# Umgebungslicht- und Näherungssensor mit IR Emitter Ambient Light and Proximity Sensor with Integrated IR Emitter Lead (Pb) Free Product - RoHS Compliant

#### **SFH 7773**



### **Preliminary datasheet**

#### **Wesentliche Merkmale**

- Näherungssensor- Detektionsbereich bis 150mm
  - 850nm Emitter, im Gehäuse integriert
  - Umgebungslicht-unempfindlich
- Umgebungslichtsensor
  - 0.03lx 65000lx
  - Gute Linearität
  - Spektrale Empfindlichkeit ähnlich dem menschlichen Auge
- I<sup>2</sup>C interface
  - 100kHz / 400kHz und 3.4MHz Mode
  - verschiedene Messmoden programmierbar (Standby, Triggered, Free-running)
  - I2C-Adresse: 0111 000X
- typ 2μA Stromverbrauch im Standby Mode

#### Anwendungen

- Mobiltelefone
- PDAs und Notebooks
- Kameras
- Consumer-Produkte

#### **Features**

- Proximity sensor (PS)
  - Detection-range up to 150mm
  - 850nm IR emitter integrated in package
  - Insensitive to ambient light
- Ambient light sensor (ALS)
  - 0.03lx 65000lx
  - High linearity
  - S<sub>rel</sub> well matched to the human eye
- I<sup>2</sup>C interface
  - 100kHz / 400kHz and 3.4MHz mode
  - Measurement modes programmable (Standby, Triggered, Free-running)
  - I2C slave address: 0111 000X
- Current consumption typ. 2μA in Standby mode

### **Applications**

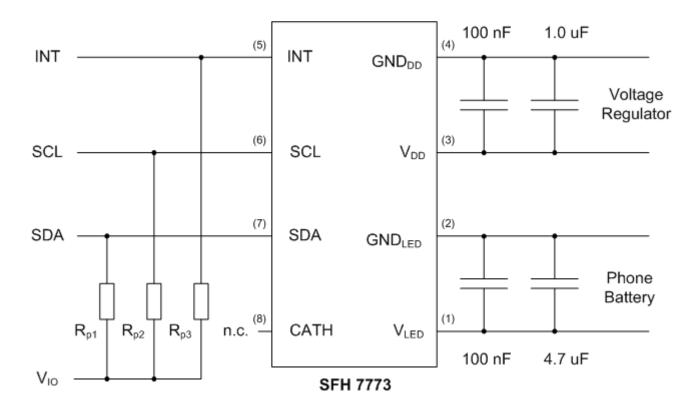
- Mobile phones
- PDAs and notebooks
- Cameras
- Consumer products

<b>7</b> 1	Bestellnummer Ordering Code
SFH 7773	Q65111A1258

2012-02-20



### Application diagram and basic information



- Blocking capacitors for VDD and VLED are required for proper operation of the device. Based on the power supply quality the capacitor values can be reduced.
- Proposed size for the pull-up resistors is 560 Ohm.

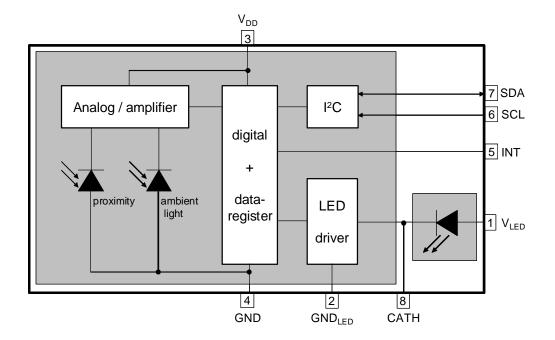
### **Short Evaluation program**

Adress	Command	Action						
0x80	Write 03	Ambient light Sensor in FREE-RUNNING mode						
0x81	Write 03 Proximity Sensor in FREE-RUNNING mode							
Wait 110 ms								
0x8C	Read data	read LSByte data from ambient light measurement						
0x8D	Read data	read MSByte data from ambient light measurement						
0x8F	Read data	read data from proximity measurement						



#### I<sup>2</sup>C interface

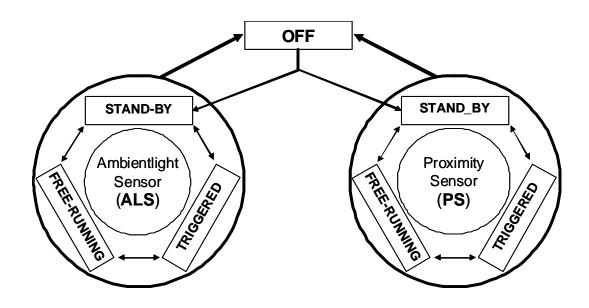
- 1.8V I/O-logic level for SDA and SCL
- I/O-pins are open drain type and logic high level is set with external pull-up resistor
- SFH 7773 operates in slave mode with address 0x38.
- Designed for the I<sup>2</sup>C-modes: Standard (100 kb/s), Fast (400 kb/s) and High Speed (3.4 Mb/s)
- Combined format is supported (see I<sup>2</sup>C Bus specification UM10204 from NXP) for data reading
- Block READ and WRITE modes are available. In these modes several registers can be read or written
  during a single I<sup>2</sup>C traffic period. Registers are returned in a cyclic manner until the bus master sends
  the stop condition. E.g. if master uses block read and starts from register 0x8C, the slave returns the
  following register values: 0x8C, 0x8D, 0x8E, 0x8F, 0x90, 0x91, 0x92, 0x93, 0x94 and so on until the
  master sends stop condition.
- Interrupt pin (INT): open-drain output (like SDA and SCL)





#### **Measurement modes**

OFF	$I_{\rm DD}$ is below $2\mu \rm A$ and the device is inactive. Other units may use the I $^2 \rm C$ bus without any restrictions; I/O pins and INT are in Z state. There is no sink current through the LED
STAND-BY	This is the initial mode after power-up. $I_{\rm DD}$ is below $5\mu A$ . No measurement is performed. Device can be activated by I <sup>2</sup> C bus communication. Data registers can be read and written. The data will be stored in the registers when the device goes from TRIGGERED or FREE-RUNNING to STAND-BY.
TRIGGERED	Every measurement is separately initiated by MCU. This mode can be used for ambient light sensor and proximity sensor. Measurement data are available in the registers after a defined delay time.
FREE-RUNNING	Measurements are triggered internally by SFH7773. This mode can also be used for ambient light sensor and proximity sensor. The measurement repetition rate and current through the LED is defined by MCU. Measurement results can be read from the data register, the status from the interrupt register.



If  $V_{\rm DD}$  exceeds the threshold-voltage , the sensor will switch from OFF mode to STAND-BY mode. As shown in the transition-diagram above it is possible to switch between all modes without any restriction. The transition time between modes  $(t_{\rm trans})$  is < 10ms. The delay time between STAND-BY and start of measurement is max. 10ms for the ambient light sensor.



#### **Maximum limits**

Parameter	Symbol		Unit		
		min.	typ.	max.	
Storage temperature	$T_{stg}$	- 40		+ 85	°C
Supply voltage (between $V_{\rm DD}$ and GND)	$V_{DD}$	- 0.3		+ 4.5	V
Maximum Voltage of SDA, SCL and INT to GND	$V_{dig}$	- 0.3		+ 3.6	V
Maximum Voltage of V <sub>LED</sub> to GND	$V_{LED}$	- 0.3		+ 5.5	V
Maximum Voltage between GND and GND <sub>LED</sub>	$V_{LED}$	- 0.5		+ 0.5	V
Electrostatic discharge - Human Body Model (according to JESD22-A114-E; Class2)	ESD			2	kV

### **Operating conditions**

Parameter	Symbol		Unit		
		min.	typ.	max.	
Operation temperature	$T_{\sf op}$	- 20		85	°C
Supply Voltage	$V_{DD}$	2.3		3.1	V
Ripple on Supply Voltage ( $V_{DD}$ min and max must stay in the $V_{DD}$ range, DC 100MHz)	$V_{DD,rip}$			10	mV
Voltage for I/O (SDA, SCL, INT) <sup>1)</sup>	$V_{I/O}$	1.6		2.1	V
Supply Voltage LED	$V_{LED}$	2.3		4.25	V
	$V_{LED,rip}$			TBD TBD	mV mV

The limits for the logic levels of SCL and SDA pins are the same as in the l²C bus specification from NXP (UM10204 "l²C bus specification and user manual", Rev. 03 - 19 June 2007). The same limits are valid for the logic levels of the interrupt pin (INT): the maximum level for logic "LOW" level is 30% of the I/O voltage  $V_{\rm I/O}$ , the minimum level for logic "HIGH" level is 70% of the I/O voltage  $V_{\rm I/O}$ .



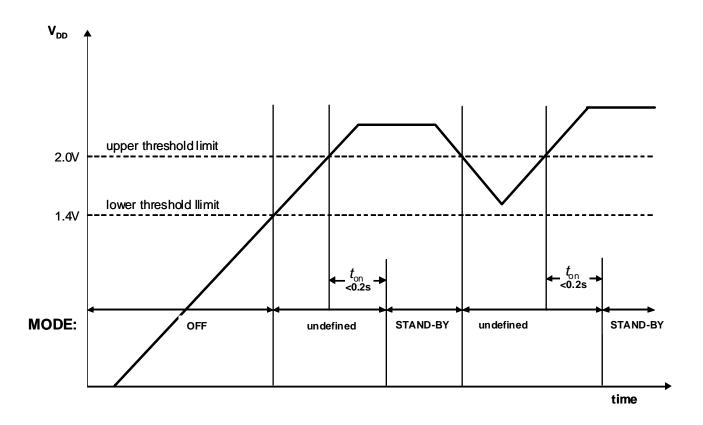
# Characteristics ( $Ta = 25^{\circ}C$ )

Parameter	Symbol		Unit		
		min.	typ.	max.	
General					
Conditions for OFF mode <sup>1)</sup>	$V_{DD,off}$			1.4	V
On-time (from OFF to STAND-BY mode) <sup>1)</sup>	$t_{\sf on}$			0.2	s
Threshold level for STAND-BY mode <sup>1)</sup>	$V_{DD,on}$	2.0			V
Transition time between modes (STAND-BYTRIGGEREDFREE-RUNNING)	t <sub>trans</sub>			10	ms
STAND-BY mode current consumption	$I_{ m DD,stby}$			5	μΑ
OFF mode current consumption	$I_{DD,off}$			2	μΑ
Interrupt voltage level in LOW state ( $V_{\text{I/O}}$ =1.8V)	$V_{ m INT,low}$			0.5	V
Interrupt voltage level in HIGH state ( $V_{\text{I/O}}$ =1.8V)	$V_{ m INT,high}$	1.7			٧
Proximity Sensor (PS) Wavelength of max. sensitivity	$\lambda_{S,max}$	<u> </u>	850		nm
	2		850		nm
Spectral range of sensitivity (50% of S <sub>max</sub> )	λ <sub>S,50%</sub>		tbd		nm
LED centroid wavelength (If = 100mA)	$\lambda_{ m centroid}$		850		nm
Spectral bandwidth (If = 100mA)	Δλ		42		nm
Temperature coefficient of LED emission	TC		-0.5		%/K
Sensor signal (pseudo-logarithmic) 2)			0 255		count
LED current, programmable, (only when $V_{\rm LED}$ - $V_{\rm f}$ >= 0.4V)	$I_{LED}$	5		200	mA
Accuracy of LED current source	$\Delta I_{LED}$	-20		+20	%
Mean current consumption, FREE-RUNNING ( LED "ON", If=100mA, $t_{rep}$ = 100ms, Vdd=2.65V, without LED current)	$I_{act}$			300	μΑ
Modulation frequency of LED current	f <sub>mod</sub>		667		kHz
Switching distance (Iled=200mA; t_int=750µs; R=90%; A=10x10cm²)	Z			5	cm
Repetition time in free-running mode programmable	t <sub>rep</sub>		10 2000		ms
Length of a single LED burst, programmable (burst length = integration time)	t <sub>burst</sub>	100		2500	μs



Parameter	Symbol	Value			Unit
		min.	typ.	max.	
Update of register data after MCU request	t		10		ms
Insensitive to sunlight up to		50			klx

# 1) Start-up sequence



The threshold limit where the device switches from OFF to STAND-BY mode is between  $V_{\rm DD}$  =1.4V and  $V_{\rm DD}$  =2.0V.

Within 0.2s after exceeding the threshold voltage the device will switch from OFF to STAND-BY mode.

# <sup>2)</sup> Output signal of the proximity sensor

The proximity sensor delivers output values in the range from 0 to 255, depending on integration time settings. Low output values correspond to low irradiance of the sensor, while high values indicate high irradiance. A threshold level for the proximity switch can be programmed via the I<sup>2</sup>C bus.



# **Characteristics** (Ta = $25^{\circ}$ C)

Parameter	Symbol		Unit		
		min.	typ.	max.	
Ambient Light Sensor (ALS)					
Wavelength of max. sensitivity	$\lambda$ S max		555		nm
Spectral range of sensitivity (10% of Smax)	λ S10%	tbd		tbd	nm
Illuminance measurement range, programmable		0.03		65000	lx
Resolution of the digital output signal (0.1 x 6.5k x) <sup>1)</sup>	Out		0.1		count/lx
Deviation from linear output characteristics <sup>2)</sup> X = 10-6500lx X = 1-10lx X = 0.3-1lx	f <sub>lin</sub>		±5 ±10 ±30		%
Temperature coefficient for $E_{ m V}$ measurement 0°C 50°C -15°C 70°C	$T_{ m cEv}$	- 0.20 - 0.25		+ 0.20 + 0.25	%/K %/K
Update of register data after MCU request <sup>1)</sup>	t		100	120	ms
Measurement repetition time in FREE-RUNNING mode, programmable	t <sub>rep</sub>		100 2000		ms
integration time, programmable <sup>1)</sup>	t <sub>int</sub>	10		1000	ms
Mean current consumption, $t_{rep} = 500 \text{ms}$ ; $t_{int} = 10 \text{ms}$ ; Vdd=2.65V; Ev=1000lx	I <sub>act</sub>			200	μА
Current consumption in STAND-BY mode	$I_{stby}$		2	5	μΑ
Error by Flicker noise (caused by bulbs or fluorescent lamps) (f = 50 or 60Hz, 100% modulation)		-5		+5	%

The absolute resolution range of the ALS depends on the integration time. This can be set in register 0x26. Default value is 100ms resulting in a resolution range of 0.3 lx ... 6500 lx. To access register 0x26, register 0x20 must first be set to 0x01. After changing the integration time it is recomended to set register 0x20 back to 0x00.

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2) The deviation of the linear output characteristic is referenced to 1000lx and follows the formula:

$$f_{lin} = \left(\frac{Y_X}{Y_{1000lx}} \times \frac{1000lx}{X} - 1\right) \times 100\%$$

X: sensor illumination level in lux

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Y<sub>X</sub>: sensor output / measurement value at illumination level X

 $Y_{1000IX}$ : sensor output / measurement value at illumination level 1000lx



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Note: Some of the following registers are marked as <u>unused</u>. They can still be accessed by block write and read procedures.

#### **Integration Time access register**

Note: After setting bit '0' there must be stop condition to confirm writing.

R/W-Register 0x20										
Bit 7 6 5 4 3 2 1 0										
			no	t us	sed					
default	0	0	0	0	0	0	0	0 not accessible		
								0 not accessible		
1 accessible										

### Ambient light sensor Integration Time

Note: Register 0x26 is only accessible if access-bit '0' of register 0x20 is set to '1'. Integration time can then be changed. It is recommended to set access-bit '0' of the Integration Time Access register afterwards back to '0'. When reading or writing in block-read/-write mode, it is recomended to start at reister 0x26 and stop at register 0x27, as there are other registers accessible which are not intended for user access. Afterwards set the access bit of register 0x20 back to 0.

Note that the absolut ambient light sensor range depends on the integration time. I.e. default setting range is 0.3 lx to 6.5 klx with resolution of 0.1 lx per count, whereas 10 ms results in a range of 3 lx to 65 klx with 1 lx resolution per count.

R/W-Re	R/W-Register 0x26												
Bit	7	6	5	4	3	2 1 0							
		no	t us	sed				ALS	integra	ation tim	пе		
default	00	00	000	)		000	100 ms						
						000	100 ms						
						001	200 ms						
						010	500 ms						
						011	1000 ms						
						100	10 ms						
						101	20 ms						
						110	50 ms						
						111	50 ms						



### **Proximity sensor Integration Time**

Note: Register 0x27 is only accessible if access-bit '0' of register 0x20 is set to '1'. Integration time can then be changed. It is recommended to set access-bit '0' of the Integration Time Access register afterwards back to '0'. When reading or writing in block-read/-write mode, it is recomended to start at reister 0x26 and stop at register 0x27, as there are other registers accessible which are not intended for user access. Afterwards set the access bit of register 0x20 back to 0.

Note that the PS Integration Time sets the absolute PS signal count. I.e. an integration time of 1000 us delivers a signal count which is around 50 counts higher compared to an integration time of 100 us. A factor of 10 in signal level (resp. integration time) corresponds to around an increase of 50 counts (pseudo-logarithmic relationship).

R/W-Re	gis	ter	0x2	27											
Bit	7	6	5	4	3		2 1 0								
	not used						PS integration time								
default	00	000	000	)		010	300 us								
						000	100 us								
						001	200 us								
						010	300 us								
						011	500 us								
						100	750 us								
						101	1000 us								
						110	1500 us								
						111	2500 us								

# Software reset and control of ambient light sensor

R/W-Register 0x80												
Bit	7	6	5	4	3	2	1 0					
		nc	ot us	ed		complete SW reset	mode of ambient light sensor					
default	000	00				0	00	STAND-BY				
						1 SW reset	00	STAND-BY				
							01	STAND-BY				
							10	TRIGGERED (by I	MCU)			
							11	FREE-RUNNING (	internally triggered)			

SW reset (Bit 3 "H") sets all registers to default (same as POWER UP). The bit is set back to "L" by SFH7773 automatically.

# **Control of proximity sensor**

R/W-Re	R/W-Register 0x81											
Bit	7	6	5	4	3	2		1	0			
			not	used			mode of Proximity Sensor					
default	XXXX	XX					00	STAND-BY				
							00	STAND-BY				
							01	STAND-BY				
							10	TRIGGERED by M	1CU			
	11 FREE-RUNNING (internally triggered)											



# **Emitter current setting**

R/W-Re	gister 0x82									
Bit	7	6	5	4	3	2 1 0				
	activation	of LEDs	not used			setting LED pulse current				
default	00		011			011 50 mA				
	00 LED ac	tive	XXX			000 5 mA				
						001 10 mA				
						010 2	.0 mA			
						011 5	0 mA			
						100 10	0 mA			
						101 15	60 mA			
						110 20	0 mA			

# Register is not used, but might be read during block read mode

R/W-Register 0x83												
Bit	it 7 6 5 4 3 2 1 0											
		Not used Not used										
default	00000					011						

# MCU-triggered measurement (for ambient light sensor and proximity sensor)

R/W-Re	R/W-Register 0x84												
Bit	Bit 7 6 5 4 3 2 1 0												
	not used trigger ambient light trigger proximity												
default	XXX	XXX					1	1					

If "1" is set a new measurement will start after  $I^2C$  stop commmand from MCU. As soon as the measurement is finished the corresponding bit of the register will be set to "0" automatically by the SFH7773

### Proximity measurement: time interval settings (repetition time) for FREE-RUNNING mode

R/W-Re	R/W-Register 0x85												
Bit	7	6	5	4	3		2	1	0				
		not u	ısed		time-interval								
default	XXXX				0101	10	0 ms						
					0000	10	0 ms						
					0001	20	0 ms						
					0010	3(	0 ms						
					0011	50	0 ms						
					0100	70	0 ms						
					0101	10	0 ms						
					0110	20	0 ms						
					0111	50	0 ms						
					1000	100	0 ms						
					1001	200	0 ms						

# Ambient light measurement: time interval settings (repetition time) for FREE-RUNNING mode

R/W-Register 0x86												
Bit	7	6	5	4	3	2	1	0				
		not used time-interval										
default	XXXXX											
					000 100 ms							
						001 20	0 ms					
						010 50	0 ms					
						011 100	0 ms					
	100 2000 ms											

#### Part number and revision Identification

R-Regis	R-Register 0x8A										
Bit	7	6	5	4	3	2	1	0			
		Part nui	mber ID		Revision ID						
	1001				0111						

#### **Manufacturer Identification**

R-Register 0x8B											
Bit	7 6 5 4 3 2 1 0										
	Manufacturer Identification										
	0000				0011						



### Ambient light measurement data (0x8C: LSB, 0x8D: MSB)

R-Regis	R-Register 0x8C										
Bit	7 6 5 4 3 2 1 0										
		LSB data									
default		0000000									

R-Regis	R-Register 0x8D										
Bit	7 6 5 4 3 2 1 0										
		MSB data									
default		00000000									

The result of the ambient light sensor is a 16bit word with MSB and LSB and is stored in two registers.. The binary data can be converted directly to decimal "lx" values (max. 65535lx)

### Status of measurement data for ambient light sensor (ALS) and proximity sensor (PS)

R-Regis	R-Register 0x8E										
Bit	7 6 5 4 3 2 1 0										
	ALS threshold	ALS data		Not	PS LED threshold	PS LED data					
default	0	0	0000 00								

When the measurement is available in the register the corresponding statusbit (bit 6 for ambient-light; bit 0 for proximity) in register 0x8E is set to "1"; when the measurement has been read by the MCU the statusbit is automatically set back to "0".

Bit 7 is set "1" when the measured ALS value is outside the threshold level settings (register 0x96... 0x99). Bit 1 is set when the measured PS value is above the threshold level (register 0x93).

The status of register 0x8E will always be updated when a new measurement is available.

#### Proximity measurement data (8bit, logarithmic scale)

R-Regis	R-Register 0x8F										
Bit	7 6 5 4 3 2 1 0										
		data									
default		0000000									



### Register is not used, but might be read during block read mode

R-Register 0x90									
Bit	7 6 5 4 3 2 1 0								
	Not used								
default		00000000							

### Register is not used, but might be read during block read mode

R-Register 0x91									
Bit	7 6 5 4 3 2 1 0								
		Not used							
default	00000000								

### Interrupt register / INT output.

R/W-Re	R/W-Register 0x92									
Bit	7	6	5	4	3	2	1	0		
	not used	Inter trigger	rupt source	not used	Output mode	Output polarity	Interrup (trigger	ot mode ed by)		
R/W	not used	Ro	nly	not used	R/W	R/W	R/	W		
default	X	00		X	1	0	00			
		00 ALS			0 latched	0 active L	00 Z state	Э		
		01 PS			1 not latched	1 active H	01 only P	S		
							10 only A	LS		
							11 PS an	d ALS		

In Bit6/5 the source which triggers the interrupt is noted. Data from Status Register (0x8E) are used. In latched mode (set by bit3) this remains unchanged until the Interrupt register has been read by the MCU, afterwards it is set to 0 automatically. In unlatched mode it is updated after every measurement. The Output polarity (pin 5 of the SFH7773) can be changed by bit 2.

Interrupt can be triggered by the ambient light sensor and / or by the proximity sensor; this can be set in the Interrupt mode (bit 1/bit 0); when bit 1 and bit 0 is set to 0 the INT Output is in the Z state (high impedance).



# **Threshold level for Proximity Sensor**

RW-Register 0x93									
Bit	7	6	5	4	3	2	1	0	
		data							
default	1111111								

### Register is not used, but might be read during block read mode

RW-Register 0x94										
Bit	7 6 5 4 3 2 1 0									
		Not used								
default		1111111								

# Register is not used, but might be read during block read mode

RW-Register 0x95									
Bit	7	6	5	4	3	2	1	0	
		Not used							
default	11111111								

Upper threshold level for ambient light Sensor (LSB)

RW-Register 0x96									
Bit	7	6	5	4	3	2	1	0	
	LSB data (upper threshold)								
default		1111111							

**Upper threshold level for ambient light Sensor (MSB)** 

RW-Register 0x97									
Bit	7	7 6 5 4 3 2 1 0							
	MSB data (upper threshold)								
default		1111111							

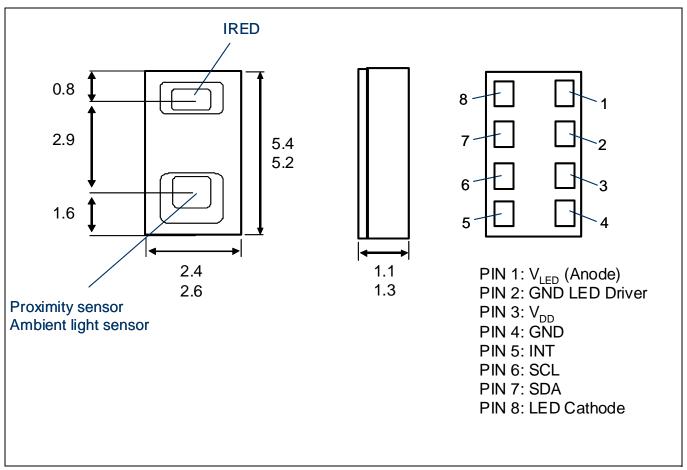
Lower threshold level for ambient light Sensor (LSB)

RW-Register 0x98									
Bit	7	6	5	4	3	2	1	0	
	LSB data (lower threshold)								
default		00000000							

Lower threshold level for ambient light Sensor (MSB)

RW-Register 0x99									
Bit	7 6 5 4 3 2 1 0								
	MSB data (lower threshold)								
default		00000000							

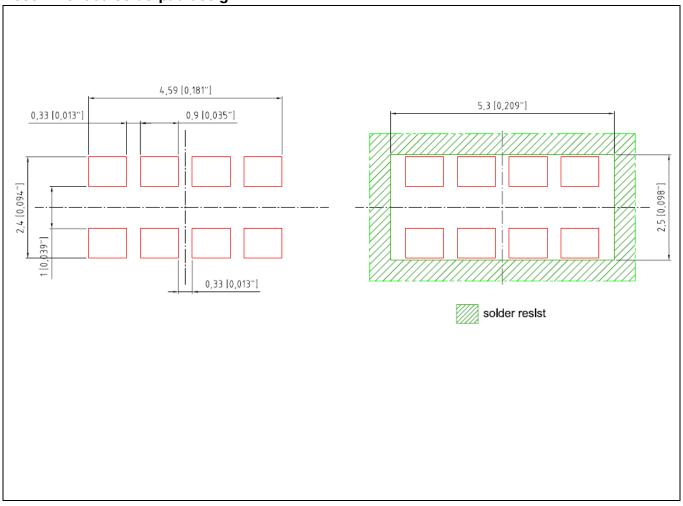
### **Package Outlines**



Dimensions in mm

Tolerance of package dimensions is +/- 0.1mm if not stated otherwise.

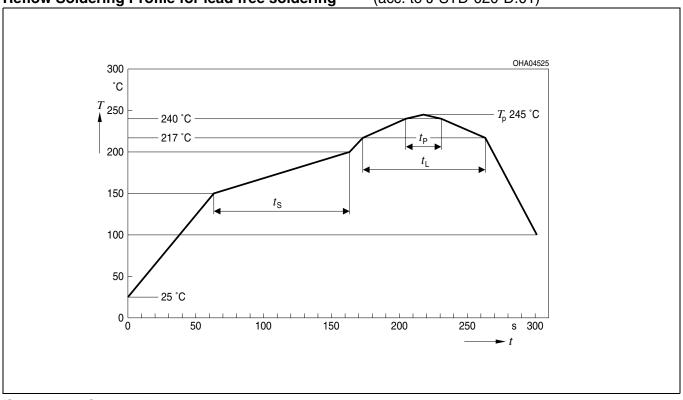
# Recommended solderpad design



Dimensions in mm [inch]

Soldering Conditions
Reflow Soldering Profile for lead free soldering

Preconditioning acc. to JEDEC Level 3 (acc. to J-STD-020-D.01)



# Cleaning / Washing

In general, OSRAM Opto Semiconductors does not recommend a wet cleaning process for components like the OSTAR SMT, OSTAR Compactand SFH777x 3in1 as the package is not hermetically sealed. Due to the open design, all kind of cleaning liquids can infiltrate the package and cause a degradation or a complete failure of the LED / ASIC. It is also recommended to prevent penetration of organic substances from the environment which could interact with the hot surfaces of the operating chips. Ultrasonic cleaning is generally not recommended for all types of LEDs (see also the application note "Cleaning of LEDs"). As is standard for the electronic industry, OSRAM Opto Semiconductors recommends using low-residue or no-clean solder paste, so that PCB cleaning after soldering is no longer required. In any case, all materials and methods should be tested beforehand in order to determine whether the component will be damaged in the process.

	Pb-Free (SnAg	Cu) Assembly	
Profile Feature	Recommendation	Max. Ratings	
Ramp-up Rate to Preheat*) 25°C to 150°C	2°C / sec	3°C / sec	
Time t <sub>s</sub> from T <sub>Smin</sub> to T <sub>Smax</sub> (150°C to 200°C	100s	min. 60sec max. 120sec	
Ramp-up Rate to Peak*) T <sub>Smax</sub> to T <sub>P</sub>	2°C / sec	3°C / sec	
Liquidus Temperture T <sub>L</sub>	217	7°C	
Time t <sub>L</sub> above T <sub>L</sub>	80sec	max. 100sec	
Peak Temperature T <sub>P</sub>	245°C	max. 260°C	
Time $t_P$ within 5°C of the specified peak temperature $T_P$ - 5K	20sec	min. 10sec max. 30sec	
Ramp-down Rate* T <sub>P</sub> to 100°C	3°C / sec	6°C / sec maximum	
Time 25°C to Peak temperature		max. 8 min.	

All temperatures refer to the center of the package, measured on the top of the component

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#### Leibnizstr. 4, D-93055 Regensburg

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The information describes the type of component and shall not be considered as assured characteristics. Due to the special conditions of the manufacturing processes of Sensor, the typical data or calculated correlations of technical parameters can only reflect statistical figures. These do not necessarily correspond to the actual parameters of each single product, which could differ from the typical data and calculated correlations or the typical characteristic line. If requested, e.g. because of technical improvements, these typ. data will be changed without any further notice. Terms of delivery and rights to change design reserved. Due to technical requirements components may contain dangerous substances. For information on the types in question please contact our Sales Organization.

#### **Packing**

Please use the recycling operators known to you. We can also help you – get in touch with your nearest sales office. By agreement we will take packing material back, if it is sorted. You must bear the costs of transport. For packing material that is returned to us unsorted or which we are not obliged to accept, we shall have to invoice you for any costs incurred.

Components used in life-support devices or systems must be expressly authorized for such purpose! Critical components <sup>1</sup>, may only be used in life-support devices or systems <sup>2</sup> with the express written approval of OSRAM OS. <sup>1</sup> A critical component is a component used in a life-support device or system whose failure can reasonably be expected to cause the failure of that life-support device or system, or to affect its safety or effectiveness of that device or system.

<sup>2</sup> Life support devices or systems are intended (a) to be implanted in the human body, or (b) to support and/or maintain and sustain human life. If they fail, it is reasonable to assume that the health of the user may be endangered.



<sup>\*</sup> slope calculation  $\Delta T/\Delta t$ :  $\Delta t$  max. 5 sec; fulfillment for the whole T-range