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# Instrument Source and Specifications—QuantStudio 5 Dx Real-Time PCR System

**Instrument model:** Applied Biosystems™ QuantStudio™ 5 Dx Real-Time PCR System
(Cat. Nos. A47326, A47327)

**Intended use:** The QuantStudio 5 Dx Real-Time PCR System is an *in vitro* diagnostic device intended to perform fluorescence-based PCR to provide detection of nucleic acid sequences in human-derived specimens.

The QuantStudio 5 Dx Real-Time PCR System is intended for use by trained personnel in a professional environment with FDA-cleared or approved assays.

**Manufacturer:** Thermo Fisher Scientific

Thermo Fisher Scientific is the manufacturer of the QuantStudio 5 Dx Real-Time PCR System and is the sole supplier, by itself or through its authorized distributors, of the QuantStudio 5 Dx system.

## Technology overview

### Real-time PCR overview

The polymerase chain reaction (PCR) is a powerful technology that amplifies DNA or cDNA targets up to a million-fold or more. 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 in each cycle. The ability of the real-time PCR instrument to monitor the amount of target that is amplified 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 in fluorescent signal is directly proportional to the amount of PCR product generated in the exponential phase of the reaction. The number of cycles and fluorescent signal can be used to calculate the quantity of genetic material by comparing the amplification data of the sample to that of a known standard.

The fluorescent reporters that are used include double-stranded DNA (dsDNA)-binding dyes, or dye molecules attached to PCR primers or probes that hybridize with PCR products 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 run.

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### Real-time PCR for research applications*

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

- Gene expression analysis
- Genotyping
- Copy number variation analysis
- Pathogen detection, strain typing, and viral load determination
- miRNA profiling
- Protein analysis with proximity ligation assays

### Real-time PCR advantages

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

- The ability to monitor the progress of the PCR run as it occurs in real time (on both the instrument touchscreen and software client)
- The ability to accurately 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, eliminating post-PCR manipulations

## The QuantStudio 5 Dx system has the following differentiating features and benefits:

### System

1. The instrument system includes the instrument, software, user documentation, and either a desktop or laptop computer. The desktop computer may sometimes be referred to as a “tower”.

### Instrument

2. The instrument’s dimensions are 27 x 50 x 40 cm (W x D x H), designed to maximize horizontal and vertical bench space.
3. The instrument’s block is accessible from the front of the instrument to maximize bench space, and is fully motorized.
4. The instrument’s melt curve or dissociation takes place in steps ranging from $0.015°C \leq \Delta T \leq 3.66°C$
5. The instrument has a maximum block ramp rate of 6.5°C/sec.
6. The instrument block has a temperature range of 4–99.9°C.
7. The instrument heated cover has a temperature range of 50–110°C.
8. The instrument includes a long-lasting bright white LED (light-emitting diode) source that has a median lifetime of at least 60,000 hours.

* Applications for *in vitro* diagnostic (IVD) usage will depend on assay developers’ cleared or approved content.

9. The instruments uses a CMOS imager for data acquisition and collects data for each filter combination in <2 seconds.
10. The instrument includes a heated lid assembly that heats the top half of the sample plates and provides an effective seal to minimize evaporation of the reaction mixture.
11. The 96-well sample block is made up of 6 separate Peltier elements (known as Applied Biosystems™ VeriFlex™ Blocks). 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.
12. The instrument is designed to support reaction volumes of 10–100 µL on the 0.2 mL 96-well block.
13. The instrument is factory calibrated with FAM™, SYBR™ Green I, VIC™, ABY™, NED™, TAMRA™, JUN™, ROX™, Mustang Purple™, and Cy®5 dyes.

### Performance

14. The instrument is designed to complete a 40-cycle real-time PCR run using a fluorogenic 5′ nuclease assay and Fast chemistry in under 30 minutes. The instrument can also run in standard ramping mode with standard chemistry.
15. The instrument includes an Applied Biosystems™ OptiFlex™ System that combines 6 excitation (450–670 nm) and 6 emission (500–720 nm) filters, to enable collection of up to 21 unique combinations of wavelengths during a single run for multiplexing.
16. The instrument supports at least two reaction chemistries, the fluorogenic 5′ nuclease assay using Applied Biosystems™ TaqMan® probes, and the DNA-binding chemistry of Applied Biosystems™ SYBR™ Green dye.
17. The instrument has real-time quantitative PCR installation specifications to demonstrate the ability to distinguish 5,000 template copies from 10,000 copies at a 99.7% confidence level.

### Dx software (IVD)

18. The instrument software allows for locked, IVD use for cleared or approved assays.
19. The instrument software provides secured access and audit records of all user changes.
20. The instrument software includes the ability to assign sample IDs and controls to individual wells.
21. The instrument software helps prevent accidental modifications to run or analysis conditions.

### Design

22. The instrument is NRTL TUV SUD certified (tested to safety UL and CAN/CSA standards), EMC certified (tested to IEC 60601-1-2), WEEE compliant, and California Proposition 65 compliant.

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### Software

23. The software enables users to operate the instrument in either *In Vitro* Diagnostic (IVD) Mode or Test Development (DEV) Mode. Test Development Mode is for Research Use Only.

24. The instrument desktop software includes security and auditing features, with the ability to maintain centralized settings for multiple units.

### Vendor service and support

25. The instrument is provided with a limited warranty for a period of 12–15 months from date of shipment (region dependent). Optional post-warranty service contracts that include next-business-day on-site repairs are available.

26. The instrument is provided with an orientation session by eLearning module or a trained technical scientist.

27. The vendor can supply all the necessary consumables to perform instrument qualification (IQ), operational qualification (OQ), and instrument performance verification (IPV).

28. The vendor can provide computer system validation consulting services with flexible and comprehensive audit-style documentation packages that help users reduce risk and comply with regulations and standards.

29. The vendor offers telephone technical support and field applications, sales, and service support to help resolve chemistry and instrumentation problems.

IVD