Healthcare AIDC:
Product Identification

Canadian Implementation Guideline and Leading Practices

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Document Summary

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23 September, 2009	1.1	Healthcare Product ID Task Group	Modification of wording throughout to align with Global documents. Addition of section 11 Marking Grid Use	Wording and clarification.
27 October 2009	1.2	GS1 Canada Public Affairs	Branding and language.	Wording and clarification.

Disclaimer

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2 EXECUTIVE SUMMARY

The **Healthcare Automatic Identification and Data Capture (AIDC): Product Identification – Canadian Implementation Guidelines and Leading Practices** is the result of international recommendations and Work Group results that have been reviewed by members of the Canadian industry. GS1 Healthcare established a global AIDC Application Standards Work Group, as well as a Symbol Placement Team, to review the existing GS1 System of standards for symbol placement on packaging in order to identify gaps and propose recommendations to the Application Standards Development Team. The results are for inclusion into the initial GS1 Application Standard for Healthcare.

3 INTRODUCTION

The GS1 Canada Healthcare Product Identification Task Group was assembled to review current and ongoing global recommendations and reports related to the identification of pharmaceutical and medical-surgical devices using AIDC techniques. This document is the result of those discussions and is meant as an aid to the manufacturers, distributors and end users to implement a capability for encoding and decoding this data in their systems.

These recommendations are for manufacturers and resellers who are marketing their products in multiple jurisdictions with the goal of reducing the number of localised package designs and/or AIDC markings applied there-on. All users of this guide are encouraged to familiarize themselves with the regulations and trade agreements set forth by the governments and trade associations in the regions where these items are traded to ensure conformity to those requirements.

3.1 Scope of Work

For pharmaceuticals (e.g. vaccines, nutritionals) and medical devices, the team was to:

- Collect, define and evaluate both business and technical needs specific to the Canadian healthcare sector;
- Determine how current and/or emerging healthcare regulations impact data capturing requirements;
- Examine the current AIDC standards and determine the possible use of these standards as the basis for future published healthcare standards; and
- Identify and document gaps between local Canadian market needs and global standards, dialogue with GS1 Healthcare to develop recommendations to close the gaps.

3.2 Out of Scope

Out of scope items that this document will not include are:

- Modifications to the Marking Grids
- Introduction of Radio Frequency Identification (RFID)

3.3 Product Marking Grids

The product marking grids were prepared to aid the development of the application standard and to provide an illustration to readers of the AIDC data that will be carried by healthcare products at different packaging levels for different product applications.

4 BASICS OF PRODUCT IDENTIFICATION

Proper product identification should be able to respond to each of the following requirements:

- The symbology must work in the environment it is intended for.
- The symbology must contain the required data.
- The symbology must fit into the space available.

4.1 Static vs. Dynamic Data

As the name implies, static data remains constant throughout the manufacturing of products and is directly linked to the Global Trade Item Number (GTIN). Static data includes the GTIN, size, or strength.

Dynamic data changes in the production process and requires identification at a shipment or item level. Dynamic data includes the lot, or expiration/ manufacturer dates.

Exact dynamic data fields will be based on legislated requirements, trade partner agreements, and affiliated association recommendations.

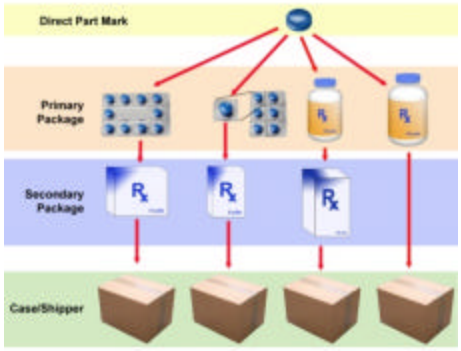
Notes:
Standards are written to meet virtually all government requirements. If there is a difference between the global standards and a particular country's requirements. dialogue must be established to determine why there is a difference and how to close that gap.

At no point should these requirements limit any government-required information.

5 MARKING LEVEL HIERARCHY

The marking levels for symbol placement in this study are:

- Direct Part Mark
- Primary Package
- Secondary Package
- Case/Shipper
- Pallet



5.1 Direct Part Mark (DPM)

As the title implies, this level includes items without any form of packaging is directly marked. In this document this level of marking is reserved for medical devices classified in the highest level of AIDC marking. Includes many (or all) complex medical devices that are subject to Track/Trace requirements. The suggested markings are therefore likely to be scanned and utilized by downstream trading partners.

Examples include complex medical devices, re-usable medical devices, and implants requiring special medical training and/or additional special processes to ensure proper use and administration (e.g. implants, surgical equipment, re-processed instruments, software-controlled devices, pacemakers, assets – i.e. infusion pumps, ventilators, monitors).

Note:
Implants are not required to be direct part marked with AIDC technology to ensure biocompatibility, infection control, and comfort. The brand owner should determine if direct part marking DPM is appropriate.

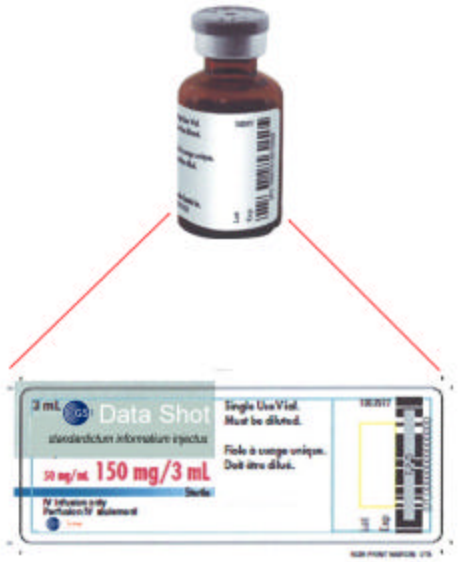
5.2 Primary Package

Primary or first level of packaging symbology would be placed either on the packaging or on a label affixed to the packaging. It may consist of one single item or a group of items for a single therapy, such as a kit.

The marking grid should be used to determine what information is required at what level based on government regulations. Please note that to standardize the information required on the items, it may be necessary to increase the level of identification.

Note:
At the time this document was created, the GS1 General Specifications requires that a GTIN-12 be used to identify the lowest level of product. The Indicator Digit Work Group is reviewing the possibility of allowing the marking of items out of hierarchical order. Please review the GS1 General Specifications before attributing any GTIN other than a GTIN12 to this level of packaging to ensure conformity to the standards.

Examples of Primary Packaging



Vial

Pill Bottle

Pre-Filled Syringe

5.2.1 Perforated Blister Cells

It is recommended that at the immediate package level for pharmaceutical products packaged with perforated blister cells, the symbol shall be placed on each blister cell (see image below).

5.2.2 Non-Perforated Blister Cells

It is recommended that at the immediate package level for pharmaceutical products packaged with non-perforated blister cells, the symbol shall be placed once on the blister card and may be placed anywhere on the blister card.

If random printing is used the symbol may be placed multiple times to ensure that the symbol remains scannable until the last blister has been used (see image below).

Examples of Blister Cell Marking

5.2.3 Pharmacy Labelled Bottles Placed in Boxes

It is recommended that retail and hospital pharmacies include or expand the symbol placement for labels on bottles placed in boxes.

The GTIN Allocation Rules should be referred to when taking any product marking decisions to ensure supply chain accuracy.

5.3 Secondary Package

Secondary or next level of packaging, containing one or more single items in their immediate packaging include a box containing blister packs, a bottle, or other like items.
The marking grid should be used to determine what information is required at what level based on government regulations. Please note that to standardize the information required on the items, it may be necessary to increase the level of identification.

Examples of Secondary Packaging

5.3.1 All Packaged Transactional Item Levels

As indicated in the marking grids, all levels of packaging should be identified with the minimum required information.

Each packaging hierarchy should be identified with a symbology containing the GTIN and any corresponding Application Identifiers (AIs) defined at that level.

Items bundled for ease of manipulation in clear plastic need not be identified with a bar code as an item grouping so long as the item code(s) can be read through substrate. If this level is a defined trade item, all Marking Grid recommendations should be applied to the information encoded.

If an item is not destined for the retail market, all levels of marking should include all the data elements as outlined by regulation and/or trade agreements.

Note:

Where possible, both the GTIN and the additional information should be encoded on each level of packaging to increase the accuracy and ease of capture as the product moves throughout the supply chain.

5.4 Non-Retail Case/Shippers/Pallets

It is recommended that only one bar code should be scanned to capture all the required data(i.e. GTIN, lot and serial number).

Current GS1 standards include the GS1-128symbology, which can incorporate all required data elements to meet regulatory requirements for product identification.

6 HUMAN READABLE INTERPRETATION (HRI)

It is common sense to have Human Readable Interpretation (HRI) of the AIs and their associated data near the GS1 Symbol in which they are encoded. Typical conventions place the primary information, such as the GTIN, in the human readable data underneath the bar code. The characters must be clearly legible and must be obviously associated with the symbol.

AIs should be clearly recognizable within the HRI to facilitate key entry in the event that the symbol cannot be scanned – achieved by putting the AI between parentheses.

Notes:
The parentheses are not part of the data and are not encoded in the symbol.

This is in clear contrast to the use of the Function 1 (FNC1) character that must be encoded in the symbol when used as a start or separate character. This does not appear in the HRI.

The following examples illustrate the encoded data in the GS1 DataMatrix bar code symbol and how the HRI could appear:

Example 1: FNC1010345312000001117091125 10ABCD1234

Example 2: FNC1019501101020917 1708050810ABCD1234 FNC14109501101020917

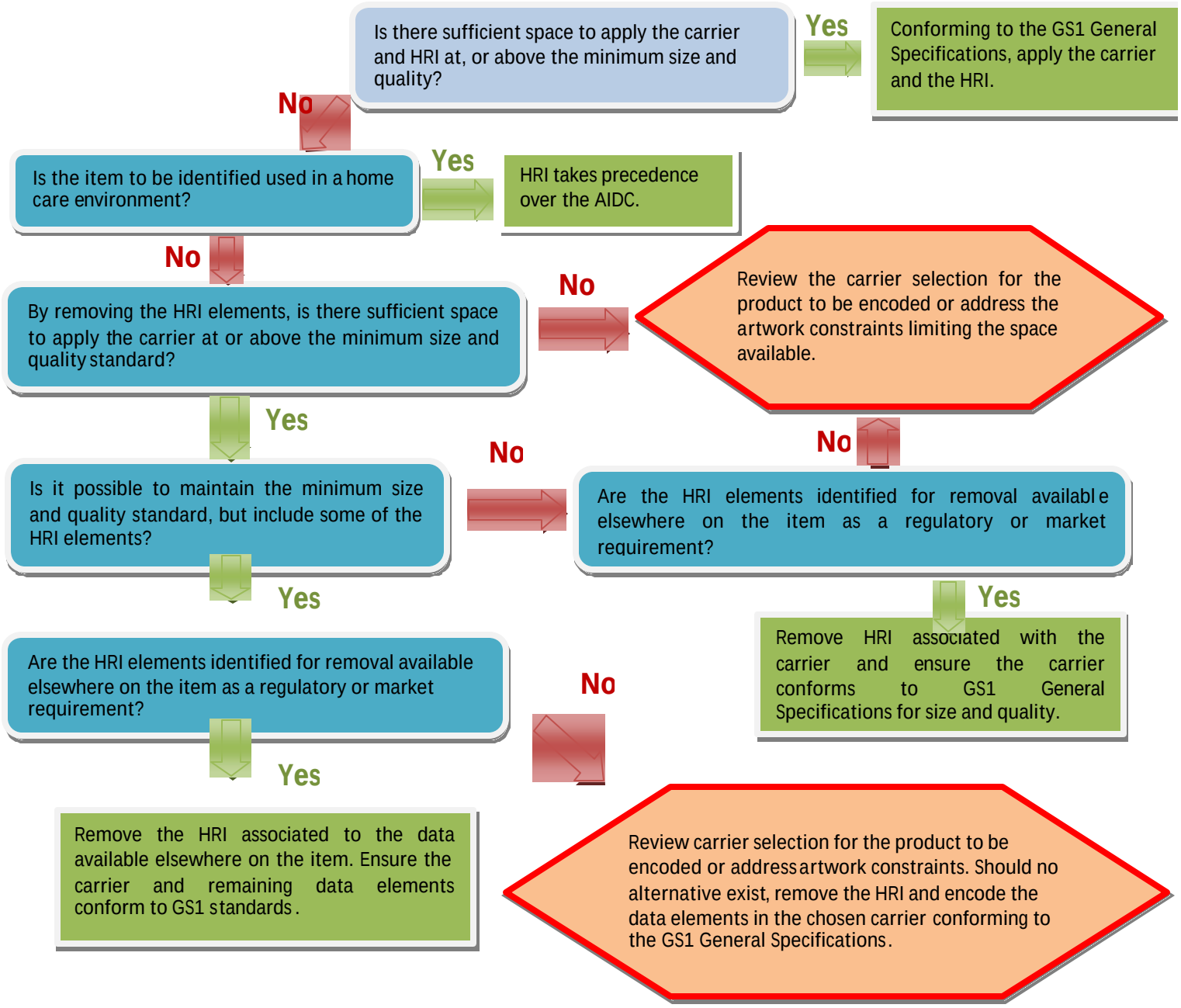
Example 3: FNC1010345312000001117091125 10ABCD1234

The HRI may also use legible text rather than employing AI digits using standardized data titles.

7 HRI DECISION TREE

Given the space requirements for government legislated information, the following decision tree has been developed to aid the manufacturer/distributor in the attribution of required HRI.

Please Note:
According to the GS1 General Specifications, medical devices (instruments and implants) require only the carrier. HRI not is required.



8 APPLICATION IDENTIFIERS (AIS)

Current AIs include:

00	Serialized Shipping Container Code (SSCC)
01	GTIN
10	Batch or Lot Number
17	Expiration Date (YYMMDD)
21	Serial Number
7003	Expiration Date + Time (YYMMDD HHMM)
8003	Global Returnable Asset Identifier (GRAI)
8004	Global Individual Asset Identifier (GIAI)
8008	Date and Time of Production (YYMMDD HHMMSS) *Canadian Change Request (CR) in process to have this AI added for the purposes of nuclear medicine.
NEW	Potency

The above mentioned list contains the approved healthcare standard AIs.

For a full list of GS1 AIs, please see the GS1 General Specifications.

9 SYMBOLOGY

Most discussions centered on symbology applications during the development of these guidelines, as well as the flexibility to support the information required through local regulations.

A data carrier is a means of representing data in machine readable form. The GS1 System specifies the data carrier used to represent any given element string. Section 2.0 of the GS1 General Specifications covers rules indicating which data carrier should be used to represent which element strings in particular applications.

The GS1 System uses the data carriers in the following sections.

9.1 EAN/UPC

EAN/UPC bar code symbols (UPC-A, UPC-E, EAN-13, EAN-8; two- and five-digit add-on symbols) can be read omnidirectionally. These symbols must be used for all items that are scanned at the Point-of-Sale (POS) and may be used on other trade items. Please refer to the GS1 General Specifications for size and quality requirements.

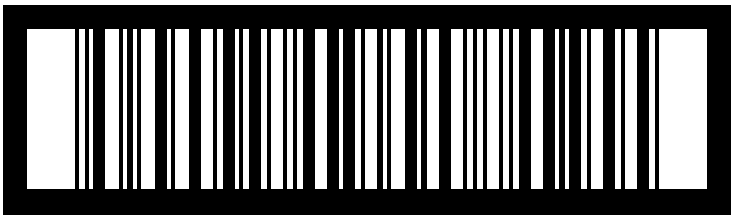
EAN-13 UPC-A

Symbol Type: Linear
Application Type: Printed

Note:
This symbology type is limited in the amount of information it can contain. Given the large surface area required for the accurate readability of this symbol, it was determined to be inadequate for applications where space constraints and additional information would be required for capture within a data system.

9.2 Interleaved 2 of 5 (ITF)

ITF-14 (Interleaved 2 of 5) bar code symbols carry identification numbers only on trade items that are not expected to pass through POS. ITF-14s are better suited for direct printing onto corrugated fibreboard. Please refer to the GS1 General Specifications for size and quality requirements.



18931234567894

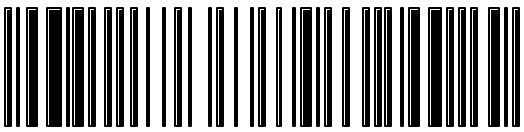
Symbol Type: Linear
Application Type: Printed

Notes:
This symbology type is limited in the amount of information it can contain. Given the large surface area required for the accurate readability of this symbol, it was determined to be inadequate for applications where space constraints and additional information would be required for capture within a data system.

However, it is possible to encode additional information in an add-on code (i.e. GS1-128 symbology) whereby the additional information can be added at a later time (e.g. GTINs printed with ITF, AIs printed on a separate but closely located GS1-128). This duality could allow a bridge from current to enhanced systems and/or for cost-saving methods.

9.3 GS1-128

The GS1-128 is a subset of the Code 128 bar code symbology. Its use is exclusively licensed to GS1. This extremely flexible symbology encodes element strings using AIs. Please refer to the GS1 General Specifications for size and quality requirements.



(01) 10614141543219

Symbol Type: Linear
Application Type: Printed

Notes:
This code type is recommended for the identification of cases where additional information must be captured.

The minimum printing requirements make the direct printing of these codes to corrugate impractical and therefore the recommended method of use is the printed label system.

Given the large surface area required for the accurate readability of this symbol, it was determined to be inadequate for application on small items. Symbol size varies with amount of information to be included.

9.4 GS1 DataBar™

The GS1 DataBar™ (previously Reduced Space Symbology® (RSS)) is a linear symbology used in the GS1 System. In most cases, GS1 DataBar™ implicitly encodes AIs (01) and, in the case of GS1 DataBar™ Expanded, explicitly encodes element strings using AIs. Please refer to the GS1 General Specifications for size and quality requirements.

(01)20012345678909

Composite Component™ symbols do not exist in isolation. The primary identification number is always encoded in the linear symbol and supplementary AI element strings may be encoded in the two-dimensional (2D) component where they take up less space. Please refer to the GS1 General Specifications for size and quality requirements.

A Canadian pilot was completed by Loblaw Companies Limited (Loblaw) and Wal-Mart Stores Inc. (Wal-Mart) on apples and bananas by electronically scanning the produce at POS using GS1 DataBar™. Loblaw and Wal-Mart realized a decrease in pricing errors that used to result from the manual price look-up (PLU) process. For example, organic loose produce can easily be mistaken for a lower-priced, non-organic product; a GS1 DataBar™ bar code enables products to be identified electronically and scanned, diminishing the chance for pricing errors when such products are entered manually using PLU. As a result, Loblaw announced that GS1 DataBar™ would be a business requirement for all their produce suppliers effective 2008.

(17)050101(10)ABC123

(01)04012345678901

Symbol Type: Linear and 2D (image-based)
Application Type: Printed

Note:
This is a versatile code type and is based on the GS1-128 framework. This code allows the addition of AIs to transmit additional information. Multiple subsets of this family of code types

have different size restraints and data capabilities. Symbol size varies with amount of information to be included.

9.5 GS1 DataMatrix

GS1 DataMatrix (e.g. ISO version ECC 200) is the only version that supports GS1 System data structures, including FCN1. Implementation of the GS1 DataMatrix must align with the GS1 System application guidelines (i.e. very small healthcare items). Please refer to the GS1 General Specifications for size and quality requirements.

(21) ABCDEFG123456789

(01) 04012345678901

Symbol Type: 2D (image-based)
Application Type: Printed, dot peened, etched

Note:
This is the recommended code type for use in the healthcare sector due to the flexibility of this code type for use on items requiring multiple AIs. Its application method allows for use on packaged and hard items where the code can be imprinted into the material of the item (i.e. metal, glass). Symbol size varies with the amount of information to be included.

10 SHIPPING LABEL REQUIREMENTS

This information is currently available in the GS1 General Specification, Section 6.8.
Please refer to this document to ensure information integrity.

11 MARKING GRID USE

The marking grid was developed as a single reference source for manufacturers to determine what information was required on packaging to ensure conformity with government regulations around the globe. With this in mind, it is important to update this document with any modifications to those regulations in an effort to maintain its effectiveness.

To properly use this marking grid, the user must first determine in what column and row their respective product(s) fit(s). The examples given are to clarify or exemplify and should not be used as a gauge for product identification requirements.

The markings identified in the grid reflect the strictest requirements set forth by the regulations established by different governments. It is possible that the requirements stated exceed those established by our own regulations.

GLOSSARY

These terms and descriptions are being used by the Healthcare Product Identification Task Group for the development of their deliverables. They are added here for consistency in use. For a complete glossary, please refer to the GS1 General Specifications at http://www.gs1ca.org/GS1GeneralSpecifications.

AI	Application Identifier
AIDC	Automatic Identification and Data Capture
Case/Shipper	AIDC marked onto a shipping container. It may contain one or more items in their immediate packaging and/or secondary packaging.
DPM	Direct Part Mark is AIDC marked directly onto a single, unpackaged item.
FCN1	Function Code 1 is a symbology character used in some GS1 data carriers for specific purposes.
GTIN	Global Trade Item Numbers are the GS1 Identification Key used to identify trade items. The key is comprised of a GS1 or UPC. Company Prefix, followed by an Item Reference Number and a Check Digit.
HRI	Human Readable Interpretation are characters that can be read by persons – such as letters and numbers – as opposed to symbol characters within bar code symbols, which are read by machines.
Primary Package	AIDC marked onto the first level of packaging, either on the packaging or on a label affixed to the packaging. It may consist of 1 single item, or a group of items for a single therapy such as a Kit.
Pallet	AIDC marked onto a pallet. It may contain one or more case/shippers.
RFID	Radio Frequency Identification
Secondary Package	AIDC marked onto the next level of packaging and containing one or more single items in their immediate packaging.
SSCC	Serialized Shipping Container Code is the GS1 Identification Key used to identify logistics units. The key is comprised of an extension digit, GS1 Company Prefix, serial reference, and check digit.

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