[redacted]

Clinical Investigation Plan (CIP)

[redacted]

Revision: A

Parent Procedure: [redacted]

[redacted]		[redacted]	[redacted]	[redacted]	
[redacted]	A	Clinical Investigation Plan: F&P [redacted] US, 2023	[redacted]	[redacted]	1.2

Additional Notes: Not applicable

[redacted]

[redacted]	[redacted]	Date 18 Oct 2023

Approval:

[redacted]

Table of Contents

Term	Abbreviation	Definition
Adverse event	AE	Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device. *See also serious adverse event.*
Apnea-Hypopnea Index	AHI	Measure of sleep apnea severity calculated from the number of apneic and hypopneic episodes combined per hour of sleep which last more than 10 seconds and are associated with a decrease in blood oxygenation[1].
Auto-titrating positive airway pressure	APAP	Mode of non-invasive ventilation during which a low set pressure is supplied to the airway, unless an obstruction is detected, in which case pressure ramps up to a higher level, up to a set maximum limit.[2,3]
Bilevel positive airway pressure	BPAP	Mode of non-invasive ventilation during which two distinct pressure, one on inhalation and the other on exhalation, are supplied to the airway[3].
[redacted]	[redacted]	A[redacted]
Clinical Investigation Plan	CIP	A document(s) that state the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation. This is synonymous with Protocol.
Clinical Master Data	CMD	Collates the body of knowledge related to the therapy and clinical procedures by documenting therapy background, and the latest clinical literature search strategy, results, and conclusions.
[redacted]	[redacted]	[redacted]
Case Report Form/ electronic Case Report Form	CRF/eCRF	Deidentified document used by the sponsor of a clinical investigation to record source information relating to a study subject, including investigational data which is collected, procedures that are followed, and adverse events that occur. This can be physical or stored on an electronic server.
Design History File	DHF	Compilation of documentation that describes the design history of a medical device.
Delegation of Authority	DoA	This document will define, establish and allocate all investigation related duties and functions.
Design Review	DR	A milestone in the product development process whereby a design is evaluated against its requirements in order to verify outcomes of previous activities or identify issues.
Ethics Committee	EC	An independent body whose responsibility it is to review a Clinical Investigation in order to protect the rights, safety and wellbeing of participating human subjects. This is synonymous with Institutional Review Board (IRB).
Excessive Daytime Sleepiness	EDS	Subjective difficulty in maintaining an awake state, accompanied by increased ease of falling asleep when sedentary[4].

Term	Abbreviation	Definition
Epworth Sleepiness Scale	ESS	A widely used scale in the field of sleep medicine as a subjective measure of a patient's sleepiness. The scale estimates whether you are experiencing excessive sleepiness that possibly requires medical attention.
Fisher & Paykel Healthcare	F&P	Fisher & Paykel Healthcare Ltd.
Good Clinical Practice	GCP	A standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of Clinical Investigations that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of Investigation subjects are protected. Forms an integral part of ISO 14155:2020.
Investigators Brochure	IB	A compilation of the clinical and non-clinical data on the investigational medical device(s) which is relevant to the Clinical Investigation.
Informed Consent Form	ICF	A document that captures that the potential subject has discussed and understands what is being proposed by the clinical investigation and what is expected of them if they decide to sign the form and continue into the clinical investigation. Informed consent procedures are defined by the clinical investigation plan.
International Council for Harmonization	ICH	International body comprised of representatives from various national standards organizations, and intended to promote worldwide proprietary, industrial, and commercial standards.
Instructions For Use	IFU	Also known as UI (user instructions); A document supplied with the investigational product that outlines how to use, clean, assemble and disassemble the investigational product. It also contains any relevant warnings and cautions and additional information about the operating requirements of the investigational product.
Institutional Review Board	IRB	See also *Ethics Committee (EC)*
Good Clinical Practice	GCP	A standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of Clinical Investigations that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of Investigation subjects are protected. Forms an integral part of ISO 14155:2020.
General Safety and Performance Requirements	GSPR	Set of requirements/product characteristics which are considered by the European authorities as being essential to ensuring that any new device will be safe and perform as intended throughout its life.
Non-invasive Ventilation	NIV	Airway support administered through a mask wherein inhaled gases are supplied with positive end-expiratory pressure, often at a set tidal volume and rate. [5]
Obstructive Sleep Apnea	OSA	Sleep-related breathing disorder characterized by recurrent interruptions in breathing during sleep due to temporary obstruction of the airway by lax, excessively bulky, or malformed pharyngeal tissues, with resultant hypoxemia and chronic lethargy[6].
Obesity Hypoventilation Syndrome	OHS	Sleep-related disorder accompanied by severe overweightness, hypoxemia during sleep, and hypercapnia during the day, resulting from excessively slow or shallow breathing[7].

Term	Abbreviation	Definition
Positive Airway Pressure	PAP	Mode of respiratory ventilation during which compressed air is supplied to the lungs to prevent episodes of airway collapse and to facilitate normal breathing[3].
Principal/Primary Investigator	PI	The qualified individual responsible for conducting the Clinical Investigation at an investigational site.
[redacted]	[redacted]	[redacted]
Protocol Deviation Form	PDF	The record of all diversions from the procedures outlined in the clinical investigation plan.
Recruitment Script	RS	A standardized text delegated recruiters for the clinical investigation to use during the recruitment phase of the trial to ensure full disclosure of important points and consistency across staff.
Serious adverse event	SAE	Any adverse event that led to any of the following: Death Serious deterioration in the health of the subject, that resulted in any of the following: • Life-threatening illness or injury • Permanent impairment of a body structure or a body function • Hospitalization or prolongation of patient hospitalization • Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function Fetal distress, fetal death or a congenital physical or mental impairment or birth defect *See also adverse event*
Serious Adverse Event Form	SAEF	A record of all serious adverse events and required additional analysis and review. Each serious adverse event is required to have its own completed serious adverse event form.
[redacted]	N/A	[redacted]
[redacted]	N/A	[redacted]

1. Clinical Trial Summary Information

Information	Details
Clinical Investigation Details	
Title of Clinical Investigation	F&P [redacted] US, 2023
[redacted]	[redacted]

Information	Details
Clinical Investigation Description	This clinical investigation is designed to validate and confirm the overall performance and acceptability, of the F&P [redacted]
Clinical Investigation Device(s) used	[redacted] PAP therapy, both in clinical settings and in-home environments for the treatment of various respiratory conditions, including obstructive sleep apnea (OSA).The F&P [redacted] will be offered similarly to existing [redacted] products on the market.

Information	Details
Inclusion / Exclusion Criteria(s)	[redacted] Inclusion criteria: • Persons who are ≥22 years of age • Persons who weigh ≥66 pounds (or 30 kg) • Persons who have been prescribed PAP therapy by a physician • Persons who are existing nasal mask or sub-nasal mask users with ≥3 months of use prior to enrolment in the clinical trial • Persons who are compliant with PAP therapy for ≥4 hours per night for ≥70% of nights for a 14-day period within 30 days prior to enrolment in the clinical trial • Persons who are fluent in spoken and written English • Persons who possess the capacity to provide informed consent Exclusion criteria: • Persons who are intolerant to PAP therapy • Persons who possess, or suffer from, anatomical or physiological conditions which make PAP therapy inappropriate • Persons who are required to use PAP therapy for >12 hours per day or for extensive periods, not including sleep or naps • Persons who are trying to get pregnant, are pregnant, or think they may be pregnant • Persons who have an IPAP pressure of >30 cmH_2O if on BPAP • Persons who use a PAP therapy device for the delivery of medicines, except supplemental oxygen • Persons who use a PAP therapy device that does not possess data recording capabilities to capture AHI and a numerical indicator of leak that is accessible to the investigation site [redacted]

Information	Details
Number of Subjects	Recruitment target for patient participants: Between 40 and45 [redacted]
Duration of Clinical Investigation	[redacted]
Total number of visits in clinical investigation	[redacted]
Background and Rationale	The F&P [redacted]
Phase of Development	As per ISO-14155:2020, '*Annex I*', the F&P [redacted] mask is considered in the pivotal stage of device development.
Study Design	[redacted] clinical investigation.
Study Hypotheses	**Patient Participant** Primary hypothesis: The F&P [redacted] mask is safe and effective in providing adequate PAP therapy, or treatment comparable to that provided by the usual mask used by participants, for managing a respiratory condition during in home use. Secondary hypothesis: The F&P [redacted] mask presents an acceptable safety profile when used by participants with PAP therapy for the management of a respiratory condition during in-home use. [redacted]

Information	Details
Clinical Investigation Objective(s)	**Patient Participant:** To evaluate the performance, comfort, stability and reliability of the F&P [redacted] mask among patient participants using PAP therapy, with regards to patient participant views on overall experience, satisfaction and acceptance. [redacted]
Sponsor Details	
Sponsor Name	[redacted]
Sponsor Representative Name	[redacted]
Sponsor Address	[redacted]
Co-ordinating Investigator Name(s)	[redacted]
Co-ordinating Investigator Professional Position(s)	[redacted]
Co-ordinating Investigator Business / Clinic / Hospital Name	Fisher & Paykel Healthcare
Co-ordinating Investigator Business / Clinic / Hospital Address	15 Maurice Paykel Place East Tamaki Auckland 2013 New Zealand
Investigator Details	
Principal Investigator Name	[redacted]
Principal Investigator Professional Position	[redacted]
Principal Investigator Clinic	[redacted]
Principal Investigator Clinic Address	[redacted]

Information	Details
Co-ordinating Investigator Name(s)	[redacted]
Co-ordinating Investigator Professional Position(s)	[redacted]
Co-ordinating Investigator Business / Clinic / Hospital Name	[redacted]
Investigation Site details	
Investigation site	[redacted]
Investigation site address	[redacted]

2. Identification and Description of the Investigational Device

Information	Details
Summary Description of Medical Device	[redacted] mask used for the delivery of positive airway pressure to the upper airways.
Details concerning the manufacturer of the investigational device	[redacted]
Name/Number of model	F&P [redacted]
Description of how traceability shall be achieved	Product accountability logs will be used to keep a record for product traceability. [redacted].
Intended purpose of the investigational device	The F&P [redacted] mask is intended to be used as a patient interface in a non-invasive positive airway pressure (PAP) therapy system to deliver pressurized air from the breathing tube to the patient's upper airway.
Populations and indications for which the investigational device is intended	The patients are intended to be adults weighing ≥30 kg or 66 pounds. [redacted]

Information	Details
Description of the investigational device	[redacted].
Summary of the necessary training and experience needed to use investigational device	Training sessions covering the investigational product and protocol for the investigation sites and PI's will be conducted prior to the investigation starting. The investigational device will be fitted to the subjects by a trained F&P staff member. [redacted]
Description of any specific medical or surgical procedures involved in the use of the clinical device.	N/A
Reference to IB and IFU	The IB can be found [redacted] for this clinical investigation [redacted]

[redacted]

3. Justification for the Design of the clinical investigation

3.1. Synopsis

The investigation is a prospective, non-randomized, non-blinded study. This clinical investigation is designed to validate and confirm the overall performance and acceptability of the F&P [redacted] provides positive airway pressure (PAP) therapy for existing patients which is equivalent to the treatment provided by their usual mask. [redacted] are commonly used as part of PAP therapy, both in clinical settings and in-home environments for the treatment of various respiratory conditions, including obstructive sleep apnea (OSA). [redacted].

3.2. Literature Review

A full description of PAP therapy and the associated conditions which can be effectively treated PAP is located [redacted].

[redacted]

Positive airway pressure (PAP) and non-invasive ventilation (NIV) are common treatments used in chronic care to assist in airway management for several respiratory conditions present in both adults and adolescents, including obstructive sleep apnea (OSA), obesity hypoventilation syndrome (OHS), among others. The prevalence of these conditions, as well as others, continues to rise as the prevalence of noncommunicable diseases, such as obesity, increase across many parts of the world[8,9] Historically, invasive methods of ventilation were required to maintain airway patency, but this is often associated with significant long-term medical complications as well as increased susceptibility to other conditions[10]. Non-invasive methods, if appropriate for a patient, are now more appealing to practicing physicians, especially if treatment is administered in a non-clinical setting, such as the home.

[redacted]

PAP therapy was first described in 1981[11] for the treatment of OSA, a form or sleep-disordered breathing (SDB) characterized by upper airway collapse during sleep. PAP therapy is now a well-established, effective, and the clinically preferred treatment for OSA, helping resolve many of the primary markers of disease severity[3]. It has evolved to include a variety of modes including auto-titrating positive airway pressure (APAP), bilevel positive airway pressure (BPAP), and continuous positive airway pressure (CPAP), as well as comfort features such as humidification and expiratory relief (ER) which improve uptake and long-term adherence among those prescribed with the treatment[3]. PAP therapy is delivered through a system of components which includes a flow generator, breathing tube, and interface, sometimes with the addition of a humidifier or mask accessory.

It is generally accepted that PAP therapy:

- Is safe to use among adults with OSA
- Reduces Apnea-Hypopnea Index (AHI) and excessive daytime sleepiness (EDS) among adults with OSA
- Reduces AHI among adults with OHS
- In the form of APAP and CPAP are equally efficacious for treating adults with OSA

PAP and NIV therapies are still considered the most effective and reliable treatment options for those with OSA and OHS, despite advancements in alternative treatments such as oral appliances (OA) and surgical interventions to remodel structures at the back of the throat such as tonsillectomies or uvulopalatopharyngoplasties[10,12]. Professional organizations continue to recommend PAP or NIV therapy, where applicable and appropriate, over alternative treatments. In order to deliver effective therapy, the components which make up the treatment system must work harmoniously. While the effective pressure is determined by a practicing physician, the machine which generates flow must accurately and consistently deliver required prescribed constant or fluctuating pressures.

The interface should provide an effective seal over the face to minimize leak, a factor which significantly impacts the sleep quality and level of comfort experienced by patients, as well as their long-term tolerance and adherence to treatment[3,13]. While there are a significant number of benefits to using PAP and NIV therapies for the relevant indications, both also come with some risks to the patient. These include potential sleep disruption, facial irritation, mandibular pain, internal trauma, anxiety sensitivity, abdominal discomfort, physiological compromise, facial discomfort, facial dryness, mucosal congestion, and facial inflammation. However, manufactures of medical devices which deliver PAP and NIV therapies can address a number of these side effects with improving design and functionality. This may involve the incorporation of humidification and ER technologies in machines, or the use of comfortable and non-irritating materials for interfaces

3.3. Pre-Clinical Testing

PAP therapy is a treatment designed to be administered to humans. [redacted] a series of bench tests is conducted on the investigational product to ensure it is safe and will perform as expected when used on human subjects. [redacted]

3.4. Previous Clinical trial

The main objective of the F&P [redacted] mask is to develop a [redacted]. The F&P [redacted]

The F&P [redacted]

[redacted]

3.5. Justification for Administration

There is an ongoing need for advancement in design and technology for PAP therapy masks on the market, specifically as a means of improving comfort for patients and encouraging log-term adherence to treatment.

[redacted]

4. Benefits and Risks of the investigational device, clinical procedure and clinical investigation

4.1. Anticipated benefits

[redacted]

4.2. Risks associated with participation in the clinical investigation

PAP therapy is currently one of the least invasive and most widely recommended treatments for OSA, and serves as the generally accepted state of the art within the field of sleep and respiratory medicine. The acceptability of risk associated with PAP therapy devices, interfaces, accessories, and supporting information technology for delivering treatment to the target population are shared, and is appropriate, as the benefits of PAP therapy outweigh most risks. [redacted]

4.3. Possible interactions with concomitant medical treatments

[redacted]

4.4. Steps that will be taken to control or mitigate risks

The F&P [redacted]

- [redacted]
- [redacted]
- [redacted]

4.5. Rationale for benefit-risk ratio

PAP therapy is considered standard treatment for those diagnosed with OSA, [redacted]

5. Objectives & Hypotheses of the clinical investigation

5.1. Objectives

5.1.1. Patient participant objective

To evaluate the performance, comfort, usability, stability, and reliability of the F&P [redacted] mask among participants using PAP therapy, with regards to participant views on overall experience, satisfaction, and acceptance.

[redacted]

5.2. Hypotheses

5.2.1. Patient participant hypothesis

Primary hypothesis: The F&P [redacted] mask is effective in providing adequate PAP therapy, or treatment comparable to that provided by the usual mask used by participants, for managing a respiratory condition during in-home use.

Secondary hypothesis: The F&P [redacted] mask presents an acceptable safety profile when used by participants with PAP therapy for the management of a respiratory condition during in-home use.

[redacted]

- [redacted]

[redacted]

5.4. Methods and Timing for assessing, recording and analysing variables

[redacted]

[redacted]

5.5. Equipment used for assessing clinical investigation variables and arrangements for monitoring maintenance and calibration

[redacted]

[redacted]

5.7. Investigation sites

This is a single-site clinical investigation. [redacted].

5.7.1. Definition of completion of clinical investigation

- Phase 1 will be complete when the patient participants have completed [redacted]
- The participants will be offered to participate in Phase 2, [redacted]
- [redacted]

5.8. Investigational device(s) and comparator(s)

[redacted]

[redacted]

6. Participants

6.1.1. Inclusion criteria for participants selection

F&P [redacted] following inclusion and exclusion criteria.

Inclusion criteria for patient participant:

- Persons who are ≥22 years of age
- Persons who weigh ≥66 pounds (or 30 kg)
- Persons who have been prescribed PAP therapy by a physician
- Persons who are existing nasal mask or sub-nasal mask users with ≥3 months of use prior to enrolment in the clinical trial
- Persons who are compliant with PAP therapy for ≥4 hours per night for ≥70% of nights for a 14-day period within 30 days prior to enrolment in the clinical trial
- Persons who are fluent in spoken and written English
- Persons who possess the capacity to provide informed consent

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

6.1.2. Exclusion criteria for participants selection

Exclusion criteria for patient participant:

- Persons who are intolerant to PAP therapy
- Persons who possess, or suffer from, anatomical or physiological conditions which make PAP therapy inappropriate

- Persons who are required to use PAP therapy for >12 hours per day or for extensive periods, not including sleep or naps
- Persons who are trying to get pregnant, are pregnant, or think they may be pregnant
- Persons who have an IPAP pressure of >30 cmH_2O if on BPAP
- Persons who use a PAP therapy device for the delivery of medicines, except supplemental oxygen
- Persons who use a PAP therapy device that does not possess data recording capabilities to capture AHI and a numerical indicator of leak that is accessible to the investigation site

[redacted]

[redacted]

[redacted]

6.1.3. Criteria and procedures for patients withdrawal / lost to follow-up

Participants will be informed that they have the right to withdraw from the clinical investigation at any time, without prejudice or compromise to their medical care, and are not obliged to state their reasons. [redacted]

The PI may withdraw a participant at any time for the following reasons:

- Protocol violation
- Safety concerns
- Serious illness
- AEs

[redacted]

6.1.4. Point of Enrolment

[redacted].

[redacted]

[redacted]

[redacted]

Patient participants completing Phase 1 will be participating in the clinical investigation [redacted]

Clayton Sleep Institute will recruit up to 45 patient participants for the F&P Nova Nasal clinical investigation [redacted]

There is no intention to recruit individuals in vulnerable populations. [redacted]

7. Procedures

The protocol of this clinical investigation is summarized [redacted]

[redacted]

[redacted]

7.1.1. Clinical-Investigation Procedures

Details of the key events that will occur during the F&P N[redacted]

A. **Recruitment** [redacted]

The following will take place during recruitment:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

B. [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

C. [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

D. [redacted]

Procedures that will be carried out [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

E. [redacted]

Below are the activities [redacted]

- [redacted]

- [redacted]

F. [redacted]

Below are the activities [redacted]

- [redacted]
- [redacted].

G. [redacted]

Below are the activities [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

H. [redacted]

Procedures that will be carried out [redacted]

- [redacted]
- [redacted]

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

Details of the key events that will occur [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

7.2. Roles and Responsibilities

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

7.2.4. Follow-up period during clinical investigation

Participants will be monitored for the duration of their enrolment in the clinical investigation [redacted] ational product arising. Moreover, the clinical investigation may be terminated if progress is unsatisfactory.

The following is required [redacted]

- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

7.3. Monitoring Plan

Fisher & Paykel Healthcare (F&P) will appoint [redacted]

[redacted]

Responsibilities

[redacted]

Specific tasks include:

[redacted]

[redacted]

[redacted]

8. Statistical Design and Analysis

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

8.1.1. Safety Data

Adverse events (AE) and serious adverse events (SAE) will be captured as part of the clinical investigation [redacted]

8.2. Sample size calculation and justification

Patient Participant:

Between 40 and 45 patient participants will be recruited for this clinical investigation. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

All participants who consent and who use the investigational product [redacted]

9. Data Management

[redacted]

.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

The following persons have authority to amend the CIP:

[redacted]

11. Deviations from clinical investigation plan (CIP)

[redacted]

[redacted].

[redacted]

All deviations from the CIP shall be recorded together with an explanation for the deviation. [redacted]

[redacted]

[redacted]

[redacted]

12. Device Accountability

[redacted]

[redacted]

[redacted]

[redacted]

[redacted].

13. Statements of Compliance

[redacted]

[redacted]

The F&P [redacted] clinical investigation is being conducted in the USA and therefore must meet the requirements [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

14. Informed Consent Process

[redacted]

[redacted]

[redacted]

15. Adverse Events, Adverse device effects and device deficiencies

[redacted]

- [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

- [redacted]

- [redacted]

[redacted]

[redacted]

[redacted]

15.5. Emergency contact details for reporting SAEs and SADEs

[redacted]

[redacted]	[redacted]
[redacted] [redacted]	[redacted] [redacted]

[redacted]

[redacted]	[redacted]
[redacted] [redacted] [redacted]	[redacted] [redacted]

16. Suspension or premature termination of clinical investigation

[redacted]

[redacted]

[redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[redacted]

[redacted]

[redacted]

Participants will be followed up with throughout the duration of their enrolment in the clinical investigation, [redacted]

17. Publication Policy

[redacted]

[redacted] Results from this clinical investigation may be made public through requirements by the relevant clinical trial registry.

18. Regulatory and Other References

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
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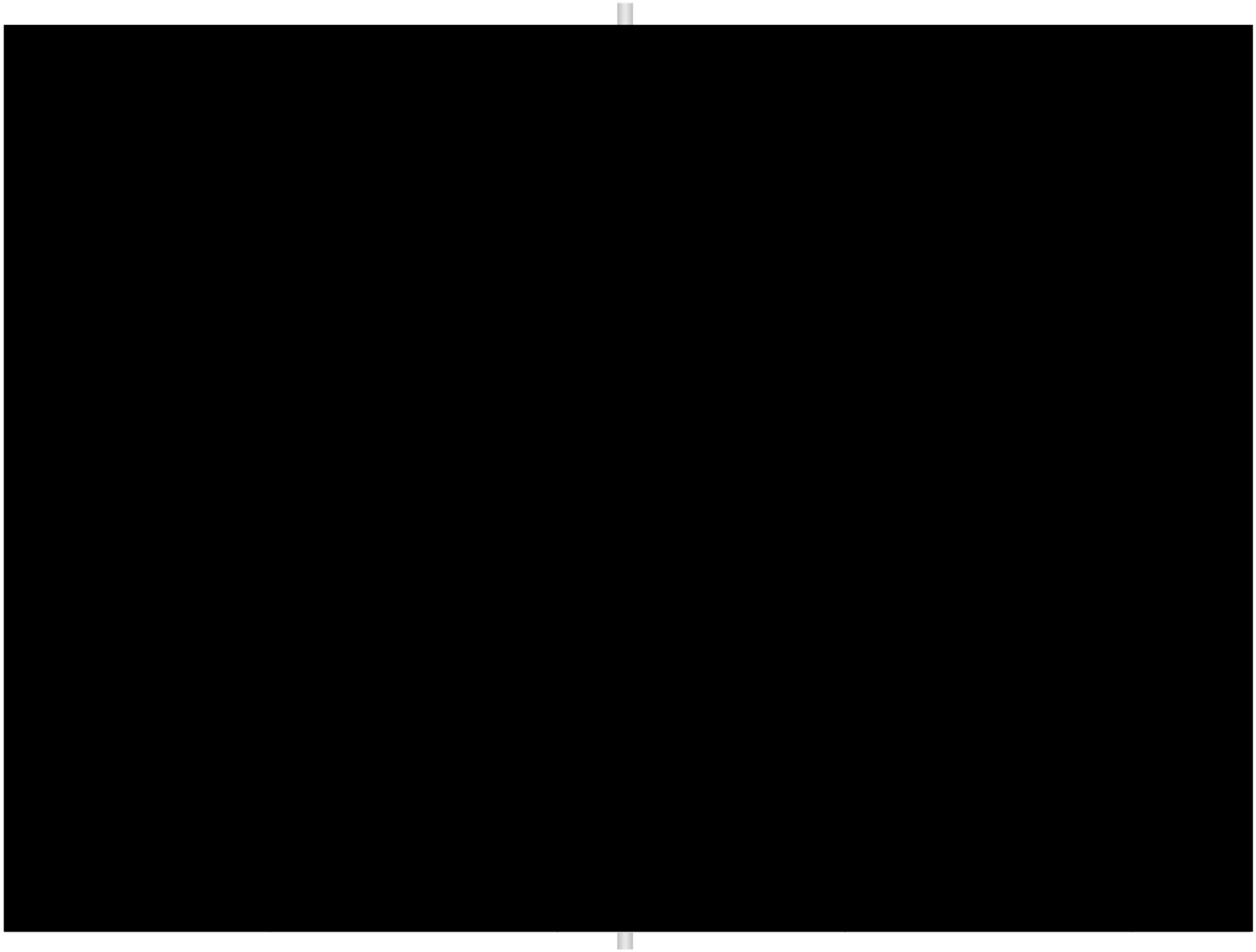

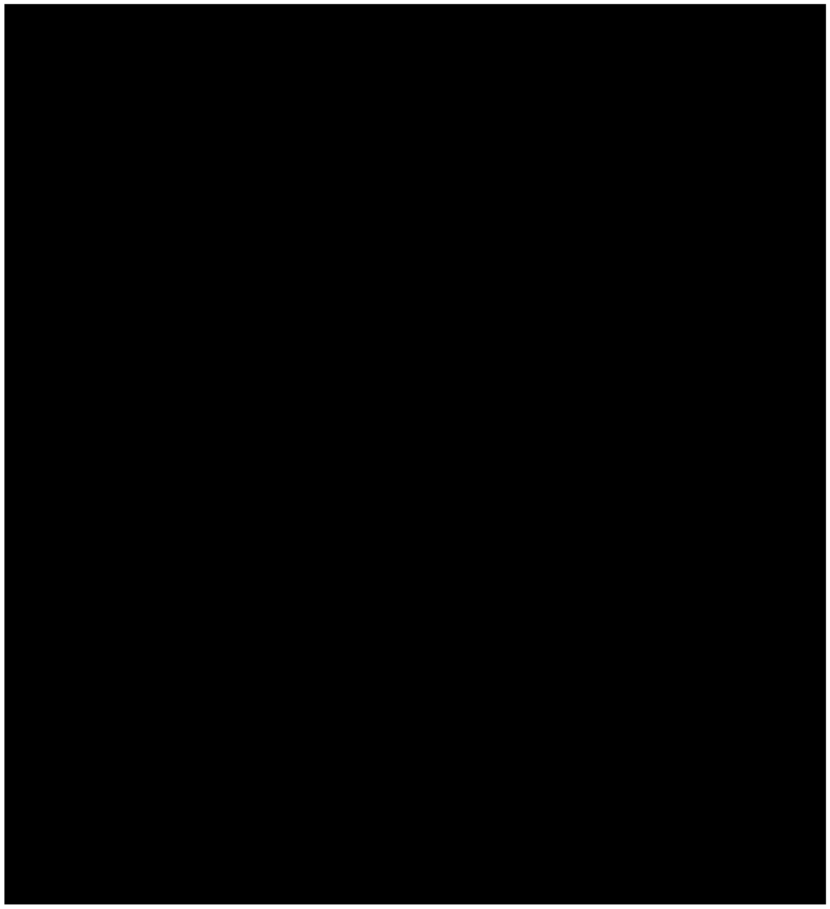

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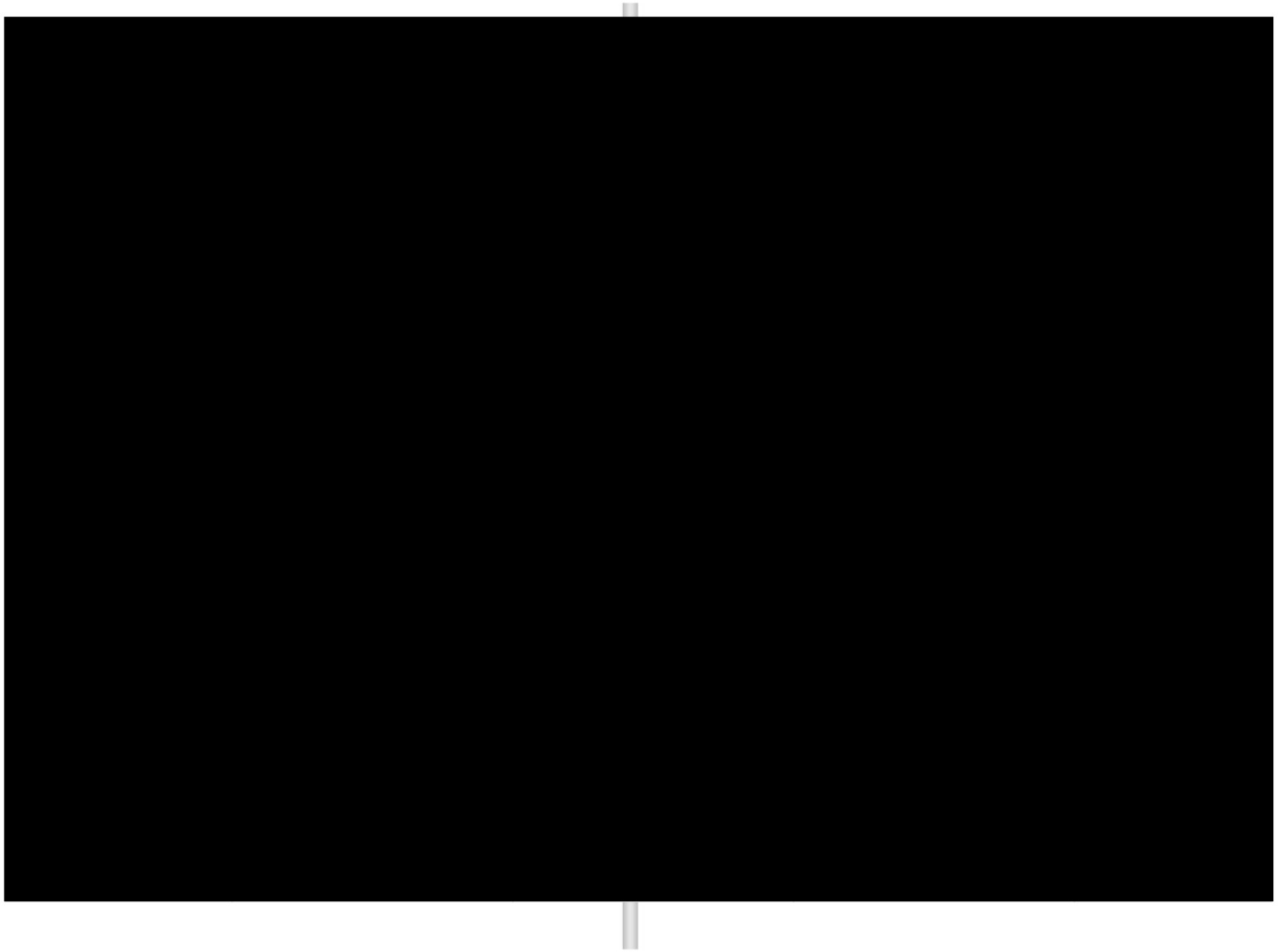

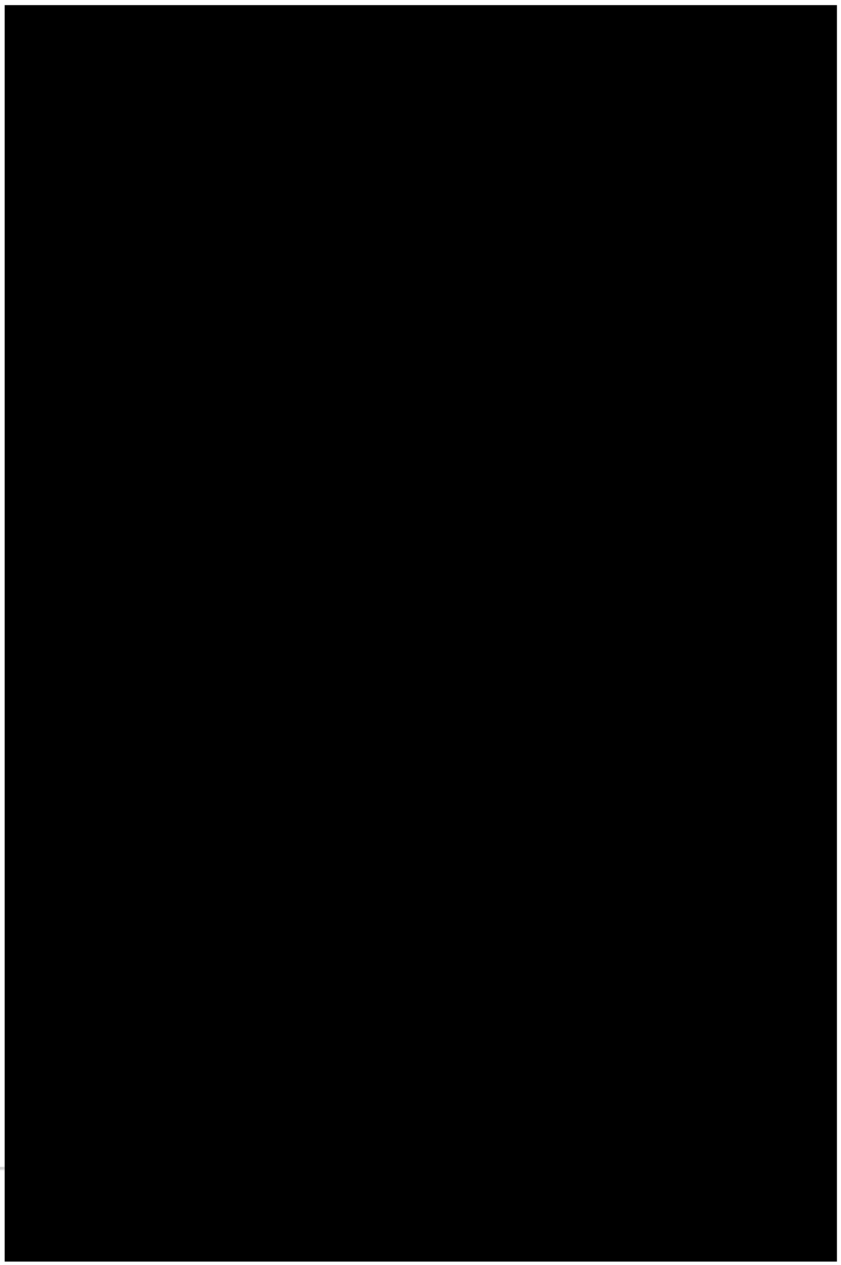

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