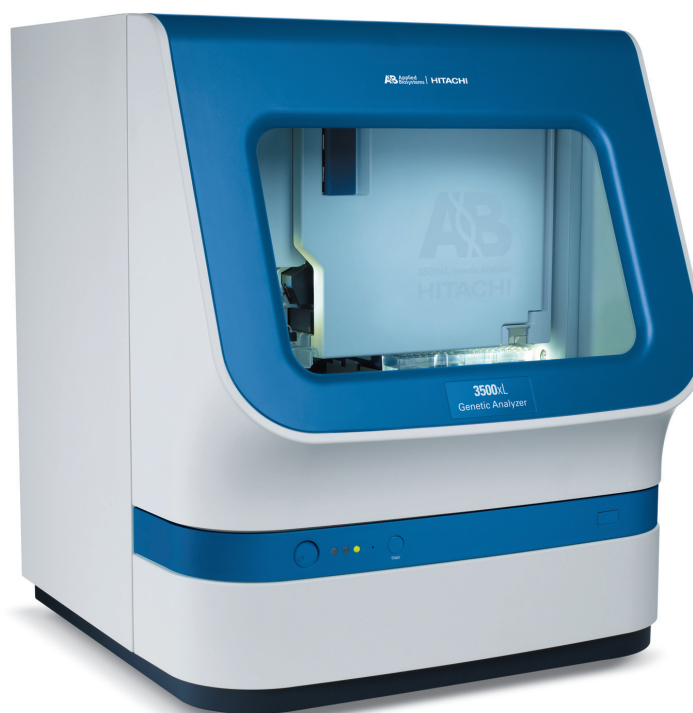


Applied Biosystems 3500 and 3500xL Genetic Analyzers

Key Features

- 8-capillary 3500 System and 24-capillary 3500xL System
- Advanced thermal system design improves temperature control for demanding DNA fragment analysis applications
- Single-line 505 nm, solid-state long-life laser—utilizes a standard power supply; requires no heat-removal
- Significantly improved signal uniformity from instrument-to-instrument, run-to-run, and capillary-to-capillary
- Powerful, integrated data collection and primary analysis software provide real-time assessment of data quality
- Radio Frequency Identification (RFID) technology tracks key consumables data and records administrative information
- Advanced multiplexing capabilities for DNA fragment analysis with up to six unique dyes
- Unrivaled application flexibility—one array and one polymer are used for most applications
- Simple setup, operation, and maintenance—the easiest-to-run, easiest-to-own, DNA sequencer to date



Overview

Applied Biosystems sets a new standard in capillary electrophoresis with the 8-capillary 3500 and 24-capillary 3500xL Genetic Analyzers. The 3500 Series Genetic Analyzers¹ are specifically designed to support the demanding performance needs of validated and regulated environments while retaining the unsurpassed application versatility that life science researchers expect from Applied Biosystems.

System Components

The Applied Biosystems 3500 and 3500xL Genetic Analyzers are supplied as follows:

- Capillary electrophoresis instrument
- 8-capillary (3500 system) or 24-capillary (3500xL system) array and polymer
- DNA Sequencing and/or Fragment Analysis, reagents and consumables for system qualification

1. For Research Use Only. Not for use in diagnostic procedures.

- Dell computer workstation with flat-screen monitor
- Integrated software for instrument control, data collection, quality control, and auto-analysis of sample files for basecalling and fragment sizing

System Consumables

Applied Biosystems provides the following consumables for use on the 3500 Series System:

- **Capillary Arrays:** The internally uncoated capillaries are supplied in assemblies of 8 or 24 capillaries per array, with a built-in frame for easy installation. Arrays are available in 36 cm and 50 cm capillary lengths to support multiple applications and run methodologies. The 50 cm array has been optimized for many applications for use with POP-7™ polymer and specific run modules. This simplifies user selection and provides run times

approximately equivalent to those observed with previous-generation systems using the 36 cm array. The 3500 and 3500xL capillary arrays are specified for 160 injections.

- **POP-7™, POP-6™ and POP-4™**

Performance Optimized Polymers:

The 3500 and 3500xL POP-7™, POP-6™, and POP-4™ polymers are designed in ready-to-use, load-and-run pouches. POP polymers are available in two sizes, 384 samples (a maximum of 60 injections on the 3500 system or 20 injections on the 3500xL system) and 960 samples (a maximum of 120 injections on the 3500 system or 50 injections on the 3500xL system). The pouch has adequate polymer to support the stated number of samples or injections, plus additional volume for initial setup and installation operations. Most applications may be run with POP-7™ polymer, along with the 50 cm array.

- **Buffers and Conditioning Reagent Consumables:** Similar to the 3500 system polymer pouches, the 3500 Series Genetic Analyzer Cathode Buffer, Anode Buffer, and Conditioning Reagent are designed for ready-to-use, load-and-run installation. Consumable containers are disposed of when the maximum number of samples has been processed.

- **Cathode Buffer Container (CBC):** Pre-filled container with 1X Buffer to support all electrophoresis applications. The container has two separate compartments; the left side contains the cathode buffer for electrophoresis, and the right side contains spent polymer waste from the capillary wash between injections. The CBC is specified to be used on the instrument for up to 7 days after first installation (or a maximum of 120 injections on the 3500 system,

TABLE 1. Sequencing Throughput and Performance Specifications

Run Module	Throughput			Configuration		Performance	
	Average Run Time (Minutes)	Average Throughput, 3500xL (Samples/Day)	Average Throughput, 3500 (Samples/Day)	Array Separation Distance (cm)	Polymer Type	Median Bases Collected in 90% of Samples	KB QV20 CRL in 90% of Samples
RapidSeq50_POP7	≤40	≥840	≥280	50	POP-7™	≥600	≥500
StdSeq50_POP6	≤135	≥240	≥80	50	POP-6™	≥700	≥600
FastSeq50_POP7	≤65	≥504	≥168	50	POP-7™	≥750	≥700
StdSeq50_POP7	≤125	≥264	≥88	50	POP-7™	≥1,000	≥850
ShortReadSeqPOP7	≤30	≥1,104	≥368	50	POP-7™	≥325	≥300
MicroSeq_POP7	≤125	≥264	≥88	50	POP-7™	≥1,000	≥850
MicroSeq_POP6	≤135	≥240	≥80	50	POP-6™	≥700	≥600
RapidSeq_BDX_50_POP7	≤40	≥840	≥280	50	POP-7™	≥600	≥500
StdSeq_BDX_50_POP6	≤140	≥240	≥80	50	POP-6™	≥700	≥600
FastSeq_BDX_50_POP7	≤65	≥504	≥168	50	POP-7™	≥750	≥700
StdSeq_BDX_50_POP7	≤125	≥264	≥88	50	POP-7™	≥1,000	≥850
ShortReadSeq_BDX_POP7	≤30	≥1,104	≥368	50	POP-7™	≥325	≥300

1. The specifications are reported using long-read Sequencing Standard.

2. Throughput (Samples/Day) is determined by the total number of samples that can be run in 23 hours (allows time for sample preparation, instrument maintenance, and warm-up).

3. QV20 CRL is defined as the longest uninterrupted segment of bases with an average of QV≥20, calculated over a sliding window of 21 base pairs.

4. The fast ShortReadSeq module collects 300 bp in 30 minutes for operations requiring short verification of sequence content, e.g., clone QC verification.

5. BDX classified run modules are optimized with the 3500 Series Systems to obtain more usable data when sequencing reactions are purified using the BigDye® X Terminator™ purification kit.

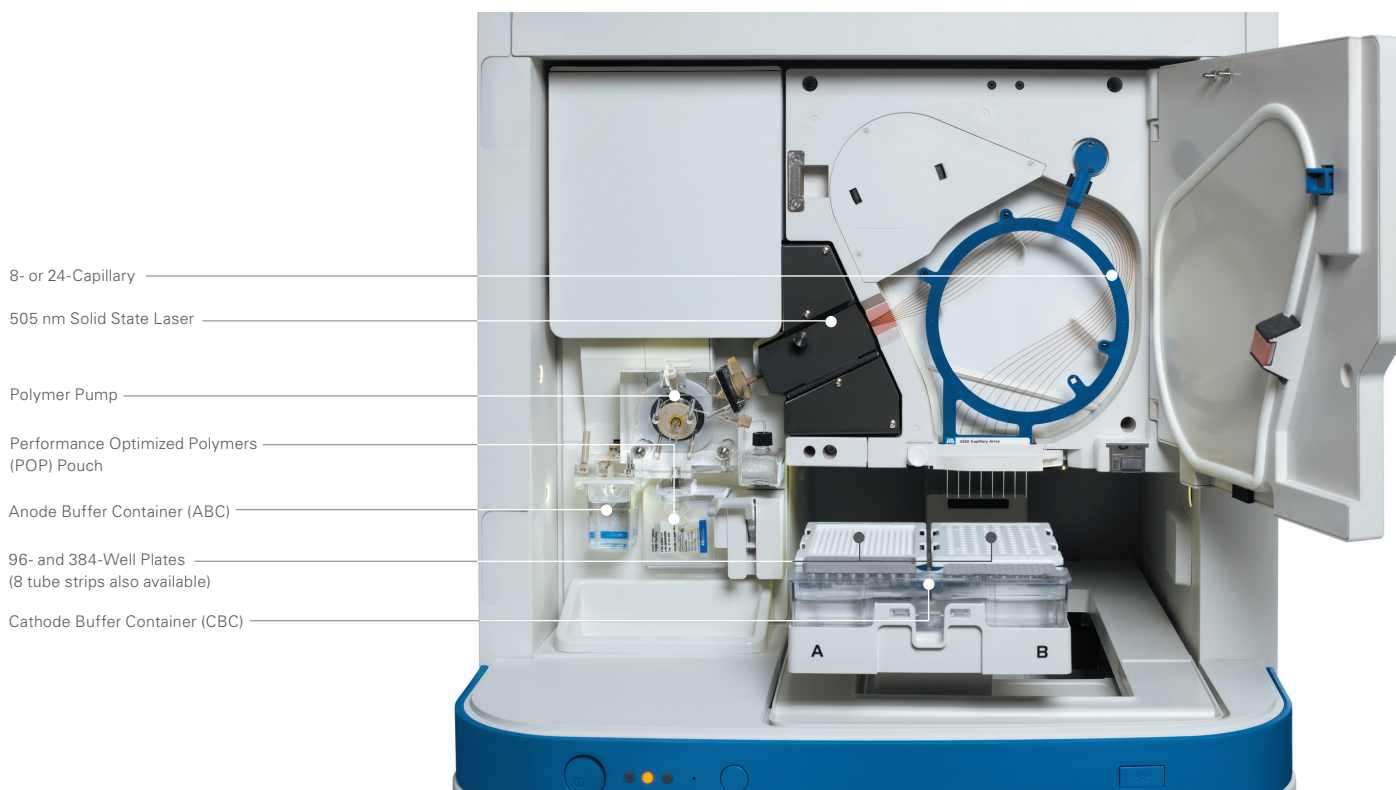


TABLE 2. Fragment Analysis Throughput and Performance Specifications

Module Name	Throughput			Configuration	
	Average Run Time (Minutes)	Average Throughput, 3500xL (Samples/Day)	Average Throughput, 3500 (Samples/Day)	Array Separation Distance (cm)	Polymer Type
FragAnalysis50_POP7	40	≥840	≥280	50	POP-7™
FragAnalysis50_POP6	100	≥336	≥112	50	POP-6™
LongFragAnalysis50_POP7	125	≥264	≥88	50	POP-7™
HID36_POP4	35	≥936	≥312	36	POP-4™
HID36_POP7	26	≥1,272	≥424	36	POP-7™
SNaPshot50_POP7	30	≥1,104	≥376	50	POP-7™

1. Throughput (Samples/Day) is determined by the total number of samples that can be run in 23 hours (allows time for sample preparation, instrument

2. Resolution Range is defined as the range of bases over which the peak spacing interval divided by the peak width at half peak height is greater than 1.

3. Sizing Precision is the standard deviation of sizes for a given allele size across all capillaries in the same run.

4. Multirun Sizing specification is a measure of the precision of the 3500 across multiple runs. For example, it would be expected that a 200 bp allele across

50 injections on the 3500xL system, whichever comes first).

- Anode Buffer Container (ABC):

Pre-filled container with 1X Buffer to maintain a source of ions and the correct pH for electrophoresis. The ABC is specified to be used on the instrument for up to 7 days after first installation (or a maximum of 120 injections on the 3500 system, 50 injections on the 3500xL system, whichever comes first).

- The Cathode and Anode Buffer Containers are made from a recyclable plastic material, reducing the systems' impact on the environment. **Note:** The containers are marked with the #7 recycling symbol (Other – polycarbonate). Follow your local regulations for proper disposal.

- Conditioning Pouch: Pre-filled pouch with a conditioning reagent used for priming the polymer pump, washing the pump between polymer type changes, and during instrument shut down. The pouch has sufficient volume for a one-time use.

Radio Frequency Identification (RFID) Labeling

The 3500 Series Systems incorporate RFID labels on all capillary arrays, polymer pouches, buffer containers, and conditioning pouches. These labels allow for tracking and reporting of consumable usage, lot and part numbers, expiration dates, and on-instrument life time. The tracked consumables data are stored and retrievable from the 3500 Series Data Collection Software even if the consumable is removed from the instrument.

Instrument Normalization Reagent

The GeneScan™ 600 LIZ® Size Standard v2 is specially formulated for dual-purpose use on the 3500 Series Systems. The reagent may be used as a size standard for DNA fragment sizing applications. In addition, the reagent can be used as a normalization standard by enabling the normalization feature in the Data Collection Software. The 3500 Series Systems, working together with the GeneScan™ 600 LIZ® Size Standard v2 (and specific normalization software features), minimize instrument-to-instrument, run-to-run, and capillary-to-capillary variation.

Reagents

Reagents Available for use with the 3500 Series Genetic Analyzers:

- BigDye® Terminator v1.1 and 3.1 Cycle Sequencing Kits



Performance							
General		Sizing Precision of 100% of Alleles in ≥90% of Samples			Multirun Sizing of 100% of Alleles in ≥90% of Samples		
Resolution Range in ≥90% of Samples	Largest Fragment Collected in ≥90% of Samples	50–400 bp	401–600 bp	601–1,200 bp	50–400 bp	401–600 bp	601–1,200 bp
≤40 to ≥520	≥600	<0.15	<0.30	NA	<1 bp	<2 bp	NA
≤20 to ≥550	≥600	<0.15	<0.30	NA	<1 bp	<2 bp	NA
≤40 to ≥700	≥1,200	<0.15	<0.30	<0.45	<1 bp	<2 bp	<3 bp
≤60 to ≥400	≥420	<0.15	NA	NA	<1 bp	NA	N/A
≤60 to ≥400	≥420	<0.15	NA	NA	<1 bp	NA	NA
≤40 to ≥120	≥120	<0.50	NA	NA	<1 bp	NA	NA

maintenance, and warm-up).

3 runs would have an average deviation of <1 bp in 90% of all samples.

- GeneScan™ LIZ® Size Standards
- GeneScan™ ROX™ Size Standards
- Application-specific kits

System Software

• Primary Analysis with 3500 Series Data Collection Software

The Applied Biosystems 3500 and 3500xL Genetic Analyzers include Data Collection Software with a simple user interface and clean design for easy display of consumable and array usage information, quick-start functionality, system maintenance reminders, and several convenient features. Basecalling and fragment sizing functionalities are performed within the primary Data Collection Software allowing for real-time data quality evaluation. An optional upgrade provides security, audit, and eSig features to assist laboratory compliance with 21 CFR Part 11 requirements.

• Secondary Analysis Software Options

- Sequencing Analysis Software v5.4 with KB™ Basecaller v1.4.1— for sequence base call editing, re-basecalling, reporting, and printing
- Variant Reporter™ Software v1.1—for mutation detection SNP discovery, comparative sequencing, resequencing, validation, and sequence confirmation
- SeqScape® Software v2.7— for resequencing applications with library identification
- GeneMapper® Software v4.1— for microsatellite, LOH, SNP, MLPA, AFLP, and t-RFLP analyses
- GeneMapper® ID-x Software v1.2— for analysis of Human Identification data using AmpFℓSTR® kits
- MicroSEQ® ID Analysis Software v2.2—for microbial sequence typing using MicroSEQ® Kits

3500 System Operating Specifications

Laser

Long-life, single-line 505 nm, solid-state laser excitation source

Electrophoresis Voltage

Up to 20 kV

Oven Temperature

Active temperature control from 18°C to 70°C

Minimum Computer Requirements

Hardware: Pentium® IV 1.86 GHz Processor

Operating system: Windows® Vista SP1

Installed RAM: 2 GB

Hard Drive: 1X 80 GB 7200 RPM SATA 3.0GB/s and 8 MB Data Burst Cache

Operating Environment

Temperature: 15°C–30°C

(Room temperature should not fluctuate more than ±2°C during an instrument run)

Humidity: 20–80% (non-condensing)

Main Power Voltage

100–240 V ±10%

50–60 Hz ±10%

Current

Maximum: 15 A

Maximum Power Dissipation

417 VA, 371 W (approximately, not including computer and monitor)

Dimensions

Width (closed-door): 61 cm

Width (open-door): 122 cm

Depth: 61 cm

Height: 72 cm

Weight: 82 kg (approximately)

Service and Warranty

1-year limited warranty on parts and labor

Service installation

Application training

Sample Requirement

The 3500 Series Systems can analyze many types of templates prepared by a variety of sample preparation protocols. Samples are automatically injected directly

from 96- or 384-well* microtiter plates. The 3500 Series Systems are also designed for use with 96-well Fast and 8-tube standard or Fast strips.

* The 3500xL Genetic Analyzer is compatible with 384-well plates.

ORDERING INFORMATION

3500 Series System Packages

		3500	3500xL
Package Name	Description	P/N	P/N
3500 Series Genetic Analyzer for Resequencing & Fragment Analysis	3500 Series System with Data Collection Software, Sequencing Analysis, Variant Reporter™, and GeneMapper® Software packages. System package also includes DNA Sequencing and Fragment analysis reagent kits for system qualification.	4440462	4440463
3500 Series Genetic Analyzer for Resequencing & Fragment Analysis With SAE	3500 Series System with Data Collection Software (includes additional functionality for Security, Audit Trail, and Electronic Signature (SAE) capabilities), Sequencing Analysis, Variant Reporter™, and GeneMapper® Software packages. System package also includes DNA Sequencing and Fragment analysis reagent kits for system qualification.	4440464	4440465
3500 Series Genetic Analyzer for Resequencing	3500 Series System with Data Collection Software, Sequencing Analysis, and Variant Reporter™ Software packages. System package also includes DNA Sequencing reagent kits for system qualification.	4440466	4440467
3500 Series Genetic Analyzer for Fragment Analysis	3500 Series System with Data Collection Software and GeneMapper® Software. System package also includes DNA Fragment Analysis reagent kits for system qualification.	4440468	4440469
3500 Series Genetic Analyzer for Sequence Typing & Fragment Analysis	3500 Series System with Data Collection Software, Sequencing Analysis, SeqScape®, and GeneMapper® Software packages. System package also includes DNA Sequencing and Fragment analysis reagent kits for system qualification.	4440470	4440471

System Consumables and Reagents

Description	P/N
3500xL Capillary Array (50 cm)	4404689
3500 Capillary Array (50 cm)	4404685
3500 POP-7™ Polymer (960 samples)	4393714
3500 POP-7™ Polymer (384 samples)	4393708
Anode Buffer Container (ABC) 3500 Series	4393927
Cathode Buffer Container (CBC) 3500 Series	4408256
Septa Cathode Buffer Container 3500 Series	4410715
Conditioning Reagent 3500 Series	4393718
Hi-Di™ Formamide (5 mL) 1 bottle	4401457
BigDye® Terminator v3.1 Cycle Sequencing Kit (1,000 rxns)	4337456
BigDye® XTerminator™ Purification Kit (1,000 rxns)	4376487

Visit www.AppliedBiosystems.com/3500Series or contact your local Sales Representative for more information.

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For those who require IVD-marked devices, the 3500 Dx and 3500xL Dx Genetic Analyzers and system accessories meet the requirements of the In Vitro Diagnostics Medical Devices Directive (98/79/EC). The 3500 Dx and 3500xL Dx systems are for distribution and use in specific European countries only. For more information about the 3500 Dx Series Systems, contact your Applied Biosystems representative. The purchase price of this Instrument includes a grant of a limited, non-transferable license under U.S. Patent No. 5,567,292 and method claims of its foreign counterparts, and under U.S. Patent No. 6,358,385 and element claims of its foreign counterparts, to use this particular instrument for electrophoresis methods employing fluorescence as a means of detection. No other licenses or rights are hereby conveyed either expressly, by implication, or estoppel including, but not limited to, any claims to a composition. This instrument incorporates technology subject to one or more patents licensed from Hitachi, Ltd. as well as patents and patented technology owned by or under control of Applied Biosystems. This instrument is Authorized for use in DNA sequencing and fragments analysis only. This Authorization is included in the purchase price of the instrument and corresponds to the up-front fee component of a license under process claims of U.S. Patent Nos. 5,821,058 and 5,332,666 and under all process claims for DNA sequence and fragment analysis of U.S. patents now or hereafter owned or licensable by Applied Biosystems for which an Authorization is required, and under corresponding process claims in foreign counterparts of the foregoing for which an Authorization is required. The running royalty component of licenses may be purchased from Applied Biosystems or obtained by using Authorized reagents purchased from Authorized suppliers in accordance with the label rights accompanying such reagents. Purchase of this instrument does not itself convey to the purchaser a complete license or right to perform the above processes. This instrument is also licensed under U.S. Patent No. 5,171,534 and apparatus and system claims in foreign counterparts thereof. No rights are granted expressly, by implication, or by estoppel under composition claims or under other process or system claims owned licensable by Applied Biosystems. For more information regarding licenses, please contact the Director of Outlicensing at Applied Biosystems, 850 Lincoln Centre Drive, Foster City, California 94404, USA.

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