ORDIN DE PLATA NR.: 178 TIP.DOC. 1

DATA EMITERII:luni, 11 decembrie

PLATITI: 5500-00 LEI: Cinci Mii Cinci Sute lei 00 bani

PLATITOR: (R) S.C. "OXIVIT-MED" S.R.L.
CONTUL DE PLATI/CODUL IBAN MD44ML000000002251729503
CODUL FISCAL :1007600044280 /

PRESTATORUL PLATITOR BC"Moldindconbank"S.A. fil."Invest" Chisinau
CODUL BANCII: :MOLDMD2X329:

BENEFICIAR (R) I.M.S.P. "Spitalul Clinic Republican Timofei Mosneaga"
CONTUL DE PLATI/CODUL IBAN MD57MO2251ASV96476607100
CODUL FISCAL :1003600150783 /

PRESTATORUL BENEFICIAR Mobiasbanca-OTP Group S.A.
CODUL BANCII: :MOBBMD22 :

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-1700833281298 din 12.12.2023

TIPUL TRANSFERULUI NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001

DATA PRIMIRII:11/12/2023

DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Kojevnikov Dmitrii

MIIGdAYJKoZIhvcNAQcCoIIGZTCCBmECAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
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(semnatura electronica)

CONTABIL-SEF:Web Kojevnikov Dmitrii

MIIGdAYJKoZIhvcNAQcCoIIGZTCCBmECAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
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L.S. (semnatura electronica)

CONDUCATOR: _____ (semnatura manuala)

CONTABIL-SEF: _____ (semnatura manuala)

SEMNATURA PRESTATORUL _____ L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Kojevnikov Dmitrii
Date: 2023.12.11 16:20:12 EET
Reason: MoldSign Signature
Location: Moldova

MOBIAS BANCA

Nr. 12101-304

18.03.2016

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

GROUPE SOCIETE GENERALE

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1007600044280

Data înregistrării **30.07.2007**

Data eliberării **30.07.2007**

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531861** data **19.09.2023**

Denumirea completă: **Societatea Comercială "OXIVIT-MED" S.R.L.**
Denumirea prescurtată: **S.C. "OXIVIT-MED" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1007600044280**
Data înregistrării de stat: **30.07.2007**
Sediul: **MD-2032, bd . Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
2. Comerţul cu ridicata al parfumurilor şi produselor cosmetice
3. Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă
4. Intermedieri pentru vînzarea unui asortiment larg de mărfuri
5. Alte tipuri de comerţ cu amănuntul în magazine nespecializate
6. Alte tipuri de comerţ cu ridicata
7. Închirierea altor maşini şi echipamente

Capitalul social: **5400** lei,

Administrator: **KOJEVNIKOV DMITRII, IDNP 0972305012362,**

Asociaţii:
1. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 5400 lei, ce constituie 100%
Beneficiar efectiv:
1.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **19.09.2023**.

Registrator în domeniul înregistrării de stat **Rusu Diana**

Digitally signed by Rusu Diana
Date: 2023.09.19 11:22:47 EEST
Reason: MoldSign Signature
Location: Moldova

EB 0461498

Date cu caracter personal

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

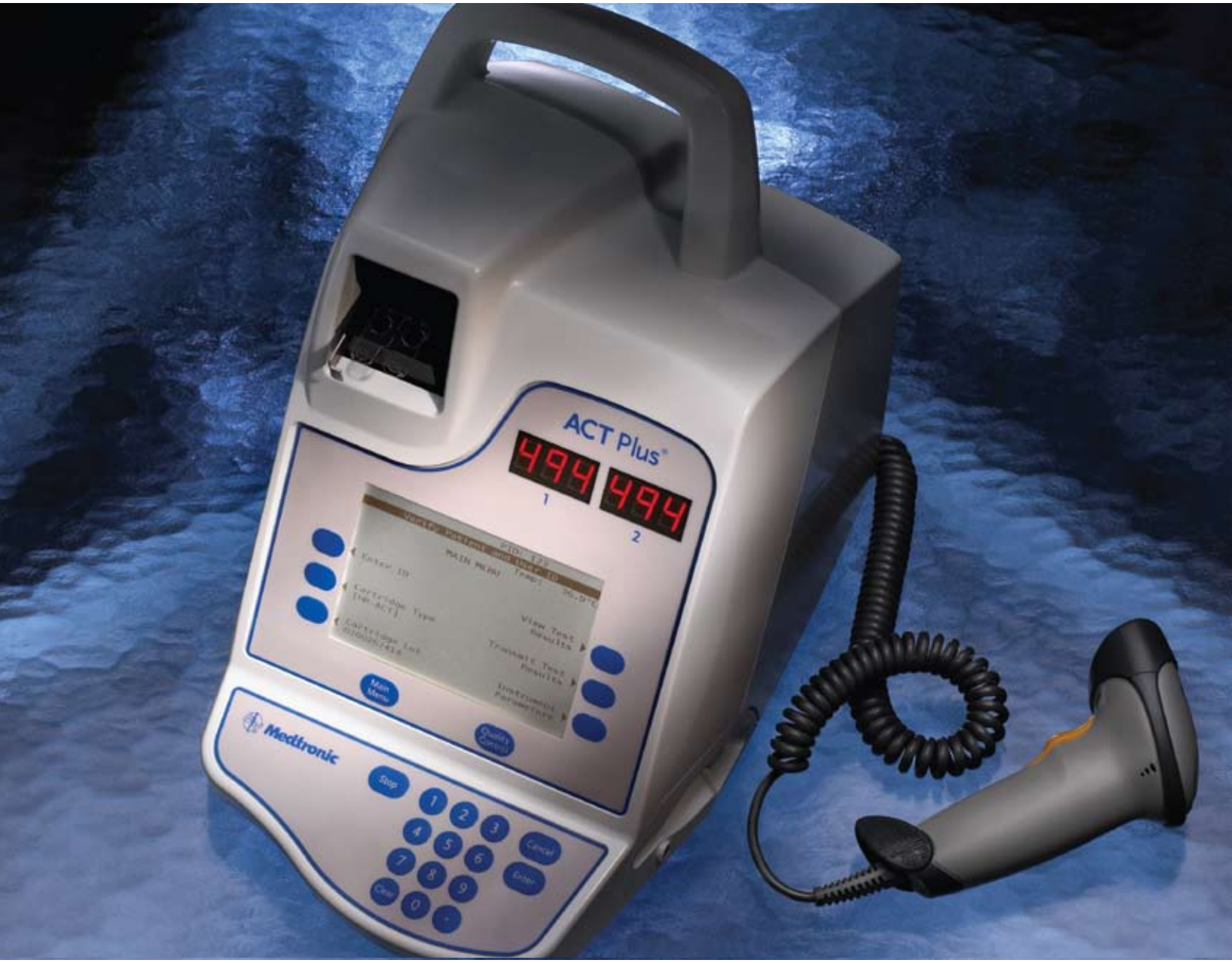
Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

Medtronic

ACT PLUS® SYSTEM

Automated Coagulation Timer



Precise, reliable – the trusted standard

ACT Plus® Sys

The ACT Plus® Automated Coagulation Timer is recognized worldwide as the trusted standard for activated clotting time testing, delivering the accurate, precise and timely results you need.

The ACT Plus® System is used with point-of-care testing during critical procedures, when accurate ACT results are necessary.

- Cardiovascular and vascular surgery
- Cardiac catheterization lab
- Critical care units
- Hemodialysis units
- Pediatric care
- ECMO
- Interventional radiology

Medtronic is the global leader in medical technology — alleviating pain, restoring health, and extending life for millions of people around the world.

As an acknowledged expert in the area of blood management and clot detection technology for more than 20 years, Medtronic leads the way in delivering reliable, cost-effective solutions.

Precise, Reliable Clot Detection Technology

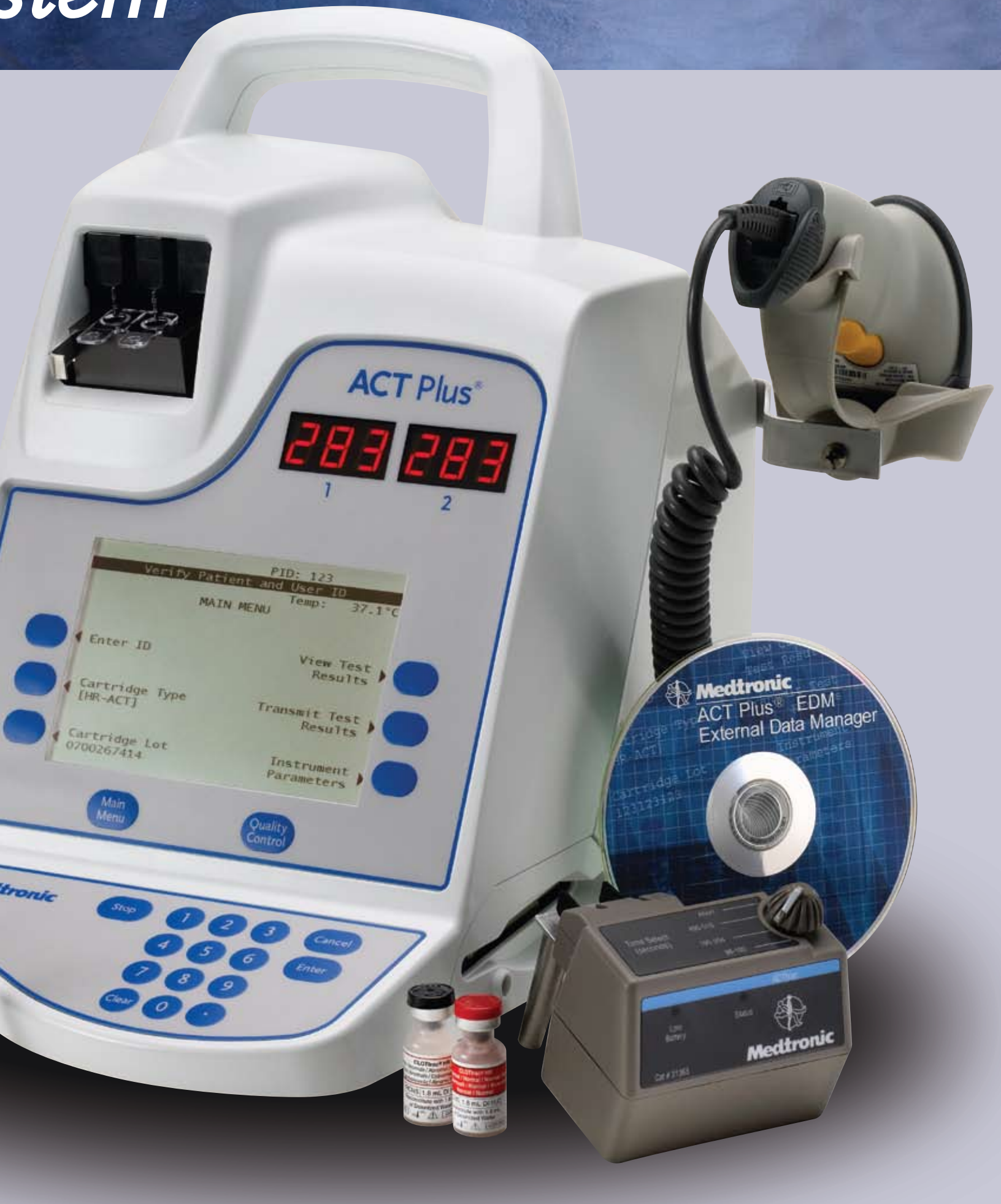
The ACT Plus® System combines the trusted standard in precise clot detection technology with data management and connectivity-ready capabilities. Unlike algorithm-based test measurement, the ACT Plus® System provides real-time clot detection, ensuring accurate and precise clotting time results.

SYSTEM HIGHLIGHTS

- Dual well testing verifies your results are accurate
- Real-time clot detection ensures precise results
- Connects to industry standard point-of-care LIS interfaces, including MAS RALS®-Plus, TELCOR Quick-Linc®, AegisPOC®, and others.*
- Enhanced data management meets all POC testing requirements
  - Stores up to 1000 patient and QC records
  - Holds up to 600 operator IDs
  - Downloads data to a USB or floppy storage device
  - Enables QC and user lockout
  - Bar code scanner available for quick, accurate entry of cartridge and control information, and patient and user IDs

* Check with your local Medtronic representative for country-specific information.

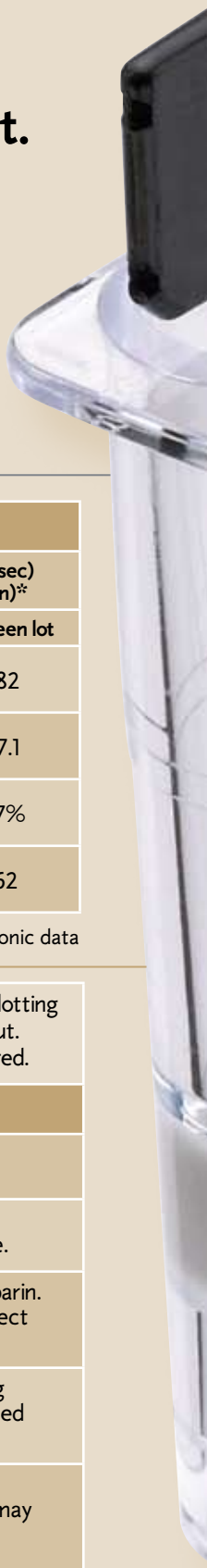
stem


ACT Plus®
283
283
1
2
PID: 123
Verify Patient and User ID
MAIN MENU
Temp: 37.1°C
Enter ID
Cartridge Type
[HR-ACT]
Cartridge Lot
0700267414
View Test Results
Transmit Test Results
Instrument Parameters
Main Menu
Quality Control
Stop
Cancel
Enter
Clear
Medtronic
ACT Plus® EDM
External Data Manager
Medtronic

Cartridges, Controls and Accessor

Our unique dual channel cartridge design allows you to instantly verify your results, eliminating the need to retest.

- **Real-time clot detection** reflects patient's ability to form a clot (rather than mathematically calculated results)
- **Liquid suspended Kaolin activator** for uniform mixing with blood sample
- **Room temperature storage** saves refrigerator space



MULTIPLE TESTING APPLICATIONS

- **High Range Activated Clotting Time (HR-ACT)** for use with fresh whole blood samples in cardiovascular surgery, vascular surgery and percutaneous transluminal coronary angioplasty (PTCA)
- **Low Range Activated Clotting Time (LR-ACT)** for use with fresh whole blood samples in dialysis, ECMO and therapeutic heparin monitoring
- **Recalcified Activated Clotting Time (RACT)** for use with citrated whole blood samples in dialysis and therapeutic heparin monitoring

High Range ACT Precision

	Baseline ACT (sec) (0 units/ml heparin)		Heparinized ACT (sec) (4 units/ml heparin)*	
	Within lot	Between lot	Within lot	Between lot
Mean	130	130	582	582
SD	3.3	6.6	19.0	27.1
%CV	2.6%	5.1%	3.3%	4.7%
N	63	63	162	162

* Internal Medtronic data

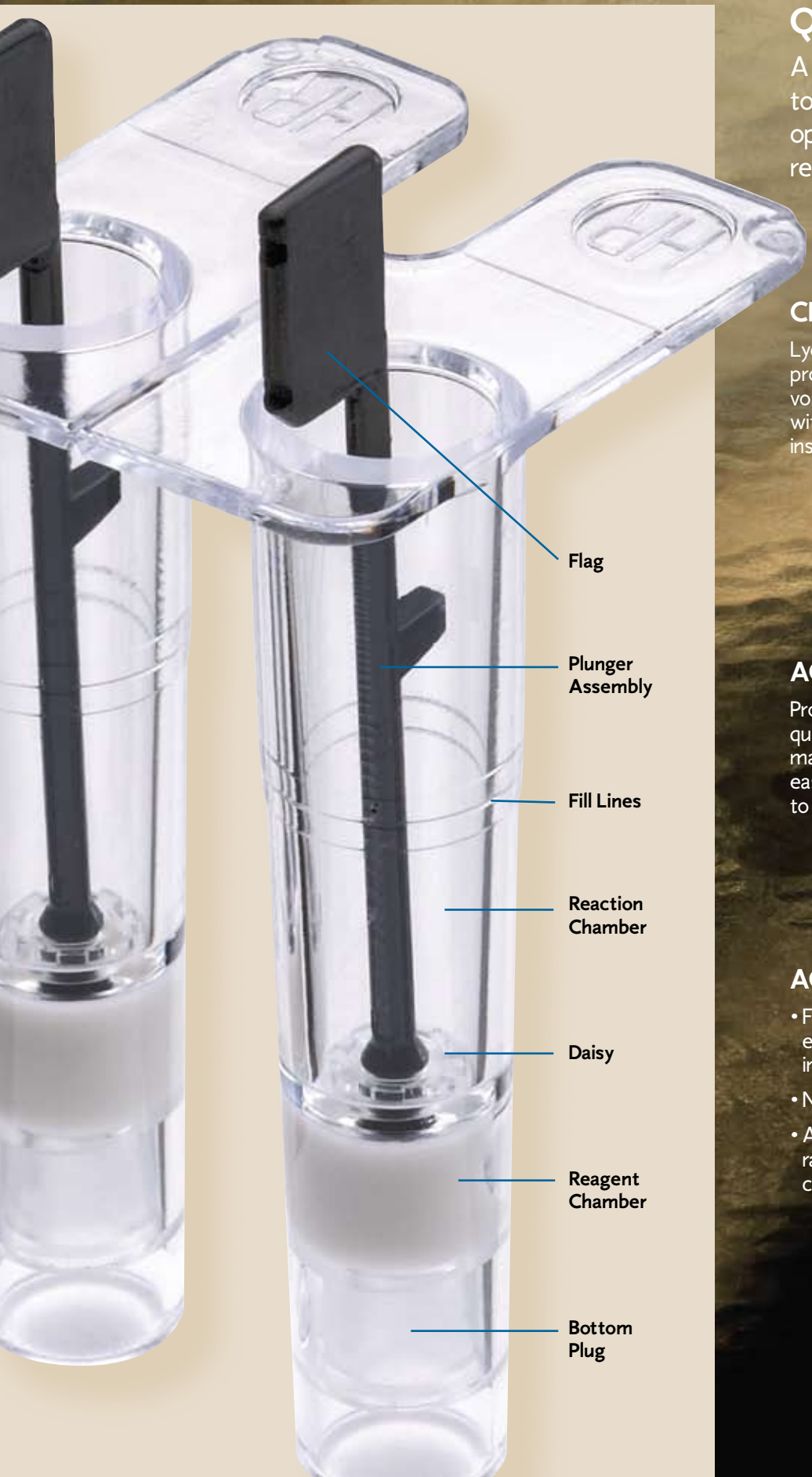
- **Heparinase Test Cartridge (HTC)** for use with fresh whole blood samples to identify the presence of presurgical and postsurgical heparin in various clinical settings, allowing you to:
  - Determine baseline clotting time in the presence of heparin
  - Determine the appropriate time to pull sheath
  - Confirm heparin reversal
  - Identify heparin rebound

The HR Heparinase Cartridge is a two channel activated clotting time test: Channel 1 with heparinase and Channel 2 without. The clotting time results for the two channels are compared.

Example for Interpreting HR Heparinase Results

CHANNEL 1 (with heparin)	CHANNEL 2 (without heparin)	INTERPRETATION
120	120	Patient at baseline. No heparin in sample.
120	260	Sample contains heparin. Extension due to effect of heparin only.
260	260	May be an underlying coagulopathy unrelated to heparin.
260	360	Heparin in the blood sample and patient may have an underlying coagulopathy.

ries



QUALITY CONTROL

A full range of controls are available to verify instrument, cartridge and operator performance and meet regulatory guidelines for testing.

CLOTtrac® Coagulation Controls

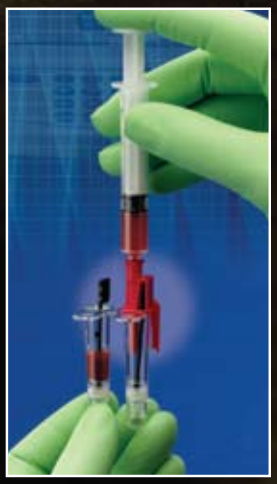
Lyophilized controls provide sufficient volume for testing with multiple instruments

ACTtrac® Electronic Control

Provides a multi-level quality check to make quality control easier and faster to perform

ACT® Easy Fill Accessory

- Fill lines are easily visible, even in low light settings
- Needleless system
- Available for high range and low range cartridges



ACT Plus® EDM External Data Man

Manage your ACT Plus® System data efficiently and effectively.

Get instant access to the charts, reports and spreadsheets you need when you combine the ACT Plus® EDM External Data Manager with the ACT Plus® System. This versatile Microsoft Access-based software solution helps you to analyze test results and make informed decisions more effectively — allowing you to stay focused on improving patient outcomes.

- Manages patient, QC, instrument and user ID data efficiently
- Provides powerful PC-based software to manage data, without an LIS interface
- Delivers 13 preformatted patient and quality control reports

FEATURES AND BENEFITS

Easy-to-Use Interface

- Intuitive features allow users to be up and running with minimal training
- Prompts lead EDM users through the data import function, eliminating all guesswork

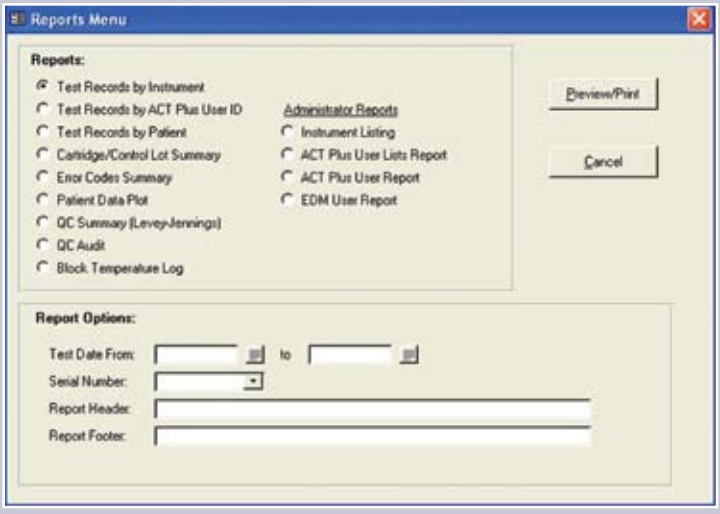
Time-Saving Reports

- Preformatted reports increase efficiency
- Provides visual assessment of QC data and ability to trend QC results
- Ability to track all results for a specific patient

Custom Reporting

- Flexibility in report design and data management
- Data can be exported to Microsoft Excel for graphical and statistical analysis

Reports Menu



Users can select from a list of all preformatted reports to view the desired information and associated options

ager

Simplified Administrative Management

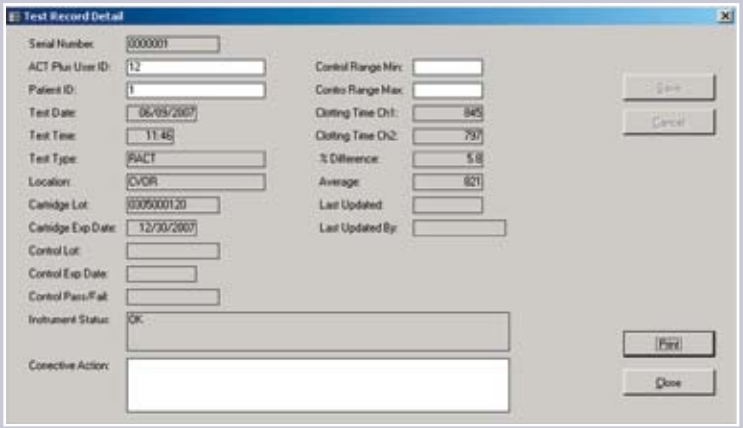
- View the location of all ACT Plus® Systems at your site
- Group ACT Plus® System users into lists to upload into the ACT Plus® System
- Manage your list of all ACT Plus® System users and their certification

Secure System

- Password protection ensures that only authorized EDM users access the information
- Can be backed up onto your network server to ensure safety of and access to information anytime

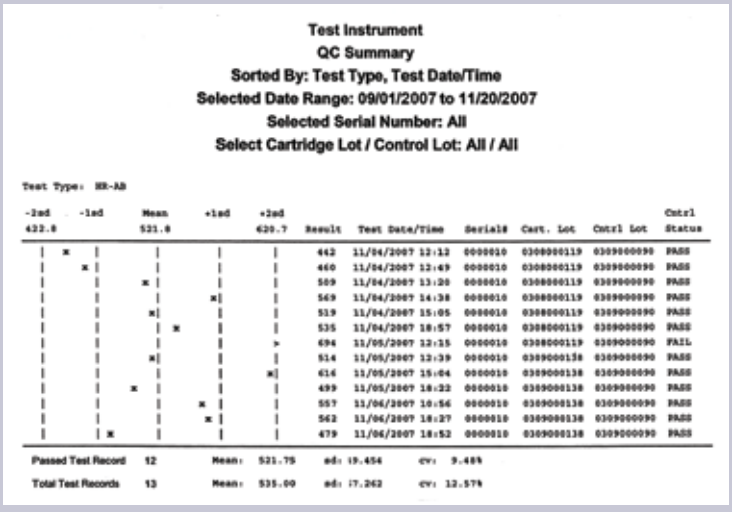
The ACT Plus® EDM External Data Manager is not available in all countries.

Display Detail Option



Users can view a complete listing for a single record and note corrective action taken

QC Summary (Levey-Jennings)



Test Instrument
QC Summary
Sorted By: Test Type, Test Date/Time
Selected Date Range: 09/01/2007 to 11/20/2007
Selected Serial Number: All
Select Cartridge Lot / Control Lot: All / All

Test Type: HR-AB

-2sd 422.8	-1sd	Mean 521.4	+1sd	+2sd 620.7	Result	Test Date/Time	Serial#	Cart. Lot	Cntrl Lot	Cntrl Status
| x |		|	|	|	442	11/04/2007 12:12	0000010	0308000119	0309000090	PASS
| x |		|	|	|	460	11/04/2007 12:49	0000010	0308000119	0309000090	PASS
| | x |		|	|	|	509	11/04/2007 13:20	0000010	0308000119	0309000090	PASS
| | |		x|	|	|	569	11/04/2007 14:38	0000010	0308000119	0309000090	PASS
| | x|		|	|	|	519	11/04/2007 15:05	0000010	0308000119	0309000090	PASS
| | | x		|	|	|	535	11/04/2007 18:57	0000010	0308000119	0309000090	PASS
| | |		|	>	694	11/05/2007 12:15	0000010	0308000119	0309000090	FAIL
| | x|		|	|	|	514	11/05/2007 12:39	0000010	0309000138	0309000090	PASS
| | |		|	|	x|	616	11/05/2007 15:04	0000010	0309000138	0309000090	PASS
| | x |		|	|	|	499	11/05/2007 18:22	0000010	0309000138	0309000090	PASS
| | |	x |	|	|	|	557	11/06/2007 10:56	0000010	0309000138	0309000090	PASS
| | |	x |	|	|	|	562	11/06/2007 18:27	0000010	0309000138	0309000090	PASS
| | x |		|	|	|	479	11/06/2007 18:52	0000010	0309000138	0309000090	PASS

Passed Test Record	12	Mean: 521.75	sd: 19.454	cv: 3.48%	
Total Test Records	13	Mean: 535.00	sd: 37.262	cv: 12.57%	

ORDERING INFORMATION

ACT PLUS® SYSTEM COMPONENTS

Catalog Number	Description
ACT100	ACT Plus® Instrument
ACT200	ACT Plus® Instrument Outside US Version
ACTSC	ACT Plus® Bar Code Scanner
31363	ACTtrac® Electronic Control for ACT Plus®
ACTEDM	ACT Plus® External Data Manager Software

CARTRIDGES AND CONTROLS

Catalog Number	Description	Packaging
ACT® DISPOSABLE TEST CARTRIDGES		
402-03	High Range Activated Clotting Time (HR ACT™)	50 cartridges per box
402-01	Low Range Activated Clotting Time (LR ACT™)	50 cartridges per box
402-07	Heparinase Test Cartridge (HTC)	20 per box
402-02	Recalcified Activated Clotting Time (RACT™)	50 cartridges per box
ACT® CLOTtrac® COAGULATION CONTROLS		
550-07	CLOTtrac® HR Coagulation Control	15 vials of control and deionized water per box
550-08	CLOTtrac® HR Abnormal Coagulation Control	15 vials of control and deionized water per box
550-13	CLOTtrac® HR Control Pack	1 box of HR 550-07 and 1 box of 550-08
550-01	CLOTtrac® CWB Control (normal) – for Low RangeACT® and RACT cartridges	15 vials of control and deionized water per box
550-09	CLOTtrac® LR Abnormal Coagulation Control	15 vials of control and deionized water per box
550-10	CLOTtrac® RACT Abnormal Coagulation Control	15 vials of control and deionized water per box
550-11	Calcium Chloride – for use with the Low Range ACT controls	1 vial per box
550-12	CLOTtrac® HTC Coagulation Control	15 vials of control and deionized water per box
ACT® ACCESSORIES		
313-11	Temperature Verification Cartridge for ACT Plus®	1 per box
313-50	HEPline Kit	Each
303-58	Actuator Cleaning Kit	Each
ACTFILHR	High Range ACT® Easy Fill Accessory	100 per box
ACTFILLR	Low Range ACT® Easy Fill Accessory	100 per box

ACT PLUS® SYSTEM SPECIFICATIONS

DIMENSIONS
Height: 11.9 in (30.2 cm)
Width: 9.0 in (22.9 cm)
Depth: 13.6 in (34.5 cm)
Weight: 11.5 lb (5.22 kg)

DATA PORTS
- Serial Data Port: 19200 baud, 8 data bits, 1 stop bit, no parity
- Bar Code Scanner Port: used with the optional ACT Plus® Bar Code Scanner
- Floppy Drive: PC compatible, 1-44 MB, 3.5 inch floppy disk
- USB: used with Medtronic approved USB storage device

POWER
Voltage: 100-240 V ~ Single Phase
Frequency: 50-60 Hz
Maximum current: 1.0 A (100-240)

OPERATING LIMITS
Temperature: 14°C to 32°C (57°F to 90°F)
Humidity: 10% to 90%, noncondensing

STORAGE LIMITS
Temperature: 0°C to 49°C (32°F to 120°F)
Humidity: 5% to 90%, noncondensing

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Fax: (763) 514-4879
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Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians and medical professionals)

Revascularization & Surgical Therapies
7611 Northland Drive
Minneapolis, MN 55428-1088
Internet: www.perfusionsystems.com
FAX: (763) 391-9100

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Toll-free at 1-800-854-3570

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Tel: (905) 826-6020
Fax: (905) 826-6620
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enquiryap@medtronic.com
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Miami, FL 33178
USA
Tel: (305) 500-9328
Fax: (786) 709-4244
www.medtronic.com

UC200802006 EN

Medtronic
Alleviating Pain · Restoring Health · Extending Life

Medtronic

autoLog®

Autotransfusion System

Medtronic: A Pioneer in Blood Component Technologies

Medtronic has been a key participant in the area of blood component therapies for more than a decade. We are committed to setting the industry standard by providing innovative, cost-effective products designed to meet your needs and enable you to continue to provide the best possible care.

The Medtronic Mission

To contribute to human welfare by the application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health and extend life.

Sophisticated, Effective Processing System

- The autoLog Autotransfusion System's fully automated design consistently produces a high-quality end product.
- The System's preset operating program completes one processing cycle (fill, wash, empty) in approximately three minutes and returns approximately 135 ml of blood to the holding bag.
- The autoLog System uses a two-stage filling process capable of first stage fill speed of 600 ml/min followed by a second stage fill speed at either 600 or 250 ml/min based on incoming volume.
- While a processing cycle can be initiated manually, the autoLog System has a unique self-start feature.

A Source of High-Quality Blood Product

- The autoLog System is designed to consistently produce a blood product with a **hematocrit of 50% or greater**.
- The autoLog System's unique bowl design packs blood tightly to produce an increased hematocrit and allows blood to enter at a moderate G-force to **minimize hemolysis**. The end product remains consistent and is independent of the type of surgical procedure.
- The variable speed wash process, coupled with the unique design of the bowl, promotes the **effective removal** of free-plasma hemoglobin, residual anticoagulant agents, activated platelets, white blood cells, and activated clotting factors of 90% or greater in accordance with AABB guidelines.[6]

Simplicity of Operation

- Continuous software monitoring **improves quality** of end product and speed of processing.
- Easy system set-up and intuitive feature design increase efficiency and **save time** for system operators.
- The autoLog® System is an all-inclusive processing system, **saving you money, storage space** and **time on inventory management.**

REFERENCES

1. LeGrand, Richard. American Red Cross letter to customers, January 2003, available at: http://www.redcross.org/services/biomed/profess/legrand.pdf
2. American Red Cross. American Red Cross Statement on Blood Pricing. May 24, 2001 press release available at: http://www.redcross.org/press/biomed/bm_pr/010524price.htm
3. American Red Cross. Blood Banking Community Issues National Appeal for Immediate Donations. January 12, 2004 press release available at: http://www.redcross.org/pressrelease/0,1077,0_114_2164,00.html
4. Speiss, BD. Transfusion and outcome in heart surgery. *Ann Thorac Surg 2002*; 74(4):986-7.
5. Hannon, Timothy. Medtronic autoLog™ Autotransfusion System: Comparative Wash Quality and Clinical Assessment. *Technical Concept Paper* published by Medtronic. June 1999.
6. Guidance for Standards for Perioperative Autologous Blood Collection and Administration. First Edition. American Association of Blood Banks Sec. 5.1.2, p. 21.

"From a clinical standpoint, the compact design, economy, ease of set-up, and simplicity of operation are major advantages of the autoLog Autotransfusion System. Combined with our controlled laboratory data showing its wash program to be fast, sophisticated and quite efficient, the autoLog has proved to be a very capable and desirable autotransfusion machine."[5]

The Vacuum Regulator: VR702
Regulates the vacuum from 0-700mmHg (recommended operation 150-210 in accordance to AABB guidelines in order to minimize hemolysis).[6]

Hardshell Cardiotomy Reservoir with 120 Micron Filter (shown)
Vacuum canister and softshell blood collection reservoir bag with micron filter also available.

Self-contained vacuum source provides convenience.

The device's compact design and small footprint are beneficial in a crowded operating room.

autoLog® Autotransfusion System Specifications

Electrical Classification
Class I, Type B, Ordinary, Continuous Operation

Power
Voltage: 110/120 or 220/240 V
Cycles: 50-60 Hz
Phase: Single
Current: 1.6/0.8 amps (depending upon voltage selection)
Fuses: 4 AT/240 V
Power cord: 2 wires plus ground (earth) connector; 3-prong hospital grade (USA only)

Speed and Flow Rate Specifications
Centrifuge: 0-10,000 RPM (±5%)
Pump: 0-600 ml/min (±5%)
Vacuum: 200-280 mbar

Dimensions
Width: 33 cm (13 inches)
Height: 75 cm (30 inches)
Depth: 22 cm (9 inches)

Weight
32 kg (70 lb.)

Temperature Limit
Operational: 10°C - 30°C (50°F-86°F)
Storage: 5°C - 30°C (41°F-86°F)

Humidity Range
Operational: 10-95% non-condensing
Storage: 10-95% non-condensing

NOTE: Technical data, features, and options referenced are based on the latest information available at the time of printing. Medtronic reserves the right to change specifications without notice.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

For more information contact your local Medtronic Revascularization and Surgical Therapies Sales Representative or call Customer Service toll-free at 1-800-328-1357.

Ordering Information

autoLog® System Product Codes

Part #	Description	Qty
ATLG	autoLog® Autotransfusion System	1
VR702	Vacuum Regulator	1
ATL2001	Wash Kit	6
BT725	Suction/Anticoagulation Line	10
BT1000SC	Blood Holding Bag	24
ELUWB1	Waste Bag	10
EL2120	Hardshell Blood Collection Reservoir with 120 micron filter	6
EL240	Hardshell Blood Collection Reservoir with 40 micron filter	6
EL400	4 Liter Hardshell Cardiotomy Reservoir with 120 micron filter	6
EL402	4 Liter Hardshell Cardiotomy Reservoir with 20 micron filter	6
EL404	4 Liter Hardshell Cardiotomy Reservoir with 40 micron filter	6
ATLHB	Hardshell Reservoir Bracket	1
ATLHBI	Hardshell Reservoir Bracket-International	1
ATBAG300	Autologous Transfer Bag - 300 mL	48
ATBAG600	Autologous Transfer Bag - 600 mL	48
ATBAG1000	Autologous Transfer Bag - 1000 mL	48

One Source Packs

Part #	Description	Qty
ATLS21	Includes One of Each	4
ATL2001	Wash Kit	
BT725	Suction/Anticoagulant Line	
EL2120	4 Liter Hardshell Blood Collection Reservoir with 120 micron filter	
ATLS24	Includes One of Each	4
ATL2001	Wash Kit	
BT725	Suction/Anticoagulant Line	
EL240	4 Liter Hardshell Blood Collection Reservoir with 40 micron filter	
ATLS00	Includes One of Each	4
ATL2001	Wash Kit	
BT725	Suction/Anticoagulant Line	
EL400	4 Liter Hardshell Cardiotomy Reservoir with 120 micron filter; ¼" and ⅜" prime ports	
ATLS02	Includes One of Each	4
ATL2001	Wash Kit	
BT725	Suction/Anticoagulant Line	
EL402	4 Liter Hardshell Cardiotomy Reservoir with 20 micron filter; ¼" and ⅜" prime ports	
ATLS04	Includes One of Each	4
ATL2001	Wash Kit	
BT725	Suction/Anticoagulant Line	
EL404	4 Liter Hardshell Cardiotomy Reservoir with 40 micron filter; ¼" and ⅜" prime ports	

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Fax: (763) 526-7888
E-mail: rs.cstechsupport@medtronic.com

Medtronic

Why Use Autologous Red Blood Cell Salvage?

Autologous red blood cell salvage is a safe, reliable, cost effective method of returning red blood cells back to patients. The autologous red cell salvage procedure maximizes patient safety, overall cost savings, and blood quality.

Additional benefits include:

- Eliminates the risk of clerical errors during blood handling.
- Minimizes costs associated with the use of allogenic blood transfusion.
- Minimizes the use of banked blood products, thereby reducing the risk for transmission of blood-borne diseases, lowering the risk of transfusion reaction, and providing an option for those with religious objections to transfusions.
- Addresses the issue of blood shortages. Blood shortages are common and will become more acute in the next few years.[4]
- Provides red blood cells with normal 2, 3 DPG levels and viability superior to preoperative autologous blood donation.[5]

Facts on Blood Prices and Supply

- Blood product prices have increased significantly due to the rising costs of safety measures and requirements for the blood supply. [1,2]
- National blood inventory levels have dropped well below a safe and adequate supply. Certain critical blood types are not routinely available and as a result some elective surgeries have been postponed or cancelled.[3]
- Transfusion for cardiac surgery utilizes approximately 20% of the United States' blood supply.[4]

Rev	CO#	Description of Change
1A	CO10260821	DC1065 ACT Plus has been obsoleted. This new DoC has been created (previously assigned to TF-0065) to align with new TF-0166 number Update header, footer and format to current document template 11025 Update reference to Essential Requirements Checklist to reference 10678816DOC Update 710 Medtronic Parkway address to 710 Medtronic Parkway N.E.
AA	RCH00016990	Update ISO 13485 Certificate number to Q5 039709 121 Rev. 00
AB	RCH00241399	Remove certificate Q5 039709 1211 Rev. 00 as it is not required for IVD. Remove ISO13485:2016 standard reference from body of the document. Add new Manager signature

EC DECLARATION OF CONFORMITY

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway N.E. Minneapolis, MN 55432 United States of America
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Manufacturing Facility	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 USA Medtronic Parker Blood Management 18501 East Plaza Drive, SS-66 Parker, CO 80134 USA
Product:	**Attachment A**
Classification, Rules:	IVDD Class "Other" not included in Annex II, List A or B, not for self-testing
Conformity Assessment Route	Annex III (excluding section 6)

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 98/79/EC of 27 October 1998 including amendments issued.
This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied: See **Attachment B**

Place of Issue: Minneapolis, Minnesota USA

Authorized Signature:

Name: Kristyn Benson
Title: Sr. Director, Regulatory Affairs
Date: 25 Mar 2022

Attachment A to Declaration of Conformity DC1166

This attachment specifies the class "Other" not included in Annex II List A or B and not for self-testing In Vitro Diagnostic Devices included in the above referenced Declaration of Conformity.

A.) ACT Plus

Device Description	Model Number	Variant(s)
ACT Plus	ACT100	NA
ACT Plus	ACT200	NA
ACT Plus	ACT2000BV	NA
ACT Plus	ACT20001	NA
ACT Plus	ACT20002	NA
ACT Plus	ACT20003	NA
ACT Plus	ACT20004	NA
ACT Plus	ACT20005	NA
ACT Plus	ACT20006	NA
ACT Plus	ACT20008	NA
ACT Plus	ACT20024	NA
ACT Plus	ACT20041	NA
ACT Plus	ACT20046	NA
ACT Plus – reconditioned unit	RACT200	NA
ACT Plus External Data Manager	ACTEDM	NA
ACT Plus Barcode Scanner	ACTSC	ACTSCC4 ACTSC66

B.) Activated Clotting Time (ACT) Cartridges

Device Description	Model Number	Variant(s)
Low Range Activated Clotting Time Cartridge	402-01	NA
Recalcified Activated Clotting Time Cartridge	402-02	NA
High Range Activated Clotting Time Cartridge	402-03	NA
High Range ACT Easy Fill Device	ACTFLHR	NA
Low Range ACT Easy Fill Device	ACTFILLR	NA

C.) Heparinase Test Cartridge (HR-HTC)

Device Description	Model Number	Variant(s)
Heparinase Test Cartridge	402-07	NA

D.) HR Normal and Abnormal Controls

Device Description	Model Number	Variant(s)
CLOTtrac HR Normal Coagulation Control	550-07	NA
CLOTtrac HR Abnormal Coagulation Control	550-08	NA
CLOTtrac HR Coagulation Control Pack	550-13	NA

E.) CWB Control

Device Description	Model Number	Variant(s)
CLOTtrac CWB Control	550-01	NA

F.) LR Abnormal Control and Calcium Chloride

Device Description	Model Number	Variant(s)
CLOTtrac LR Abnormal Coagulation Control	550-09	NA
Calcium Chloride	550-11	NA

G.) RACT Abnormal Control

Device Description	Model Number	Variant(s)
CLOTtrac RACT Abnormal Coagulation Control	550-10	NA

H.) HTC Control

Device Description	Model Number	Variant(s)
CLOTtrac HTC Coagulation Control	550-12	NA

Attachment B to the Declaration of Conformity DC1166: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned this Declaration of Conformity

Standard	Description
EN ISO 13485: 2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

For product specific standards refer to the 10678816DOC for the product.

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www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1263 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis MN 55432
USA

Product Category(ies):

- **Autotransfusion Systems and Associated Disposables**
- **Centrifugal Blood Pumps**
- **Bio-Console Drive Units**
- **Flow Monitoring Systems**
- **Bio-Cal Blood Temperature Controller**
- **Temperature Monitoring Systems and Associated Disposables**
- **Blood Monitoring Systems**
- **Cardioplegia Delivery Systems**
- **Disposable Blood Handling Devices used for Open Heart Surgery**
- **Arterial Filters**
- **Oxygenators including Heat Exchangers, with and without Cardiotomy Reservoirs**
- **Cardiotomy Venous Reservoirs**
- **Venous Reservoir Bags**
- **Perfusion Equipment and Disposable Perfusion Devices**
- **Disposable Medical Devices for Drainage Systems**
- **Disposable Medical Devices for use in Cardiopulmonary Surgery: Cardioplegia, Cannulae, Venting, Suction**
- **Pressure Display System & related accessories of class IIa**
- **Tissue Positioning/Stabilizing Devices**
- **Surgical Site Clearing Devices**
- **Intravascular Shunts**
- **Surgical Retractors**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1263 Rev. 00

inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72150396

Valid from: 2020-02-12
Valid until: 2024-05-26

Date, 2020-02-12

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1263 Rev. 00

Facility(ies):

Medtronic Mexico S.de R.L.de CV
Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, MEXICO

Medtronic Perfusion Systems
7611 Northland Drive, Minneapolis, MN 55428, USA

Medtronic, Inc.
710 Medtronic Parkway, Minneapolis MN 55432, USA

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Rev	CO#	Description of Change
1E	CO10218985	Update to G1 QS Certificate Update font to Effra Update Branding and Trademark where appropriate Update header and footer to match Technical File template Update Authorized Signature
1F	CO10270569	Update to Attachment A to align with the devices listed in the corresponding technical file Update Attachment B with the 13485:2016 ISO Standard
AA	RCH00058744	Update EC Quality System Certificate from G1 16 08 39709 01060 to G1 039709 1263 Rev. 00 Update template and minor formatting changes

EC DECLARATION OF CONFORMITY

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 United States of America
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Product:	**Attachment A**
Classification, Rules:	Class IIa, Rule 3 (Uncoated models)
Conformity Assessment Route	Annex II excluding section 4

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC which apply to them. This declaration is supported by the Certificates according to the provisions of relevant Annex of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied:	See **Attachment B**
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstr 65 D-80339 München, Germany
Identification Number:	0123
EC Quality System Certificate:	G1 039709 1263 REV. 00
Place of Issue:	Minneapolis, Minnesota USA
Authorized Signature:	 Name: Jake Roeller Title: Senior Manager, Regulatory Affairs Date: 19-Feb-2020

Attachment A to Declaration of Conformity DC1135

This attachment specifies the products included in the above referenced Declaration of Conformity.

A.) AutoLog Auto-transfusion Disposables

Device Description	Model Number	Variant(s)	MDD Rule	QS Certificate
Autotransfusion System, Centrifuge Bowl	ATL2001	NA	3	G1 039709 1263 REV. 00
Autolog One Source Pack (ATL2001, BT725, EL400)	ATLS00	NA	3	G1 039709 1263 REV. 00
Autolog One Source Pack (ATL2001, BT725, EL402)	ATLS02	NA	3	G1 039709 1263 REV. 00
Autolog One Source Pack (ATL2001, BT725, EL404)	ATLS04	NA	3	G1 039709 1263 REV. 00
Autolog One Source Pack (ATL2001,BT715,EL404)	ATLS14	NA	3	G1 039709 1263 REV. 00
Autolog One Source Pack (ATL2001, BT725, EL2120)	ATLS21	NA	3	G1 039709 1263 REV. 00
One Source Pack	ATLS24	NA	3	G1 039709 1263 REV. 00
Special holding bag 1000 ml	BT1000SC	NA	3	G1 039709 1263 REV. 00
Autotransfusion Centrifuge Bowl 125ml	BT125E	NA	3	G1 039709 1263 REV. 00
ELMD Vacuum ext line with 4 ft	BT133	NA	3	G1 039709 1263 REV. 00
Vacuum ext line with filter	BT133F	NA	3	G1 039709 1263 REV. 00
Autotransfusion Centrifuge Bowl, 225ml	BT225E	NA	3	G1 039709 1263 REV. 00
Suction/Anticoagulation line 15 ft	BT715	NA	3	G1 039709 1263 REV. 00
Suction/Anticoagulation assembly	BT725	NA	3	G1 039709 1263 REV. 00
Tandem cardiotomy "Y" adaptor	BT920	NA	3	G1 039709 1263 REV. 00
Reservoir "Y" adaptor with ¼" outlets	BT926	NA	3	G1 039709 1263 REV. 00
Straight stepdown 3/8"-1/4" connector	BT946	NA	3	G1 039709 1263 REV. 00
Suction/Anticoagulant Line including "Y" Adapter with ¼" outlets	BTC93	NA	3	G1 039709 1263 REV. 00
Suction & Anticoagulant line with stepdown 3/8" – ¼" adaptor	BTC96	NA	3	G1 039709 1263 REV. 00

Device Description	Model Number	Variant(s)	MDD Rule	QS Certificate
Transfer spike	BT945	NA	3	G1 039709 1263 REV. 00
Plasma Sequestration kit for blood bags	BT727SP	NA	3	G1 039709 1263 REV. 00
Waste Bag, Universal 10 liter	ELUWB1	NA	3	G1 039709 1263 REV. 00
Blood Processing One-Source Packs	STANDBY1	NA	3	G1 039709 1263 REV. 00
Blood processing kit w/125 ml bowl	TK1	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK1S00	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK1S02	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK1S04	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK1S21	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK1S24	NA	3	G1 039709 1263 REV. 00
Blood Processing Kit w/225 ml bowl	TK2	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S00	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S02	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S04	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S21	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S24	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S2469	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S247	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood Processing	TKSP	NA	3	G1 039709 1263 REV. 00

Attachment B to the Declaration of Conformity DC1135: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard / Directive	Description
EN ISO 13485: 2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

For product specific standards refer to the Essential Requirements Checklist for the product.