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Feasibility of Type 3 Polygraphy for Evaluating Leak Determinants in CPAP-Treated OSA Patients A Step Toward Personalized Leak Management

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4 **Feasibility of type 3 polygraphy for evaluating leak** 5 **determinants in CPAP-treated OSA patients: a step** 6 **towards personalized leak management**

7

8 **Running head:** type 3 polygraphy for evaluating leak determinants in CPAP-treated
9 OSA patients

10

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37

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39 ML and JCB are employees of “AGIR à dom.”, a non-profit home care provider. JCB has received
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48

49

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51 **Abbreviations list**

52 AHI Apnea Hypopnea Index

53 BMI Body Mass Index

54 CPAP Continuous Positive Airway Pressure

55 ESS Epworth Sleepiness Scale

56 IQR Inter Quartile Range

57 NC Non-calculable

58 OR Odds Ratio

59 OSA Obstructive Sleep Apnea

60 REM Sleep Rapid Eye Movement Sleep

61 SD Standard Deviation

62 SpO2 Peripheral capillary oxygen saturation

63

64 **Abstract**

65

66 **Background:** Unintentional leaks (ULs) are frequent adverse effects in CPAP-treated
67 patients. We previously published a novel methodology for analyzing the determinants of UL
68 using polysomnography. We now propose a simplified recording system using a type-3
69 polygraphic device (Somnolter®).

70 **Objectives:** 1) To describe individual UL determinants provided by the Somnolter® software
71 in automatic-CPAP-treated OSA patients; 2) To subsequently describe the clinical consensus
72 of 4 physicians on how to manage each individual UL situation.

73 **Methods:** Somnolter® recordings performed under nasal automatic-CPAP were automatically
74 analyzed with APIOS software. For each polygraphic recording, APIOS provided the odds
75 ratio and the confidence intervals for potential determinants of UL: mouth opening, CPAP
76 pressure, body position and mandibular oscillation. Based on these results, each of four
77 physicians was asked to choose one of four strategies: (i) increase/decrease therapeutic
78 pressure; (ii) change nasal mask for oro-nasal mask/chinstrap; (iii) favor a non-supine/supine
79 position; (iv) no action for individual leak management. Subsequently, a meeting was held to
80 determine a consensus choice for each individual case.

81 **Results:** 78 consecutive patients underwent home-polygraphy with Somnolter®. Fifty
82 recordings were analyzed (16 females; 65[57; 75]years; BMI=31.1[27.4; 35.3]kg/m²).
83 Individual diagnosis of UL was routinely feasible. The determinants of UL were
84 heterogeneous in the population and diagnosis of UL was not feasible in 10 patients. Based
85 on the results from this analysis, we established consensus leak management strategies at the
86 individual level. The average Cohen κ coefficient for the 4 raters was 0.58. Pressure
87 modification was proposed in 36% of patients, no action in 24%, installation of a facial
88 mask/chinstrap in 22% and positional treatment in 18%.

89 **Interpretation:** the use of type-3 polygraphy for characterizing leak determinants in patients
90 treated with nasal automatic-CPAP is feasible in routine practice. Leak determinants are
91 patient-specific. Inter-rater concordance for determining individual leak management
92 strategies demonstrated a “fair” level of agreement.

93

94 Clinical trial registration: NCT03381508

95 Key-words: sleep apnea; continuous positive airway pressure; CPAP; unintentional leak;
96 mask; leakage; home polygraphy.

97 Continuous Positive Airway Pressure (CPAP) is the first-line treatment for
98 moderate to severe Obstructive Sleep Apnea (OSA)^{1,2}. Although adherence to CPAP
99 is crucial for improving symptoms³, more than 50% of patients discontinue or are
100 poorly adherent over the long term^{4,5}. The causes of CPAP discontinuation are
101 multifactorial^{6,7}, with unintentional leakage from the mouth or around the mask being
102 one of the most common side effects of CPAP-therapy contributing to non-
103 adherence^{8,9}. However, the explanatory factors behind unintentional leaks are poorly
104 understood, and as a consequence, their management poorly established¹⁰.

105 In daily practice, when a patient is complaining of unintentional leakage,
106 caregivers adjust the mask, frequently shift from a nasal to an oro-nasal mask, or
107 install a chinstrap. Nevertheless, these strategies are not always effective in
108 reducing leakage or improving patient complaints¹¹, and the identification of the true
109 determinants of leakage remains elusive¹². The potential mechanisms triggering leak
110 emergence are not addressed by the software embedded by manufacturers in CPAP
111 devices. Furthermore, the terminology used to report leaks varies across CPAP
112 brands and there are no clear thresholds defining when it would be appropriate to
113 implement a leak correction process¹³.

114 In a recent study, we proposed a novel methodology for characterizing and
115 analyzing the overnight determinants of unintentional leakage using
116 polysomnographic recordings in OSA patients treated with automatic CPAP (i.e. the
117 OSA-auto-CPAP population)¹². We demonstrated that REM sleep, mouth opening,
118 sleep position and pressure level were determinants of leakage. However, due the
119 size of the problem and the inaccessibility, resource use and costs associated with
120 polysomnography, we further proposed a simplified recording system using a type-3
121 polygraphic device (Somnolter®, Liège, Belgium).

122

123 **Our primary objective** was to describe the individual specific determinants of
124 unintentional leaks provided by the Somnolter® device software in an OSA-auto-
125 CPAP population using nasal masks in real life conditions. **The secondary objective**
126 **was** to describe, based on this analysis, the clinical consensus of 4 physicians on
127 how to manage individual leak situations.

128

129 **Methods**

130 **First phase: data collection**

131 A retrospective analysis of polygraphic recordings carried-out in routine care
132 in 3 French centers (Boujan sur Libron Polyclinic, Montpellier and Grenoble
133 University Hospitals, France) was performed. This study was approved by a local
134 institutional review board (2017_CLER-MTP_12-03) and was registered on
135 <https://clinicaltrials.gov> (NCT03381508). All participants were informed about the
136 research objectives and were given the opportunity to oppose the use of their
137 personal data as required per French law.

138 Between June 1, 2017 and December 31, 2017, consecutive adult patients
139 diagnosed with moderate to severe OSA (apnea-hypopnea index [AHI] > 15/h) who
140 had a type III polygraphy (with Somnolter®) for control of auto-CPAP efficacy were
141 included. All recordings that presented the selection criteria cited above,
142 independently of mask type (nasal, nasal pillows and oro-nasal masks), were initially
143 selected. In order to avoid introducing a confounding factor by taking into account
144 oronasal and nasal pillows, which are second-line interfaces, only recordings from
145 patients using nasal masks were finally analyzed.

146 Polygraphy was performed with the Somnolter® (Fig 1) equipped with:

- 147 • A midsagittal mandibular magnetic movement sensor to measure the
148 distance in millimeters between two parallel coupled resonant circuits
149 placed on the forehead and the chin¹⁴.
- 150 • A pneumotachograph measuring the patient's airflow, CPAP level, and
151 leakage.
- 152 • A digital oximeter that displayed the pulse waveform (Nonin, Nonin
153 Medical) and measured the arterial oxygen saturation.
- 154 • A positional sensor that recorded body position during sleep.

155 **(See online supplement, paragraph I for further details)**

156 Medical history, anthropometric data, the Epworth Sleepiness Score at the
157 time of the polygraphy, smoking status, the use of a chinstrap, the use of a heated
158 tube/humidifier, the type and model of the mask, and the initial AHI were collected
159 from patient medical charts.

160

161 **Second phase: detailed analysis of polygraphic recordings**

162 Polygraphic recordings were analyzed with APIOS software version 2.0. This
163 version of APIOS deploys the automatic analysis of the determinants of unintentional
164 leaks previously developed by our team¹²: Signals from the polygraphic recording
165 are automatically computed as mean values over non-overlapping 10-s intervals
166 (mouth opening and CPAP pressure). Categorical data (sleep position), as well as
167 dichotomous data (mandibular oscillation (≤ 0.3 vs > 0.3 , mm)), are also computed for
168 intervals of 10 s. Then, each variable is analyzed for every consecutive 10-s interval.
169 Univariate conditional regression models are used to estimate the risk of leakage
170 during a "T-interval" using the above-mentioned variables predefined from the
171 previous interval ("T-1"). Since there are no reports of a clinically significant threshold

172 of unintentional leakage in the literature, the presence of unintentional leakage in an
173 interval can be classified in a dichotomous manner regarding a chosen threshold “X”
174 in L/min (yes or no: \geq “X” L/min).

175 For each polygraphic recording analyzed with APIOS, the software provided
176 the odds ratio and the confidence intervals of the following potential determinants of
177 unintentional leaks:

- 178 • Mouth opening (\leq median vs $>$ median of the night)
- 179 • CPAP pressure (\leq median vs $>$ median of the night)
- 180 • Body position (other versus supine)
- 181 • Mandibular oscillation (\leq 0.3 vs $>$ 0.3, mm)

182 *(see online supplement, paragraph II for further details)*

183

184 **Leakage calculation**

185 The pressure/flow curve for intentional leaks corresponding to each mask
186 model used was embedded into the APIOS software and used for the calculation of
187 the unintentional leaks *(see online supplement, paragraph I for further details)*.

188 Since there is no clear threshold of unintentional leaks defining when it would be
189 appropriate to implement correcting interventions¹³, we ran the automatic analysis at
190 3 arbitrary unintentional leak thresholds: 5 l/min, 10 l/min and 20 l/min.

191

192 **Third phase: clinical consensus**

193 Based on the results provided by the automatic analysis of the determinants
194 of unintentional leaks provided by APIOS, each of four physicians (DJ, JPM, ML,
195 JCB) was asked to choose one of four strategies [(i) increase or decrease
196 therapeutic pressure; (ii) change nasal mask for oro-nasal mask or add a chinstrap;

197 (iii) favor a non-supine or supine position; (iv) no action] for individual leak
198 management in a blinded fashion. Although they are not completely interchangeable
199 in clinical practice, the switch towards an oro-nasal mask or the addition of a
200 chinstrap were two actions grouped together for simplicity's sake.

201 Subsequently, a meeting was held to discuss blinded results and then
202 determine a collective consensus choice from among the four strategies for each
203 individual case. **See figure 2 for methods overview.**

204

205 **Statistical analysis**

206 Data did not follow a Gaussian distribution and were summarized as medians
207 and interquartile ranges (IQR). Qualitative parameters (characteristics and type of
208 interface) were expressed as counts and percentages. All statistical analyses were
209 performed with SAS enterprise guide (V.7.1).

210 To achieve the first objective, patient-specific heatmaps were created and
211 reported the crude odds ratios (OR) and 95% confidence intervals (95%CI) for
212 potential leak determinants as provided by APIOS. To achieve the second objective,
213 the latter heatmaps were provided to the participating physicians who then
214 independently proposed one of the four above-listed leak management strategies.
215 Finally, kohen κ coefficients were used to measure inter-rater concordance for
216 clinical strategies and the average coefficient for all raters was calculated using the
217 Krippendorff's alpha coefficient.

218 **Sample size calculation:** considering the exploratory nature of this study that
219 use an original analysis, no previous data from which sample size could be
220 calculated were available. However, we aimed to include 50 patients who had
221 performed Somnolter® polygraphy while using nasal masks between June 1st and

222 December 31st 2017. Considering that about 75% of patients use a nasal mask in
223 routine care in France (sample size equivalent to previous studies comparing
224 different types of masks^{7,12}), we estimated that at least 75 consecutive patients
225 would need to be screened in order to analyze 50 patients treated with a nasal mask.
226

227 **Results**

228 Over a 6-month period, 78 consecutive adult patients underwent a home
229 polygraphy with Somnolter® under auto-CPAP. e-Figure 6 in the online supplement
230 depicts the study flow chart. Two recordings could not be used because of missing
231 data related to technical problems, and 26 polygraphies were carried out using an
232 oronasal mask. In consequence, a total of 50 home-polygraphy recordings were
233 finally analyzed.

234

235 *Patient characteristics and treatment parameters*

236 Patient characteristics are presented in Table 1. All patients were
237 parameterized with 4-14 cmH20 for auto-CPAP, as is typical of OSA-auto-CPAP
238 populations.

239

240 *Main objective, description of unintentional leak determinants*

241 Figure 3 represents the determinants of unintentional leaks according to three
242 different thresholds. Each cell represents the individual risk for (i) a given patient, for
243 a given determinant (ii) and at (iii) a given threshold of unintentional leaks.

244 As an example, patient #37 should be interpreted as follows: the mouth
245 opening above the overnight median increased the risk of leaks regardless of leak
246 thresholds; similarly, a non-supine position also increased the risk of leaks across all

247 thresholds. In contrast, a pressure above the overnight median pressure reduced the
248 risk of leaks across all leak threshold for this patient. For patient #1, a mandibular
249 oscillation superior to 0.3 mm (a surrogate marker of respiratory effort) increased the
250 risk of leaks regardless of thresholds.

251 In four subjects, there were inconsistencies in leak determinants across the
252 different leak thresholds in our analysis (subjects #2, #7, #24 and #47). For example,
253 in subject #2 a "non-supine position" was "protective" at 5 l/min, but increased the
254 risk of leakage at 10 l/min; in subject # 7, mouth opening was "protective" at 10 l /
255 min, but favored leaks at 20 l / min. Last, for 10 patients (examples # 23, 39, 40), the
256 automatic analysis was incalculable for reasons cited in the paragraph II of the online
257 supplement. Among those subjects, "no action" was chosen because there was no
258 evidence to support any clinical measure due to absence of data. Only 2 patients (#2
259 and 4) were classified as "no-action" despite calculable ORs following the consensus
260 because the analyses did not allow to choose for a particular strategy.

261 A sub analysis was also carried out using a 24 l/min threshold since the latter
262 is a commonly used indicator in clinical practice (e-figure 7).

263

264 *Secondary objective, clinical consensus for individualized leak management*

265 Table 2 reports the Cohen κ coefficients among clinicians. The Krippendorff'
266 alpha coefficient for all raters was 0.57. Figure 3 reports the final consensus of the 4
267 clinicians on individual clinical management. Pressure modification was proposed in
268 36% of patients, no action in 24% of patients, installation of a facial mask or a
269 chinstrap in 22% of patients and positional treatment in 18%.

270

271 **Discussion**

272 We have demonstrated that a routine inspection with a ventilatory type III pol-
273 ygraph providing an individual diagnosis of unintentional leaks is routinely feasible. In
274 this 50-patient, OSA-auto-CPAP population, the determinants of intentional leakage
275 were heterogeneous, which highlights the importance of individualized leak man-
276 agement. Finally, based on the results from this analysis, we were able to establish
277 consensus leak management strategies at the individual level.

278 To date, there are no data defining a tolerable unintentional leakage threshold
279 beyond which leakage correction measures should be undertaken^{13, 9}. For this rea-
280 son, we performed the leak determinant analyses with 3 arbitrarily chosen leakage
281 thresholds (5, 10 and 20 l/m). In addition, because leakage-related disturbances are
282 not correlated with the magnitude of leaks objectively reported by built-in software¹⁵,
283 it remains challenging to a priori determine an appropriate leak threshold for future
284 analyses. One benefit, therefore, of our automatic analysis is that a clinician can rap-
285 idly screen for the determining factors of leaks at different leakage thresholds in or-
286 der to identify the most relevant one.

287 Overall, the risk of unintentional leakage associated with a given determinant
288 was consistent across the different leakage thresholds for a given patient. Mouth
289 opening remained the principal leak determinant (27 patients). This is consistent with
290 our previous results in which mouth opening was independently associated with the
291 presence of unintentional leakage during sleep¹². However, the interpretation of leak
292 determinants for a given patient appeared to be more complex when the determi-
293 nants were inconsistent across different leak thresholds (as occurred for 4 patients in
294 our study).

295 Figure 3 spotlights the individual specificity of leak determinants, their great
296 diversity and illustrates the need for a tailored, patient-by-patient, clinical approach.

297 The difficulty resides in choosing the appropriate strategy for leak correction. For ex-
298 ample, increasing or decreasing the therapeutic pressure with an auto-CPAP would
299 allow the clinician to adjust the pressure window in order to modulate the median
300 pressure. We demonstrated that the inter-rater reliability when choosing a preferred
301 unintentional leak management strategy among experts was “moderate” with an av-
302 erage alpha coefficient of 0.57¹⁶. Further progress can perhaps be made in this do-
303 main.

304 Our work has two important limitations that must be taken into account: first,
305 the patients included in this retrospective study were consecutive subjects in whom
306 the severity of complaints related to leaks was not documented. One can argue that
307 the leak determinants found in a population with few, weak or no specific complaints
308 are different from those of a population actively complaining about leaks, and may
309 represent a selection bias. In addition, the fact that the study population did not spe-
310 cifically complain about leaks may also explain why the number of non-calculable
311 ORs was high in Fig 3. Secondly, the consensus strategies indicated by the partici-
312 pating physicians remain “theoretical” and we don’t know how much they helped pa-
313 tients with the current dataset (this will of course be addressed by future studies).
314 Agreement on clinical decision was not ideal. This could be due to the high number
315 of non-calculable variables and the lack of thorough clinical information to help guide
316 the decision. Furthermore, generalizability to the entire OSA-auto-CPAP population
317 is compromised because only patients who used a nasal mask were analysed. In-
318 deed, we previously demonstrated that mask type influences leak determinants,¹²
319 and were unwilling (for simplicity’s sake) to introduce this confounding factor by tak-
320 ing into account oronasal and nasal pillows, which are second-line interfaces.

321

322

323 **Conclusion**

324 The use of type-3 polygraphy for characterizing leak determinants in OSA
325 populations requiring automatic CPAP treatment with nasal masks is feasible in rou-
326 tine practice. Leak determinants are heterogeneous, patient specific, and can vary
327 with leak thresholds in certain cases. A first estimation of concordance among physi-
328 cians for determining individual leak management strategies demonstrated only a
329 “fair” level of agreement, indicating room for improvement in how leak determinants
330 are interpreted. A prospective interventional trial is needed in order to validate the
331 clinical relevance of these individual-based clinical strategies in the management of
332 unintentional leaks.

333

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337

338 **Author contributions:**

339 Conception: ML, JCB, DJ, NM, JPM.

340 Data Interpretation: ML, JLP, EML, DJ, JCB; NM, JPM.

341 Drafting the manuscript or revising it: ML, LL, JLP, EML, DJ, MCR, CMS, JCB.

342 Language editing: CMS.

343 All authors agree with manuscript results and conclusions.

344

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347

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350

351

352 **References**

- 353 1. Lévy P, Kohler M, McNicholas WT, et al. Obstructive sleep apnoea syndrome.
354 *Nat Rev Dis Primer.* 2015;1:15015. doi:10.1038/nrdp.2015.15
- 355 2. Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of
356 Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American
357 Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med JCSM*
358 *Off Publ Am Acad Sleep Med.* 2019;15(2):335-343. doi:10.5664/jcsm.7640
- 359 3. Weaver TE, Maislin G, Dinges DF, et al. Relationship between hours of CPAP
360 use and achieving normal levels of sleepiness and daily functioning. *Sleep.*
361 2007;30(6):711-719.
- 362 4. Weaver TE, Grunstein RR. Adherence to continuous positive airway pressure
363 therapy: the challenge to effective treatment. *Proc Am Thorac Soc.*
364 2008;5(2):173-178. doi:10.1513/pats.200708-119MG
- 365 5. McEvoy RD, Antic NA, Heeley E, et al. CPAP for Prevention of Cardiovascular
366 Events in Obstructive Sleep Apnea. *N Engl J Med.* 2016;375(10):919-931.
367 doi:10.1056/NEJMoa1606599
- 368 6. Gagnadoux F, Le Vaillant M, Goupil F, et al. Influence of marital status and
369 employment status on long-term adherence with continuous positive airway
370 pressure in sleep apnea patients. *PloS One.* 2011;6(8):e22503.
371 doi:10.1371/journal.pone.0022503
- 372 7. Borel JC, Tamisier R, Dias-Domingos S, et al. Type of mask may impact on
373 continuous positive airway pressure adherence in apneic patients. *PloS One.*
374 2013;8(5):e64382. doi:10.1371/journal.pone.0064382
- 375 8. Bachour A, Hurmerinta K, Maasilta P. Mouth closing device (chinstrap) reduces
376 mouth leak during nasal CPAP. *Sleep Med.* 2004;5(3):261-267.
377 doi:10.1016/j.sleep.2003.11.004
- 378 9. Valentin A, Subramanian S, Quan SF, Berry RB, Parthasarathy S. Air Leak is
379 Associated with Poor Adherence to Autopap Therapy. *SLEEP.* 2011;34(06):801-
380 806. doi:10.5665/sleep.1054
- 381 10. Lebret M, Martinot J-B, Arnol N, et al. Factors Contributing to Unintentional Leak
382 During CPAP Treatment: A Systematic Review. *Chest.* 2017;151(3):707-719.
383 doi:10.1016/j.chest.2016.11.049
- 384 11. Bachour A, Vitikainen P, Maasilta P. Rates of initial acceptance of PAP masks
385 and outcomes of mask switching. *Sleep Breath.* December 2015:1-6.
386 doi:10.1007/s11325-015-1292-x
- 387 12. Lebret M, Arnol N, Martinot J-B, et al. Determinants of Unintentional Leaks
388 During CPAP Treatment in OSA. *Chest.* 2018;153(4):834-842.
389 doi:10.1016/j.chest.2017.08.017
- 390 13. Schwab RJ, Badr SM, Epstein LJ, et al. An Official American Thoracic Society

391 Statement: Continuous Positive Airway Pressure Adherence Tracking Systems.
392 The Optimal Monitoring Strategies and Outcome Measures in Adults. *Am J*
393 *Respir Crit Care Med.* 2013;188(5):613-620. doi:10.1164/rccm.201307-1282ST

394 14. Senny F, Destin e J, Poirrier R. Midsagittal jaw movement analysis for the
395 scoring of sleep apneas and hypopneas. *IEEE Trans Biomed Eng.*
396 2008;55(1):87-95. doi:10.1109/TBME.2007.899351

397 15. Bachour A, Vitikainen P, Virkkula P, Maasilta P. CPAP interface: satisfaction and
398 side effects. *Sleep Breath Schlaf Atm.* 2013;17(2):667-672. doi:10.1007/s11325-
399 012-0740-0

400 16. Landis JR, Koch GG. The measurement of observer agreement for categorical
401 data. *Biometrics.* 1977;33(1):159-174.

402

403

TABLE 1. Population characteristics (n = 50)**Demographics**

Age (yrs)	65 [57; 75]
Gender, female n(%)	16 (32)
BMI (kg/m ²)	31.1 [27.4; 35.3]
AHI (nb events/h) at diagnosis	37.1 [31.0; 46.7]
Current smokers n(%)	5 (10,9) ^a
Epworth Sleepiness Scale (1-24)	11 [9; 15]

Comorbidities

Chronic cardiac insufficiency n(%)	15 (30.6) ^b
Chronic respiratory insufficiency n(%)	6 (12.2) ^b
High blood pressure n(%)	24 (50) ^c
Diabetes type 1 n(%)	0 (0) ^c
Diabetes type 2 n(%)	7 (14,6) ^c

Device

Heating humidifier n(%)	35 (70)
Heating circuit n(%)	2 (4)
Chinstrap n(%)	1 (2.2) ^a

Reported side effects

Nasal/mouth dryness, n(%)	5 (13.2) ^d
Nasal obstruction, n(%)	15 (36.6) ^e

AHI : Apnea-Hypopnea Index, score, BMI : Body Mass Index, CPAP: Continuous Positive Airway Pressure, ESS: Epworth Sleepiness Scale. Medians [quartile 1-quartile 3] are provided.

^aData from 4 patients were missing; ^bData from 1 patient was missing; ^cData from 2 patient were missing; ^dData from 12 patients were missing; ^edata from 9 patients were missing was missing.

	Physician 1	Physician 2	Physician 3	Physician 4
Physician 1	1			
Physician 2	0.70 [0.55-0.84]	1		
Physician 3	0.56 [0.41-0.71]	0.61 [0.46-0.76]	1	
Physician 4	0.54 [0.40-0.69]	0.47 [0.32-0.66]	0.58 [0.43-0.73]	1

408 Table 2 : Cohen K coefficients among all raters regarding choice of clinical leak management
409 strategy.
410

411 **Figure legends**

412

413 Figure 1: polygraphic assesment with the somnolter device

414 **A.** Patients' vital signs were recorded at home with the somnolter device while treated with
415 CPAP (pneumotachograph, mandibular movement sensor, oxymetry, thoracic belts and body
416 position sensor). **B.** Data of interest were obtained with the polygraphic device for each
417 patient (unintentional leak flow, mandibular lowering and oscillation, CPAP pressure, body
418 position, respiratory flow and SpO₂).

419

420 Figure 2: Analysis of the determining factors of unintentional leaks and consensus on
421 individual leak management (methods).

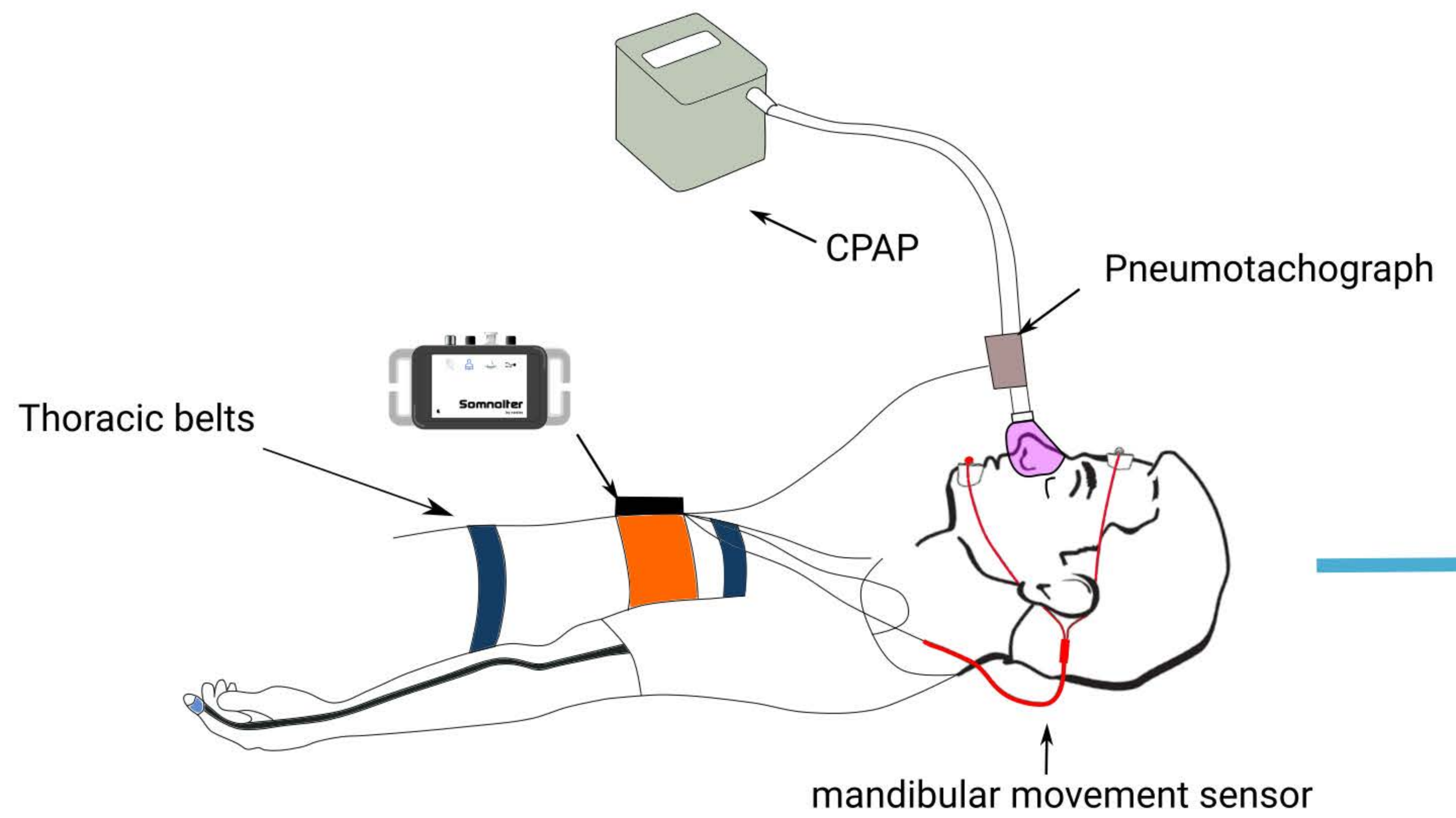
422 *the new version of APIOS embeds the automatic analysis of the determinants of leaks;
423 †example for a given patient

424

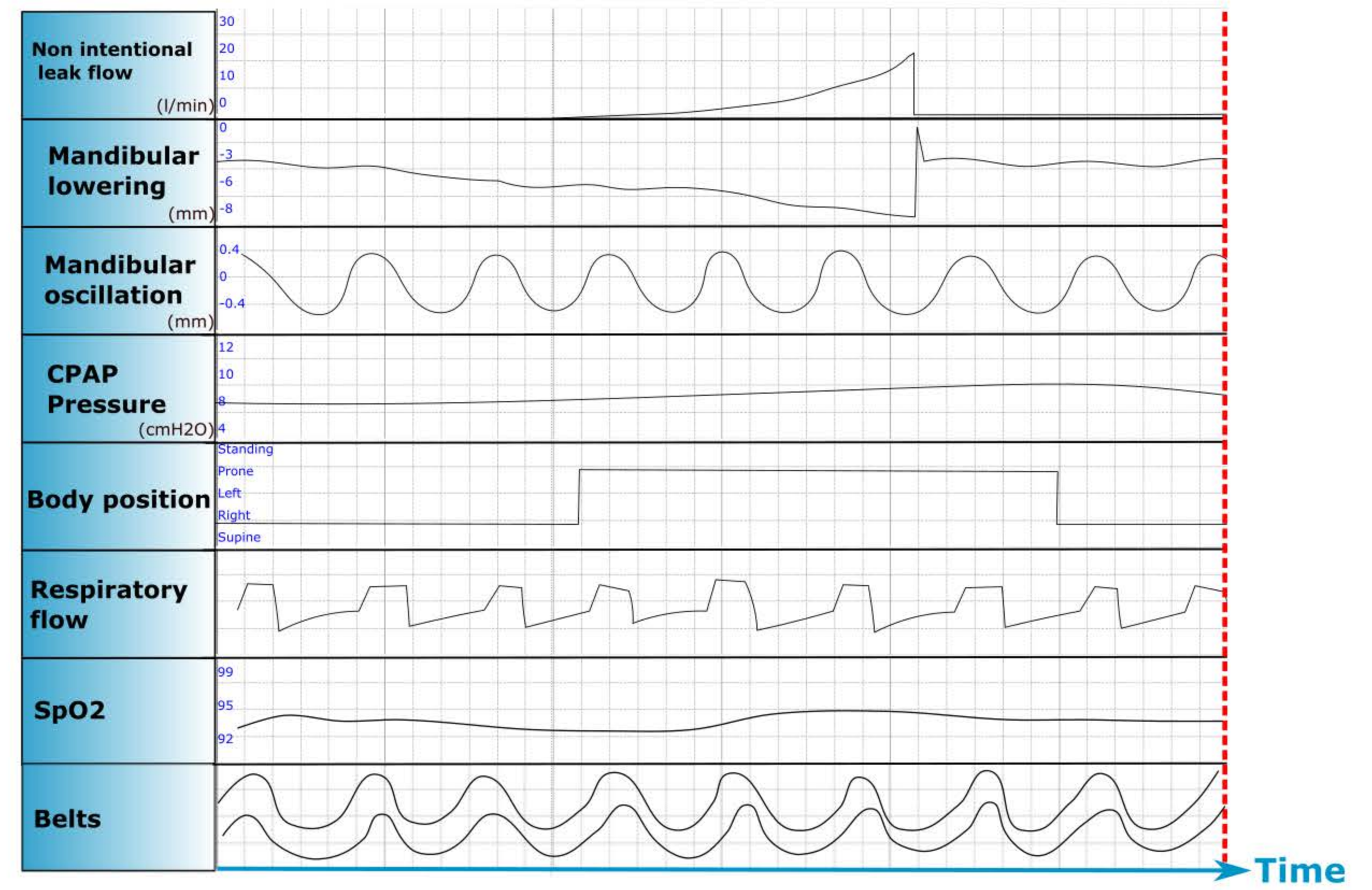
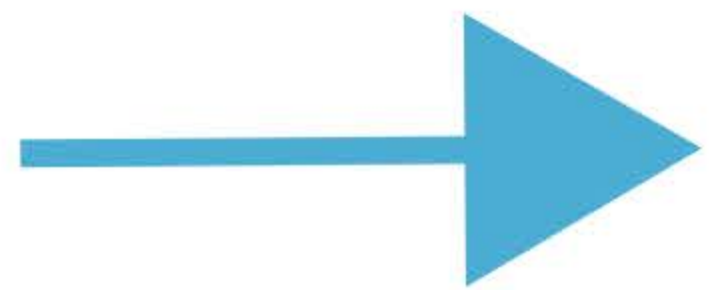
425 Figure 3: Heat Map displaying the individualized representation of the determinants of leaks.
426 This figure reports the risk (OR: Odds Ratio) associated with the 4 determinants of leaks for
427 every patient according to three different leak thresholds. Every cell represents the individual
428 risk for a given patient, for a given determinant at a given threshold of NI leaks using a color
429 code. Side effects reported by patients during CPAP treatment are displayed in the first two
430 columns.

431 Green represents an OR<1. The darker it is, the closer the OR is to 0. Conversely, red
432 represents an OR>1, the darker it is, the higher the OR and therefore the risk. White cells
433 represent an OR for which the confidence interval crosses 1 (non-significant).

434 Mouth opening > median overnight mouth opening; CPAP pressure > median overnight
435 pressure; mandibular oscillation > 0.3 mm. NC: non-calculable, there were specific
436 conditions for which the odds ratios were non-calculable (supplemental material).



A



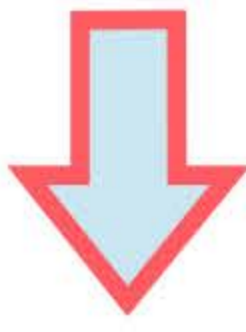
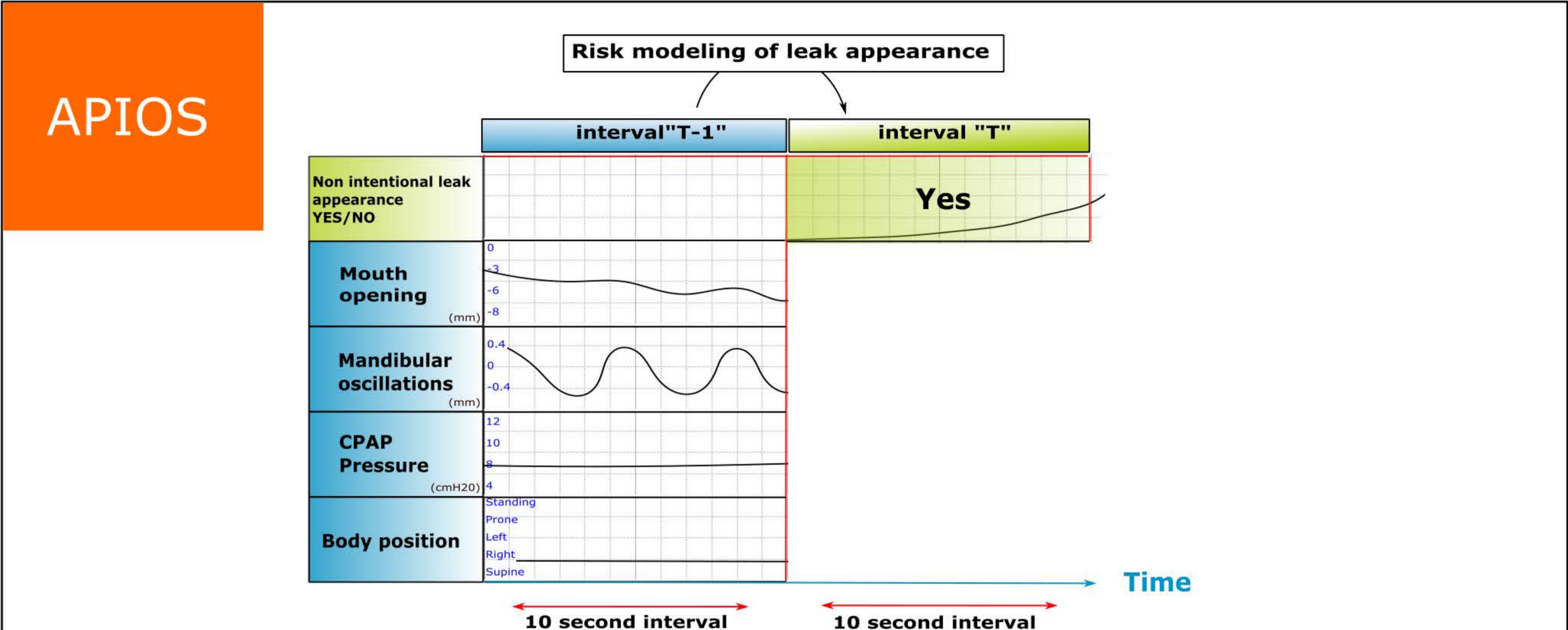
B

Time

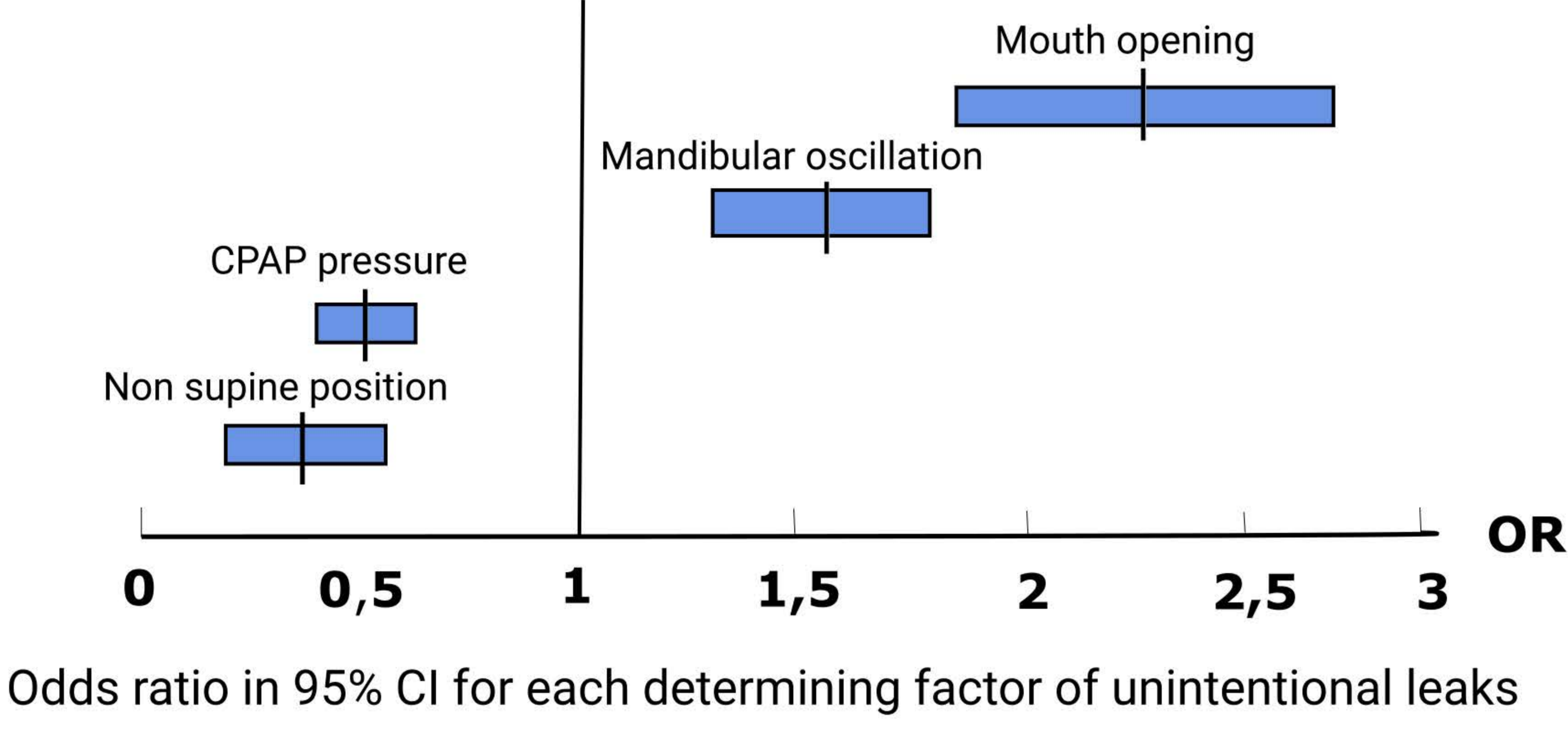
STEP 1 - data collection

Collection of polygraphic recordings carried-out in routine care

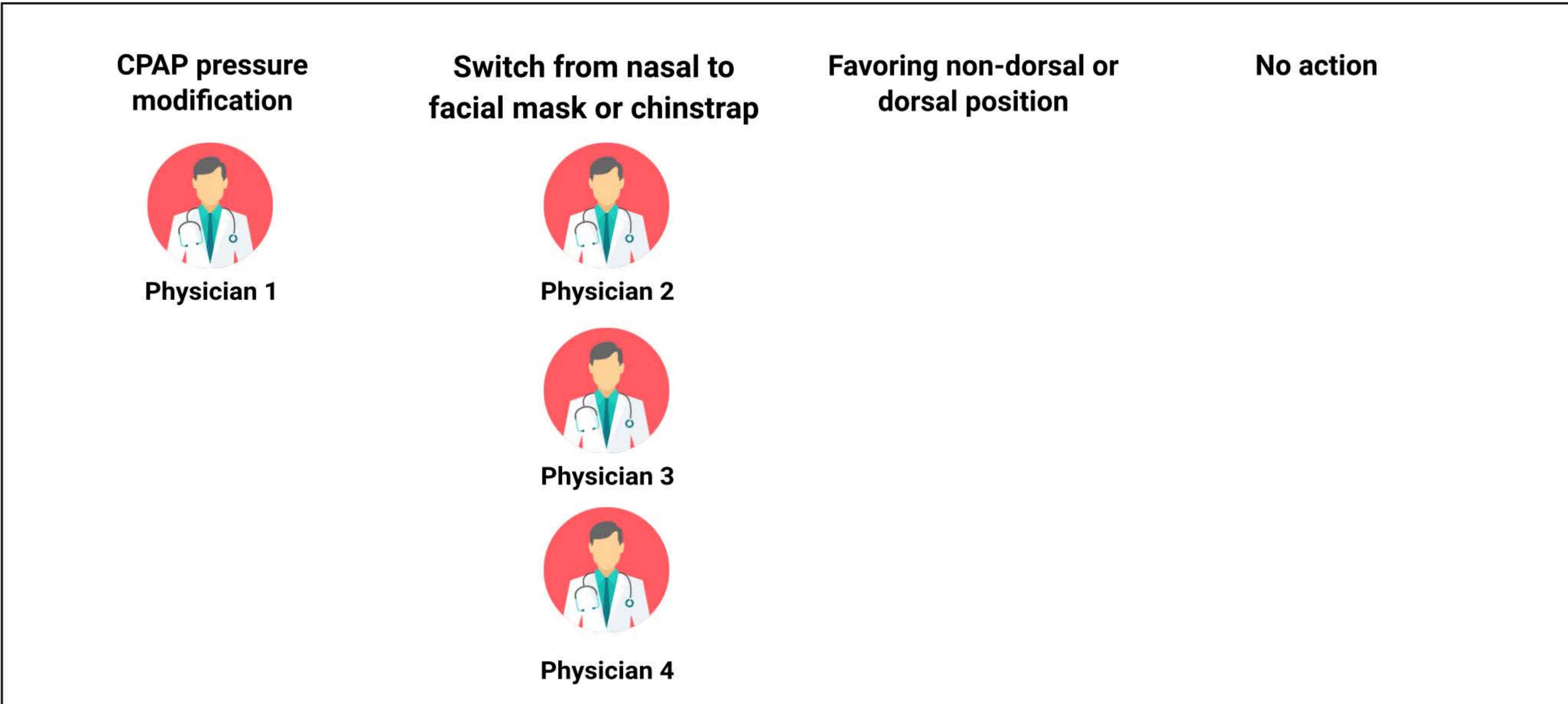
STEP 2 - re-analysis with the new version of APIOS*



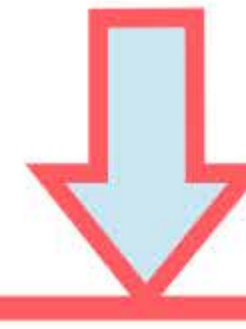
Output of the analysis for each patient



STEP 3: clinical consensus on individual leak management



Example of physicians' choices for a given patient



Switch from nasal to facial mask or chinstrap

Example of final clinical consensus

	Reported side effects		Mouth opening			CPAP pressure			Non-supine position			Mandibular oscillation			Consensus
			Leak thresholds			Leak thresholds			Leak thresholds			Leak thresholds			
	Nasal obstruction	Nasal dryness	5 l/min	10 l/min	20 l/min	5 l/min	10 l/min	20 l/min	5 l/min	10 l/min	20 l/min	5 l/min	10 l/min	20 l/min	
#1														Increase CPAP	
#2					NC		NC	NC			NC		NC	No action	
#3			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action	
#4				NC	NC		NC	NC	NC	NC	NC	NC	NC	No action	
#5					NC			NC			NC			Favor supine position	
#6			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action	
#7			NC			NC			NC			NC		Decrease CPAP	
#8	Missing data	Missing data			NC			NC					NC	Increase CPAP	
#9			NC	NC	NC			NC			NC		NC	Decrease CPAP	
#10			NC	NC		NC	NC		NC	NC		NC	NC	Increase CPAP	
#11			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action	
#12			NC	NC		NC	NC		NC	NC		NC	NC	Favor non-supine position	
#13			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action	
#14	Missing data			NC	NC			NC	NC	NC		NC	NC	Install facial mask or chinstrap	
#15				NC	NC	NC	NC	NC		NC	NC		NC	Install facial mask or chinstrap	
#16					NC			NC			NC			Install facial mask or chinstrap	
#17				NC	NC			NC	NC	NC		NC	NC	Install facial mask or chinstrap	
#18					NC			NC		NC	NC		NC	Increase CPAP	
#19				NC	NC			NC	NC	NC		NC	NC	Install facial mask or chinstrap	
#20					NC			NC			NC		NC	Favor supine position	
#21					NC			NC			NC		NC	Favor non-supine position	
#22			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action	
#23			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action	
#24					NC			NC			NC			Favor non-supine position	
#25									NC	NC	NC			Decrease CPAP	
#26					NC			NC			NC		NC	Favor non-supine position	
#27														Install facial mask or chinstrap	
#28														Increase CPAP	
#29					NC			NC	NC	NC			NC	Decrease CPAP	
#30					NC			NC			NC		NC	Install facial mask or chinstrap	
#31				NC	NC			NC	NC	NC		NC	NC	Favor non-supine position	
#32	Missing data	Missing data			NC			NC			NC		NC	Favor non-supine position	
#33			NC	NC		NC	NC	NC	NC	NC		NC		Increase CPAP	
#34					NC								NC	Decrease CPAP	
#35				NC	NC			NC	NC	NC		NC	NC	Increase CPAP	
#36				NC	NC			NC	NC	NC		NC	NC	Favor non-supine position	
#37											NC	NC	NC	Install facial mask or chinstrap	
#38				NC	NC			NC	NC	NC		NC	NC	Decrease CPAP	
#39			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action	
#40			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action	
#41		Missing data		NC	NC			NC	NC	NC	NC	NC	NC	Increase CPAP	
#42	Missing data	Missing data	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action	
#43		Missing data			NC			NC	NC	NC			NC	Increase CPAP	
#44	Missing data	Missing data									NC	NC	NC	Install facial mask or chinstrap	
#45		Missing data							NC	NC	NC			Increase CPAP	
#46	Missing data	Missing data	NC		NC	NC		NC	NC	NC	NC	NC	NC	Install facial mask or chinstrap	
#47	Missing data	Missing data			NC			NC		NC			NC	Increase CPAP	
#48	Missing data	Missing data	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action	
#49		Missing data		NC	NC			NC		NC	NC	NC	NC	Install facial mask or chinstrap	
#50	Missing data	Missing data			NC			NC	NC	NC	NC	NC	NC	Decrease CPAP	

