumeric lot/batch field to follow the five-digit Julian date field (for example +YYJJJDDDDDDDDDDDDDLC). Software that interprets encoded HIBCC secondary data fields should allow lot/batch data following the fixed-length numeric Julian date. Users who wish to encode a five-digit Julian date followed by a lot/batch field should use the current format of the secondary data field "+$$5".

Note 2: Secondary Supplemental Data can be included in the data string by the following the rules defined in Section 2.3.

Appendix H – Backward Compatibility

Every effort has been made to insure this standard is backwardly compatible. Some infrequently used aspects of the previous standard were dropped or replaced. Among these is the use of quantity in the secondary data structure. From this point forward labelers that wish to include quantity will do so in the supplemental data field as indicated in section 2.3.2.4 of this document. Existing labels are still valid, but should not be used for Unique Device Identification (UDI).

References to ISO/IEC 15434 and ANS MH10.8.2 have been removed from this document. For more information refer to the previous standard or ISO/IEC 15434 and ANS MH10.8.2 directly.

Appendix I – Bibliography

ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols

ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols

ISO/IEC 15417 Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification

ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification

ISO/IEC 16388 Information technology -- Automatic identification and data capture techniques -- Code 39 bar code symbology specification

ISO/IEC 18004 Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification

ISO/IEC 24778 Information technology -- Automatic identification and data capture techniques -- Aztec Code bar code symbology specification

ISO/IEC 29158, Information technology – Automatic identification and data capture techniques – Direct Part Mark (DPM) Quality Guideline

ANS MH10.8.2-2006 American National Standard – Data Identifier and Application Identifier Standard

The above International Standards can be obtained at either http://www.ansi.org or http://www.iso.org