Umwelt Bundesamt

TÜVRheinland®
Precisely Right.

CERTIFICATE

of Product Conformity (QAL1)

Certificate No.: 0000035016_02

AMS designation:	TEOM 1405-F Ambient Particulate Monitor with PM_{10} pre-separator for PM_{10}
Manufacturer:	Thermo Fisher Scientific 27, Forge Parkway Franklin, MA 02038 USA
Test Laboratory:	TÜV Rheinland Energy GmbH

This is to certify that the AMS has been tested and found to comply with the standards VDI 4202-1 (2010), VDI 4203-3 (2010), EN 12341 (1998), Guide to the demonstration of equivalence of ambient air monitoring methods (2010) as well as EN 15267-1 (2009) and EN 15267-2 (2009).

Certification is awarded in respect of the conditions stated in this certificate (this certificate contains 10 pages).
The present certificate replaces certificate 0000035016_01 of 28 February 2017.

TÜVRheinland® CERTIFIED

Suitability Tested
Complying with
2008/50/EC
EN 15267
Regular Surveillance

www.tuv.com
ID 0000035016

Publication in the German Federal Gazette (BAnz) of 02 March 2012

This certificate will expire on:
01 March 2027

German Federal Environment Agency
Dessau, 16 February 2022

TÜV Rheinland Energy GmbH
Cologne, 15 February 2022

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Test institute accredited to EN ISO/IEC 17025 by DAkkS (German Accreditation Body).
This accreditation is limited to the accreditation scope defined in the enclosure to certificate D-PL-11120-02-00.

10/221 2.08

Test report:	936/21209885/B of 25 November 2011
Initial certification:	16 March 2012
Expiry date:	01 March 2027
Certificate	Renewal (of previous certificate 0000035016_01 of 28 February 2017 valid until 01 March 2022)
Publication:	BAnz. 02 March 2012, no. 36, p. 920, chapter IV number 1.1

Approved application
The tested AMS is suitable for continuous ambient air monitoring of PM_{10} (stationary operation).

The suitability of the product for this application was assessed on the basis of a laboratory test and a 3-month field test for four different test sites or time periods respectively.

The AMS is approved for an ambient temperature range of +8° to +25°C.

The notification of suitability of the AMS, performance testing and the uncertainty calculation have been effected on the basis of the regulations applicable at the time of testing. As changes in legal regulations are possible, any potential user should ensure in consultation with the manufacturer that this AMS is suitable for monitoring the limit value relevant to the application.

Any potential user should ensure, in consultation with the manufacturer, that this AMS is suitable for the intended purpose.

Basis of the certification
This certification is based on:

- Test report 936/21209885/B of 25 November 2011
  by TÜV Rheinland Energie und Umwelt GmbH
- Suitability announced by the German Federal Environment Agency (UBA)
  as the relevant body
- The ongoing surveillance of the product and the manufacturing process

Publication in the German Federal Gazette: BAnz. 02 March 2012, no. 36, p. 920, chapter IV number 1.1, UBA announcement dated 23 February 2012:

AMS designation:

TEOM 1405-F Ambient Particulate Monitor with PM_{10} pre-separator for PM_{10}

Manufacturer:

Thermo Fisher Scientific, Franklin, USA

Field of application:

For continuous ambient air monitoring of suspended particulate matter, PM_{10} (stationary operation)

Measuring ranges during performance testing:

Component	Certification range	Unit
PM_{10}	0 – 1,000	µg/m³

Software version:

1.55

Restrictions:

The permissible ambient temperature range at the installation site of the measuring system is 8 °C to 25 °C.

Notes:

1. The requirements for the coefficient of variation R^2 according to guideline EN 12341 were not met for the Teddington (summer) and Bornheim (summer) sites.
2. The requirements according to the guide "Demonstration of Equivalence of Ambient Air Monitoring Methods" are met for the measured component PM_{10}.
3. The measuring system must be calibrated on site at regular intervals by using the gravimetric PM_{10} reference method according to EN 12341.
4. The test report on performance testing is available on the internet at www.qal1.de.

Test Report:

TÜV Rheinland Energy GmbH, Cologne

Report no.: 936/21209885/B of 25 November 2011

Publication in the German Federal Gazette: BAnz AT 20.07.2012 B11, chapter IV
31st notification, UBA announcement dated 06 July 2012:

31 Notification as regards Federal Environment Agency (UBA) notice of 23 February 2012 (BAnz. p. 920, chapter IV number 1.1)

The current software version of the TOEM 1405-F Ambient Particulate Monitor measuring system with PM_{10} pre-separator for suspended particulate matter PM_{10} manufactured by Thermo Fisher Scientific is: 1.56

Statement issued by TÜV Rheinland Energie und Umwelt GmbH dated 2 May 2012

Publication in the German Federal Gazette: BAnz AT 23.07.2013 B4, chapter V
19th notification, UBA announcement dated 03 July 2013:

19 Notification as regards Federal Environment Agency (UBA) notices of 23 February 2012 (BAnz. p. 920, chapter IV number 1.1) and of 06 July 2012 (BAnz AT 20.07.2012 B11, chapter IV, 31st notification)

The ambient air measuring system TEOM 1405-F Ambient Particulate Monitor with PM_{10} pre-separator for particulate matter PM_{10} manufactured by Thermo Fisher Scientific can also be operated with the vacuum pump GAST 75R647 V45-H306X.

Statement issued by TÜV Rheinland Energie und Umwelt GmbH dated 18 March 2013

Publication in the German Federal Gazette: BAnz AT 01.04.2014 B12, chapter VI
32nd notification, UBA announcement dated 27 February 2014:

32 Notification as regards Federal Environment Agency (UBA) notices of 23 February 2012 (BAnz. p. 920, chapter IV number 1.1) and of 03 July 2013 (BAnz AT 23.07.2013 B4, chapter V 19th notification)

The current software version of the TEOM 1405-F Ambient Particulate Monitor measuring system with PM_{10} pre-separator by Thermo Fisher Scientific for particulate matter PM_{10} is: 1.57

Statement issued by TÜV Rheinland Energie und Umwelt GmbH dated 1 October 2013

Publication in the German Federal Gazette: BAnz AT 02.04.2015 B5, chapter IV
20th notification, UBA announcement dated 25 February 2015:

20 Notification as regards Federal Environment Agency (UBA) notices of 23 February 2012 (BAnz. p. 920, chapter IV number 1.1) and of 27 February 2014 (BAnz AT 01.04.2014 B12, chapter VI 32nd notification)

The current software version of the TEOM 1405-F Ambient Particulate Monitor measuring system with PM_{10} pre-separator by Thermo Fisher Scientific for particulate matter PM_{10} is: 1.70

Statement issued by TÜV Rheinland Energie und Umwelt GmbH
dated 22 September 2014

Publication in the German Federal Gazette: BAnz AT 26.08.2015 B4, chapter V
39th notification, UBA announcement dated 22 July 2015:

39 Notification as regards Federal Environment Agency (UBA) notices of 23 February 2012 (BAnz. p. 920, chapter IV number 1.1) and of 25 February 2015 (BAnz AT 02.04.2015 B5, chapter IV 20th notification)

The current software version of the TEOM 1405-F Ambient Particulate Monitor with PM_{10}-pre-separator for suspended particulate matter PM_{10} manufactured by Thermo Fisher Scientific is: 1.71

The switching valve of the FDMS unit was redesigned in order to improve its mechanical stability.

The measuring system can also be used with the GAST 87R647-PDS-HV-913 vacuum pump.

Statement issued by TÜV Rheinland Energie und Umwelt GmbH
dated 17 March 2015

Publication in the German Federal Gazette: BAnz AT 14.03.2016 B7, chapter V
38th notification, UBA announcement dated 18 February 2016:

38 Notification as regards Federal Environment Agency (UBA) notices of 23 February 2012 (BAnz. p. 920, chapter IV number 1.1) and of 22 July 2015 (BAnz AT 26.08.2015 B4, chapter V 39th notification)

The TEOM 1405-F Ambient Particulate Monitor with PM_{10} pre-separator manufactured by Thermo Fisher Scientific for the suspended particles PM_{10} meets the requirements stipulated in CEN/TS 16450 (August 2013 version). An addendum to the test report with the report number 936/21221597/B can be viewed on the online at www.qal1.de.

Statement issued by TÜV Rheinland Energie und Umwelt GmbH
dated 20 November 2015

Publication in the German Federal Gazette: BAnz AT 01.08.2016 B11, chapter V
38th notification, UBA announcement dated 14 July 2016:

38 Notification as regards Federal Environment Agency (UBA) notices of 23 February 2012 (BAnz. p. 920, chapter IV number 1.1) and of 18 February 2016 (BAnz AT 14.03.2016 B7, chapter V 38th notification)

The current software version for the TEOM 1405-F Ambient Particulate Monitor with PM_{10} pre-separator for particulate matter PM_{10} manufactured by Thermo Fisher Scientific is: 1.72

Statement issued by TÜV Rheinland Energie und Umwelt GmbH
dated 29 February 2016

Publication in the German Federal Gazette: BAnz AT 26.03.2019 B7, chapter IV
73rd notification, UBA announcement dated 27 February 2019:

73 Notification as regards Federal Environment Agency (UBA) notices of 23 February 2012 (BAnz. p. 920, chapter IV number 1.1) and of 14 July 2014 (BAnz AT 01.08.2016 B11, chapter V 38th notification)

Connectors produced by the manufacturer HAM-LET can now be used as connecting elements for gas lines for the TEOM 1405-F Ambient Particulate Monitor measuring system with PM_{10} pre-separator for suspended particulate matter PM_{10} manufactured by Thermo Fisher Scientific alternatively and in connection with the previously used connectors from the company Swagelok.

The current software version of the measuring system is: 1.73

Statement issued by TÜV Rheinland Energy GmbH dated 10 January 2019

Publication in the German Federal Gazette: BAnz AT 05.08.2021 B5, chapter IV
1st notification, UBA announcement dated 29 June 2021:

1 Notification as regards Federal Environment Agency (UBA) notices of 23 February 2012 (BAnz. p. 920, chapter IV number 1.1) and of 27 February 2019 (BAnz AT 26.03.2019 B7, chapter VI 73rd notification)

The current software version of the TOEM 1405-F Ambient Particulate Monitor measuring system with PM_{10} pre-separator for suspended particulate matter PM_{10} manufactured by Thermo Fisher Scientific is: 1.74

Statement issued by TÜV Rheinland Energy GmbH dated 24 February 2021

Certified product
This certification applies to automated measurement systems conforming to the following description:

The ambient air measuring system TEOM 1405-F Ambient Particulate Monitor is based on the measuring principle of oscillating micro weighing.

For the weighing principle, which is used in the TEOM mass transducer in the measuring system TEOM 1405-F Ambient Particulate Monitor, the change in mass determined with the sensor, results from the measurement of the change in frequency of the tapered element.

The particle sample passes the PM_{10} pre-separator at a flow rate of 16.67 l/min (=1 m³/h). Subsequently, the flow is directed over a flow-splitter and divided into two sub-flows – the PM_{10}-flow of 3 l/min and the bypass-flow of 13.67 l/min. The PM_{10}-flow is directed to the actual measuring system TEOM 1405-F via the FDMS-unit. There it is secreted to the respective TEOM-filter (constantly heated at 30 °C) and the secreted mass of particles is quantified.

To take into account non-volatile as well as volatile particulate during the measuring, the FDMS technology is used. The FDMS-unit is placed between the flow-splitter and the measuring device TEOM 1405-F in the so called FDMS-tower. The FDMS-unit compensates automatically the part of the semi-volatile particulate using a switching valve and two operation modi – the base mode and the reference mode.

Every six minutes the switching valve changes the sampling flow rate from base to reference mode. In the base mode the sampling is done on a straight way via a dryer directly to the mass measuring. In the reference mode the air flow is directed through a cooled filter after the dryer, to remove and restrain the non-volatile and volatile part of the particulate from the sample. During normal operation the temperature of the cooler is maintained at 4 °C constantly

Based on the mass concentration measuring during the base and reference-modi the FDMS-system updates the 1h-average of the following results every six minutes:

Base-MC	=	Particle concentration of the particle-loaded sampling flow.
Ref-MC	=	Particle concentration of the particle-free sampling flow after passing through the cooled filter.
MC	=	Base-MC adjusted for Ref-MC Base-mass-concentration (normally positive) Reference-mass-concentration (negative, in case mass of the filter evaporates).

After the mass determination the sampling flows are directed over a mass flow rate regulator. To guarantee a constant sampling volume flow at the inlet, bearing in mind the ambient temperature and pressure, the volume flow control shall be operated in the mode „active/ actual“.

The tested measuring system consists of the PM_{10}-sampling inlet, flow splitter, the respective sampling tubes, a tripod to support the sample, the measuring device TEOM 1405-F incl. FDMS-tower, the vacuum pump with its respective power supply cord and cables as well as adapters, the hole in the roof incl. a flange and a manual in German/English. The software version is 1.72.

The measuring system is operated via a display at the front of the instrument. The user is able to check measurement data and instrument information, change parameters and check correct functionality of the AMS.

General remarks

This certificate is based upon the equipment tested. The manufacturer is responsible for ensuring that on-going production complies with the requirements of the EN 15267. The manufacturer is required to maintain an approved quality management system controlling the manufacturing process for the certified product. Both the product and the quality management systems shall be subject to regular surveillance.

If a product of the current production does not conform to the certified product, TÜV Rheinland Energy GmbH must be notified at the address given on page 1.

A certification mark with an ID-Number that is specific to the certified product is presented on page 1 of this certificate.

This document as well as the certification mark remains property of TÜV Rheinland Energy GmbH. Upon revocation of the publication the certificate loses its validity. After the expiration of the certificate and on request of TÜV Rheinland Energy GmbH this document shall be returned and the certificate mark must no longer be used.

The relevant version of this certificate and its expiration date are also accessible on the internet at **qal1.de**.

Document history

Certification of the TEOM 1405-F Ambient Particulate Monitor with PM_{10} pre-separator is based on the documents listed below and the regular, continuous surveillance of the manufacturer's quality management system:

Initial certification according to EN 15267

Certificate no. 0000035016_00: 16 March 2012
Expiry date of the certificate: 01 March 2017
Test report: 936/21209885/B of 25 November 2011
TÜV Rheinland Energie und Umwelt GmbH
Publication: BAnz. 02 March 2012, no. 36, p. 920, chapter IV number 1.1
UBA announcement dated 23 February 2012

Notifications according to EN 15267

Statement issued by TÜV Rheinland Energy GmbH dated 02 May 2012
Publication: BAnz AT 20.07.2012 B11, chapter IV notification 31
UBA announcement dated 06 July 2012
(Software updates)

Statement issued by TÜV Rheinland Energy GmbH dated 18 March 2013
Publication: BAnz AT 23.07.2013 B4, chapter V notification 19
UBA announcement dated 3 July 2013
(Design changes)

Statement issued by TÜV Rheinland Energy GmbH dated 01 October 2013
Publication: BAnz AT 01.04.2014 B12, chapter VI notification 32
UBA announcement dated 27 February 2014
(Software updates)

Statement issued by TÜV Rheinland Energy GmbH dated 22 September 2014
Publication: BAnz AT 02.04.2015 B5, chapter IV notification 20
UBA announcement dated 25 February 2015
(Software updates)

Statement issued by TÜV Rheinland Energy GmbH dated 17 March 2015
Publication: BAnz AT 26.08.2015 B4, chapter V notification 39
UBA announcement dated 22 July 2015
(Design and software changes)

Statement issued by TÜV Rheinland Energy GmbH dated 20 November 2015
Publication: BAnz AT 14.03.2016 B7, chapter V notification 38
UBA announcement dated 18 February 2016
(Addition of new regulation (CEN/TS 16450:2013))

Statement issued by TÜV Rheinland Energy GmbH dated 28 February 2016
Publication: BAnz AT 01.08.2016 B11, chapter V notification 38
UBA announcement dated 14 July 2016
(Software updates)

Renewal of the certificate

Certificate no. 0000035016_01: 28 February 2017
Expiry date of the certificate: 01 March 2022

Notifications according to EN 15267
Statement issued by TÜV Rheinland Energy GmbH dated 10 January 2019
Publication: BAnz AT 26.03.2019 B7, chapter IV notification 73
UBA announcement dated 27 February 2019
(Design changes)

Statement issued by TÜV Rheinland Energy GmbH dated 24 February 2021
Publication: BAnz AT 05.08.2021 B5, chapter IV notification 1
UBA announcement dated 29 June 2021
(Software updates)

Renewal of the certificate

Certificate no. 0000035016_02: 16 February 2022
Expiry date of the certificate: 01 March 2027

PM10 1405F FDMS	23,3% > 28 µg m-3	Orthogonal Regression				Between Instrument Uncertainties	
	W_{CM} / %	n_{c-s}	r^2	Slope (b) +/- u_b	Intercept (a) +/- u_a	Reference	Candidate
All Data	8,4	215	0,973	0,994 +/- 0,011	0,395 +/- 0,291	0,48	1,09
< 30 µg m-3	12,0	169	0,882	1,055 +/- 0,028	-0,567 +/- 0,501	0,46	1,03
> 30 µg m-3	9,5	46	0,963	0,992 +/- 0,029	0,218 +/- 1,274	0,55	1,35

SN 20006	Dataset	Orthogonal Regression				Limit Value of 50 µg m-3	
		n_{c-s}	r^2	Slope (b) +/- u_b	Intercept (a) +/- u_a	W_{CM} / %	% > 28 µg m-3
Individual Datasets	Teddington Summer	42	0,895	1,112 +/- 0,057	0,055 +/- 0,883	23,71	2,4
	Cologne Winter	74	0,987	0,992 +/- 0,013	0,327 +/- 0,461	6,23	55,4
	Bornheim Summer	55	0,931	1,134 +/- 0,041	-2,097 +/- 0,750	20,10	3,6
	Teddington Winter	66	0,987	0,959 +/- 0,014	-1,549 +/- 0,337	15,22	16,7
Combined Datasets	< 30 µg m-3	186	0,860	1,069 +/- 0,029	-1,377 +/- 0,528	12,26	2,2
	> 30 µg m-3	51	0,966	0,986 +/- 0,026	-0,104 +/- 1,147	9,36	100,0
	All Data	237	0,970	0,994 +/- 0,011	-0,170 +/- 0,294	9,01	23,2

SN 20107	Dataset	Orthogonal Regression				Limit Value of 50 µg m-3	
		n_{c-s}	r^2	Slope (b) +/- u_b	Intercept (a) +/- u_a	W_{CM} / %	% > 28 µg m-3
Individual Datasets	Teddington Summer	57	0,927	1,065 +/- 0,039	0,807 +/- 0,605	17,19	1,8
	Cologne Winter	74	0,978	1,005 +/- 0,017	0,710 +/- 0,609	9,35	55,4
	Bornheim Summer	54	0,906	1,112 +/- 0,047	-0,860 +/- 0,859	21,03	3,7
	Teddington Winter	45	0,983	0,934 +/- 0,019	0,108 +/- 0,455	14,07	13,3
Combined Datasets	< 30 µg m-3	184	0,886	1,052 +/- 0,026	-0,062 +/- 0,467	13,06	2,2
	> 30 µg m-3	46	0,949	1,010 +/- 0,034	-0,139 +/- 1,526	11,60	100,0
	All Data	230	0,970	0,996 +/- 0,011	0,795 +/- 0,292	9,07	21,7