



# Sleep Quality in CPAP/APAP Therapy

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Despite good compliance and unremarkable AHI in PAP therapy, patients may still suffer from non-restorative sleep with related symptoms. Therefore in the future, devices in the prisma series will offer another criterion for the assessment of therapy success: a deep sleep indicator.

## The key to success with PAP therapy

**Compliance:** With good compliance, CPAP therapy can reduce symptoms, prevent secondary cardiovascular disease and prolong life. Diverse studies have proven the effectiveness of CPAP therapy in connection with compliance or with compliance of more than four hours (Palm, Midgren, Theorell-Haglöw, Janson, & Lindberg, 2017), (Antic et al., 2011), (Billings M.E. et al., 2014), (Bouloukaki I. et al., 2017), (Kasai T., Narui K. et al., 2008), (Kingshott R.N. et al., 2000), (Peker Y. et al., 2016), (Abuzaid A.S. et al., 2017), (Weaver et al., 2007).

**AHI/Leakage:** A second decisive factor is effectiveness. Only therapeutically effective CPAP – and not sub-therapeutic treatment – improves symptoms and secondary diseases (Siccoli M.M. et al., 2008), (Mulgrew et al., 2010), (Habukawa M. et al., 2005), (Bakker et al., 2014). Leaks at mask and mouth, which are unpleasant for the patient, impair pressure stability, event recognition and APAP regulation of the PAP devices.

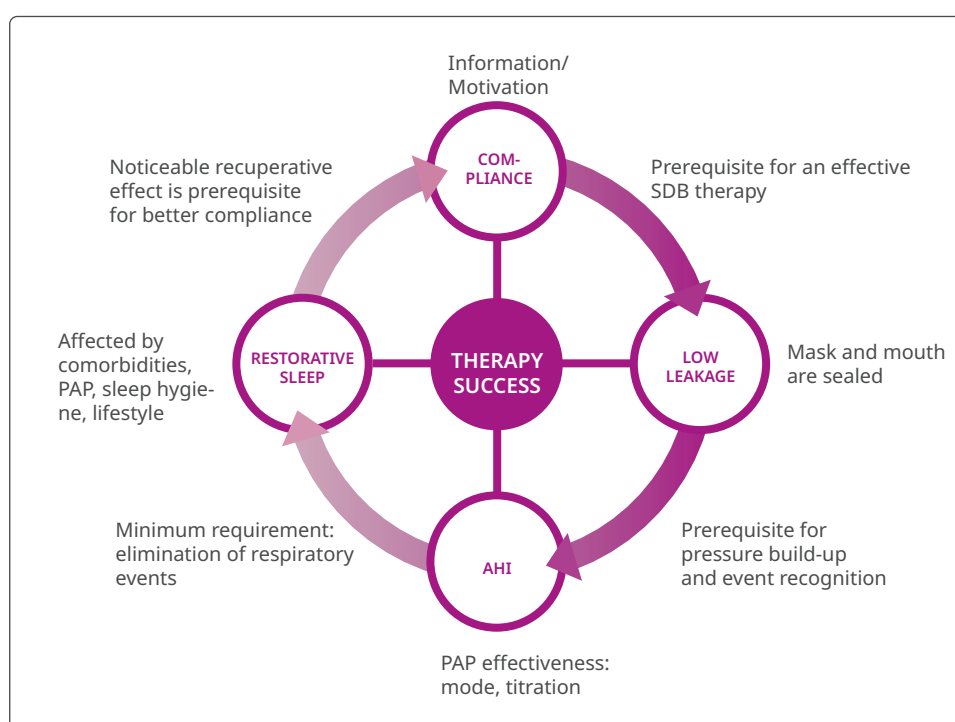


Figure 1: The PAP therapy chain of effects with patient's therapy success at the center.

**Restorative Sleep:** Even with good compliance and effectively reduced AHI, increased daytime sleepiness remains a problem for up to 40 percent of patients (Antic et al., 2011). AHI is a poor predictor of improvement in daytime function (Kingshott R.N. et al., 2000), (Weaver, Woodson, & Steward, 2005), (Kirkham, Heckbert, & Weaver, 2015). Causes other than a persistent respiratory disorder may be responsible for continued poor sleep.

An increased risk of reduced compliance exists for patients with insomnia because the patients consider the respiratory mask and the therapy device to be particularly bothersome. Insomnia persists in up to 30 percent of patients treated with PAP (Björnsdóttir E. et al., 2013), (Philip et al., 2017).

Compared to AHI, hypnogram-based parameters with and without PAP therapy show that the amount of deep sleep has a higher correlation with an improvement in symptoms (McArdle N. & Douglas N.J., 2001), (Walsh et al., 2008), (Kasai T. et al., 2008).

Even the extent of a fall in blood pressure in CPAP treatment correlates more strongly with improvements in the sleepiness scale than with improvements in AHI/ODI resulting from therapy (Robinson G.V., Langford B.A., Smith D.M., & Stradling J.R., 2008).

When symptoms improve, the patient is motivated to adhere to therapy. When compliance improves, therapy succeeds and thus the chain of events continues in a self-reinforcing feedback loop. Restorative Sleep is the true goal of PAP therapy.

## prisma RECOVER: Estimation of deep sleep from breathing pattern

The innovative prisma RECOVER algorithm continuously analyzes the patient's breathing pattern during PAP therapy. Respiration during deep sleep is more stable than in all other sleep or wake stages (see Figure 2).



Figure 2: Stable breathing in deep sleep stage as compared to variable breathing in REM sleep; above: airflow [l/min]; below: relative minute volume [%]

prisma RECOVER determines the current breathing variability from the fluctuations in respiratory minute volume, which are based on the deviation of rMV from 100 percent. When the variability is lower than the threshold optimized across several patients, stable breathing indicates deep sleep; the respective time period is then added to the estimated length of the deep sleep stage.

It can thus be assessed whether the patient has slept soundly and long enough. This means of assessment requires no additional sensors or extra effort. Stable NREM sleep combined with a low AHI throughout the night can indicate sufficient undisturbed REM sleep.

In summary, in devices of the prisma series for the first time therapy success can be evaluated with regard to sleep quality in prisma JOURNAL, prismaTS or in telemonitoring with prisma CLOUD.

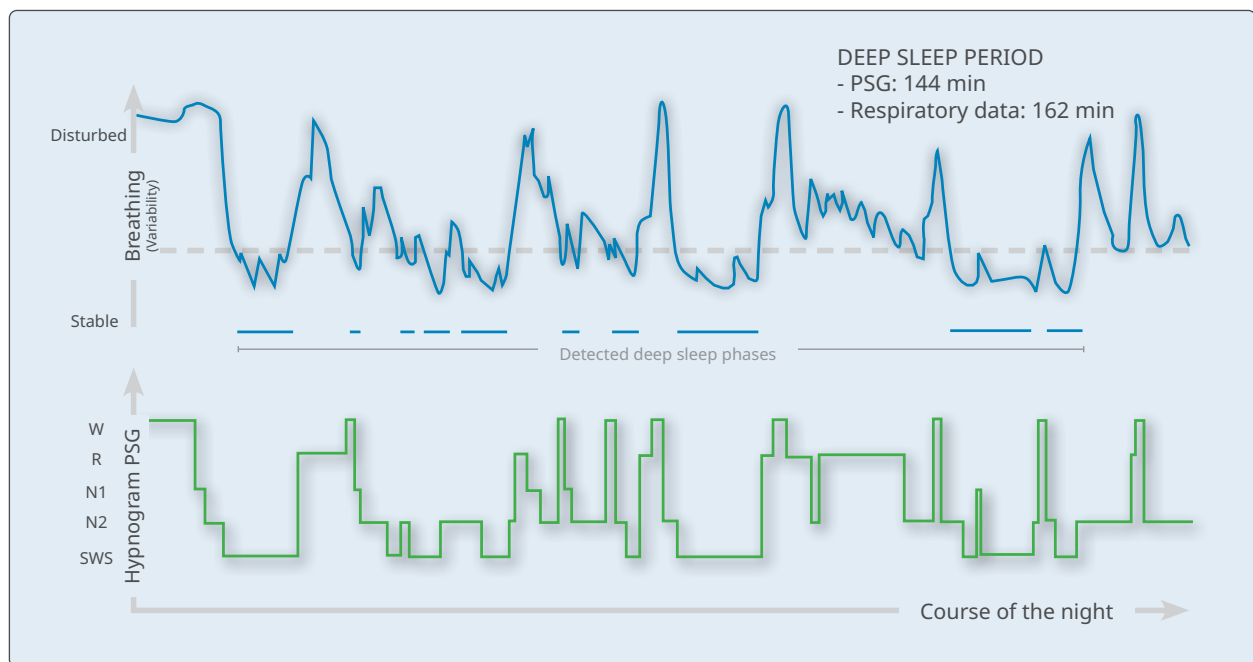


Figure 3: Example of deep sleep recognition in a patient during the first night of APAP therapy

## Internal validation data compared to PSG recording

A retrospective comparison (re-simulation of respiratory signals with prisma RECOVER) with n=41 patients in APAP therapy yielded a correlation of  $r = 0.649$ ,  $p < 0.0001$ .

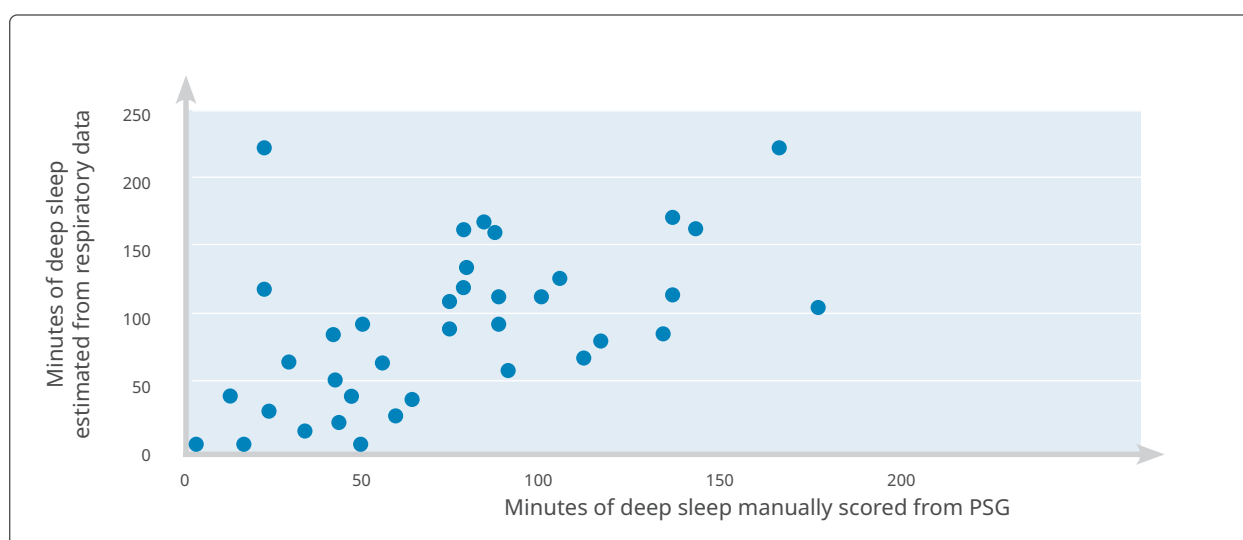


Figure 4: Comparison of length of deep sleep, determined from PSG and respiratory data

In an assessment of agreement among human scorers using the EEG, the intraclass correlation for time spent in deep sleep was 0.628 (R&K) and 0.698 (AASM) (Danker-Hopfe et al., 2009). The results underscore the performance of prisma RECOVER. Because different measurement methods and even different scorers using identical measurement methods can deviate in the assessment of deep sleep duration, patients should always be asked about their subjectively perceived symptoms in a suspected case and as part of routine monitoring.

### Limitations:

- Periods of sleep without PAP use cannot be taken into account for deep sleep duration. They do not correspond per se to the therapy goal, and it must be assumed that such periods have a limited restorative effect for patients affected by Sleep-Disordered Breathing (SDB).
- In the presence of increased undesired leaks, the airflow signals measured by the PAP device are likely to be faulty. Consequently, the time spent in deep sleep is underestimated. Before AHI and deep sleep are evaluated, problems with mask and mouth leaks should be resolved.

## Mean values for length of deep sleep periods

The literature (Dorffner, Vittr, & Anderer, 2015) provides the following age-dependent mean values for deep sleep periods of healthy subjects with application of AASM 2012 rules.

Age	Women	Men
40 years	99 minutes	84 minutes
60 years	94 minutes	69 minutes
80 years	90 minutes	55 minutes

## Possible causes of non-restorative sleep in PAP therapy

**Sub-optimum PAP therapy:** In isolated cases moderately high AHIs or leakage values can disturb sleep; in such cases other events such as snoring, RERAs (Respiratory Effort-Related Arousals) and flow limitations should be investigated. In the case of increased central AHI (e.g., TECSA or treatment-emergent Central Sleep Apnea), the AcSV mode (prismaCR) should be used.

**Impairment caused by PAP therapy itself:** Patients may be bothered by dry mouth, mask problems or the therapy pressure (Kasai T. et al., 2008). That applies especially to patients with anatomic narrowing of the upper airways (Park P. et al., 2017). If necessary, a change of mask should be made or a humidifier – additionally with heated tube system – should be used (Palm et al., 2017).

The devices in the prisma series are distinguished by their very low operating sound and proven comfort functions. Furthermore, the pressure reaction in APAP mode is therapeutically effective without unnecessarily high pressure increases, according to an independent bench test (Isetta et al., 2016).

**Comorbidities:** Diverse disorders such as insomnia (Björnsdóttir E. et al., 2013), (Philip et al., 2017), PLM (Mwenge G.B., Rougui I., & Rodenstein D., 2017), diabetes, allergies, anemia, depression (Fernandez-Mendoza et al., 2015) can impair restorative sleep. They must be treated separately from respiratory disorders in order to improve sleep.

**External factors:** Sleep hygiene, stress, noise, diet, alcohol consumption, not enough sleeping time can likewise impair sleep's restorative power. These factors can be identified in a conversation with the patient and action taken to improve them.

## Conclusion

Assessing and optimizing the time spent in deep sleep in combination with compliance, AHI and leakage can significantly improve therapeutic success under PAP therapy. Such results conform to the objective of sleep medicine, which is not only the elimination of respiratory events, but the improvement in the restorative effect of sleep.

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