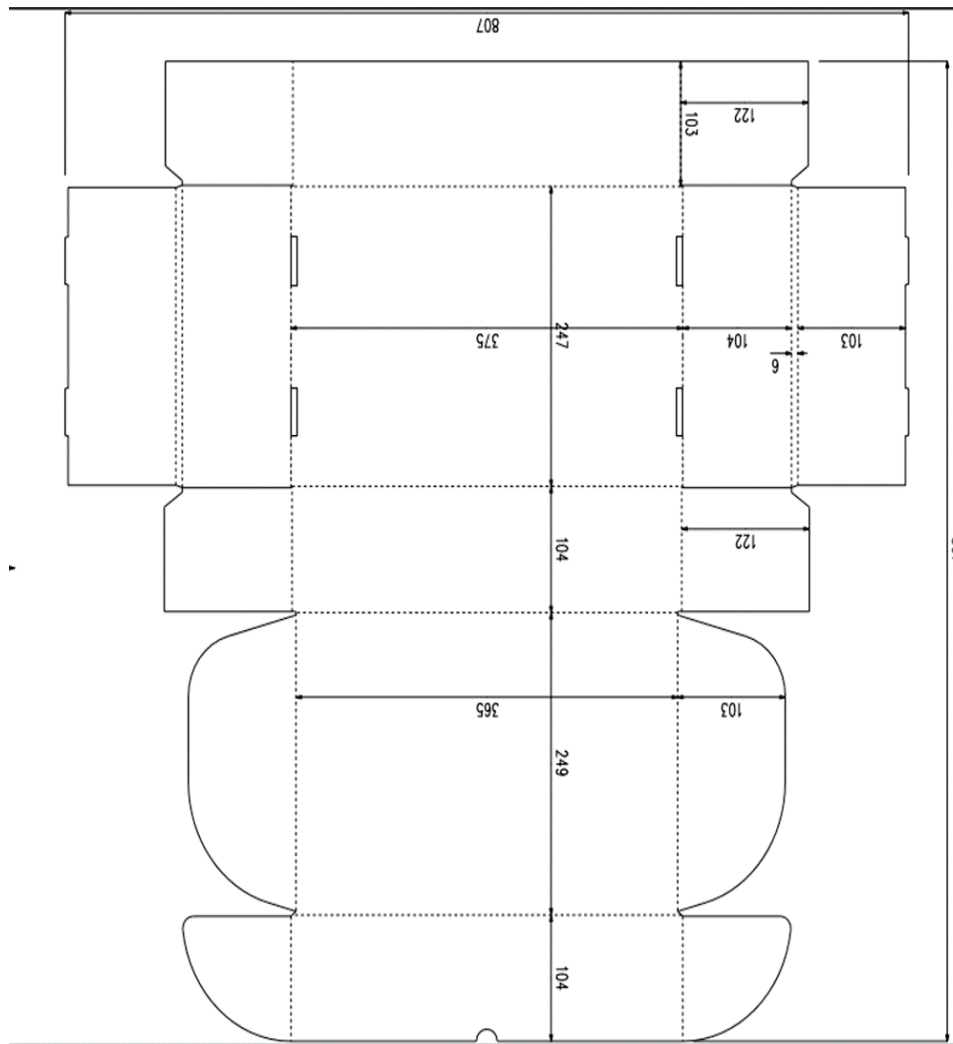


Manufacturing Specification	Calcivis Imaging Device Label Specification (US)		CALCIVIS
Code No.:	MSPEC001-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Supply Chain

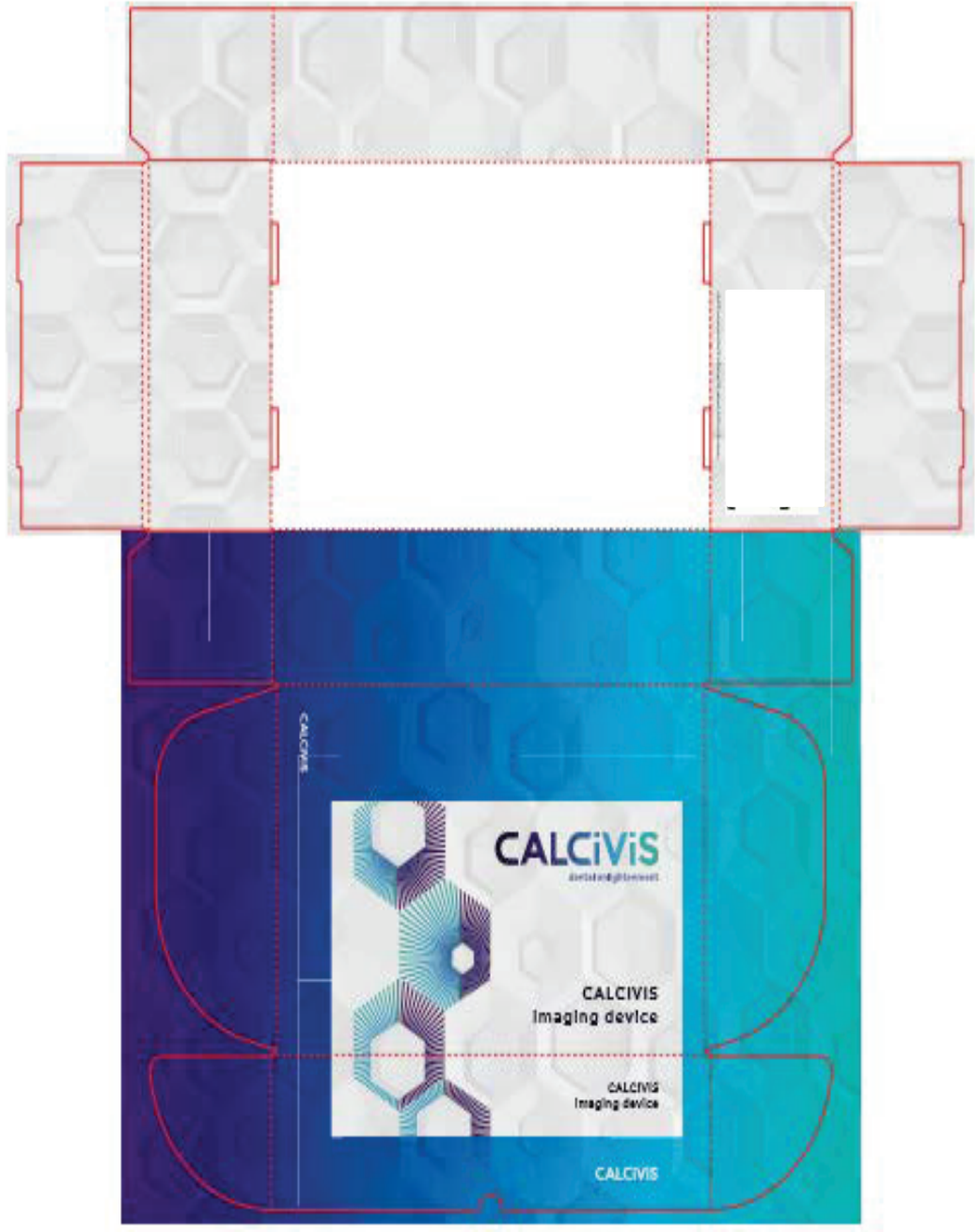
1 Secondary Packaging Specification

1.1 The secondary packaging key line and dimensions are below:



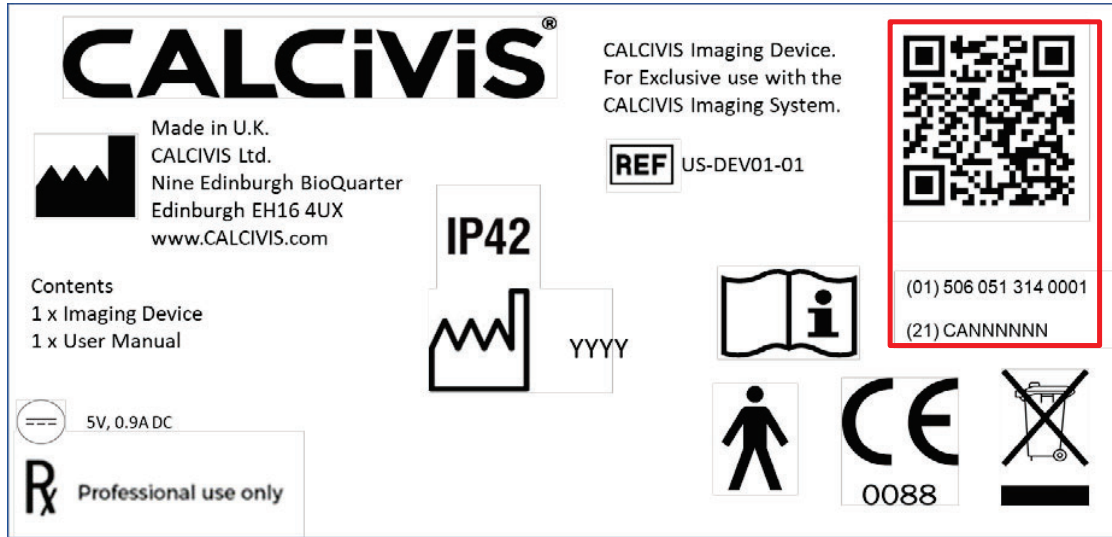
Manufacturing Specification	Calcivis Imaging Device Label Specification (US)		CALCiViS
Code No.:	MSPEC001-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Supply Chain

1.2 The secondary packaging artwork is below. This illustration is to show how the artwork fits onto the key line. Due to the size the label is not legible, for an exploded view of the label please see section 1.3.



Manufacturing Specification	Calcivis Imaging Device Label Specification (US)		CALCIVIS
Code No.:	MSPEC001-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Supply Chain

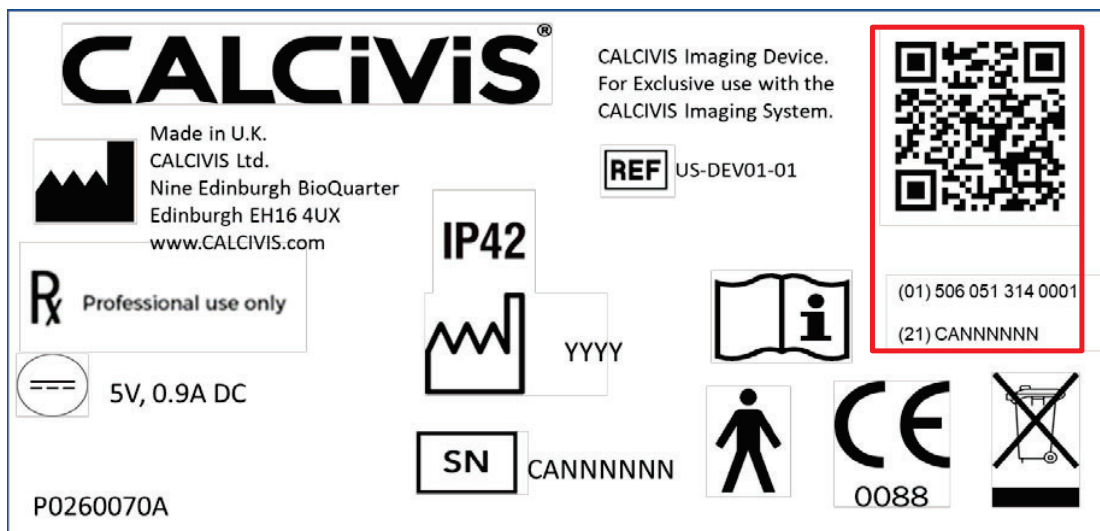
1.3 Box Label



The UDI (highlighted in the red box) is variable text printed by the contract manufacturer.

The variable text label is created and applied by the device manufacture. There are 3 aspects to this label (1) the unique identification 2D bar code (2) the unique device identification number (top number) and (3) the sequential device serial number CAXxxxxx (bottom number).

1.4 The Device Label L65mm x H25mm (illustrative image below).

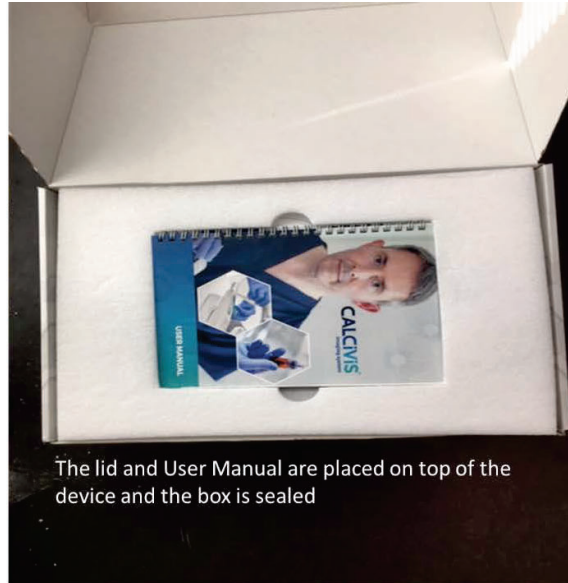


The UDI (highlighted in the red box) is variable text printed by the contract manufacturer.

Manufacturing Specification	Calcivis Imaging Device Label Specification (US)		CALCIVIS
Code No.:	MSPEC001-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Supply Chain

4 Secondary Packaging Configuration (used for illustration)

The packaging system includes a foam fitment to support the device, the cradle and the USB cable assembly. The box is secured by putting the lid and User Manual in place.



Specification	Calcivis Applicator Main Body Label Specification (US).		CALCIVIS
Code No.:		Effective Date:	
Replaces No.:		Department:	Supply Chain

APPROVAL / AUTHORISATIONS

Written By: _____ Steven Valenti _____
Print Name Signature Date

FURTHER REVIEWS (IF REQUIRED)

Other Departmental Signatures

Department	Print Name	Signature	Date
CTO & Quality Director	Bruce Vernon		
Senior Scientist	Graham Bailey		

Document Control Review by: _____
Print Name Signature Date

REASON FOR ISSUE / REVISION HISTORY

- | |
|--|
| <ul style="list-style-type: none"> Initial release. |
|--|

TRAINING REQUIREMENTS

<input type="checkbox"/> Read and Understand Changes <input type="checkbox"/> Training Required	[Author to Tick Relevant Box]
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Specification	Calcivis Applicator Main Body Label Specification (US).		CALCiViS
Code No.:		Effective Date:	
Replaces No.:		Department:	Supply Chain

1 Packaging Specification

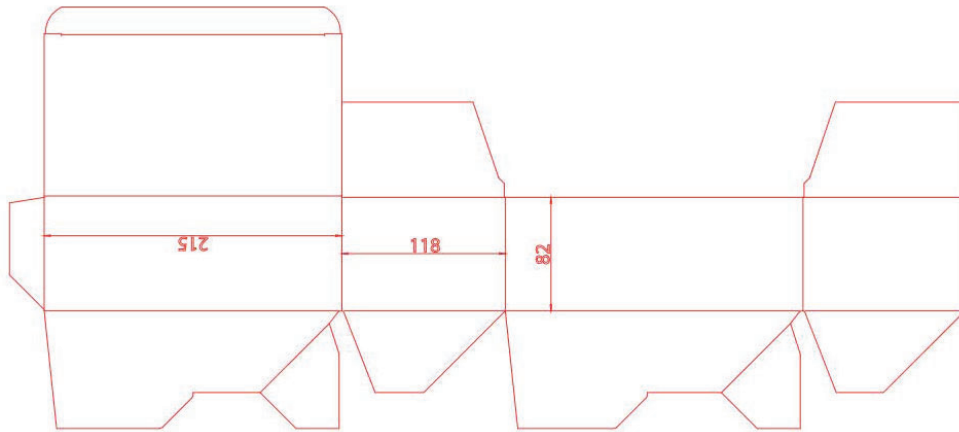
The applicator main body kit packaging consists of 4 components

- The outer cardboard box.
- The foam fitment tray and lid.
- The information for use leaflet (IFU).
- The variable text label.

2 Box Dimensions

The box dimensions are in image 1.

Image 1



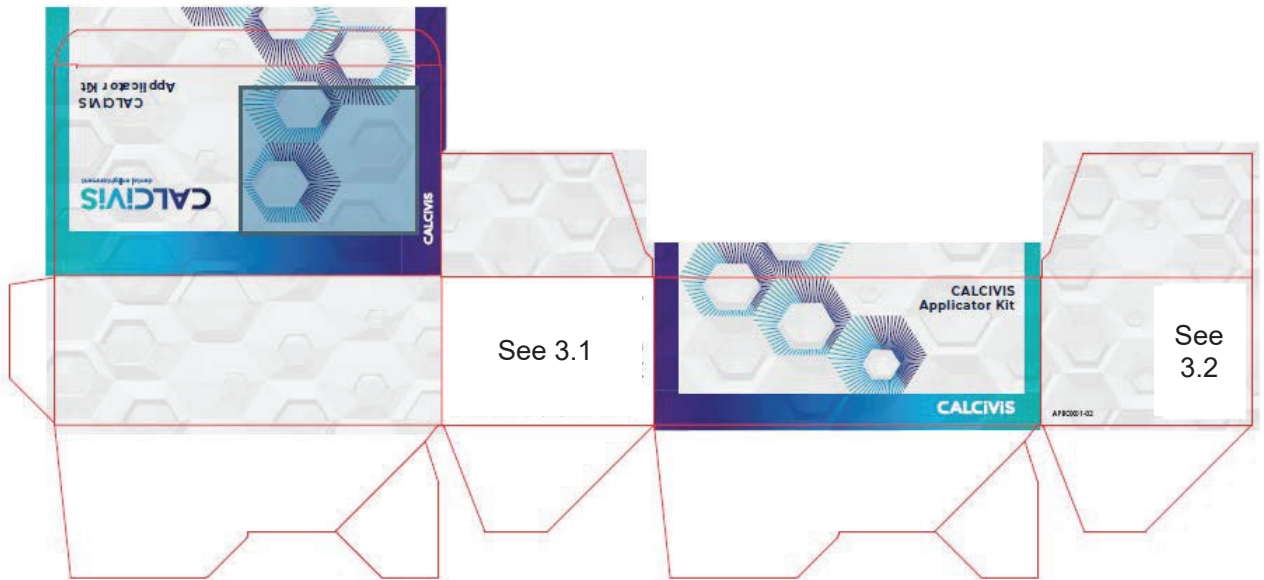
Specification	Calcivis Applicator Main Body Label Specification (US).		CALCIVIS
Code No.:		Effective Date:	
Replaces No.:		Department:	Supply Chain

3 Artwork and Labeling

The applicator box artwork (overlaid on the die cut) is in image 2. The box is 201 white line chipboard, laminated board and is a 4 color print process and UV varnish. For ease of viewing the label has been increased in size and can be seen 3.1.

There is a variable text label containing unique device identification (UDI) information, this is placed on the blank space on the box side panel (see 3.2).

Image 2 (fixed print, branding)



Specification	Calcivis Applicator Main Body Label Specification (US).		CALCIVIS
Code No.:		Effective Date:	
Replaces No.:		Department:	Supply Chain

3.1 Image 3 (fixed print)

This is the fixed print on the box in image 2 enlarged for ease of reading.

CALCIVIS CALCIVIS Applicators.
For exclusive use with the CALCIVIS imaging system.

Made in UK
CALCIVIS Ltd,
Nine Edinburgh BioQuarter,
9 Little France Road,
Edinburgh EH16 4UX, UK.
www.CALCIVIS.com

REF US-APR01-01



Contents
5 x Applicators
1 x Instructions for Use



Retain original packaging.

CALCIVIS is a trademark of CALCIVIS Ltd (Edinburgh, UK) registered in the USA and other Countries.

3.2 Image 4 (variable print)

The 3 lines are i) UDI Calcivis Company and product reference, ii) batch number and iii) expiry date.



5 Foam Fitment and Lid

The foam fitment tray is a custom design component to present the applicators and keep them secure in transit. Images below for illustration purposes only.

Tray



XXXXXXXX

Specification	Calcivis Applicator Main Body Label Specification (US).		CALCiViS
Code No.:		Effective Date:	
Replaces No.:		Department:	Supply Chain

Lid



6 IFU


The instructions for use (IFU) leaflet is placed in the box with the applicators.

7 Kit Assembly

Applicators are placed in the tray in the box, the IFU and lid are also added before the box is sealed. The kitting process is performed and controlled by the applicator contract manufacturer.

Specification	Calcivis Applicator Main Body Label Specification (US).		CALCiViS
Code No.:		Effective Date:	
Replaces No.:		Department:	Supply Chain



Manufacturing Specification	Calcivis Imaging Kit Label Specifications (US).		
Code No.:	MSPEC003-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Document Control

APPROVAL / AUTHORISATIONS

Written By: _____
Print Name
Signature
Date

FURTHER REVIEWS (IF REQUIRED)

Other Departmental Signatures

Department	Print Name	Signature	Date

Authorised By
Head of Department: _____
Print Name
Signature
Date

REASON FOR ISSUE / REVISION HISTORY

- Initial release

TRAINING REQUIREMENTS

Read and Understand Changes Training Required [Author to Tick Relevant Box]

_____ _____
Copy Number **Location**

Manufacturing Specification	Calcivis Imaging Kit Label Specifications (US).		CALCIVIS[®]
Code No.:	MSPEC003-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Document Control

1. Calcivis Imaging Kit Packaging Specifications

1.1 Kit contents:

- a) 1 x vial of freeze dried Calcivis photoprotein. (multi use)
- b) 1 x 20mm Calcivis photoprotein vial adaptor. (multi use)
- c) 1 x vial of Calcivis diluent (single use)
- d) 1 x 20mm Calcivis diluent vial adaptor. (single use)
- e) 10 x Calcivis single use applicators. (single use)
- f) 10 x device syringes. (single use)
- g) Instructions for use.
- h) 10 x IPA swabs.

The imaging kit is supplied in a multiple (3) box configuration.

1.2 Box 1 in the outer box and contains all of the items listed in 1.1

1.3 Box 2 is located inside box 1 and contains:

- a) 1 x vial of freeze dried Calcivis photoprotein (multi use)
- b) 1 x 20mm Calcivis photoprotein vial adaptor (multi use)
- c) 1 x vial of diluent for reconstitution (single use)
- d) 1 x 20mm diluent vial adaptor (single use)

1.4 Box 3 is located inside box 2 and is used for the refrigerated storage of the post-reconstitution photoprotein.



Manufacturing Specification	Calcivis Imaging Kit Label Specifications (US).		CALCIVIS®
Code No.:	MSPEC003-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Document Control

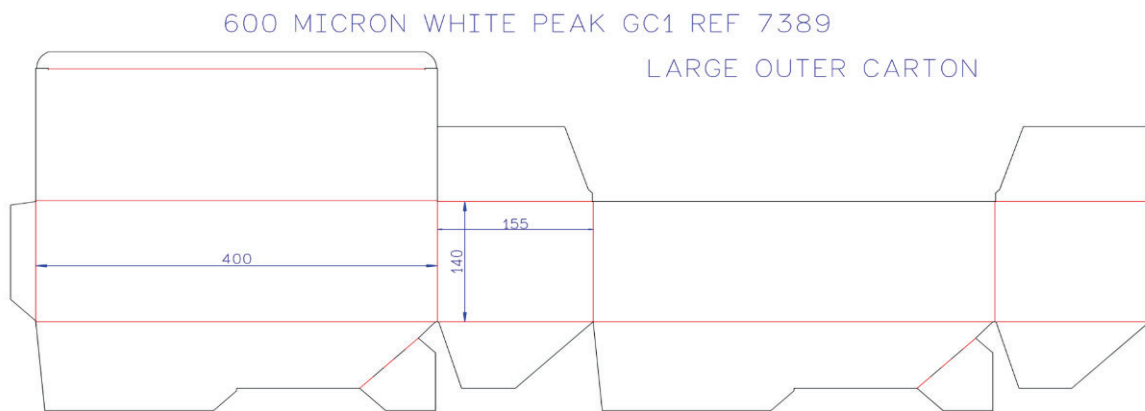
2. Secondary Packaging and Labelling Specifications

The components are presented in a carton with the following specification and layout;

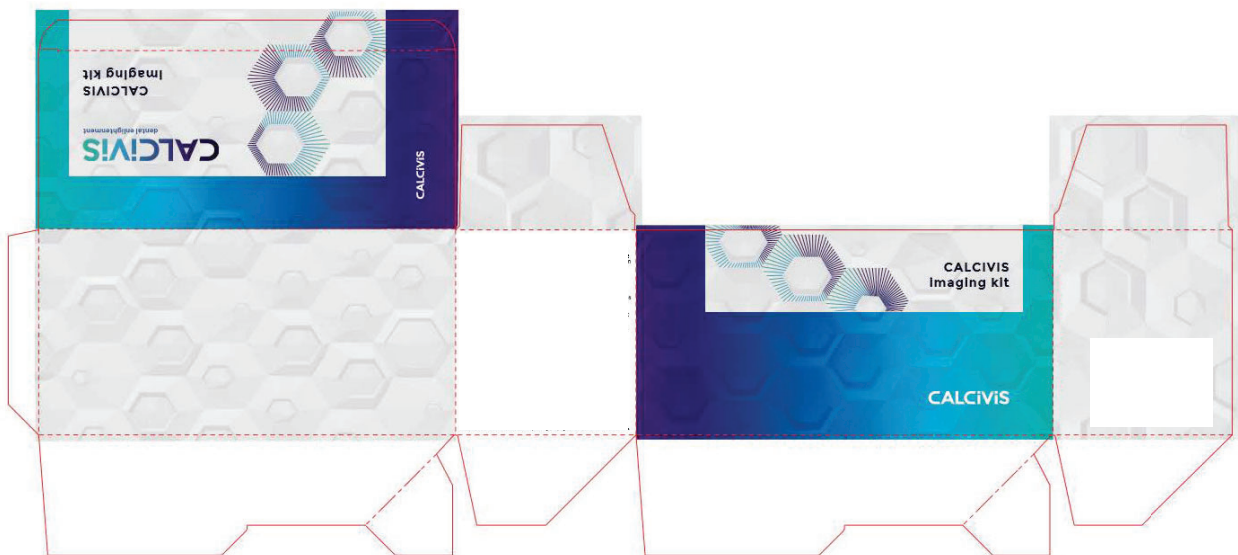
2.1 Box 1 Calcivis Imaging Kit

Box 1 is the outer box containing all the consumables required to operate the Calcivis Imaging System.

Box 1 dimensions



Box 1 artwork (whole box)




Manufacturing Specification	Calcivis Imaging Kit Label Specifications (US).		CALCIVIS®
Code No.:	MSPEC003-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Document Control

2.1.1 Box 1 artwork (fixed regulatory and legal print)

CALCIVIS CALCIVIS imaging kit.
For exclusive use with the
CALCIVIS imaging system

REF

Contents <ul style="list-style-type: none"> • 1 diluent vial adaptor • 1 diluent vial • 10 x device syringes • 10 x device applicators • 10 x 70% IPA wipes 	 SINGLE USE
---	--


SEE INSTRUCTIONS FOR USE


TEMPERATURE LIMITS

- 1 photoprotein multiuse vial adaptor
- 1 photoprotein vial
- Instructions for use

CE
0088



Made in UK

CALCIVIS Ltd, Nine Edinburgh BioQuarter,
9 Little France Road, Edinburgh EH16 4UX, UK.

www.CALCIVIS.com

CALCIVIS is a trademark of CALCIVIS Ltd (Edinburgh, UK) registered in the USA and other Countries.

2.2 Box 1 labelling requirements

Box 1 has 1 label with lot number and expiry information. This is a variable text label applied during the packing process (sample for illustration).



(01) 5060513140018
(10) US-CIK-YY-NNN
(17) YYYY-MM-DD

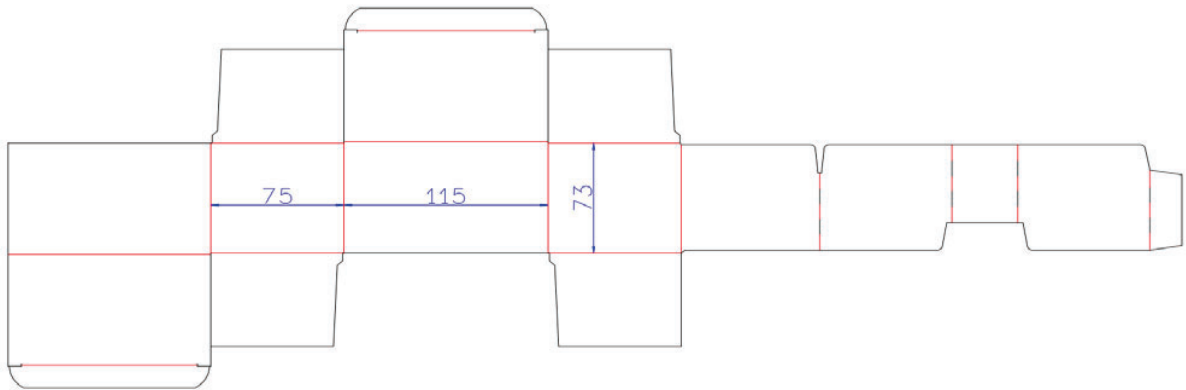
REF US-CIK01-01

3 Box 2 Calcivis Imaging Kit

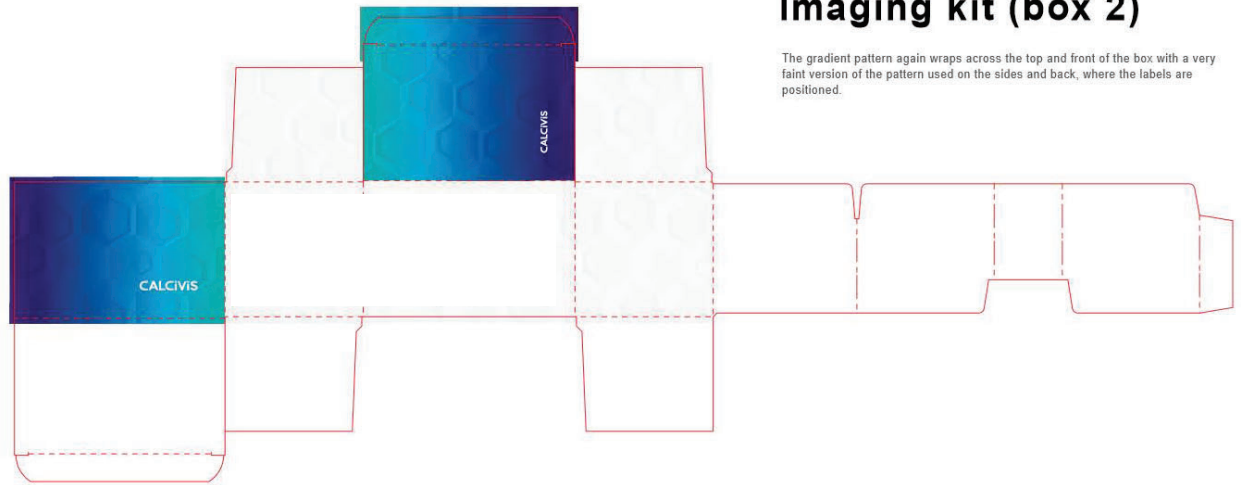
Box 2 contains the 10ml vial of pre-reconstitution Protoprotien, the 10ml vial of Diluent and the vial adaptors used to transfer the diluent to the dry photoprotein.

Manufacturing Specification	Calcivis Imaging Kit Label Specifications (US).		CALCIVIS[®]
Code No.:	MSPEC003-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Document Control

Box 2 dimensions



Box 2 artwork (whole box)

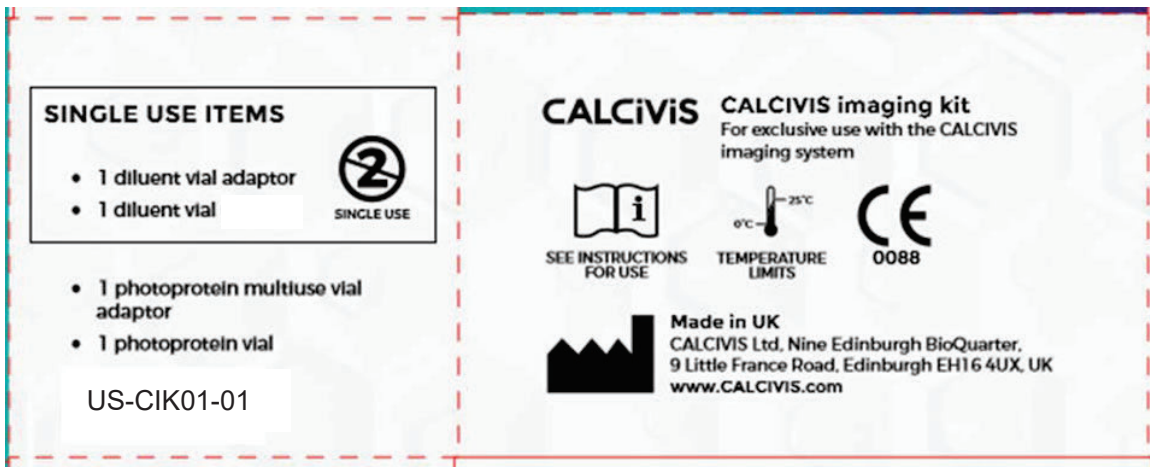


Imaging kit (box 2)

The gradient pattern again wraps across the top and front of the box with a very faint version of the pattern used on the sides and back, where the labels are positioned.

Manufacturing Specification	Calcivis Imaging Kit Label Specifications (US).		CALCIVIS[®]
Code No.:	MSPEC003-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Document Control

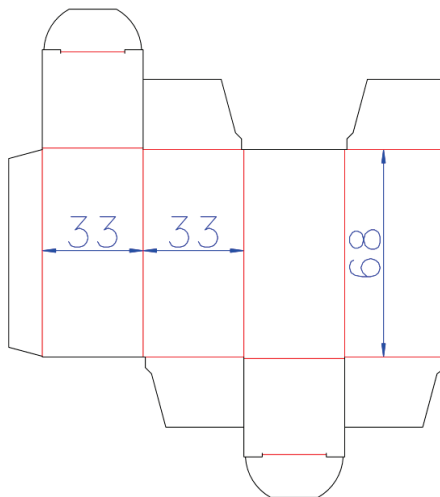
3.1 Box 2 artwork (fixed regulatory and legal print enlarged for ease of reading)



4 Box 3

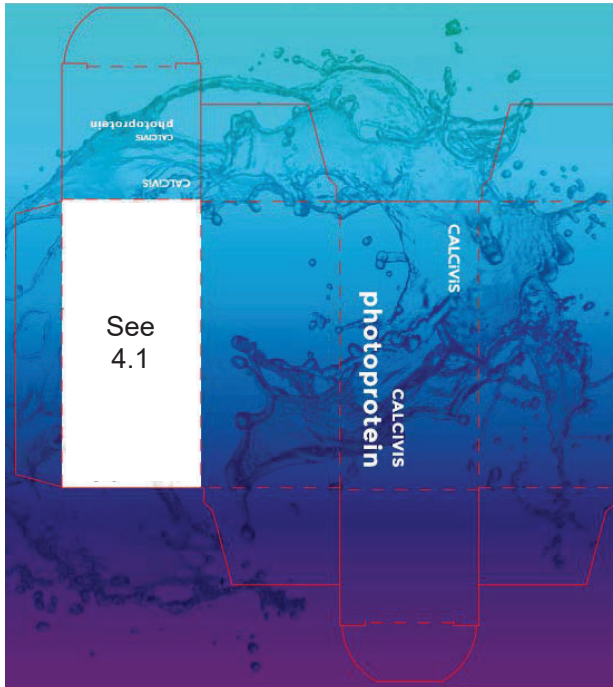
Box 3 is used for refrigerated storage of the post-reconstitution photoprotein vial and its multi-use adaptor.

Box 3 dimensions

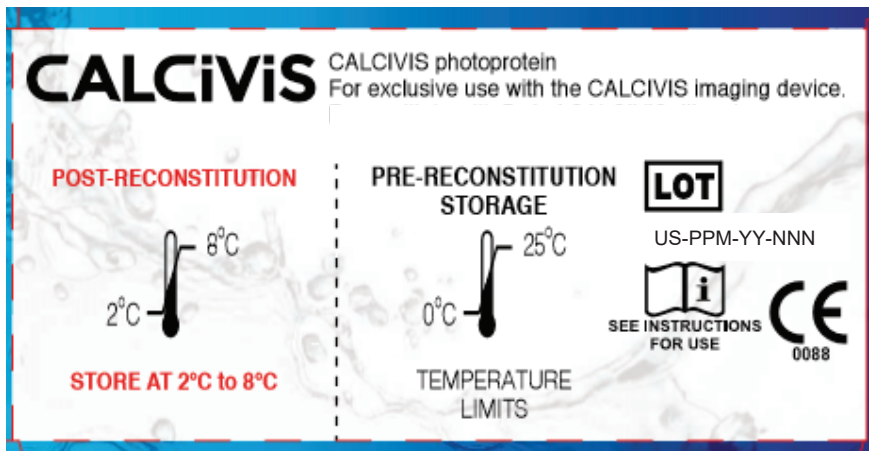


Box 3 artwork (whole box)

Manufacturing Specification	Calcivis Imaging Kit Label Specifications (US).		CALCIVIS[®]
Code No.:	MSPEC003-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Document Control



4.1 Box 3 (fixed regulatory and legal text expanded for ease of reading)



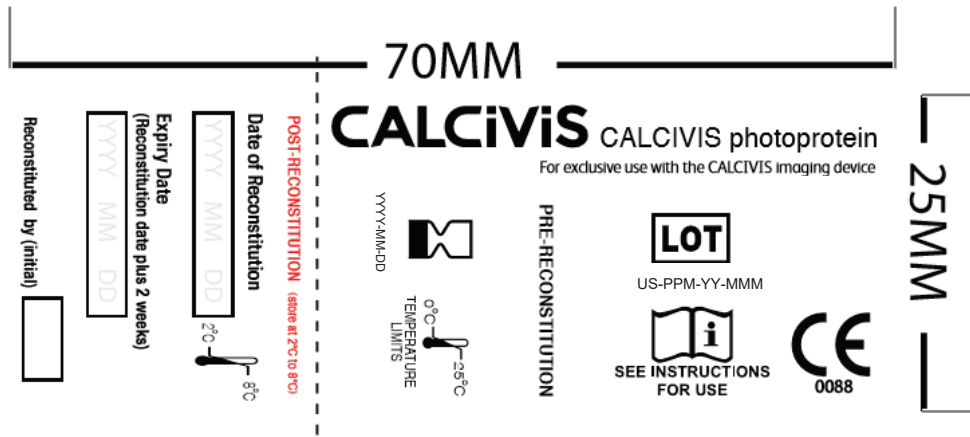
Manufacturing Specification	Calcivis Imaging Kit Label Specifications (US).		CALCIVIS®
Code No.:	MSPEC003-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Document Control

5. Component Labeling Requirements (Vials)

The individual vials of freeze dried Calcivis photoprotein are labelled as follows:

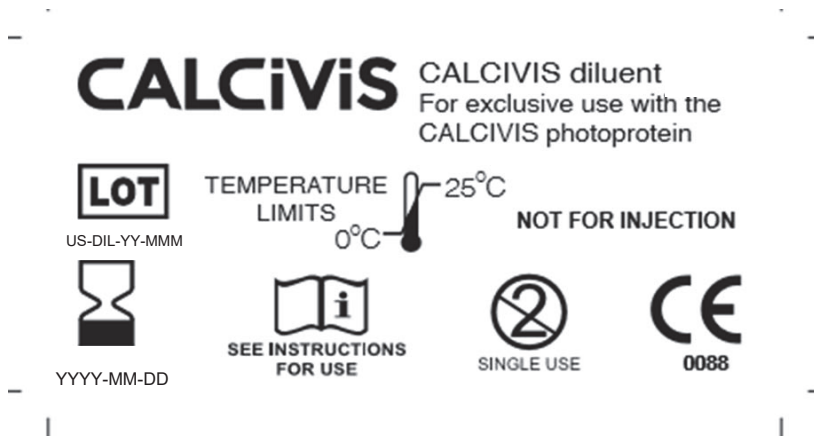
5.1 Photoprotein Vial Label (Sample for illustration):

Post-reconstitution information is completed by the end user.



5.2 Diluent Vial Label

Sample for illustration:



Manufacturing Specification	Calcivis Imaging Kit Label Specifications (US).		CALCIVIS®
Code No.:	MSPEC003-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Document Control

6. Applicator Pouch Label (Supplied by contract manufacturer)
Sample for illustration:



Manufacturing Specification	Calcivis Imaging Kit Label Specifications (US).		CALCIVIS®
Code No.:	MSPEC003-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Document Control

7. Unique Device Requirements (UDI)

This label is applied to the main kit box (box 1) and the external shipping container.



(01) 5060513140018
 (10) US-CIK-YY-NNN
 (17) YYYY-MM-DD

REF US-CIK01-01

8 Other Components with Manufacturers Supplied Label

8.1 Device Syringes and the 2 x 20mm vial adaptors are received pre-packaged in their primary packaging and labelled with source manufacturer's batch number and CE details.



8.2 2 vial adaptors are received pre-packaged in their primary packaging and labelled with source manufacturer's batch number and CE details.

Manufacturing Specification	Calcvivis Imaging Kit Label Specifications (US).		CALCIVIS®
Code No.:	MSPEC003-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Document Control



8.3 IPA wipes are received pre-packaged in their primary packaging and labelled with source manufacturer's batch number and expiry.



9 Cartons and labels must be supplied by an approved supplier for packaging components.

Manufacturing Specification	Calcivis Function Check Label Specification (US)		CALCIVIS
Code No.:	MSPEC004-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Supply Chain

1 Packaging Specification Overview

The function check packaging has 3 elements;

- [1] The thermoformed tray with the 12 wells containing dried calcium chloride with individual well foil sealing.
- [2] The secondary packaging is a cardboard sleeve which the tray slides into and is secured with tamper labels and
- [3] The label on the tray.

2 Primary Packaging

2.1 Thermoform Tray (with 12 individual wells)

Part: CTF Tray 0077

Material of Composition: TDX Recoupet R-PET plastic, black.



2.2 Lidding

Part: CTF Tray Lidding Foil AKBT

Material of Composition: Mediflex MAP type AKBT (PET 12µm / Alum 9 µm / 50 µm Ragopeel R1)



3 Secondary Packaging Specification (the printed paper sleeve)

The secondary packaging artwork, overlaid on the key line, is below:

Manufacturing Specification	Calcivis Function Check Label Specification (US)		CALCIVIS
Code No.:	MSPEC004-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Supply Chain

Material of Composition: 300GSM White Silk Digital Paper. Formed to shape with thumb tabs, creased and glued.

Dimension: L192mm x W94mm x H9mm



The primary packaging label (i.e. the thermoform tray) artwork is below. This label is applied to the end of the tray.

Manufacturing Specification	Calcivis Function Check Label Specification (US)		CALCIVIS
Code No.:	MSPEC004-US-01	Effective Date:	
Replaces No.:	N/A	Department:	Supply Chain



4 Instructions for Use

Material of Composition: 60GSM White Offset paper
Dimension: Digitally printed to A4 and folded to 38mm x 105mm