

# Technical Description for EMC

## **Device** information

Manufacturer's name: QIAGEN GmbH

Qiagen Strasse 1 40724 Hilden

Germany

Equipment Type/Environment: QIAstat-Dx Rise

Trade Name/Model No: 9003163

**Environment:** Professional healthcare facility environment

Essential performance: Essential performance for QIAstat-Dx Rise comprises the following:

 Cartridge Transport (Gripper, Robotic Arm x/y/z, Distance sensors)

· Barcode reading

• Sample Recognition

Assay test

• Temperature control

# EMC report data

#### EMC emissions test levels

Emission test	Test level/compliance level	Environment	
Radiated emissions CISPR 11	Class B, Group 1 emissions level	Suitable for use in Professional Healthcare Facility Environment.*	
Conducted emissions CISPR 11	Class B, Group 1 emissions level	Also suitable for use in residential	
Harmonic distortion IEC 61000-3-2	As per IEC 61000-3-2	environments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic	
Voltage fluctuation and flicker IEC 61000-3-3	As per IEC 61000-3-3	purposes†.	

<sup>\*</sup> Locations include hospitals, clinics, diagnostic laboratories, or scientific environments.

Table 4 & 5. IEC 60601-1-2:2014, AMD1:2020 Electromagnetic immunity requirements for ME equipment and ME systems

		Immunity test levels	
Phenomenon	Basic EMC standard or test method	Professional healthcare facility environment	
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table 9 below	
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	

<sup>†</sup> Locations include diagnostic laboratories or clinics located in residential areas.

		Test frequency	Modulation	Immunity test level (A/m)
Proximity magnetic fields	IEC 61000-4-39	30 kHz	CW	8
		134.2 kHz	Pulse mod- ulation 2.1 kHz	65
		13.56 MHz	Pulse mod- ulation 50 kHz	7.5
Electrical fast transients/bursts	IEC 61000-4-4	± 2 kV 100 kHz repe	tition frequency	
Surges Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1	kV	
Surges Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1	kV, ± 2 kV	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 8 6 V in ISM ba between 0.15 80% AM at 1	nds MHz and 80 M	Hz
Voltage dips	IEC 61000-4-11	315°	o°, 135°, 180°, 2 e and 70 % UT;	
Voltage interruptions	IEC 61000-4-11	0% UT; 250/3	300 cycle	

Table 9. Test specifications for enclosure port immunity to RF wireless communication equipment

Test frequency (MHz)	Band* (MHz)	Service*	Modulation	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse Modulation† 18 Hz	27
450	430 -470	GMRS 460, FRS 460	FM‡ ± 5 kHz deviation 1 kHz sine	28
710 745 780	704-787	LTE Band 13, 17	Pulse Modulation† 217 Hz	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse † 18 Hz	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE-Band 1, 3, 4, 25; UMTS	Pulse Modulation† 217 Hz	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation† 217 Hz	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse Modulation† 217 Hz	9

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME equipment or ME system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

<sup>\*</sup> For some services, only the uplink frequencies are included.

<sup>†</sup> The carrier shall be modulated using a 50% duty cycle square wave signal.

<sup>‡</sup> As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

### Conclusion



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