

# Package ‘bpAcc’

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**Title** Blood Pressure Device Accuracy Evaluation: Statistical Considerations

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**Depends** R (>= 3.5.0), methods, stats

**Description** A comprehensive statistical analysis of the accuracy of blood pressure devices based on the method of AAMI/ANSI SP10 standards developed by the AAMI Sphygmomanometer Committee for indirect measurement of blood pressure, incorporated into ISO 81060-2. The 'bpAcc' package gives the exact probability 'of accepting a device D' derived from the joint distribution of the sample standard deviation and a non-linear transformation of the sample mean for a specified sample size introduced by Chandel et al. (2022) and by the Association for the Advancement of Medical Instrumentation (2003, ISBN:1-57020-183-8).

**License** GPL-2

**NeedsCompilation** yes

**BuildVignettes** yes

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notDocumentedYetbpAcc *Not-documented functions and classes in **bpAcc**.*

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### Description

Those functions not documented yet in **bpAcc** are aliased to this file.

### Details

These functions are still under review or being tested, and will be documented over time.

### Value

Overall, these functions returns objects required by functions from **bpAcc**.

Further details will be given shortly.

### Author(s)

T. Chandel, V. Miranda, A. Lowe, T. Lee

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ProbAccept *Probability of device acceptance - AANSI/AAMI-SP10 standard.*

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### Description

Probability of device acceptance - AANSI/AAMI-SP10 standard.

### Usage

```
ProbAccept(n, mu, sd, ptolerror = 0.85,  
           distribution = "normal",  
           criteria = "SP10:2006",  
           simulate = FALSE, sim.count = 1e4,  
           noshow = FALSE)
```

**Arguments**

n	Sample size (evaluated people, as defined by Chandel et al. (2022)).
mu, sd	mean and standar deviation of the average errors distribution (normal).
ptolerror	Probability of tolerable error. Default is 0.85
distribution	Underlying distribution the errors $\delta$ are pulled from. The default is normal, i.e. a normal distribution.
criteria	SP10 criteria used.
simulate	Logical. If TRUE, the acceptance probability is simulated from sim.count samples form a normal distribution. Else, the exact probability is returned. Default is FALSE.
sim.count	Integer, positive. Number of samples taken from normal distribution to estimate the probability of accepting the device.
noshow	Logical. If FALSE then results are prompted on terminal.

**Details**

Computes the *acceptance probability* of a device D for blood pressure measuring under the ANSI/AAMI-SP10 standards for a size-n sample of average errors from a normal distribution with mean mu and stadard deviation sd. The probability of tolerable error is set to 0.85, by default. A *tolerable error*, according to the ANSI/AAMI-SP10, is a an error of 10mmHg or less on a single person, using the average of that person's readings.

Fuller details in Chandel, et al. (2022). The paper outlines the mathematical and statistical aspects behind ProbAccept. Two random variables are involved: the sample standard deviation and a transformation of the sample mean, resulting in a double integral over a two-dimensional region.

**Value**

It returns the probability of accepting the device (either simulated or exact).

**Author(s)**

Tanvi Chandel, Tet-Chuan Lee, Andrew Lowe, Victor Miranda.

**References**

Chandel, T. and Lee, TC. and Lowe, A. and Miranda, V. (2022) Blood Pressure Device Accuracy Evaluation: Statistical Considerations with an Implementarion in R, *Statistical Methods in Medical Research* (under review).

**See Also**

[ProbAccept psigmaami](#)

## Examples

```
## Probability of accepting a device with bias (mu) = 5, and true standard
## deviation = 5.
ProbAccept(n = 85, mu = 5, sd = 5, ptolerror = 0.85)

## Probability of accepting a device with bias (mu) = 5, and true standard
## deviation = 7.
ProbAccept(n = 85, mu = 5, sd = 7, ptolerror = 0.85)
```

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ProbTolError	<i>Probability of tolerable error - AAMI-SP10 standard.</i>
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## Description

Probability of tolerable error - AAMI-SP10 standard.

## Usage

```
ProbTolError(distribution = "normal", mu, std.dev, delta)
```

## Arguments

distribution	The errors distribution. Default and only option is "normal".
mu, std.dev	Mean and standar deviation of the average errors distribution (normal).
delta	Maximum average error allowed for the device D.

## Details

Computes the *probability of tolerable error* for a device D for blood pressure measuring under the ANSI/AAMI-SP10 standard for a size-n sample of average errors from a normal distribution with mean mu and stadard deviation sd. The maximum error accepted is 0.85, A *tolerable error*, according to the ANSI/AAMI-SP10, is a an error of 10mmHg or less on a single person, using the average of that person's readings.

Currently, only normally distirbuted errors are handled. Further choices will be implemented over time.

Fuller details in Chandel, et al. (2022).

**Value**

It returns the probability of tolerable error based on a normal distribution.

**Author(s)**

Tanvi Chandel, Tet-Chuan Lee, Andrew Lowe, Victor Miranda.

**References**

Chandel, T. and Lee, TC. and Lowe, A. and Miranda, V. (2022) Blood Pressure Device Accuracy Evaluation: Statistical Considerations with an Implementarion in R, *Statistical Methods in Medical Research* (under review).

**See Also**

[ProbAccept psigmaami](#)

**Examples**

```
## Probability of tolerable error, mu = 4, sd = 5, delta = 10 (ANSI/AAMI-SP10)
ProbTolError(mu = 4, std.dev = 5, delta = 10)
```

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psigmaami	<i>Distribution function of the sigma-aami transformation (not vectorized).</i>
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**Description**

Distribution function of the sigma-aami transformation (not vectorized).

**Usage**

```
psigmaami(sigmaami, mu, std.dev, n, ptolerror = 0.85, lower.tail = TRUE)
```

**Arguments**

sigmaami	A single, positive, quantile. See below for further details.
mu, std.dev	mean and standar deviation of the average errors distribution (normal).
n	sample size
ptolerror	Probability of tolerable error, Default is 0.85
lower.tail	logical; it <i>TRUE</i> (default), probabilities are $P[\textit{sigmaami} \leq x]$ otherwise, $P[\textit{sigmaami} > x]$ .

**Details**

This is the distribution function of the `sigmaami` transformation.

A size- $n$  sample of blood pressure average errors (average of the difference between three *device* measurements and the three corresponding reference readings) is drawn from a normal distribution with mean  $\mu$  and standard deviation `std.dev`. The r.v. `sigmaami` results from transforming  $\bar{x}$ , the sample mean, assuming the proportion of drawn errors lie in  $(-\delta, \delta)$  with probability `ptolerror`, that is  $\text{sigmaami} = \text{sigmaami}(\bar{x})$ .

**Value**

`psigmaami` gives the distribution function.

**Author(s)**

Tanvi Chandel, Tet-Chuan Lee, Andrew Lowe, Victor Miranda.

**References**

Chandel, T. and Lee, TC. and Lowe, A. and Miranda, V. (2022) Blood Pressure Device Accuracy Evaluation: Statistical Considerations with an Implementarion in R, *Statistical Methods in Medical Research* (under review).

**See Also**

[ProbAccept](#)

**Examples**

```
## Sample of n = 85 average errors from a normal distribution with mean 3 and st.dev = 2.  
psigmaami(sigmaami = 4, mu = 3, std.dev = 2, n = 85)
```

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Supplementary functions

*Supplementary fuctions of the package **bpAcc**.*

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**Description**

Supplementary function required to compute the acceptance probability of a device for BP measurement.

**Usage**

```
fsup1(mu, sd.aami, ptolerror)
fsup2(mu.aami, sdev, ptolerror)
toint(xbar, mean, sd, n)
```

**Arguments**

mu	True mean error (bias). This is 'mu' of the errors distribution (normal).
sd.aami	Standard deviation of a normal distribution meeting the ANSI/AAMI-SP10 standards.
ptolerror	Probability of tolerable error. Default is 0.85.
mu.aami	Mean of a normal distribution meeting the ANSI/AAMI-SP10 standards.
sdev	True standard deviation of the errors (normal distribution).
xbar, mean, sd, n	Auxiliary arguments.

**Details**

Supplementary functions to compute the *probability of accepting the device D*. The errors (average of the differences from three *device* measurements and the three corresponding reference readings) are by default normally distributed with mean `mean` and `sd`. Function `fsup1` is called by `root`, `fsup2` is needed by `rootinv`, and `toint` is required by `psigmaami`.

See `psigmaami` for further details on `ptolerror`.

**Value**

No value returned. These are function internally called by `ProbAccept`.

**Author(s)**

Tanvi Chandel, Tet-Chuan Lee, Andrew Lowe, Victor Miranda.

**References**

Chandel, T. and Lee, TC. and Lowe, A. and Miranda, V. (2022) Blood Pressure Device Accuracy Evaluation: Statistical Considerations with an Implementarion in R, *Statistical Methods in Medical Research* (under review).

**See Also**

[ProbAccept](#) [psigmaami](#)

**Examples**

```
#### 'sd' that meets the AAMI-sp10 standars
root(mu = 5, ptolerror = 0.9)
# root(mu = 11, ptolerror = 0.85) # Error

#### 'mu' that meets the AAMI-sp10 standars
rootinv(sdev = 3, ptolerror = 0.9)
# rootinv(sdev = 2, ptolerror = 0.85) # Error
```



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