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# **German experience and conclusions from the National Consensus Conference**

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# Recommendations of the German BAT consensus group 2017



## Baroreceptor activation therapy for therapy-resistant hypertension: indications and patient selection.

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S. Parmentier<sup>15</sup> · S. Lüders<sup>16</sup> · B. K. Krämer<sup>17</sup> · S. Büttner<sup>18</sup> · F. Limbourg<sup>19</sup> ·  
J. Jordan<sup>20</sup> · O. Vonend<sup>21</sup> · H.-G. Predel<sup>22</sup> · H. Reuter<sup>6</sup>

# Topics of Consensus Conference

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- **Evidence**
  - ✓ Efficacy and safety
  - ✓ Acute effects and long-term response
- **Patient selection:**
  - ✓ Indications and contraindications
  - ✓ Structured evaluation of patients
- **Implantation procedure:**
  - ✓ Anatomical limitations
  - ✓ Anaesthesia
  - ✓ Electrode mapping
- **Programming and Follow up:**
  - ✓ Initiation and titration of BAT
  - ✓ Handling of side effects

# Evidence: The Rheos Pivotal Trial

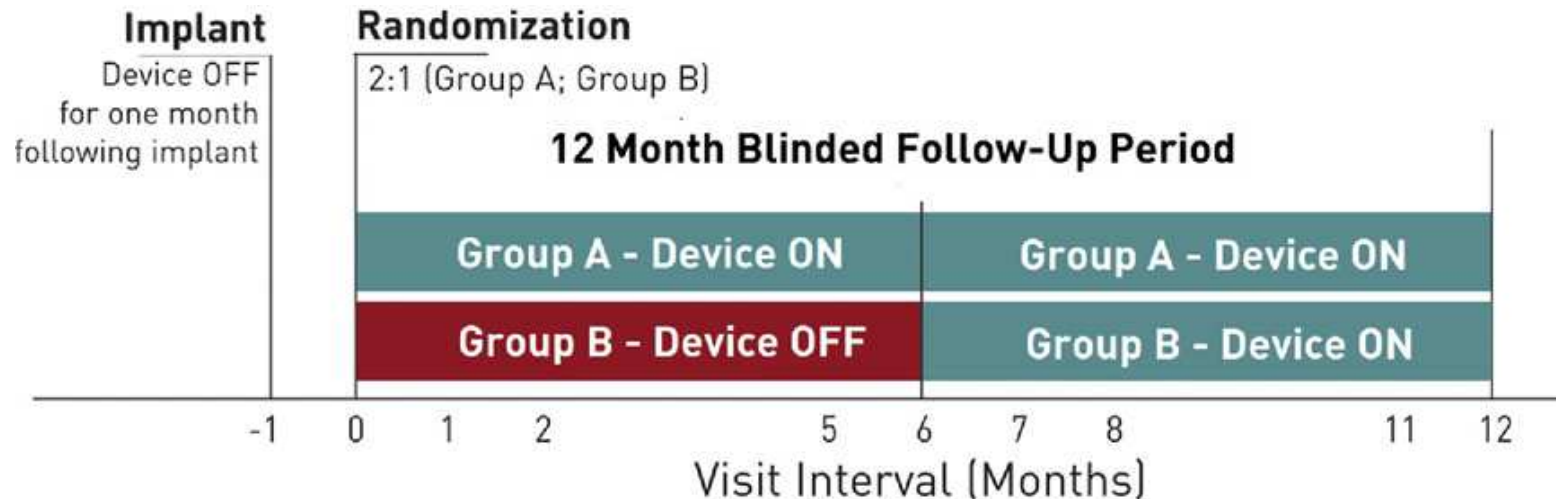


[J Am Coll Cardiol. 2011 Aug 9;58\(7\):765-73. doi: 10.1016/j.jacc.2011.06.008.](#)

**Baroreflex activation therapy lowers blood pressure in patients with resistant hypertension: results from the double-blind, randomized, placebo-controlled rheos pivotal trial.**

[Bisognano JD<sup>1</sup>](#), [Bakris G](#), [Nadim MK](#), [Sanchez L](#), [Kroon AA](#), [Schafer J](#), [de Leeuw PW](#), [Sica DA](#).

**265 Patients**



# Evidence: The Rheos Pivotal Trial

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## Efficacy and Safety

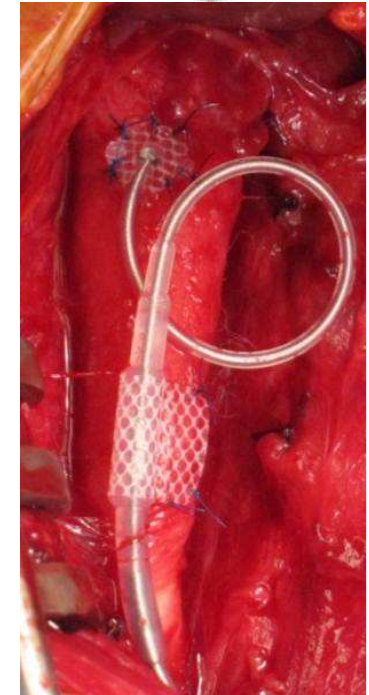
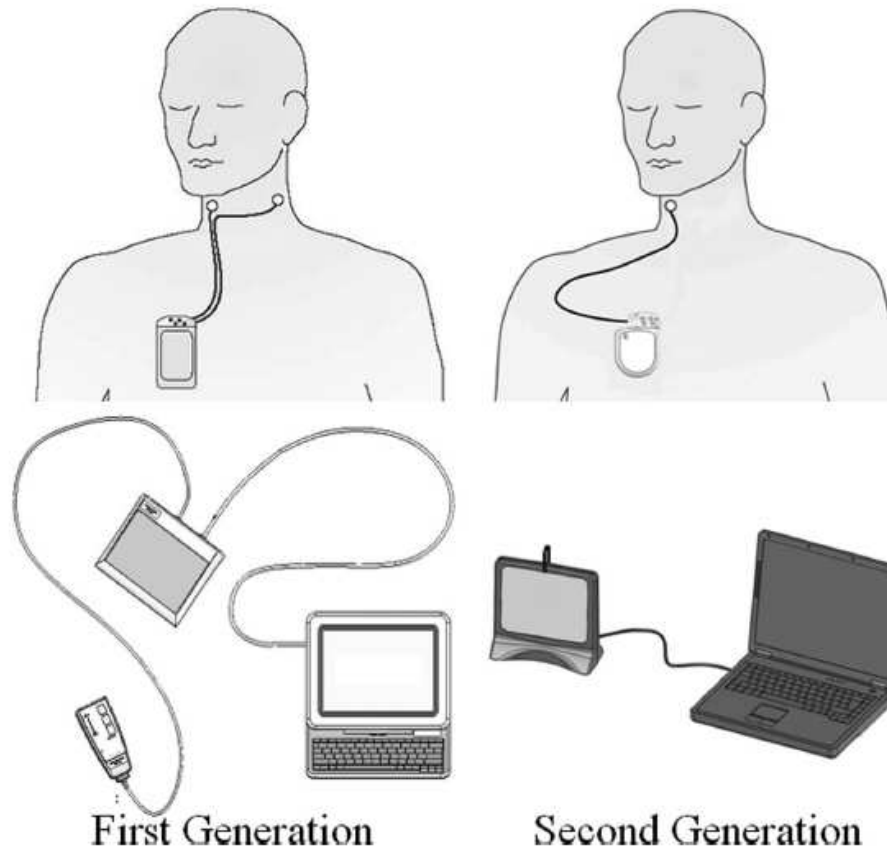
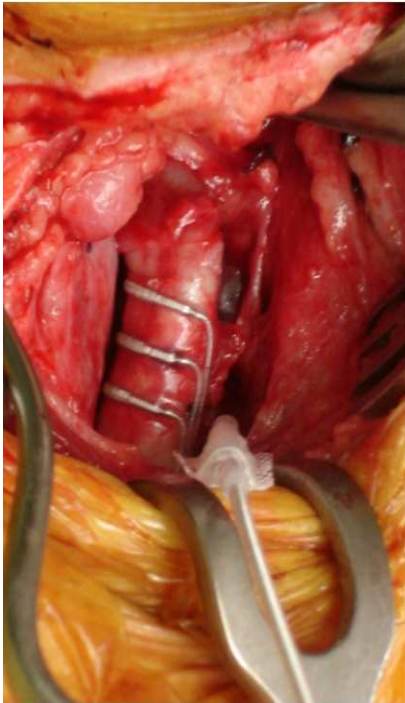
5 pre-specified co-primary endpoints

1. **Acute efficacy**

**non significant: responder rate 54% group A vs. 46% group B @ 6 months**

„The consensus group speculates that the unexpectedly strong BP reduction in the control group right after device implantation (before activation) may have negatively influenced the primary efficacy endpoint.“

# Is there evidence on the efficacy of the 2<sup>nd</sup> generation Neo™ system?



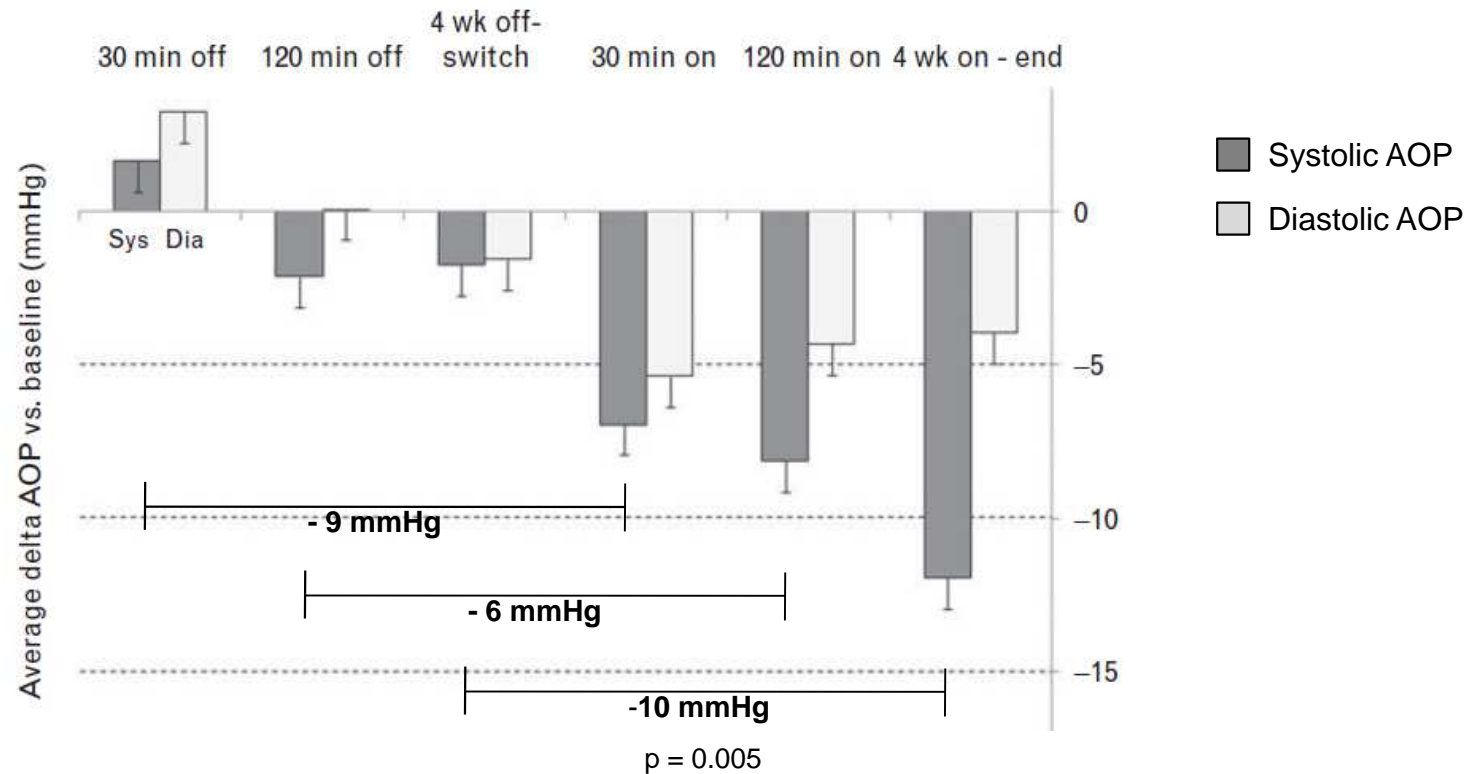
**Figure 1.** Schematic illustration of the first- (Rheos, left) and second-generation (Barostim *neo*) BAT systems. The second-generation system is smaller, less invasive, more efficient, and more easily programmable than the first. BAT, baroreflex activation therapy.

# Efficacy: the Barostim *neo* 2<sup>nd</sup> generation device



Blood pressure after blinded, randomized withdrawal, and resumption of baroreceptor-activating therapy

Joachim Beige<sup>a,\*</sup>, Theresa Jentzsch<sup>a,\*</sup>, Ralph Wendt<sup>a</sup>, Gert Hennig<sup>b</sup>, Michael Koziol<sup>c</sup>, and Manuel Wallbach<sup>c</sup>



AOP: automated office blood pressure

Beige J et al, J Hypertens 2017

## Potential effects of BAT on end organ damage



**[1]** BAT may improve left atrial and ventricular structure and function.

BAT may reduce left ventricular mass.

**[2]** Potential nephroprotective effects of BAT in patients with chronic kidney disease (CKD) by stabilization of estimated GFR and mild reduction of proteinuria.

**[3]** Limited acute effect of BAT on muscle glucose metabolism (insulin sensitivity, glucose- or insulin-concentration).

**[4]** No effect of BAT on oral glucose tolerance, fasting insulin levels, C-peptide levels, hemoglobin A1c, HOMA-IR, HOMA- $\beta$ .

**[5]** BAT reduces central blood pressure, augmentation index and pulse wave velocity, suggesting a strong potential to reduce cardiovascular risk.

HOMA-IR: Homeostasis model assessment – insulin resistance

HOMA- $\beta$ : Homeostasis model assessment – beta-cell function

[1] Bisognano et al. JACC 2011;57:1787-91

[2] Walbach M et al. Am J Nephrol 2014;40:371-80

[3] May M et al. Diabetes 2014;63:2833-37

[4] Walbach M et al. Acta diabetol 2015;52:829-35

[5] Walbach M et al. J Hypertens 2015;33:181-86

## Patient selection

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According to the evidence from clinical trials BAT should be considered in patients with therapy resistant hypertension:

- ✓ Office cuff blood pressure  $>160/90$  mmHg
- ✓ after lifestyle modification and
- ✓ under at least 3 antihypertensive drugs (incl. diuretics)

## Patient selection

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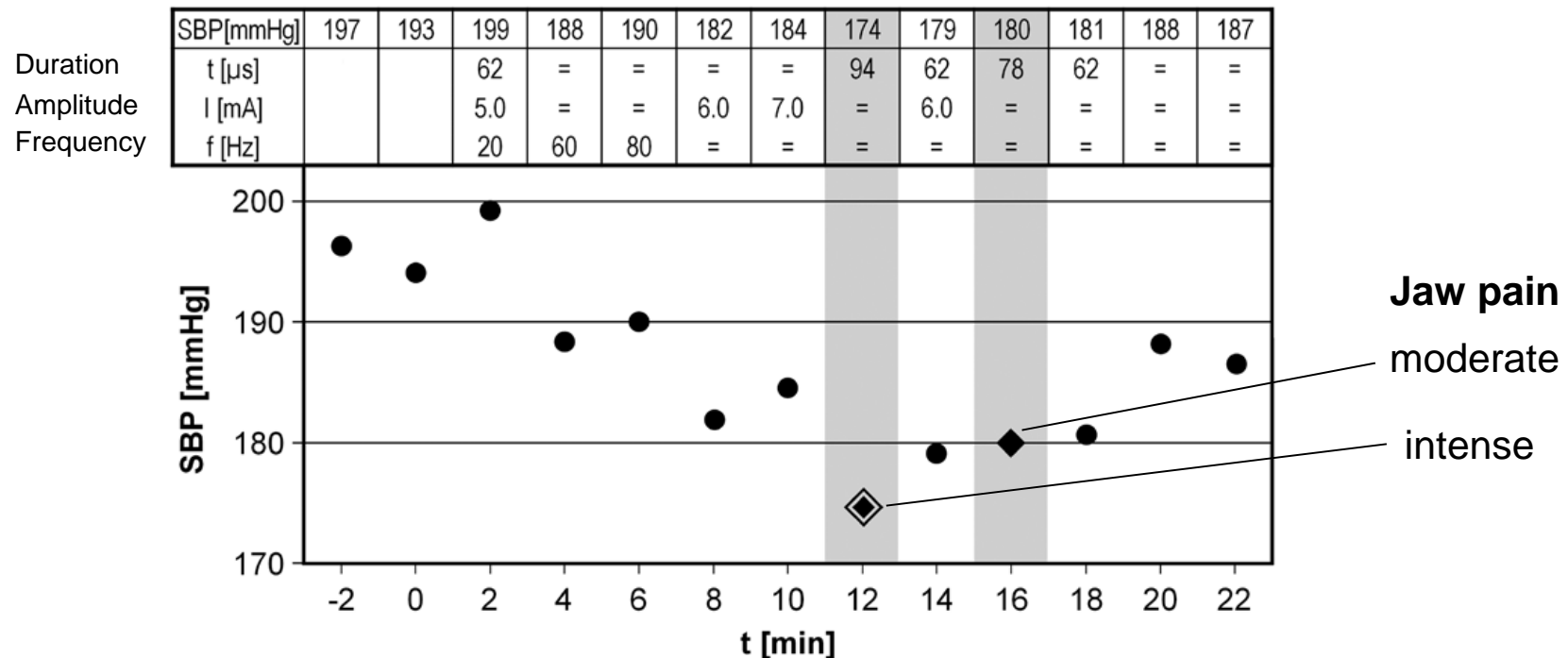


- ✓ Initiation of MRA treatment (i.e. Spironolactone) prior to BAT evaluation.
  
- ✓ Exclusion of pseudoresistance and/or secondary causes.  
(repeat in case of doubt or after longer intervals)
  
- ✓ End organ damage:
  - BAT in heart failure - symptomatic improvement [1]
  - BAT in renal failure - potentially nephroprotective
  - BAT in carotid artery disease >50% - **contraindication**

# Programming: stimulation intensities and side effects



Systematic augmentation of stimulation intensities  
is limited by local sensations or side effects



## **Programming: stimulation intensities and side effects**

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Achieve maximum Barostim efficacy by:

- ✓ maximizing Barostim dose
- ✓ maintaining patient comfort and safety



**Establish uniform programming guideline at centre**

## BAT Centres: Facility / Structural requirements



Criterion	Recommended minimal standard
Centre	Interdisciplinary hypertension clinic with routine in surgical carotid interventions
	Emergency plan for complications available
Implantation	Frequent performance of surgical carotid interventions (>50/year)
	Continuous peri- procedural monitoring of vital signs.
Follow-up	Standardized outpatient program for follow-up During first year, intervals: months 1, 2, 3, 6, 12
	Establish uniform programming guideline at centre



## BAT Centres: Personnel requirements



Criterion	Recommended minimal standard
Hypertension Specialist	<p>2 certified hypertension specialists on site</p> <p>Staff trained on BAT Programming System and current software</p>
Surgeon	<p>Specialist for vascular or heart surgery</p> <p>Should have performed at least 50 carotid reconstructive surgeries</p> <p>Professional proctoring recommended for the first 3 procedures</p>
Neurologist	<p>Consultant available</p>

## Summary & conclusions

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**In addition to antihypertensive medication and lifestyle changes BAT effectively lowers blood pressure in patients with resistant hypertension.**

**Patient selection and standardized procedures for implantation and programming of the device are crucial for the success in BAT.**

**In Germany the formulation of guidelines and the implementation of standardized pathways for the follow-up of patients has facilitated the integration of BAT in clinical routine.**