

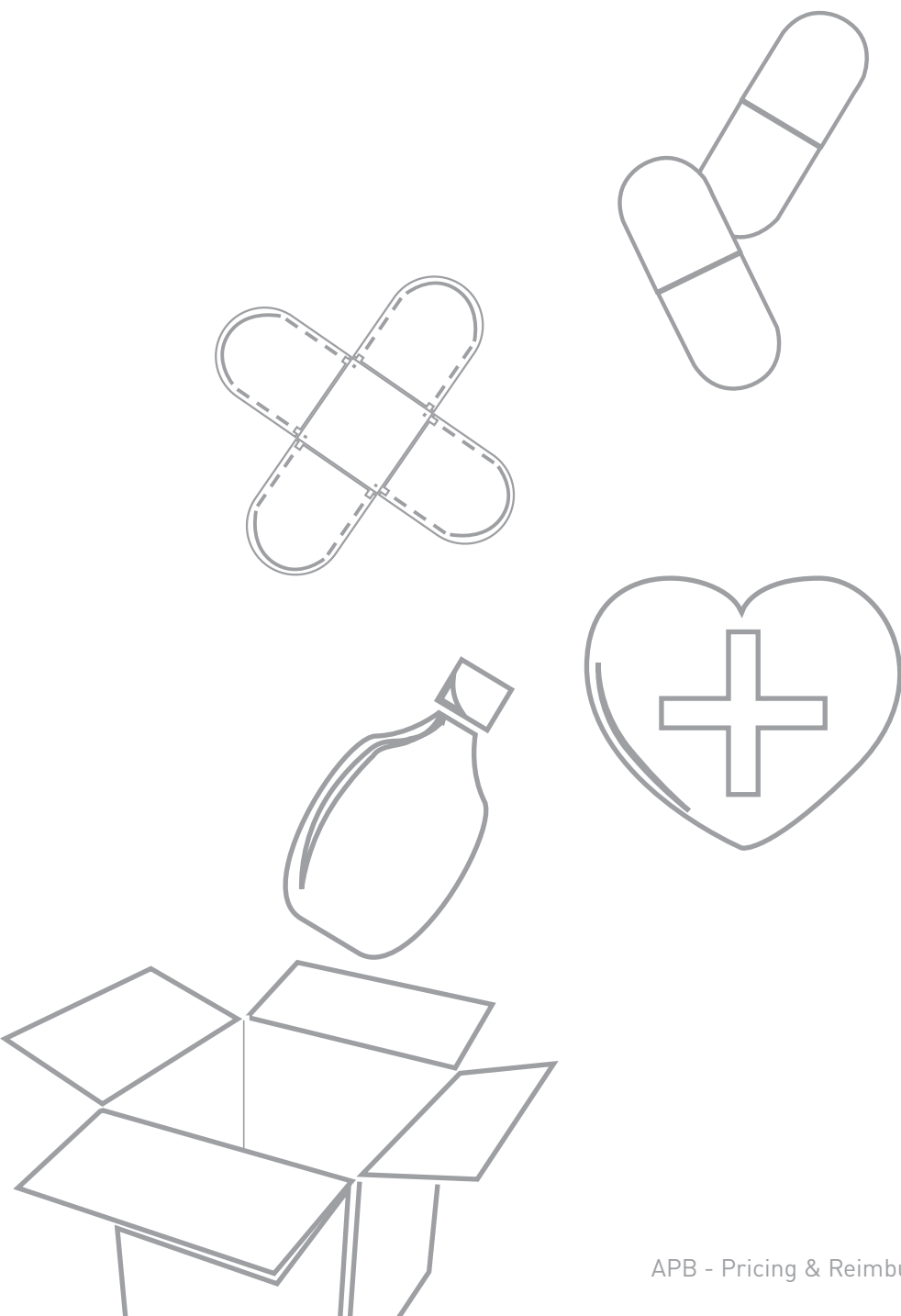


National Code Number & Barcode



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INTRODUCTION

This brochure is intended mainly for manufacturers, distributors and importers of pharmaceutical and parapharmaceutical products, but it is also a useful source of information for pharmaceutical wholesalers, pharmacists, or anyone involved in the distribution or dispensing of medicines or parapharmaceutical products.

This brochure gives you a clear overview of the coding process for pharmaceutical and parapharmaceutical products, how changes should be notified to APB, as well as the use of barcodes and several other applications of the National Code Numbers (CNK).

The APB's CNK system enables every package dispensed in community pharmacies, as well as any medicine dispensed in other care facilities (hospitals, nursing homes, etc.) to be unambiguously identified. It allows digital data sharing between the stakeholders of the pharmaceutical sector.

The importance of the National Code Numbers (CNK) has grown steadily with the increasing computerization of community and hospital pharmacies, the use of automated ordering systems, digital communication between wholesalers and manufacturers, and the use of EDI applications.

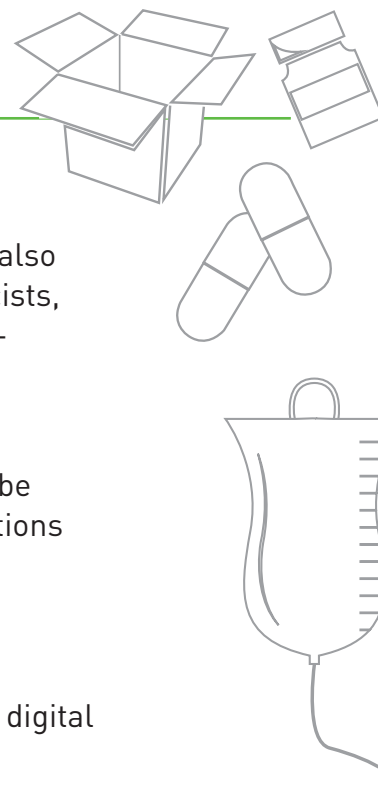
It is important to know that CNK are issued in close cooperation with the relevant authorities. The coding for the medicines that are covered by the National Institute for Health and Disability Insurance (INAMI) is done in cooperation with its Health Care Department. The collection of hospital pharmacy dispensing statistics is also based on the CNK system. Both the Federal Public Service Economy and the Federal Public Service Public Health use the CNK to complete their own information.

Access to the National Code Numbers is open to anyone interested. CNK are made available to the various stakeholders in the pharmaceutical chain, hence their widespread use. This forces us to offer the most comprehensive and accurate database. Keeping and maintaining such a database require particular care and attention. This can only be done with the kind cooperation of all the parties concerned.

As a partner of our organisation, you are one of those parties, and we hope that this brochure will answer the questions you might have about the CNK.

Pharm. Luc Vansnick,
Director Political Affairs

Pharm. Lieven Zwaenepoel,
APB President



NATIONAL CODE NUMBERS

Description

A National Code Number (**CNK**) is assigned to **all** the pharmaceutical and parapharmaceutical products (i.e. medical devices, biocides, food supplements, cosmetics...) that are dispensed in Community Pharmacies, both for human and animal uses, or for phytosanitary purposes.

This code number is merely a serial number without any analytical significance. It is assigned to each product on the basis of the following data:

- name,
- galenic form,
- composition,
- dosage,
- packaging,
- marketing authorization.

The **CNK** is an administrative number. When a **CNK** is issued, it does not imply any form of recognition by APB that the product duly complies with the regulatory requirements it should meet before being placed on the market. This is the sole responsibility of the operator who places the product on the market since the APB entirely depends on the information provided by the applicant when issuing a **CNK**.

When any of the above-mentioned data is modified, a **new CNK** must be requested. The only exception to that rule is when there is a change in the name of a product (pharmaceuticals, medical devices or healthcare nutrition products) that is covered by the National Institute for Health and Disability Insurance (INAMI).

When a Code Number (CNK) is assigned to a product, data such as price, VAT rate, reimbursement conditions, manufacturer, distributor... are **not taken into account**. But these data are very important when it comes to maintaining the various databases that the APB offers (Pharmaceutical and Parapharmaceutical Products, Orthotics, Compounded Medication, Database for Hospitals, and Database for Physicians).

Therefore, we kindly request you to inform us quickly **whenever a change is made** to one of your products so that we can update our databases rapidly. Since 1st January 1993, the CNK is made up of 7 digits: the first six are random digits and the seventh is a check digit calculated with the Luhn algorithm (also known as "modulus 10").

How is a "modulus 10" check digit generated ?

The digits of the CNK should be multiplied alternately by 2 then 1, starting from the right. Make the sum of all the numbers, except those greater than 10, whose figures must be added up separately. Subtract from the next highest multiple of ten.

e.g. CNK = 1013168, where the check digit is 8.

1	0	1	3	1	6	8
x 1	x 2	x 1	x 2	x 1	x 2	
=	=	=	=	=	=	
1	+0	+1	+6	+1	+1+2	=12 20-12 =>8

The CNK should be verified each time with the check digit. Failure to do so makes the CNK system unreliable and can lead to errors. A verification program should be installed on computers, barcode readers and any other decoding equipment.

1. Overview of coded series

The current structure (7 digits + 1 check digit) makes it possible to assign a code number to 999,999 products.

However, some series are reserved for specific types of information or operator :

from	0000-018	to	0009-999	Community Pharmacy Billing Services
	0010-000		0499-999	National Code Numbers
	0500-000		0599-999	Compounded medication billing
	0600-000		0699-999	National Code Numbers
	0700-000		0799-999	INAMI (hospital products)
	0800-000		0899-999	National Code Numbers
	0900-000		0999-999	Community Pharmacists (for their own use)
	1000-000		3999-999	National Code Numbers
	4000-000		4006-999	Oxygen
	4100-000		4999-999	National Code Numbers
	5000-000		5499-999	Compounded medication billing
	5500-000		5599-999	Community Pharmacists' fees and flat-rate fees
	7700-000		7799-999	INAMI
	9910-000		9919-999	Wholesalers

The remaining code numbers have not been assigned so far and should not be used. They will gradually be brought into use in the future.

HOW TO APPLY FOR NATIONAL CODE NUMBERS

When assigning a CNK to a product, the APB depends entirely on the information provided by the applicant.

Therefore, specific information about the product must be provided when applying for a CNK. The web application *CNK Request* gives you the necessary details.

Every application for a CNK must be made online through the web application* [<https://cnk.apb.be/en-US/>].

If you need further information, please contact :

Pricing and Reimbursement Department

Mrs Lieve Wuyts : 02 285 42 72 - lieve.wuyts@apb.be

Mrs Kerlijne Van Den Broeck : 02 609 46 72 - kerlijne.vandenbroeck@apb.be

Mrs Mélanie Bonni : 02 609 46 53 - melanie.bonni@apb.be

Email : CNK@apb.be

We would like to draw your attention to the following points:

- Always use the web application to apply for Code Numbers (CNK);
- Always mention a contact person;
- If you want to convert CNKs to barcodes (for a fee), please use the web application to request the conversion;
- If the data submitted may not be disclosed to third parties before a certain date, please specify it on the web form. **Please contact our Pricing and Reimbursement Department at least 15 days before the release of the CNK may take place.**
- Hospital packaging: please specify on the web form whether the CNK are intended for hospital products (bulk or UD packaging);
- Please contact us for assistance if you have difficulties completing the web form.

If you need CNKs for a whole range of products (more than 10 products), please contact our Pricing and Reimbursement Department so that your request can be handled quickly and efficiently. For this kind of application, an Excel file may be sent by mail.

[*] : only for the products that do not fall under the Falsified Medicines Directive.

Your product already has a CNK - When to apply for a new one?

You **don't need** to apply for a new CNK when there is a change in:

- the product price,
- the product VAT rate,
- the reimbursement conditions,
- the distributor or licensee.

However, such changes must be communicated to our *Pricing and Reimbursement Department* so that all the users of the CNKs can be informed in due course.

You **need** to apply for a new CNK when there is a change in:

- the product name,
- the galenic form of the product (or when there is a significant change in the way the galenic form is presented),
- the active substance composition (qualitative or quantitative changes),
- the excipient composition (qualitative changes only),
- the package content (weight, size or number of units).

It is strictly forbidden to reuse a CNK for parapharmaceutical products since mandatory price display has been introduced in Belgian community pharmacies by the Federal Public Service Economy.

Exception :

When there is a change in the name of a product (pharmaceuticals, medical devices or healthcare nutrition products only) **that is covered by the National Institute for Health and Disability Insurance (INAMI)**, you can apply for keeping the same CNK (only if there is no other change). Such applications must be made online through the web application [<https://cnk.apb.be>]. Such applications are handled **in close collaboration with the INAMI**. Keeping a CNK is allowed only if all the necessary documents are provided to INAMI's Healthcare Department.

Please contact us if you have any further question.



NOTIFICATION OF CHANGES



Any change must be notified without delay to:

APB - Pricing and Reimbursement Department

Mrs Lieve Wuyts : 02 285 42 72 - lieve.wuyts@apb.be

Mrs Kerlijne Van Den Broeck : 02 609 46 72 - kerlijne.vandenbroeck@apb.be

Mrs Mélanie Bonni : 02 609 46 53 - melanie.bonni@apb.be

Email : CNK@apb.be

1. Product-related changes

The following changes may occur:

- product name,
- storage conditions (temperature, light, ...),
- VAT rate,
- galenic form,
- package content (*pack size*),
- qualitative composition (active substance(s) and/or excipients),
- quantitative composition (active substance(s)),
- manufacturer or distributor,
- market situation (temporary unavailability, product registration cancelled, product launch),
- price,
- product registration,
- returns policy,
- package type (unit dose, strip...).

2. Other changes related to the company or product

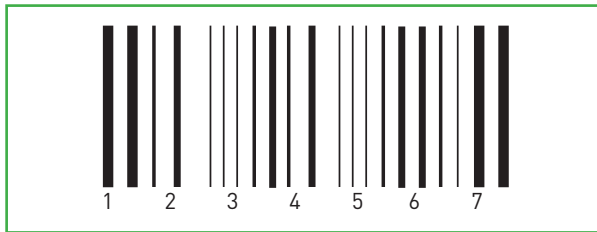
Please notify to our *Pricing and Reimbursement Department* any change in the address, phone number, fax number, contact person, VAT number, etc. or in case of a product acquisition.

Please notify such changes to our *Pricing and Reimbursement Department* at least 15 days before the change becomes effective.

If you have any further questions or need further information or details, please contact our *Pricing and Reimbursement Department*. If the changes concern a product covered by the INAMI, its *Healthcare Department* must be notified too.

THE BARCODE

CNKs are affixed to the product packaging as follows :



The barcode type (= symbology) used is MSI Barcode.

The MSI standard is implemented by all the software providers who work with the Belgian community pharmacy sector.

The barcode symbol contains 8 digits, i.e. the 7 digits of the CNK followed by an additional check digit. There is no hyphen in the barcode symbol.

- The standard size is 28mm x 8mm.
- Black printing on a white background offers the best colour contrast, hence readability.

For further technical information see the appendix.

The APB can send you the MSI barcodes by email (EPS or PDF file) or by mail (printed out on labels).

The price of a MSI barcode is **€ 36.80** (2020 VAT excluded price – VAT rate is 21%). Please don't hesitate to contact our *Pricing & Reimbursement Department* to ask for a personalised quotation for large quantities. Please note that the use of MSI barcodes is only allowed on products that do not fall under the Falsified Medicines Directive (see below).

In the future, if you want to change the packaging layout of a product with an old CNK (6 digits), we strongly recommend applying for a new barcode which will feature the old number preceded by a 0.

This should allow for standardized barcodes (7 digits).

While the CNK system is an indispensable tool for product file management in Community pharmacies and for communication with wholesalers (product identification, data transmission, etc.), using barcodes on the packages offers numerous advantages in product delivery.

In Community pharmacies, barcodes enable to identify products quickly, find product information in the pharmacy's management system, make stock management easier, and to place orders.

In hospitals, barcodes are used for the registration of incoming orders, the distribution to the various departments, and for stock management.

Moreover, barcodes allow for quick and personalized recording of the drugs administered to a patient. The use of barcodes has become indispensable in integrated pharmacovigilance, pricing and billing systems.

Falsified Medicines Directive (FMD)

Since the FMD has entered into force, it is no longer allowed to use CNKs in barcode form on the outer packaging of the medicines that fall under the FMD. The relationship between the GTIN and the CNK is maintained by a conversion table which is managed by APB. Please communicate us the GTIN/CNK relationships by mail (gtin@apb.be) before the products are released on the market, preferably with an Excel file which we can send you on request.

Data management

We can grant you access to our database so that you can consult and update your own products' data. The procedure is explained in the information sheet CNK EDIT (in [French](#) or [Dutch](#)).



1. List of the databases published by the Association of Pharmacists, Belgium (APB) that use the CNK as a product identification key

A. Price databases

- **Pharmaceutical and Parapharmaceutical Product Database (PPPD)**
The PPPD lists all the products that are available in Community pharmacies as well as the drugs for hospital use. Besides the name and CNK of the products, the database also contains their price, VAT rate, reimbursement conditions, storage conditions and other useful information. It is updated twice a month. Please contact our *Pricing & Reimbursement Department* to know the closing dates for the updates.
- **Compounded Medication Database (CMD)**
The CMD allows for the pricing of compounded medication (covered or not by the Belgian national health insurance). The database lists all commercially available bulk products with their prices and reimbursement conditions.
- **Hospital Database (HD)**
The HD defines the unit dose of all the drugs for hospital use and their national codes (CNK-UD). The database lists the pricing and billing information for in- and outpatients. Moreover, the HD contains the necessary information for the management of pharmaceutical products under the magnetic media billing arrangement. The HD is monthly updated.
- **Physician Database (PD)**
The PD lists all drugs available for prescription by physicians.

B. Scientific databases

- **DelphiCare**
The national code number (CNK) is the access key to the scientific database DelphiCare. DelphiCare gives a full description of the medicinal products for human use marketed on the Belgian market: quantitative composition of the active ingredients, qualitative composition of the excipients, maximum dosage, therapeutic class, contraindications and precautions for use, drug interactions, patient information at first dispensing, copies and generics (INN prescribing), equivalent brand names in foreign countries, and monographs for pharmaceutical raw materials.

A detailed description of our databases and their contractual conditions can be obtained on request.

2. Other applications

A. The use of barcodes

Data entry through barcode scanning is one of the most efficient data entry systems available today, since it combines the following characteristics:

Flexibility

- In the choice of the optical reader;
- In the connection with the PC;
- Easily compatible with printers.

Reliability

- Absence of reading errors.

Accuracy

- No more human errors.

Speed

- Optical reading is 4 times faster than manual data entry.

User-friendliness

- The use of barcode systems does not require any preliminary user training;
- Compact, easily portable equipment.

Low running costs

B. Use in Community pharmacies

1) Data entry for the products dispensed in the community pharmacy

The following steps can be distinguished:

a) The Unique Digital Register:

The pharmacist uses the CNK affixed to the drug packages to look up in the database for the rules and regulations that will enable him/her to create the Unique Digital Register in relation with the patient register and the prescribing physician's name.

b) Pricing & billing

The pharmacist's computer needs to have a drug database in which data such as public prices and reimbursement conditions are regularly updated.

Scanning the barcode at each dispensing allows pharmacists to see directly on their screen the information they need about whether and how the drug is covered.

c) Pharmanet

Pharmanet is a scheme that allows to collect, per prescriber, data about reimbursed pharmaceutical products and services (medicines, compounded medications, sterile insulin syringes and out of hours additional fees...) dispensed from Community pharmacies. Data collection is done through the Community pharmacies, Community Pharmacy Billing Services and health insurers. The health insurers then communicate their data to the INAMI. The main objective of Pharmanet is to inform the prescribing physicians about their prescribing practices and to allow them to see how their colleagues' prescribing behaviour compare with theirs. Therefore it is extremely important that CNKs are used correctly and that every change related to reimbursed products is notified as soon as possible to our *Pricing & Reimbursement Department* and to the INAMI.

d) Pharmacovigilance & Patient Safety

When pharmacists have access to our scientific database DelphiCare (interactions, contraindications, maximum dosage...), barcode scanning allows them to be warned about the potential risks associated with the dispensing of certain drugs. The use of CNKs also contributes to patient safety as they are used in the recall procedures managed by our Medicine Control Department (SCM/DGO). CNKs and/or UBCs (unique barcodes) are also used for medicine authentication in the fight against falsified medicines.

e) Accounting

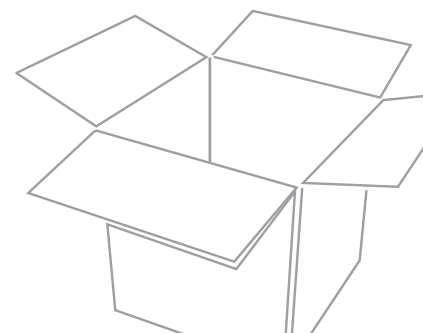
A sales journal (broken down by VAT rate or drug group) can be easily created, provided that the products dispensed can be entered quickly through barcode scanning.

2) Integrated stock management

Stock management is a delicate task that requires careful attention in any branch of activity.

Every stock movement (sales, incoming orders, product returns to suppliers, destruction, sales to staff...) must be recorded.

Stock errors may quickly lead to missed sales or over-stocking. Barcode scanning makes it easier to record stock movements in Community pharmacies and makes it possible to reduce the risk of errors.



a) Continuous stock monitoring

Pharmacists can rapidly scan their actual stock on the shelves with a handheld device and compare it with the theoretical stock in the pharmacy's stock management system.

This allows pharmacists to correct errors and to have a reliable stock management system.

b) Incoming order control

At product reception, the recording in the pharmacist's management system can be done easily through scanning the barcode affixed to the products' packaging.

Keeping track of stock history is useful.

c) Annual stocktaking

Barcode scanning allows the quick recording of the actual stock on the shelves with a handheld device.

When connected to the pharmacist's computer, such a device allows the calculation of the inventory value, as well as the comparison of the pharmacy's actual stock with the theoretical stock in its stock management system.

C. Use in hospital pharmacies and nursing homes, or for Individual Medication Preparation (IMP)

Medication administration in hospitals, in nursing and elderly homes, or in the form of Individual Medication Preparation (IMP) increases unit dose drug dispensing.

In hospital settings, assigning code numbers to every unit dose packaging is necessary, as is the automation of the following processes:

- Prescription writing;
- Pharmaceutical analysis of prescriptions (with our scientific database DelphiCare);
- Hospital pharmacy stock management;
- Recording medication use in each hospital unit;
- Medication dispensing to patients;
- Communication with other IT applications;
- Integration in the hospital management system (patient medical record management...).

D. Uses in the distributors' and manufacturers' communication

The CNK is a unique identification key. When used by all the partners in the sector, it allows them to speak the same language.

Therefore, it is an essential tool for all the communications applications and EDI, for instance:

- Data exchange between wholesalers;
- Communicating price changes (from the manufacturer to the APB or the wholesaler);
- Industry publications or ads aimed at pharmacists;
- Folders and price lists aimed at pharmacists;
- Sales representatives process orders in community pharmacies through barcode scanning with a handheld device.

An efficient use of the CNKs and their barcode symbology enhances a company's image

Manufacturers also use the barcodes for their own management processes since data capture through barcode scanning makes it easier to record, check and monitor the various steps in the production or distribution process.

Barcodes allow far-reaching automation and make it easier to control order processing operations.

CONCLUSION

In concluding, we would like to draw your attention again to the importance of communicating rapidly and in detail any information or change related to the products placed on the market by your company.

We would like to thank you in advance for your kind cooperation that enables us to provide high quality databases to pharmacists, thereby enhancing the collaboration between Community pharmacists and the pharmaceutical industry.



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Appendix: MSI Barcode Specifications

Introduction

The following information is intended to provide information to persons responsible for printing bar code symbols that will be scanned by MSI scanners. This information is subject to change without notice.

A high degree of printing quality is required for bar code symbols. An MSI representative can help you contact printers who have demonstrated the required expertise in the past.

Description

The symbol consists of the following elements: a forward start code, four bars with intervening spaces for each encoded digit, one or two symbol check digit(s) and a reverse start code. The MSI scanner contains a light source that illuminates the symbol. The light is either absorbed by the dark bars or reflected by the spaces between the bars. The scanner reads the encoded digits by comparing the width of each dark bar to the space following it, as the scanner is moved across the symbol. If the bar is wider than the space, it is considered to be a "one bit". A bar that is narrower than the space following it, is a "zero bit" in the forward direction.

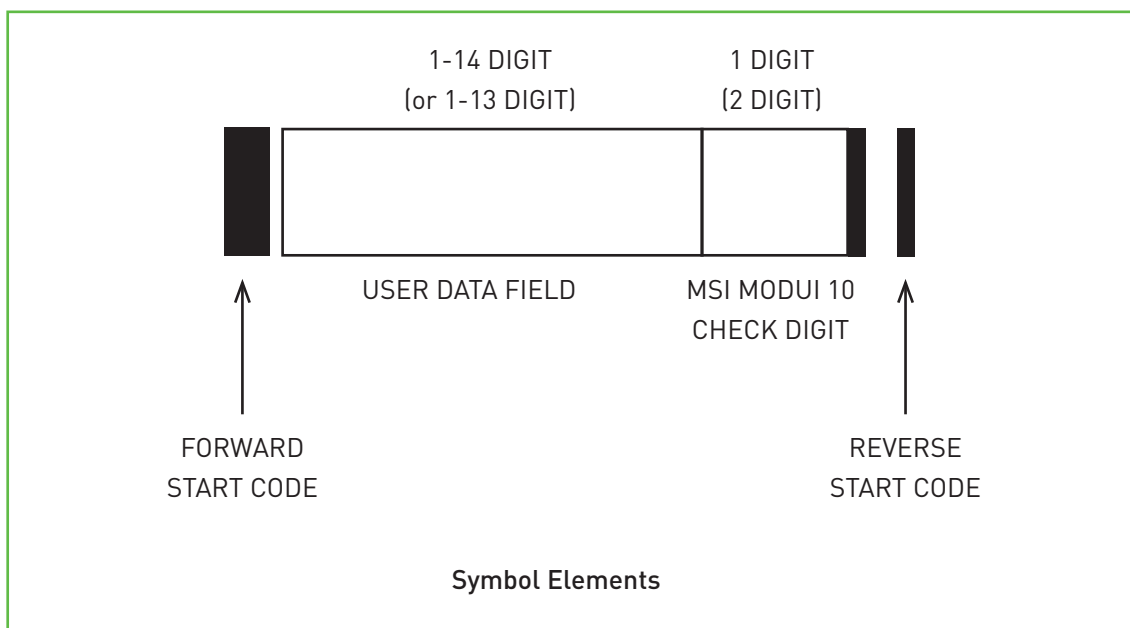
Data Code

Each digit consists of four bits in binary coded decimal (BCD) form. In the following table an "0" is the equivalent of a narrow bar/wide space and a "1" is equal to a wide bar/narrow space.

Decimal	BCD
0	0000
1	0001
2	0010
3	0011
4	0100
5	0101
6	0110
7	0111
8	1000
9	1001

Symbol elements

- **Start code, forward:** The forward start code is a single 'one' bit (wide bar/narrow space).
- **Data Field:** The user may have up to 14 digits in the data field if the check digit is included. If the user does not provide a check digit, a maximum of 13 digits can be used in the data field.
- **Check Digit:** The modulus 10 MSI check digit which is transparent to the user is one or two digits, depending on the user's data field format.
- **Start Code, Reverse:** The reverse start code is a single 'zero' bit followed by a narrow bar (narrow bar/wide space/narrow bar).



A. Bar Edge

Bar edge is defined as the half-amplitude point between maximum reflection from the background and minimum reflection from the bar. For instrumented measurements a .008 inch diameter aperture shall be used.

B. Bar Width

The actual bar/space width depends on the print tolerances that can be maintained in production. The bar and space edges must fall within the specified tolerances over at least 80% of the bar heights, exclusive of the top and bottom 5%.

Narrow Bar or Space	Wide Bar or Space	Tolerance
.008	.017	+/- .0015
.012	.025	+/- .003
.016	.032	+/- .004
.020	.040	+/- .006
.024	.048	+/- .008

All dimensions are in inches

C. Bar Height

Minimum bar height is 0.3 inch. In practice, the user would be advised to make the bars as high as possible for acceptable first pass read rates. This is most significant in shelf labels.

D. Edge Roughness

Edge roughness is included in the bar width specification (A above).

E. Margins

A blank reflective area of at least 0.25 inch shall be at the left and right of the bar code.

F. Digit Spacing

The digits are not dimensionally independent. The spaces between digits must fall within the tolerances listed in A. above.

Print Quality Factors

A. Background Diffuse Reflectance

There are no requirements on background diffuse reflectance provided the contrast requirements (D below) are met.

B. Background Uniformity

There shall be no detectable patterns in the background within the bar code area or margins.

C. Ink Film Reflectance

The ink film reflectance shall be 25% maximum measured with a Macbeth model PCMII print contrast meter or equivalent with a standard response “D” filter. The aperture is .008 inch diameter and the filter is a 30nm Interference filter peaked at 905nm with 3050K source and a silicon detector. The reflectance shall be the maximum reading obtained over the total bar height exclusive of the top and bottom 5%.

D. Print Contrast Signal

Minimum print contrast signal (PCS) between bars, and spaces between bars, is 50% over the bar coded height exclusive of the top and bottom 5%. It is measured under the same conditions as ink film reflectance (C) and defined as :

$$PCS = \frac{Rw - Rb}{Rw}$$

Rw = % reflectance of spaces
Rb = % reflectance of bars

E. Voids

Voids (poorly inked areas within bars) are not separately specified but included within ink film reflectance requirements(C).

F. Ink and Dirt Spots

These are not separately specified but included in the contrast requirements (D).

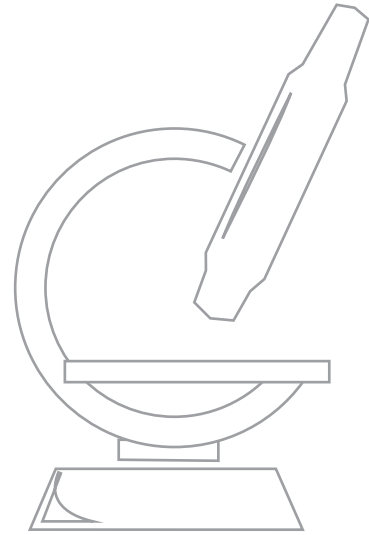
G. Smear and Scratch Resistance

The ink must not smear during the life of the label. The wand may have a plastic tip that reduces the scratching effect on the label surfaces. If the symbol life will be short and the symbol will be in a protected environment, a protective coating over the symbol may not be required. It is recommended that adequate testing with various inks and paper stock be done prior to committing to such an application. For applications such as supermarket shelf labels where months of use and many scans are expected, a transparent protective coating is virtually mandatory.

H. Testing

Before the printer begins production runs for the first time, he/she should have samples tested. The purpose of the test will be to insure that:

- a) the symbol dimensions and printing are within tolerances;
- b) the ink and background reflectivity will provide reliable scanning;
- c) the protective coating does not degrade the printing quality or reflectivity to an unacceptable degree.



The initial approval of the samples must not be construed to mean that there is a high quality of subsequent symbols produced by that printer. It is simply a method whereby the printer may determine at the outset whether the methods and materials he intends to employ are suitable for the purpose.

For quality assurance of his production runs, the printer should acquire or have easy access to an MSI Data Corporation data entry terminal equipped with a scanner unit.