Problem and Cause Codes Guide

Contents

Correct Use of Problem and Cause Codes

The following document is a guide to assigning problem and/or cause codes when creating/updating service requests and/or complaint records.

The document is available in German and French.

Selecting a Problem Code

- When selecting a problem code, look for the description that most closely matches what the customer is describing.
- If there has been no complaint about the product's performance, including requests for upgrade, then the 'General service and evaluation' code should be used.

Note: *Problem codes that should **ONLY** be used for LIFE SUPPORT have 'Life' as a prefix.*

Selecting a Cause Code

- Do not select cause codes based on precautionary or mandatory service procedures, e.g. unit was recalibrated even though the device passes the general inspection procedure, or main PCB replaced as a precaution even though the fault could not be reproduced.
- If the reported complaint or fault cannot be reproduced, (i.e. device is performing to specification), select the 'No fault found' code.
- Use the 'Unable to determine cause' code only when you can confirm or reproduce the complaint or reported fault, but unable to determine the cause of the fault.
- Use 'Other' code only when the cause of complaint is not related to any of the available cause codes.

Definitions

NON LIFE SUPPORT – This applies to all products except ASTRAL

LIFE SUPPORT – This applies only to the ASTRAL product family

NARVAL MAD – This applies only to the NARVAL product family

Non-Life Support – Devices

Problem Codes

Problem Code	Complaint Category	Description	Example of Correct Use
Alarm operation	6	Incorrect alarm operation	• Low pressure alarm did not trigger • Patient apnea alarm continually triggers • Inaudible alarm – LED lit but no sound • No breath alarm was triggered though patient was breathing
Appearance	6	Discoloration marks on product	• New device has scratches on case • Grease marks on touch screen • Yellowed keys or casing
Auto triggering	6	Device is not triggering or cycling correctly between inspiration and expiration (bi-level devices, POC devices)	• Device would not properly synchronise with patient breathing • Device would not detect patient breath • POC device keeps toggling between Active and Rest mode
Battery autonomy	6	Issue with device switching over and running off internal or external battery	• Incorrect voltage output • Device only runs for 1 hour off internal battery • Device did not switch to battery backup when mains power was removed • Device will not switch from external to internal battery power when external battery is depleted • "X" is displayed over internal or external battery symbol on display • Device will not charge external battery after internal battery reaches full charged
Charging problem	6	Battery related issue	• Internal battery does not charge • Charges too slowly • Does not charge fully • Short battery life • Charger will not charge the device • LED on charger pack does not luminate • Damaged charger port

Problem Code	Complaint Category	Description	Example of Correct Use
Commercial/Service complaint	4	Complaint related to commercial transactions or service quality	• Invoice had wrong quantity of products ordered • Customer service not responsive • Products delivered to wrong address
Contaminated	6	Contamination such as dust, fuzz, fluff, insect/s, hair, wool, cotton, dirt, foreign matter, white powder, powder, fire soot, candle soot, tobacco residue, specks, spots, black particles, black debris, debris, particles, water, other liquids	• Customer has seen dust, fuzz, fluff, insect/s, hair, wool, cotton, dirt, foreign matter, white powder, powder, fire soot, candle soot, tobacco residue, specks, spots, black particles, black debris, debris, particles, water, other liquids from external source
Cyber Security/Privacy	2	For Air11 product family only: Device/software security breach which can compromise device/software settings, patient reports or patient data	• Customer complaints device/software was hacked (settings changed) • Customer received another patients report • Patient data was maliciously changed
Data/Communications	6	Inability to interface with computer Any problem with device data or SD card data	• Cannot download data from device • ResScan cannot recognise device • Service software cannot recognise device • ResScan does not detect SD Card • Data is missing from SD Card • SD Card has an error • Cannot update firmware • Firmware freezes on device, will not perform electronic reset
Death	1	A patient death has been reported	• Death on a patient on a flow generator • OSA patient user of ResMed device died after stroke • Death of patient on a portable oxygen concentrator
Device failure not specified	6	Device alleged faulty but customer has not provided a problem description	• Customer has claimed that device is not working properly, but has not provided any more specific details • Device problem not stated

Problem Code	Complaint Category	Description	Example of Correct Use
Diagnostic Data (AirView and Peripheral devices only)	6	Incorrect or no diagnosis arising from Apnealink to Cloud	• Incorrect or no diagnosis from the apnea link device • Inability to achieve or report a diagnosis from an Apnealink device
Display issues	6	Fault on LCD, LED, touchpad and other panel displays	• LCD displays black squares or unrecognisable text • LEDs do not light up • Any display fault (lines, blurry or coloured) • Device will power on but display has no text or backlight • Able to change device settings via touchscreen
Durability	6	Premature wear out of parts	• The O2 cell had to be replaced after only 3 months of use • Filter has lasted only 2 months instead of 4 to 6 as expected
Electrical burnt smell or arcing	6	Electrical burnt smell or visible/audible arcing	• Smells like something is burning • Arcing occurs when switching on or inserting power cord • Burning smell, smoke without allegation of fire/flame event
Electromagnetic Interference (Compatibility)	6	The device has been associated with interference of other electrical devices	• The device is alleged to cause interference on PSG signals • The interference from other devices is affecting device performance • The device is alleged to have caused electromagnetic disturbance on patient monitoring equipment
Error message displayed	6	Any error message displayed on unit	• Device is displaying ‘System error! Call Service’ • General malfunction error • Error present but no information provided about error type
Faulty Bluetooth	6	No Bluetooth communication	• Smartphone Bluetooth not syncing with the device

Problem Code	Complaint Category	Description	Example of Correct Use
Fire/Flame	1	Device involved in fire-related incident or evidence of smoke, burn or melted parts	• Caught on fire • Fire damaged • Device was smoking, with allegation of fire/flame event
Flow	6	Device flow is too high or low or device measured flow is out of specification	• Device peak flow is too low • Continuous flow • No flow but device indicates breath detected • Compressor stalls or does not turn on • POC device does not charge according to the flow setting configured
Foam particles	6	Contamination via device source: Foam particles, green particles, broken foam pieces, green debris or blue debris (not applicable to Elisee and Stellar product family)	• Customer has seen foam particles such as green particles, broken foam pieces, green debris or blue debris from the device
General service and evaluation	Not a complaint	Customer request to check device with NO ASSOCIATED COMPLAINTS; also upgrade	• Customer would like device checked to ensure it is still in good condition • Checking a returned ex-loan unit prior to returning to loan pool • Checking device with no alleged fault • Device returned as part of service contract with no alleged fault
Heating	6	Device with reported heating related issues	• Overheating • Not heating • Enclosure temperature too high • Fan not spinning
Incorrect Diagnostic Data/Therapy delivered	2	Reported evidence of misdiagnosis leading to incorrect treatment or no treatment at all (Apnealink, Night Owl) Reported evidence of incorrect therapy delivered (Airview)	• Evidence of misdiagnosis leading to incorrect treatment or no treatment at all (Apnealink, Night Owl) • Evidence of incorrect therapy delivered (Airview)
Information request	Not a complaint	Request for information with no associated complaint	• Customer has requested a clinical manual or user guide • Customer has requested for relevant information about the products (eg. Is device made of BPA free materials?)

Problem Code	Complaint Category	Description	Example of Correct Use
Injury	1	Any actual or perceived injury not included in skin irritation or skin breakdown	• Patient burns themselves on humidifier • Patient had a stroke because device keeps shutting down • Patient had electric shock because of therapy • Patient desaturated on a flow generator/ventilator/portable oxygen concentrator
Leaking	6	Excessive air, oxygen leakage or any water leaking from humidifier, FG, connector, tubing	• Humidifier chamber is leaking • Excessive air leakage from flow generator • Oxygen leakage from oxygen connector
Loan return	Not a complaint	Unit on loan returned to ResMed with no associated complaint	• Rental or loan device returned as it is no longer required or loan/rental period has expired. • There are no reported faults with the device.
Machine interface	6	Button operation Peripheral equipment interfaces, e.g. ResLink, Humidifier or Tubing	• Touchpad not responding • Dial not responding • Button not responding • Humidifier not attaching; difficult to remove • Flow generator not recognising ResLink attachment • Keypad/Button sticking (eg. Permanent depressed or stuck) • Tube not attaching
Melted	1	Melted appearance with no signs of flame or fire	• Tube melted • Climateline melted • Device case deformed
Mislabel/Incorrect label	1	Device or packaging is labelled incorrectly	• Lot number was missing off packaging • AirSense 10 has AirCurve 10 fascia • Device website is not accurate • Product label was not affixed on device
Missing part	6	Missing part noticed when package opened	• Flow generator arrives without power cord and air hose

Problem Code	Complaint Category	Description	Example of Correct Use
Noisy	6	Objectionable noise from product	• Whining noise • Tonal noise • Noise during inhalation • Noise during exhalation • Noise at start up • Noise when pressure is at X • Unit is louder than other units
No reported complaint	Not a complaint	No complaint on unit; unit is returned together with a complaint unit	• Humidifier is faulty, the co-packed flow generator is returned with the humidifier. An SR created for the flow generator will use this problem code.
Others/Malfunction	2	A new or unexpected fault type has been reported	• Fault type cannot be aligned to any of the existing problem codes
Oxygen Issue	6	Issue with connection or measurement of oxygen	• Measurement of FiO2 was incorrect • Low oxygen purity alarm or test result • Patient felt that no or low purity oxygen provided by device • Patient felt oxygen delivery is not regulated
O2 fitting	6	O2 fitting is loose or missing	• O2 fitting loose • O2 fitting broken off
Patient circuit detection	6	Device is not correctly detecting the connected patient circuit	• Device won't detect the double limb circuit • Device not recognising the climateline tubing
Physical damage	6	Device has obvious physical damage	• Case has a crack or dent mark • Knob is broken
Power	6	No response or intermittent response when unit is turned on	• Device won't power up after switching on • Device powering on intermittently • Device shutting off during use
Pressure	6	Device pressure too high or low	• Pressure ramps straight up to maximum pressure • S9 surge in pressure • Pressure dropped

Problem Code	Complaint Category	Description	Example of Correct Use
			• Pressure running above set pressure
Product improvement suggestion	5	Suggestions for improving the product or service, WITH NO COMPLAINT	• Customer suggests a new on-screen message for a product feature (e.g. CSAD message on screen when activated) • Suggestion of product size reduction
Rainout	6	Customer keeps getting rainout.	• Water in tube and/or mask
Smell/odour	6	Smell unacceptable to customer (e.g. strong new smell, vinegar smell, cigarette smell etc.)	• Has a cherry-like smell • Strong plastic smell
Start-up self test	6	The unit has power, but fails to initialise or pass the self-test and does not show an error message	• Unit stays at the Welcome screen after power up • Device starts and stops by itself • Unit will not enter Auto Pulse mode so testing can be performed
Treatment issue	6	Customer believes that system is not delivering prescribed therapy. Device may be over-treating or under-treating patient.	• Patient feels that they are still having too many apneas because the device is under-treating them
Volume out of specification	6	Device reported volume measurements are not within specification	• Tidal volume displayed by the device is inaccurate when compared with other measurement device • Deviation in volume measurement • Bolus size incorrect

Cause Codes

Cause Code	Description
AC inlet socket	Any fault associated with the AC inlet socket. *Example: Open solder joints on the AC inlet socket*
AIB PCB (Ventilator)	Fault with AIB PCB. *Example: Faulty AIB PCB caused error message to occur*
Alarm module	Any fault with an alarm module.
Battery	Any fault with the battery or batteries (internal or external) used within the device.
Bluetooth module	Fault with the communication module used with current ventilators. *Example: Bluetooth could not be detected as it was faulty*
Buzzer	Any fault with the device buzzer.
Calibration	Calibration out of limits.
CAM PCB Failure	No signal symbol displayed on AirSense 10, CAM registration fails.
Closed - GSS	Issue is closed in GSS.
Component incorrect or missing	The device has a component missing or has an incorrect component fitted.
Connector	Connector defective, loose or poorly fitted.
Contaminated	Smoke, dust, chemical contamination, tobacco or pest infestation.
Cooling fan	Fault with device cooling fan (used in some ventilator models and POC devices). *Example: Cooling fan has seized up*
Data Storage	Fault with SD card. Fault with USB data storage stick. *Example: SD card cover has cracked* *PC fails to recognize USB data storage stick*
Decal	Faults with device decals e.g. cracked, peeling.
Documentation	Any issue related to lack of or misleading information in product literature. *Example: Setting ranges for Start Pressure in clinical manual are incorrect*
Duckbill valve	Duckbill valve caused fault. *Example: Clogged duckbill preventing air flow, duckbill squeaking caused noise*
Electronic component failure	Faulty electronic component on main PCB. *Example: Fault was caused by resistor R3 on the main PCB going open circuit*
Electrovalve I/E (Ventilator only)	Faulty I/E electro valve. *Example: I/E electro valve was sticking*
Electrovalve O2 (Ventilator only)	Faulty O2 electro valve. *Example: O2 electro valve will not open*
Electrovalve (other) (Ventilator only)	Covers electrical faults not related to either I/E or O2 electro valves. *Example: Auto-offset valve is intermittently sticking*

Cause Code	Description
EMI-RFI problems	Electrical interference generated internally or externally.
End of Life	Reported fault was due to product is reaching the end of useful life.
Expiratory valve (Ventilator only)	Any fault with the expiratory valve assembly.
Filter	Filter very dirty.
Flow element	Fault has been caused by flow element (do not use for flow sensor faults).
Flow sensor	Flow sensor is faulty. *Example: Flow calibration offsets are out of range due to faulty flow sensor*
Foam	Faults associated with foams on or in the device. *Example: Foam is deteriorating, foam is coming loose*
Fuse	A fuse within the device is faulty and is the cause of the device problem.
Incorrect labelling	Device has been received with incorrect labelling, either on the device itself or on the packaging.
Indicators	Faulty panel indicators (does not include LCD screen).
Integrated circuit	An IC or chip within the device is found to be faulty and is the cause of the reported problem. *Example: Circuit breaker tripped, had to use breaker reset (DUO)*
Java	New Java version released. *For example: Persons PC has incompatibility with current Java version*
Keypad	Device keypad is cause of the fault. *Example: Start/Stop button has torn away from keypad*
LCD module	Faulty LCD or LCD module. *Example: Characters missing from LCD*
Main PCB	Fault with the main PCB was the cause of problem. *Example: System error caused by fault with main PCB. Replacing main PCB fixes problem*
Manifold	Manifold defect caused fault. *Example: Cracked manifold, orifice loose in manifold, cracked elbow, leak in manifold*
Manufacturing defect	Defects that can be attributed directly to manufacturing or assembly process (not faults in silicone moulding or plastic parts).
Material degradation	Material within the device is degrading or deteriorating.
Mechanical driver (Ventilator only)	Fault with mechanical assembly used in ventilator models that use a bellows device. *Example: Bellows not functioning because of fault with mechanical driver*
Membrane (Ventilator only)	Fault is caused by issue with membrane (part of the expiratory valve). *Example: Membrane was not seated correctly in the expiratory valve which caused the fault*
Motor brushes (Ventilator)	Fault with the motor brushes.

Cause Code	Description
	Example: Motor brush was not making contact with the commutator
Motor/blower	Motor/blower faults. *Example: Defective compressor causes the fault*
No fault found	Unit fully tested and found to be working within service specifications.
Not related to device	The incident/malfunction that occurred is confirmed to have been caused by something other than the device or usage. Fault (if any) found is not related and the device did not contribute to the reported event. *Example: Unrelated medical circumstance led to the death of a patient (drug overdose)*
Not yet determined	The default cause code setting when a service request has been created. Indicates that the device has not yet been serviced.
O2 fitting	O2 fitting broken, missing or O2 fitting clip is loose.
O2 sensor	Oxygen sensor not operating properly causing device to alarm when O2 levels are in specifications. Example: O2 sensor was thermally damaged due to overheating. O2 sensor cable was not connected properly.
Off-label/Contraindicated use	Reported fault was due to use of product for which it is contraindicated, or not listed on the label.
Operator error	Reported fault was due to incorrect operation of product.
Optical sensor	Fault with the optical sensor. *Example: HumidAire 3i could not be detected because of fault with the optical sensor*
Other	The cause of the complaint is not related to any of the other cause codes.
Oxygen cell (Ventilator only)	Fault with the oxygen cell.
Oxygen PCB (Ventilator only)	Fault with the oxygen PCB.
Oxygen pressure reducer (Ventilator only)	Fault with the oxygen pressure reducer.
Ozone damage	Fault/Damage/Degradation of device determined to be caused by ozone (e.g. sanitizing machine) with signs of ozone exposure/contamination found in the device.
Packaging	Faults caused by inadequate part or device packaging. Applies to new devices or spare parts that arrive damaged due to inadequate packaging. *Example: Main PCB spare part was not properly packaged in carton and arrived damaged*
PEEP amplifier (Ventilator only)	Fault with PEEP amplifier.
PEEP pump/turbine (Ventilator only)	Fault with PEEP pump/turbine.
Physical abuse	Faults/defects attributable to physical abuse of product by customer.
Plastic moulded part	Defect of plastic part (deformed, marks, colour variation etc.).

Cause Code	Description
Pneumatic Block (Ventilator only)	Any fault that can be directly related to the pneumatic block.
Poor fit	Fit of part lacks strength, requires too much force or lacks positive sound/feel.
Potentiometer	Fault with the potentiometer.
Power cord	Fault with power cord. *Example: The device could not be powered on because one of the power cord pins was broken* *The internal wire(s) of the power cord was broken*
Pressure sensor	Fault with pressure sensor. *Example: The pressure sensor was sticking and causing the system error* *Pressure sensor intermittently functions or does not provide consistent output data*
Production Operator	Fault that can directly be attributed to human error in the manufacturing process. *Example: Missing filters from a 50 filter pack*
PSU	Fault with whole power supply PCB (does not include batteries or regulators). Example: Defective PSU does not provide intended output voltage to power up the device.
Rotary valve (Ventilator only)	Fault with rotary valve. *Example: A faulty rotary valve was causing the device to prematurely cycle out of inspiratory phase*
Seal	Fault with seals/O-rings.
Signal Strength	No signal detected.
Silicone moulding	Defect of silicone part - deformed, split, inclusions, etc.
Software	Fault attributed directly to a known software/firmware issue. Electronic reset of device resolved issue. Example: Device not functioning properly due to inaccurate calibration of sensor. Upgrade of software/firmware resolves the issue.
Solder problems	Fault due to solder problems - bridges, splashes, dry joints etc.
Switch	Fault with device switch - usually related to the on/off switch. Not to be used for keypad faults.
Touch screen (Ventilator only)	Faulty touch screen pads or modules. *Example: Touch screen does not respond when pressed*
Transformer (Ventilator only)	Fault with transformer. *Example: No voltage out from the transformer*
Transit damage	Device has been damaged when being shipped from supplier to customer
Tubing	Faults related to any tubing used within the device. *Example: The sensor tubing connected to the pressure sensor was kinked.* *Tubing disconnected within the device due to tubing ID too large and not within specification.*
Unable to determine	A fault exists, but the cause cannot be determined. The reported problem can be confirmed or reproduced, intermittently or consistently, but the cause of the problem is not known.

Cause Code	Description
Unit was never returned	Customer never returned the device.
Upgrade Failure	Software upgrade failed due to operator error, intermittent connection to the device or a software problem.
Valve	Portable Oxygen Concentrator Valve not actuating, sticking or clogged causing fault. Valve leaking. Example: Valve was defective and thus, not actuating or open/close fully.
Vocal synthesizer (Ventilator only)	Fault in the digital sound output module.
Water damage	Water is in the device, or evidence of water having been spilled into the device.
Interconnect cable	Fault with any cable, cable assemblies, wiring harness, FFC (Flat Flexible Cable), FPC (Flat Plastic Cable), etc. that is used for interconnecting between modules or boards. Example: Wire crimping of the cable assemblies was not done properly and caused intermittent connection. Cable jacket was found damaged upon receiving from manufacturer/supplier. The pitch or cable width of the FPC/FFC was out of specifications.

Remedy Codes

Beyond repair - scrapped
Closed as duplicate
Convert to Repair - – returned unit warranty voided
Device replaced
Installed missing component
Minor repairs – returned unit warranty voided
No corrective action
No Customer Response-Returned to Customer Unrepaired
Reassembled
Recalibrated
Reconfigured settings
Regular maintenance - Device was initially returned for routine or regular maintenance
Reloaded software
Repairs Declined-Returned to Customer unrepaired
Resoldered
Returned for third party servicing
Sub-assembly Replaced
Training
Upgraded
Z-GSS ticket

Life Support – Devices and Accessories

Problem Codes

Problem Code	Complaint Category	Description	Example of Correct Use
Life-Appearance	6	Discoloration marks on product	• New device has scratches on case • Grease marks on touch screen • Yellowed keys or casing
Life-Device Inoperable	1	Life support device will not deliver therapy or error preventing ventilation. Device alleged faulty but customer has not provided a problem description.	• 'Device Inoperable' Error message • Freezes on Start-up • Red/black or frozen screen • Unable to change device settings via touchscreen • Touchscreen inoperable • Device inoperable due to physical damage while on a patient
Life-Ventilation Stopped	1	Life support device stops temporarily or unexpectedly restarts	• Ventilation stops with an alarm • An 'Unexpected Restart' alarm is triggered
Life-Alarm Raised	1	Astral alarm/error is triggered and cannot be rectified.	• All system fault alarm messages except error codes related to learn circuit • Total Power Failure (TPF) alarm message
Life-Alarm Not Raised	1	Incorrect alarm operation	• Likely due to an incorrect understanding of alarm operation • Ventilation stopped without an alarm • No audible sound with visual alarm • No visual alarm with audible sound
Life-Auto triggering	6	Device is not triggering or cycling correctly between inspiration and expiration	• Device would not properly synchronise with patient breathing
Life-Battery Problem	1	Life support device ventilate but there is issue with the battery	• Reoccurring battery alarm that cannot be cleared • Issue with device switching over and running off internal or external battery • Battery not charging

Problem Code	Complaint Category	Description	Example of Correct Use
Life-Circuit Test Failure	6	Learn Circuit or Circuit test cannot be performed successfully	• Circuit test always fails • Learn Circuit doesn't work with humidifier
Commercial/Service complaint	4	Complaint related to commercial transactions or service quality	• Invoice had wrong quantity of products ordered • Customer service not responsive • Products delivered to wrong address
Life-Communications	6	Inability to interface with computer	• Service software does not detect device
Life-Contaminated	6	Contamination such as dust, insect, hair, dirt, foreign matter, water, other liquids	• Customer has seen insect, hair, dust, white powder, water or liquid in the device
Life-Data	6	Any problem with device data	• ResScan does not detect data • Device data is missing • Data has an error
Display Issues	6	Complaints related to the display of the device	• Screen flashing • Screen flickering • Screen glittering • Able to change device settings via touchscreen • Cannot be used if the device is inoperable
Durability	6	Premature wear out of parts	• Top case gets scratched easily • Customer reports spare part has an out of box failure (excluding battery) while trying to replace the part in the device
Life-Death	1	A patient death has been reported	• Death of a patient on a Life Support product • User of ResMed device died after stroke
Life-Electrical burnt smell or arcing	1	Electrical burnt smell or visible/audible arcing	• Smells like something is burning • Arcing occurs when switching on or inserting power cord

Problem Code	Complaint Category	Description	Example of Correct Use
			• Burning smell, smoke without allegation of fire/flame event
Life-Fire/Flame	1	Device involved in fire-related incident or evidence of smoke, burn or melted parts	• Caught on fire • Fire damaged • Device was smoking
General Service and evaluation	Not complaint	Customer request to check device with **NO ASSOCIATED COMPLAINTS**; also upgrade	• Customer would like device checked to ensure it is still in good condition • Checking a returned ex-loan unit prior to returning to loan pool • Checking device with no alleged fault • Device returned as part of service contract with no alleged fault
Life-Heating	6	Device over heating (enclosure temperature)	• Overheating • Enclosure temperature too high
Information Request	Not a complaint	Request for information with no associated complaint	• Customer has requested a clinical manual or user guide
Life-Injury	1	Any actual or perceived injury not included in skin irritation or skin breakdown	• Patient burns themselves on Humidifier • Patient had a stroke because device keeps shutting down • Patient had electric shock because of therapy
Loan Return	Not complaint	Unit on loan returned to ResMed with no associated complaint	• Rental or loan device returned as it is no longer required or loan/rental period has expired. There are no reported faults with the device.
Life-Malfunction	2	• A new or unexpected fault type has been reported • SF180 alarm (Power fault/No charging alarm on R5 and above)	• Fault type cannot be aligned to any of the existing problem codes • Power fault/no charging/SF180 alarm activated during charging of the internal battery

Problem Code	Complaint Category	Description	Example of Correct Use
Life-Mislabel/Incorrect label	1	Device or packaging is labelled incorrectly	• Lot number was missing off packaging • Device website is not accurate
Missing part	6	Missing part noticed when package opened	• Accessories missing
Noisy	6	Objectionable noise from product	• Noisy double limb adapter
Life-Oxygen Issue	6	Issue with connection or measurement of oxygen	• Measurement of FiO2 was incorrect • Connection of FiO2 was incorrect • Measurement of O2 was incorrect
Life-Physical Damage	6	Device has obvious physical damage	• Case has a crack • Screen has a crack
Life-Power	1	Life support device not powering on or unable to turn off or intermittent response when turned on	• Not powering up when turned on • Device unable to recognise the power source
Life-Pressure	6	Device pressure too high or low	• Pressure ramps straight up to maximum pressure • Surge in pressure • Pressure dropped • Pressure running above set pressure
Product Improvement suggestion	5	Suggestions for improving the product or service, **WITH NO COMPLAINT**	• Customer suggests a new on-screen message for a product feature (e.g. CSAD message on screen when activated) • Suggestion of product size reduction
Life-Rainout	6	Customer keeps getting rainout. Water in tube and or mask.	• Wakes up with water gurgling in tube

Problem Code	Complaint Category	Description	Example of Correct Use
Life-RSS Test Failure	6	Applicable to RSS (ResMed Service Software) service test failures only when there is no field failure reported.	• Device returned for preventative maintenance and failed a RSS test during evaluation or calibration on the bench. • Customer reports device fails RSS test or device fails calibration.
Life-Smell/odour	6	Smell unacceptable to customer (e.g. strong new smell, vinegar smell, cigarette smell etc.)	• Has a cherry-like smell • Strong plastic smell
Life-Treatment issue	6	Customer believes that system is not delivering prescribed therapy. Device may be over-treating or under-treating patient.	• Patient feels the device is under-treating them.
Life-Warning Alarm	6	Device alarmed as designed to alert user for attention or action. Alarm does not indicate any fault with device and unlikely to result in an adverse event.	• All adjustable alarms (high leak) • Incorrect circuit alarm • Circuit fault alarm • High PEEP alarm • Critically low internal battery alarm • Pressure line disconnected alarm • Internal battery degraded alarm

Cause Codes

Cause Code	Description
AC inlet socket	Any fault associated with the flow generator AC inlet socket. *Example: Open solder joints on the AC inlet socket*
Alarm module	Any fault with an alarm module.
Battery	Any fault with the battery or batteries used within the device.
Buzzer	Any fault with the device buzzer.
Calibration	Calibration out of limits.
Closed - GSS	Issue is closed in GSS.
Component incorrect or missing	The device has a component missing or has an incorrect component fitted.
Connector	Connector defective or poorly fitted.
Contaminated	Smoke, dust, chemical contamination, or pest infestation.
Cooling fan	Fault with device cooling fan (used in some ventilator models). *Example: Cooling fan has seized up*
Data Storage	Fault with SD card. Fault with USB data storage stick. *Example: SD card cover has cracked* *PC fails to recognise USB data storage stick*
Decal	Faults with device decals e.g. cracked, peeling.
Documentation	Any issue related to lack or misleading information in product literature. *Example: Setting ranges for Start Pressure in clinical manual are incorrect*
Electronic component failure	Faulty electronic component on main PCB. *Example: Fault was caused by resistor R3 on the main PCB going open circuit*
Electrovalve I/E	Faulty I/E electro valve. *Example: I/E electro valve was sticking*
Electrovalve O2	Faulty O2 electro valve. *Example: O2 electrovalve will not open*
Electrovalve (other)	Covers electrical faults not related to either I/E or O2 electro valves. *Example: Auto-offset valve is intermittently sticking*
EMI-RFI problems	Electrical interference generated internally or externally.
End of Life	Reported fault was due to product is reaching the end of useful life.
Expiratory valve	Any fault with the expiratory valve assembly.
Sensor PCB	Astral fails quick flow test or calibration test at Service Centre.
Flow element	Fault has been caused by flow element (Do not use for flow sensor faults).
Flow sensor	Flow sensor is faulty. *Example: Flow calibration offsets are out of range to due faulty flow sensor*

Cause Code	Description
Foam	Faults associated with foams on or in the device. *Example: Foam is deteriorating, foam is coming loose*
Fuse	A fuse within the device is faulty and is the cause of the device problem.
Incorrect labelling	Device has been received with incorrect labelling, either on the device itself or on the packaging.
Indicators	Faulty panel indicators (does not include LCD screen).
Integrated circuit	An IC or chip within the device is found to be faulty and is cause of the reported problem.
Keypad	Device keypad is cause of the fault. *Example: Start/Stop button has torn away from keypad* *Alarm button not working*
LCD module	Faulty LCD or LCD module. *Example: Characters missing from LCD*
Main PCB	Fault with the main PCB was the cause of problem. *Example: System error caused by fault with main PCB. Replacing main PCB fixes problem*
Manufacturing defect	Defects that can be attributed directly to manufacturing or assembly process (not faults in silicone moulding or plastic parts).
Material degradation	Material within the device is degrading or deteriorating.
Membrane	Fault is caused by issue with membrane (part of the expiratory valve). *Example: Membrane was not seated correctly in the expiratory valve which caused the fault*
Motor/blower	Motor/Blower faults.
Motor Capacitor	A fault with the device motor capacitor.
No fault found	Unit fully tested and found to be working within service specifications.
Not related to device	The incident/malfunction that occurred is confirmed to have been caused by something other than the device or usage. Fault (if any) found is not related and the device did not contribute to the reported event. *Example: Unrelated medical circumstance led to the death of a patient (drug overdose)*
Not yet determined	The default cause code setting when a service request has been created. Indicates that the device has not yet been serviced.
NRV	Any fault that can be directly related to the non-return valve. This component in typically used in ventilators.
Off-label/Contraindicated use	Reported fault was due to use of product for which it is contraindicated, or not listed on the label.
Operator error	Reported fault was due to incorrect operation of product.
Optical sensor	Fault with the optical sensor. *Example: Fault with the optical sensor*
Other	The cause of the complaint is not related to any of the other cause codes, such as a commercial complaint. *Example: Customer has complained that the S8 device does not have on/off switch*

Cause Code	Description
Oxygen cell	Fault with the oxygen cell.
Oxygen PCB	Fault with the oxygen PCB.
Ozone damage	Fault/Damage/Degradation of device determined to be caused by ozone (e.g. sanitizing machine) with signs of ozone exposure/contamination found in the device.
Packaging	Faults caused by inadequate part or device packaging. Applies to new devices or spare parts that arrive damaged due to inadequate packaging. *Example: Main PCB spare part was not properly packaged in carton and arrived damaged*
PEEP amplifier	Fault with PEEP amplifier.
PEEP pump/turbine	Fault with PEEP pump/turbine.
Physical abuse	Faults/defects attributable to physical abuse of product by customer.
Plastic moulded part	Defect of plastic part (deformed, marks, colour variation etc.).
Pneumatic Block	Any fault that can be directly related to the pneumatic block.
Poor fit	Fit of part lacks strength, requires too much force or lacks positive sound/feel.
Potentiometer	Fault with the potentiometer.
Power cord	Fault with power cord. *Example: The device could not be powered on because one of the power cord pins was broken*
Pressure sensor	Fault with pressure sensor. *Example: The pressure sensor was sticking and causing the system error*
Production Operator	Fault that can directly be attributed to human error in the manufacturing process. *Example: Missing filters from a 50 filter pack*
PSU	Fault with whole power supply PCB (does not include batteries or regulators).
Rotary valve	Fault with rotary valve. *Example: A faulty rotary valve was causing the device to prematurely cycle out of inspiratory phase*
Seal	Fault with seals/O-rings.
Silicone moulding	Defect of silicone part - deformed, split, inclusions, etc.
Software	Fault attributed directly to a known software issue.
Solder problems	Fault due to solder problems - bridges, splashes, dry joints, etc.
Switch	Fault with device switch - usually related to the on/off switch. Not to be used for keypad faults.
Touch screen	Faulty touch screen pads or modules. *Example: Touch screen does not respond when pressed*
Transformer	Fault with transformer. *Example: No voltage out from the transformer*

Cause Code	Description
Transit damage	Device has been damaged when being shipped from supplier to customer.
Tubing	Faults related to any tubing used within the device. *Example: The sensor tubing connected to the pressure sensor was kinked*
Unable to determine	A fault exists, but the cause cannot be determined. The reported problem can be reproduced, intermittently or consistently, but the cause of the problem is not known.
Unit was never returned	Customer never returned the device.
Upgrade Failure	Software upgrade failed due to operator error, intermittent connection to the device or a software problem.
Water damage	Water is in the device, or evidence of water having been spilled into the device.
Interconnect cable	Fault with any cable, cable assemblies, wiring harness, FFC (Flat Flexible Cable), FPC (Flat Plastic Cable), etc. that is used for interconnecting between modules or boards. Example: Wire crimping of the cable assemblies was not done properly and caused intermittent connection. Cable jacket was found damaged upon receiving from manufacturer/supplier. The pitch or cable width of the FPC/FFC was out of specifications.

Remedy Codes

Beyond repair - scrapped
Closed as duplicate
Convert to Repair - – returned unit warranty voided
Device replaced
Installed missing component
Minor repairs – returned unit warranty voided
No corrective action
No Customer Response-Returned to Customer Unrepaired
Reassembled
Recalibrated
Reconfigured settings
Regular maintenance - Device was initially returned for routine or regular maintenance
Reloaded software
Repairs Declined-Returned to Customer unrepaired
Resoldered
Returned for third party servicing
Sub-assembly Replaced
Training
Upgraded
Z-GSS ticket

Mask codes

Problem Codes

Problem Code	Complaint Category	Description	Example of Correct Use
Appearance	6	Discoloration marks on product	• New mask has black marks on frame
Commercial/Service complaint	4	Complaint related to commercial transactions or service quality	• Invoice had wrong quantity of products ordered • Customer service not responsive • Products delivered to wrong address
Contaminated	6	Contamination such as dust, fuzz, fluff, insect/s, hair, wool, cotton, dirt, foreign matter, white powder, powder, fire soot, candle soot, tobacco residue, specks, spots, black particles, black debris, debris, particles, water, other liquids	• Customer has seen dust, fuzz, fluff, insect/s, hair, wool, cotton, dirt, foreign matter, white powder, powder, fire soot, candle soot, tobacco residue, specks, spots, black particles, black debris, debris, particles, water, other liquids from external source
Death	1	A patient death has been reported	• Patient dies whilst using UMFFM
Device failure not specified	6	Device alleged faulty but customer has not provided a problem description	• Customer has claimed device is not working properly, but has not supplied any more specific details
Durability	6	Complaints related to a user replaceable part that has worn out well before its expected life	• Mask too soft after 2 weeks of use • Headgear material frayed after a month
Electromagnetic Interference (Compatibility)	6	The device has been associated with interference of other electrical devices	• Causing electromagnetic interference with a pacemaker
General service and evaluation	Not a complaint	Customer requests to check device with no associated complaint; also upgrade	• Customer would like product checked where no alleged product fault exists
Information request	Not a complaint	Requested for information with no associated complaint	• Customer has requested a clinical manual or user guide • Customer has requested for relevant information about the products (eg. Is device made of BPA free materials?)
Injury	1	Any actual or perceived injury not included in skin irritation or skin breakdown	• Mask is causing alignment of teeth to be off • Skull deformation from use of mask
Leaking	6	Excessive air leakage, or any water leaking from mask, flow generator, humidifier or tubing	• Excessive air leaking from full face mask • Mask fitting is too loose
Mislabel/Incorrect label	1	Device or packaging is labelled incorrectly	• Labelled Large on package with Medium mask • Swift FX packaged with Swift LT pillows
Missing part	6	Missing part noticed when package opened	• Mask assembly arrives without associated head-gear
Noisy	6	Objectionable noise from product	• Whistling from vent

Problem Code	Complaint Category	Description	Example of Correct Use
No reported complaint	Not a complaint	No complaint on this particular unit; this unit is returned together with a complaint unit	• Complaint regarding user guide, the guide is returned with the mask. An SR created for the mask will use this problem code.
Others/Malfunction	2	A new or unexpected fault type has been reported	• Leaking of the gel
Physical damage	6	Device has obvious physical damage • transportation damage • customer abuse	• Mask frame has cracked • AAV is squeaking • Cushion slip has broken
Physical damage - cushion	6	Cushion tears	• Cushion is torn
Product improvement suggestion	5	Suggestions for improving the product or service, with no complaint	• Suggest to use feminine colors for your masks
Skin breakdown/Wound	1	Scar, open wound or skin damage REQUIRING MEDICAL ATTENTION	• Excessive bleeding on face • Deep wound around ears and cheeks
Skin irritation	6	Typically for mask products reddening, rash or discomfort of skin (not skin breakage) and DID NOT require medical attention	• Customer has red marks on face from cushion • Made face sore • Sore on nose bridge • Blisters on nose
Smell/odour	6	Smell unacceptable to customer (e.g. strong new smell, vinegar smell, cigarette smell etc.)	• Mask cushion smells of perfume
Treatment issue	6	Customer believes that system is not delivering prescribed therapy.	• Feels like suffocating • Difficult to exhale • Choking when using mask • Mask fitting is too tight

Cause Codes

Cause Code	Description
Closed - GSS	Issue is closed in GSS.
Component incorrect or missing	The device has a component missing or has an incorrect component fitted.
Connector	Connector defective or poorly fitted.
Contaminated	Smoke, dust, chemical contamination, or pest infestation.
Documentation	Any issue related to lack or misleading information in product literature. *Example: Setting ranges for Start Pressure in clinical manual are incorrect*
End of Life	Reported fault was due to product is reaching the end of useful life.
Incorrect labelling	Device has been received with incorrect labelling, either on the device itself or on the packaging.
Manufacturing defect	Defects that can be attributed directly to manufacturing or assembly process (not faults in silicone moulding or plastic parts).
Material degradation	Material within the device is degrading or deteriorating.
No fault found	Unit fully tested and found to be working within service specifications.
Not related to device	The incident/malfunction that occurred is confirmed to have been caused by something other than the device or usage. Fault (if any) found is not related and the device did not contribute to the reported event. *Example: Unrelated medical circumstance led to the death of a patient (drug overdose)*
Not yet determined	The default cause code setting when a service request has been created. Indicates that the device has not yet been serviced.
Off-label/Contraindicated use	Reported fault was due to use of product for which it is contraindicated, or not listed on the label.
Operator error	Reported fault was due to incorrect operation of product.
Other	The cause of the complaint is not related to any of the other cause codes, such as a commercial complaint. *Example: Customer has complained that the replacement cushions are too expensive.*
Ozone damage	Fault/Damage/Degradation of device determined to be caused by ozone (e.g. sanitizing machine) with signs of ozone exposure/contamination found in the device.
Packaging	Faults caused by inadequate part or device packaging. This code applies to new devices or spare parts that arrive damaged due to inadequate packaging.
Physical abuse	Fault/defects attributable to physical abuse of product by customer.
Plastic moulded part	Defect of plastic part (deformed, marks, colour variation etc.).
Poor fit	Fit of part lacks strength, requires too much force or lacks positive sound/feel. *Example: Poor fit of mask to patient face.*
Seal	Fault with seals/O-rings.
Silicone moulding	Defect of silicone part - deformed, split, inclusions, etc.
Transit damage	Device has been damaged when being shipped from supplier to customer.
Tubing	Faults related to any tubing used within the device.
Unable to determine	A fault exists, but the cause cannot be determined.
Unit was never returned	Customer never returned the device.

Remedy Codes

Beyond repair - scrapped
Closed as duplicate
Device replaced
Installed missing component
No corrective action
Reassembled
Sub-assembly Replaced
Training
Z-GSS ticket

Peripheral Device Codes

Peripheral devices include: ApneaLink series, Ectosense Night Owl, Oximeter, Passover humidifier, HumidAire, HumidAire 2i, HumidAire 3i, H4i, ResControl and ResControl II, ResMed Power Station and third party modules/devices.

Problem Codes

Problem Code	Complaint Category	Description	Example of Correct Use
Abdominal/Thoracic Track HS	6	The abdominal or thoracic sensor does not record the movements of the abdomen or thorax	• Thoracic movement records are flat
Alarm operation	6	Incorrect alarm operation	• Red LED on Power Station is flashing even though unit has been recharged
Appearance	6	Discoloration marks on product	• New ResControl II has scratches on case
Bad Contact	6	The sensor stops recording the polygraph/polysomnography	• The values intermittently display or disappear
Battery	6	Battery no power, leakage Session wasn't recorded as battery fell below minimum power	• Battery has no power or battery leaks • Session wasn't recorded as battery fell below minimum power • No lights indicating device hasn't powered on
Charging Problem	6	Battery related issue	• External battery does not charge • RPSII does not charge
Commercial/Service complaint	4	Complaint related to commercial transactions or service quality	• Invoice had wrong quantity of products ordered • Customer service not responsive • Products delivered to wrong address
Contaminated	6	Contamination such as dust, fuzz, fluff, insect/s, hair, wool, cotton, dirt, foreign matter, white powder, powder, fire soot, candle soot, tobacco residue, specks, spots, black particles, black debris, debris, particles, water, other liquids	• Customer has seen dust, fuzz, fluff, insect/s, hair, wool, cotton, dirt, foreign matter, white powder, powder, fire soot, candle soot, tobacco residue, specks, spots, black particles, black debris, debris, particles, water, other liquids from external source
Cyber Security/Privacy	2	For NightOwl only: Device/software security breach which can compromise device/software settings, patient reports or patient data	• Customer complaints device/software was hacked (settings changed) • Customer received another patients report • Patient data was maliciously changed

Problem Code	Complaint Category	Description	Example of Correct Use
Data/Communications	6	• Inability to interface with computer or peripheral equipment • Any problem with data/settings	• Cannot download data from the device • SmartData cannot be accessed
Death	1	A patient death has been reported	• Death of patient on ApneaLink
Defective Position Sensor	6	The position sensor does not function during a polygraphy/polysomnography	• The record indicates that the patient spent the night standing but in fact, patient was lying down
Device failure not specified	6	Device alleged faulty but customer has not provided a problem description	• Customer has claimed that device is not working properly, but has not provided any more specific details
Diagnostic Data (AirView and Peripheral devices only)	6	No diagnosis arising from Apnealink to Cloud No data from Night Owl resulting in delayed diagnosis	• No diagnosis arising from Apnealink • No data from Night Owl resulting in delayed diagnosis
Display issues	6	Fault on LCD, LED, touchpad and other panel displays	• LCD displays black squares or unrecognisable text • LEDs do not light up • Any display fault (lines, blurry or coloured) • Device will power on but display has no text or backlight • Able to change device settings via touchscreen
Durability	6	Premature wear out of parts	• Humidifier chamber only lasted 4 months before needing to be replaced
Electrical burnt smell or arcing	6	Electrical burnt smell or visible/audible arcing	• Smells like something burning • Arcing occurs when switching on or inserting power cord • Burning smell, smoke without allegation of fire/flame event
Error message displayed	6	Any error message displayed on unit or in software	• Flow generator with ResLink attached displays error message ‘Ox3FA’
Faulty Bluetooth	6	No Bluetooth communication	• unable to establish connection with device using Bluetooth

Problem Code	Complaint Category	Description	Example of Correct Use
			• The polygraph is not communicating with the oximeter on the T3 • Intermittent Bluetooth connection
Fire/Flame	1	Device involved in fire-related incident or evidence of smoke, burn or melted parts	• Caught on fire • Fire damaged • Device was smoking, with allegation of fire/flame event
Flow Problem: Flat	6	No flow is recorded on the track of the nasal cannula	• On the record, the flow appears flat
General service and evaluation	Not a complaint	Customer requests to check device with NO ASSOCIATED COMPLAINT; also upgrade	• Customer would like device checked to ensure it is still in good condition • Checking a returned ex-loan unit prior to returning to loan pool • Checking device with no alleged fault • Device returned as part of service contract with no alleged fault
Heating	6	Device over or under heating (for humidifiers only)	• Water in chamber is always cold • Water in chamber is bubbling and chamber feels hot • Overheating • Not heating • Doesn't stay hot during night
Incorrect Diagnostic Data/Therapy delivered	2	Reported evidence of misdiagnosis leading to incorrect treatment or no treatment at all (Apnealink, Night Owl) Reported evidence of incorrect therapy delivered (Airview)	• Evidence of misdiagnosis leading to incorrect treatment or no treatment at all (Apnealink, Night Owl) • Evidence of incorrect therapy delivered (Airview)
Information request	Not a complaint	Request for information with no associated complaint	• Customer has requested relevant user guide
Injury	1	Any actual or perceived injury not included in skin irritation or skin breakdown	• Patient burns themselves on Humidifier
Leaking	6	Excessive air leakage, or any water leaking from flow generator, humidifier or tubing	• Humidifier chamber is leaking

Problem Code	Complaint Category	Description	Example of Correct Use
Loan return	Not a complaint	Unit on loan returned to ResMed with no associated complaint	• Rental or loan devices returned because they are no longer required or the loan/rental period has expired. There are no reported faults with the device.
Machine interface	6	Fault related to button operation and peripheral equipment	• ResLink not recognising oximeter attachment • Keypad sticking
Melted	1	Melted appearance with no signs of flame or fire	• Melted bottom case • Melted Chassis
Mislabel/Incorrect label	1	Device or packaging is labelled incorrectly	• Lot number was missing off packaging
Missing part	6	Missing part noticed when package opened	• ResControl II arrives without power cord
Noisy	6	Objectionable noise from product	• PowerStation charger hums loudly when running
No reported complaint	Not a complaint	No complaint on this particular unit; this unit is returned together with a complaint unit	• Flow generator is faulty, the co-packed humidifier is returned with the flow generator. An SR created for the humidifer will use this problem code.
Others/Malfunction	2	A new or unexpected fault type has been reported	• Fault cannot be aligned to any of the existing problem codes
Oximetry Track HS	6	An oximetry track does not function	• The oximetry channel is missing and the polygraph/polysomnography record has to be recorded again
Physical damage	6	Device has obvious physical damage	• Case has a crack • Knob is broken
Power	6	No response or intermittent response when turned on	• Unit won't power up after switching on • Unit powering on intermittently
Product improvement suggestion	5	Suggestions for improving the product or service, WITH NO COMPLAINT	• Suggest to make the ApneaLink smaller
Rainout	6	Customer is getting water droplets in humidifier, tubing or mask	• Rainout from humidifier

Problem Code	Complaint Category	Description	Example of Correct Use
Skin breakdown/Wound	1	Scar, open wound or skin damage REQUIRING MEDICAL ATTENTION	• Open wound or skin damage on finger requiring medical attention
Skin irritation	6	Typically for peripheral devices, reddening, rash or discomfort of skin (not skin breakage) and DID NOT require medical attention	• Customer complaints of blisters on finger from Night Owl • Customer complaints of soreness on finger from Night Owl
Smell/odour	6	Smell unacceptable to customer (e.g. strong new smell, vinegar smell, cigarette smell, etc.)	• Vinegar smell on the cannula of ApneaLink
Start-up self-test	6	The unit has power, but fails to initialise or pass the self-test and does not show an error message	• ResControl II stays at the Welcome screen after power up.
Volume out of specification	6	Device reported volume measurements are not within specification	• Tidal volume displayed by the device is inaccurate when compared with other measurement device • Deviation in volume measurement • Bolus size incorrect

Cause Codes

Cause Code	Description
AC inlet socket	Any fault associated with the flow generator AC inlet socket. *Example: Open solder joints on the AC inlet socket*
Alarm module	Any fault with an alarm module.
Battery	Any faulty with the battery or batteries used within the device.
Buzzer	Any fault with the device buzzer.
Calibration	Calibration out of limits.
Closed - GSS	Issue is closed in GSS.
Component incorrect or missing	The device has a component missing or has an incorrect component fitted.
Connector	Connector defective or poorly fitted.
Contaminated	Smoke, dust, chemical contamination, or pest infestation.
Decal	Faults with device decals e.g. cracked, peeling.
Documentation	Any issue related to lack or misleading information in product literature. *Example: Setting ranges for Start Pressure in clinical manual are incorrect*
Electronic component failure	Failure of any electronic component on the device main PCB e.g. diode, resistor, etc. *Example: Fault was caused by resistor R3 on the main PCB going open circuit*
EMI-RFI problems	Electrical interference generated internally or externally.
End of Life	Reported fault was due to product is reaching the end of useful life.
Foam	Faults associated with foams on or in the device. *Example: Foam is deteriorating*
Fuse	A fuse within the device is faulty and is the cause of the device problem.
Heating element	Fault with the device heating element.
Incorrect labelling	Device has been received with incorrect labelling, either on the device itself or on the packaging.
Indicators	Fault panel indicators (does not include LCD screen).
Integrated circuit	An IC or chip within the device is found to be faulty and is cause of device problem.
Keypad	Device keypad is cause of the fault. *Example: Start/Stop button has torn away from keypad*
LCD module	Faulty LCD or LCD module. *Example: Characters missing from LCD*
Main PCB	Fault with the main PCB was the cause of problem. *Example: System error caused by fault with main PCB. Replacing main PCB fixes problem*
Manufacturing defect	Defects that can be attributed directly to manufacturing or assembly process (not faults in silicone moulding or plastic parts).
Material degradation	Material within the device is degrading or deteriorating.

Cause Code	Description
No fault found	Unit fully tested and found to be working within service specifications.
Not related to device	The incident/malfunction that occurred is confirmed to have been caused by something other than the device or usage. Fault (if any) found is not related and the device did not contribute to the reported event. *Example: Unrelated medical circumstance led to the death of a patient (drug overdose)*
Not yet determined	The default cause code setting when a service request has been created. Indicates that the device has not yet been serviced.
Off-label/Contraindicated use	Reported fault was due to use of product for which it is contraindicated, or not listed on the label.
Operator error	Reported fault was due to incorrect operation of product.
Other	The cause of the complaint is not related to any of the other cause codes.
Ozone damage	Fault/Damage/Degradation of device determined to be caused by ozone (e.g. sanitizing machine) with signs of ozone exposure/contamination found in the device.
Packaging	Faults caused by inadequate part or device packaging. This code applies to new devices or spare parts that arrive damaged due to inadequate packaging. *Example: Main PCB was not properly packaged in carton and arrived damaged*
Patient circuit	Any fault associated with the patient circuit used with the device. Patient circuits include hoses, sensor lines, etc.
Physical abuse	Fault/defects attributable to physical abuse of product by customer.
Plastic moulded part	Defect of plastic part (deformed, marks, colour variation, etc.).
Poor fit	Fit of part lacks strength, requires too much force or lacks positive sound/feel.
Potentiometer	Fault with the potentiometer.
Power cord	Fault with power cord. *Example: Device could not be powered on because one of the power cord pins was broken*
PSU	Fault with whole power supply PCB (does not include batteries or regulators).
Seal	Fault with seals/O-rings.
Silicone moulding	Defect of silicone part - deformed, split, inclusions, etc.
Software	Fault attributed directly to a known software issue.
Solder problems	Fault due to solder problems - bridges, splashes, dry joints, etc.
Switch	Fault with device switch - usually related to the on/off switch. Not to be used for keypad faults.
Thermostat	Fault with device thermostat.
Third party module	Fault related to third party external module or devices used with ResMed equipment, such as SpO2 sensor, TcO2 monitor or Sentec module.
Transit damage	Device has been damaged when being shipped from supplier to customer.
Tubing	Faults related to any tubing used within the device.

Cause Code	Description
	Example: The sensor tubing connected to the pressure sensor was kinked
Unable to determine	A fault exists, but the cause cannot be determined. The reported problem can be confirmed or reproduced, intermittently or consistently, but the cause of the problem is not known.
Unit was never returned	Customer never returned the device.
Water damage	Water is in the device, or evidence of water having been spilled into the device
Wiring harness	Fault with wiring harness

Remedy Codes

Beyond repair - scrapped
Closed as duplicate
Convert to Repair - – returned unit warranty voided
Device replaced
Installed missing component
Minor repairs – returned unit warranty voided
No corrective action
No Customer Response-Returned to Customer Unrepaired
Reassembled
Recalibrated
Reconfigured settings
Regular maintenance - Device was initially returned for routine or regular maintenance
Reloaded software
Repairs Declined-Returned to Customer unrepaired
Resoldered
Sub-assembly Replaced
Training
Upgraded
Z-GSS ticket

Narval MAD Codes

Problem Codes

Problem Code	Complaint Category	Description	Example of Correct Use
Appearance	6	Discoloration marks on product.	Product is discolored.
Contaminated	6	Contamination such as dust, insect, hair, dirt, white powder.	Customer has seen insects, hair, dust, dirt, white powder in the product.
Death	1	A patient death has been reported.	A patient death has been reported and device associated with incident. Device not necessarily identified to be the cause.
Device failure not specified	6	Device alleged faulty but customer has not provided a problem description.	Customer has claimed that the device is not working properly, but has not provided any more specific details; 'Device problem not stated.
Durability	6	Premature wear out of parts.	Broken splint, triangles, band, connecting rods. Rods and splint no longer holding together.
Insertion difficulty	6	The practitioner is unable to insert the device on the patient's teeth or has difficulty inserting the device.	The practitioner is unable to insert the device on the patient's teeth or has difficulty inserting the device.
Low retention	6	The orthosis does not stay on patient's teeth. It removes without patient intervention.	The orthosis is 'loose,' i.e. does not stay on patient's teeth. It removes without patient intervention.
Mislabel/Incorrect label	1	Device or packaging is labelled incorrectly: the Instructions of use are missing or not usable (damaged).	IFU not included in the packaging or not usable (damaged).
Missing part	6	Missing part noticed when package opened (excluding IFU).	Device received by Dentist or Patient, with parts missing (excluding IFU).
Narval-Allergy	1	Severe allergy reaction (Quinck edema and Anaphylactic shock) OR mucosal damage REQUIRING SIGNIFICANT MEDICAL ATTENTION.	Anaphylactic shock Quinck edema
Narval-Dental fracture/dislodgement	6	Dental or prosthetics fracture / Prosthetics loosening.	Dental fracture, fixed prosthetic dislodgement. Total or partial loss of tooth / fixed prosthetic.

Problem Code	Complaint Category	Description	Example of Correct Use
Narval-Inadequate feature	6	At reception, practitioner identifies an issue with device regarding design features or manufacturing process.	Design features not meeting practitioner request or design/manufacturing specification: Vertical dimension Latero-deviation Triangles Protrusion Bulk (cumbersome) Occlusal balance Band design Polishing (finishing touch)
Narval-Incorrect device	6	Practitioner received an incorrect device / device does not correspond to the patient / device received with wrong part.	Practitioner received an incorrect device / device does not correspond to the patient / device received with wrong part.
Narval-Material fragmentation	1	Broken or worn device with material fragment / small pieces coming off the device during wear.	Break of a free piece of triangle, band or splint during wear.
Narval-Mucosal damage	6	Open wound or mucosal damage (including irritation).	Open wound or damage, including contact (localized) irritation of the inner mouth, lips, gums or tongue (mucosal).
Narval-Obstruction of breathing	1	Obstruction of oral breathing with suffocation.	Obstruction of oral breathing with suffocation.
Narval-Side effect	6	Predictable side effect appearance when patient wears the orthosis.	Tooth/dental movement, occlusion modification, dental/gingival soreness Temporomandibular pain and temporomandibular joint dysfunction Hypersalivation Morning dental, gingival or joint soreness during adjustment period Gingival irritation, minor bleeding during adjustment period Temporary tooth pain (upon awakening) Other temporary discomfort
No reported complaint	Not a complaint	No alleged deficiency on unit.	Customer misuse of the device, for example dental treatment, wrong cleaning, etc.

Problem Code	Complaint Category	Description	Example of Correct Use
Others/Malfunction	2	A new or unexpected fault type has been reported.	New or unexpected fault type; fault type cannot be aligned to any of the existing problem codes.
Physical damage	6	Model has obvious physical damage. Transportation damage. Customer abuse.	Broken plaster model.
Product improvement suggestion	5	Suggestions for improving the product or service, with no complaint.	Suggest to use colorless material.
Treatment issue	6	System not delivering prescribed therapy (under or over treatment); for MAD, customer believes that system is not delivering prescribed therapy. Device may be under or over-treating patient.	Customer believes that system is not delivering prescribed therapy. Device may be under or over-treating patient.

Cause Codes

Cause Code	Description
Biocompatibility	The patient is not tolerant to the materials of the orthosis.
Component incorrect or missing	A component is missing on the device, or the component is different than it was expected.
Contaminated	Smoke, dust, chemical contamination, or pest infestation.
Device inversion	Information required for the manufacturing of the orthosis have been mixed up prior to production or during production or at shipping, resulting in a wrong device delivered to the final customer.
Documentation	Any issue related to lack or misleading information in product literature.
Incorrect impressions	The impressions used for manufacturing the orthosis were not consistent with the patient set of teeth.
Incorrect labelling	Device has been received with incorrect labelling, either on the device itself or on the packaging.
Manufacturing defect	Defects that can be attributed directly to manufacturing or assembly process (not faults in dental impressions).
Material degradation	Material within the device is degrading or deteriorating.
No fault found	Unit fully tested and found to be working within service specifications.
Not related to device	The incident/malfunction that occurred is confirmed to have been caused by something other than the device or usage. Fault (if any) found is not related and the device did not contribute to the reported event. *Example: Unrelated medical circumstance led to the death of a patient (drug overdose)*
Operator error	Reported fault was due to incorrect usage of the device by the patient or the practitioner, e.g. wrong cleaner, dental treatment, too much adjustment.
Other	The cause of the complaint is not related to any of the other cause codes.
Physical abuse	Fault/defects attributable to physical abuse of product by customer.
Practitioner request not clear	The specifications asked by the practitioner for his patient's orthosis were not legible/suitable/clear.
Teeth grinding	The patient applies excessive force on the device because of teeth grinding. *Example: Evidence of damage due to teeth grinding.*
Training	Training.
Transit damage	Device has been damaged when being shipped from supplier to customer.
Unable to determine	A fault exists, but the cause cannot be determined.
Unit was never returned	Customer never returned the device.

Remedy Codes

Beyond repair - scrapped
Closed as duplicate
Device replaced
No corrective action
Training

When Did Fault Occur?

Other (not one of the values below)
Unknown (complaint did not indicate when failure occurred)
OoBF - Distributor (New unit failed during distributor acceptance testing)
OoBF - Patient (New unit failed during first 3 days of patient use)
OoBF – Service (Out of Box Failure (After Repair))
Used Unit - Distributor (used unit failed during testing by distributor)
Used Unit - Patient (used unit failed during patient use)

Change Table

Rev	Change Note	Date Document Drafted	Document Prepared By (Name)	Document Checked By (Name)
11	C36814	14/08/2014	Adam Shore	Alex Patterson
12	C38839	25/03/2015	Jaklin Aziz	Alex Patterson
13	C39469	14/07/2015	Jaklin Aziz	Alex Patterson
14	C39730	20/11/2015	Jaklin Aziz	Alex Patterson
15	C40829	03/06/2016	Jaklin Aziz	Alex Patterson
16	K002820-00	14/12/2018	Jun Thing Teh	Michelle Hughes
17	K007236-00	09/06/2020	Jun Thing Teh	Michelle Hughes
18	K008757-00	25/03/2021	Jun Thing Teh	Michelle Hughes
19	K012444-00	01/07/2022	Jun Thing Teh	Michelle Hughes
20	K014921-00	19/06/2023	Jun Thing Teh	Michelle Hughes
21	K015363-00	08/08/2023	Jun Thing Teh	Jaklin Aziz
22	K016035-00	19/10/2023	Elizabeth Shin	Jaklin Aziz
23	K016421-00	05/12/2023	Sven Allegaert	Jaklin Aziz

Note: *From Rev20 onwards, 19832 will only has one version in English. The German and French Translation of 19832 are obsoleted in Rev20.*

Problem and Cause Codes Guide

1. DETAILS

Dimensions: A4 (297 H x 210 W) ± 5 mm

2. SAMPLING, INSPECTION & TESTING

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