

EFFORTLESS DELIVERY



The Autopen® Classic has a number of unique features and benefits that make it simple, easy, and reliable to use.



Unique Side Release Button for Effortless Delivery



- **Automatic insulin delivery**

The conveniently positioned side release button is gently pressed and held to deliver the insulin dose.

- **Less force to deliver**

Pens which operate using a manual plunger mechanism to deliver the insulin rely on the strength and dexterity of the user. The force to deliver the insulin differs depending on the size of the dose to be delivered and the gauge of the pen needle used.

Autopen® requires the same force to deliver the insulin, regardless of the dose size or pen needle gauge. This force is significantly less than for all other insulin pens ¹.

- **Less distance to deliver**

The plunger mechanism of most commercially available insulin pens extends in length in proportion to the size of the dose selected. This can make performing the injection difficult for users with smaller hands or with manual dexterity problems, such as children and the elderly.



AUTOPEN



MANUAL PLUNGER

Autopen®'s unique automatic delivery system uses a side-mounted release button which is pushed the same minimal distance to inject, regardless of the dose size and the needle gauge.

- **Improved comfort and control**

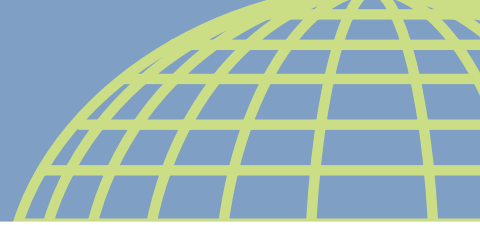
Manually operated plunger pens can cause excess downward pressure and lateral movement at the injection site during use. Autopen®'s automatic delivery system enables the hand to be held closer to the injection site, allowing for a more stable injection, which helps to reduce side effects such as bruising or bleeding.



AUTOPEN®



MANUAL PLUNGER



Easy to read dose selector



- **Audible clicks as the dose is dialled**

Audible clicks allow the patient to count the dose up as they dial, giving an extra level of reassurance that the correct dose has been selected.

- **Positive dialling action**

Allows for more positive dialling and reduces the likelihood of dialling errors.

- **Large, bold clear numbers**

Clear numbers for easy readability.

- **Visible indicator of dose delivery**

When injecting, the dose selector rotates until the start line lines up with the arrow on the pen body. This shows that the dose has been fully delivered.

Stylish Design

- **Convenient**

The Autopen[®] is lightweight, to allow it to be easily carried and discreetly used by the patient ².

- **Simple**

Autopen[®] is simple to learn, and easy to teach. Simple means less chance of human error and therefore fewer complaints ³.

- **Pens to suit every user**

There are 2 Autopen[®] variants:

- 1-21 pen which dials up in increments of 1 unit.
- 2-42 pen which dials up in increments of 2 units.

The 1 and 2 unit pens are further differentiated by either dots or numbers on the top of the dose selector.

Reliable

- The Autopen[®] has been conclusively tested and proven to be dose accurate in extremes of both hot and cold temperatures, and the robust design permits storage in a refrigerator.
- The Autopen[®] has been proven to maintain dose accuracy after being test-fired 5,000 times.
- All Autopens meet the strict dose accuracy requirements ISO 11608-1:2000.

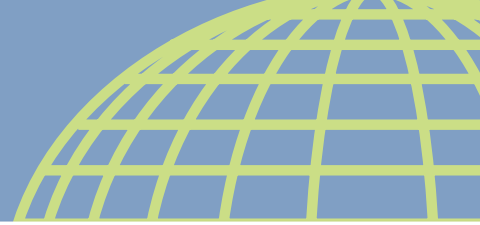
1. Data on file. Internal trials performed by **MANSELL, D.** "Investigation Into The Force Required To Activate A Range Of Commercially Available Insulin Pens", October 2006, Document Reference: T R-00417.
2. **LARBIG M, FORST T, FORST S, LORRA B, KÖNIG K, FITTKAU T, PFÜTZNER A.:** Evaluation of the insulin application system Autopen 24, Practical Diabetes International, Vol 22, Issue 9, Pages 364-366a November 2005.
3. Internal data on file. Correct at time of publication (June 2004- February 2007)

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Description Of Autopen[®] Classic^{1,2}

• General Description

The Autopen[®] Classic is a non-sterile, reusable, mechanical pen injector intended for the subcutaneous injection of insulin for the treatment of diabetes.

The Autopen[®] Classic is used in conjunction with separately supplied 3ml Eli Lilly insulin cartridges and 3ml Wockhardt UK insulin cartridges and is compatible with a range of sterile single-use pen needles including Unifine[®] Pentips[®].

• Intended Use

The Autopen[®] Classic is a non-sterile, reusable, mechanical pen injector intended for the subcutaneous injection of insulin for the treatment of diabetes.

• Target Patient Population

The Autopen[®] Classic is intended for insulin administration and the target patient population is individuals with diabetes.

• Principles of Operation

Refer to the Instructions For Use for Autopen[®] Classic.

• MDA Classification Rule

The Device is classified according to MDA/GD-04 Guidance on the Rules of Classification of Medical Device 2014 as Class C, Rule 11.

• Accessories or Complementary Devices

The Autopen[®] Classic is used in conjunction with separately supplied 3ml Eli Lilly insulin cartridges and 3 ml Wockhardt UK insulin cartridges and is compatible with a range of sterile single-use pen needles including Unifine[®] Pentips[®].

The Autopen[®] Classic is compatible with the following OM Unifine[®] Pentips[®] and Unifine[®] Pentips[®] Plus pen needles:-

- 0.23 x 4mm (32G x 5/32")
- 0.25 x 5mm (31G x 3/16")
- 0.25 x 6mm (31G x 1/4")
- 0.25 x 8mm (31G x 5/16")
- 0.33 x 12mm (29G x 1/2")

• Variants

Name Of Medical Device : Autopen Classic
Proposed Grouping For Medical Device: Family

Name As Per Device Label	Identifier
Autopen Classic 3.0ml x 1 unit 1-21 units	AN3810
Autopen Classic 3.0ml x 2 unit 2-42 units	AN3800

• Device Features

Figure 1 – Autopen[®] Classic 1-unit (upper picture) and 2-unit (lower picture)



1 Unit Autopen[®] Classic



2 Unit Autopen[®] Classic

For the 1-unit device, 1 click of the dose setting knob selects a dose of 0.01 ml insulin, and the maximum dose per single injection that can be selected is 0.21ml (21 clicks).

For the 2-unit device, 1 click of the dose setting knob selects a dose of 0.02 ml insulin, and the maximum dose per single injection that can be selected is 0.42ml (21 clicks).

• Indications

Both variants of the Owen Mumford Autopen[®] Classic are non-sterile, handheld mechanical devices, intended for the subcutaneous injection of insulin for diabetics who are dependent on one or more variable doses of insulin in a day.

The device is designed for use with pre-filled 3.0ml 'Lilly style' insulin cartridges for use in the home to aid, support and reduce patient trauma due to the treatment regime.

The device has been tested and has been shown to operate for at least 5,000 uses. Based upon 3 injections of insulin per day, 5,000 uses equates to 1666 days, or 4.5 years.

• Contraindications, Warnings, Precautions, Potential Adverse Effects

Refer to the Instructions For Use for Autopen[®] Classic.

Reference:

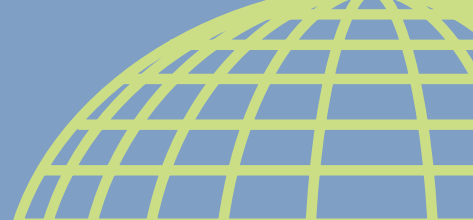
1. TF-22 AP1 Classic_STED_Section 1_General Description and List of Specified Features Rev.00
2. D2874-20150617-31041, Ver.01 - CSDT Common Submissin Dossier Template Autopen Classic. 25 Aug 2017

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Product Information

Product Description ¹	
Common Name	Autopen
Classification Name	Piston Syringe
CFR Number	880.5860
Panel	80.HO General Hospital
FDA Classification	II
Performance Standard:	None
EC Classification:	IIb Rule 11 Non-invasive. Transient use.
Canadian Classification	II

System Compatibility ²	
Product	Description
Cartridge	3ml Glass Cartridge with Plunger Stopper
Solution	Insulin
Needle	OM Unifine Pentips and Pentips Plus range: 0.23 x 4mm (32G x 5/32") 0.25 x 5mm (31G x 3/16") 0.25 x 6mm (31G x 1/4") 0.25 x 8mm (31G x 5/16") 0.33 x 12mm (29G x 1/2")
Insulin storage details (temp)	5°C ± 3°C
Insulin density	Density: 1.0053+/- 0.010 g/ml

Usage specifications ²	
Product Design Requirement	Specification
Device intended use	Subcutaneous injection of Insulin drug for Diabetics Treatment
Device usage	5,000 uses. Up to 5 Injections per day for 2 years plus 1 year for on the shelf storage
Intended user	Self-injection by patient
User Age	Between 11 and 90 years old
Device Type	Reusable

References:

- Owen Mumford Autopen – TF-22 April 2004
- STF-22 AP1 Classic_STED_Section 1_General Description and List of Specified Features Rev.00