CONFIDENTIAL

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SMITHS MEDICAL INTERNATIONAL LTD		RA INDEX	
Product Family:	**MS Series Syringe Drivers**	Product Family:	**002**
Compiled by:	Barry Fitch	Issue:	01

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Compliance with EN 14971:2000

Substantial changes

In the event that a substantial change was made (effective after 2004-04-01) and if it was deemed that this affected Risk Management, then the product would be reviewed against the new standard (EN 14971:2000).

B A Fitch Quality Assurance Manager	DATE:	DATE EFFECTIVE:
Code A	8th April 2005	8th April 2005

GRASEBY MEDICAL LIMITED - CONFIDENTIAL - RISK ANALYSIS			
Product Family:	**Ambulatory Syringe Drivers**	Report No.:	**RA002/01**
Compiled by:	B. A. Fitch	Issue No.:	5
Compilation Date:	9th October, 2001		

This report covers the devices listed in the table below and has been reviewed and approved for entry on to the Device Master Record Index.

This report shall be held and maintained by the Technical Department.

Product Description	Product Code Numbers
SYRINGE DRIVER TYPE MS16A	0105-0504, 0105-0702, 0105-0711, 0105-0712, 0105-0715, 0105-0717, 0105-0718, 0105-0725, 0105-0744, 0105-0742, 0105-0748, 0105-0753*
SYRINGE DRIVER TYPE MS18	0112-0002, 0112-0711, 0112-0748
SYRINGE DRIVER TYPE MS26	0113-0001, 0113-0705, 0113-0707, 0113-0711, 0113-0712, 0113-0715, 0113-0717, 0113-0718, 0113-0725, 0113-0742, 0113-0744, 0113-0748
SYRINGE DRIVER TYPE MS32	0113-0707
LOCK BOX	0105-0639†*
HOLSTER (MS DRIVERS)	0105-0027†*
SYRINGE DRIVER BASE	0105-0108†*
COVER	0105-0529†*
RATE ADJUSTER TOOL	0113-0023†*

* - denotes additions to document since previous issue

† - Identifies Class I devices and accessories

B. A. Fitch Originator Code A	DATE: 9th October, 2001	
D BREWERTON Technical Manager Code A	DATE: 9/10/01	DATE EFFECTIVE: 9th October, 2001

GUIDANCE ON RISK ANALYSIS
REFERENCE EN 1441 - MEDICAL DEVICES - RISK ANALYSIS

Identification of qualitative and quantitative characteristics

a) What is the intended use and how is the device to be used?	To be used for administering medication, as liquids, from most of the syringe brands and sizes from 2 ml up to 35 ml capacity. To allow this the delivery rate is in millimetres per hour or day (24 hour). The MS32 has a delivery rate in millilitres per hour and is limited to one brand and size of syringe. Administration can be by the epidural, intra-arterial, intravenous, intramuscular or subcutaneous routes. The devices are intended for use under medical supervision. The devices are suitable for ambulatory use. The devices are not suitable for: 1. Use for infusing medication where pulsatile delivery action is unacceptable. 2. Use in environments with flammable gas mixtures or with oxygen enriched atmospheres. 3. Use in strong magnetic fields, for example; NMR scanners.
b) Is the device intended to contact the patient or other persons?	NO - The only contact with the user or patient is when operating the external controls and changing the syringe or battery.

c)	**What materials and/or components are incorporated in the device or are used?**	The devices primarily incorporate: External surfaces: Plastic materials, stainless steel. Internal: Electronic components on epoxy glass-fabric circuit board. Electric motor. Small steel parts. Batteries: Primary alkaline type (IEC LR type).
d)	**Is energy delivered to and/or extracted from the patient?**	NO.
e)	**Are substances delivered to and/or extracted from the patient?**	YES - The devices push the plunger of a syringe forwards at a controlled rate as an aid to delivering substances to the patient.
f)	**Are biological materials processed by the device for subsequent re-use?**	NO.
g)	**Is the device supplied sterile or intended to be sterilised by the user or are other microbiological controls applicable?**	NO.
h)	**Is the device intended to modify the patient environment?**	NO.
i)	**Are measurements made?**	NO.
j)	**Is the device interpretative?**	NO.

k)	**Is the device intended to control or to interact with other devices or drugs?**	YES - The devices are intended to be used with sterile medical syringes.
l)	**Are there unwanted outputs of energy or substances?**	NO.
m)	**Is the device susceptible to environmental influences?**	YES - Temperatures, humidities, and pressures outside the limits specified, mechanical shocks, electromagnetic interference and contact with certain substances, may affect the devices.
n)	**Are there essential consumables or accessories associated with the device?**	YES - The devices need a suitable syringe and battery.
o)	**Is maintenance and/or calibration necessary?**	YES - The devices require routine maintenance checks on the performance.
p)	**Does the device contain software?**	NO.
q)	**Does the device have a restricted 'shelf-life'?**	NO.
r)	**Possible delayed and/or long term use effects?**	NO.
s)	**To what mechanical forces will the device be subjected?**	The devices are expected to be subjected to the normal forces that apply to hand-held electrical equipment.

t) What determines the lifetime of the device?	The devices have a lifetime of 5 years. This is determined by the Company policy on providing maintenance support for its products. With continued maintenance the devices would be expected to last longer than this.
u) Is the device intended for single use or re-use?	The devices are intended for continuous use.

RISK ANALYSIS

Key: L - Low M - Medium H - High

KNOWN OR REASONABLY FORESEEABLE HAZARDS	ASSESSMENT OF INITIAL RISK			SOLUTION(S) ADOPTED TO REDUCE RISK	ACCEPTABILITY OF RESIDUAL RISK
	RATE (of occurrence)	HARM	RISK		
Design related hazards					
Hazard 1 Patient or user trauma caused by harm due to electric shock.	**L**	**L**	**L**	Products have a low voltage internal power supply and a passive non-electrical connection to the patient. The products are not intended to be used with an external power source.	**Acceptable**
Hazard 2 Patient or user trauma caused by harm due to fire or explosion.	**L**	**H**	**L**	Products have a low energy internal power supply. Accompanying Instructions for use contain a warning about using the products in flammable or oxygen enriched atmospheres. The battery is a consumer type and the battery manufacturer is responsible for giving the currently prevailing warnings and cautions on use and disposal.	**Acceptable**
Hazard 3 Patient or user trauma caused by harm due to high external temperatures.	**L**	**M**	**L**	Products have a low energy internal power supply. No discernible heat is generated when the products are operating under normal conditions. The patient applied part is passive and does not generate any heat in normal or fault conditions.	**Acceptable**
Hazard 4 Patient or user trauma or compromised treatment caused by equipment failure due to liquid ingress into equipment.	**M**	**H**	**M**	Accompanying Instructions for use advise that products are not waterproof and to remove them from use immediately if they get wet.	**Acceptable**

Hazard 5 Patient or user trauma caused by harm due to toxicity of product materials or their by-products.	**L**	**L**	**L**	Design control and selection of materials. Consideration of nature of contact, the patient is not in direct contact with the products. The battery is a consumer type and the battery manufacturer is responsible for giving the currently prevailing warnings and cautions on use and disposal.	**Acceptable**
Hazard 6 Patient or user trauma caused by harm due to physical features i.e. shape, size, weight or moving parts.	**L**	**L**	**L**	Product design, ergonomics, materials, manufacturing and packaging methods selected to minimise risk of trauma to patient or user. The products are small and light-weight and operate with low speed moving parts.	**Acceptable**
Hazard 7 Patient or user trauma caused by harm due to electromagnetic radiation.	**L**	**L**	**L**	Products designed with due regard to standards. The products radiate no electromagnetic fields intentionally and only low levels of stray em radiation.	**Acceptable**
Hazard 8 Patient or user trauma or compromised treatment caused by leakage of substances due to loss of mechanical integrity.	**L**	**M**	**L**	Only the battery contains any substances that could leak out from the products and it is a sealed consumer type.	**Acceptable**
Hazard 9 Patient or user trauma or compromised treatment caused by inadequate equipment performance due to incorrect requirements specification.	**L**	**H**	**L**	Design control includes validation plans and reviews of product requirements for adequacy for intended purpose.	**Acceptable**
Hazard 10 Patient or user trauma or compromised treatment caused by deterioration in equipment performance due to reaction with other substances.	**L**	**H**	**L**	Appropriate material selection. Cleaning advice is given in the accompanying Instructions for use.	**Acceptable**

Hazard 11 Patient trauma or compromised treatment caused by deterioration in equipment performance due to poor security of union between assembled component parts.	**L**	**H**	**L**	Product design, materials, manufacturing and packaging methods selected to minimise the risk of component parts detaching.	**Acceptable**
Hazard 12 Patient trauma or compromised treatment caused by deterioration in equipment performance due to incompatibility with other associated devices.	**L**	**H**	**L**	Products designed with due regard to standards and knowledge of associated devices particularly the syringes and batteries. Accompanying Instructions for use show how to select syringe and check it can be safely fitted. The right battery type to use is marked on the products and shown in the Instructions.	**Acceptable**
Hazard 13 Patient trauma or compromised treatment caused by failure to deliver at rate set. - equipment failure.	**L**	**H**	**L**	Products designed with due regard to standards, specified and tested to ensure a high level of reliability. There is an integral safety system to prevent continuous motor operation.	**Acceptable**
Hazard 14 Patient trauma or compromised treatment caused by failure to deliver at rate set. - battery or contact failure.	**L**	**H**	**L**	Products designed with due regard to standards, specified and tested to ensure a high level of reliability of the battery contacts. Exhausted batteries are indicated visually (except MS18).	**Acceptable**
Hazard 15 Patient trauma or compromised treatment caused by failure to deliver at rate set. - accidental switch on or off.	**L**	**H**	**L**	Products designed so direct intervention by the user is required. The design of the control button reduces the chance of accidental switch operation. There is an integral safety system to prevent continuous motor operation.	**Acceptable**

Hazard 16 Patient trauma or compromised treatment caused by failure to deliver at rate set. - accidental change of rate setting.	**L**	**H**	**L**	Products designed so direct intervention by the user is required. The design of the control switches reduces the chance of accidental switch operation. Changing the setting requires a tool.	**Acceptable**
Hazard 17 Patient trauma or compromised treatment caused by failure to deliver at rate set. - uncontrolled syringe plunger or barrel movement.	**L**	**H**	**L**	Products incorporate features designed to hold syringe parts securely. Accompanying Instructions for use specify that only syringes that can be secured safely must be used.	**Acceptable**
Hazard 18 Patient trauma or compromised treatment caused by failure to deliver at rate set. - poor electromagnetic compatibility (EMC).	**L**	**H**	**L**	Products designed with due regard to standards to achieve required levels of immunity to electromagnetic interference. Warning given about risks of using products in strong magnetic fields. Examples of products subjected to programme of EMC tests.	**Acceptable**
Process related hazards					
Hazard 19 Patient trauma or compromised treatment caused by equipment failure due to either incorrect or faulty materials, components or processes.	**L**	**H**	**L**	Products made to established procedures and checked using accepted process controls. Every product is tested before final packing to assure performance meets required levels.	**Acceptable**
Packaging related hazards					
Hazard 20 Patient trauma or compromised treatment caused by deterioration in equipment performance due to an extended period of storage.	**L**	**H**	**L**	Evidence shows that storage does not adversely affect the basic safety or performance characteristics. Battery is not fitted into products when supplied. Accompanying Instructions for use advise that batteries should be removed from the products for prolonged storage and on how products must be tested before every application.	**Acceptable**

Hazard 21 Patient trauma or compromised treatment caused by equipment failure due to damage to equipment in pack.	**L**	**H**	**L**	Pack design and materials selected to reduce the risk of this. Products made to established procedures and checked using accepted process controls. Labelling and accompanying Instructions for use advise on how products must be tested before every application.	**Acceptable**
Hazard 22 Patient trauma or compromised treatment caused by equipment failure due to detached or missing component.	**L**	**H**	**L**	Products made and packed to established procedures and checked using accepted process controls. Labelling and accompanying Instructions for use advise on how products must be tested before every application.	**Acceptable**
Hazard 23 Patient trauma or compromised treatment caused by inappropriate use due to missing labelling or Instructions for Use.	**L**	**H**	**L**	Products designed with due regard to standards. Products made and packed to established procedures and checked using accepted process controls.	**Acceptable**
Hazard 24 Patient trauma or compromised treatment caused by inappropriate use due to inadequate labelling or Instructions for Use.	**L**	**H**	**L**	Products designed with due regard to standards and intended use. Products carry distinctive distinguishing labelling. Comprehensive instructions are included in the packaging with every product.	**Acceptable**
Hazard 25 Patient trauma or compromised treatment caused by deterioration in performance due to inappropriate storage conditions.	**L**	**H**	**L**	Packaging designed with due regard to standards. No special or abnormal storage conditions apply. Packaging labelled with appropriate storage conditions under which there is no known or foreseeable hazard.	**Acceptable**
User related hazards					
Hazard 26 Patient trauma or compromised treatment caused by inappropriate use due to wrong rate being set.	**M**	**H**	**M**	Accompanying Instructions for use give the correct procedure and examples of how to calculate and set the rate. Training materials, including dummy examples of products, are available.	**Acceptable**

Hazard 27 Patient trauma or compromised treatment caused by inappropriate use due to incorrectly fitting the syringe.	**L**	**H**	**L**	Accompanying Instructions for use specify that only syringes that can be secured safely must be used. Labelling of MS32 has prominent warning to only use the syringe indicated.	**Acceptable**
Hazard 28 Patient trauma or compromised treatment caused by inappropriate use due to confusing rate setting measurement units.	**L**	**H**	**L**	Labelling shows units of measurement for delivery rate. Accompanying Instructions for use give the correct procedure and examples of how to calculate and set the rate. Where appropriate a warning is given about delivery rate being in millimetres per time interval and not millilitres.	**Acceptable**
Hazard 29 Compromised treatment caused by inappropriate use due to confusing different product types.	**M**	**H**	**M**	Accompanying Instructions for use give intended purpose of each product. Products carry distinctive distinguishing labelling. Training materials, including dummy examples of products, are available.	**Acceptable**
Hazard 30 Patient trauma or compromised treatment caused by inappropriate use due to not testing equipment before use.	**L**	**H**	**L**	Advice given on labelling and in accompanying Instructions for use to test the safety system each time the products are used. An audible and/or visual indication of correct operation is given.	**Acceptable**
Hazard 31 Compromised treatment caused by inappropriate use due to patient or carer not hearing or seeing alarm.	**L**	**H**	**L**	Alarms designed to give good audibility and/or visibility. No means of reducing any alarm volume is provided. Validation of alarm output when used with a Lockbox – warning added to IFU for Lockbox	**Acceptable**
Hazard 32 Patient trauma or compromised treatment caused by failure of equipment due to accidental mechanical damage by either patient or user.	**L**	**H**	**L**	Products are designed with due regard to standards and validated to ensure they have adequate mechanical strength for their intended use.	**Acceptable**

Hazard 33 Patient trauma or compromised treatment caused by inappropriate use due to using damaged equipment.	**M**	**H**	**M**	Advice given on labelling and in accompanying Instructions for use to test the safety system each time the products are used and not to use products if they are damaged.	**Acceptable**
Hazard 34 Patient trauma or compromised treatment caused by inappropriate use due to wrong battery size or type.	**L**	**H**	**L**	Correct type to use marked on products and given in accompanying Instructions for use.	**Acceptable**
Hazard 35 Patient trauma or compromised treatment caused by inappropriate use due to failure to have equipment maintained.	**L**	**H**	**L**	Advice given in accompanying Instructions for use to have the products performance checked at least annually.	**Acceptable**
Hazard 36 Patient trauma or compromised treatment caused by failure of equipment due to length of time used.	**L**	**H**	**L**	Products are intended for continuous use. Battery replacement is indicated visually.	**Acceptable**
Hazard 37 Unauthorised tampering of the syringe when fitted to pump	**L**	**H**	**M**	Customers have requested the addition of a security cover to discourage syringe tampering. Lock-box added to range to answer this requirement.	**Acceptable**

The above risk analysis was conducted having due regard to the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and to EN 1441 "Medical devices - Risk analysis".

CONCLUSION OF RISK ANALYSIS

A total of 37 hazards were identified as known or foreseeable hazards, using the methods defined in EN 1441 'Medical devices - Risk analysis'

The risks associated with the use of the devices tabled in this risk analysis are deemed acceptable when weighed against the benefits to the patient.

Action for QA Department arising from this analysis:

None.

Revision History.

Issue No.	Issue Date	Reason
1	13/03/98	First issue.
2	28/08/98	New product codes added to list. New codes identified *. Products added as range extension - no new risks identified.
3	04/01/99	New product codes added (marked *): 0105-0702, 0112-0748, 0113-0705, 0113-0707. No new risks identified, changes reflect local language versions only.
4	17/09/01	Hazard 37 added to assessment. Lock-box added to range.
5	09/10/01	1. 0105-0753 added to front page (product variant . No new risks identified 2. Hazard 31 modified to include use of Lockbox and possibility of reducing alarm output. Mitigated by addition of warning in Lockbox IFU 3. Class I accessories added for completeness