

Troubleshooting

Cepheid HBDC Training Centre



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Troubleshooting Approach

- 1. In case of an issue, a message will be displayed (often, with an error code)
- 2. Check if the error affects one particular module
- 3. Refer to the Operator Manual and look for the error code, and follow the recommended corrective actions
- 4. If the problem remains, contact your **local service provider** or **Cepheid**

Service	Telephone	Email address	
Training Center (Europe)	+33.5.63.82.53.94	training@cepheidhbdc.com	
Technical hotline (Europe based)- Instrument errors	+33.5.63.82.53.19	support@cepheideurope.com	
Technical hotline (U.S.A based)- Instrument errors	888-838-3222, Option 2	techsupport@cepheid.com	



Most common situations

GeneXpert or module(s) not detected

Failures without error codes

- « INVALID » result
- « NO RESULT »
- Cartridge stuck in a GeneXpert module

Failures with error codes

- Temperature errors: codes 1001, 1002, 2014, 4009, 4017...
- Probe Check failures: codes 5006 or 5007
- Syringe pressure failure: code 2008
- Communication loss: codes 2120, 2120, 2122, 2124
- Signal loss: code 5011







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Where to find Software messages?





Where to find Software messages?





Refer to the Operator Manual

Look for the specific Error Code in the Troubleshooting Section of the latest Operator Manual

Error code	Error message	Possible causes	Solution
5007	X probe check failed. Probe check value of n for reading number m was below the minimum of p. (x is the analyte name, n, m, and p are values that the software displays. The values can vary.)	 One or more of the following might have caused the error: An incorrect amount of reagent was inserted into the cartridge. The reagent is bad. Fluid transfer failed. The sample was processed incorrectly in the cartridge. 	 Check the following: Reagents are added to the cartridge correctly. Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.
5008	X probe check failed. Probe check delta value n between reading number m and reading number p was below the minimum of q. (x is the analyte name. n. m. and p are values that the software displays. The values can vary.)	 One or more of the following might have caused the error: An incorrect amount of reagent was inserted into the cartridge. The reagent is bad. Fluid transfer failed. 	 Check the following: Reagents are added to the cartridge correctly. Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.



COMMUNICATION ISSUES GeneXpert not detected or Module not detected



Whole GeneXpert not detected



Whole GeneXpert not detected Troubleshooting Checklist: external parts

GeneXpert

- 1. First switch on the GeneXpert then, the computer (restart)
- 2. Is the front blue LED illuminated? If not, check the power source is functional
- 3. Ethernet cable : check for visible damage + Reconnect
- 4. Room temperature (15-30°C)
- 5. Fan functionality and filter cleanliness

UPS

1. The status of your UPS (fully charged?)

Computer

- 1. Ethernet cable is in the right computer port (as indicated by a white label)
- 2. Check for visible damage on the ethernet cable+ Reconnect
- 3. Check the IP address: refer to Operator Manual (Chapter 2.4.1)
- 4. Scan for computer virus/ check if antivirus is updating (disable it, if required)



Whole GeneXpert not detected Troubleshooting Checklist: internal parts

Only upon request of Cepheid Technical Support Specialist, you may have to check:

- 1. GeneXpert power supply
- 2. GeneXpert gateway board...
- 3. Ethernet ports (Computer & GX): swap with another GX/computer
- 4. Network adaptor: wobbling, loose?



Individual module(s) not detected





Module(s) not detected: Troubleshooting checklist: External parts

• Identify the affected module (s): Serial number and position

• Check the module(s) internal temperature

- Click on the Maintenance icon and check « Ambient Temp » for each module. You
 may have to report these values when you contact Cepheid Technical Support
- Check fan functionality* and filter cleanliness





*Place a wipe on the filter and check if it remains stuck to the back panel

• Restart the system (GeneXpert and Computer)

- If the module is still not detected, please contact Technical Suppot for guidance



Module(s) not detected: Troubleshooting checklist: Internal parts

Only upon request of Cepheid Technical Support Specialist, you may have to check:

- 1. Connection between module and gateway board
- 2. Gateway failure (specific position) or module failure: Swap module position





Failures without error codes



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INVALID



Solution(s)

- Use the correct specimen type
- Check the sample quality (density, viscosity, purity, etc.)
- Follow recommended instructions on sample collection, preparation and storage
- Check Xpert kit storage conditions and shelf life
- Collect a new sample when necessary and retest



An Internal Control failed (for a negative result)

SPC/CIC* or IQS* or SAC*

* (assay dependent)

Origin(s)

- PCR was inhibited due to inferring substances
- Inadequate sample was used
- Improper specimen
 storage/collection/preparation
- Improper kit storage conditions



NO RESULT

GeneXpert® Dx System			
User Data Management Reports Setup	View Results About		User <none></none>
Create Test	Stop Test	View Results Define Assays Define Graphs	Maintenance
Module Name A3	Views	Test Result Analyte Result Detail Errors History Support	
Patient ID	Result View	Assay Name Xpert MTB-RIF Assay G4	Version 5
patient 1	Primary Curve	Test Result NO RESULT	
Patient ID 2			
		For In Vitro Diagnostic Use Only.	
Sample ID			
001			
Assay Xpert MTB-RIF Ass ay G4			
Version 5	Views		
Reagent Lot ID* 05904	Result View		
Test Type Specimen 💌	Primary Curve		
Sample Type Other		<no available="" data=""></no>	
Other Sample Type			
Notes			
-			
Save Changes Export Report	Select Graphs	View Test	

NO RESULT

Test could not be completed and insufficient data was collected

Origin(s)

- Power failure during test
- "Stop Test" function was used.
- Computer freeze or crash during test

Solution(s)

Ensure there is a consistent power supply Use "Stop Test" only when it is necessary Do not open other applications on the computer while a test is running



Cartridge stuck inside a GeneXpert module

Causes:

Module mechanical malfunction during the test

Electrical failure

Solutions:

1. Remove the cartridge using the software



- Select the module. Click "Open Door" to open the module door.
 - If the door does not open, restart the system and repeat the above steps.
- 2. Remove the cartridge manually

If the above steps did not resolve this issue, contact Cepheid in order to receive guidance







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Error Messages

User Unter Management Reports Setup View Results About User Alone Create Test Check Status Stop Test View Results Define Assays Define Graphs Maintenance Module Name A3 Patient ID Patient ID 2 Patient ID 2 Sample ID Result View Results Define Assays Define Graphs Maintenance Patient ID 2 Patient ID 2 Patient ID 2 Sample ID Result View Result View Result Check Value of 1.8 for p2/18/15 reading number 2 Was below the minimum d27.0 Sample ID Result View Result View Result Check Value of 1.1 for p2/18/15 reading number 2 was below the minimum d27.0 Sample ID Result View Result View Result View Result Check Value of 1.1 for p2/18/15 Result View Result View	GeneXpert® Dx System						
Module Name A3 Views Test Result Analyte Result Detail Errors History Support Patient ID Primary Curve If Description Detail Trop Bescription Time 1 Post-run analysis Error 5007. [QC-1] probe check failed. Probe check value of 1.8 for 102/18/15 reading number 2 was below the minimum of 27.0 2. Post-run analysis Error 5007. [QC-2] probe check failed. Probe check value of 14.1 for 02/18/15 reading number 2 was below the minimum of 25.0 2. Post-run analysis Sample ID Xpert M 021815145735 Error 5007. [QC-2] probe check failed. Probe check value of 14.1 for 02/18/15 reading number 2 was below the minimum of 35.0 15.21.20 Sample ID Xpert M 021815145735 Error 5007. [QC-2] probe check failed. Probe check value of 14.1 for 02/18/15 reading number 2 was below the minimum of 35.0 15.21.20 Views Reault View Primary Curve Result View Primary Curve Result View Primary Curve Kesult View Primary Curve Views Result View Result View Result View Primary Curve Views Result View Result View Result View Primary Curve Views Kesult View Views Kesult View Kesult View Notes	User Data Management Reports Setup Create Test Check Status	S Stop Test	View Res	ults Defi	0 2 3 ne Assays	Define Graphs	User «None»
Patient ID Result View Primary Curve # Description Detail Time Post-run analysis For 5007: [QC-1] probe check failed. Probe check value of 1.8 for 02/18/15 Patient ID 2 2 Post-run analysis Error 5007: [QC-2] probe check failed. Probe check value of 14.1 for 02/18/15 Sample ID 2 Post-run analysis Error 5007: [QC-2] probe check failed. Probe check value of 14.1 for 02/18/15 Assay Xpert MTB-RiF Ass ay G4 Version 5 Reagent Lot ID* 66001 Result View Test Type Other Views Other Sample Type Other Venous whole blood Notes	Module Name A3	Views	Test Result Analy	te Result Detail	Errors	History Support	
Primary Curve # Description Detail Time Patient ID 2 1 Post-run analysis error Forror 5007; [QC-1] probe check failed. Probe check value of 1.8 for reading number 2 was below the minimum of 27.0 15/21:20 Sample ID 2 Post-run analysis error Error 5007; [QC-1] probe check failed. Probe check value of 14.1 for 02/18/15 02/18/15 Assay Xpert MTB-RIF Ass ay G4 Version 5 Fore 5007; [QC-1] probe check failed. Probe check value of 14.1 for 02/18/15 02/18/15 Reagent Lot ID* 06001 Fore 5007; [QC-1] probe check failed. Probe check value of 14.1 for 05/02/18/15 15/21:20 Sample Type Second Post-run analysis Error 5007; [QC-1] probe check failed. Probe check value of 14.1 for 02/18/15 Version 5 Reagent Lot ID* 06001 Post-run analysis Error 5007; [QC-1] probe check failed. Probe ch	Patient ID	Result View	Troublesh	oot			
1 Post-run analysis Error 5007: [QC-1] probe check failed. Probe check value of 1.8 for 02/18/15 error error 1521:20 1521:20 Sample ID 2 Post-run analysis error 102/18/15 Xpert M 021815145735 Assay Xpert MTB-RIF Ass ay G4 Version 5 Views 15:21:20 Reagent Lot IDP 06001 Reagent Wiew Result View Primary Curve Sample Type Other Sample Type Version 5 Reserver Notes Notes		Primary Curve	# Description		1	Detail	Time
Patient ID 2 error iradica number 2 was below the minimum of 22 0. 115:21:20 2 Post-run analysis Error 5007 (DC-2) probe check value of 14.1 for 02/18/15 eading number 2 was below the minimum of 35.0 15:21:20 Sample ID Xpert M 021815145735 eading number 2 was below the minimum of 35.0 15:21:20 Assay Xpert MTB-RIF Ass ay G4 Version 5 Reagent Lot ID* 06001 Result View Test Type Specimen Other Sample Type Other Sample Type Venous whole blood Notes			1 Post-run analysis E	Error 5007: [QC-1] pr	obe check fail	led. Probe check value of 1.8 for	02/18/15
Sample ID Xpert M 021815145735 Assay Xpert MTB-RIF Ass ay G4 Version 5 Reagent Lot ID* 06001 Test Type Sample Type Other Sample Type Other Sample Type Version 5 Version 5 Result Views Primary Curve Sample Type Other Sample Type Version 4	Patient ID 2		error r 2 Post-run analysis	eading number 2 wa	as below the r	minimum of 27.0 led. Probe check value of 14.1 for	15:21:20
Sample ID Xpert M 021815145735 Assay Xpert MTB-RIF Ass ay G4 Version 5 Reagent Lot ID* 06001 Test Type Specimen ~ Sample Type Other ~ Other Sample Type venous whole blood Notes			error	eading number 2 wa	as below the r	minimum of 35.0	15:21:20
Sample ID Xpert M 021815145735 Assay Xpert MTB-RIF Ass ay G4 Version 5 Reagent Lot ID' 06001 Test Type Specimen ~ Sample Type Other ~ Other Sample Type Views Notes			•				
Assay Xpert MD2-1315145/35 Assay Xpert MTB-RIF Ass ay G4 Version 5 Reagent Lot ID* 06001 Test Type Specimen V Sample Type Other V Other Sample Type Vencus whole blood Notes	Sample ID						
Assay Xpert MTB-RIF Ass ay G4 Version 5 Reagent Lot ID ⁶ 06001 Test Type Specimen V Sample Type Other V Other Sample Type Vencus whole blood Notes	xpert M 021815145735						
Version 5 Reagent Lot ID [®] 06001 Test Type Specimen ▼ Sample Type Other ▼ Other Sample Type Venous whole blood Notes No Data Available>	Accay Yoart MTB-RIF Acc						
Version 5 Reagent Lot ID* 06001 Test Type Specimen Sample Type Other Other Sample Type Venous whole blood Notes Notes	ay G4		2				
Reagent Lot ID* 06001 Test Type Specimen Sample Type Other Other Sample Type Venous whole blood Notes	Version 5	Vioue				*****	
Test Type Specimen Sample Type Other Other Sample Type Venous whole blood Notes	Reagent Lot ID* 06001	Result View					
Sample Type Other Venous whole blood Notes Venous whole blood Venous whole blood Venous whole blood Venous whole blood	Test Type Specimen	Primary Curve					
Sample Type Other Other Sample Type Venous whole blood Notes Venous whole blood Venous whole blood Venous whole blood Venous whole blood Ve							
Other Sample Type <no available="" data=""> venous whole blood </no>	Sample Type Other						
Venous whole blood Notes	Other Sample Type				<no a<="" data="" th=""><th>vailable></th><th></th></no>	vailable>	
Notes	venous whole blood						
	Notes						
Save Changes Export Report Select Graphs View Test	Save Changes Export Report	t Select Graphs	View Test				

An Error is displayed

 Click on the Error tab to get error code & description

Origin(s)

- Mainly linked to sample preparation
- Addressed in the next slides

All other issues should be reported to Cepheid Technical Support

Recommended action(s)

It is essential that all operators understand and identify the root causes of errors that may occur in order to avoid high (rising) error rates



Temperature issues: codes 1001, 1002, 2014, 4009, 4010, 4017,

Causes:

- Ambient temperature is not within acceptable range
- GeneXpert fan failure (broken or filter is dirty)
- Module Heater component is malfunctioning

Key Question: Does this error affect only one module?

Recommended actions:

- Check room temperature (must be 15 to 30°C)
- Check clearance around the system (must be 10-15 cm on all sides)
- Check the internal temperature of the modules (in the Maintenance menu < 39°C)
- Check the fan functionality (exhaust at rear of the instrument)
- Check the filters are clean





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Probe check failed: codes 5006/5007

GeneXpert® Dx Sy:	stem					×
lser Data Manager	nent Reports Setup	View Results About				User <none< th=""></none<>
A CONTRACT	No.				Na	Ê
Module Na	ame A3	S Stop Test	Tost Posult Analyto	Detail From	History Support	Maintenance
Patie	ent ID	Result View	Troubleshor	tesuit Detail Errors	instory support	
		Primary Curve	# Description		Datail	Time
			1 Post-run analysis Err	r 5007: IOC-11 probe check f	ailed Prohe check value of 1.8 for	02/18/15
Patie	nt ID 2		error			15:21:20
			2 Post-run analysis Err	or 5007: [QC-2] probe check f	ailed. Probe check value of 14.1 for	02/18/15
			error	ding number 2 was below the	a minimum of 35.0	15:21:20
Sam	ple ID					
Kpert M 0218151457	735					
Assay	Xpert MTB-RIF Ass ay G4					
Version	5	Views				
Reagent Lot ID*	06001	Result View				
Test Type	Specimen 💌	Primary Curve				
Sample Type	Other -					
Other Sar	mple Type			<no data<="" td=""><td>Available></td><td></td></no>	Available>	
Venous whole blood						
No	tes					
Save Changes	Export Repo	rt Select Graphs	View Test			

Error 5006 or 5007

Probe Check control failed and test was stopped before amplification

Origin(s)

- Sample density (viscosity)
- Incorrect sample volume
- Improper fluid transfer (bubbles)
- Incorrect storage of cartridges (damaged reagent)
- Insufficient maintenance
- Xpert Check overdue

- Make sure the sample is liquid before transferring to the cartridges
- Add correct volume of specimen (per Package insert)
- Avoid transferring bubbles
- Store the cartridges as per Package Inserts instructions (temperature+humidity)
- Perform regular maintenance as advised in HBDC Maintenance Presentation



Abnormal Pressure detected: codes 2008

GeneXpert® Dx System			
User Data Management Reports Setup	View Results About		User <none></none>
Create Test Check Status	s Stop Test	View Results Define Assays Define Graphs	Maintenance
Module Name B3	Views	Test Result Analyte Result Detail Errors History Support	
Patient ID	Result View	Techlohed	
	Primary Curve	Troubleshoot	
		# Description Detail	Time
		1 Operation Error 2008: Syringe pressure reading of 120.1 PSI exceeds the proto terminated limit of 120.0 PSI	001 01/28/15
Patient ID 2		2 Error occurred Error 1010: A volve positioning error of 16 count(e) was detected at	1/28/15
		end of the run	20:34:01
Sample ID			
935			
Assay Xpert MTB-RIF Ass ay G4			
Version 5	Views		
Reagent Lot ID 06107	Result View		
Test Type Specimen 🔻	Primary Curve		
Sample Type Other 💌			
Other Sample Type		<no available="" data=""></no>	
Notes			
10/03			
	19 1		
Save Changes Export Report	nt Select Graphs	View Test	

Error 2008

Pressure reading exceeds the maximum

Origin(s)

- Cartridge filter is clogged (due to highly viscous sample or debris)
- Pressure sensor failure

- Make sure sample does not contain any solid particles
- Make sure the sample is liquid before transferring to the cartridge
- Use a new cartridge and add DEPC treated water (same volume as sample). Load cartridge and note final result. If this problem persists it's likely module related: contact Cepheid



Module communication loss was detected: codes 212X



Errors 212X

Loss of communication between module(s) and software, while test is running

Origin(s)

- Power supply issue (Mains or UPS)
- Faulty PC-GX Ethernet connections
- Faulty connections between gateway board and modules
- Room temperature above or below expected range

- Check mains supply and use appropriate UPS with surge protector
- Unplug and replug Ethernet cable between computer and instrument, restart the system
- Check the module internal temperature in the Maintenance menu
- Unplug and replug the communication cables inside GX, upon Technical Support request

Signal loss detected in the amplification curve: code 5011

GeneXpert® Dx System			
User Data Management Reports Setup	View Results About		User <none></none>
Create Test Check Status	s Stop Test	View Results Define Assays Define Graph	is Maintenance
Module Name B4	Views	Test Result Analyte Result Detail Errors History Support	
Patient ID	Result View	Troubleshoot	
	Primary Curve	# Description	Time
	1000	Post-run analysis Error 5011: Signal loss detected in the amplification curv	ve for analyte 01/10/15
Patient ID 2		error [Probe B]. 15.1 decrease in signal with 29.0% decrease	at cycle 8. 00:39:08
279 Assay Xpert MTB-RIF Ass ay G4 Version 5 Reagent Lot ID* 16108 Test Type Specimen Sample Type Other	Views Result View Primary Curve	200 160 120	Legend Z Probe D; Primary Probe C; Primary Probe C; Primary Probe B; Primary Probe B; Primary SPC; Primary SPC; Primary
Other Sample Type Notes		40 0 1 2 3 4 5 6 7 8 Cycles	Probe A; Primary QC-1; Primary QC-2; Primary QC-2; Primary √
Save Changes Export Repor	t Select Graphs	View Test	

Error 5011

Signal loss detected in the amplification curve

Origin

Loss of PCR tube pressure because the cartridge tube is not airtight, or cartridge valve is not working correctly

- Avoid transferring bubbles to the cartridge
- Use a new cartridge. If the error persists, this can be module related. Contact Cepheid Support



Training and assistance

Should you need some training please contact us or your local service provider if available in your country

Service	Telephone	Email address
Training Center (Europe)	+33.5.63.82.53.94	training@cepheidhbdc.com
Technical hotline (Europe based)- Instrument errors	+33.5.63.82.53.19	support@cepheideurope.com
Technical hotline (U.S.A based)- Instrument errors	888-838-3222, Option 2	techsupport@cepheid.com

For more information please visit http://www.cepheidcares.com/tb/index.php



Technical information of your Genexpert

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Information of your GeneXpert	
Person in charge (name)	
Phone number	
Serial number of your GeneXpert (on the back panel)	
E-mail address	
Address City Country	
Computer Service Express Service Tag Number	
Installation date of the system	/
Windows Password (Should never be changed)	cphd
UPS (manufacturer, model)	
UPS Battery (V and AH)	
© Cenheid – Confidential	ase prepare this information in advance



Thank You.

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