In POC coagulation, all eyes on ease and accuracy

Anne Ford

In theory, Medicare started reimbursing home mon-itoring of anticoagulation therapy for patients with heart valves over a year ago. But Dale Clendon, HemoSense executive vice president for business development, didn't start celebrating until last month. That's when Medicare changed its type-of-service classification of independent diagnostic testing facilities, or IDTFs, which distribute home anticoagulation meters to patients and provide reports on patient test results to physicians.

"The type of service was incorrect on the original codes," Clendon says, "so the carriers that contracted with Medicare weren't recognizing IDTFs—they were denying claims. But just as of July 1, Medicare has cleaned that up."

Now that the ball's rolling on reimbursement, HemoSense and other manufacturers of home coagulation monitoring devices are emphasizing their products' accuracy and convenience. LifeScan, maker of the Harmony INR monitoring system, has "clinical data showing that Harmony is clinically accurate to the standard of care—the lab test," says senior marketing manager Lawrence Chan. "Whether a health care professional runs a test or a patient does it, both consistently obtain accurate results."

Test strips for the Harmony system don't have to be refrigerated, Chan adds, which makes it convenient for patients who travel. Meanwhile, HemoSense's INRatio meter has built-in quality controls to make the instrument simpler to use, a feature attractive to "the elderly population we're primarily dealing with," Clendon says.

Point-of-care anticoagulation monitor manufacturers, too, are showcasing their products' accuracy and ease of use. Abbott product manager Joey Baugh says the i-Stat platform's ubiquity makes using its prothrombin time cartridge simple. "The challenge a lot of POC programs have today is, they have multiple analyzers for different tests. You might have a blood gas machine, a hematology machine, a coagulation machine. But with the i-Stat you've got everything on just the one

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Coagulation Analyzers (Point-of-care or self-monitoring)

platform," he says. And on the accuracy front, he adds, the i-Stat prothrombin time cartridge uses a high-sensitivity tissue factor reagent with an International Sensitivity Index of 1.1.

With a new test strip, Roche plans to lighten the QC load for users of its CoaguChek S point-of-care analyzer. The strip, called the CoaguChek PT•S test, will be launched in early 2004. The PT•S will provide "a streamlined quality control process, so our customers won't have to run as much QC," POC coagulation marketing manager Kimberly Ward says. "It'll be less time in their day, less work for them, and less cost." She adds that the new test strip will have room-temperature stability, will not be sensitive to heparin, and will feature an ISI of 1.0.

Monitors from Medtronic and International Technidyne offer convenience to POC users by eliminating some of the calculation necessary to administer heparin. International Technidyne's Hemochron Response v. 2.0 with RxDx dosing, says senior product manager Bill Fitzgerald, takes information from quantitative heparin tests, "asks you the height, weight, and sex of a patient, and gives you the recommended dose. Prior to this you had to use a calculator or a pencil." Like the Hemochron Response, Medtronic's HMS Plus monitor can also calculate the amount of protamine needed to reverse the heparin, Medtronic representative Marsha Cusulos says.

Along with accuracy and expediency, another watchword is cropping up in the field—connectivity, says Jim Campbell, Helena Laboratories point-of-care division manager. Helena's Actalyke monitors, he says, combine connectivity with convenience because they can be set to radio frequency output, so that operating room staff can move equipment quickly without unplugging and replugging the instrument.

The Rapidpoint Coag analyzer, distributed by Bayer, offers several connectivity options. "The Coag can transmit the data into many kinds of programs," says Jan Price, senior marketing manager for near patient testing. "There is a program called the RapidLink Coag Reporter that resides on our data manager, and you can just interface and download the Coag into the RapidLink. You can also interface the RapidLink directly into LISs. The Rapidpoint Coag also works with the Rals-Plus," which is manufactured by Medical Automation Systems. She says within approximately 60 days the Coag will have an interface to Telcor's Quick-Multi-Linc system as well.

Further down the road, fans of the former Avosure handheld coagulation monitor—originally offered by Avocet for both home and professional use—can look for it again in late 2004. Beckman Coulter, which acquired the monitor, plans to offer it as the Icon PT. "Right now our initial thoughts are to offer it for professional use" only, says Michael Cote, tactical marketing manager for coagulation and microalbumin testing. "It'll look a little bit different than when it was under the Avosure name, but it's still going to be a fluorescent-based technology."

CAP TODAY's lineup of self-monitoring and point-of-care coagulation analyzers includes, in addition to those mentioned here, Abbot's i-Stat 1, Bayer's Rapidpoint Accent, Instrumentation Laboratory's Gem PCL Plus, International Technidyne's Hemochron Jr. and ProTime microcoagulation system, Medtronic's ACT II and ACT Plus, and Roche's CoaguChek Pro DM. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities. □

Anne Ford is CAP TODAY *senior editor.*

Part 1 of 6

	Abbott Laboratories **Joey Baugh** joey.baugh@abbott.com **4A Crosby Drive** **Bedford, MA 01730-1402** **781-276-7774**	**Abbott Laboratories** **Joey Baugh** joey.baugh@abbott.com **4A Crosby Drive** **Bedford, MA 01730-1402** **781-276-7774**
Instrument name	**i-Stat**	**i-Stat 1**
First year sold	**1992**	**2000**
No. of units sold in U.S./Outside U.S.	**25,000/—**	**3,000/2,500**
Country where analyzer designed/Manufactured	**U.S./U.S.**	**U.S./U.S.**
Is instrument POC or self-monitoring analyzer?	**—**	**—**
Specimen type	**fingerstick, venipuncture (whole blood, anticoagulated whole blood)**	**fingerstick, venipuncture (whole blood, anticoagulated whole blood)**
Model type	**handheld/portable**	**handheld/portable**
Dimensions in inches (H x W x D)/Weight	**8.25 x 2.52 x 2.05/18.34 oz**	**8.26 x 2.52 x 2.05/18.34 oz**
Specimen volume needs	**accurate volume required (fill line on cartridge)**	**accurate volume required (fill line on cuvette)**
Clotting-based tests for which device has FDA-cleared applications	**PT, ACT**	**PT, ACTc**
Tests using other methodologies for which device has FDA-cleared applications	**none**	**—**
FDA-cleared tests but not yet clinically released	**none**	**—**
Tests submitted for 510(k) clearance	**ACTk**	**ACTk**
Tests in development but not yet submitted for clearance	**PTT**	**PTT**
Method of endpoint detection	**electrogenic**	**electrogenic**
Quality control methods		
• Electronic	**yes**	**yes**
• Liquid	**yes**	**yes**
• Lyophilized	**no**	**no**
• Integrated QC with each analysis	**yes**	**yes**
• Automatic lockout for QC failure	**yes**	**yes**
• Other	**n/a**	**—**
Time (in minutes) to perform control plus specimen test		
• PT:	**2 min**	**2 min**
• PT & PTT:	**—**	**—**
• ACT:	**2 min**	**2 min**
Data management capability	**onboard & optional add-on (SW mftr: iStat)**	**onboard & optional add-on (SW mftr: iStat)**
Includes QC	**yes (L-J plots)**	**yes**
System can automatically transfer data to information system		
• Patient data	**yes**	**yes**
• QC data	**yes**	**yes**
Interface supplied by instrument vendor	**yes (additional cost)**	**yes (additional cost)**
LOINC codes transmitted with results	**—**	**yes**
How labs get LOINC codes for reagent kit	**—**	**package insert**
Commercially available systems for which interfaces are up and running in active user sites	**Cerner, Misys, McKesson, Citation, Meditech, others**	**Cerner, Misys, McKesson, Citation, Meditech, others**
Lab can control analyzer remotely	**yes**	**yes**
Real-time wireless linkage to LIS or HIS	**yes (infrared)**	**yes**
Positive identification system (e.g. bar code) for:		
• Patient specimen	**yes**	**yes**
• Reagent	**yes**	**yes**
Onboard system for automatic error detection	**yes, for sample (volume)**	**yes, for sample (volume), reagent/cuvette expiration date**
Training provided with instrument purchase	**yes (on site)**	**yes (on site)**
Approx. No. of training hours needed for:		
• Medical staff	**—**	**1 hr**
• Patient	**n/a**	**n/a**
Patient self-testing program is available	**no**	**no**
Instrument list price	**$7,900**	**$9,500**
Reagent rental or lease only	**no**	**no**
Cost per sample for:		
• PT: Cost per sample for reagent rental	**n/a**	**n/a**
Cost per sample if device purchased	**n/a**	**n/a**
• PTT: Cost per sample for reagent rental	**n/a**	**n/a**
Cost per sample if device purchased	**n/a**	**n/a**
• ACT: Cost per sample for reagent rental	**call for pricing**	**n/a**
Cost per sample if device purchased	**call for pricing**	**n/a**
CLIA '88 complexity rating	**moderate**	**moderate**
Unique advantages (provided by the vendor)	**• handheld** **• QC lockout/operator lockout** **• bar-code scanner**	**• handheld portable device** **• QC lockout/operator lockout** **• menu: blood gas, chemistry, electrolytes, coagulation**

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Survey editor: Raymond D. Aller, MD

Coagulation Analyzers *(Point-of-care or self-monitoring)*

Part 2 of 6

See accompanying article on page 34

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Instrument name	Rapidpoint Coag	Rapidpoint Accent	Actalyke XL
First year sold	1995	2001	2002
No. of units sold in U.S./Outside U.S.	—/—	n/a/n/a	25+/—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC	POC	POC
Specimen type	fingerstick, venipuncture (whole blood, anticoagulated whole blood, plasma)	whole blood, anticoagulated whole blood (for OR use)	venipuncture (whole blood)
Model type	handheld/portable	handheld/portable	portable
Dimensions in inches (H x W x D)/Weight	3.9 x 6 x 10.5/4.25 lb	11.7 x 9.3 x 17/8.8 lb, 13 lb with coag analyzer	5.6 x 10.7 x 10.3/15 lb
Specimen volume needs	accurate volume not necessary (drop-35 µL); test tube citrated sample must be accurately drawn (9:1 blood to citrate)	accurate volume not necessary (drop-35 µL)	accurate volume required (fill line on cuvette)
Clotting-based tests for which device has FDA-cleared applications	PT (reportable range: low 6 sec, high 150 sec; INR: low 0.8, high 10.0); PTT (reportable range: low 15 sec, high 300 sec); heparin management test (HMT) alternative to ACT (measures 1–10 units per mL of heparin); low heparin management test (LHMT)	heparin management test (HMT) alternative to ACT (measures 1–10 units per mL of hep.); heparin titration test (HTT); protamine response test (PRT)	activated clotting time (ACT)–whole blood, MAX-ACT: maximum factor XII activation ACT, celite, kaolin, glass
Tests using other methodologies for which device has FDA-cleared applications	ENOX—low molecular weight heparin	none	—
FDA-cleared tests but not yet clinically released	—	none	none
Tests submitted for 510(k) clearance	ecarin clotting time	none	none
Tests in development but not yet submitted for clearance	none	none	APTT (whole blood), PT (whole blood), heparin assay, protamine assay, therapeutic assessment kit (TAK), LMWH
Method of endpoint detection	fibrin clot impedes movement of small metal particles in a flat test chamber	fibrin clot impedes movement of small metal particles in a flat test chamber	two-point electromechanical soft-clot detection principle
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	yes (plasma)	yes (plasma)	yes (simulated whole blood)
• Lyophilized	yes (plasma)	yes (plasma)	yes (simulated whole blood)
• Integrated QC with each analysis	no	no	no
• Automatic lockout for QC failure	yes	yes	yes
• Other	analyzer can be programmed to prevent patient testing unless QC performed at specified intervals	analyzer can be programmed to prevent patient testing unless QC performed at specified intervals	data management for entering heparin dose, L-J chart generation for all controls
Time (in minutes) to perform control plus specimen test			
• PT:	<5	n/a	n/a
• PT & PTT:	<5	n/a	n/a
• ACT:	<5	n/a	5
Data management capability	onboard, optional add-on	onboard, optional add-on	yes
Includes QC	yes	yes (L-J plots)	yes
System can automatically transfer data to information system			
• Patient data	yes	yes	yes
• QC data	yes	yes	yes
Interface supplied by instrument vendor	yes (additional cost, can be included in reagent rental and lease programs)	yes (additional cost, can be included in reagent rental and lease programs)	n/a
LOINC codes transmitted with results	—	—	no
How labs get LOINC codes for reagent kit	—	—	n/a
Commercially available systems for which interfaces are up and running in active user sites	connects to LIS via Helix Interface for scripting, ASTM, HL7, RALS+ System, etc.	connects to LIS via Helix Interface, RALS+ System	n/a
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	no	no	yes
Positive identification system (e.g. bar code) for:			
• Patient specimen	no	no	yes
• Reagent	yes; each test card contains lot-specific information for reagents; instrument allows patient and operator IDs to be entered via alphanumeric keypad	yes; each test card contains lot-specific information for reagents; instrument allows patient and operator IDs to be entered via touchscreen	yes; all disposables have bar-code for identification with use on any Actalyke model
Onboard system for automatic error detection	yes, for reagent/card expiration date	yes, for reagent/card expiration date	yes, stuck magnet, no tube; mechanical instrument parameters only; well rotation, temperature, and detection settings
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approx. No. of training hours needed for:			
• Medical staff	1–2 hr	2–4 hr	1–2 hr
• Patient	n/a	n/a	n/a
Patient self-testing program is available	no	no	no
Instrument list price	$5,000	$14,000	$3,595
Reagent rental or lease only	purchase or reagent rental	purchase or reagent rental	purchase, lease, or reagent rental
Cost per sample for:			
• PT: Cost per sample for reagent rental	varies based on volume of instruments and test cards	n/a	n/a
Cost per sample if device purchased	$3.50–$6.00	n/a	n/a
• PTT: Cost per sample for reagent rental	—	n/a	n/a
Cost per sample if device purchased	$3.50–$6.00	n/a	n/a
• ACT: Cost per sample for reagent rental	$3.50–$6.00	n/a	n/a
Cost per sample if device purchased	$3.50–$6.00	n/a	$0.74–$1.76
CLIA '88 complexity rating	moderate	moderate	moderate
Unique advantages (provided by the vendor)	• will analyze/monitor citrated or noncitrated samples • menu of PT, APTT, HMT (ACT), LHMT, ENOX tests with expansion capability • Rapidlink Data Management system will allow connectivity to LIS/HIS; users can generate accession numbers for patient test results • patient and operator ID, restricted analyzer access, 1,000-result memory, QC lockout, QC range assignment	• brings patients into safe coagulation range sooner • reduces risk of post-op complications • improves decision-making speed and accuracy • ease-of-use (touchscreen)	• two-point electromechanical "soft-clot" detection principle • MAX-ACT: maximum factor XII activation ACT test, 0.5 mL blood volume, linear up to 10 units of heparin, safer plastic tube construction, for use on Actalyke and Hemochron instruments • electronic clotting tube (EQC) that simulates and mimics actual blood clot formation for accurate EQC challenges • integrated printer • 3.5-in diskette storage

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Coagulation Analyzers *(Point-of-care or self-monitoring)*

Part 3 of 6

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	Helena Point of Care Jim Campbell pointofcare@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 800-231-5663 www.helena.com	HemoSense Inc. Dale Clendon 600 Valley Way Milpitas, CA 95035 408-719-1393 www.hemosense.com	Instrumentation Laboratory Elizabeth Walsh ewalsh@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4165 www.ilus.com
Instrument name	Actalyke Mini	INRatio	Gem PCL Plus (Portable Coagulation Laboratory)
First year sold	2001	cleared for professional and self-test use, 2002	2003
No. of units sold in U.S./Outside U.S.	n/a/400+	n/a/n/a	—/—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC	POC and self-monitoring analyzer	POC
Specimen type	venipuncture (whole blood)	fingerstick	fresh whole blood, citrated whole blood (fingerstick for PT)
Model type	benchtop	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/Weight	6.25 x 6 x 4.75/5.3 lb	6.5 x 3 x 2 in/7 oz	5.5 x 2 x 3.5/0.75 lb
Specimen volume needs	accurate volume required (fill line on cuvette)	accurate volume not necessary (drop)	accurate volume not necessary (~50 µL), low sample volume error message if well not filled
Clotting-based tests for which device has FDA-cleared applications	ACT—MAX-ACT, C-ACT, K-ACT, G-ACT	PT	PT and citrate PT (reportable range: 10–150 sec; INR: 0.8–12), APTT (reportable range: 20–300 sec), ACT (65–1,005 sec), ACT–low range (67–400 sec)
Tests using other methodologies for which device has FDA-cleared applications	—	none	none
FDA-cleared tests but not yet clinically released	—	none	citrate APTT
Tests submitted for 510(k) clearance	—	PT (reportable range: low 7 sec, high 75 sec; INR: low 0.7, high 7.5)	none
Tests in development but not yet submitted for clearance	LMWH, APTT (whole blood), PT (whole blood)	planned tests: APTT, ACT	none
Method of endpoint detection	two-point electromechanical	change in impedance of the sample when clotting occurs	mechanical endpoint clotting mechanism, monitored optically
Quality control methods			
• Electronic	yes	no (not required, built-in QC on patient strip)	yes
• Liquid	yes (simulated whole blood)	no (not required, built-in QC on patient strip)	yes (simulated whole blood)
• Lyophilized	yes (simulated whole blood)	no	yes
• Integrated QC with each analysis	no	yes (automatic self-check diagnosis)	no
• Automatic lockout for QC failure	no	yes	yes
• Other	—	impedance check strip	n/a
Time (in minutes) to perform control plus specimen test			
• PT:	n/a	<2	2
• PT & PTT:	n/a	n/a	2
• ACT:	5	n/a	1–5
Data management capability	no	onboard	onboard (via Gem Premier 3000)
Includes QC	—	no	yes
System can automatically transfer data to information system			
• Patient data	—	yes	yes
• QC data	—	yes	yes
Interface supplied by instrument vendor	—	yes (included in instrument price)	n/a
LOINC codes transmitted with results	no	—	no
How labs get LOINC codes for reagent kit	n/a	n/a	n/a
Commercially available systems for which interfaces are up and running in active user sites	—	n/a	n/a
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	—	planned	no
Positive identification system (e.g. bar code) for:			
• Patient specimen	no	no	no
• Reagent	no	no	yes
Onboard system for automatic error detection	yes, for specimen placement	yes, for sample (volume), reagent stability	yes, for sample (volume), reagent, and instrument
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approx. No. of training hours needed for:			
• Medical staff	1 hr	1 hr	0.5 hr
• Patient	n/a	1 hr	n/a
Patient self-testing program is available	no	available when cleared	no
Instrument list price	$1,049–$1,149 with printer	$1,595 professional; $1,995 self-test	$5,329 (volume dependent)
Reagent rental or lease only	purchase, lease, or reagent rental	no	outright purchase, lease, reagent rental
Cost per sample for:			
• PT: Cost per sample for reagent rental	—	$10 per strip self-test	varies with volume
Cost per sample if device purchased	—	$5.50 per strip professional	varies with volume
• PTT: Cost per sample for reagent rental	—	n/a	varies with volume
Cost per sample if device purchased	—	n/a	varies with volume
• ACT: Cost per sample for reagent rental	—	n/a	varies with volume
Cost per sample if device purchased	$0.74–$1.76	n/a	varies with volume
CLIA '88 complexity rating	not yet rated	waived	non-waived
Unique advantages (provided by the vendor)	• two-point electromechanical "soft-clot" detection • magnetic detection device—electronic QC/revolution • MAX-ACT tubes, 0.5 mL volume and linear to 6 U/mL	• onboard QC—no external QC needed; therefore the best value for clinician and patient • fast total test of <2 min • very simple test procedure	• Gem PCL Plus can be used in conjunction with the Gem Premier 3000; consolidating BG/Lytes/Glu/Lac/Hct testing • comprehensive POC coagulation menu that allows for POC coagulation analysis throughout an institution; whole blood PT, citrate PT, APTT, ACT, and ACT–low range • onboard data management • mandatory operator ID and patient ID options

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Coagulation Analyzers *(Point-of-care or self-monitoring)*

Part 4 of 6

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	International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com	International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com	International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com
Instrument name	ProTime Microcoagulation System/ProTime 3	Hemochron Jr.—Signature/Signature+	Hemochron Response
First year sold	ProTime Micro: 1996; ProTime 3: 2001	1998; Signature+ introduced in 2002	2000
No. of units sold in U.S./Outside U.S.	—/—	—/—	—/—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	—	—	—
Specimen type	fingerstick	fingerstick, venipuncture (whole blood)	venipuncture (whole blood, anticoagulated whole blood)
Model type	handheld/portable	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/Weight	2.5 x 4.5 x 9/3 lb	2 x 7.5 x 3.75/12 oz	8.7 x 10.5 x 7.5/6.4 lb
Specimen volume needs	small blood sample volume needed, ~25 µL	accurate volume not necessary (drop)	accurate volume required (fill line on tubes)
Clotting-based tests for which device has FDA-cleared applications	PT (reportable range: low 10 sec, high 130 sec; INR: low 0.8, high 9.9)	PT (reportable range: low 11.4 sec, high 129 sec; INR: low 0.8, high 12.0), PT (citrated), PTT (reportable range: low 20 sec, high 400 sec plasma equiv.), APTT (citrated), ACT low-range, ACT+	PT (reportable range: low 50 sec, high 340 sec; INR: low 1, high 6), PT (citrated), PTT (reportable range: low 24 sec, high 120 sec), APTT (citrated), ACT, (FTCA510, KACT, P214), HiTT, TT, HNTT, Fib., HRT, KHRT, PRT, KPRT, PDA0, KPDA0
Tests using other methodologies for which device has FDA-cleared applications	none	none	none
FDA-cleared tests but not yet clinically released	none	none	none
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted for clearance	—	—	—
Method of endpoint detection	optical detection of clot	optical detection of clot	mechanical clot detection
Quality control methods			
• Electronic	no (not required, onboard QC)	yes	yes
• Liquid	yes (available as an option but not required due to onboard controls)	yes (simulated whole blood)	yes (simulated whole blood)
• Lyophilized	no	yes (simulated whole blood)	yes (simulated whole blood)
• Integrated QC with each analysis	yes	no	no
• Automatic lockout for QC failure	yes	Signature, no; Signature+, yes	yes
• Other	2 levels of onboard QC integrated into each cuvette	Signature+, operator lockout	operator lockout
Time (in minutes) to perform control plus specimen test			
• PT:	<5	2	2
• PT & PTT:	n/a	2	2
• ACT:	n/a	1–5	1–5
Data management capability	yes	onboard	onboard
Includes QC	yes	yes (QC Data Management)	yes
System can automatically transfer data to information system			
• Patient data	no	yes	yes
• QC data	no	yes	yes
Interface supplied by instrument vendor	n/a	yes	yes
LOINC codes transmitted with results	—	—	—
How labs get LOINC codes for reagent kit	—	—	—
Commercially available systems for which interfaces are up and running in active user sites	n/a	yes	yes
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	no	no	no
Positive identification system (e.g. bar code) for:			
• Patient specimen	no	no	no
• Reagent	yes	yes	yes
Onboard system for automatic error detection	yes, for sample (volume) and reagent/cuvette expiration date	yes, for sample (volume)	yes, for sample volume and reagent/expiration date
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approx. No. of training hours needed for:			
• Medical staff	1 hr	1 hr	1–2 hr
• Patient	1.5 hr	n/a	n/a
Patient self-testing program is available	yes (programmed instruction/video/Web-based training)	no	no
Instrument list price	$1,699 professional, $2,350 consumer	Signature, $3,825; Signature+, $5,100	$4,055
Reagent rental or lease only	no	no	no
Cost per sample for:			
• PT: Cost per sample for reagent rental	volume dependent	n/a	n/a
Cost per sample if device purchased	volume dependent	$3.31	$2.10
• PTT: Cost per sample for reagent rental	n/a	n/a	n/a
Cost per sample if device purchased	n/a	$3.50	$2.10
• ACT: Cost per sample for reagent rental	n/a	n/a	n/a
Cost per sample if device purchased	n/a	$2.58	$0.86–$1.84
CLIA '88 complexity rating	waived	moderate	moderate
Unique advantages (provided by the vendor)	• two levels of integral reagent control automatically run with each patient • internal instrument checks verify optical, electrical, and mechanical functions—no further calibration required • sensitive thromboplastin reagent (ISI = 1.0), as recommended by AHA, CAP, and WHO • results in less than 5 min • 30-day room storage of cuvettes	• blood volume—15 µL • ease-of-use • data management storing/printing • connectivity options • configurable lockout for Signature+	• gold standard for ACT • QC lockout • data storage and management • connectivity options • RxDx heparin/protamine dosing system

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Coagulation Analyzers *(Point-of-care or self-monitoring)*

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	LifeScan Inc., a Johnson & Johnson company Customer Service customerservice@harmonyinr.com 1000 Gibraltar Drive Milpitas, CA 95035 877-520-8608 www.harmonyinr.com	Medtronic Cardiac Surgery 7611 Northland Drive North Minneapolis, MN 55428 800-328-3320 www.medtronic.com	Medtronic Cardiac Surgery 7611 Northland Drive North Minneapolis, MN 55428 800-328-3320 www.medtronic.com
Instrument name	Harmony INR Monitoring System	ACT II	HMS Plus
First year sold	2003	1994	1999
No. of units sold in U.S./Outside U.S.	—/—	—/—	—/—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	self-monitoring	POC	POC
Specimen type	fingerstick	venipuncture	venipuncture
Model type	handheld/portable	benchtop	benchtop
Dimensions in inches (H x W x D)/Weight	7.9 x 3.3 x 2.2/12.9 oz	6.5 x 6.5 x 9.5/8 lb	15.7 x 15 x 13/34 lb
Specimen volume needs	accurate volume not necessary (drop)	0.2 to 0.4 cc/test, fill to line	accurate volume required (automated dispensing)
Clotting-based tests for which device has FDA-cleared applications	PT (INR: low, 0.8; high, 8.0)	ACT (high range, low range, recalcified, and heparinase test)	ACT, heparin dose response, heparin protamine titration, platelet function
Tests using other methodologies for which device has FDA-cleared applications	none	none	none
FDA-cleared tests but not yet clinically released	—	—	—
Tests submitted for 510(k) clearance	none	—	—
Tests in development but not yet submitted for clearance	—	—	ATIII
Method of endpoint detection	direct optical detection of clot	mechanical clot detection	mechanical clot detection
Quality control methods			
• Electronic	no (not required, onboard QC integrated into test strip)	yes	yes
• Liquid	no (not required, onboard QC integrated into test strip)	no	no
• Lyophilized	no	yes	yes
• Integrated QC with each analysis	yes	no	no
• Automatic lockout for QC failure	yes	no	optional (user defined)
• Other	two levels of onboard QC integrated into test strip	n/a	n/a
Time (in minutes) to perform control plus specimen test			
• PT:	1.5	n/a	n/a
• PT & PTT:	n/a	n/a	n/a
• ACT:	n/a	up to 12 (depending on patient sample)	up to 12 (depending on patient sample)
Data management capability	onboard	yes	yes
Includes QC	—	yes	yes
System can automatically transfer data to information system			
• Patient data	—	yes	yes
• QC data	—	yes	yes
Interface supplied by instrument vendor	—	no	no
LOINC codes transmitted with results	—	—	—
How labs get LOINC codes for reagent kit	—	Web site	Web site
Commercially available systems for which interfaces are up and running in active user sites	—	yes	yes
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	no	no	no
Positive identification system (e.g. bar code) for:			
• Patient specimen	no	no	no
• Reagent	no	no	no
Onboard system for automatic error detection	yes, for sample (volume)	yes	yes
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approx. No. of training hours needed for:			
• Medical staff	n/a	2 hr	6 hr
• Patient	1 hr	n/a	n/a
Patient self-testing program is available	yes	no	no
Instrument list price	$2,950 for patient self-testing	$2,900	$26,000
Reagent rental or lease only	—	yes	yes
Cost per sample for:			
• PT: Cost per sample for reagent rental	—	—	—
Cost per sample if device purchased	$24.75 for patient self-testing	—	—
• PTT: Cost per sample for reagent rental	n/a	—	—
Cost per sample if device purchased	n/a	—	—
• ACT: Cost per sample for reagent rental	n/a	—	—
Cost per sample if device purchased	n/a	customer dependent, per contract	customer dependent, per contract
CLIA '88 complexity rating	CLIA '88 waived	moderate	moderate
Unique advantages (provided by the vendor)	• recombinant human thromboplastin reagent equivalent to WHO standard—ISI range 1.0–1.3 • onboard QC eliminates need for separate test strips and control solutions—only one sample needed for a controlled INR result • room temperature storage of test strips enables ease of use for patient testing anytime, anywhere	• automated mixing of reagent and sample • constant temperature control • complete QC program	• automated sample dispensing • constant temperature control • multiple testing capability • HDR: heparin dose response • HPT: heparin protamine titration • high-range ACT

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Coagulation Analyzers *(Point-of-care or self-monitoring)*

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See accompanying article on page 34

	Medtronic Cardiac Surgery 7611 Northland Drive North Minneapolis, MN 55428 800-328-3320 www.medtronic.com	Roche Diagnostics Corp. Point of Care 9115 Hague Rd., Bldg. H Indianapolis, IN 46250 800-852-8766 www.roche.com	Roche Diagnostics Corp. Point of Care 9115 Hague Rd., Bldg. H Indianapolis, IN 46250 800-852-8766 www.roche.com
Instrument name	ACT Plus	CoaguChek Pro DM System	CoaguChek S System for Prothrombin Time Testing (Professional Use)
First year sold	2003	1999	2001
No. of units sold in U.S./Outside U.S.	to be introduced in U.S. Aug. 2003/to be introduced outside U.S. Jan. 2004	—/—	10,000/52,000
Country where analyzer designed/Manufactured	U.S./U.S.	Germany/Germany	Germany/Germany
Is instrument POC or self-monitoring analyzer?	POC	POC	POC and self-monitoring analyzer
Specimen type	venipuncture (whole blood, anticoagulated whole blood)	fresh whole blood (venous, arterial, or fingerstick capillary)	capillary, venous, whole blood
Model type	—	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/Weight	11 x 8 x 13/11.5 lb	8.1 x 4.5 x 2/1.5 lb	1.8 x 4.9 x 6.8/1.0 lb
Specimen volume needs	accurate volume required (fill line on cuvette)	accurate volume not necessary (drop), minimum of approx. 25 µL to 45 µL	accurate volume not necessary (drop), minimum 10 µL
Clotting-based tests for which device has FDA-cleared applications	ACT (high range, low range, recalcified, high range heparinase)	ACT, APTT, PT	PT (reportable range: low 9.6 sec, high 33.9 sec; INR: low 0.6, high 8.0)
Tests using other methodologies for which device has FDA-cleared applications	—	none	none
FDA-cleared tests but not yet clinically released	—	none	none
Tests submitted for 510(k) clearance	—	none	none
Tests in development but not yet submitted for clearance	—	none	none
Method of endpoint detection	—	laser photometry detects change in blood flow when clot forms	iron particles mixed with the sample move in magnetic fields; reflectance photometry detects change in particle movement with clot formation
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	no	yes	yes
• Lyophilized	yes (simulated whole blood)	yes (simulated whole blood)	no
• Integrated QC with each analysis	—	no	no
• Automatic lockout for QC failure	yes	yes	no
• Other	—	password protected QC lockouts by time of day, shift, or QC level	n/a
Time (in minutes) to perform control plus specimen test			
• PT:	—	within 4	1 min for either test or QC result; QC not required with every sample
• PT & PTT:	—	within 5 each	n/a
• ACT:	up to 12 min (depends on patient sample)	within 6	n/a
Data management capability	onboard	onboard	no
Includes QC	yes (L-J plots)	yes (L-J plots and QC results report)	no
System can automatically transfer data to information system			
• Patient data	yes	yes	no
• QC data	yes	yes	no
Interface supplied by instrument vendor	no	yes (via additional DataCare software)	no
LOINC codes transmitted with results	—	n/a	n/a
How labs get LOINC codes for reagent kit	Web site	n/a	n/a
Commercially available systems for which interfaces are up and running in active user sites	—	AccuChek HDM 3.2.1, Roche DataCare, MAS-RALS+	n/a
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	no	no	no
Positive identification system (e.g. bar code) for:			
• Patient specimen	no	yes, patient and operator IDs can be entered by bar-code reader	no
• Reagent	no	yes, reagent type and expiration date contained on each test cartridge; lot-specific code key contains calibration data and expiration date	no
Onboard system for automatic error detection	yes (reagent/cuvette expiration date)	yes, for sample (volume), reagent expiration date, and internal monitor operation	yes, for sample (volume) and reagent/cuvette expiration date
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approx. No. of training hours needed for:			
• Medical staff	1 hr	1.5 hr	1 hr
• Patient	n/a	n/a	n/a
Patient self-testing program is available	no	no	no
Instrument list price	$4,200	$3,795	$1,295
Reagent rental or lease only	no	contact Roche Diagnostics sales	contact Roche Diagnostics sales
Cost per sample for:			
• PT: Cost per sample for reagent rental	—	usage dependent	contact Roche Diagnostics sales
Cost per sample if device purchased	—	usage dependent	$6
• PTT: Cost per sample for reagent rental	—	usage dependent	n/a
Cost per sample if device purchased	—	usage dependent	n/a
• ACT: Cost per sample for reagent rental	—	usage dependent	n/a
Cost per sample if device purchased	customer dependent, per contract	usage dependent	n/a
CLIA '88 complexity rating	moderate	moderate	CLIA waived for professional use
Unique advantages (provided by the vendor)	• data management software application • duplicate test results • optional bar-code scanner	• user-defined QC lockout, new lot lockout, and operator lockout options • can establish mandatory entry of operator IDs, patient IDs, and comment codes • monitor can interface with AccuCheck HDM 3.2.1 data management software and with hospital LIS via RALS+ or DataCare software • 11 different types of reports can be directly printed from monitor	• fast: patient results in as little as 30 sec • small sample: 10 µL from fingerstick • alliance partnerships with Bristol Myers Squibb and Standing Stone for patient management software

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