

Anexa 15 Analizator automat ale gazelor si electroliților în sange

Caracteristici solicitate	Caracteristici oferite Stat Profile Prime+ Nova Biomedical, SUA
<p>Analizator automat ale gazelor si electroliților în sange Cod 150700 Descriere Analizator de gaze si electroliților în sange complet automat, utilizat în secția de reanimare pentru diagnosticarea rapidă a stării pacienților în stare critică Parametrul Specificația Tip analizator sistem de tip deschis da complet automat da Tip probă Ser da Plasmă da Sînge arterial da venos da capilar da mixt da Volum probă Seringă ≤ 200 μL Capilar ≤ 100 μL Tip analize Gaze in sange pH da pCO2 da pO2 da HCO3 da HCO3 act da HCO3 std da BE(B) da BE(ecf) da TCO2 / ctCO2 da Electroliti Na+ da K+ da Ca++ da Ca++(7.4) da Cl- da Anion gap da Metaboliți Glucoza da Lactat da CO-oximetrie Hct da tHb da sO2 da O2Hb da COHb da MetHb da HHb da Spălare automată da Detector de cheag de sange da "Calibrare pentru toți parametrii măsurați" Automat da Manual da "Printarea rezultatelor de calibrare la necesitate" da "Controlul intern (QC)" Automat da Manual da Analiza Durata analizei ≤ 2 min. Stocarea datelor Date analize si date calibrari "min. 1000 înregistrări" Reagenți Forma de reagenți cartuş Valabilitatea de la deschidere min. 27 zile Numarul de teste disponibile într-un singur cartuş ≥ 450 teste Display Touchscreen da LCD sau LED da Cititor de bar cod da Imprimantă termică da Data management da Interfața PC da Conexiune la rețea informațională / Comunicare cu LIS da UPS inclus, pentru menținerea funcționării analizatorului în</p>	<p>Analizator automat ale gazelor si electroliților în sange Cod 150700 Descriere Analizator de gaze si electroliților în sange complet automat, utilizat în secția de reanimare pentru diagnosticarea rapidă a stării pacienților în stare critică Parametrul Specificația Tip analizator sistem de tip deschis da complet automat da Tip probă Ser da Plasmă da Sînge arterial da venos da capilar da mixt da Volum probă Seringă 135 μL Capilar ≤ 60 μL, Tip analize Gaze in sange pH da pCO2 da pO2 da HCO3 da HCO3 act da HCO3 std da BE(B) da BE(ecf) da TCO2 / ctCO2 da Electroliti Na+ da K+ da Ca++ da Ca++(7.4) da Cl- da Anion gap da Metaboliți Glucoza da Lactat da CO-oximetrie Hct da tHb da sO2 da O2Hb da COHb da MetHb da HHb da Spălare automată da Detector de cheag de sange da "Calibrare pentru toți parametrii măsurați" Automat da Manual da "Printarea rezultatelor de calibrare la necesitate" da "Controlul intern (QC)" Automat da Manual da Analiza Durata analizei ≤ 2 min. Stocarea datelor Date analize si date calibrari - nelimitat Reagenți Forma de reagenți cartuş Valabilitatea de la deschidere min. 27 zile Numarul de teste disponibile într-un singur cartuş – sunt disponibile cartuse de : 100, 200, 300, 400, 500 teste Display Touchscreen da LCD sau LED da Cititor de bar cod da Imprimantă termică da Data management da Interfața PC da Conexiune la rețea informațională / Comunicare cu LIS da UPS inclus, pentru menținerea funcționării analizatorului în</p>

caz de întrerupere accidentată a luminii cât și protejare în cazul fluctuației de lumină ≥ 30 min. Reagenți Cartușe necesare pentru ≥ 1500 teste / pacienți Perioada de valabilitate a reagenților din momentul livrării. ≥ 3 luni Hirtie termică 5 buc.	caz de întrerupere accidentată a luminii cât și protejare în cazul fluctuației de lumină ≥ 30 min. Reagenți Cartușe necesare pentru - 1500 teste / pacienți (3x500 teste) Perioada de valabilitate a reagenților din momentul livrării. ≥ 3 luni Hirtie termică 5 buc.
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Product Service

Certificate

No. Q5 020747 0242 Rev. 00

Holder of Certificate: **Nova Biomedical Corporation**

200 Prospect Street
Waltham MA 02454
USA

Certification Mark:



Scope of Certificate:

Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Clinical Chemistry and Hematology (Co-Oximeter) Medical Devices including Near Patient / Point of Care Analyzers, Calibrators, Controls, Reagents, Sensors, Kits used in the Detection of Blood Analytes, Electrolytes, pH, Metabolites; Self Testing and Near Patient / Point of Care In-Vitro Diagnostic Devices for the Management of Diabetes Blood Glucose, Ketone, Cholesterol and Uric Acid, including Meters, Test Strips and Controls; Self Testing In-Vitro Diagnostic Medical Devices for the Determination of the percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood, and Albumin and Creatinine in Urine including Analyzers, Test Cartridges and Controls; Contract Manufacturing of Electronic Medical Devices; Contract Manufacturing of Disposable Medical Devices; and Distribution of Lancets

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 00

Report No.: 72166286

Valid from: 2021-10-29

Valid until: 2024-10-28

Date, 2021-10-29

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 020747 0242 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Nova Biomedical Corporation
165 Lexington Road, Billerica MA 01821, USA

Production of Near Patient / Point of Care, and Self-Testing Meters
for the Management of Diabetes Blood Glucose, Ketone,
Cholesterol and Uric Acid.

Nova Biomedical Corporation
39 Manning Road, Billerica MA 01821, USA

Production of Near Patient / Point of Care, and Self-Testing Test
Strips for the Management of Diabetes Blood Glucose, Ketone,
Cholesterol and Uric Acid.
Distribution of Near Patient / Point of Care, and Self-Testing Test
Strips, Meters and Controls. Distribution of Lancets.

Nova Biomedical Corporation
200 Prospect Street, Waltham MA 02454, USA

Design and Development, Production, Distribution, Installation,
Servicing and Technical Support of In-Vitro Diagnostic Clinical
Chemistry and Hematology (Co-Oximeter) Medical Devices
including Near Patient / Point of Care Analyzers, Calibrators,
Controls, Reagents, Sensors, Kits used in the Detection of Blood
Analytes, Electrolytes, pH, Metabolites; Self Testing and Near
Patient / Point of Care In-Vitro Diagnostic Devices for the
Management of Diabetes Blood Glucose, Ketone, Cholesterol and
Uric Acid, including Meters, Test Strips and Controls; Self Testing
In-Vitro Diagnostic Medical Devices for the Determination of the
percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density
Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood,
and Albumin and Creatinine in Urine including Analyzers, Test
Cartridges and Controls; Contract Manufacturing of Electronic
Medical Devices; Contract Manufacturing of Disposable Medical
Devices

Stat Profile Prime Plus® Critical Care Analyzer



New Technologies Simplify Use and Offer Additional Tests

Stat Profile Prime Plus is a comprehensive, whole blood critical care analyzer that combines blood gases, electrolytes, metabolites, CO-Oximetry, and 32 calculated results in a simple, compact analyzer. Prime Plus combines maintenance-free, component cartridge technology for sensors and reagents with patented, new, maintenance-free, and non-lysing whole blood CO-Oximetry technology.

Prime Plus results are produced rapidly, a complete test menu panel in about one minute, and are combined with bidirectional connectivity, a robust data management system, and comprehensive cybersecurity protection.

Nova MicroSensor Card™ Technology

Most comprehensive critical care menu

PO₂ PCO₂ pH Hct tHb Na Cl K iCa TCO₂ iMg Glu Lac Urea (BUN) Creat SO₂%
O₂Hb COHb MetHb HHb

- All Stat Profile Prime Plus biosensors use proven Nova technology in a miniaturized, maintenance-free sensor card format.
- Nova MicroSensor cards combine all 20 whole blood assays including CO-Oximetry.

Important New Assays

Urea (BUN), Creatinine and eGFR

Over 50% of patients admitted to the ICU will develop some stage of acute kidney injury (AKI).¹ Stat Profile Prime Plus is the only blood gas analyzer to provide whole blood urea (BUN) and creatinine (plus eGFR) test options for rapid assessment of kidney function.

Ionized magnesium (iMg)

Disruptions in the balance of iMg, Na, K, and iCa can cause cardiac arrhythmias, reduced cardiac contraction, and cardiac arrest. Prime Plus is the only blood gas analyzer to provide a comprehensive profile of electrolytes including iMg.

New Disposable CO-Oximetry Technology Eliminates Maintenance

Prime Plus incorporates a new, patented multi-wavelength optical system that scans a continuous spectrum of optical wavelengths to enable a comprehensive CO-Oximetry panel result without lysing the sample. The optical components in contact with blood are contained in the disposable sensor card.

- Cleaning and deproteinising are completely eliminated.
- Lysing and all its required mechanical components are eliminated, as are lysing and deproteinising reagents. This improves reliability and reduces maintenance and costs.

CO-Oximetry test menu

O₂Hb COHb MetHb HHb tHb

Fast Stat Results

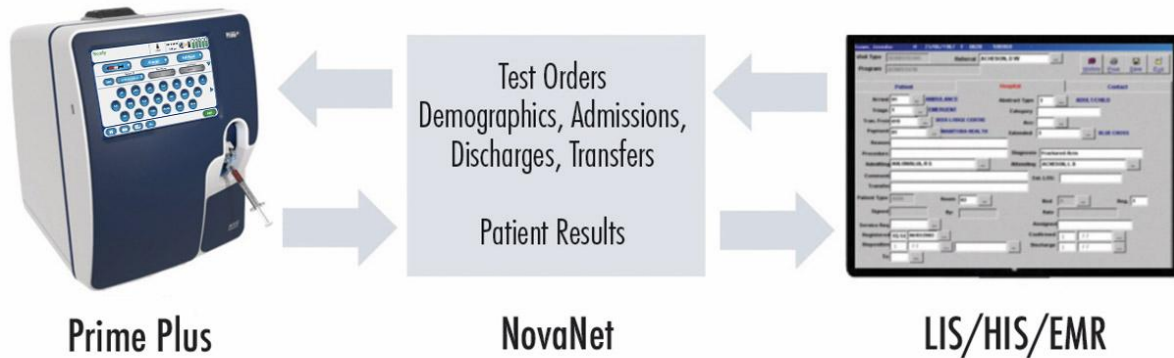
Prime Plus's exceptional throughput easily handles the high sample workload of a busy critical care setting. Prime Plus delivers a 20-test critical care profile in about one minute. Competitors' analyzers can require up to four minutes, even with fewer tests reported.

Clot Protection

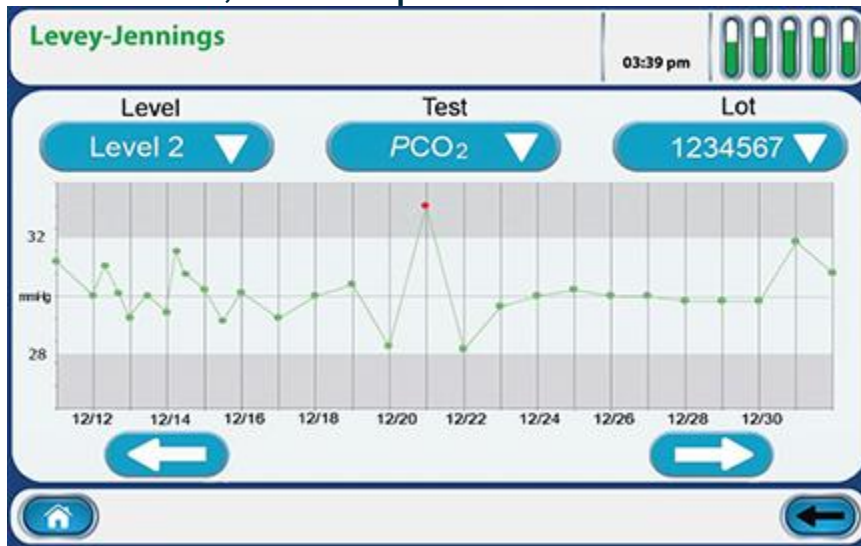
Prime Plus's unique Clot Block™ sample flow path protects sensor cards from blood clot blockages.

Bidirectional Connectivity Patient Management

NovaNet bidirectional middleware for all Nova connected devices
 NovaNet ensures timely, accurate capture of Nova analyzer test results for clinicians and managers to retrieve wherever and whenever needed. Also included is comprehensive cybersecurity protection and encryption that provides protection against attempts to access a hospital's network.



Automated, True Liquid QC



Liquid QC provides

the only reliable test of analyzer performance

United States federal government regulations and many international government regulations have eliminated electronic equivalent QC and are requiring true liquid QC.²

Automated QC complies with U.S. CLIA, German RiLiBAK, and other international QC requirements

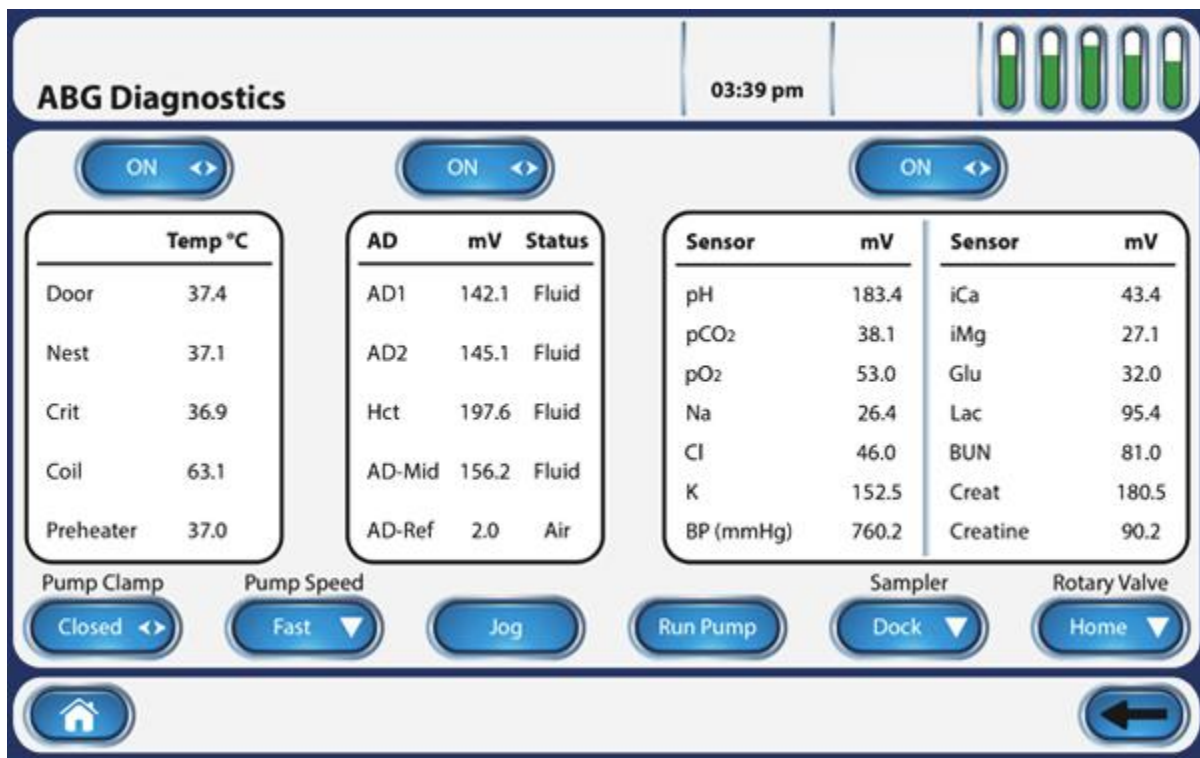
QC cartridges contain a 30-day supply of liquid QC material. Controls are run automatically at user-selected intervals. Prime Plus quality controls:

- Are comprised of a similar matrix to that of patient samples.

- Are treated in the same manner as patient samples.
- Follow the exact sample pathway as patient samples, from sample probe to waste container.
- Challenge all analytical phases of testing.
- Challenge testing at patient low, normal, and high value ranges.

Supplemental Quality Monitoring (SQM)

Prime Plus provides an automated electronic quality monitoring supplement to liquid QC. SQM continuously monitors the status and performance of all analytical components (including sensors, reagents, calibrators, sample integrity, software, and electronics), providing real-time, sample-to-sample assurance of correct performance.



[For more general product information, click here or contact Nova Biomedical at: Nova Biomedical / 200 Prospect Street / Waltham, MA 02454 / 781-894-0800](#)

1. Mandelbaum T et al. Outcome of critically ill patients with acute kidney injury using the Akin criteria. *Crit Care Med* 2011;39:2259-2264.
2. Centers for Medicare and Medicaid Services, Center for Clinical Standards and Quality/Survey and Certification Group. Policy clarification on acceptable control materials used when quality control (QC) is performed in laboratories. Baltimore, MD: CMS, April 8, 2016.

Stat Profile Prime Plus® Specifications

Critical Care Test Menu	Methodology
pH	Direct ISE
PCO ₂	Severinghaus
PO ₂	Amperometric
SO ₂ %	Optical, reflectance
Hematocrit	Conductivity/Na correction
Na	Direct ISE
K	Direct ISE
Cl	Direct ISE
iCa	Direct ISE
iMg	Direct ISE
Glucose	Enzyme/Amperometric
Lactate	Enzyme/Amperometric
Urea (BUN)	Enzyme/Amperometric
Creat	Enzyme/Amperometric

Calculated Tests

eGFR	A-aDO ₂	iCa/iMg Ratio
HCO ₃ ⁻	a/A	Normalized iCa
TCO ₂	PO ₂ /FIO ₂	Normalized iMg
BE ⁻ ecf	Anion Gap	Osmolality
BE ⁻ b	SBC	Hemoglobin
A	Base Excess	O ₂ Saturation

pH/PCO₂/PO₂, Corrected to Patient Temperature
Respiratory Index (If % FIO₂ value entered)
Actual Bicarbonate
Standard Bicarbonate

CO-Oximetry Tests

HHb, deoxyhemoglobin

O₂Hb, oxyhemoglobin

MetHb, methemoglobin

COHb, carboxyhemoglobin

tHb, total hemoglobin

SO₂%, oxygen saturation

Compact Size

Dimensions for Prime Plus, including CO-Oximetry and bidirectional connectivity:



Other Features

Full color, 10.1-inch touchscreen, multilingual, QC statistics, onboard data management, automatic sampler, integrated capillary adapter, optional barcode scanner, QC data storage, optional mobile cart with UPS

MicroSensor Card

60 µL Sample Volume

Electrical Power Requirement

< 90 Watts

Acceptable Samples

Whole blood (heparinized), arterial, venous, mixed venous
135 µL Sample draw requirement

Communication Protocols

ASTM, HL7, or POCT01-A2 connectivity formats
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Certifications and Compliance: Nova Biomedical is certified to FDA Quality System Regulations and EN ISO 13485:2016 Complies to IVDD Tested according to: EN 61010-1:2010, EN 61010-2-101:2015, EN 60825-1/A1:2014.
Specifications current as of revision date.



**Self-Declaration of Conformity To European Parliament and Council Directive 98/79/EC
In Vitro Diagnostic Medical Device Directive (IVDD)**

Product name: Nova Stat Profile Prime Analyzer System Family including Reagents, Calibrators and Controls

Catalog Numbers: List Attached (two pages)

Classification: Other/General

Near Manufacturer: Nova Biomedical Corporation
200 Prospect Street
Waltham, MA 02454 USA

Representative: William Jacques, Director of Regulatory and Quality

Authorized Representative: Nova Biomedical GmbH
Hessenring 13 A, Geb. G
64546 Mörfelden-Walldorf
Germany
Tel: +49 6105 4505-0

Conformity Assessment Route: Annex III

Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained under the premises of the manufacturer.

Nova Biomedical, Inc. declares that the electronic products listed are in conformity with the provisions of the Council Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Standards Applied:

- EN ISO 13485:2016 Medical devices. Quality management systems. Requirements for regulatory purposes
- EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
- EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use -Part 1: General requirements
- EN 61010-2:101:2015 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Signature: 
William Jacques, Director of Regulatory and Quality



Date: Jul/22/2020

List of Catalog items covered:

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code
14631	Power Cord Int 230V	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
38846	Nova Biomedical Capillary Tube Clot Catcher	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
38883	Stat Profile Critical Care Xpress Syringe Clot Catcher	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42032	Prime Sensor Card CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42033	Prime Sensor Card CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42043	Prime Reference Cartridge	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52484	Prime Pump Harness	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52582	Prime Probe S Line 100 ul	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52616	Prime Tubing L1 L2 L3	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52617	Prime Tubing Harness ABG/CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52669	Prime Safety Sample Port 5 Pk	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52703	Prime Acc Pack	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52856	Prime CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
52857	Prime CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53418	Remanufactured Prime CCS	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53420	Remanufactured Prime CCS Comp	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53656	Prime CCS w/Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53657	Prime CCS Comp w/Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53666	Remanufactured Prime CCS w/ Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
53667	Remanufactured Prime CCS Comp w/ Scanner	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
55263	Prime Sensor Card CCS (High Volume)	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
55264	Prime Sensor Card CCS Comp (High Volume)	56672	Point-of-Care blood gas/haemoximetry analyser IVD	21-02-02
42031	Prime Sensor Card ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
52855	Prime ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53421	Remanufactured Prime ABG	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53655	Prime ABG w/ Scanner	56671	Point-of-Care blood gas analyzer IVD	21-02-02
53665	Remanufactured Prime ABG w/ Scanner	56671	Point-of-Care blood gas analyzer IVD	21-02-02
55262	Prime Sensor Card ABG (High Volume)	56671	Point-of-Care blood gas analyzer IVD	21-02-02
25217	Linearity Standard Set A Levels 1,2,3,4 Multipack	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
55229	Nova Linearity Level 1,2,3,4	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
56198	Linearity Standard Set G Multipack	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-90-00

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code
45150	Prime Auto QC Cartridge CCS 200 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52714	Prime Ampuled Control ABG/CCS	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52864	Prime Auto QC Cartridge CCS 300 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53107	Prime Auto QC Cartridge ABG 200 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53108	Prime Auto QC Cartridge ABG 300 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53455	Prime Auto QC Cartridge CCS 100 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
53456	Prime Auto QC Cartridge ABG 100 Sample	52860	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	11-50-90-01-00
52427	Prime Calibrator Cartridge CCS Comp 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52861	Prime Calibrator Cartridge CCS Comp 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52862	Prime Calibrator Cartridge CCS 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52863	Prime Calibrator Cartridge CCS 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53104	Prime Calibrator Cartridge ABG 100 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53105	Prime Calibrator Cartridge CCS Comp 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53359	Prime Calibrator Cartridge ABG 300 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53360	Prime Calibrator Cartridge ABG 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53364	Prime Calibrator Cartridge CCS 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53365	Prime Calibrator Cartridge CCS Comp 200 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53463	Prime Calibrator Cartridge ABG 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53464	Prime Calibrator Cartridge ABG 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53465	Prime Calibrator Cartridge ABG 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53466	Prime Calibrator Cartridge CCS 400 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53467	Prime Calibrator Cartridge CCS 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53468	Prime Calibrator Cartridge CCS 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53469	Prime Calibrator Cartridge CCS Comp 500 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
53470	Prime Calibrator Cartridge CCS Comp 600 Sample	52859	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	11-04-04-03-00
52865	Stat Profile Prime Calibrator Flush Fixture	56672	Point-of-Care blood gas/haemoximetry analyzer IVD	21-02-02