

U. K. Intra-operative Cell Salvage Action Group
Intraoperative cell salvage devices: manufacturers' questionnaire

Please complete sections 1 and 2 for each machine type

Section 1: Machine		Additional comments
Name of device/manufacture	Medtronic Limited	
Recommended anticoagulant (Name/volume/weight) & rate of administration	Clinician Choice	In line with American Association of blood bank guidelines clinicians normally choose between Citrate (ACD-A) and/or Heparinised Saline (normally 30000 units to each litre of saline). As a general guideline, the ratio of volumes of citrate solution to blood should range between 1:5 and 1:10 or approx 70mL citrate per 500ml of recovered blood. When Heparinised saline is used the flow should be regulated so that approximately 15mL of anticoagulant is added to each 100mL of blood. NB: The use of Citrate based anticoagulant in patients with impaired liver function may require additional monitoring and may, in certain circumstances be contraindicated. Improperly processed red cells may contain residual citrate based solution which, in excess quantities, could cause citrate toxicity, depression of serum calcium, or bleeding tendencies.
Speed of processing (ml/min):	Standard:	The Medtronic autolog uses a two stage filling process capable of first stage fill speed of 600ml/min followed by a second stage fill at either 600 or 200ml/min based on incoming volume. A total process of 135ml Red Blood Cells (Autolog bowl size) should take approximately 3 minutes (Hannon paper) or 1500ml initial blood volume will be fully processed in less than 15 minutes (Geiger paper) – clinical papers available on request.
	Emergency (fastest):	2 minutes per cycle (the wash process can be skipped in an emergency at clinician's discretion). NB: Due the potential compromise of losing RBC's and wash quality by speeding up processing, the Medtronic Autolog was designed to have one standard programme as noted above. With the reduced wash quantity required (250mls only) the standard programme of the autolog should prove efficient in emergency situations.
Minimum process volume (ml)	Depends on incoming Hct of the blood	The Medtronic Bowl size is 135ml. Assuming an incoming Hct of e.g. 25% this would infer a minimum process volume of 550mls-600mls (4 x 135ml bowl size) of good quality recovered blood. If the incoming Hct is higher this minimum process volume would be less.
Standard wash volume (ml saline/ml blood)	250mls	Due to unique bowl design and pulse wash the Medtronic autolog has the advantage of using only 250ml of Saline wash aiding minimal operator intervention.
Average Hct of product	45-70% Hct Range	The autolog system is designed to consistently product a blood product with a Hct of 50% or Greater.
Standard washing efficiency (% clearance of anticoagulant + evidence)	99% +/- 0.2	Serrick et al, Quality of Red Blood Cells using Autotransfusion Devices: A Comparative Analysis. JECT. 2003;35:28-34 Hannon, Medtronic autolog Autotransfusion System: Comparative Wash Quality and Clinical Assessment. Technical Concept Paper. Washing efficiency of other parameters also noted in the above references.

Integral vacuum pump	Yes	
Automatic recognition of bowl size	1 size bowl	135ml unique bowl design
Data management system	No	Data on Input volume and RBC transferred available from screen
Clinical use	Recommended for:	Intended use in: General; Cardiovascular; Orthopaedic; Vascular; Plastic/Reconstructive; Obstetric/Gynecologic; Neurosurgical; Postoperative treatment areas.
	Caution in:	Caesarean Sections – refer to NICE guidelines due to potential for Amniotic Fluid Embolism using Cell Salvage devices in general. See AABB standards for Contraindications, complications of Red Blood Cell Salvage e.g. Cancer; Gross contamination; when using haemostatic agents.

Section 2: Disposables		<i>Additional comments</i>
<u>Basic components:</u>	Method of sterilisation	Ethylene Oxide (EtO)
	shelf-life	Approximately 3 years
Available via central purchasing authorities	Yes	NHS Logistics, NHS Supply Chain, Foxbridge Way, Normanton. WF6 1TL Tel: +44 (0)1924 328816
<u>Suction assembly:</u> packaged separately: Minimum purchase (units per case)	Yes – BT725 Suction Anticoagulant line and BT133 vacuum line. Minimum purchase = 10 units per box.	
<u>Reservoir:</u> volume (ml) filter pore size (µm) packaged separately: Minimum purchase (units per case)	Yes - EL240 4000ml Reservoir; 40 micron screen (20 micron also available) Minimum purchase = 6 units per box	
<u>Processing set:</u> Bowl/Belt: standard bowl size packaged separately: Minimum purchase (units per case)	Yes – ATL2001 Wash Set (including bowl; waste bag; holding bag) Minimum purchase = 6 units per box	
<u>Other components available:</u> Varied bowl sizes (please list)	No	Medtronic have one size bowl (135ml)
ACD-A solution shelf-life: Minimum purchase (units per case):	No	
Additional reinfusion bags Minimum purchase (units per case):	Yes	Spare blood holding bags – BT1000SC – Minimum purchase 24 units per box.
Y-connectors Minimum purchase (units per case):	Yes	BT926 Y connector (20 units per case)
QC sampling kit Minimum purchase (units per case):	Y/N	BT926 Y Connector (20 units per case) BT945 Transfer Spike (20 units per case)
Other (specify): Minimum purchase (units per case):	Y/N	

Section 3: Customer Service		<i>Additional comments</i>
Machine purchase options: lease purchase available(please describe)	Y	The Medtronic autolog can be purchased outright or via a lease option or via a premium price loaded onto the disposable components.
Machine trials:	Y	The Medtronic Autolog is available for trial/evaluation. A machine will be left on loan for the trial period agreed by both parties. The Medtronic Product Representative will support by first doing and in-service to the key users and be available to support the first clinical cases (level of support agreed with both parties). Each trial/evaluation is tailored to meet the customer needs whenever possible.
Helpline access/prompt response	Y	Response time to first call = 2 hours. Product specialist Service engineer Customer Services
Training & educational support	Y	Product Specialist to train the key users on the operation of the Medtronic Autolog Machine to fulfil the National Competency Agreement Framework. Quick reference guides available for ease of set up. Clinical paper support (if required) to help Trust generate protocols.
Maintenance contracts	Y	Comprehensive Warranty Plan (fully comprehensive) Planned Preventative Maintenance (one-off service) In-House maintenance options available on request.
How many UK based engineers do you have?	1	
What is your average response time to call outs?	2-72hours	
Are software upgrades freely available?	Yes	
Can disposables be ordered by a call-off order?	Yes	
How quickly can disposables be shipped?	Next day	Normal delivery is 2-3 days. Emergency next day delivery available.
Do you provide a cell salvage service for one-off cases?	No	