



V2 NIV Mask: Evaluation

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Introduction

This paper will discuss the evaluation of the performance of the Eakin Healthcare V2 NIV face mask.

Scope

This report presents responses of a product evaluation assessing the performance of the V2 NIV face mask conducted between December 2025 and June 2026 in a selection of German hospitals.

Background

Multiple German hospitals were all looking for an alternative NIV mask supplier. They reached out to Eakin Healthcare and after initial discussions decided to evaluate the V2 NIV mask.

For the purpose of this white paper, all participating hospitals will remain anonymised.

Hospitals B - J are part of one of Germany's largest private healthcare providers. It operates a nationwide network of hospitals, specialist clinics, rehabilitation centres, and outpatient facilities.

They cover the full spectrum of healthcare services:

- Acute-care hospitals
- University-affiliated hospitals
- Maximum-care and specialist centres
- Psychiatric hospitals
- Rehabilitation clinics
- Outpatient medical centres (MVZs)
- Digital health and e-health services

Hospital A is a specialist hospital located in north west Germany.

The hospital is known for:

- Pneumology (lung and respiratory medicine) – treatment of asthma, COPD, pneumonia, pulmonary fibrosis, pulmonary hypertension, and other lung diseases.
- Infectious diseases, including specialized care for tuberculosis patients.
- Sleep medicine and respiratory support.
- Weaning and ventilation medicine (helping patients come off long-term mechanical ventilation).
- Ear, Nose and Throat (ENT/HNO) medicine.
- Palliative care.

- Pain management (Schmerzzentrum).
- General internal medicine.
- Anesthesiology and intensive care medicine.

Hospital L is one of Germany's five military hospitals operated by the German Armed Forces (Bundeswehr) Medical Service. It is located in the north of Germany and serves both military personnel and civilian patients.

The hospital offers a broad range of specialties, including:

- Trauma and orthopedic surgery
- General and vascular surgery
- Neurosurgery
- Psychiatry and mental health
- Dentistry and oral surgery
- Intensive care medicine
- Emergency medicine
- Tropical medicine and infectious disease expertise through partnerships in Hamburg's medical community.

Product Application Area

Intensive Care Unit (ICU)

The Eakin Healthcare V2 NIV face mask range as shown in Figure 1 was extensively tested on patients by the ICU staff, and its clinical application was subsequently evaluated. This product evaluation included, among other aspects, the fit of the NIV mask on the patient, the sealing performance of the ventilation mask, and patient comfort.



Figure 1: Eakin Healthcare V2 NIV mask range.

Problems and / or challenges

Before the product evaluation, patients undergoing NIV CPAP therapy were ventilated using NIV face masks from other manufacturers within the group of hospitals B - J.

In one of the hospitals where our product was evaluated (Hospital G) CPAP treatments were often challenging because the masks they used showed air leakage between the mask and the patient's skin. These leaks exceeded 5% of the total airflow.

To reduce the leakage, the masks had to be tightened using the headgear straps to achieve an effective skin seal. This frequently resulted in skin redness on the bridge of the nose during therapy and, in cases of prolonged NIV ventilation, even ulcerations.

Within this hospital, prior to the product evaluation, bronchoscopies were also performed using an NIV face mask from another manufacturer. The main challenges were limited connectivity options, restricted adaptability, and often the complicated handling and adjustment of the mask headgear.

Objectives

- Identify that sufficient training was conducted on how to properly size and fit the mask by an Eakin Healthcare representative.
- Compare the fit of the V2 NIV face mask on the patient, the sealing performance of the ventilation mask, patient comfort and patient response to the therapy with the product they were currently using.
- Evaluate ease of use and overall effectiveness of the ventilation mask.
- Evaluate overall performance of the V2 NIV face mask.
- Identify if they are satisfied with the range of sizes available for the ventilation mask.
- Identify if staff would recommend continued use of the V2 NIV face mask.
- Gather any other general product feedback.

Participants

Eakin Healthcare V2 NIV face mask range was planned to be evaluated in the German market on multiple patients within a selection of hospitals.

It was confirmed that twelve hospitals were suitable to carry out the product

evaluation. The aim was to gather a minimum of ten evaluation responses. The product evaluation was conducted at the following hospitals:

- Hospital A
- Hospital B
- Hospital C
- Hospital D
- Hospital E
- Hospital F
- Hospital G
- Hospital H
- Hospital I
- Hospital J
- Hospital K
- Hospital L

Data Collection

Evaluation data was collected via a product performance and feedback form, available in either English or German. The evaluation form was provided in hard copy.

Hospital staff were asked to collate the following data during the product evaluations:

- Date of V2 NIV face mask usage on each patient
- Hospital name
- Department
- NIV mask and model
- Size(s) available
- Intended use

All data received was consolidated and analysed.

Results

Twenty-one responses were received from the product evaluation of the V2 NIV face mask within the selection of German hospitals. Two of these forms were unusable and therefore results are based on nineteen responses only. (Hospital C and Hospital F have been omitted)

Market	Hospital name	Number of patients
German	Hospital A	1
	Hospital B	1
	Hospital D	1
	Hospital E	1
	Hospital G	1
	Hospital H	1
	Hospital I	4
	Hospital J	1
	Hospital K	7
	Hospital L	1

Table 1: Patient Hospital Locations

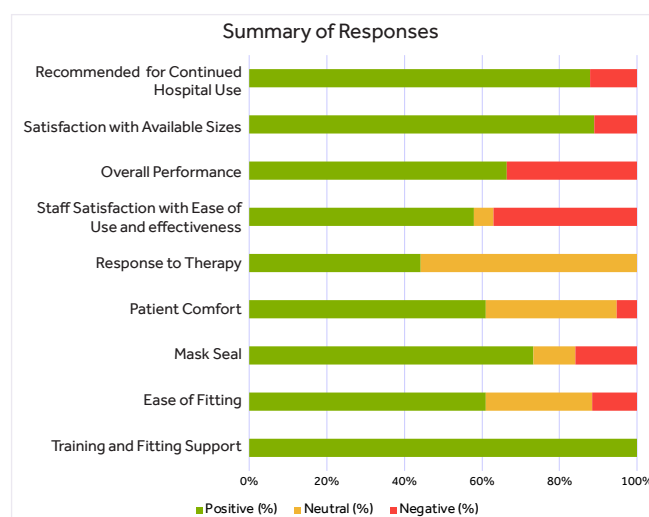


Figure 2: Summary of Results

Patient Hospital Locations

The hospitals that took part in the product evaluation are listed in Table 1.

Product Observations

Respondents were asked to provide feedback on overall mask performance. Results from the respondents for each question are discussed below.

Summary of Results

Overall feedback from clinical users was positive, with the Eakin Healthcare V2 NIV face mask performing well across the majority of evaluation criteria.

See a summary of all results displayed in Figure 2. Note in Question 3 and 4 :1-2 star rating has been recorded as a negative response, 3 star rating has been recorded as a neutral response and 4-5 star rating has been recorded as a positive response.

Q1 – Training and Fitting Support

All respondents (100%, n= 19) confirmed that they had been shown how to size and fit the mask correctly by an Eakin Healthcare representative. This indicates that users were adequately supported during the evaluation process.

Q2 – Comparison with Current Product of Choice

The mask was generally rated favourably when compared with users' existing products. The strongest results were seen for Mask Seal, where 74% (n= 14) of respondents considered the product better than their current option. Positive ratings were also reported for Ease of Fitting (58% better, n= 11) and Patient Comfort (58% better, n= 11). For Patient Response to Therapy, most respondents rated the mask as either better (42%, n= 8) or equivalent (53%, n= 10) to their current product, with no negative responses recorded.

No response was selected by the user in Hospital B however they did comment that ease of fitting was "unusually different" and that there were "mixed reactions" for the patient response to therapy.

Q3 – Staff Satisfaction with Ease of Use and Effectiveness

Staff satisfaction ratings were predominantly positive, with 37% (n= 7) of respondents awarding four stars and with 21% (n= 4) of respondents awarding five stars. Only a small number of low ratings (n=8, awarding 1-3 stars) were recorded, indicating generally favourable perceptions of the mask's usability and effectiveness.

Q4 – Overall Performance of the NIV Mask

Overall performance was rated highly, with 26% (n= 5) of respondents awarding four stars and with 37% (n= 7) of respondents awarding five stars. Five-star ratings were the most common response, (with 37%, n= 7) demonstrating strong confidence in the product's overall clinical performance.

Q5 – Satisfaction with Available Sizes

The available size range was well received, with 89% (n= 17) of respondents indicating satisfaction with the sizes provided. This suggests that the product range is suitable for most patient populations encountered during the evaluation.

Q6 – Recommendation for Continued Hospital Use

Approximately 79% (n= 15) of evaluators stated that they would recommend continued use of the Eakin Healthcare V2 NIV face mask within their hospital.

One user from Hospital K stated that "A pressure sore developed due to continuous NIV therapy. This is what happens with our standard mask too." However, they still would recommend continued use of our product.

Some respondents (n= 2) from Hospital k did not select an answer but one of them mentioned that it was “More expensive than anaesthesia masks. Wouldn't recommend due to the price. Would recommend for patients who require a bronchoscopy, if this is obvious at the beginning of the therapy.”

However, the high recommendation rate reflects overall satisfaction with product performance, fit, comfort, and clinical effectiveness.

Key Themes from User Comments

Qualitative feedback highlighted secure sealing and effective performance when the correct size was selected.

Users (n= 2) also reported straightforward handling and compatibility with patients using feeding or nasal tubes. One of these users from Hospital l commented that “This is the best mask for patients with beards or NG tubes.”

One comment (n=1) suggested that sizing templates could be improved, as incorrect sizing was associated with reduced comfort and fit.

One user also highlighted that the clip mechanism was not suitable for neurological patients, and they would recommend the use of magnetic clips.

Overall, the comments support the quantitative findings and indicate a positive user experience when appropriate sizing is achieved.

Conclusion

Primary Objectives

- Identify that sufficient training was conducted on how to properly size and fit the mask by an Eakin Healthcare representative.
- Compare the fit of the V2 NIV face mask on the patient, the sealing performance of the ventilation mask,

patient comfort and patient response to the therapy, with the product they are currently using.

- Evaluate ease of use and overall effectiveness of the ventilation mask.
- Evaluate overall performance of the V2 NIV mask.
- Identify if they are satisfied with the range of sizes available for the ventilation mask.
- Identify if staff would recommend continued use of the V2 NIV face mask.
- Gather general product feedback.

The evaluation of the Eakin Healthcare V2 NIV face mask across the selection of German hospitals successfully met the objectives of the study. Nineteen evaluation responses were received from clinicians across multiple hospital sites, providing a broad assessment of the mask's clinical performance, usability, and user satisfaction.

The first objective, to confirm that sufficient training was provided on mask sizing and fitting, was fully achieved, with 100% of respondents confirming that they had received appropriate instruction from an Eakin Healthcare representative. This ensured that the product was evaluated under appropriate conditions and that users were equipped to apply the mask correctly.

Compared with the NIV face masks currently used in the participating hospitals, the V2 NIV face mask demonstrated favourable performance across key clinical parameters. The strongest improvements were observed in mask sealing performance, with 74% of respondents rating the seal as better than their existing product. Positive outcomes were also reported for ease of fitting, patient comfort, and patient response to therapy, indicating that the mask effectively addresses several of the challenges previously identified within participating hospitals, including

air leakage and patient discomfort associated with prolonged NIV therapy.

The objectives relating to ease of use, effectiveness, and overall product performance were also achieved. Most respondents rated the mask highly for usability and effectiveness, while approximately two-thirds awarded four- or five-star ratings for overall performance. These findings demonstrate strong confidence in the product's clinical suitability and day-to-day application in ICU settings.

Satisfaction with the available size range was high, with nearly 90% of respondents indicating that the available sizes adequately met patient needs. While some feedback suggested that sizing templates could be further refined to support optimal size selection, users consistently reported secure sealing and effective performance when the correct size was chosen.

Importantly, 79% of evaluators stated that they would recommend continued use of the V2 NIV face mask within their hospital. This high recommendation rate reflects the positive experiences reported across all key evaluation criteria, including fit, seal, comfort, usability, and overall clinical effectiveness.

In conclusion, the results demonstrate that the Eakin Healthcare V2 NIV face mask is a well-performing and clinically effective NIV interface for ICU applications. The product was positively received by healthcare professionals across the participating German hospitals and has shown the potential to serve as a suitable alternative to existing NIV mask solutions. Continued adoption of the V2 NIV face mask is supported by both the quantitative evaluation data and the qualitative feedback gathered during the study.