

ThermoFisher SCIENTIFIC

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RE: Sole Source Supplier Applied Biosystems™ Instruments, Consumables and Software

Dear Valued Customer:

Thank you for your interest in Thermo Fisher Scientific's Applied Biosystems™ brand of instruments, software and consumables. Please accept this letter to document that Thermo Fisher Scientific is the sole manufacturer and distributor of the Applied Biosystems Genetic Analyzers (models 3130, 3130xL, 3500, and 3500xL), real time thermal cyclers (models 7500 and QuantStudio 5), thermal cyclers (models 9700, Veriti, and ProFlex) and associated software (including 3500/3500xL Data Collection Software, GeneMapper ID-X, and HID Real-Time PCR Analysis).

Each Genetic Analyzer and real time PCR thermal cycler contains a laptop/desktop that is customized to operate the system and is compatible with our data collection software. The computer attached to these systems is imaged specifically for Thermo Fisher Scientific and is not available from another source.

The Applied Biosystems Genetic Analyzers are the only commercially available four, eight, sixteen or twenty-four capillary systems in the world that have been validated by the forensics community to analyze DNA samples for the purpose of Human Identification. Thermo Fisher Scientific is the sole distributor of capillaries and replacement parts required by Applied Biosystems genetic analyzers. Only Thermo Fisher Scientific factory trained and certified engineers are authorized to service these instruments.

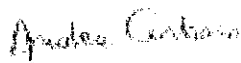
Further documentation describing the unique specifications of the Applied Biosystems brand of genetic analyzers and thermal cyclers can be found on the Thermo Fisher Scientific website, including user manuals.

In addition to Applied Biosystems instruments and software, Thermo Fisher Scientific is the sole manufacturer of all Applied Biosystems consumables, including the Globalfiler, Yfiler Plus, Quantifiler Duo, Human and Trio kits.

This information should justify Thermo Fisher as "Sole Source" supplier for all Applied Biosystems instruments, software, consumables and services that you need to perform DNA Analysis, for the purpose of Human Identification.

We appreciate your business and request that if you have any further questions that you contact me directly.

Regards,

A handwritten signature in cursive script that reads "Andrea Carbonaro".

Andrea Carbonaro, Ph.D.
Director, Product Management
Human Identification Business

Applied Biosystems
Veriti™ Thermal Cycler
DIFFERENTIATING FEATURES

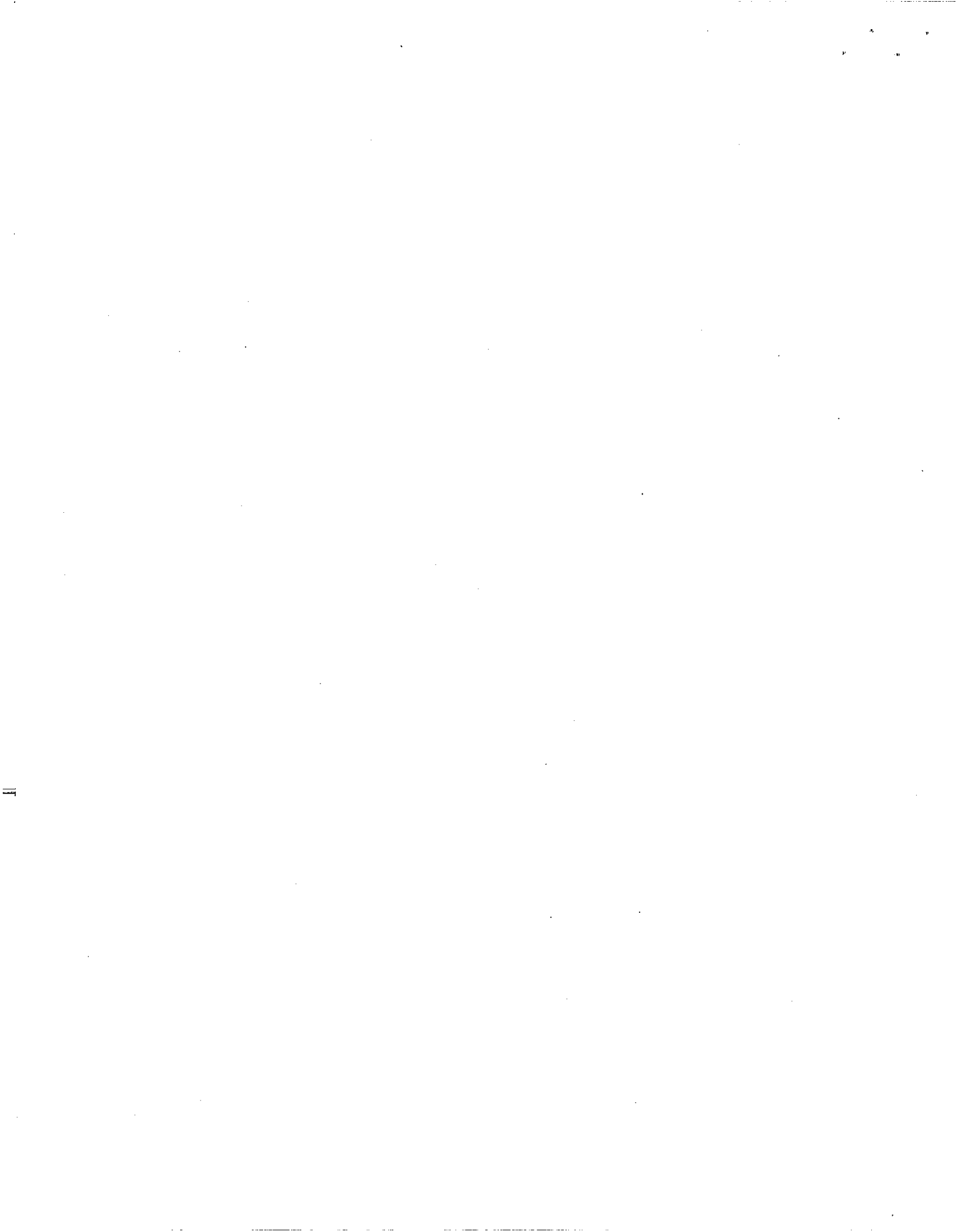
1. The instrument is designed for controlling the times and temperatures required for the polymerase chain reaction (PCR) process for nucleic acid amplification.
2. The instrument is available in one of 4 formats. 96-well Fast 0.1mL, 96-well 0.2mL, 384-well or 60-well 0.5mL.
3. The 96-well Fast 0.1mL and 96-well 0.2mL format instruments will each have at least 6 separate Peltier-controlled blocks. Each of the 6 blocks can be set to a different temperature during any temperature hold step.
4. The 384-well or 60-well 0.5mL systems are single block systems for independent protocol control.
5. The instrument is designed with a sample cover that heats the top half of the sample tubes and caps so to eliminate the need for oil overlays in the sample tubes.
6. Sample cover temperature is adjustable and it must press down equally on all tubes.
7. Sample Temperature Uniformity across the sample block is designed to be +/-0.5°C, 10 seconds after the clock starts at 95° C.
8. The system must be self-contained for heating and cooling and has no external requirements for refrigeration. The temperature range is designed to be between 4.0° C and 99.9° C settable to 0.1° C. Times must be settable to 1 second.
9. The instrument is controlled by a high- performance microprocessor within the instrument.
10. When heating and cooling, the displayed sample temperature is designed to show less than 0.5° C overshoot for up ramps and down ramps. The displayed temperature is the calculated sample temperature and it is this temperature which starts the Hold Segment clock.
11. The instrument has a touch-screen for ease-of-use. The touch-screen must be at least 6.5" with full VGA (260k) TFT color resolution which graphically shows the PCR method being programmed or ran.
12. The instrument has a safety feature that is designed to indicate to the user when the sample block is above 50° C.
13. The instrument has a safe memory for 800+ PCR methods.
14. PCR methods is stored in folders for easy organization and access.
15. The instrument is designed to control security levels for accessing each folder. The security scheme involves usernames and passwords.

Password protection can also be turned off under the Administrative setting.

16. The instrument is designed to show run-time data and status messages stored in a Log File that is viewable on the display and printable at the end of each PCR method run. Run-time data is display the method name, the time the method started and the total run time of the method.
17. The instrument software is designed to allow for instrument system diagnostic tests to be performed.
18. The instrument software is designed to allow the programming of time and temperature HOLDS in a PCR CYCLE with an INSERT function to allow further HOLDS and CYCLES.
19. The instrument software is designed to allow programming an Auto-Delta program, which can increment and decrement set-point times and/or temperatures by a fixed amount every cycle.
20. The instrument software is designed to allow programming variable up-ramp and down-ramp temperature rates.
21. The instrument software is designed to allow programming pauses within a method, which can be manually executed or programmed as infinite hold steps.
22. The instrument software is designed to allow the user to view the current step of the PCR method which is running. The graphical user interface is designed to show a high-lighted bar as the temperature increases or decreases.
23. The instrument has an Ethernet port for connecting to a printer or networking together to other instruments. The instrument has a USB interface that can be used for any future software upgrades or transporting methods.
24. Up to 12 instruments can be networked together such that from any instrument, a method can be started simultaneously at any of the 12 networked instruments.
25. Instrument is designed to transfer protocols from one instrument to another using a USB memory stick.
26. The instrument software is designed to allow the downloading/uploading, editing or creating of methods during a PCR method run.
27. The vendor supplies all the necessary disposables to perform PCR. Disposables must be available in a variety of colors.
28. The instrument is UL approved. The instrument is manufactured to ISO 9001 standards and temperatures calibrated to standards traceable to NIST and the vendor offers a suitable Temperature Verification Kit,

which is also calibrated to standards traceable to NIST (National Institute for Standards and Technology, U.S.).

29. The vendor provides a warranty for a limited two years from receipt of instrument. All repairs is be performed by factory trained service engineers. Optional service contracts after warranty period must also be offered.
30. Instrument must ship with a start up kit of disposables plus a User's Manual and Quick Reference Guide.



Differentiating Features and Benefits of the Applied Biosystems HID Real-Time PCR Analysis Software v1.3 (P/N: A31150, A31153, A31152, A31154)

The HID Real-Time PCR Analysis software v1.3 integrates both the HID validated Quantifiler Real Time PCR systems QuantStudio 5 and 7500 into one convenient software package.

The software is an essential component of the Applied Biosystems Quantifiler DNA sample quantitation and assessment solution, which includes the QuantStudio 5 system and 7500 instrument, HID Real-Time PCR Analysis Software, and Quantifiler Kits.

The software includes the following key features and benefits:

- Flexibility of the virtual Standard curve feature which allows the user to input standard curve values (slope and y-intercept), therefore eliminating the need for an in-plate standard curve dilution series
- Dynamic analysis workflow allowing for initial or re-analysis with in-plate standards and/or a virtual standard curve to calculate quantity.
- Accessibility to the library of different VSC files to support different Quantifiler kits, qPCR instruments, kit lots and analysis and re-analysis pipelines.
- Easy to navigate user interface and specially designed Quantifiler assay templates dramatically streamline the DNA quantification workflow
- Intuitive software design that supports a one-click step to switch between the two supported platforms (QuantStudio 5 System and the 7500 Instrument)
- Human Identification (HID) specific quality flags and analysis summary allow users to quickly assess the DNA sample quality and identify samples that need further review
- Degradation Index, M: F Ratio and IPCCT flags guide users in downstream Applied Biosystems PCR Amplification Kit selection as well workflow selection to go NGS or CE route.
- Dilution Calculation and Applied Biosystems Kit Reaction Setup Tools speed up STR analysis workflow
- Configurable reporting function allows users to select desired information to be added to the exportable or printable report
- Step-by-step wizard-based calibration instructions and automated calibration analysis simplifies the calibration process and minimizes the need for time consuming manual calibration analysis
- Easy switch between HID Quantifiler Assay and Custom Assay mode provides users maximum flexibility (supported only on 7500 Instrument)

- Multiple licensing options with single user or five user license package.
- Easy upgrade options available for customers on HID Real Time SW v1.2
- Validated for HID Quantifiler kits Trio, Duo, Human Plus and Human on both 7500 and QuantStudio 5 platform.

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Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System for Human Identification differentiating features

Instrument Model Number: Applied Biosystems QuantStudio 5 Real-Time PCR System for Human Identification

Instrument Description: The QuantStudio 5 Real-Time PCR System for Human Identification (HID) is the latest addition to Applied Biosystems HID quantification solutions. This instrument is designed for both new and experienced users who need a simple, reliable and affordable real-time PCR system that does not require compromise on performance or quality. Used with our latest advances in quantification chemistry and HID real-time PCR software to provide a sensitive, robust solution for forensic DNA quantification. It also helps prepare laboratories for future quantification technologies. Going beyond the Applied Biosystems 7500 Real-Time PCR System, with a 6 dye maximum versatility; this HID solution offers accurate, trusted results in a small benchtop footprint.

Manufacturer: Life Technologies Corporation

Life Technologies is the sole manufacturer and vendor of the QuantStudio 5 Real-Time PCR System for human identification (Part Numbers A34321, A34322).

Technology overview

Real-Time PCR Overview

Polymerase Chain Reaction (PCR) is a powerful technology that amplifies DNA or cDNA targets up to a million-fold. Real-Time PCR amplifies the target in the presence of fluorescent dyes and the instrument captures the fluorescent signal in "real-time" to determine how many copies of DNA are present at each cycle. The ability of the real-time PCR instrument to monitor the amount of target that amplifies over the course of the run enables very precise, sensitive and accurate quantitative measurements to determine the number of starting copies in the reaction.

Real-Time PCR amplifies DNA exponentially, doubling the number of molecules present with each amplification cycle. The increase of fluorescent signal is directly proportional to the amount of PCR product generated in the exponential phase of the reaction. The number of cycles and the amount of PCR end-product can be used to calculate the initial quantity of genetic material by comparing the final quantity with a known standard.

Fluorescent reporters used include double-stranded DNA (dsDNA)-binding dyes, or dye molecules attached to PCR primers or probes that are incorporated into the product during amplification. By plotting fluorescence against the cycle number, the real-time PCR instrument generates an amplification plot that represents the accumulation of product over the duration of the entire PCR reaction.

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Real-Time PCR Applications

Real-Time PCR is very flexible and can be used for the following applications:

- Forensic Database
 - Laboratories without direct amplification workflows
- Forensic Casework
 - Confirmatory screening of male DNA
 - Sexual assault sample workflow
 - Quality and quantity sample assessment
- Gene Expression
- Genotyping
- Copy Number Variation
- miRNA profiling

Real-Time PCR Advantages

The advantages of real-time PCR over other methods include:

- The ability to monitor the progress of the PCR reaction as it occurs in real-time
- The ability to precisely measure the amount of amplicon at each cycle
- An increased dynamic range of detection compared to other nucleic acid detection methods
- The combination of amplification and detection in a single tube, which eliminates post-PCR manipulations

Over the past several years, real-time PCR has become the leading tool for the detection and quantification of DNA or RNA. Using these techniques, you can achieve precise detection that is accurate down to 1.5 fold range, and a dynamic range of up to 10 orders of magnitude. Because of the high quality data, Real-Time PCR is commonly used to verify the results of other nucleic acid analysis methods including microarray.

During the last two decades, real-time PCR has been leveraged within modern forensic laboratories. In particular, forensic laboratories use DNA Quantification for upfront decision support to streamline sample processing. Forensic quantification is undergoing a technological revolution driving lab instruments to become increasingly efficient, reliable, interactive, future-proof, and economical.

The QuantStudio 5 Real-Time PCR System for HID contains the following differentiating features and benefits:

Instrument

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1. The instrument excitation (light source) includes a long-lasting bright white LED (Light Emitting Diode) source that has a median lifetime greater than 5 years. The light source has a median lifetime of at least 60,000 hours.
2. The instrument is validated for use with HID Real-Time Software v1.3.
3. The instrument has whole-plate imaging data acquisition.
4. The instrument works in conjunction HID Real-Time Software, which allows for single plate run setup and analysis.
5. The instrument is sold with the option of a Tower or Laptop computer workstation.
6. The instrument can externally connect with a 2D barcode reader via USB port.
7. The instrument sample capacity is validated with a 0.2mL block 96-well plate configuration.
8. The instrument does not require a Field Service Engineer (FSE) visit for installation and can be set up directly out of the box by the end-user or with the on-site support of a Human Identification Field Application Specialist (FAS) Specialist included with instrument purchase.
9. The instrument is factory calibrated with FAM™, SYBR™ Green I, VIC™, NED, ABY, JUN, Mustang Purple, TAMRA, Cy5, and ROX™ dyes. In order to run the HID Trio and HP Assays; HID ABY and HID JUN Dyes will be delivered with each instrument and require calibration using a custom workflow upon installation.
10. The instrument's block is accessible from the front of the instrument to maximize bench space and is fully motorized.
11. The instrument's dimensions are 27 W x 50 D x 40 H cm, significantly smaller than the Applied Biosystems 7500 Real-Time PCR System, designed to maximize horizontal and vertical bench space.
12. The instrument is <26kg in weight, significantly lighter than the Applied Biosystems 7500 Real-Time PCR System
13. The instruments with a 96-well block are designed to analyze 96 samples simultaneously in any of the following formats: 96-well plate with optical adhesive cover. Strips and tubes are RUO options Not-validated for human identification)
14. The 96-well sample block is made up of at least 6 separate Peltier-controlled blocks (known as VeriFlex zones). The maximum temperature difference that can be programmed across the block is 25°C. The maximum difference in temperature allowed between adjacent blocks is 5°C.
15. The instrument is designed to support reaction volumes of 10µl to 100µl on the 0.2ml 96-well block.

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16. The instrument's melt curve or dissociation takes place in steps varying from $0.015^{\circ}\text{C} \leq \Delta T \leq 3.66^{\circ}\text{C}$
17. The instrument has a maximum block ramp rate of 6.5C/sec for the 0.2ml 96-well block.
18. The instrument block has a temperature range of $4^{\circ}\text{C} - 99.9^{\circ}\text{C}$.
19. The instrument heated cover has a temperature range of $50^{\circ}\text{C} - 110^{\circ}\text{C}$.
20. The instrument temperature uniformity is 0.4°C .
21. The instrument has IEC and CE electrical approvals.
22. The instrument meets the ISO 13485 international standard
23. The instruments uses a CMOS imager for data acquisition to collect data for each filter combination in <2 seconds.
24. The instrument can be used with 100V-240V without modification or special plug requirements.
25. The instrument includes a heated lid assembly that heats the top half of the sample plates and provides an effective seal to minimize reaction mixture evaporation.
26. The instrument can be connected to an online ecosystem and instrument data/status will be automatically uploaded (Not-validated for human identification)

Instrument On-Board Computer

27. The instrument touch screen interface enables viewing of amplification plots and filtering by Sample, Target, and Task.
28. Instrument's touch screen interface allows for downloading of run files using a USB interface.
29. The instrument contains on-board storage capability with memory capacity of 10GB for storing between 1000-5000 standard absolute quantification run files and is designed for run protection in case of network or power outage.
30. The instrument can be customized, through the touch screen, to include the correct time zone and service/calibration notifications settings.
31. Instrument's touch screen interface allows user to load run files from USB or LAN network

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32. Instrument's touch screen interface allows user to designate destination for completed run files to the USB port or on a LAN network
33. Instrument's touch screen interface allows user to perform dye calibrations and view results on the instrument touch screen.
34. Instrument's touch screen interface allows user to perform an RNaseP Verification plate run and automatically provide Pass/Fail results.
35. Instrument's touch screen interface allows user to Backup and Restore data and settings.
36. Instrument's touch screen interface allows user to run a Self-Verification Test.
37. The instrument can run in standalone mode, without a computer attached. (Not-validated for human identification)
38. The instrument also a Power Recovery function, giving the choice to continue a run if power was interrupted for less than 1hr. Not-validated for human identification)

Performance

39. The instrument has a dynamic range of 10 logarithmic units.
40. The instrument can detect changes as little as 1.5-fold in target quantities in a singleplex reaction
41. The instrument runtime is ~70 minutes for Applied Biosystems™ Quantifiler™ Trio and HP kits ~100 min for Applied Biosystems™ Quantifiler™ Duo and human kits
42. The instrument includes an OptiFlex System which combines 6 decoupled excitation and emission filter sets to enable collection of up to 21 unique combinations of wavelengths during a single run for multiplexing on the 96-well block instrument.
43. The instrument has real-time quantitative PCR installation specifications which demonstrate the ability to distinguish between 5,000 and 10,000 template copies with a 99.7% confidence level.

Software

44. The HID Real-Time PCR Analysis software v1.3 integrates both the HID validated Quantifiler Real Time PCR systems QuantStudio 5 and 7500 into one convenient software package. It's also the only commercially available Real-Time PCR analysis software designed specifically for the Human Identification marketplace.

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45. The software is an essential component of the Applied Biosystems' Quantifiler DNA sample quantitation and assessment solution, which includes the Quant Studio 5 system and 7500 instrument, HID Real-Time PCR Analysis Software, and Quantifiler Kits.

The software includes the following key features and benefits:

- Flexibility of the virtual Standard curve feature which allows the user to input standard curve values (slope and y-intercept), therefore eliminating the need for an in-plate standard curve dilution series
- Easy to navigate user interface and specially designed Quantifiler® assay templates dramatically streamline the DNA quantification workflow
- Intuitive software design that supports a one-click step to switch between the two supported platforms (QuantStudio 5 System and the 7500 Instrument)
- Human Identification (HID) specific quality flags and analysis summary allow users to quickly assess the DNA sample quality and identify samples that need further review
- Degradation Index, M: F Ratio and IPCCT flags guide users in downstream Applied Biosystems® PCR Amplification Kit selection as well workflow selection to go NGS or CE route.
- Dilution Calculation and Applied Biosystems® Kit Reaction Setup Tools speed up STR analysis workflow
- Configurable reporting function allows users to select desired information to be added to the exportable or printable report
- Step-by-step wizard-based calibration instructions and automated calibration analysis simplify the calibration process and eliminate the need for time consuming manual calibration analysis
- Easy switch between HID Quantifiler® Assay and Custom Assay mode provides users maximum flexibility (supported only on Applied Biosystems 7500 Real-Time PCR System for Human Identification)

Design

46. The instrument is cUL (tested to CAN/CSA standards), UL, CE, C-TICK, WEEE compliant.

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47. The instrument is developed and manufactured in accordance with quality system requirements that comply with ISO 13485 standards.

Vendor Service and Support

48. Instrument calibration required is less frequent (every 2 years) in comparison to the Applied Biosystems 7500 Real-Time PCR System for Human Identification.
49. The instrument is provided with a limited warranty for a period of one year from the date of installation (or fifteen months from the date of shipment – whichever is earlier). Optional post-warranty service contracts including next-business-day on-site repairs are available.
50. The instrument is provided with a one-day installation training session by a Human Identification FAS (Field Application Specialist).
51. Vendor is able to supply all the necessary consumables to perform real-time quantitative PCR and SNP genotyping, including PCR reagents designed for use with the fluorogenic 5' nuclease assay, PCR reagents designed for use with SYBR® Green I dye assay chemistry, fluorogenic probes, reaction plates and adhesive plate sealing covers. PCR reagents are also available with an optional passive internal reference ROX dye to minimize well-to-well variability.
52. Vendor provides comprehensive assay design and development guidelines for real-time quantitative PCR and SNP genotyping assays.
53. Vendor offers Telephone Technical Support and Field Applications/Sales/Service Support to help solve software, chemistry and instrumentation problems.

