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Review Article **Open Access**

Understanding Clinical Investigation and preparation of Technical file for Continuous Positive Airway Pressure (CPAP) Medical Device

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Abstract

Continuous Positive Airway Pressure (CPAP) devices are essential medical tools for managing Obstructive Sleep Apnoea (OSA) it is a disorder marked by frequent blockages of the upper airway while a person is asleep. This review delves into the clinical investigation, design considerations, regulatory standards, and technical documentation involved in CPAP development. CPAP devices deliver continuous airflow through a mask to prevent airway collapse, thereby restoring normal respiration during sleep. Due to their moderate risk classification across various regulatory bodies (e.g., FDA Class II, CDSCO Class B/C, EMA Class IIa/IIb), manufacturers must adhere to stringent global standards, including ISO 13485 (Quality Management System), ISO 14971 (Risk Management), ISO 10993 (Biocompatibility), and IEC 60601 (Electrical Safety), and IEC 62366 (Application of Usability Engineering) This review elaborates on the structure and importance of the Device History File (DHF) and the Technical File, which document all phases from design inputs and outputs to risk analysis, usability, validation, and post-market surveillance. Detailed insights are provided into biocompatibility assessments, environmental testing, and clinical evaluations comparing CPAP with Mandibular Advancement Splints (MAS). The study highlights CPAP's superiority in reducing the Apnoea-Hypopnea Index (AHI) and improving physical health scores, although MAS demonstrated better adherence and comfort. A critical case study of Philips' 2021 recall further emphasizes the importance of material biocompatibility and robust risk management. This review ultimately serves as a comprehensive resource for developers aiming to ensure regulatory compliance and patient safety in CPAP manufacturing.

Keywords: Medical Device; Continuous Positive Airway Pressure (CPAP); Obstructive Sleep Apnoea(OSA); Device History File (DHF); ISO 13485; ISO 14971; IEC 60601; Regulatory Compliance; Clinical Evaluation

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1. Introduction

In today's healthcare landscape, medical devices serve as vital tools that significantly enhance the way we diagnose, treat, and manage various health conditions. Among these, Continuous Positive Airway Pressure (CPAP) machines have emerged as a cornerstone in the management of Obstructive Sleep Apnoea (OSA). This condition, widespread across populations, involves repeated instances of the upper airway either partially narrowing or completely closing during sleep, which interrupts normal airflow even when the person continues to make breathing efforts. These interruptions can cause periodic drops in oxygen saturation and lead to disturbed sleep with frequent awakenings throughout the night. The primary reason behind OSA is often the relaxation of muscles in the throat, which results in the collapse of the airway passage during sleep. (1) Symptoms typically include loud snoring, sudden choking, or gasping sensations while sleeping. OSA has been linked to several systemic health issues, including inconsistent oxygen levels, disturbed sleep cycles, persistent daytime fatigue, and heightened risks of developing cardiovascular problems, hypertension, and metabolic disorders. (2-4) CPAP devices counter these effects by maintaining a continuous flow of pressurized air via a mask, which helps keep the airway open throughout the sleep cycle, ultimately supporting better sleep quality and general health restoration.

Due to their continuous and direct interaction with the patient's airway and respiratory functions, CPAP devices are typically categorized as moderate-risk medical equipment by regulatory authorities across different regions.

Table 1. classification of CPAP device

Regulatory Body	Risk Classes
FDA (USA)	Class II: Moderate risk
CDSCO (INDIA)	Class B: Low to moderate risk Class C: Moderate to high risk
EMA (EU)	Class IIa: Low to moderate risk Class IIb: Moderate to high risk

Being categorized as a moderate-risk medical device places a significant responsibility on manufacturers to strictly comply with established regulatory frameworks that prioritize safety, performance, and product integrity. To meet these expectations, developers must follow a range of globally recognized standards. These include ISO 13485, which outlines the requirements for implementing a robust Quality Management System (5), ISO 14971, which provides a systematic approach to risk identification and mitigation throughout the product lifecycle (6), and ISO 10993, which ensures biocompatibility testing for materials that come into contact with the patient. (7). Additionally, adherence to the IEC 60601 series is essential for guaranteeing electrical safety in medical devices.(8) A crucial part of fulfilling these requirements lies in maintaining well-documented records, specifically the Device History File (DHF) and the Technical File**.** These documents serve as detailed repositories of the device's design process, performance testing, risk analysis, and post-market activities. (9-10) This paper focuses on clarifying these regulatory obligations and the structure of technical documentation required for CPAP device approval, offering guidance for achieving regulatory conformity and safeguarding patient health.

1.1 Regulation for CPAP Devices

Regulatory frameworks for medical devices play a critical role in balancing innovation with public safety, ensuring that new technologies can reach the market while upholding high standards of patient protection. To fulfil this dual goal, strict regulatory oversight is essential. Continuous Positive Airway Pressure (CPAP) systems, which are non-invasive devices commonly used in the management of Obstructive Sleep Apnoea (OSA), fall under this regulatory purview due to their close interaction with the patient's respiratory function. (11) Recognizing the therapeutic significance and potential risks associated with their use, most global health authorities categorize CPAP devices as moderate-risk medical equipment. (12) Consequently, their development and distribution must align with a well-defined set of national and international regulatory standards designed to assure product safety, effectiveness, and quality.

a) ISO 13485

- Among the key regulations, **ISO 13485** stands out as a foundational standard. It specifies the quality management system (QMS) requirements for organizations involved in the lifecycle of medical devices. This includes everything from the design and development to production, storage, distribution, installation, and servicing. The standard is designed to help manufacturers consistently meet both regulatory obligations and customer expectations by establishing procedures that ensure product quality and traceability throughout all phases of manufacturing and delivery.

Table 2. content of ISO 13485

Quality management system	General requirement, Documentation requirement
Management responsibility	Customer focus, Quality policy, Planning
Resource management	Work environment Infrastructure Human resource
Product realization	Planning of product realization, Design and development Control of monitoring and measuring device
Measurement, Analysis and improvement	Monitoring and measurement, Control of nonconforming product, Data analysis, improvement

b) ISO 14971

- **ISO 14971** is a globally recognized standard that guides medical device manufacturers in establishing a structured and continuous risk management process throughout the entire life cycle of a device. This includes everything from initial design and development to manufacturing, usage, and post-market activities. Regulatory authorities like the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) require compliance with this standard as part of their approval processes. The core objective of ISO 14971 is to ensure that all potential risks associated with a medical device are properly identified, analysed, evaluated, controlled, and monitored to safeguard patient safety and device performance.

Table 3. content of ISO 14971

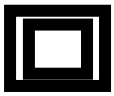
Content	Function
Assignment of responsibilities and authorities	Involves personal and their function

Risk Management File	It includes documentation and records that are generated during various stages of risk management, capturing all activities related to ensuring the safety of the medical device across its entire life span.
Risk Analysis	process to identify, estimate, and evaluate risks associated with a medical device
Risk Estimation.	Using available data for estimation of risk and probability of its occurrence
Risk Control	Used to reduce risk to acceptable level

c) IEC 60601

- The **IEC 60601** standard governs all safety-related aspects—both direct and indirect—that pertain to the handling and use of medical electrical equipment. Often cited as IEC 60601 or IEC 601, these standard plays a crucial role in minimizing the risk of electrical hazards for patients and users. It categorizes medical devices into three distinct classes, each associated with specific symbols and testing protocols designed to verify protection against electrical shock and ensure patient safety during operation.

Table 4. Classification of medical electrical equipment according to IEC 60601

Class	Symbols	Meaning
Class I		Has protective earth covering
Class II		Protected against electric shock by double insulation or reinforced insulation
Class III		Protected by Safety Extra Low Voltage (SELV), which involves no voltages higher than 25 V AC or 60 V DC

- The IEC 60601 standard includes a range of tests to ensure the electrical safety of medical devices, safeguarding both patients and users from potential hazards. Among these, earthbound testing is performed to confirm proper grounding, while leakage current measurements assess any unintentional flow of electrical current. These measurements include earth leakage, enclosure leakage, and applied part or patient leakage, all of which help verify that the device remains within safe operational limits. Furthermore, patient leakage current is evaluated to ensure that current levels are safe when in direct contact with the user.
- In addition, the extended standard IEC 60601-1-2 focuses on the electromagnetic compatibility (EMC) of medical electrical equipment, ensuring devices function reliably in environments with electromagnetic disturbances. The EMC tests are divided into two main categories. Under emissions testing, devices are checked for harmonic distortion, voltage fluctuations and flicker, as well as radiated and conducted emissions that may interfere with nearby equipment. Immunity testing examines how well the device withstands external electromagnetic influences. This includes exposure to electrostatic discharges, radiated RF and wireless proximity fields, electrical fast transients, power surges, RF-induced conducted disturbances, voltage dips and interruptions, and power-frequency magnetic fields. Together, these evaluations ensure that the medical equipment remains safe and functional under real-world electrical and electromagnetic conditions.

d) ISO 80601-2-70

- Specific requirements for basic safety and performance of sleep apnoea breathing equipment or CPAP device it consists of

Table 5. content of ISO 80601-2-70

General requirement	For essential performance, testing,
Identification, Marking and Documents	Legibility of marking
Protection against electrical hazards	Protection mechanical, radiation hazards
Electromagnetic compatibility	Protection against electromagnetic distributions
Training	Training for the personal
Usability	Easy to use for customer

e) ISO 10993

- This international standard provides a detailed framework for evaluating the biological safety of materials used in medical devices that come into direct or indirect contact with the human body. It requires manufacturers to conduct thorough assessments of the materials' properties, including their chemical structure, toxicological effects, physical and electrical characteristics, morphological features, and mechanical strength. Such comprehensive evaluation ensures that the materials used are biocompatible and do not pose any harm to the patient during device use. (13)

2. Device History File (DHF) And Technical

2.1 Document for medical device

The Device History File (DHF) serves as an essential organizational tool used to confirm that proper design

control procedures were implemented and documented throughout the development of a medical device. These

design controls are a foundational component of the broader Quality Management System (QMS) that governs product development. (14) As outlined in 21 CFR Part 820.30, manufacturers are required to compile a DHF that contains or references all necessary records demonstrating that the design was carried out in accordance with an approved plan. The thoroughness and accuracy of the DHF play a vital role in regulatory inspections, particularly during FDA audits. (15)

In contrast, the Technical File represents a comprehensive collection of documents that encapsulates all relevant technical data associated with the medical device. This includes detailed information on the design, manufacturing process, product testing, clinical evaluations, and risk management activities. The purpose of this file is to provide clear and verifiable evidence that the medical device complies with all applicable regulatory standards. (16)

Table 6. Difference between DHF and Technical File

Feature	DHF	Technical File
Required by	FDA (USA)	EU MDR (Europe)
Focus	Design process documentation	Full device compliance evidence
Target audience	Internal QA & FDA inspectors	Notified Body
Includes manufacturing details?	Partially	Fully
Includes clinical evaluation?	No	Yes
Includes labelling?	Yes	Yes
Required for CE Mark?	No	Yes

2.2 Content of Device History File (DHF)

a) Design input

- include procedures for establishing design input that addresses intended use and user needs and the approved design input documentation.
  - User Needs / Intended Use
  - Functional Requirements
  - Performance Requirements
  - Regulatory Requirements
  - Human Factors / Usability Requirement
  - Environmental Requirements
  - Reliability and Lifespan Requirements

b) Design output

- include procedure for defining and documenting design output in compliance with this part, and approved design output documentation.
  - Final Product Specifications
  - Bill of Materials (BoM)
  - Mechanical Drawings
  - Testing and Acceptance Criteria
  - Labelling and Instructions for Use (IFU)
  - Verification & Validation Documentation
  - Risk Controls Implemented (from Risk Management File)(17)

c) Design review

- includes the procedure for conducting reviews of design process and any documentation related to the reviews that were conducted. Format for design review Include:

Table 7. Design Review Meeting

DHF	Design Review Phase:	Date

Table 8. Meeting Detail

Design Review Meeting Detail	
Purpose of Meeting	
Background:	
Documents Reviewed:	
General Discussion	
Action Items Identified:	

Table 9. Approval status

Design and Development Approval Status
☐ Approved – The items reviewed are approved for the next step in the design and development process.
☐ Approved with Actions – The items reviewed are approved for the next step in the design and development process when all action items have been completed.
☐ Rejected – Additional design and development work is not approved.

d) Design verification and validation

- include a document describing your design validation, verification process and the approved results of the design validation, verification
- Design of device: same as Fig no 2
  - Airflow Generator
  - Tubing / Hose
  - Filter

e) Design transfer

- The design transfer phase involves compiling and submitting all essential documentation required to move a medical device from the development stage into full-scale manufacturing. This critical step ensures that the device specifications, as finalized during the design phase, are accurately translated into production requirements. As part of this process, manufacturers must verify that all design validation and verification activities have been successfully completed, and that the Device Master Record (DMR) is both thorough and precise.
- To streamline this process, many medical device companies implement a design transfer checklist, which serves as a quality assurance tool to confirm that all required steps have been addressed. This checklist typically includes crucial documents such as the Bill of Materials (BoM), detailed assembly drawings, and final product specifications—all of which must be shared with the manufacturing team to ensure consistency and compliance during production.

f) Design changes

- During the design process design changes are controlled within the Design Control process. The manner in which change is request, review, authorization and documentation take place is dependent upon the nature of the change and the design cycle stage in which the change is being conducted. As applicable, these changes can be documented within design documents and/or in Design Review Meeting.(18)

2.3 Technical Document for medical device

A **medical device technical file** serves as a comprehensive repository of all technical details and supporting documentation related to a medical device. This file typically includes critical information about the device's design, methods of manufacturing, testing protocols, clinical performance data, and the overall risk management strategy. (16) Often referred to as **technical documentation**, this file is a mandatory component for demonstrating regulatory compliance, especially under European frameworks such as the **Medical Device Regulation (MDR)** and the **In Vitro Diagnostic Regulation (IVDR)**. It ensures that every aspect of the device's development and performance is well-documented and can be reviewed by regulatory authorities when needed. Contain of technical file in Figure 1.

a) Executive summary

- Continuous Positive Airway Pressure (CPAP) systems are widely recognized medical devices used to treat sleep-related breathing disorders such as sleep apnoea, as well as other chronic respiratory conditions. With their direct influence on respiratory function and patient well-being, it's essential to understand the regulatory processes that govern the design, approval, and post-market monitoring of these devices.
- CPAP devices are classified as low-to-moderate risk medical equipment. They are designed to deliver a constant stream of ambient air or medical-grade oxygen under pressure, typically through a nasal interface, to maintain airway patency during sleep.
- Individuals diagnosed with Obstructive Sleep Apnoea Syndrome (OSAS) often benefit from CPAP therapy, as this condition involves repeated blockages of the upper airway during sleep. These obstructions can be either partial or complete and disrupt normal breathing. CPAP devices counteract this issue by supplying a steady level of positive pressure throughout the breathing cycle, preventing the airway from collapsing.
- According to the operating principle of CPAP, a regulated air pressure must be continuously maintained within the respiratory pathway. The device achieves this by using a motorized pump that pushes air through a hose connected to a face or nasal mask, creating a sealed system. Many CPAP machines are designed to automatically increase air pressure during inhalation and reduce it during exhalation to enhance comfort and maintain therapeutic effectiveness. (19)
- In patients with untreated sleep apnoea, the relaxed airway muscles can lead to significant breathing obstruction and a drop in oxygen levels reaching the brain. This can result in a wide spectrum of health issues—ranging from minor symptoms like morning headaches to more serious conditions such as high blood pressure, depression, cardiac complications, and even stroke. (20) CPAP therapy also offers cardiovascular benefits by decreasing the heart's workload. It reduces cardiac preload and afterload by lowering filling pressures and left ventricular transmural stress. (21)
- Technically, a CPAP device consists of several key components: a microprocessor, a pressure sensor, a brushless DC motor with an air blower, a motor controller, flexible tubing, and a nasal or face mask. The blower draws filtered air, pressurizes it, and directs it through the hose into the patient's airway.
- As non-invasive respiratory aids, CPAP machines have shown additional benefits such as lowering blood pressure in hypertensive patients, enhancing alertness and mental performance, and reducing excessive daytime sleepiness in individuals with OSA. (22)
- An alternative to CPAP is the Bi-level Positive Airway Pressure (BiPAP) machine. Unlike CPAP, BiPAP delivers two distinct pressure levels—higher during inhalation and lower during exhalation.

  This dual-pressure mechanism can be especially helpful for patients with restrictive respiratory issues, as it improves gas exchange, supports more efficient breathing, and promotes better sleep quality. (23)

Figure 1. Summary of technical file

b) Device Description and Product Specification

- **Device Name**: Continuous Positive Airway Pressure (CPAP) Machine
- **Intended Use:** Treatment of sleep apnoea by maintaining continuous airway pressure.
- **Classification:** Class II (FDA), Class B/C (CDSCO), Class IIa
- **Principle of Operation:** Delivers a continuous flow of air at a prescribed pressure to prevent airway collapse.
- **Technical Specifications**:
- **Pressure Range:** 10 cmH2O
- **Noise Level:** 27 dB
- **Power Supply:** Power Consumption 80W power supply, 50/60 H

Table 10. Instruction for use

Step No.	Procedure	Instructions	Additional Notes
1	Intended Use	Ensure the device is prescribed by a licensed physician for treating Obstructive Sleep Apnoea (OSA) in patients weighing over 30 kg (66 lbs).	Device is for home or hospital use.
2	Device Placement	Place the device on a flat, firm surface, away from heating or cooling equipment. Keep it below the sleeping position and ensure the power cord is accessible.	Avoid placing on carpet or near water.
3	Power Supply Connection	Plug the power cord into power supply and connect it to an electrical outlet. - Ensure the power inlet connection is secure.	Do not use outlets controlled by a switch.
4	Connecting the Breathing Circuit	Attach the flexible tubing to air outlet. - If using a heated tube, snap the connector into place. - Connect the tubing to the device	Ensure secure connections to prevent leaks.
5	Starting the Device	Ensure the device is powered on. - Put on the mask properly and press Therapy On/Off button. - Adjust mask for minimal leaks.	Some air leaks are normal.
6	Adjusting Therapy Settings	control dial. Adjust humidification, ramp, and pressure settings as prescribed. - Ensure adequate water level in humidifier.	Use prescribed settings only.
8	Checking Mask Fit	Use the Check Mask Fit feature to detect leaks. - Adjust straps or replace mask if leakage is excessive.	Adjust the mask
10	Cleaning and Maintenance	Weekly: Clean device exterior with damp cloth. - Monthly: Rinse reusable filter, check tubing. - Every 6 months: Replace filter and tubing.	Disconnect power before cleaning.

11	Traveling with the Device	Use the carrying case. - If traveling internationally, use an appropriate adapter. - Approved for airline use	Keep power cords accessible for checks.
12	Troubleshooting	No power: Check connections. Excessive noise/leaks: Inspect tubing/mask. Heated tube issue: Ensure 80W power supply is used.	Use Performance Check if issues arise.
13	Safety Precautions	Do not block air inlet or place on flammable surfaces. -Do not use ozone-based cleaners. Disconnect power before cleaning.	Use Philips-approved accessories only.

c) Device Design

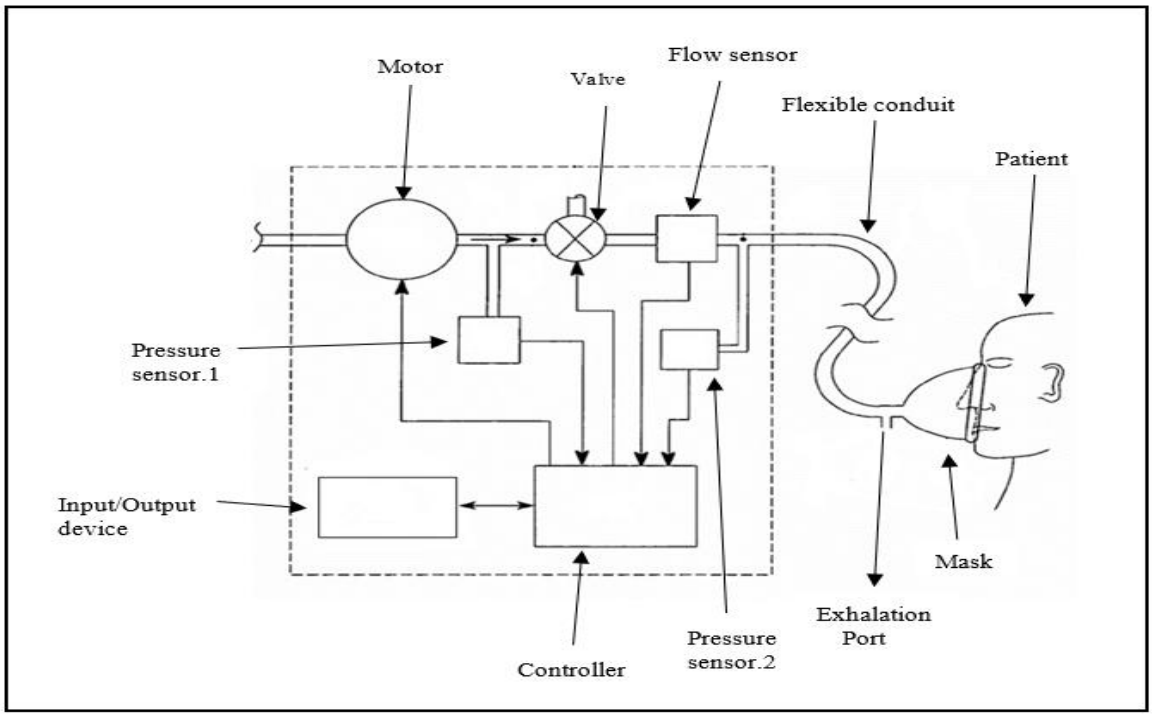


Figure 2. Design of CPAP device

d) Applied Standards list:

- **IEC 60601-1**: Focuses on the fundamental requirements necessary to ensure the basic safety and key performance capabilities of medical electrical devices.
- **IEC 60601-1-2**: Defines the standards for managing electromagnetic disturbances and immunity in medical equipment.
- **IEC 62366**: Outlines guidelines for integrating usability engineering into the development process of medical devices to enhance user safety and performance.
- **ISO 14971**: Establishes a systematic approach for identifying, evaluating, and controlling risks associated with medical devices.
- **ISO 10993**: Provides a framework for evaluating the biocompatibility of medical device materials to ensure they are safe when in contact with the human body.
- **ISO 13485**: Specifies the requirements for a comprehensive quality management system tailored to the design and manufacture of medical devices.

e) Essential principles (EP) Checklist:

- **Chemical, Physical, and Biological Characteristics**: Ensuring materials used are safe and appropriate for their intended application.
- **Manufacturing and Environmental Considerations**: Emphasizing production practices and environmental conditions that affect product safety and performance.
- **Protection Against Radiation Hazards**: Safeguarding patients and users from risks related to radiation exposure.
- **Medical Devices Containing Software**: Addressing specific safety and performance requirements for devices integrated with software or functioning as standalone medical software.
- **Mechanical Safety**: Ensuring devices are designed to minimize the risk of mechanical failure or injury.
- **Safeguarding Against Risks from Energy or Substances Delivered to Patients**: Preventing harm that could result from the device supplying energy or therapeutic substances.
- **Information Provided by the Manufacturer**: Guaranteeing that all necessary details, such as labelling and instructions for use, are clear, accurate, and support the safe use of the device.(24-25)

f) Risk Analysis and Control summary

- Risk Management for Medical Devices is a systematic process of identifying, assessing, controlling, and monitoring risks throughout a medical device's lifecycle to ensure its safety and performance. It is mandated by

global regulatory bodies, such as the FDA, European Medicines Agency (EMA).(26)

Table 11. Assignment of responsibilities and authorities

Personnel	Function
Regulatory affairs	Regulatory requirements pertaining to safety and risk management in countries/regions where the medical device is intended for marketing
Quality assurance	Quality management systems and quality practices
Packaging, storage, handling and distribution	Hazards and risk control measures in relation to packaging, storage, handling and distribution
Service engineer, biomedical engineer or medical physicist	Hazards and risk control measures in relation to installation, maintenance, repair, calibration, service and support reporting, processes and practices
Post-production	Customer complaints and adverse event reporting post-market surveillance
Information services	Data mining processes, methodologies for literature search
All individuals involved for review and approval of the records	Experiences in the functional area reviewing and approving

g) Risk Management File:

- The **Risk Management File (RMF)** is a critical component of the technical documentation, serving as evidence that the medical device complies with all applicable regulatory requirements related to risk management. It systematically demonstrates that risks associated with the device have been properly identified, evaluated, controlled, and monitored throughout its lifecycle.
- The **Risk Management File** typically includes the following key elements:
  - **Intended Use**: A clear and precise description of the device's intended purpose, target users, and operating environment.
  - **Risk Acceptance Criteria**: Defined thresholds that determine the acceptability of risks, based on applicable standards and regulatory expectations.
  - **Risk Management Plan**: A structured plan outlining the processes, responsibilities, and methodologies to be employed during risk management activities.
  - **Risk Analysis**: Identification and assessment of potential hazards, hazardous situations, and their associated risks.
  - **Risk Control Measures**: Actions taken to eliminate hazards or reduce risks to acceptable levels, including verification of control effectiveness.
  - **Risk Management Report**: A comprehensive summary compiling the results of all risk management activities, confirming that residual risks are acceptable and that overall device safety has been achieved.(27)

h) Risk Analysis

- Risk analysis is a systematic process used to identify, estimate, and evaluate risks associated with medical device. It is a critical component of the overall risk management process and forms the basis for risk evaluation and control measures.
- ***The risk analysis process consists of the following steps:***
  - Intended use and reasonably foreseeable misuse
  - Identifying the characteristics of medical device regarding safety
  - Identifying hazards and hazardous situations associated with the medical device

i) Types of hazards

- Energy hazard
- Electrical energy
- Voltage
- Magnetic field
- Biological and Chemical hazard
- Bacteria
- Fungi
- Carcinogenic
- Solvent
- Heavy metals

j) Risk Estimation.

- Manufacture shall estimate the associated risk using information available for estimation of hazardous situation for which probability of occurrence cannot be estimated for harm and consequences should be listed for using in risk control the result should be recorded in risk management file.
- ***Probability of risk***

Table 12. probability levels

Common terms	Possible description
High	Likely to occur, often, frequently, always
Medium	Can occur, but not frequently
Low	Unlikely to occur, rare, remote

- ***Severity of risk***

Table 13. Severity levels

Common terms	Possible description
Significant	Death or loss of function
Moderate	Reversible or minor injury
Negligible	No injury or slight injury

k) Risk Control

- Risk control is a critical step in the risk management process where measures are medical device option for reducing risk to acceptable levels are
  - Inherently safe design, manufacturing
  - Protective measures in medical
  - Information for safety and safety to user

l) Evaluation of overall residual risk

- After all the risk control measures have been verified the manufacture will start evaluating the overall risk residual posed by medical device taking into account the contributions for all residual risks in relation to the benefit in risk management plan.
- If overall residual risks are acceptable the manufacture will inform user of significant risk residual and include the necessary information in documentation in order to disclosed those risk residual.

m) Production and post-production activities

- The crucial step which allows manufacturers to close the feedback loop and make risk management a continuous life cycle activity is monitoring of production and post-production data. In order to ensure safety of medical device, data is gathered from a variety of sources, examined for safety relevance, and, when necessary, fed back into previous stages of the risk management procedure.

n) Information review

- Is the intended use still valid?
- Are the anticipated benefits achieved?
- Is there evidence of hazards or hazardous situations not previously identified?
- Are there occurrences of misuse which were previously not foreseen?
- Is there an increasing trend of use for applications other than the intended use?
- Does the frequency of occurrence of a particular hazardous situation or harm suggest that the probability of occurrence of harm was underestimated?
- Does the reported harm indicate that the severity of harm was underestimated?
- Is there evidence that the risk control measures are not effective?
- Are there indications that the criteria for risk acceptability should be adjusted?

o) Environmental Testing Results

- Operating Temperature: 5° to 35° C (41° to 95° F). Storage Temperature: -20° to 60° C (-4° to 140° F). Relative Humidity (operating & storage): 15 to 95% (non-condensing). Atmospheric Pressure: 101 to 77 kPa (0 - 2286 m / 0 - 7500 ft). (30)

p) Labelling

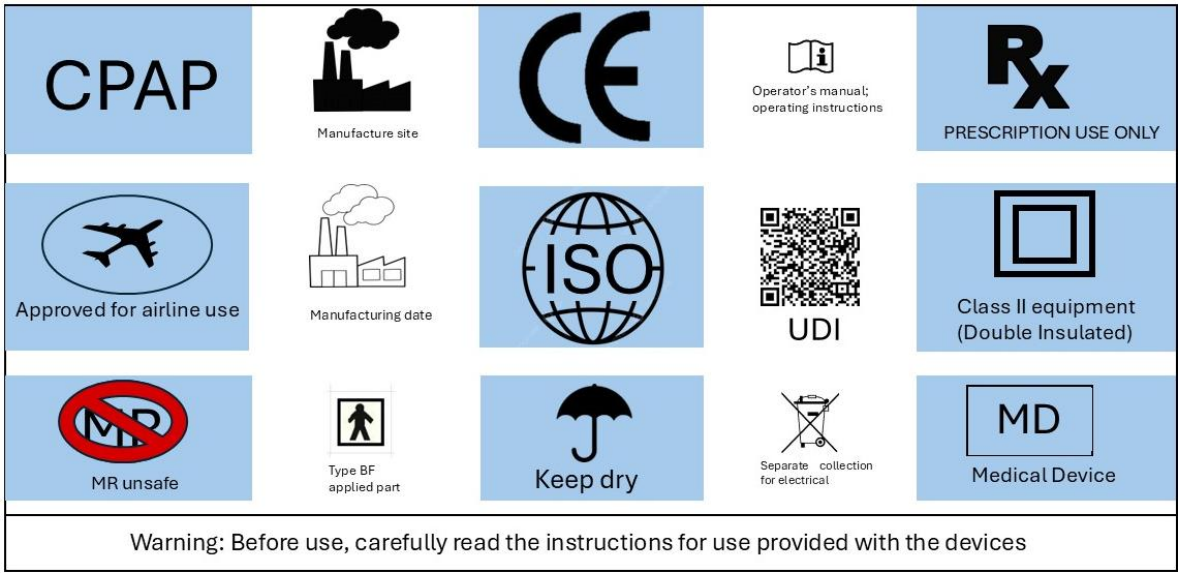


Figure 3. Labelling for CPAP

q) Declaration of Conformity

- CE Marking Technical Documentation (28)

Table 14. Data sources for production and post-production information

Data Sources	Information
Production	Data from supplier monitoring, performance, Process monitoring, In-process inspection/testing Internal/external audits
Complaint handling	By customer (physician, healthcare facility, patient, etc.). Reason of complaint, Severity of harm, Component involved
Risk management	Published adverse event reports for similar medical devices
Security data sources	Independent security researchers, Health care facilities, Information Sharing and Analysis Centre (ISAC)

Table 15. CE marking documentation

Section	Content
Device Description & Intended Use	Overview of the CPAP device, models, accessories, clinical use
Design & Manufacturing Information	Device schematics, materials, design verification, software design
Risk Management File	Risk analysis, Failure Mode and Effects Analysis (FMEA), risk mitigation strategies
General Safety & Performance Requirements (GSPR)	Compliance with biocompatibility, EMC testing, labeling
Bench Testing & Performance Data	Functional tests (airflow accuracy, noise levels, humidity control)
Usability Engineering Report	Usability validation (interface testing, patient interaction, human factors study)
Clinical Evaluation Report (CER)	Literature review, clinical trials, Post-Market Clinical Follow-up (PMCF)
Post-Market Surveillance (PMS) Plan & Reports	Complaint handling, Periodic Safety Update Reports (PSUR), risk monitoring
Labeling & IFU (Instructions for Use)	User manual, symbols compliance, safety warnings
Declaration of Conformity (DoC)	Manufacturer's legal statement of compliance
Verification & Validation Data	Software validation, sterilization validation (if applicable)

r) product validation and Verification

- ***Biocompatibility***
- Provides a framework for establishing a biological assessment for components of medical device which is in contact with patient. It states that material selected for manufacturing should be characterised for properties including chemical, toxicological, physical, electrical, morphological and mechanical properties. (29)

Table 16. Tests for biocompatibility

Test	Applicable to
Cytotoxicity	Mask, tubing, headgear, humidifier
Sensitization	Mask, headgear, straps
Acute Systemic Toxicity	Mask, tubing (if leachable substances exist)
Material-Mediated Pyrogenicity	Mask, tubing (if systemic exposure is possible)
Chemical Characterization	Mask, tubing, humidifier
Respiratory Irritation	Air pathway materials (mask, tubing)
Volatile Organic Compounds (VOCs) Emissions	Mask, tubing, humidifier

s) Post Marketing Surveillance Data (Vigilance Reporting)

- The PMS plan is part of device's required technical documentation and details strategy for continuously monitoring and collecting data and safety information on the device.(31)

t) Periodic Safety Update Report (PSUR)

- The PMS plan is part of the requirements for surveillance system, and intended to outline the criteria for risk-benefit assessment of the device and processes for:
- Collecting and analysing data
- Addressing submitted complaints
- Communicating data to regulatory bodies and users

Table 17. Device Identification & Regulatory Information

Parameter	Details
Device Name	Philips Dream Station CPAP
Model Numbers	ABCD
Intended Use	Treatment of Obstructive Sleep Apnoea (OSA)
Risk Class	Class II (FDA), Class B/C (CDSCO)
Applicable Standards	ISO 13485, ISO 14971, IEC 62366-1, IEC 60601-1

Table 18. Summary of Safety & Performance Data

Source	Data Collected	Key Findings
Post-Market Surveillance (PMS)	Complaints, device failures, usage reports	No new major safety concerns identified
Post-Market Clinical Follow-up (PMCF)	Therapy adherence, effectiveness	patients achieve compliance
Adverse Event Reports (MDR, Vigilance System)	Device-related injuries, side effects	No critical safety events reported
Regulatory Actions (Recalls, FSNs)	Any recalls, corrective actions	Field correction for filter replacement in humidifier models

u) The Corrective and Preventive Action (CAPA) system is a critical part of quality management (ISO 13485) to ensure medical devices remain safe and effective

Table 19. The Corrective and Preventive Action (CAPA)

Issue Identified	Root Cause Analysis	Corrective Action (Fix the Problem)	Preventive Action (Prevent Recurrence)
Excessive mask leaks	Poor fit, wrong mask size	Enhanced mask fit detection feature	Redesigned mask
Device overheating	Blocked filter, high room temp	Added temperature warning system	Improved filter design & user guidance
Power supply failure	Loose connections, voltage fluctuation	Reinforced power connector	Added surge protection & quality checks
Noisy airflow/motor issues	Fan degradation over time	Introduced quieter motor design	Upgraded motor components for durability
Bluetooth/App connectivity failures	Software bug, interference	Released firmware update	Enhanced app compatibility testing
Filter clogging too soon	Poor air quality, weak material	Extended filter lifespan	Stronger filter materials & change alerts

Table 20. IEC60601-1 TEST LIMITS

Leakage Current Type	Normal Condition (NC)	Single Fault Condition (SFC)	Compliance
Earth Leakage	0.5mA	1mA	Complies
Enclosure Leakage	0.1mA	0.5mA	Complies
Patient Leakage (dc)	0.01mA	0.05mA	Complies
Patient Leakage (ac)	0.1mA	0.5mA	Complies
Patient Leakage F-Type	NA	5mA	Complies
Patient Auxiliary (dc)	0.01mA	0.05mA	Complies
Patient Auxiliary (ac)	0.1mA	0.5mA	Complies

- **IEC 60601-1-2: Electromagnetic compatibility requirements**

Table 21. Emission testing

Test Type	Standard Applied	Compliance Level
RF Emissions (CISPR 11)	CISPR 11 (Group 1, Class B)	Complies
Harmonic Emissions	IEC 61000-3-2	Class A
Voltage Fluctuation & Flicker	IEC 61000-3-3	Complies

- ***Immunity Testing as per IEC 60601-1-2 involve 7 possible immunity tests:***
- Electrostatic Discharges
- Radiated RF EM Fields and Proximity Wireless fields
- Surges
- Voltage Dips and Interruptions
- Rated Power-frequency Magnetic Field (32)

Table 22. immunity testing

Test Type	Test Conditions	Compliance Level
Electrostatic Discharge (ESD)	±8 kV contact, ±15 kV air	Complies
Electrical Fast Transients/Bursts (EFT)	±2 kV on power lines	Complies
Surge Protection	±1 kV differential, ±2 kV common mode	Complies
Conducted RF Immunity	3V (0.15–80 MHz)	Complies
Radiated RF Immunity	10V/m (80 MHz–2.7 GHz)	Complies
Voltage Dips & Interruptions	0% for 0.5 cycles, 70% for 25 cycles	Complies
Power Frequency Magnetic Fields	30 A/m at 50/60 Hz	Complies

v) IEC 62366: Application of Usability Engineering to Medical Devices

- The Usability Engineering (UE) is intended to identify and minimise the errors and reduce use-associated risks. IEC 62366 specifies a process for manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety.
- UE considerations in the development of medical devices involve three major components of the device
- device users,
- device use environments
- device user interfaces
- It describes a usability engineering process of medical device and provides guidance on how to implement it. It focused to minimise errors and accompanying use-associated risks. (33)
- process of the usability standard.
- Specify application of medical device
- Identify device's frequently used functions
- Identify hazards and hazardous situations
- Identify device's primary operating functions
- Develop usability specification
- Design and implement the user interface
- Verify the user interface design
- Validate the usability of the medical device (34)

Table 23. Usability

Usability Aspect	Tested Features	Compliance Requirements
User Interface (UI) Design	LCD screen, control dial, therapy buttons	Must be intuitive, easy to navigate
Setup & Installation	Power connection, tubing, humidifier assembly	Clear setup instructions must be provided
Mask Fit Check	Check Mask Fit feature	Must provide clear feedback on leaks
Alerts & Notifications	LED indicators, display messages, audible alarms	Must be easy to understand and respond to
Therapy Comfort Adjustments	Ramp, Humidification, Flex pressure relief	Customizable for patient comfort
Maintenance & Cleaning	Filter replacement, humidifier cleaning, tubing care	Must be simple and clearly guided
Bluetooth & Data Syncing	App connectivity	Must allow easy data transfer

w) Clinical Evidence

Obstructive Sleep Apnoea (OSA) is a chronic sleep disorder with daytime fatigue, cardiovascular risks, and impaired quality of life (QoL). Continuous Positive Airway Pressure (CPAP) is the gold standard for treatment, but Mandibular Advancement Splints (MAS) offer an alternative for mild-to-moderate OSA cases.(35)

Study Objective:

- Compare the long-term effects of CPAP and MAS on:
- Health-related quality of life (HRQoL)
- Sleep quality
- Treatment adherence
- Daytime sleepiness (Epworth Sleepiness Scale - ESS)

Study Design

- Type: Randomized, controlled, parallel-group clinical trial
- Duration: 12 months of follow-up
- Study Population: Mild-to-moderate OSA patients

Study Interventions

- All participants underwent polysomnography (PSG) at baseline and after treatment.
- Adherence was monitored using CPAP usage logs and self-reported MAS compliance.

Outcome Measures

Primary Outcome:

- Improvement in Health-Related Quality of Life (HRQoL) scores using:
- SF-36 questionnaire (Short Form Health Survey-36)
- Functional Outcomes of Sleep Questionnaire (FOSQ)

Secondary Outcomes:

- Sleep Quality: Pittsburgh Sleep Quality Index (PSQI)
- Daytime Sleepiness: Epworth Sleepiness Scale (ESS)
- Apnoea-Hypopnea Index (AHI) changes (via PSG)
- Adherence rate (≥4 hours/night for CPAP, ≥5 nights/week for MAS)
- Blood pressure and cardiovascular markers

Findings

- **HRQoL Improvements**
- CPAP and MAS both significantly improved QoL scores.
- CPAP had a greater impact on physical health scores, while MAS showed better adherence and comfort scores.
- **Sleep Quality & Daytime Sleepiness**
- Both CPAP and MAS reduced daytime sleepiness, but CPAP had a slightly stronger effect

Apnoea-Hypopnea Index (AHI) Reduction

- CPAP reduced AHI significantly more than MAS ($p<0.001$).

Adherence & Tolerability

- MAS had higher adherence rates and was better tolerated.
- CPAP had slightly more dropouts (10%) due to discomfort.(35)

Table 24. Finding of clinical report

Measure		CPAP	MAS	P-Value
HRQoL Improvements	SF-36 Physical Component	+9.4	+5.8	0.02
	SF-36 Mental Component	+8.1	+7.5	0.48
	FOSQ Total Score	+5.2	+4.1	0.04
Sleep Quality & Daytime Sleepiness	PSQI (Sleep Quality Index)	-3.4	-3.1	0.21
	ESS (Daytime Sleepiness)	-5.6	-4.2	0.03
Apnoea-Hypopnea Index (AHI) Reduction	Baseline AHI	22.3 ± 4.2	21.8 ± 3.9	<0.001
	Post -Treatment AHI	4.1 ± 1.8	8.3 ± 2.6	0.02
Adherence & Tolerability	Usage (Hours/Night)	4.8 ± 1.5	6.1 ± 1.2	0.01
	Adhereance(% patients using device correctly)	72.4%	85.1%	0.02

3. Case study

Case study: Philips Issues a Recall Notification to Mitigate Potential Health Risks Related to the Sound Abatement Foam Component in Certain Sleep and Respiratory Care Devices

In June 2021, Philips initiated a voluntary recall of specific Bi-Level Positive Airway Pressure (Bi-Level PAP),

Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices due to potential health risks associated with the polyester-based polyurethane (PE PUR) sound abatement foam used in these devices. The PE-PUR foam, intended to reduce sound and vibration, was found to potentially degrade into particles that could enter the device's air pathway, posing risks of ingestion or inhalation by users.(36)

3.1 FDA Activities Related to Recalled

The FDA organized a response team to work on the recall's regulatory activities and respond to queries and concerns from patients and healthcare professionals as soon as the recall began in June 2021. To keep tabs on Philips' handling of this recall, this team meets with the company on a regular basis.(37)

3.2 Regulatory action

Regarding the introduction and execution of the anticipated correction, Philips is giving the necessary information to the appropriate regulatory bodies. The business has started making the necessary arrangements, including securing the necessary regulatory clearances, in order to replace the existing sound abatement foam with a new substance.(36)

4. Conclusion

The regulation of medical devices like Continuous Positive Airway Pressure (CPAP) systems is a critical to ensuring patient safety, therapeutic efficacy, and market readiness. Through this study, a comprehensive understanding of global regulatory frameworks—namely the FDA (USA), and EU MDR (Europe)—has been developed, highlighting the classification of CPAP as a moderate-risk device and the specific technical documentation required for its approval.

CPAP devices, while non-invasive, directly interact with the respiratory system, necessitating robust design controls, usability engineering, and risk management protocols. The essential principles of safety and performance, as guided by international standards such as ISO 13485, ISO 14971, and IEC 60601 series, human factors engineering and post-market surveillance in maintaining device compliance and patient trust.

In light of recent safety concerns, such as the Philips CPAP recall, this thesis reaffirms the need for manufacturers to integrate regulatory strategy early in product development. Doing so not only accelerates time-to-market but also ensures long-term safety, compliance, and user satisfaction.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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